



# Medicare Benefits Schedule Review Taskforce

## Taskforce Report on Gynaecology MBS Items



## IMPORTANT NOTES

1. This report does not constitute the final position on these items, which is subject to:
  - consideration by the Minister for Health, and
  - the Government.
2. The views and recommendations in this report originated from the clinical committee. Following consultation with stakeholders, the clinical committee made amendments and presented this report to the MBS Review Taskforce for its consideration.
3. Any eliminations, amendments or commentary from the MBS Review Taskforce are noted in boxed comments in the body of the report:

**[Group] Recommendation [#] – Taskforce’s Advice**

**[The Taskforce’s rationale behind their decision.]**



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## 2. Executive summary

***The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a programme of work that considers how more than 5,700 items on the MBS can be aligned with contemporary clinical evidence and practice in order to improve health outcomes for patients. The Taskforce also seeks to identify any services that may be unnecessary, outdated or potentially unsafe.***

The Taskforce is committed to providing recommendations to the Minister for Health that will allow the MBS to deliver on the following key goals:

- Affordable and universal access.
- Best-practice health services.
- Value for the individual patient.
- Value for the health system.

The Taskforce has endorsed a methodology whereby the necessary clinical review of MBS items is undertaken by Clinical Committees and Working Groups. The Taskforce has asked the Clinical Committees to undertake the following tasks:

1. Consider whether there are MBS items that are obsolete and should be removed from the MBS.
2. Consider identified priority reviews of selected MBS services.
3. Develop a programme of work to consider the balance of MBS services within its remit and items assigned to the Committee.
4. Advise the Taskforce on relevant general MBS problems identified by the Committee in the course of its deliberations.

The Gynaecology Clinical Committee (the Committee) was established in June 2016 to make recommendations to the Taskforce regarding MBS items in its area of responsibility, based on clinical expertise and rapid evidence review. The Taskforce originally asked the Committee to review 141 items related to gynaecology. Since the Committee commenced work some items have been removed from the MBS. For example, some procedural services that had different items and fees for when the service was performed by a GP [a G item] or specialist [an S item]. On 1 November 2017, all 'G' items were removed from the MBS and the 'S' items were amended to enable the higher rebate to be paid for all services provided, regardless of the practitioners who performed the service. As a result of this recommendation 10 'G' gynaecological items were deleted, seven 'S' gynaecological items were amended and a further three 'S' items were consolidated into other MBS items (as a result of Committee deliberations).



On 1 July 2018, changes were made to the MBS to address patient safety concerns regarding the use of transvaginal mesh in pelvic organ prolapse (POP) surgery. These changes were based on the recommendations of this Committee but were brought forward to urgently address safety concerns for patients who have transvaginal mesh implants, including reports of chronic, severe and life-changing pain and complications. As a result, the MBS items for the repair of POP via vaginal approach (items 35570, 35571, 35573, and 35577) were amended to clarify that MBS rebates will only be payable for procedures that do not employ the use of mesh and to introduce three new interim items for the surgical removal of mesh in symptomatic patients.

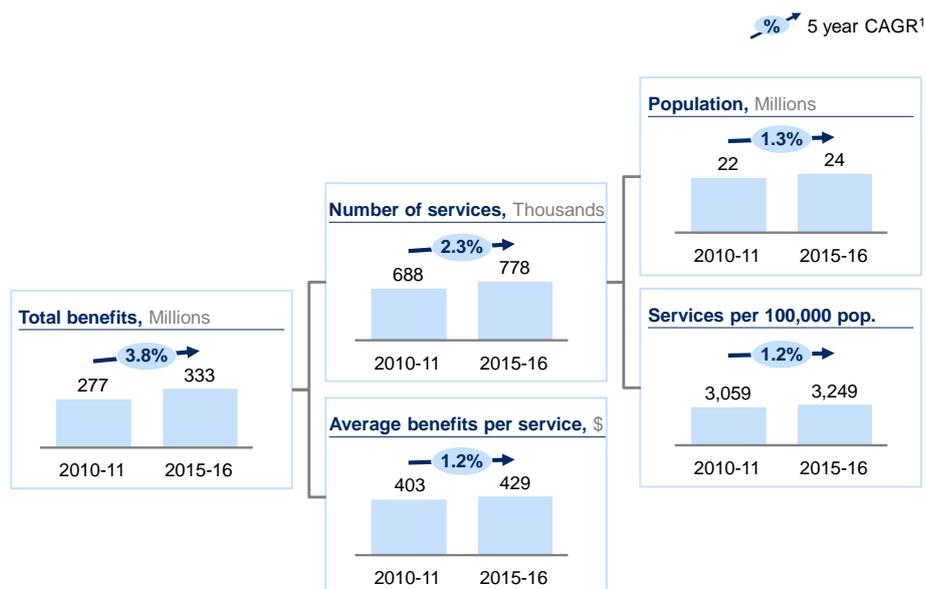
Nonetheless, all recommendations relating to these items are included in this Review Report.

## 2.1 Areas of responsibility of the Gynaecology Clinical Committee

The Committee was originally assigned 141 MBS items to review, covering attendance and procedural services related to gynaecology. A complete list of these items can be found in Appendix B – Index of Items.

In the 2015–16 financial year (FY), these items accounted for approximately 777,784 services and \$333.3 million in benefits. Over the past five years, service volumes for these items have grown at an average rate of 2.3 per cent per year, and the cost of benefits has increased by 3.8 per cent per year. This growth was driven by the combination of a 1.2 per cent increase in average benefits paid per service, a 1.2 per cent increase per year in the number of services delivered per head of population, and 1.3 per cent growth in the Australian population during the FY2011–16 period (Figure 1).

**Figure 1: Drivers of growth in the Committee's MBS items**



<sup>1</sup> Compound Annual Growth Rate

**Source:** Publicly available data from Department of Human Services and Australian Bureau of Statistics. All items in Gynaecology Clinical Committee scope (see Appendix B for Index), 2010-11 and 2015-16, by date of processing.



## 2.2 Key recommendations

The Committee structured its review of gynaecological items by allocating each of its items to one of four subspecialty-focused Working Groups:

- Assisted Reproductive Technologies Working Group (ARTWG).
- General Gynaecology Working Group (GGWG).
- Urogynaecology Working Group (UGWG).
- Gynaecological Oncology Working Group (GOWG).

The Committee, along with the relevant Working Group, reviewed each of the allocated items and formulated a number of recommendations to change aspects of the MBS, as it applies to gynaecological services. Among these, the following were considered likely to have a marked and positive impact on consumers, clinicians and/or the community.

### 2.2.1 Assisted reproductive technologies

The Committee made several recommendations relating to stimulated assisted reproductive technology (ART) cycle items.

1) The Committee recommended introducing restrictions to the number of ART stimulated cycle items that can be claimed by each consumer, and to the maximum consumer age up to which MBS funding will be provided for these items. These changes are intended to encourage consumers to seek ART treatment at a younger age than they otherwise might, thereby increasing their chances of treatment success. Australian data shows that live birth rates from an ART stimulated cycle and subsequent 'frozen' cycles decline rapidly with increasing age, falling below 2 per cent for some age groups. Similarly, successive cycles of stimulated ART treatment offer progressively smaller chances of having a live birth.

2) The Committee recommended providing MBS funding support to those undergoing an ART stimulated cycle as part of an altruistic (non-commercial) egg donation or surrogacy arrangement. This is intended to provide access for consumers for whom autologous ART stimulated cycle treatment (with their own eggs) is not ideal for valid medical reasons.

3) The Committee recommended enacting measures to improve consumers' understanding of the potential benefits and costs of ART treatment, making greater use of detailed Australian ART data collected by ART industry bodies. These measures would aim to provide the Department of Health with continuous access to a selection of ART-related outcomes data. This could enable future community education initiatives such as an ART 'success calculator,' which would help potential consumers to better understand their likelihood of success from ART treatment.



### 2.2.2 General gynaecology

The Committee made key recommendations in relation to items for the insertion of intrauterine devices (IUDs), diagnostic hysteroscopy services and laparoscopic/hysteroscopic surgical procedures.

1) The Committee recommended consolidating the two existing items used for the insertion of an IUD into one item, no longer specifying the indication for insertion, and keeping endometrial biopsy as a separate item. In addition, the Committee recommended increasing the schedule fee for the item to promote IUD insertions by general practitioners (GPs), which is currently limited in Australia but has potential benefits for patient safety, convenience and access.

2) The Committee recommended consolidating the three existing items for diagnostic hysteroscopy procedures into two items, specifying that one item is for use in an outpatient (out of hospital) setting, while the other is for in-patient procedures requiring general anaesthetic (usually in an operating theatre). The schedule fee for the outpatient item would be increased above that of the in-patient item. These changes are intended to increase the relative usage of the outpatient procedure, which research shows is preferred by consumers and is equally safe and effective when compared with the in-patient procedure. In addition, reducing the number of procedures done in surgical theatres can improve theatre availability for other cases and reduce costs (anaesthetist and hospital). The Committee found that less than 1 per cent of diagnostic hysteroscopies are currently performed in an outpatient setting, despite the potential benefits for consumers and the community.

3) The Committee recommended restructuring or splitting items relating to laparoscopic hysterectomy, complex laparoscopic surgery and hysteroscopic surgery. These changes are intended to more accurately reimburse consumers and clinicians for the specific procedures performed, while also promoting a higher quality of care by more carefully explaining which groups of patients should receive which type of surgery.

### 2.2.3 Urogynaecology

The Committee's key recommendations concern the use of mesh/graft materials in vaginal repair procedures.

1) In late 2017 the Therapeutic Goods Administration (TGA) removed mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods. The recommendations of the Committee were expedited to address patient safety concerns. From 1 July 2018, amendments were made to the MBS items for the repair of pelvic organ prolapse via vaginal approach (items 35570, 35571, 35573 and 35577) to clarify that MBS rebates will only be payable for procedures that do not employ the use of synthetic mesh although these items continue to be available for native tissue repairs without mesh.

2) The Committee recommended introducing three new items describing the removal of mesh/graft for consumers who suffer severe mesh-related side effects. These items promote access to



necessary surgery for patients who could not easily have this surgery in Australia due to the lack of an MBS item for such a procedure. These items were also introduced on 1 July 2018.

### **2.2.4 Gynaecological oncology**

The Committee made several recommendations to update the descriptions of certain MBS items and increase their consumer rebates because the procedures have become more complex (but also safer and more effective) since the creation of the current MBS items.

1) The Committee recommended amending or splitting the current items for ovarian cancer debulking, radical hysterectomy, lymph node dissection and biopsy, and cervical cone biopsy so that they better describe the differing extent and complexity of the surgery required. These changes are intended to more accurately reimburse consumers and clinicians for the specific procedures performed, while also promoting a higher quality of care by more carefully explaining which groups of patients should receive which type of surgery.

2) The Committee recommended adding new surgical techniques and information from the latest Australian clinical guidelines to the explanatory notes of several items. In addition, it is recommended that the explanatory notes be amended to outline the expectation that certain procedures should only be performed by gynaecological oncologists or after discussion with, or review by, a gynaecological oncologist or gynaecological oncology multidisciplinary team (MDT). These changes are intended to promote safer and more effective care for consumers.

## **2.3 Consumer impact**

This section of the report is intended to support and encourage health consumers to comment on the recommendations. The Committee's main recommendations are presented in table format in Appendix C, which includes plain English descriptions of the relevant item's medical service, the recommendation itself, and why the recommendation has been made.

Although consumers rarely engage with MBS item numbers (unless they are following up on out-of-pocket expenses), their description and restrictions form an important part of healthcare accountability. It is hoped that the outcomes of the review (including clearer item descriptors) support clinical decision-making and improve clarity around the delivery of optimal care for women.

## **1.4 Key consumer impacts**

This section summarises the report's key recommendations from a consumer perspective.

Both women and clinicians are expected to benefit from these recommendations because they address concerns regarding patient safety and quality of care, and because they simplify the MBS in order to make it easier to use and understand. Patient access to services was considered for each



recommendation. The Committee also considered each recommendation's impact on clinicians to ensure that any changes were reasonable and fair. However, if the Committee identified evidence of potential item misuse or safety concerns, recommendations were made to encourage best practice, in line with the overarching purpose of the MBS Review.

Consumer impacts associated with the Committee's recommendations fall into three main categories: consumer safety, consumer access and consumer costs.

#### **1.4.1 Consumer safety**

A number of the recommendations aim to improve patient safety. For example, the changes to the vaginal compartment repair items for pelvic organ prolapse were expedited to address patient safety concerns relating to the use of synthetic mesh products. The Committee has recommended that nerve-sparing techniques be used in surgery for appropriately selected gynaecological cancer in order to improve women's quality of life and recovery time after surgery.

#### **1.4.2 Consumer access**

Many of the Committee's recommendations aim to increase consumer access to appropriate care. Increasing the schedule fees for IUD insertion, for example, will improve patient access by encouraging GPs to perform the procedure, rather than referring consumers to a gynaecologist. The Committee has also recommended measures to support the performance of simple outpatient hysteroscopic procedures, thereby avoiding the need for an operating theatre or general anaesthesia. This will improve women's access to and experience of the service, without any sacrifice in quality of care and at reduced total cost. There are also situations in which recommendations aim to restrict access to MBS funding in order to discourage treatment where the prospects of a successful outcome are not sufficiently high to justify the risks and burdens of the treatment. The Committee's suggested changes to the ART stimulated cycle items were made for this reason.

#### **1.4.3 Consumer costs**

A large number of the Committee's recommendations aim to clarify the components included in a procedure. This will reduce inappropriate co-claiming and unnecessary costs for women and the community. The Committee has also sought to ensure that schedule fees incentivise appropriate care. This has resulted in recommendations for higher rebates for some items (for example, debulking for severe ovarian cancer) and lower rebates for other items (for example, calibrating the schedule fees for operative laparoscopy procedures to reflect different levels of complexity).



## 3. About the Medicare Benefits Schedule (MBS) Review

### 3.1 Medicare and the MBS

#### What is Medicare?

Medicare is Australia's universal health scheme. It enables all Australian residents (and some overseas visitors) to have access to a wide range of health services and medicines at little or no cost.

Introduced in 1984, Medicare has three components:

- Free public hospital services for public patients.
- Subsidised drugs covered by the Pharmaceutical Benefits Scheme (PBS).
- Subsidised health professional services listed on the MBS.

#### What is the MBS?

The MBS is a listing of the health professional services subsidised by the Australian Government. There are over 5,700 MBS items, which provide benefits to patients for a comprehensive range of services including consultations, diagnostic tests and operations.

### 3.2 The MBS Review Taskforce

#### What is the MBS Review Taskforce?

The Government established the MBS Review Taskforce (the Taskforce) as an advisory body to review all of the 5,700 MBS items to ensure that they are aligned with contemporary clinical evidence and practice, and to improve health outcomes for patients. The Taskforce will also modernise the MBS by identifying any services that may be unnecessary, outdated or potentially unsafe. The review is clinician-led, and there are no targets for savings attached to the review.

#### What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister for Health that will allow the MBS to deliver on each of these four goals:

- **Affordable and universal access:** The evidence demonstrates that the MBS supports very good access to primary care services for most Australians, particularly in urban Australia. However, despite increases in the specialist workforce over the last decade, access to many specialist services remains problematic, with some rural patients particularly under-served.



- **Best-practice health services:** One of the core objectives of the review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base, where possible. Although the Medical Services Advisory Committee (MSAC) plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items pre-date this process and have never been reviewed.
- **Value for the individual patient:** Another core objective of the review is to maintain an MBS that supports the delivery of services that are appropriate to the patient's needs, provide real clinical value and do not expose the patient to unnecessary risk or expense.
- **Value for the health system:** Achieving the above elements will go a long way towards achieving improved value for the health system overall. Reducing the volume of services that provide little or no clinical benefit will enable resources to be redirected to new and existing services that have proven benefits but are underused, particularly for patients who cannot readily access these services.

### 3.3 The Taskforce's approach

The Taskforce is reviewing existing MBS items, with a primary focus on ensuring that individual items and usage meet the definition of best practice. Within the Taskforce's brief, there is considerable scope to review and provide advice on all aspects that would contribute to a modern, transparent and responsive system. This includes not only making recommendations about adding new items or services to the MBS, but also about an MBS structure that could better accommodate changing health service models. The Taskforce has made a conscious decision to be ambitious in its approach, and to seize this unique opportunity to recommend changes to modernise the MBS at all levels, from the clinical detail of individual items, to administrative rules and mechanisms, to structural, whole-of-MBS issues. The Taskforce will also develop a mechanism for an ongoing review of the MBS once the current review has concluded.

As the MBS Review is to be clinician-led, the Taskforce decided that Clinical Committees should conduct the detailed review of MBS items. The committees are broad-based in their membership, and members have been appointed in an individual capacity, rather than as representatives of any organisation.

The Taskforce asked all committees in the third tranche of the review process to review MBS items using a framework based on Professor Adam Elshaug's appropriate use criteria (1). The framework consists of seven steps:

1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.



2. Identify items that are obsolete, are of questionable clinical value,<sup>1</sup> are misused<sup>2</sup> and/or pose a risk to patient safety. This step includes prioritising items as 'priority 1,' 'priority 2' or 'priority 3,' using a prioritisation methodology (described in more detail below).
3. Identify any problems, develop hypotheses for recommendations and create a work plan (including establishing Working Groups, when required) to arrive at recommendations for each item.
4. Gather further data, clinical guidelines and relevant literature in order to make provisional recommendations and draft accompanying rationales, as per the work plan. This process begins with priority 1 items, continues with priority 2 items and concludes with priority 3 items. This step also involves consultation with relevant stakeholders within the Committee, Working Groups, and relevant colleagues or colleges. For complex cases, full appropriate use criteria were developed for the item's explanatory notes (1).
5. Review the provisional recommendations and the accompanying rationales, and gather further evidence as required.
6. Finalise the recommendations in preparation for broader stakeholder consultation.
7. Incorporate feedback gathered during stakeholder consultation and finalise the review report, which provides recommendations for the Taskforce.

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of and timeframe for the review, each Clinical Committee had to develop a work plan and assign priorities, keeping in mind the objectives of the review. Committees used a robust prioritisation methodology to focus their attention and resources on the most important items requiring review. This was determined based on a combination of two standard metrics, derived from the appropriate use criteria (1):

- Service volume.
- The likelihood that the item needed to be revised, determined by indicators such as identified safety concerns, geographic or temporal variation, delivery irregularity, the potential misuse of indications or other concerns raised by the Clinical Committee (such as inappropriate co-claiming).

For each item, these two metrics were ranked high, medium or low. These rankings were then combined to generate a priority ranking ranging from one to three (where priority 1 items are the highest priority and priority 3 items are the lowest priority for review), using a prioritisation matrix

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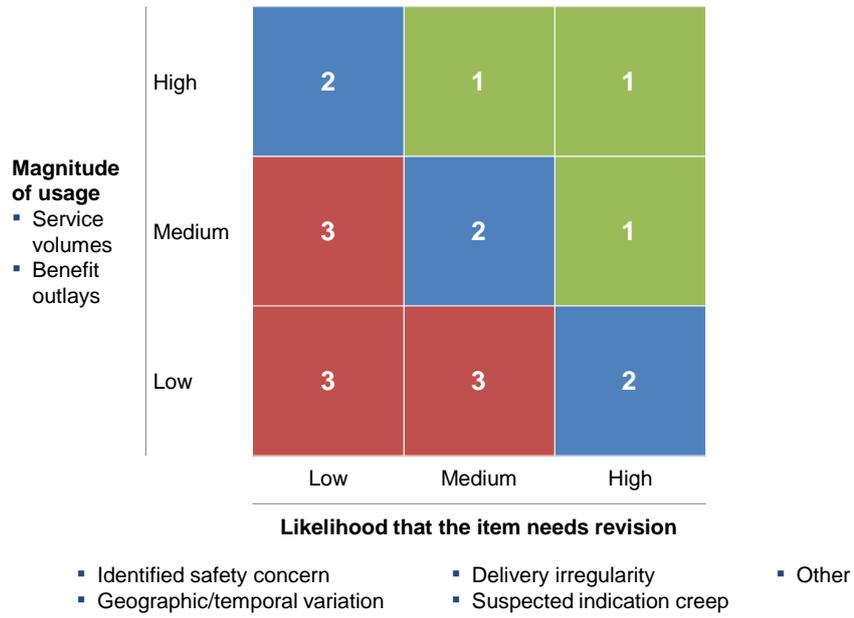
<sup>1</sup> The use of an intervention that evidence suggests confers no or very little benefit on patients; or where the risk of harm exceeds the likely benefit; or, more broadly, where the added costs of the intervention do not provide proportional added benefits.

<sup>2</sup> The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.



(Figure 2). Clinical Committees used this priority ranking to organise their review of item numbers and apportion the amount of time spent on each item.

**Figure 2: Prioritisation matrix**





## 4. About the Gynaecology Clinical Committee

The Committee is part of the third tranche of Clinical Committees. It was established to make recommendations to the Taskforce on MBS items within its remit, based on clinical expertise and rapid evidence review. The Taskforce asked the Committee to review MBS items related to gynaecology.

The Committee consisted of 11 members and an ex-officio representative from the Taskforce. Members' names, positions/organisations and declared conflicts of interest are listed in Section 4.1. All members of the Taskforce, Clinical Committees and Working Groups were asked to declare any conflicts of interest at the start of their involvement and are reminded to update their declarations periodically.

### 4.1 Committee members

**Table 1: Gynaecology Clinical Committee members**

Name	Position/Organisation	Declared interests
Professor Michael Permezel (Committee Chair)	Consultant Obstetrician, Mercy Hospital for Women Melbourne Professor of Obstetrics and Gynaecology, University of Melbourne Past President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists Private practice	None
Dr Vijay Roach	Consultant Obstetrician & Gynaecologist, Royal North Shore Hospital President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists Private practice	Claims MBS items
Professor Stephen Robson*	Consultant Obstetrician & Gynaecologist, Canberra Hospital Immediate Past President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists Associate Professor, Australian National University Secretary, Australian Medical Association (ACT) Private practice	Claims MBS items Member of the Fertility Society of Australasia. President of the Australian Medical Association of the ACT
Associate Professor Malcolm Frazer (UGWG Chair)	Private Practice Sub-specialty Urogynaecologist Clinical Lead Urogynaecology, Gold Coast Health District, Queensland Associate Professor, Griffith University School of Medicine and Bond University Medical School Fellow of the Royal College of Obstetricians and Gynaecologists Fellow of the Australian and New Zealand College of Obstetricians and Gynaecologists	Paid surgical preceptor and occasional lecturer for Johnson and Johnson, and American Medical Systems with regard to transvaginal mesh kits. No further remunerated contact with these companies for the past five years. Occasional adviser for Clayton Utz Lawyers, relating to the use of transvaginal mesh and suburethral slings in Australia.
Professor Jason Abbott (GGWG Chair)	Professor of Gynaecological Surgery, University of New South Wales President AGES Society	Claims MBS items International Advisory Board Vifor Pharmaceuticals



Name	Position/Organisation	Declared interests
	FIGO Menstrual Disorders Working Group Co-Chair ACSQHC Heavy Menstrual Bleeding Standards Committee Chair Practice Committee AAGL Medical Director Endometriosis Australia Associate Editor Human Reproduction Associate Editor ANZJOG Associate Editor JMIG	National Advisory Board Vifor Australia National Advisory Board Hologic Australia Consultant Stryker Consultant Bayer Australia
Dr Wendy Burton	General Practitioner, private practice Chair, Antenatal/Postnatal Special Interest Group, The Royal Australian College of General Practitioners Maternity Lead, Brisbane South Primary Healthcare Network Chair, Mater Mother's Hospital Shared Antenatal Care Alignment Member, Statewide Maternity and Neonatal Clinical Network Steering Committee (Qld)	None
Dr Cara Frame	GP, private practice Antenatal Share Care Provider	Claims MBS items
Professor Elizabeth Sullivan	Perinatal Epidemiologist Assistant Deputy Vice Chancellor (Research) & Professor of Public Health, University of Technology Sydney Council Member NHMRC	Previous Board Member, Fertility Society of Australia
Ms Julie Hamblin	Lawyer, HWL Ebsworth	Provided legal advice for a number of ART providers, as well as IVF Australia and Melbourne IVF Served for several years on the IVF Australia Ethics Committee
Professor William Ledger (ARTWG Chair)	Head & Professor of Obstetrics and Gynaecology, The Royal Hospital for Women Head & Professor of Obstetrics and Gynaecology, School of Women's and Children's Health, University of New South Wales Senior Fertility Specialist & Gynaecologist, IVFAustralia	Part-time paid Senior Fertility Specialist with IVF-Australia. Minority shareholder in Virtus Health. Board member of Flinders Fertility. Director of Reproductive Medicine at the Royal Hospital for Women. Research fund receives Medicare payments for this work. Receives research support from MSD, Merck Serono, Ferring Pharmaceuticals, Swiss Precision Diagnostics and Biopharma, and has received honoraria from these companies for educational activities
Dr Rhonda Farrell (GOWG Chair)	Chair of the Gynaecologic Oncology Subcommittee, RANZCOG	Claims MBS items Member of ASGO (The Australian Society of Gynaecological Oncologists)
Dr Lee Gruner	MBS Review Taskforce (ex-officio)	None
* Resigned from the Committee in November 2018.		

It is noted that the majority of Committee members share a common conflict of interest in reviewing items that are a source of revenue for them (that is, patients of Committee members claim the items under review). This conflict is inherent in a clinician-led process, and having been acknowledged by



the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.

## 4.2 Conflicts of interest

All members of the Taskforce, Clinical Committees and Working Groups are asked to declare any conflicts of interest at the start of their involvement and are reminded to update their declaration periodically.

## 4.3 Summary of the Committee's review approach

The Committee completed a review of its items across five Committee meetings and 14 Working Group meetings, during which it developed the recommendations and rationales outlined in Sections 4–8. The review drew on various types of MBS data, including data on utilisation of items (services, benefits, patients, providers and growth rates); service provision (type of provider, geography of service provision); patients (demographics and services per patient); co-claiming or episodes of services (same-day claiming and claiming with specific items over time); and additional provider and patient-level data, when required. The review also drew on data presented in the relevant published literature, all of which is referenced in the report.

**4.3.1 *The Clinical Committee considered feedback received from key stakeholders during targeted consultation. This Review Report captures the amendments they considered necessary to make to their recommendations in response to the feedback received. This Review Report will be provided to the Taskforce who will consider the amended recommendations of the Committee and the stakeholder feedback received before making recommendations to the Minister for Health for consideration by Government. Working Group structure***

The Committee reviewed the 141 items originally allocated to the review of gynaecological services and made recommendations based on the best available evidence and clinical expertise, in consultation with relevant stakeholders. The Committee formed the following four Working Groups with broader membership to provide greater content expertise on specific domains of clinical practice:

- Assisted Reproductive Technologies Working Group (ARTWG).
- General Gynaecology Working Group (GGWG).
- Urogynaecology Working Group (UGWG).
- Gynaecological Oncology Working Group (GOWG).



Each Working Group consisted of a combination of subspecialist gynaecologists, general gynaecologists, specialists from other disciplines that engage with the items in scope, GPs and consumer representatives. Each Working Group was led by a Working Group Chair and included one or more members of the Committee, in addition to non-Committee members. The Chair of the Committee served as a member in each Working Group in addition to his role on the Committee itself.

### **4.3.2 Structure of the report**

The recommendations in this report are organised by Working Group, and by assessed potential impact of the recommendation.

- Section 4 – Assisted Reproductive Technologies (ART) recommendations.
- Section 5 – General gynaecology recommendations.
- Section 6 – Urogynaecology recommendations.
- Section 7 – Gynaecological oncology recommendations.
- Section 8 – Recommendations for referral to other Committees.

### **4.3.3 Numbering of proposed items**

Throughout the report, the Committee recommends new or substantially changed items, some of which involve restructuring existing items. In general, in cases where recommended changes would be made to a particular item, that item's number has been retained and remains unchanged. Where a recommendation is made to split an item, or an entirely new service is proposed, the resulting new items are referred to using some or all of the digits of the item or group of items to which they most closely relate, with letters appended to these to assist differentiation. If the recommended items are ultimately added to the MBS, the Department of Health (the Department) will assign new numbers in the usual format. The Committee is not recommending changes to the MBS numbering system.



## 5. ART recommendations

### 5.1 Assisted Reproductive Technologies Working Group membership

The ARTWG included the members listed in the table below.

**Table 2: ARTWG members**

Name	Position/Organisation	Interests declared
Professor William Ledger (ARTWG Chair)*	Head & Professor of Obstetrics and Gynaecology, The Royal Hospital for Women Head & Professor of Obstetrics and Gynaecology, School of Women's and Children's Health, University of New South Wales Senior Fertility Specialist & Gynaecologist, IVFAustralia	Part-time Senior Fertility Specialist, IVF Australia (a subsidiary of Virtus Health). Minority shareholder, Virtus Health. Board member, Flinders Fertility. Director of Reproductive Medicine, the Royal Hospital for Women. Research fund receives Medicare payments for this work. Receives research support from MSD, Merck Serono, Ferring Pharmaceuticals, Swiss Precision Diagnostics and Biopharma, and has received honoraria from these companies for educational activities.
Professor Stephen Robson**	Consultant Obstetrician & Gynaecologist, Canberra Hospital Immediate Past President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists Associate Professor, Australian National University Secretary, Australian Medical Association (ACT) Private practice	Claims MBS items. Member, Fertility Society of Australasia. President, Australian Medical Association of the ACT.
Ms Julie Hamblin*	Lawyer, HWL Ebsworth	Provided legal advice for a number of ART providers, as well as IVF Australia and Melbourne IVF. Served for several years on the IVF Australia Ethics Committee.
Dr Ric Porter	IVFAustralia	Claims MBS items. Fertility Specialist, IVF Australia (a subsidiary of Virtus Health). Shareholder, Virtus Health Pty Ltd.
Ms Elizabeth 'Kaye' Oke	Counsellor, Melbourne IVF (retired)	Life Member, Fertility Society of Australia. Member, Australian and New Zealand Infertility Counsellors Association. Previously was manager of infertility counselling, Melbourne IVF, but has been retired for five years. Member of Licencing Committee, NHMRC. Member of Community and Consumer Advisory group, NHMRC.
Associate Professor Georgina Chambers	Director, National Perinatal Epidemiology and Statistics Unit, University of New South Wales	Associate Professor and Director, National Perinatal Epidemiology and Statistics Unit (NPESU), University of New South Wales. Data Custodian, ANZARD collection (which is funded by the Fertility Society of Australia). Chief Investigator on an Australia Research Council (ARC) Linkage Grant for which UNSW received funds from Virtus Health in 2010–13.



Name	Position/Organisation	Interests declared
		Research programme through UNSW also received a donation in 2014 from the Australian Medicine Research Foundation.
Professor Luk Rombauts	Director, Monash IVF	Claims MBS items. Vice-President, Fertility Society of Australia. Group Medical Director, Monash IVF. Minority shareholder in Monash IVF. Member of the Executive Committee, IVF Director's Group. Member of the Advisory Boards of Merck-Serono, MSD, and Ferring. Has accepted educational grants and unrestricted research grants from Merck-Serono, MSD, and Ferring.
Professor Kelton Tremellen	Strategic Professor in Reproductive Medicine, Flinders Southern Adelaide Clinical School, Flinders University Reproductive Endocrinology & Infertility Subspecialist, Repromed-Monash IVF Group	Claims MBS items. Shareholder, Monash IVF. Salaried employee, Repromed. Non-clinical academic employee, Flinders University. Flinders University is part owner of a private IVF clinic (Flinders Fertility). Holds a financial interest in the male fertility nutraceutical Menevit, marketed by Bayer Consumer Care Australia. Previously a consultant for MSD, Ferring and Merck.
Dr Linda Mann	GP	None.
Professor Michael Permezal (Committee Chair)*	Committee ex-officio	None.
Dr Lee Gruner*	Taskforce ex-officio	None.
* Also a member of the Committee ** Resigned from the Committee in November 2018.		

It is noted that the majority of members share a common conflict of interest in reviewing items that are a source of revenue for them (that is, members' patients claim the items under review). This conflict is inherent in a clinician-led process, and having been acknowledged by the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.

The ARTWG developed the following recommendations.

## Item-specific recommendations

### 5.2 ART stimulated cycle items (13200, 13201 and 13202)

The Committee reviewed 21 items relating to the treatment of subfertility and infertility. During FY2015–16, these items collectively accounted for 282,197 services and \$256.3 million in benefits. The Committee and the ARTWG limited its assessment of ART to the medical causes of infertility and subfertility (including surrogacy for medical reasons). Social causes of infertility were not within the scope of the Committee's review. Nonetheless, the Committee recommended that the issue of



social infertility be referred to MSAC to consider whether access to publically funded intrauterine insemination and other ART services should be expanded to same sex couples and single women.

ART is a complex field which has seen considerable evolution since the birth of Australia's first ART-conceived baby in 1980. This includes the development of new techniques, which have been added to the MBS and have progressively improved over time (and have sometimes been superseded). Treatment has also become more personalised, taking into account factors such as the suspected root cause of fertility problems, age, parity (whether or not a person has given birth previously), the expectations of both patients and partners, and the results of numerous diagnostic interventions that assist in calibrating therapy to each patient's specific situation. Over the past two decades, Australian ART providers have distinguished themselves globally, achieving some of the lowest IVF multiple pregnancy rates in the world and providing treatment over the course of 2014 that led to the birth of 12,875 Australian babies (2).

Among medical specialities, ART is unique in many ways. Most importantly, its desired outcome is not only to treat the patient's immediate problem—subfertility—but also to assist in the creation of new life. ART is also reliant on highly specialised laboratory services that perform delicate scientific procedures behind the scenes. Perhaps inevitably, given the strong social forces surrounding childbearing in our society, it is frequently a subject of controversy.

ART treatment is relatively expensive to perform because of the pharmaceuticals required to stimulate ovulation, the laboratory & imaging infrastructure that supports ART, and the multiple visits and discrete procedures required to provide effective treatment. Today, Australia's ART providers work almost exclusively in private practice. Medicare funds over 60 per cent of the average fees associated with stimulated cycles, and patients self-fund the remainder. (Only a very limited subsection of ART care is eligible for private health insurance coverage.) In addition, the PBS funds almost 100 per cent of the cost of pharmaceuticals for Medicare-eligible stimulated cycles. ART providers collect detailed information about every treatment performed, which is collated in an industry-funded database that provides very detailed process and outcomes data (the Australia and New Zealand Assisted Reproduction Database [ANZARD]).

Few would deny the high level of psychological, financial and social stress associated with treatment failure, nor the jubilation expressed by those whose treatment is successful. These contrasting outcomes tend to polarise debate on public funding for ART. Removing outcomes from the equation, there is still wide variability in both the therapeutic needs and psychosocial circumstances of individual patients. The data around treatment outcomes is also complex and open to interpretation, which means that trying to make comparisons across treatment modalities, countries, clinicians and patients is fraught with difficulties.

The Committee and the ARTWG held wide-ranging discussions over the course of five months in late 2016 and early 2017, culminating in the recommendations below, having considered multiple technical, clinical and societal factors. The Committee found that unrestricted public funding for ART



treatment had led to clear instances of what it considered to be “low-value” care—for example, the provision of autologous in vitro fertilisation (IVF) cycles to patients aged over 45, whose expected live birth rate from their first complete cycle is just 1.2 per cent (3). There have also been instances of patients undergoing cycle after cycle with no success, at great cost to both society and themselves. For example, MBS data shows that almost 1 per cent of patients undergo 10 or more stimulated IVF cycles. The ABC program, “Four Corners” cited an example of a patient undergoing 37 cycles without success (4).

The Committee notes that the recommendations below apply only to MBS funding for ART, and that patients will still be fully entitled to privately fund their ART treatment at their own discretion.

### 5.2.1 Items 13200, 13201 and 13202 – Recommendation 1

**Table 3: Item introduction table for items 13200, 13201 and 13202**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13200	Assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13201, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – initial cycle in a single calendar year	\$3,110.75	26,462	3.0%	\$116,792,359
13201	Assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – each cycle subsequent to the first in a single calendar year	\$2,909.75	13,653	5.7%	\$67,561,535
13202	Assisted reproductive technologies stimulated treatment cycle that is cancelled before oocyte retrieval, involving the use of drugs to induce superovulation and including	\$465.55	4,353	6.9%	\$1,782,014



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
	quantitative estimation of hormones, semen preparation, ultrasound examinations, but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13201, 13203, 13206, 13218, applies being services rendered during 1 treatment cycle				

### Recommendation 1

- Change the stimulated cycle item descriptors to:
  - Restrict the MBS rebate to patients who undergo a service before their 44th birthday.
  - Restrict the MBS rebate so that it covers the patient's first six cycles of stimulated IVF treatment only. Up to two 13202 (cancelled) stimulated cycles will not count toward the 6 cycle limit.
  - Allow a patient's tally of MBS-reimbursable stimulated cycles to be reset if the patient becomes pregnant as a result of an IVF cycle and reaches 20 weeks' gestation. That cycle would be termed the 'index cycle.' A reset can only occur once, allowing patients a maximum of 12 reimbursable stimulated cycles. Any stimulated IVF cycle claimed after the reset should be claimed using one of three new items created specifically for this purpose (items 132XX, 132XY and 132XZ), which are outlined below.
  - Include intracytoplasmic sperm injection (ICSI) in these items. (The rationale for including ICSI in the stimulated cycle items is discussed in Section 5.7.1, which focuses on items used for the preparation, processing and transfer of gametes and embryos.)
- Create new items 132XX, 132XY and 132XZ to track the number of complete cycles a patient undergoes after a reset. This will allow for an additional six funded stimulated IVF cycles in patients who achieve a pregnancy of 20 weeks' gestation during their first six reimbursed cycles. These items would have descriptors equivalent to those for items 13200 (\$3110.75), 13201 (\$2909.75) and 13202 (\$465.55) respectively (see below), but they are only to be used after a reset.
- Item 13200
  - The proposed descriptor for item 13200 is as follows:
    - Assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative



estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services including Intracytoplasmic Sperm Injection but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13201, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – initial cycle in a single calendar year.

- Initiation of administration of stimulation drugs not to commence on or after female patient's 44th birthday.
  - Maximum number of stimulated IVF cycles (sum of 13200, 13201 and 13202) not to exceed 6, unless an IVF-conceived pregnancy of at least 20 weeks' gestation is achieved within these 6 stimulated cycles. Should an IVF-conceived pregnancy of at least 20 weeks' gestation be achieved, the cycle resulting in that pregnancy is termed the 'index cycle,' and further stimulated IVF cycles must be claimed using items 132XX, 132XY or 132XZ in accordance with those items' descriptors.
  - Up to two 13202 (cancelled) stimulated cycles will not count toward the 6 cycle limit.
- Item 13201
    - The proposed descriptor for item 13201 is as follows:
      - Assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services including Intracytoplasmic Sperm Injection but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – each cycle subsequent to the first in a single calendar year.
      - Initiation of administration of stimulation drugs not to commence on or after female patient's 44th birthday.
      - Maximum number of stimulated IVF cycles (sum of 13200, 13201 and 13202) not to exceed 6, unless an IVF-conceived pregnancy of at least 20 weeks' gestation is achieved within these 6 stimulated cycles. Should an IVF-conceived pregnancy of at least 20 weeks' gestation be achieved, the cycle resulting in that pregnancy is termed the 'index cycle,' and further stimulated IVF cycles must be claimed using items 132XX, 132XY or 132XZ in accordance with those items' descriptors.
      - Up to two 13202 (cancelled) stimulated cycles will not count toward the 6 cycle limit.
  - Item 13202



- The proposed descriptor for item 13202 is as follows:
  - Assisted reproductive technologies stimulated treatment cycle that is cancelled before oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones, semen preparation, ultrasound examinations, but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13201, 13203, 13206, 13218 applies being services rendered during 1 treatment cycle.
  - Initiation of administration of stimulation drugs not to commence on or after female patient's 44th birthday.
  - Maximum number of stimulated IVF cycles (sum of 13200, 13201 and 13202) not to exceed 6, unless an IVF-conceived pregnancy of at least 20 weeks' gestation is achieved within these 6 stimulated cycles. Should an IVF-conceived pregnancy of at least 20 weeks' gestation be achieved, the cycle resulting in that pregnancy is termed the 'index cycle,' and further stimulated IVF cycles must be claimed using items 132XX, 132XY or 132XZ in accordance with those items' descriptors.
  - Up to two 13202 (cancelled) stimulated cycles will not count toward the 6 cycle limit.
- New item 132XX
  - The proposed descriptor for new item 132XX is as follows:
    - Assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13201, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – initial cycle in a single calendar year.
    - This item is to be used only in female patients who have achieved an IVF-conceived pregnancy of at least 20 weeks' gestation previously (termed an 'index cycle').
    - Initiation of administration of stimulation drugs not to commence on or after female patient's 44th birthday.
    - Maximum number of stimulated cycles (sum of 132XX, 132XY and 132XZ) claimed subsequent to the index cycle not to exceed 6.
    - Up to two 132XZ (cancelled) stimulated cycles will not count toward the 6 cycle limit.
- New item 132XY



- The proposed descriptor for new item 132XY is as follows:
  - Assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – each cycle subsequent to the first in a single calendar year.
    - This item is to be used only in female patients who have achieved an IVF-conceived pregnancy of at least 20 weeks' gestation previously (termed an 'index cycle').
    - Initiation of administration of stimulation drugs not to commence on or after female patient's 44th birthday.
    - Maximum number of stimulated cycles (sum of 132XX, 132XY and 132XZ) claimed subsequent to the index cycle not to exceed 6.
    - Up to two 132XZ (cancelled) stimulated cycles will not count toward the 6 cycle limit.
- New item 132XZ
  - The proposed descriptor for new item 132XZ is as follows:
    - Assisted reproductive technologies stimulated treatment cycle that is cancelled before oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones, semen preparation, ultrasound examinations, but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13201, 13203, 13206, 13218 applies being services rendered during 1 treatment cycle.
      - This item is to be used only in female patients who have achieved an IVF-conceived pregnancy of at least 20 weeks' gestation previously (termed an 'index cycle').
      - Initiation of administration of stimulation drugs not to commence on or after female patient's 44th birthday.
      - Maximum number of stimulated cycles (sum of 132XX, 132XY and 132XZ) claimed subsequent to the index cycle not to exceed 6.
      - Up to two 132XZ (cancelled) stimulated cycles will not count toward the 6 cycle limit.



## Rationale

Recommendation 1 focuses on improving the value of MBS-funded ART care for patients and the community, based on the following.

### Relevant notes for this rationale

- The Committee noted that it is difficult to define high-value care in the ART setting for two reasons:
  - Traditional health economic measures such as quality adjusted life years (QALYs) are not readily applicable to a treatment that results in the birth of a new person. They are better suited to treatments that extend or measurably improve the quality of a patient's own health.
  - Any decision to publicly fund ART treatment is inevitably influenced by psychological, emotional, financial, social, religious, resource allocation and other socio-political factors. These factors are challenging to measure, highly variable and circumstantial, and they cannot be readily combined with outcomes data in order to reach a universally acceptable decision.
- The Committee also noted that ART cycles can be defined and measured in different ways.
  - Two common methods are:
    - To consider individual stimulated and frozen/thaw cycles separately.
    - To consider sets of cycles resulting from a single stimulated cycle. This is known as a 'complete' cycle, defined as an initial single stimulated cycle plus any frozen/thaw cycles resulting from that initial stimulated cycle.
  - The Committee chose to refer to complete cycles in its recommendations because this measure more accurately defines the complete medical service initiated with a stimulated ART cycle, and because it more closely approximates a patient's therapeutic journey and the associated outcomes and costs involved in each step.
- The Committee noted that patients must retain the option of privately funding cycles at ages or cycle numbers beyond those recommended here. Such privately funded cycles would not count toward any applicable cycle limit for MBS-funded cycles.

### Problems identified with current MBS items

- The Committee identified two problems with the existing MBS ART funding system:
  - The Committee believes that unrestricted public ART funding has led to instances of low-value care. These include the provision of stimulated ART cycles to patients with expected live delivery rates of 1.2 per cent or less per complete cycle (3), and the continued provision



of stimulated ART cycles to patients who have previously had numerous and successive unsuccessful cycles. In such instances, the Committee feels that the risks and costs to the patient and community arising from the provision of ART treatment outweigh the potential benefits associated with a live birth.

- ART is sometimes perceived as a reliable 'fall-back position' for women of any age who might seek to become pregnant. This view is not supported by the trends seen in national ART outcomes data. Despite this, the current public funding system does not discourage this perception, because it subsidises ART without regard for maternal age.

### **Approach to recommendation**

- The Committee agreed that age and funding limits should be introduced in order to promote higher value ART care for patients and the community. However, the Committee found that no singular piece of available information or evidence was (or could be) conclusive in terms of where to set such a restriction. For example:
  - ANZARD data contains highly detailed information about the effect of age and cycle numbers on live delivery rates, but it does not answer the broader question of what constitutes appropriate use or high-value care for patients and the community.
  - Clinical and societal factors such as the risks and benefits to physical, psychological, social and financial health, as well as broader ethical concerns, are also important factors influencing such a decision.
- The Committee therefore acknowledged that in order to limit MBS funding based on age or cycle numbers, it would need to consider multiple factors simultaneously and make a value-based judgment guided by data and evidence, rather than relying on data alone.
- In order to draw guidance from the data available, the Committee discussed methods to determine the age or number of cycles beyond which treatment was felt not to offer sufficient value. It decided that a reasonable approach for setting an age or cycle limit would be to identify a percentage live birth rate that the Committee agreed represented an acceptable threshold below which care could be considered low value.
- The Committee aligned (with some disagreement) around an acceptable live delivery rate threshold per complete cycle of 5 per cent or higher. However, it noted that this was a fundamentally subjective decision, and that the data did not specifically support a 5 per cent threshold over any other figure, be it higher or lower.

### **General basis of the recommendation to institute a maternal age limit**

- ANZARD data shows variation in live delivery rates from ART treatment associated with a patient's age. Having considered this, the Committee decided to recommend restricting MBS



funding for stimulated fresh IVF cycles to patients who have not yet reached their 44th birthday.

- The cycle-specific live delivery rate of the first complete cycle in patients aged 42–43 (before the 44th birthday) is 5.9 per cent, according to ANZARD data (3) (5). Given the risks inherent in ART treatment and the live birth rate per complete cycle from the 44th birthday onwards (less than 5 per cent), restricting MBS funding for stimulated fresh IVF cycle items to patients who have not yet reached their 44th birthday was considered to be in the interest of patient health, improved clinical practice and higher value care.
- The Committee felt that restricting the age of the patient to that associated with a 5 per cent or higher live birth rate might encourage prospective patients to seek ART treatment at earlier ages, thereby encouraging patients to make higher value care choices for themselves and the community. The benefit-to-risk ratio for patients beyond this limit was considered inappropriately low.

### **General basis of the recommendation to institute a cycle limit**

- Having considered the data on number of cycles, the Committee decided to recommend a limit on MBS funding of six complete cycles for all eligible patients.
  - The Committee noted that for patients of all ages, the cycle-specific live delivery rate did not fall below 5 per cent for any number of complete cycles up to eight—the maximum reported in the data.
  - The Committee also noted considerable variance in the cycle-specific live delivery rates for each individual age cohort. This meant it was not possible to apply a strict 5 per cent threshold to age and cycle limits without then recommending different cycle limits for each age cohort.
  - The Committee noted that attempting to implement different cycle limits for different ages would be complex for patients and providers and could potentially lead to confusion, stress and unintentional errors when making claims.
  - The possible negative consequences of such a system were considered to outweigh any benefit that would come from adhering to multiple age-and-cycle-specific 5 per cent live delivery rate thresholds.
- The Committee considered providing MBS funding for six complete cycles at any age before the 44th birthday to be appropriate.
  - The Committee noted that in patients of all ages, 99.2 per cent of all live deliveries expected to occur within eight complete cycles (the limit of the available data) had already occurred within six complete cycles.



- In the most recent ANZARD analysis provided, the Committee also noted that in patients aged 42 and over, the cycle-specific live delivery rate fell below 5 per cent before six complete cycles had been completed, at progressively lower cycle numbers as age increased (5).
- The Committee therefore felt that a six-cycle limit represented an improvement on the current situation, in which some patients undergo excessive numbers of unsuccessful ART treatment cycles, constituting low-value care. At the same time, however, public funding would still be provided for a sufficient number of complete cycles to adequately treat the vast majority of patients seeking ART treatment.
- The Committee also felt that by imposing a relatively high complete cycle limit, possible negative consequences—such as increased patient stress and more aggressive treatment as cycles proceed—would be minimised.
- It was decided that up to two cancelled stimulated cycles would not count toward the 6 cycle limit.
  - It was noted that good clinical practice supports placing many patients on the lowest effective dose of stimulatory drugs, so as to minimise the risk of side effects. However, it is not always clear what the lowest effective dose will be for a particular patient, which sometimes leads to undertreatment and the need to cancel a cycle (because too few oocytes mature or can be retrieved, effectively lowering the chances of having a live delivery).
  - Other circumstances not related to drug dosing, such as a death in the patient’s family, or an unrelated illness during an IVF cycle, can also lead to cycle cancellation – despite having nothing to do with the patient’s chances of having a live birth.
  - If cancelled stimulated autologous cycles (13202 and 132XZ) are counted towards the cycle limit, there will be an incentive to simply “try and hope”, by continuing on with a cycle that is expected to be sub-optimal anyway – and thus resulting in the patient undergoing additional procedures at greater cost to the patient and community.
  - However, it was noted that there might be an incentive to cancel cycles due to poor response, in order to preserve funded stimulated cycles for later use. This would run counter to the spirit of the cycle limits.
  - In order to minimise this potential form of item misuse, the Committee supported placing a limit on the number of cancelled cycles that would be waived from the overall cycle tally. Two cancelled cycles was considered to be a reasonable number to waive.
- During the Committee’s discussions, reservations were expressed in favour of both lower and higher complete cycle limits.



- It was argued that an acceptable majority of the possible total live deliveries (96.1 per cent) was reached after four complete cycles across all age groups, and that there was an inappropriately low benefit-to-risk ratio in patients beyond this limit.
- On the contrary, it was also argued that amongst women undertaking a 5<sup>th</sup> or 6<sup>th</sup> IVF cycle, the live birth rate across all ages was still in excess of 10%, and that Australia's current standard of ART care could be negatively affected by the application of too low an age or cycle restriction:
  - Australia's lack of restrictions on public ART funding in recent years was asserted to have promoted safer treatment of patients by providers, due to the lack of additional financial pressure that a limit to MBS funding might induce.
  - As such, there was concern that limiting MBS funding to too low a cycle number (in conjunction with an often extremely motivated patient population) might lead patients and providers to pursue more intensive investigation and therapy in an attempt to help patients qualify for further MBS funding. This could result in a higher incidence of ovarian hyperstimulation, multiple embryo transfers and other clinical scenarios that increase risk to both mothers and babies.
- The Committee agreed that providing MBS funding for six complete cycles would provide sufficient support to minimise the risks mentioned above, while still addressing the identified instances of low-value care. Concerns were also raised that restricting MBS funding based on the number of stimulated cycles undergone by the patient, rather than the patient's partner, implied a sex-dependent method of restriction. The equity of cycle-specific limits could also be questioned in situations where male factors are the primary cause for infertility.
  - The Committee agreed that this was a valid concern, but it felt that addressing this inequity would lead to little practical change in ART care, and that it would not be feasible due to the difficulties inherent in implementing or enforcing restrictions on partners or couples.

### **General basis of the recommendation to institute a cycle limit reset**

- The Committee decided that if a patient achieved an ART-conceived pregnancy of 20 weeks' gestation or more, the cycle would be termed the 'index cycle' and the patient would become eligible for a 'reset' of the MBS-funded complete cycle limit.
  - Research shows that patients who had previous pregnancies or live deliveries as a result of ART treatment have higher live delivery rates in subsequent cycles than those who did not (6).
  - Twenty weeks' gestation was chosen as a threshold because this is the age at which a baby is issued a birth certificate in Australia. As a birth certificate is an official document



unique to the patient and baby, documentation of the certificate's issuance would provide a reliable method for proving eligibility for a reset.

- A reset would reinstate MBS funding for up to six complete cycles before the patient's 44th birthday.

### **General basis of the recommendation to include ICSI**

The rationale for including ICSI in the stimulated cycle items is discussed as part of the full item review beginning on page 53.

### **Details of other considered systems**

- An alternative system for restricting MBS funding for these items was also investigated by the Committee, but was considered to be inferior to the recommended system.
- The Committee noted that it would be possible to limit MBS ART funding to specific situations with an expected cycle-specific success rate above a given per cent. However, this would require specific cycle limits ('tiers') for each age group, as discussed above.
- The Committee felt that a system with tiers for more than three age groups would be unnecessarily complex for both patients and providers, and too dependent on data that would change over time.
- For this reason, the Committee principally considered a simplified model with two tiers:
  - Six complete cycles for a patient before her 40th birthday.
  - Up to four complete cycles for a patient between her 40th and 43rd birthday, depending on how many cycles she had already undergone.
  - No MBS funding for cycles after a patient's 43rd birthday.
- Practical details of this model are provided below, but the Committee and the ARTWG both rejected this model on the following grounds:
  - The model is too complex.
    - It would be difficult for clinicians and consumers to understand this model, especially when considering the transition between tiers and the effects of a reset.
  - The model could have unintended consequences.
    - Having two threshold ages that affect eligibility for items is likely to result in patients experiencing significant psychological stress and pressure to have a successful cycle in the time period preceding each threshold.



- Making the upper age or cycle limits too restrictive is likely to cause patients and clinicians to attempt to maximise their chances of having a successful cycle within the age and cycle limits at the expense of patient safety. This may manifest as more intensive stimulatory drug therapy, more multiple embryo transfers, and ultimately a poorer patient safety profile and higher obstetric/neonatal care burdens.
- Details on the model considered by the Committee and the ARTWG are as follows:
  - The maximum number of funded complete cycles across a lifetime would be six complete cycles for a patient who starts treatment before the 40th birthday and does not qualify for a reset, and four complete cycles for a patient starting treatment between the 40th and 43rd birthdays without a reset. If a patient qualified for a reset, the maximum possible number of funded complete cycles across a lifetime would be 12 for a patient with a reset occurring before the 40th birthday, and 10 for a patient with a reset occurring between the 40th and 43rd birthdays.
  - Three scenarios could occur around the tier threshold at the 40th birthday. These are addressed in the following examples (all of which assume that no reset occurs):
    - If a patient had already completed two or fewer MBS-funded complete cycles prior to her 40th birthday, she would be entitled to a maximum of four further MBS-funded complete cycles between her 40th and 43rd birthday.
    - If a patient had already undergone four MBS-funded complete cycles prior to her 40th birthday, she would only be entitled to two further MBS-funded complete cycles between her 40th and 43rd birthday (bringing her total number of MBS-funded complete cycles to six).
    - If a patient had undergone six MBS-funded complete cycles prior to her 40th birthday, she would not be entitled to any further MBS-funded complete cycles between her 40th and 43rd birthday.
  - Under this model, patients in either funded tier would also receive one lifetime reset if a qualifying pregnancy occurred (that is, the pregnancy reached 20 complete weeks' gestation). This reset would reinstate MBS funding for the applicable number of complete cycles, based on the patient's age at the time of initiation of the index cycle:
    - Six MBS-funded complete cycles for patients under 40.
    - Up to four MBS-funded complete cycles for patients between their 40th and 43rd birthdays (depending on the number of MBS-funded complete cycles they had completed after the reset but prior to the 40th birthday).

## Detailed notes on the Committee's approach to formulating Recommendation 1



- The Committee considered numerous factors when formulating its recommendations, including:
  - The Australian ART context.
  - International models of funding for ART.
  - Australian & New Zealand ART data quality and relevance.
  - Age- and cycle-related clinical fertility and live delivery rates.
  - Other factors of potential relevance to live delivery rates.

### **The Australian ART context**

- The Committee noted the following:
  - Australia's first ART-conceived baby was born in 1980. Since then, Australian ART providers have achieved a high standard of care, which includes having one of the world's lowest multiple birth rates (2) (7).
  - Since the removal of a pre-existing six-cycle limit in November 2000, Australia has provided unrestricted MBS funding for patients undergoing non surrogacy-related ART treatment (up to applicable funding limits, as applied throughout the MBS system).
  - The Australian ART industry regulates itself via the Reproductive Technology Accreditation Committee (RTAC), which is a subcommittee of the Board of the Fertility Society of Australia—an industry peak body.

### **International models of funding for ART**

- The Committee noted the following:
  - Many countries limit public funding of ART, apportioning varying levels of funding to patients based on factors such as maternal age at initiation of treatment, number of previous cycles, number of pre-existing children, relationship status, and lifestyle factors such as obesity and smoking.
  - Other countries' funding systems vary in the level of public subsidy they offer for ART services (from 0 per cent to 100 per cent of costs incurred). There is no single international standard that sets reasonable limits for accessing this funding. The majority of the countries reviewed by the Committee limit funding to patients under the age of 40 to 45, for between one and four stimulated ART cycles. However, outliers exist beyond both these ranges.
    - For example, France limits ART public funding by age, cycle number, relationship status and reason for seeking treatment (medical or non-medical). In contrast, New Zealand



uses various limiting factors in conjunction with a points system, while the Canadian province of Ontario provides funding for a single cycle below a single age threshold.

### ***Australian & New Zealand ART data review***

- The ANZARD collection and ANZARD reports were considered the most directly applicable sources of data to inform the Committee's review.
  - The National Perinatal Epidemiology and Statistics Unit maintains the ANZARD collection, which contains high-quality, highly detailed information about ART treatments and outcomes in Australia and New Zealand. As part of a fertility clinic's licensing agreement, it must report all ART treatment cycles and outcomes to ANZARD.
  - The annual ANZARD reports provide data specific to ART in Australia and New Zealand and therefore reflect the combination of clinical, regulatory, societal, competitive and political factors that affect the industry in these two countries. Over 90 per cent of the ART cycles in ANZARD are performed in Australia, and less than 10 per cent are performed in New Zealand.
- The Committee acknowledged the following with regard to the ANZARD data:
  - Firstly, the ANZARD analyses provided for the review were based on a large number of data points for cycles performed between 2009 and 2014. Analyses prepared by the National Perinatal Epidemiology and Statistics Unit were provided to answer specific questions asked by the Committee and the ARTWG. Care must be taken when interpreting ART statistics because of the complex nature of treatment, which can involve multiple treatment stages, multiple cycles for each woman, multiple babies for each woman, and a substantial cohort of women who discontinue treatment before achieving a pregnancy. This means that multiple numerators, denominators, timeframes and patient groups are possible when reporting ART treatment success rates. For this reason, interpretation of statistical tables must be in the context of clear a-priori questions. The Committee benefited from the counsel of the lead author of the ANZARD reports, which included guidance on how to accurately appraise the data. It is critical that readers familiarise themselves with the published ANZARD reports in order to better understand the data discussed in this report.
  - Secondly, beyond a small subset of general analyses, the annual ANZARD reports do not distinguish between the outcomes of ART treatment clinics based in Australia and those based in New Zealand. There are important differences in the performance and outcomes of ART treatment between the two countries:
    - Ninety-two per cent of the ART treatment cycles reported to ANZARD in 2014 took place in Australia.



- In Australia, there were 13.9 cycles per 1,000 women of reproductive age (15–44 years), compared to 6.5 cycles per 1,000 women of reproductive age in New Zealand.
- The overall delivery rates for Australia and New Zealand were 18.1 per cent and 22.4 per cent, respectively.
- Women having publicly funded ART in New Zealand are only funded to have up to two cycles of treatment. Therefore, analyses related to later cycles outcomes (for example, after the second cycle) include data from very few New Zealand cycles. For example, in Australia, 10.2 per cent of women had four or more cycles, compared to 3.7 per cent in NZ.

The Committee acknowledged that the reported live delivery rate for a given mixed cohort may be skewed due to the differences between Australia and New Zealand. However, it elected to treat mixed-cohort ANZARD statistics as sufficiently representative of Australia due to insufficient country-specific data, New Zealand's low level of multi-cycle treatment, and the fact that Australia accounts for 92 per cent of cycles and 90.4 per cent of deliveries recorded in ANZARD.

- Thirdly, there are different funding environments in Australia and New Zealand, and the Committee recognised that it was important to take these into account when considering the data. Noteworthy differences include the following:
  - New Zealand restricts public funding to two cycles for patients based on a set of clinical priority access criteria (CPAC), the aim of which is to fund ART treatment for patients who have a relatively poor prognosis of success without ART treatment and a relatively good prognosis with treatment. It also considers issues of equity (for example, taking into account the patient's number of existing children). As a result, New Zealand's patient population is different from the patient population in Australia.
  - New Zealand only publicly funds single-embryo transfers, which supports the achievement of a low multiple-pregnancy rate. However, the ART multiple birth rate is similarly low in Australia and New Zealand. For example, in 2012 the multiple birth rate was 5.2 per cent in NZ and 6.5 per cent in Australia and New Zealand combined.
- The Committee primarily reviewed data from the following four reports, each of which was provided in full to the Committee members:
  - The National Perinatal Epidemiology and Statistics Unit's annual ANZARD report on ART in Australia and New Zealand performed in 2014 (2).
    - This publicly available report provides various analyses describing the ART procedures performed and resulting treatment outcomes in Australia and New Zealand.



- The majority of age-related analyses in this report present statistics for five-year age groupings (for example, patients aged 35–39, 40–44, and so on).
  - These analyses are cross-sectional and longitudinal. The cross-sectional analysis provided descriptive statistics for cycles performed during 2014. This allows one to estimate the overall outcomes for procedures performed over one year, regardless of the number of cycles a woman may have had previously. The longitudinal analysis reported cycle-specific outcomes for up to 10 discrete fresh or frozen cycles for women who commenced ART in a particular period (for example, during 2012).
  - These cross-sectional and longitudinal analyses allowed the Committee to better understand the current procedures and outcomes of ART in Australia. They also allowed the Committee to observe the relationships between a patient's age at the time of treatment and her expected live delivery rate using stimulated autologous fresh, autologous frozen/thaw and donor embryo cycles. The Committee was also able to better isolate areas where ART is less likely to result in a live birth.
- The National Perinatal Epidemiology and Statistics Unit's December 2016 supplemental paper on cumulative live birth rates after repeated ART treatment cycles in Australia and New Zealand (8).
- This report was yet to be published at the time of the review, but it was made available to the Committee to assist it in forming its recommendations.
  - The majority of analyses in this report present statistics, including the cumulative live birth rate, for five-year age groupings (for example, 35–39, 40–44, 45+), based on complete ART cycles (any fresh and frozen cycles resulting from a single stimulated ART cycle). In contrast, the annual ANZARD reports present longitudinal cycle-specific rates for discrete fresh and frozen cycles and do not report cumulative live birth rates.
  - The statistics provided describe what happened to a mixed cohort of patients who commenced ART for the first time, following them through their course of treatment until they achieved a live birth or discontinued treatment.
  - These analyses allowed the Committee to better understand the relationship between: (a) the cycle-specific live delivery rates (for example, percentage of women achieving a live birth in their third cycle); (b) the cumulative live delivery rates (for example, the percentage of women who achieved their first live birth after three cycles); (c) the impact of female patient age on commencement of treatment; and (d) the impact of the number of complete cycles the patient had previously undergone.
  - ART registries do not record why women discontinue treatment, despite not achieving a live birth. For this reason, it is necessary to make assumptions about the prognosis of



those who discontinue. There are numerous possible reasons for discontinuing treatment, including poor prognosis of continued treatment, financial/social/psychological burden, and changing personal or health circumstances. This report presents expected (probabilities) optimal and conservative cumulative live delivery rates that provide an idea of the range in which the actual rate is likely to be found. The optimal case assumes that for patients who discontinue treatment, their chance of dropping out of treatment is independent of their chance of a live delivery, and that they would have had the same chance as the remaining cohort members of having a live delivery in subsequent complete cycles. The conservative case assumes that all patients who decline further treatment would not have had a live delivery in subsequent complete cycles. This distinction affects the numerator in the cumulative probability of a live delivery calculation. It is generally accepted that the actual cumulative probability of a live delivery lies somewhere between these two expected cumulative live delivery rates. To facilitate decision-making using this highly complex data set, the Secretariat presented the Committee with graphs referring to the midpoints of these data ranges.

- The National Perinatal Epidemiology and Statistics Unit's February 2017 supplemental paper on cumulative live birth rates after repeated ART treatment cycles in Australia and New Zealand (3).
  - This analysis was specifically commissioned by the MBS Review to provide a similar view of the longitudinal data analyses in the December 2016 paper, by two-year age groups (for example, 38–39, 40–41, 42–43, 44–45, 46+), and by one-year age groupings for cross-sectional live birth rates (all cycles combined).
  - This report enabled the Committee to assess in more detail previously identified areas where ART is less likely to result in a live birth.
  - In the December 2016 and February 2017 papers described here, patients were grouped according to their age at the time they initiated their first stimulated ART cycle. This means that if a patient aged 44 initiated her seventh stimulated cycle five years after her first cycle (initiated when she was 39), she would still be counted in cycle seven for the 38–39 age group—theoretically along with younger patients who had also begun treatment at 39 but had reached their seventh cycle more quickly. The Committee felt that an alternative analytical method in which the patient was counted as belonging to the age group she fell into at the time at which she initiated a particular stimulated ART cycle would be more informative. This led to the creation of the April 2017 paper described below.



- The National Perinatal Epidemiology and Statistics Unit's April 2017 supplemental paper on cumulative live birth rates after repeated ART treatment cycles in Australia and New Zealand (5).
  - The National Perinatal Epidemiology and Statistics Unit produced this supplemental analysis in order to provide data consistent with the Committee's methodological preferences, as described above.
  - Specifically, the Committee requested cycle-specific rates based on female patients' two-year age groupings, which were based on their age at the time the specified stimulated ART cycle was performed, rather than their age at the time of initiating their first lifetime stimulated ART cycle (as was the case in the December 2016 and February 2017 papers cited above).

### **Age- and cycle-related clinical fertility and live birth rates**

The Committee reviewed data regarding the following points of interest:

- Patient age.
- Number of cycles.

#### *(i) Patient age*

- All members of the Committee and the ARTWG agreed that patient age was an appropriate factor by which to limit MBS funding for ART treatment.
  - Advancing age negatively affects the live delivery rate of patients undergoing ART treatment.
  - Fertility declines naturally as a woman ages, and this affects ART treatment outcomes. For instance, the combined autologous (fresh and thaw) live birth rate per initiated autologous fresh cycle (the live delivery rate per complete cycle) falls from approximately 44.8 per cent in patients aged 32 to 3.0 per cent in those aged 46 and over (Figure 3) (2).
- The Committee felt that restricting the age of the patient to that associated with a 5 per cent live birth rate would encourage prospective patients to seek ART treatment at earlier ages. Given the risks inherent in ART treatment and the live birth rates per complete cycle after the 44th birthday (less than 5 per cent), the Committee felt that restricting MBS funding for the stimulated fresh IVF cycle items to patients who have not yet reached their 44th birthday was in the interest of patient health and improved clinical practice. The benefit-to-risk ratio in patients was considered unacceptably low beyond this limit.

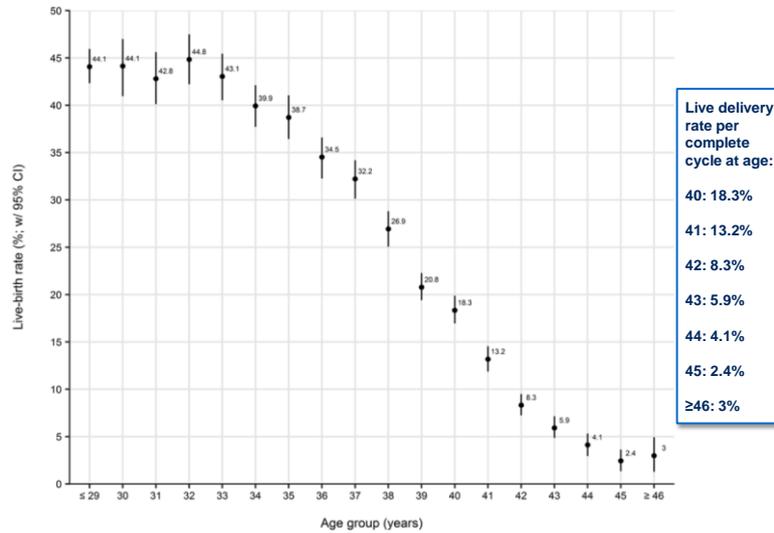


*(ii) Number of cycles*

- All members of the Committee and the ARTWG agreed that it was appropriate to limit MBS funding for ART treatment based on the number of cycles undergone by a patient.
  - The Committee noted that the cumulative live birth rate at every age declines at an accelerating rate with each successive cycle (Figure 4). (Please note that the terms ‘birth’ and ‘delivery’ are equivalent in this context and are used interchangeably here.)
  - The incremental gain in live birth rates diminishes with each unsuccessful complete cycle.
- This recommendation will affect a small subset of patients, with the intention of discouraging the ongoing provision of low-value procedures.
  - MBS data shows that 9 per cent of patients elect to undergo more than four stimulated IVF cycles, and that only 3 per cent of patients undergo more than six cycles.
  - After each of the first eight complete cycles, approximately 25–35 per cent of patients whose ART cycle is unsuccessful do not return for further treatment.
  - A subset of patients discontinues treatment after achieving a successful live delivery.
  - Research shows that approximately 60 per cent of unsuccessful patients in each cycle discontinue treatment for reasons other than their expected prognosis—for example, for financial or personal reasons (2) (9).
- The Committee also took into account the negative psychological effects of failed ART cycles, including an increased risk of depression and anxiety, both of which remain above baseline even six months after a failed procedure (10).
- The age of the patient and the number of previous cycles undergone both affect expected live delivery rates for a given complete cycle. The overall expected live delivery rate when taking into account both of these factors is estimated in Figure 5.



**Figure 3: Combined autologous (fresh and thaw) live birth rate per initiated autologous fresh cycle, with 95% confidence intervals, by women’s age at start of fresh or thaw treatment cycle, Australia and New Zealand, 2014 data**

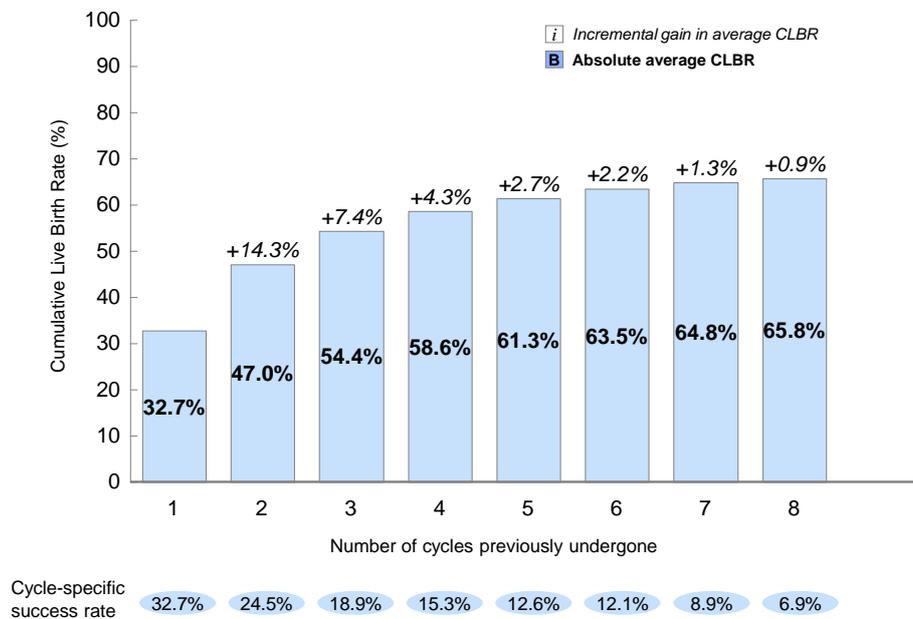


**Source:** Cumulative live birth rates after repeated assisted reproduction technology treatment cycles in Australia and New Zealand. February 2017. (Analysis 2). National Perinatal Epidemiology and Statistics Unit, UNSW.

The graph in this analysis was derived directly from the referenced paper. The blue box was added separately, and serves only to make the figures on the graph more easily legible.

**\*Important\*** Please see referenced source and Appendix A for detailed notes on the correct interpretation of this data.

**Figure 4: All ages: Cumulative live birth rate by number of complete cycles (fresh and resulting frozen cycles) – midpoint of conservative and optimal models**



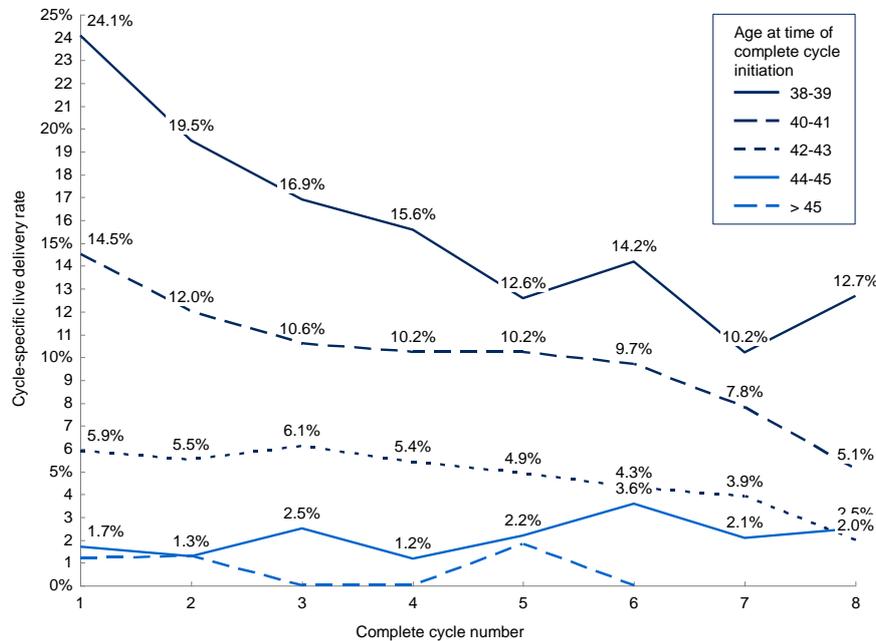
**Source:** Cumulative live birth rates after repeated assisted reproduction technology treatment cycles in Australia and New Zealand. February 2017. National Perinatal Epidemiology and Statistics Unit, UNSW.

This analysis takes the midpoint of the optimal and conservative percentage cumulative live-birth rates by cycle for each age group, as provided in the “All-age women” section of Table 2, and displays these as blue bars. The incremental gain numbers in italics indicate the absolute percentage increase from one bar to the next. The cycle-specific success rates along the bottom of the figure are derived directly from the “All-age women” section of Table 2.



**\*Important\*** Please see referenced source and Appendix A for detailed notes on the correct interpretation of this data.

**Figure 5: Live birth rate per complete cycle by women's age group at time of treatment, for women who commenced ART treatment in 2009–12, Australia and New Zealand**



**Source:** Cycle-specific live birth rates during repeated assisted reproduction technology treatment cycles in Australia and New Zealand, based on women's ages at time of treatment, April 2017. ANZARD Data Management Team, National Perinatal and Epidemiology and Statistics Unit (NPESU), UNSW.

This graph visually represents the live-birth rate per complete cycle for age groups 38-39 and over, and cycle numbers 1-8, using data derived from table "Live-birth rate per complete cycle by women's age group at time of treatment, for women who commenced assisted reproductive technology treatment in 2009-2012, Australia and New Zealand" in the referenced paper.

**\*Important\*** Please see referenced source and Appendix A for detailed notes on the correct interpretation of this data.

### Other factors of potential relevance to live delivery rates

The Committee considered alternative measures that could be used to determine access to MBS funding for stimulated cycle items.

- The Committee considered the possibility that MBS funding could be limited based on a composite prognostic measure. However, it ultimately decided that such a measure would be difficult to enforce and prone to error.
  - According to expert opinion, prognosis varies depending on a woman's age and the number of cycles she has undergone. A composite prognostic measure could take into account factors such as the patient's anti-Mullerian hormone (AMH) titre or the estimated remaining number of follicles.
  - The Committee noted that AMH assays may provide a more precise measure of the expected success of ART treatment. It also noted that the number-of-follicles approach would give patients an opportunity to try a stimulated cycle, but if they did not meet the threshold, there would be clear and persuasive reasons for not continuing with further



funded treatment. This would avoid the costs involved in ovum retrieval and subsequent ART steps.

- However, the Committee identified problems with these potential measures:
  - Most importantly, complex laboratory metrics are variable, and in some cases, performing the same test on the same patient at the same time can still yield slightly different results. This could lead to inappropriate repeat testing for those close to a threshold value, undertaken in an effort to obtain the desired result.
  - Results can also be affected by confounding factors, such as medication, supplements or certain foods ingested by the patient, as well as the handling of the laboratory sample prior to testing, among others.
  - The measures can be difficult to explain to patients, reducing the transparency of the MBS funding system.
- The Committee also considered MBS funding restrictions based on tobacco smoking, obesity, number of pre-existing children and duration of fertility. However, it decided that recommending restrictions based on these factors would inappropriately limit access and/or would be difficult to implement or enforce in the current MBS system.
  - Tobacco smoking
    - The Committee discussed the negative effects of tobacco smoking on ART, maternal and child outcomes. It noted that although potential patients can conceal the fact that they smoke, it is possible to objectively detect maternal smoking using laboratory tests.
    - However, test results can be affected by environmental factors outside of the patient's control, as well as close contact with another person who smokes.
  - Obesity
    - There is evidence that maternal obesity is correlated with poorer ART, maternal and child outcomes. For instance, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists' (RANZCOG) clinical guidelines note that there is an increased rate of complications across all stages of pregnancy in obese women (Body Mass Index [BMI]>30) and their babies.
    - However, some patients have a genetic predisposition to high BMI, and high BMI is also correlated with lower socio-economic status and regional populations. As a result, limiting MBS funding based on these factors could be construed as discrimination against those suffering genetic or socio-economic hardship, if the evidence for negative maternal and child outcomes is insufficient.



- It is also unclear what limits should be placed on BMI. Suggested limits were BMIs greater than 35, greater than 40 and greater than 50.
- Number of pre-existing children
  - The median number of children in Australian families is two, and this could be considered a socially reasonable limit for the number of children a patient might have before MBS funding for ART treatment is limited.
  - However, such a limit would be impractical to enforce as some women have children from a previous marriage, children from a male partner's previous marriage or children born overseas, which would complicate monitoring and lead to inequitable funding provision.
  - Evidence also suggests that a failed ART cycle has a negative psychological effect on a patient regardless of the number of children she already has (11).
- Duration of infertility
  - The World Health Organization (WHO) and the International Committee for Monitoring Assisted Reproductive Technology (ICMART) define infertility as failure to achieve a clinical pregnancy after 12 months or more of regular unprotected intercourse (12). This is not readily measurable and is difficult to monitor, which would make it challenging to enforce any limitation based on duration of infertility.
  - Limitations based on the duration of infertility may also be unnecessary as the current out-of-pocket funding requirement already disincentivises use of the items until patients feel they truly have a fertility problem.

## 5.2.2 Items 13200, 13201 and 13202 – Recommendation 2

### Recommendation 2

- Create new items 132ZX, 132ZY and 132ZZ to facilitate MBS funding for up to four stimulated IVF cycles for an altruistic oocyte donor under the age of 40, for the benefit of a recipient under the age of 45 years, where the recipient:
  - Has a medical cause of infertility that is or is expected to be non-responsive to autologous IVF therapy.  
  
OR
  - Is no longer eligible to use items 13200, 13201, 13202, 132XX, 132XY and 132XZ due to age.  
  
OR



- Is undergoing IVF for the purposes of a surrogacy arrangement in accordance with relevant State and Territory law.
- The proposed descriptor for item 132ZX is as follows:
  - Donor assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13201, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – initial cycle in a single calendar year.
  - This item to be used only for stimulated IVF cycles provided to an altruistic female oocyte donor, solely for the purposes of donating an oocyte(s) to a recipient who either:
    - Has a medical cause of infertility that is or is expected to be non-responsive to autologous IVF therapy
  - OR
  - Is no longer eligible to use items 13200, 13201, 13202, 132XX, 132XY and 132XZ due to age
  - OR
  - Is undergoing IVF for the purposes of a surrogacy arrangement in accordance with relevant State and Territory law.
- In addition, the following conditions apply:
  - Initiation of administration of stimulation drugs not to commence on or after oocyte donor's 40th birthday, and also not to commence on or after the oocyte recipient's 45th birthday.
  - Oocyte donor may not have claimed six or more stimulated autologous IVF cycles previously (sum of 13200, 13201, 13202, 132XX, 132XY, 132XZ).
  - Recipient of oocyte donation must be identified and documented in the provider's notes at the time of initiation of stimulated donor IVF cycle.
  - Maximum number of stimulated donor IVF cycles not to exceed four (sum of 132ZX, 132ZY and 132ZZ).
- The proposed descriptor for item 132ZY is as follows:



- Donor assisted reproductive technologies stimulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13201, 13202, 13203, 13206, 13218 applies – being services rendered during 1 treatment cycle – each cycle subsequent to the first in a single calendar year.
- This item to be used only for stimulated IVF cycles provided to an altruistic female oocyte donor, solely for the purposes of donating an oocyte(s) to a recipient who either:
  - Has a medical cause of infertility that is or is expected to be non-responsive to autologous IVF therapy
- OR
- Is no longer eligible to use items 13200, 13201, 13202, 132XX, 132XY and 132XZ due to age
- OR
- Is undergoing IVF for the purposes of a surrogacy arrangement in accordance with relevant State and Territory law.
- In addition, the following conditions apply:
  - Initiation of administration of stimulation drugs not to commence on or after oocyte donor's 40th birthday, and also not to commence on or after the oocyte recipient's 45th birthday.
  - Oocyte donor may not have claimed six or more stimulated autologous IVF cycles previously (sum of 13200, 13201, 13202, 132XX, 132XY, 132XZ).
  - Recipient of oocyte donation must be identified and documented in the provider's notes at the time of initiation of stimulated donor IVF cycle.
  - Maximum number of stimulated donor IVF cycles not to exceed four (sum of 132ZX, 132ZY and 132ZZ).
- The proposed descriptor for item 132ZZ is as follows:
  - Donor assisted reproductive technologies stimulated treatment cycle that is cancelled before oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones, semen preparation, ultrasound examinations, but excluding artificial insemination or transfer of frozen embryos or donated embryos or ova



or a service to which item 13200, 13201, 13203, 13206, 13218 applies being services rendered during 1 treatment cycle.

- This item to be used only for stimulated IVF cycles provided to an altruistic female oocyte donor, solely for the purposes of donating an oocyte(s) to a recipient who either:
  - Has a medical cause of infertility that is or is expected to be non-responsive to autologous IVF therapy

OR

- Is no longer eligible to use items 13200, 13201, 13202, 132XX, 132XY and 132XZ due to age

OR

- Is undergoing IVF for the purposes of a surrogacy arrangement
- In addition, the following conditions apply:
  - Initiation of administration of stimulation drugs not to commence on or after oocyte donor's 40th birthday, and also not to commence on or after the oocyte recipient's 45th birthday.
  - Oocyte donor may not have claimed six or more stimulated autologous IVF cycles previously (sum of 13200, 13201, 13202, 132XX, 132XY, 132XZ).
  - Recipient of oocyte donation must be identified and documented in the provider's notes at the time of initiation of stimulated donor IVF cycle.
  - Maximum number of stimulated donor IVF cycles not to exceed four (sum of 132ZX, 132ZY and 132ZZ).

### Rationale

This recommendation extends access to patients suffering from premature ovarian failure or anatomical difficulties, and to patients who have become infertile as a result of chemotherapy, radiotherapy or other medical causes. It is based on the following.

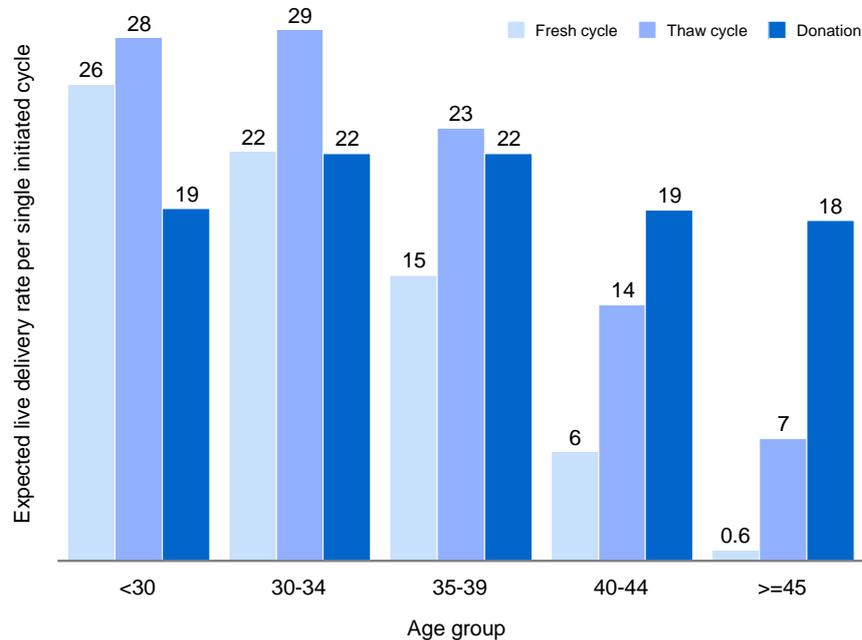
- Although the current system does not specifically exclude such patients from MBS-funded ART treatment, it does not provide clear, equal access to people who would derive more benefit from treatment with donated rather than autologous oocytes.
- ANZARD data (Figure 6) shows that the live delivery rate per initiated donor cycle remains above 18 per cent in all age groups analysed (2). The Committee felt this was sufficiently high to warrant public funding.



- However, given the decline in the live delivery rates seen as a donor's age increases, as well as the social circumstances under which a donor voluntarily undergoes invasive treatment for the benefit of another person, it was felt that a donor should only be provided with MBS funding for four complete cycles undertaken before the 40th birthday. This would discourage donors with lower expected live delivery rates from undergoing donor cycles.
- The Committee therefore agreed that it was appropriate to provide MBS funding for donor ART treatment within specific age and cycle limits.
  - Live delivery rates fall as a patient ages, although the decline is less marked when receiving a donor cycle rather than an autologous cycle.
  - In women aged 40 and over, ART cycles performed using donated oocytes result in a higher live delivery rate than those using autologous oocytes (2). This is because the oocyte donor (and therefore the donated oocyte) tends to be younger at the time of donation than the recipient is at the time of embryo transfer. In other words, an older patient benefits from treatment using a relatively younger oocyte (Figure 6).
- Given the increased obstetric risks associated with increasing age, the Committee considered it clinically appropriate to limit the oocyte recipient's age to below 45 (13) (14).
- Limiting MBS funding for oocyte donors to an identified recipient should reduce the risk of MBS funding leading to non-altruistic donation.
- A specification to allow use of this item in patients undergoing IVF for the purposes of a surrogacy arrangement supports the Committee's recommendation to remove the existing restriction on MBS funding for IVF in these situations.
- It was noted that oocyte donation has important social and ethical implications. These have been carefully considered by the National Health and Medical Research Council (NHMRC) in its 2017 report, Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (15).



**Figure 6: Live delivery rate per initiated cycle by type, 2014 data**



**Source:** Assisted Reproductive Technology in Australia and New Zealand Report 2014: Table 22, p. 30. National Perinatal Epidemiology and Statistics Unit, UNSW.

This chart represents as bars the expected live deliveries per initiated cycle (%) for different age groups, with the colours of the bars representing different types of cycles. This data was derived directly from tables 9, 14 and 22 (for fresh, thaw and donation respectively) of the referenced paper. Donation data refers to the age of the recipient at the start of a treatment cycle. Values over 1 were rounded to assist legibility.

### 5.2.3 Items 13200, 13201 and 13202 – Recommendation 3

#### Recommendation 3

- Remove the current exclusion for MBS funding for IVF cycles in patients who are engaged in surrogacy arrangements from the following:
  - The General Medical Service Tables (GMST), Regulation 2.37.7.
  - MBS explanatory note T1.4.

#### Rationale

This recommendation modernises the MBS by bringing these items into line with current state laws permitting altruistic surrogacy arrangements. It is based on the following.

- The current system does not provide clear, equal access to people who require the use of surrogacy arrangements for medical reasons.
- State laws govern surrogacy arrangements in Australia. When the MBS ART items were created, surrogacy was illegal in some states and the MBS items intentionally reflected this. Over the years, however, this situation has changed, and each of the states and territories has now legalised altruistic surrogacy arrangements.



- In view of the legalisation of surrogacy arrangements by all Australian states and territories in recent years, as well as the needs of patients who are medically unable to conceive or carry a foetus to delivery themselves, the Committee considered the current MBS restriction on funding for ART items in these situations to be unacceptable.

#### 5.2.4 Items 13200, 13201 and 13202 – Recommendation 4

##### Recommendation 4

- Enable the Department to freely access the current compulsory dataset supplied by providers to ANZARD in order to monitor the appropriateness of the MBS ART items, and to facilitate work on initiatives designed to make complex ART outcome data more understandable and informative for consumers.
- These initiatives should include:
  - A publicly accessible ‘ART success calculator’ that allows patients to anonymously provide personal prognostic indicators and receive a personalised estimate of their likely live delivery rate with ART treatment.
  - A nationally standardised informed consent form that provides an indication of the complete course of ART treatment expected to be required for each patient based on their estimated live delivery rate with ART treatment, along with the total out-of-pocket costs associated with such a course.

##### Rationale

This recommendation focuses on improving the transparency of the MBS and enabling better patient education. It is based on the following.

- The Committee found that:
  - Providers capture meaningful data on the quality and safety of care, and that privately funded entities with a close association with the ART industry collect this data and accredit providers.
  - ANZARD collects and analyses high-quality, highly detailed data on local ART treatment.
  - Neither the public nor the MBS has direct access to ANZARD data.
  - The public and the media have expressed concern about the lack of transparency regarding patient prognostic factors and expected outcomes of ART treatment.
  - The industry has been permitted to self-regulate and self-accredit, with the understanding that high standards of quality and safety would be maintained.



- In 2016, the Australian Competition and Consumer Commission (ACCC) investigated website content from all major Australian IVF clinics and found that the data and conclusions presented were sometimes misleading or inadequately qualified (16) (17).
- It was noted that ART outcomes data is extremely complex, and that expert knowledge is necessary in order to appropriately interpret the data. As a result, there were concerns that making detailed data directly available to the public would result in incorrect analyses, assumptions and conclusions about the quality and safety of ART treatment in Australia.
- The Committee noted that the Department does not have direct access to ANZARD provider data, which limits its ability to review the effectiveness and appropriateness of the funding it provides.
- The Committee considered it very important that patients are provided with information about the quality of care they can expect from a particular clinic. At present, this is difficult to ascertain because ANZARD's agreements with providers do not allow the data to be used for such purposes. This means that clinics' marketed success rates cannot easily be independently verified and monitored.
- The Committee also expressed concern that the standards used by the RTAC to accredit clinics are unclear to the government and the public, and that the RTAC may not fully utilise the clinic-level data available in ANZARD to hold clinics to data-driven minimum quality standards.
- For these reasons, the Committee agreed that it would be valuable for an outside party such as the Department to have access to appropriate datasets in order to independently verify the veracity and transparency of the industry's processes. (The Committee does not believe that there is a need to replicate the level of detail derived from ANZARD in the MBS dataset.)
- The Committee did discuss setting up a national independent regulatory body. However, this was agreed to be a large and complex undertaking. In Committee members' experience, international attempts to do this have encountered technical, legal and implementation difficulties while achieving lower-than-expected levels of positive impact on ART outcomes. The Committee did not consider this an ideal path for Australia to follow.
- The Committee felt that allowing the MBS to freely access the current compulsory dataset supplied by providers to ANZARD would enable work to begin on initiatives designed to make complex ART outcome data more understandable and informative for consumers. For example:
  - A web-based application could be developed that allows patients to input their personal characteristics and obtain an estimated live delivery rate per complete cycle (a 'success calculator'). This would be extremely valuable, addressing both concerns about patient education and expectations for treatment.



- Access to ANZARD data would facilitate accurate predictions of a patient’s likely course of ART care. Patients could then be presented with a nationally standardised informed consent form that provides an estimate of expected total out-of-pocket costs for the particular patient’s entire ART process, not just a single cycle.
- The Committee also discussed ‘league table’ or ‘five-star’ quality rating models, but it felt that these were likely to lead to undesirable behaviour within some clinics in an attempt to remain competitive. The Committee advised against implementing such an initiative in Australia.

### 5.3 Ovulation monitoring services (item 13203)

#### 5.3.1 Item 13203

Table 4: Item introduction table for item 13203

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13203	Ovulation monitoring services, for artificial insemination – including quantitative estimation of hormones and ultrasound examinations, being services rendered during 1 treatment cycle but excluding a service to which item 13200, 13201, 13202, 13206, 13212, 13215, 13218, applies	\$486.75	8,733	-2.9%	\$3,876,317

#### Recommendation 5

- Change the item descriptor to include the following indication/usage: gonadotrophin-stimulated ovulation induction.
- The proposed item descriptor is as follows:
  - Ovulation monitoring services, for artificial insemination or gonadotrophin-stimulated ovulation induction – including quantitative estimation of hormones and ultrasound examinations, being services rendered during 1 treatment cycle but excluding a service to which item 13200, 13201, 13202, 13206, 13212, 13215, 13218, applies.

#### Rationale

This recommendation focuses on modernising the MBS and promoting equal access for patients with valid indications. It is based on the following.

- Ovulation monitoring services related to gonadotrophin-stimulated ovulation induction are similar in scope and complexity to those related to artificial insemination, but rebates are not



currently provided for these services. This unintentionally limits access to a service that is very effective in anovulatory patients who do not require artificial insemination or full IVF therapy.

- Stimulating ovulation in these patients enables them to conceive naturally and avoid more invasive treatment, thereby protecting patient safety and promoting higher value care.

## 5.4 Natural/oral medication ART treatment cycle (item 13206)

### 5.4.1 Item 13206

Table 5: Item introduction table for item 13206

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13206	Assisted reproductive technologies treatment cycle using either the natural cycle or oral medication only to induce oocyte growth and development, and including quantitative estimation of hormones, semen preparation, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination, frozen embryo transfer or donated embryos or ova or treatment involving the use of injectable drugs to induce superovulation being services rendered during 1 treatment cycle but only if rendered in conjunction with a service to which item 13212 applies	\$465.55	91	-6.6%	\$42,605

### Recommendation 6

- Delete item.

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- This item represents low-value care because contemporary best practice supports either continuation of attempts at natural conception or the use of artificial insemination or IVF in cases of infertility.
- MBS data also shows that this item is seldom used.



## 5.5 Oocyte retrieval (item 13212)

### 5.5.1 Item 13212

Table 6: Item introduction table for item 13212

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13212	Oocyte retrieval for the purpose of assisted reproductive technologies—only if rendered in connection with a service to which item 13200, 13201 or 13206 applies (Anaes.)	\$354.45	38,492	4.1%	\$10,517,538

### Recommendation 7

- Change the item descriptor to restrict claiming of this item in conjunction with stimulated ART cycles that have been initiated after the 44<sup>th</sup> birthday.
- The proposed item descriptor is as follows:
  - Oocyte retrieval for the purpose of assisted reproductive technologies—only if rendered in connection with a service to which item 13200, 13201, 132XX, 132XY, 132ZX or 132ZY applies, payable where that service was initiated before the 44<sup>th</sup> birthday (Anaes.)

### Rationale

This recommendation focuses on modernising the MBS to reflect clinical best practice. It is based on the following.

- This item describes a key procedure in IVF treatment and reflects contemporary clinical best practice.
- Restricting the claiming of this item in association with a stimulated cycle that was initiated after the 44<sup>th</sup> birthday, supports the Committee’s recommendation to limit MBS funding to patients with relatively higher expected live delivery rates from IVF treatment, as described in Recommendation 1.

## 5.6 Semen collection (items 13290 and 13292)

### 5.6.1 Items 13290 and 13292

Table 7: Item introduction table for items 13290 and 13292



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13290	Semen, collection of, from a patient with spinal injuries or medically induced impotence, for the purposes of analysis, storage or assisted reproduction, by a medical practitioner using a vibrator or electro-ejaculation device including catheterisation and drainage of bladder where required	\$204.25	4	-4.4%	\$593
13292	Semen, collection of, from a patient with spinal injuries or medically induced impotence, for the purposes of analysis, storage or assisted reproduction, by a medical practitioner using a vibrator or electro-ejaculation device including catheterisation and drainage of bladder where required, under general anaesthetic, in a hospital (Anaes.)	\$408.70	-	0.0%	\$-

### Recommendation 8

- Item 13290: No change.
- Item 13292: Consolidate this service into item 13290. Delete item.

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- Item 13290:
  - Although service volumes for item 13290 are low and there are considerable risks associated with this procedure (for example, burns, sympathetic nervous system stimulation with dangerous hypertension), it is still considered appropriate clinical practice in select cases, as identified in the existing item descriptor. Item 13290 should therefore be retained to maintain patient access in appropriate situations.
- Item 13292:
  - Item 13292 can be deleted because the benefit-to-risk ratio for general anaesthesia in such a procedure is unacceptable, and because MBS data shows that it has not been used since FY2010–11. The Committee expects that services currently performed using this item will shift to item 13290.

## 5.7 Processing and transfer of gametes and embryos (items 13215, 13218, 13221 and 13251)

### 5.7.1 Items 13215, 13218, 13221 and 13251

Table 8: Item introduction table for items 13215, 13218, 13221 and 13251



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13215	Transfer of embryos or both ova and sperm to the uterus or fallopian tubes, excluding artificial insemination—only if rendered in connection with a service to which item 13200, 13201, 13206 or 13218 applies, being services rendered in one treatment cycle (Anaes.)	\$111.10	47,903	1.4%	\$4,635,478
13218	Preparation of frozen or donated embryos or donated oocytes for transfer to the uterus or fallopian tubes, by any means and including quantitative estimation of hormones and all treatment counselling but excluding artificial insemination services rendered in 1 treatment cycle and excluding a service to which item 13200, 13201, 13202, 13203, 13206, 13212 applies (Anaes.)	\$793.55	28,727	5.9%	\$32,910,190
13221	Preparation of semen for the purpose of artificial insemination—only if rendered in connection with a service to which item 13203 applies	\$50.80	7,183	-4.2%	\$356,831
13251	Intracytoplasmic sperm injection for the purposes of assisted reproductive technologies, for male factor infertility, excluding a service to which item 13203 or 13218 applies	\$417.95	25,564	3.2%	\$11,498,559

## Recommendation 9

- Items 13215:
  - Change the item descriptor to restrict claiming of this item in conjunction with stimulated ART cycles that have been initiated after the 44<sup>th</sup> birthday.
  - The proposed item descriptor is as follows:
    - Transfer of embryos or both ova and sperm to the uterus or fallopian tubes, excluding artificial insemination—only if rendered in connection with a service to which item 13200, 13201, 132XX, 132XY, 132ZX, 132ZY or 13218 applies, being services rendered in one treatment cycle, payable where that service was initiated before the 44<sup>th</sup> birthday (Anaes.)
- Item 13218:
  - Change the item descriptor to restrict claiming of this item in conjunction with stimulated ART cycles that have been initiated after the 44<sup>th</sup> birthday.
  - The proposed item descriptor is as follows:



- Preparation of frozen or donated embryos or donated oocytes for transfer to the uterus or fallopian tubes, by any means and including quantitative estimation of hormones and all treatment counselling but excluding artificial insemination services rendered in 1 treatment cycle and excluding a service to which item 13200, 13201, 13202, 132XX, 132XY, 132XZ, 132ZX, 132ZY, 132ZZ, 13203 or 13212 applies, and payable where the stimulated ART cycle service that preceded the freezing of the oocytes or embryos was initiated before the 44th birthday (Anaes.)
- Item 13221: No change.
- Item 13251: Consolidate this service into items 13200, 13201, 132XX, 132XY, 132XZ, 132ZX, 132ZY and 132ZZ and delete existing standalone item 13251.
  - The schedule fees for these items will need to be modified in order to effectively reimburse clinicians for the use of ICSI in 60 per cent of stimulated cycles, thereby encouraging appropriate use of the procedure.

## Rationale

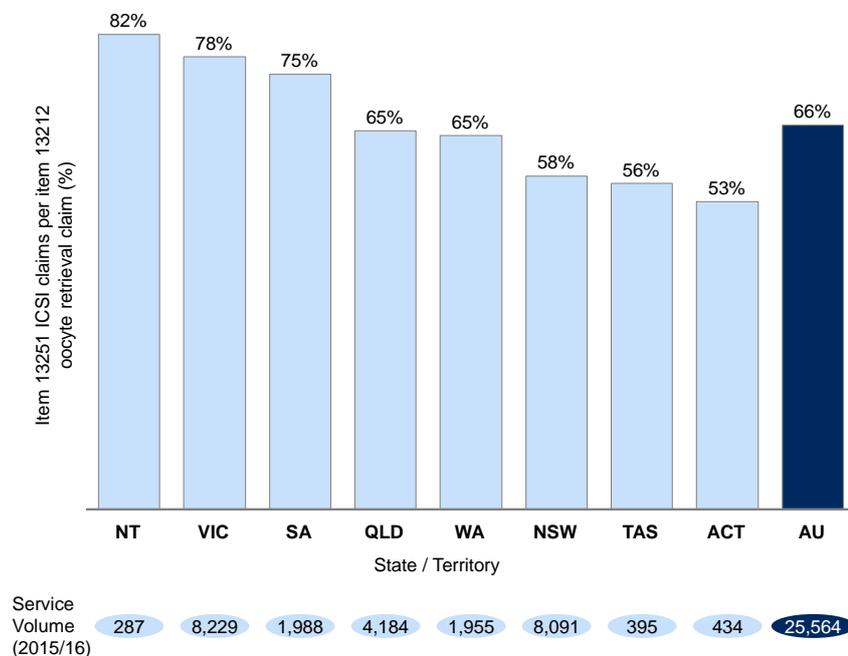
This recommendation focuses on modernising the MBS and improving the value of care. It is based on the following.

- Items 13215 and 13218:
  - The procedures covered by items 13215, 13218 are necessary components of IVF therapy and accurately reflect contemporary best practice.
  - Restricting the claiming of these items in association with a stimulated cycle that was initiated after the 44<sup>th</sup> birthday, supports the Committee's recommendation to limit MBS funding to patients with relatively higher expected live delivery rates from IVF treatment, as described in Recommendation 1.
- Item 13221:
  - The procedure covered by item 13221 is a necessary component of IVF therapy and accurately reflects contemporary best practice.
- Item 13251:
  - The Committee noted that MBS data shows considerable regional variation in the use of ICSI during IVF therapy (Figure 7).
    - For example, despite roughly equivalent service volumes, clinicians in Victoria used ICSI in 78 per cent of cycles proceeding to oocyte pickup, while clinicians in New South Wales did so in just 58 per cent of equivalent cycles.



- The Committee considered this level of variation to be inappropriate because it indicates overuse in several regions and underuse in others. The Committee’s expert opinion is that approximately 60 per cent of patients will benefit from ICSI, and that use in the remaining 40 per cent is ineffective or even to the detriment of IVF outcomes, leading to a poorer benefit-to-risk ratio and lower value patient care.
- The Committee recommended bundling ICSI procedures with the relevant inclusive stimulated cycles items for the following reasons:
  - Research focused on defining the patient populations with the best outcomes as a result of ICSI is still ongoing.
  - There is limited evidence of varying quality that ICSI is effective in ART treatment regardless of cause. The Committee felt that bundling the ICSI item may disincentivise its use as a ‘premium add-on’ and lead to more clinically rational use of the technology. For example, ANZARD data shows that 21.9 per cent of ICSI item claims are for couples with documented female-factor-only infertility (Figure 8) (18). The clinical utility of ICSI is questionable in these cases, and recent evidence suggests it may even be detrimental to the success of ART treatment. Using ICSI for couples with a proven or suspected female-only cause of infertility does not constitute high-value care.

**Figure 7: ICSI utilisation rates by state (item 13251 ICSI services per item 13212 oocyte retrieval, %), FY2015–16 data**



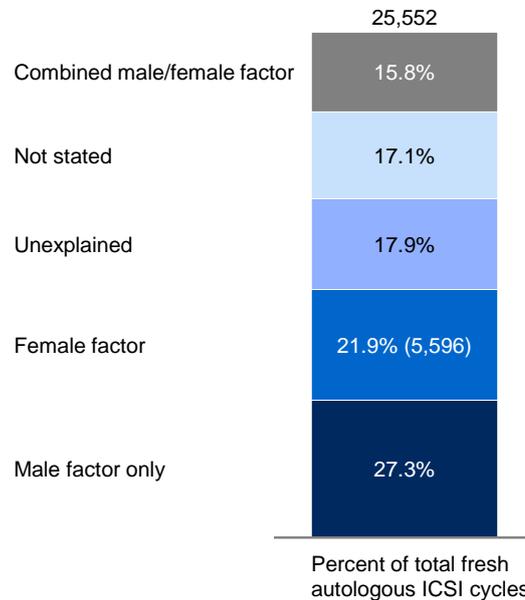
**Source:** Medicare Data, items 13251 and 13212, total services by State/Territory. July 2015–Jun 2016, date of processing, extracted January 2017.

This analysis takes the total number of 13251 ICSI services, and divides it by the total number of 13212 oocyte retrieval services funded through the MBS in 2015/16 in each State/Territory. It assumes that all ICSI services are related to a single oocyte retrieval procedure. This provides an indication of what percentage of all IVF procedures progressing to oocyte retrieval also utilized ICSI in each area, presented for comparison as a bar graph with the average across Australia indicated



in darker blue. Service volumes in each State/Territory are provided to give an idea of relative scale. Figures have been rounded to facilitate legibility.

**Figure 8: Fresh ICSI cycles in Australia and New Zealand by cause of infertility, 2014**



**Source:** Assisted Reproductive Technology in Australia and New Zealand Report 2014 Supplementary tables: Table S1, p. 2. National Perinatal Epidemiology and Statistics Unit, UNSW.

This stacked bar graph uses data directly derived from the referenced paper to illustrate the relative percentages of ICSI procedures performed for different recorded causes of infertility. The absolute service volumes for each indication found in the referenced table were divided by the total for all causes (displayed atop the bar) to obtain percentage figures. Figures have been rounded to facilitate legibility.

## 5.8 Professional attendance (items 13209 and 13210)

### 5.8.1 Items 13209 and 13210

**Table 9: Item introduction table for items 13209 and 13210**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
13209	Planning and management of a referred patient by a specialist for the purpose of treatment by assisted reproductive technologies or for artificial insemination payable once only during 1 treatment cycle	\$84.70	78,387	3.7%	\$6,154,271
13210	Professional attendance on a patient by a specialist practising in his or her speciality if: (a) the attendance is by video conference; and (b) item 13209 applies to the attendance; and (c) the patient is not an admitted patient; and (d) the patient: (i) is located both: (a) within a telehealth eligible area; and (b) at the time of	\$42.35	-	0.0%	\$-



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
	the attendance—at least 15 kms by road from the specialist; or (ii) is a care recipient in a residential care service; or (iii) is a patient of: (a) an Aboriginal Medical Service; (b) or an Aboriginal Community Controlled Health service for which a direction made under subsection 19 (2) of the act applies				

## Recommendation 10

- Item 13209: No change.
- Item 13210: Delete item.

## Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- Item 13209:
  - This item remains appropriate for contemporary care.
- Item 13210:
  - MBS data shows that item 13210 was not claimed at all in FY2015–16 or within the past five years. The Committee appreciates the intention to extend access to the patients detailed in the descriptor, but it notes that this has not yet resulted in any use of the item.

## 5.9 Tubal procedures (items 35694, 35697, 35700, 35703, 35706, 35709 and 35710)

### 5.9.1 Items 35694, 35697 and 35700

Table 10: Item introduction table for items 35694, 35697 and 35700

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35694	Tuboplasty (salpingostomy, salpingolysis or tubal implantation into uterus), unilateral or bilateral, 1 or more procedures (Anaes.) (Assist.)	\$637.70	125	-5.1%	\$40,949
35697	Microsurgical tuboplasty (salpingostomy, salpingolysis or tubal implantation into uterus), unilateral or bilateral, 1 or more procedures (Anaes.) (Assist.)	\$946.20	131	2.5%	\$87,130



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35700	Fallopian tubes, unilateral microsurgical anastomosis of, using operating microscope (Anaes.) (Assist.)	\$730.05	129	-9.2%	\$50,926

## Recommendation 11

- Item 35694:
  - Change the item descriptor to remove tubal implantation as an indication for use.
  - The proposed item descriptor is as follows:
    - Tuboplasty (salpingostomy or salpingolysis), unilateral or bilateral, 1 or more procedures (Anaes.) (Assist.)
- Item 35697:
  - Change the item descriptor to include the use of laparoscopic techniques.
  - The proposed item descriptor is as follows:
    - Microsurgical or laparoscopic tuboplasty (salpingostomy, salpingolysis or tubal implantation into uterus), unilateral or bilateral, 1 or more procedures. (Anaes.) (Assist.)
- Item 35700:
  - Change the item descriptor to include the use of laparoscopic techniques, and remove the requirement to use an operating microscope.
  - The proposed item descriptor is as follows:
    - Fallopian tubes, unilateral microsurgical or laparoscopic anastomosis of (Anaes.) (Assist.)

## Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- Item 35694:
  - It is no longer considered appropriate clinical practice to perform a tubal implantation without the use of microsurgical techniques.
- Item 35697:
  - In modern clinical practice, laparoscopic techniques can be used to perform this procedure as well.



- Item 35700:
  - This item covers a relatively inexpensive, highly effective procedure. Having added a specification for the laparoscopic approach sometimes used in modern practice, the item now represents clinically current, high-value care.
  - Since “microsurgical” implies the use of an operating microscope, and microscopes are not used in laparoscopic surgery, it is unnecessary to specifically mention the use of an operating microscope in this descriptor.

### 5.9.2 Items 35703, 35706, 35709 and 35710

**Table 11: Item introduction table for items 35703, 35706, 35709 and 35710**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35703	Hydrotubation of fallopian tubes as a nonrepetitive procedure, not being a service associated with a service to which another item in this Sub-group applies (Anaes.)	\$67.50	453	2.2%	\$22,896
35706	Rubin test for patency of fallopian tubes (Anaes.)	\$67.50	1,645	2.1%	\$28,451
35709	Fallopian tubes, hydrotubation of, as a repetitive postoperative procedure (Anaes.)	\$43.50	157	19.7%	\$1,338
35710	Fallopscopy, unilateral or bilateral, including hysteroscopy and tubal catheterization (Anaes.) (Assist.)	\$463.30	5	-27.5%	\$1,738

### Recommendation 12

- Item 35703:
  - Change the item descriptor to remove the reference to other items in the sub-group (as the Committee proposes their deletion).
  - The proposed item descriptor is as follows:
    - Hydrotubation of fallopian tubes as a nonrepetitive procedure (Anaes.)
  - Add explanatory notes to outline the expectation that the item should only be billed only once per patient per lifetime unless clinically indicated in cases where a successful pregnancy has been achieved following hydrotubation of fallopian tubes.
- Items 35706, 35709 and 35710: Delete items.



## Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- Item 35703:
  - This procedure is no longer supported by contemporary clinical evidence for most indications, but it remains a useful technique in select cases and should be retained as an item to promote continued patient access.
  - The Committee agreed this item should be limited to once per lifetime except in cases where a woman has had a successful pregnancy after a previous procedure and are attempting to have another child.
- Item 35706:
  - This procedure is obsolete now that modern alternatives offer improved patient outcomes. Deletion of the item will encourage a clinically appropriate shifting of service volumes to items such as hystero-salpingo contrast sonography (HyCoSy) and hysterosalpingography (HSG).
- Item 35709:
  - Hydrotubation in these instances is no longer supported by contemporary clinical evidence, and the Committee considers it inappropriate that use of this item has grown so rapidly (albeit from a low base) in recent years. Appropriate patient access can be achieved by using interventional radiology techniques, which have superseded this item's surgical approach.
- Item 35710:
  - This item is obsolete, as evidenced by its low service volumes and growth rate. It has been superseded by radiological selective tubal catheterisation.

## 5.10 Proposed new items

### 5.10.1 Proposed new item: MicroTESE (micro testicular sperm extraction)

#### Recommendation 13

- Create a new MBS item for surgical testicular sperm retrieval.
- The proposed item descriptor is as follows:
  - Open surgical testicular sperm retrieval, unilateral, using operating microscope, including the exploration of scrotal contents, with biopsy, for the purposes of intracytoplasmic sperm



injection, for male factor infertility, performed in a hospital, excluding a service to which item 13218 or 37604 applies. (Anaes.)

- The Committees acknowledges that MSAC evaluation would be required after a suitable sponsor submits an application.

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- MicroTESE is a relatively new surgical technique that requires the use of an operating microscope. It is a lengthy procedure (taking approximately one to two hours per side) and it requires special skills and patience. At present, the only useable item number for this procedure is item 37606, which only takes 10–15 minutes per side.
- There is good evidence that a microsurgical sperm retrieval yields better surgical outcomes than an open non-microsurgical sperm retrieval (item 37606):
  - There is a higher probability of sperm retrieval in men with non-obstructive azoospermia (19).
  - Less testicular tissue is required for adequate sperm recovery, resulting in fewer long-term consequences, such as testosterone deficiency.
  - There are fewer surgical complications, including haematoma.

### 5.10.2 Proposed new item: Endometrial scratch

#### Recommendation 14

- Create a new item for endometrial biopsy to improve the probability of successful embryo implantation in women with repeat implantation failure. The procedure can safely be carried out in an outpatient setting without anaesthesia.
- The proposed item descriptor is as follows:
  - Endometrial biopsy to improve the probability of successful embryo implantation only in women with repeat implantation failure.
- The Committee acknowledges that MSAC evaluation would be required once a suitable sponsor has submitted an application.

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.



- There is Level I evidence (evidence from a systematic review of relevant randomised controlled trials; usually high quality) that an endometrial biopsy during the menstrual cycle prior to a cycle in which an embryo transfer is planned can improve the chance of embryo implantation in women who have had at least two prior failed embryo transfers (20). This increases the probability of clinical pregnancy following embryo transfer in women with repeat implantation failure, thereby increasing the value of care for the patient and the community.

### 5.10.3 Proposed new item: Pre-implantation genetic diagnosis (PGD) testing of embryos

#### Recommendation 15

- Create a series of new item numbers for pre-implantation genetic diagnosis (PGD) technology, reflecting the various costs associated with a staged testing approach. These include:
  - The cost of feasibility testing for parents in order to assess the nature of the genetic condition and develop an appropriate test.
  - Embryo biopsy costs.
  - DNA amplification fees.
- The proposed item descriptors are as follows:
  - Preimplantation genetic diagnosis of an inheritable genetic condition in an embryo where a specialist clinical genetics physician has determined that the prospective parents are at significant risk of having a child with a genetic disorder based on history and confirmatory testing – this item to be used only for genetic feasibility studies.
  - Preimplantation genetic diagnosis of an inheritable genetic condition in an embryo where a specialist clinical genetics physician has determined that the prospective parents are at significant risk of having a child with a genetic disorder based on history and confirmatory testing – this item to be used only for embryo biopsy.
  - Preimplantation genetic diagnosis of an inheritable genetic condition in an embryo where a specialist clinical genetics physician has determined that the prospective parents are at significant risk of having a child with a genetic disorder based on history and confirmatory testing – this item to be used only for embryo DNA amplification and testing.
- The Committee noted that the MSAC is already considering an application for PGD.

#### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.



- This procedure allows the diagnosis of inheritable genetic conditions in an embryo before it is transferred into the uterus. These conditions would otherwise be transmitted from the parents, often resulting in considerable morbidity and mortality in affected children.
- This item number will only cover PGD of embryos for inheritable genetic conditions transmitted from their parents. It will not cover pre-implantation genetic screening (PGS) of embryo aneuploidy.
- The demand for PGD will be small compared to that for PGS (which could be extremely large).
- Although it is possible that one item number could cover all aspects of PGD, the Committee felt that it would be best to at least create separate items for (a) feasibility testing and (b) items related to IVF testing. This is because not all couples undergoing feasibility testing will proceed to IVF or have embryos of sufficient quality to conduct PGD testing.

#### 5.10.4 Proposed new item: Pelvic MRI for investigation of infertility

##### Recommendation 16

- The Committee noted the need for an MBS item for pelvic MRI for the investigation of fertility. The Committee sought advice from the Diagnostic Imaging Clinical Committee (DICC) regarding whether a change could be made to the descriptor for item 63440 to enable this item to be used for investigation of infertility or whether a MSAC application would be required for this purpose.
- The Committee notes that the final DICC report contains a recommendation that the MSAC Executive consider whether a new item should be added to the MBS to provide for this service.
- The Committee strongly supports the recommendation of the DICC. The Committee suggests that a proposed descriptor for the new item could be as follows:
  - Magnetic Resonance Imaging of the female pelvis/lower abdomen under the professional supervision of an eligible provider at an eligible location where the patient is referred by a specialist for the following indications:
    - Investigation of suspected Mullerian duct anomaly seen in pelvic ultrasound or hysterosalpingogram.
    - Assessment of uterine mass identified on pelvic ultrasound before consideration of surgery (myomectomy).
    - Investigation for recurrent implantation failure in IVF (> 2 good quality embryos transferred without viable pregnancy).



- Preoperative assessment of patient with suspected bowel involvement with severe endometriosis.
- This item cannot be claimed more than once in any two-year period.

## Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- An existing item number for pelvic MRI exists for girls under 16 years of age (item 63440), but this is not available to reproductive-age women.
- Pelvic MRI is the preferred imaging modality for investigating congenital abnormalities of the uterus (Mullerian duct anomalies). The existing item numbers (pelvic ultrasound and hysterosalpingogram) often incorrectly diagnose a uterine septum as a bicornuate uterus. This harms patient care because the reproductive outcomes and management for these procedures are entirely different.
- If a high-quality pelvic ultrasound has been done and confirms no abnormality, there is no need for an MRI. The Committee therefore recommended that a screening ultrasound should be performed before a pelvic MRI item can be claimed.
- Pelvic MRI is far superior to pelvic ultrasound or hysterosalpingograms at delineating the position (in relation to the uterine cavity) and the nature of uterine masses (for example, fibroids, adenomyomas, sarcomas). It therefore allows a more accurate assessment of the potential benefits of surgery for the patient.
- In an IVF context, recurrent implantation failure with good-quality embryos is usually associated with submucosal fibroids, adenomyosis and uterine septum, all of which are best identified using MRI. Pelvic ultrasound can miss adenomyosis, and the Committee therefore suggests that all women meeting the implantation failure criteria should be allowed a pelvic MRI.
- Pelvic MRI is a useful technique for identifying rectal involvement of endometriosis, allowing for better surgical planning (bowel preparation, general surgeon assistance, etc.). If rectal involvement is suspected, MRI should be permitted for clinical reasons.
- The Committee noted that pelvic MRI is already widely used for cervical cancer staging procedures in Australia.



### 5.10.5 Proposed new item: Anti-Mullerian Hormone (AMH) Testing

#### Recommendation 17

- Create a new item for AMH testing.
- The proposed item descriptor is as follows:
  - Quantitation in blood of Anti-Mullerian Hormone (AMH) for the following indications:
    - As part of routine investigations in women experiencing infertility.
    - Follow up management of a known granulosa cell tumour of the ovary.
    - Investigation of a child with ambiguous genitalia or gonadal status.
  - AMH must be ordered at an interval exceeding one year from prior testing, with the exception of granulosa tumour surveillance.
- The Committee acknowledges that MSAC evaluation would be required once a suitable sponsor has submitted an application.

#### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- AMH is now a standard test in infertility management to identify the likely response to controlled ovarian hyperstimulation in IVF, which maximises treatment efficiency and improves safety. It also helps to identify women with polycystic ovary syndrome (PCOS), and it is now the standard tumour marker for granulosa cell tumour postoperative surveillance. Due to high production of AMH by the neonatal testis but not the ovary, serum AMH is a useful test for identifying the presence of testicular tissue in a child born with ambiguous genitalia or testis not present on examination.
- AMH is commonly used to screen for ovarian reserve status in women wishing to assess their fertility potential. However, the clinical utility of this is still in question, and the demand for this type of testing would be considerable. For these reasons, this should not be an indication for MBS funding. Requiring a specialist to order AMH should prevent inappropriate use of this item for ovarian reserve screening.
- AMH may become part of the diagnostic criteria for PCOS in the future. However, it is not currently included, and it should not be an indication for testing outside the criteria for infertility management.



### 5.10.6 Proposed new item – testing for microdeletion of Y chromosome

- Create a new item for detection of microdeletions of the Y chromosome in non-obstructive azoospermia (NOA).
- The Committee acknowledges that MSAC evaluation would be required once a suitable sponsor has submitted an application.

#### Rationale

- Detection of Y chromosome microdeletions is standard care worldwide for men with non-obstructive azoospermia, idiopathic infertility or sperm densities <5 million/mL.
- This is a standardised Polymerase Chain Reaction Polymerase Chain Reaction (PCR) test that detects microdeletions of the Y chromosome.
- If a particular type of deletion is found (AZFa and/or AZFb) there is effectively no chance of successful sperm recovery using micro-TESE making.
- Such couples can then:
  - Be directed towards donor insemination and avoid the trauma and expense of a futile micro-TESE attempt
  - Elect for sex selection to avoid male offspring with vertical transmission of infertility in adulthood or have the benefit of this information so it may be addressed in the future.
- The current cost of Y chromosome microdeletion testing (~\$240) is a disincentive for patients to undergo testing and will subsequently undergo futile micro-TESE at great costs to themselves and, potentially, the MBS.



## 6. General gynaecology recommendations

### 6.1 General Gynaecology Working Group membership

The GGWG included the members listed in Table 12.

**Table 12. GGWG members**

Name	Position/Organisation	Interests declared
Professor Jason Abbott*	Professor of Gynaecological Surgery, University of New South Wales President AGES Society FIGO Menstrual Disorders Working Group Co-Chair ACSQHC Heavy Menstrual Bleeding Standards Committee Chair Practice Committee AAGL Medical Director Endometriosis Australia Associate Editor Human Reproduction Associate Editor ANZJOG Associate Editor JMIG	Claims MBS items International Advisory Board Vifor Pharmaceuticals National Advisory Board Vifor Australia National Advisory Board Hologic Australia Consultant Stryker Consultant Bayer Australia
Dr Catarina Ang	Fertility Specialist, Gynaecologist, Laparoscopic & Robotic Surgeon	Claims MBS items. Treasurer, NASOG. Department Head, Royal Women's Hospital, Melbourne. Lecturer, University of Melbourne. Affiliated with City Fertility Centre.
Dr Vijay Roach*	Consultant Obstetrician & Gynaecologist, Royal North Shore Hospital President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists Private practice	Claims MBS items.
Dr Fariba Willison	General Gynaecologist	None.
Dr Kate McIlwaine	General Gynaecologist	Claims MBS items. Member, Fertility Society of Australia. Member, AGES.
Dr Robyn Aldridge	General Gynaecologist	None.
Dr Carol Breeze	General Gynaecologist	None.
Dr Rashmi Sharma	General Practitioner	None.
Ms Joanne Baumgartner	Consumer representative	None.
Professor Michael Permezel*	Committee ex-officio	None.

\*Also a member of the Committee.

It is noted that the majority of members share a common conflict of interest in reviewing items that are a source of revenue for them (that is, members' patients claim the items under review). This conflict is inherent in a clinician-led process, and having been acknowledged by the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.



The GGWG developed the following recommendations, which were endorsed by the Committee.

## Item-specific recommendations

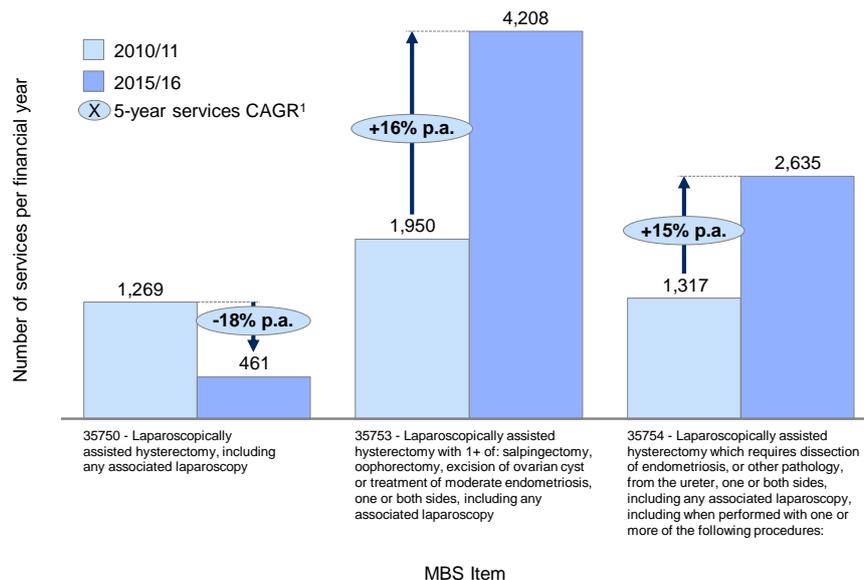
### 6.2 Laparoscopic hysterectomy items (35750, 35753, 35754 and 35756)

#### Context behind the restructuring of items 35750, 35753, 35754 and 35756

##### Context and observations

The Committee noted sharp increases in the use of items 35753 and 35754 during FY2011–16, along with a decrease in the use of item 35750 (which covers a simpler service) (Figure 9). This led to a discussion about the possible causes of this shift in practice, and whether there might be problems with compliance with the item descriptors.

**Figure 9: Comparison of growth in service volumes over time, for laparoscopic hysterectomy items without adnexal procedures (item 35750) and with adnexal procedures (items 35753 and 35754)**



<sup>1</sup> Five-year Compound Annual Growth Rate from FY2010–11 to FY2015–16

**Source:** Medicare data, items 35750, 35753 and 35754. MBS050 dataset, July 2015-June 2016, date of processing, extracted August 2016.

This graph presents the service volumes of each of the items in FY2010-11 and FY2015-16 side by side. The 5-year services CAGR indicates the average annual growth rate over 5 years that would lead to the absolute changes seen.

During its discussion, the Committee noted two major trends in the provision of hysterectomy services in Australia over time, which are likely to have had a positive overall effect on consumers:

- A shift in the approach used to perform hysterectomy.



- A shift away from simpler laparoscopic procedures and towards more complex ones.
  
- **Shift in surgical approach**
  - Hysterectomies can be performed using one of three approaches: vaginal, abdominal or laparoscopic. MBS data suggests that over the past five years, surgical practice has shifted in favour of the laparoscopic approach, which accounted for 65 per cent of hysterectomies (including only items 35750, 35753, 35754, 35756, 35653 and 35661) in FY2015–16, up from 47 per cent in FY2010–11. The Committee considered this a positive change, reflecting increasing access to laparoscopic surgical tools and growing clinician experience using these tools. Published evidence also indicates that laparoscopic hysterectomies provide better diagnostic and therapeutic outcomes than abdominal hysterectomies for women across most relevant pathologies, while also decreasing postoperative recovery times and hospital stays.
  
- **Shift towards more complex procedures**
  - Laparoscopic techniques are also increasingly used to remove structures surrounding the uterus (uterine adnexae) when these play a part in the disease process. For example, evolving evidence suggests that removing the fallopian tubes at the time of hysterectomy can reduce the risk of future ovarian malignancy. As noted above, MBS data shows a substantial increase in the number of adnexal surgeries performed in conjunction with laparoscopic hysterectomies (for example, items 35753 and 35754), as well as a decrease in the number of laparoscopic hysterectomies performed without additional adnexal procedures (item 35750) (Figure 9).
  
- **Overall effect on consumers**
  - Consumers are likely to have benefited from the better surgical outcomes and faster recovery times often achieved using laparoscopic techniques (compared with equivalent surgeries done via the abdominal route), which means that these shifts in practice could be interpreted as positive changes.

### ***Problems and possible solutions***

- The Committee noted that the full scope of these procedures is now considerably broader than in previous years, encompassing greater variety in terms of operative complexity and the level of skill required. Given the relatively non-specific item descriptors for more complex procedures, there is a risk that these items could be inappropriately claimed or could encourage the provision of unnecessary treatment. Increased item use could therefore be



interpreted as a sign of inappropriate claiming behaviour or clinical practice, rather than a sign of improving patient care.

- In order to maintain the potential consumer benefits noted above while addressing the possible risks, the Committee recommended (a) distinguishing more carefully between the different procedures covered under items 35750, 35753 and 35754, which would help to promote clinical best practice; and (b) adding objective, auditable measures that would encourage compliant claiming behaviour.
- Taken together, the proposed changes to the hysterectomy items are intended to more closely reflect modern practice; improve access (by providing appropriate patient rebates based on the complexity of their procedures); and improve value (by encouraging compliance with item descriptors).

### **Recommendation 18 (applies to the item group including 35750, 35753, 35754 and 35756)**

- Introduce a new explanatory note for this group of items to include descriptive details of the procedure.
- The proposed explanatory notes are as follows:
  - *Procedure may be undertaken using laparoscopy with any number of ports or by any approach as clinically indicated.*
  - *A laparoscopically assisted vaginal hysterectomy is defined as the introduction of the laparoscope to assess the pelvis and commence the procedure taking the round ligaments, adnexal attachments as indicated and to the level of the uterine arteries with the uterine arteries and uterosacral pedicles secured vaginally.*
  - *A total laparoscopic hysterectomy is defined as the introduction of the laparoscope to assess the pelvis and complete the procedure laparoscopically including securing the uterine arteries and uterosacral pedicles.*

#### **6.2.1 Item 35750**

**Table 13: Item introduction table for item 35750**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35750	Laparoscopically assisted hysterectomy, including any associated laparoscopy (Anaes.) (Assist.)	\$784.60	461	-18.3%	\$234,847



## Recommendation 19

- Split this item into two items that reflect the two major classes of procedure: laparoscopic assisted vaginal hysterectomy (LAVH) and total laparoscopic hysterectomy (TLH).
- Restrict co-claiming of items 35673 and 35595.
- Add explanatory notes as described in Recommendation 18.
- Item 35750:
  - The proposed item descriptor is as follows:
    - Laparoscopic Assisted Vaginal Hysterectomy – by any approach including any endometrial sampling, with or without removal of the tubes as a risk reducing surgery or ovarian cystectomy or removal of the ovaries and tubes due to other pathology, not being a service to which item 35673 or 35595 applies. (Anaes.) (Assist.)
- Item 35750X:
  - The Committee recommended a schedule fee equal to that of current item 35750 (\$784.60).
  - The proposed item descriptor is as follows:
    - Hysterectomy, Total Laparoscopic Hysterectomy – by any approach including any endometrial sampling, with or without removal of the tubes as a risk reducing surgery, not being a service to which item 35595 applies. (Anaes.) (Assist.)

## Rationale

This recommendation focuses on modernising the MBS, encouraging clinical best practice and improving the value of care for less-complex procedures. It is based on the following.

- The Committee noted that LAVH is a useful surgical technique that (in addition to its primary hysterectomy function) may aid in diagnosing additional pathology and securing the upper pedicles of the uterus and adnexae (21) (22).
- However, there is a meaningful difference in the complexity and surgical duration of the two main procedures that currently fall under this item: LAVH and TLH. The Committee's recommendation to split item 35750 into two items allows for differentiation to provide consumers with better insight into the exact procedure they have undergone and to support compliance activity
- Evolving evidence suggests that removing the fallopian tubes at the time of hysterectomy can reduce the risk of future ovarian malignancy (23). This procedure is relatively simple to



perform and should ideally take place as part of the hysterectomy procedure (rather than as a separate service provided later on) in order to reduce the need for multiple hospital admissions and general anaesthesia.

- The Committee recommended restricting co-claiming of items 35673 and 35595 for the following reasons:
  - Item 35673 covers a vaginal hysterectomy. This is already a component of this item and should not be co-claimable separately.
  - Item 35595 covers techniques used to repair a prolapse of the vaginal vault. These techniques are inherent to a hysterectomy and should not be co-claimable.
- Including removal of the fallopian tubes reflects current practice, whereby salpingectomy (removal of the fallopian tubes) is offered to women undergoing hysterectomy to reduce the risk of future gynaecological malignancy. In such cases, the tubes are not pathologic, and it is reasonable to remove the tubes with this item number without recognition of a more complex procedure.

## 6.2.2 Item 35753

**Table 14: Item introduction table for item 35753**

Item	Descriptor	Schedule Fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35753	Laparoscopically assisted hysterectomy with one or more of the following procedures: salpingectomy, oophorectomy, excision of ovarian cyst or treatment of moderate endometriosis, one or both sides, including any associated laparoscopy (Anaes.) (Assist.)	\$867.60	4,208	16.6%	\$2,580,907

### Recommendation 20

- Change this item descriptor to:
  - Specify that the item should be used for TLH procedures.
  - Restrict co-claiming with item 35595.
  - Add explanatory notes as described in Recommendation 18.
- The proposed item descriptor is as follows:
  - Complex total laparoscopic hysterectomy with one or more of the following procedures: unilateral or bilateral salpingo-oophorectomy (excluding salpingectomy as a risk reducing surgery), excision of moderate endometriosis or ovarian cyst including any associated laparoscopy and not being a service to which item 35595 applies. (Anaes.) (Assist.)



- Include in the explanatory notes that it is expected that photographic and/or histological documentation is collected and retained to demonstrate the complexity of the procedure performed. Where this documentation is not retained, the reasons for this should be clearly documented, for example, faulty equipment.

**Rationale**

This recommendation focuses on encouraging clinical best practice. It is based on the following.

- Item 35595 covers techniques used to repair prolapse of the vaginal vault. These techniques are inherent to a hysterectomy and should not be co-claimable.
- The item now covers a more complex procedure, including treatment for more forms of pathology (which should be documented for the purposes of audit with photographs and/or histology). However, the Committee has not recommended a change to the schedule fee because it felt that the current schedule fee was appropriate.
- The collection of photographic and histological documentation to demonstrate the severity of the patient’s condition (which determines the complexity and duration of the procedure) is best practice.

**6.2.3 Item 35754**

**Table 15: Item introduction table for item 35754**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35754	Laparoscopically assisted hysterectomy which requires dissection of endometriosis, or other pathology, from the ureter, one or both sides, including any associated laparoscopy, including when performed with one or more of the following procedures: salpingectomy, oophorectomy, excision of ovarian cyst, or treatment of endometriosis, not being a service to which item 35641 applies (Anaes.) (Assist.)	\$1,091.90	2,635	14.9%	\$1,973,397

**Recommendation 21**

- Change the item descriptor to:
  - Specify that the item should be used for cases that also require resection of rAFS stage IV endometriosis
  - Restrict co-claiming with item 35595.
- The Committee recommended a schedule fee that reflects the combination of items 35753 (\$867.60) and 35641 (\$1242.65), in accordance with the multiple services rule.



- The proposed item descriptor is as follows:

Hysterectomy, Total Laparoscopic Hysterectomy – by any approach including any endometrial sampling that concurrently requires resection of rAFS stage IV endometriosis including any associated laparoscopy, including when performed with one or more of the following procedures: salpingectomy, oophorectomy, excision of ovarian cyst, not being a service to which item 35641 or 35595 applies (Anaes.) (Assist.)

- Add explanatory notes as described in Recommendation 18 and specify an expected minimum surgical duration of 120 minutes for this item in these notes.
- Include in the explanatory notes that it is expected that photographic and/or histological documentation is collected and retained to demonstrate the severity of the endometriosis and the complexity of the procedure performed. Where this documentation is not retained, the reasons for this should be clearly documented, for example, faulty equipment.

## Rationale

This recommendation focuses on modernising the MBS, improving compliance and encouraging clinical best practice. It is based on the following.

- This item number now covers a complete medical service, including procedures for item 35753 (complex hysterectomy) and item 35641 (rAFS stage IV endometriosis).
- The collection of photographic and histological documentation to demonstrate the severity of endometriosis (which determines the complexity and duration of the procedure) and denote a risk of recurrence of endometriosis is best practice.
- The Committee agreed that a procedure must be sufficiently complex to warrant use of this item number.
- Item 35595 covers techniques used to repair prolapse of the vaginal vault. These techniques are inherent to a hysterectomy and should not be co-claimable.

### 6.2.4 Item 35756

Table 16: Item introduction table for item 35756

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35756	Laparoscopically assisted hysterectomy, when procedure is completed by open hysterectomy, including any associated laparoscopy (Anaes.) (Assist.)	\$784.60	83	-2.7%	\$47,496



## Recommendation 22

- Change the item descriptor to specify:
  - That the item should only be used in the presence of extensive pathology or for control of bleeding.
- Add explanatory notes as described in Recommendation 18.
- The Committee recommended a schedule fee based on the combination of laparoscopic hysterectomy item 35753 (\$867.60) and control of haemorrhage item 35759 (\$563.30 [not following the multiple operations rule]).
- The proposed item descriptor is as follows:
  - Total laparoscopic hysterectomy by any approach, when procedure is completed by open hysterectomy for control of bleeding or extensive pathology, including any associated laparoscopy not being a service to which item 35641 or 35595 applies. (Anaes.) (Assist.)

### Rationale

This recommendation focuses on modernising the MBS, improving compliance and encouraging clinical best practice. It is based on the following.

- This item number now describes a complex procedure that cannot be completed laparoscopically for reasons of patient safety. The procedure is time-consuming (more than 180 minutes), requires both laparoscopic and open surgical skills and time to change between laparoscopic and abdominal approaches (which requires the operating theatre to be set up differently during the operation).
- This is a low-volume procedure that is only performed in very complex surgical situations. It requires a high level of skill and experience, the use of two different surgical techniques, and three or more hours of operating time. The Committee recommended a rebate for this item that reflects this complexity.

## 6.3 Open hysterectomy items (35653 and 35661)

### 6.3.1 Item 35653

Table 17: Item introduction table for item 35653

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35653	Hysterectomy, abdominal, sub total or total, with or without removal of uterine adnexae (Anaes.) (Assist.)	\$674.70	2,231	-7.7%	\$1,095,418



## Recommendation 23

- Change the item descriptor to specify that uterine adnexae is included.
- The proposed item descriptor is as follows:
  - Abdominal subtotal or total hysterectomy with or without removal of fallopian tubes and ovaries. (Anaes.) (Assist.)

### Rationale

This recommendation focuses on improving the clarity of the MBS. It is based on the following.

- This is a commonly performed procedure. Although it is slowly being superseded by newer techniques, it should still be supported to promote continued access.
- The proposed item descriptor more accurately describes the procedure, as used in modern clinical practice.

### 6.3.2 Item 35661

**Table 18: Item introduction table for item 35661**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35661	Abdominal Hysterectomy, requiring extensive retroperitoneal dissection, with or without exposure of 1 or both ureters, for the management of severe endometriosis, pelvic inflammatory disease or benign pelvic tumours, with or without conservation of the ovaries (Anaes.) (Assist.)	\$871.30	1,691	-2.2%	\$1,068,092

## Recommendation 24

- Change the item descriptor to specify that:
  - Severe endometriosis is considered to be rAFS Stage III or higher.
  - Pelvic inflammatory disease must be severe in nature.
  - Pelvic tumours must cause distortion in order to qualify for use of this item.
- The proposed item descriptor is as follows:

Hysterectomy, abdominal, requiring extensive retroperitoneal dissection with exposure of 1 or both ureters, for the management of rAFS stage III or higher endometriosis, severe pelvic inflammatory disease or benign pelvic tumours causing distortion of the pelvic contents, , with or without conservation of ovaries (Anaes.) (Assist.)



- The Committee recommended that a higher schedule fee should be considered. The Committee suggested that item 35754 may be a comparable service in terms of complexity.
- Add explanatory notes to specify a minimum surgical duration of 120 minutes and to outline that it is expected that photographic and/or histological evidence of pathology is collected and retained. Where this documentation is not collected, the reasons for this should be clearly documented.

### Rationale

This recommendation focuses on improving patient safety. It is based on the following.

- Specifying that benign pelvic tumours must distort the pelvic contents promotes patient safety by preventing unnecessary resection of asymptomatic benign tumours.
- The proposed item descriptor more accurately describes the procedure, as used in contemporary clinical practice.
- Advances in laparoscopic surgery mean that many hysterectomies are now performed laparoscopically. Open procedures are increasingly reserved for more challenging cases and should therefore be remunerated at a level similar to that of complex total laparoscopic hysterectomy with extensive pelvic dissection (newly revised item 35754; \$1,676.45) or radical hysterectomy for malignant disease without node dissection (newly revised item 35667; \$1,593.40).
- The collection of photographic and histological documentation to demonstrate the severity of the patients' condition (which determines the complexity and duration of the procedure) should be collected as it is best practice.

## 6.4 Operative laparoscopy and sterilisation items (35637, 35638, 35641, 35687<sup>3</sup>, 35688 and 35691)

**Context and rationale for the restructuring of items 35637, 35638, 35641, 35687<sup>3</sup> 35688 and 35691**

### Context and observations

The Committee noted that over the last two decades, operative laparoscopy has become the predominant approach for surgical treatment of a variety of gynaecological conditions. Improved training, technology and awareness have resulted in shorter hospital stays for patients and fewer complications previously associated with laparotomy, such as infections and venous thromboembolism. For example, patients undergoing a laparoscopic myomectomy today usually

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<sup>3</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations.



return to work within 7–10 days. In comparison, open myomectomies can require up to six weeks of recovery time.

The Committee made two further observations:

- There is uniformity in technique and complexity across some laparoscopic procedures for different indications.
- There are differing levels of complexity within complex laparoscopy items.
- **Uniformity in technique and complexity between items**
  - Based on clinical experience, the Committee agreed that the general surgical technique, approach, patient experience and outcomes of several laparoscopic gynaecological procedures in this group of items are relatively uniform. For example, laparoscopic sterilisation can easily be grouped with laparoscopic procedures for adhesion division or cyst excision because the amount of time, the technique and the level of complexity involved in providing these services are essentially the same. There are also many situations in which several of these procedures are performed as part of the same operation, using the same laparoscopy ports and instruments. As a result, it is no longer necessary to have multiple separate items for such procedures.
- **Differences in complexity within items**
  - At the same time, however, there are considerable differences in the skill and time required to perform other procedures that are currently grouped with item 35638 (complex operative laparoscopy). For example, a procedure to remove a large myoma is considerably more complex than most oophorectomies or ovarian cystectomies. Similarly, laparoscopic treatment for endometriosis frequently takes over an hour, in contrast to a salpingectomy, which can be performed in under 30 minutes.

### **Problems and possible solutions**

These observations suggest that the current operative laparoscopy items are inappropriately structured and do not accurately describe or provide appropriate rebates for these procedures. The Committee therefore recommended a restructure of these services, incorporating several similar items into general operative laparoscopy items, and splitting item 35638 into two new items in order to more accurately capture the time and complexity differences between its constituent procedures. These changes will simplify the MBS and provide patients with more accurate rebates and greater transparency in billing.



### 6.4.1 Item 35637

Table 19: Item introduction table for item 35637

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35637	Laparoscopy, involving puncture of cysts, diathermy of endometriosis, ventrosuspension, division of adhesions or similar procedure - 1 or more procedures with or without biopsy - not being a service associated with any other laparoscopic procedure or hysterectomy (Anaes.) (Assist.)	\$406.65	7,644	-2.7%	\$2,243,723

### Recommendation 25

- Change the item descriptor to:
  - Remove the indication for puncture of cysts.
  - Specify that the item will now be used for laparoscopic sterilisation procedures (in place of redundant items 35687 and 35688).
  - Specify the inclusion of fallopian tube removal for risk-reduction surgery.
  - Specify that treatment of endometriosis should be by excision and biopsy, or by ablation (not only by diathermy).
  - Remove the reference to 'ventrosuspension.'
  - Specify that only pathological adhesions should be divided using this item.
- Include an explanatory note for the item to include that it is expected that service described in the 35637 will last more than 30 minutes.
- The proposed item descriptor is as follows:
  - Operative laparoscopy for excision or ablation of stage I (minor) endometriosis and/or division of pathological adhesions, and/or sterilisation by application of clips, division, destruction or removal of tubes, or tubal removal for risk reduction surgery without another associated laparoscopy. Strict legal requirements apply in relation to sterilisation procedures on minors. Medicare benefits are not payable for services not rendered in accordance with relevant Commonwealth and State and Territory law. Observe the explanatory note before submitting a claim regarding sterilisation in these circumstances. (Anaes.) (Assist.)
- The proposed explanatory note is as follows:
  - *It is expected that the service/s performed under item 35637 will last at least 30 minutes.*



## Rationale

This recommendation focuses on modernising the MBS, improving patient safety and increasing compliance with MBS item descriptors. It is based on the following.

- The proposed descriptor more accurately describes the procedure, as used in contemporary clinical practice.
- Surgical puncture of ovarian cysts is no longer considered standard practice, as the potential benefit of temporary symptomatic relief is outweighed by the small but serious risk of spreading malignancy in patients with undiagnosed ovarian cancer. Current practice supports simple observation over three to six months, and excision of ovarian cysts that do not resolve spontaneously and require surgical treatment.
- Removal of the fallopian tubes in patients who do not plan to have more children has been shown to be an effective method for decreasing the risk of ovarian cancer, but this indication is not yet specifically included in any MBS item.
- Laparoscopic sterilisation procedures and fallopian tube removal for the purposes of risk reduction are very similar procedures, with similar surgical complexity and duration to the other indications specified by this item. For this reason, they can be included as part of this item in order to simplify the MBS.
- Excision and biopsy and ablative techniques other than diathermy are all valid means of treating endometriosis laparoscopically.
- The Committee is not aware of robust data to support ventrosuspension in modern clinical practice. The few case series studies that have been done constitute low grade evidence. The Committee does not support the clinical role of this procedure.
- Specifying that adhesions should be pathological will reduce unnecessary adhesiolysis and inappropriate division of naturally occurring non-pathological anatomical variants, promoting patient safety.

### 6.4.2 Item 35638

**Table 20: Item introduction table for item 35638**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35638	Complicated operative laparoscopy, including use of laser when required, for 1 or more of the following procedures; oophorectomy, ovarian cystectomy, myomectomy, salpingectomy or salpingostomy, ablation of moderate or severe endometriosis requiring more than 1 hours operating time, or division of utero-sacral ligaments for significant	\$711.50	16,720	4.7%	\$8,743,506



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
	dysmenorrhoea - not being a service associated with any other intraperitoneal or retroperitoneal procedure except item 30393 (Anaes.) (Assist.)				

## Recommendation 26

- Split this item into two new items (35638X and 35638Y), based on the differing complexity, and the RANZCOG/AGES training requirements.
- The Committee recommended that the schedule fee for items be calibrated to recognise the difference in the complexity between the two procedures. It is recommended that the schedule fee for 35638Y be higher than the schedule fee for item 35638X.
- Item 35638X:
  - The proposed item descriptor is as follows:
    - Operative laparoscopy including unilateral or bilateral ovarian cystectomy, salpingo-oophorectomy, salpingectomy for tubal pathology (excluding sterilisation, but including ectopic pregnancy by tubal removal or salpingostomy), or excision of stage II (mild) endometriosis one or more – not being a service associated with any other intraperitoneal or retroperitoneal procedure except item 30393 (Anaes.) (Assist.)
- Item 35638Y:
  - The proposed item descriptor is as follows:
    - Complicated operative laparoscopy including excision of stage III endometriosis or laparoscopic myomectomy for a myoma of at least 4cm including incision and repair of the uterus – not being a service associated with any other intraperitoneal or retroperitoneal procedure except items 30393 or 35658. (Anaes.) (Assist.)

Include in the explanatory notes that it is expected that photographic and/or histological documentation, which demonstrates the complexity of the procedure performed, is collected and retained. Where this documentation is not retained, the reasons for this should be clearly documented, for example, faulty equipment

### Rationale

This recommendation focuses on improving the clarity of the MBS, as well as improving compliance with item descriptors. It is based on the following.



- At present, item 35638 covers a variety of different procedures with differing levels of scope and complexity.
  - The proposed item descriptor of item 35638X corresponds to RANZCOG/AGES training requirements level 3 procedures and has been modernised to reflect contemporary practice.
  - The procedures covered by proposed item 35638Y are complex and time-consuming, requiring more advanced surgical skills. The item aligns with RANZCOG/AGES training requirements level 4 and 5 procedures.
  - The procedure to remove larger myomata is more complex and time-consuming and a higher rebate may be appropriate. The Committee recommended removal of a myoma (item 35638Y) be co-claimable with an additional procedure (debulking item 35658) to allow higher remuneration according to the multiple services rule for this RANZCOG/AGES training requirements level 5 procedure. Should an audit ever be required to differentiate the procedures the co-claimed item 35658 would indicate the more complex procedure. This reflects the higher skill level required for the procedure and is appropriately remunerated and results in another item number being removed from the MBS.
  - Photographic and histological documentation to demonstrate the complexity and duration of the procedure performed under item 35638Y should be collected and retained to support claiming of this item.

### 6.4.3 Item 35641

**Table 21: Item introduction table for item 35641**

Item	Descriptor	Schedule Fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35641	Endometriosis level 4 or 5, laparoscopic resection of, involving any two of the following procedures, resection of the pelvic side wall including dissection of endometriosis or scar tissue from the ureter, resection of the Pouch of Douglas, resection of an ovarian endometrioma greater than 2 cms in diameter, dissection of bowel from uterus from the level of the endocervical junction or above: where the operating time exceeds 90 minutes (Anaes.) (Assist.)	\$1,242.65	2,576	5.5%	\$2,383,249



## Recommendation 27

- Change the item descriptor to remove the reference to the minimum operating time.
- The proposed item descriptor is as follows:
  - Endometriosis rAFS stage IV, laparoscopic resection of, involving two of the following procedures, resection of the pelvic side wall including dissection of endometriosis or scar tissue from the ureter, resection of the Pouch of Douglas, resection of an ovarian endometrioma greater than 2 cms in diameter, dissection of bowel from uterus from the level of the endocervical junction or above (Anaes.) (Assist.)
- Include in the explanatory notes that it is expected that photographic and/or histological documentation, which demonstrates the complexity of the procedure performed, is collected and retained as it is best practice. Where this documentation is not retained, the reasons for this should be clearly documented, for example, faulty equipment.

### Rationale

This recommendation focuses on improving the clarity of MBS item descriptors. It is based on the following.

- rAFS IV endometriosis (stage 4 endometriosis, as per the Revised American Fertility Society scale) refers to severe endometriosis, for which a specific item is needed to promote patient access to adequate services.
- These operations require substantial time, surgical skill and experience to perform successfully, and they warrant the current rebate. This is in keeping with a RANZCOG/AGES training requirements level 6-B procedure.
- In practice, it is difficult for the MBS to ascertain the severity of endometriosis after the procedure has taken place, which may lead to misuse of this item. Outlining that it is expected that photographic and/or histopathological documentation is collected and retained for these cases would provide a clinically acceptable basis for auditing this item. This documentation will also record the risk of recurrence of the disease and show when there is fibrosis only or endometriosis. The collection of photographic and/or histological documentation is best practice.

### 6.4.4 Items 35687, 35688 and 35691



Table 22: Item introduction table for items 35687, 35688 and 35691

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35687 <sup>4</sup>	Sterilisation by transection or resection of fallopian tubes, via abdominal or vaginal routes or via laparoscopy using diathermy or any other method. Note: Strict legal requirements apply in relation to sterilisation procedures on minors. Medicare benefits are not payable for services not rendered in accordance with relevant Commonwealth and State and Territory law. Observe the explanatory note before submitting a claim. (Anaes.) (Assist.) - G	\$325.20	55	13.7%	\$11,449
35688 <sup>5</sup>	Sterilisation by transection or resection of fallopian tubes, via abdominal or vaginal routes or via laparoscopy using diathermy or any other method note: Strict legal requirements apply in relation to sterilisation procedures on minors. Medicare benefits are not payable for services not rendered in accordance with relevant Commonwealth and State and Territory law. Observe the explanatory note before submitting a claim. (Anaes.) (Assist.) - S	\$397.25	1,251	-6.7%	\$293,828
35691	Sterilisation by interruption of fallopian tubes, when performed in conjunction with Caesarean section note: Strict legal requirements apply in relation to sterilisation procedures on minors. Medicare benefits are not payable for services not rendered in accordance with relevant Commonwealth and State and Territory law. Observe the explanatory note before submitting a claim. (Anaes.) (Assist.)	\$158.70	943	-4.3%	\$109,369

## Recommendation 28

- Item 35688: Consolidate this item into item 35637. Delete item.
- Item 35691: No change.

### Rationale

This recommendation focuses on rationalising the MBS and reflecting contemporary best practice. It is based on the following.

- Item 35688:
  - It is important to retain access to sterilisation procedures, but performing these laparoscopically is now considered clinical best practice because it benefits patients' recovery times.
- Item 35691:

<sup>4</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations.

<sup>5</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists.



- There have been no changes to the surgical technique or legal restrictions regarding minors. This procedure remains an effective and appropriate mode of contraception for selected patients at the time of caesarean section.

## 6.5 Uterine curettage (items 35639, 35640 and 35643)

### 6.5.1 Items 35639, 35640 and 35643

**Table 23: Item introduction table for items 35639, 35640 and 35643**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35639 <sup>6</sup>	Uterus, curettage of, with or without dilatation (including curettage for incomplete miscarriage) under general anaesthesia or under epidural or spinal (intrathecal) nerve block where undertaken in a hospital, including procedures to which item 35626, 35627 or 35630 applies, where performed (Anaes.) - G	\$134.90	1,068	12.9%	\$102,795
35640 <sup>7</sup>	Uterus, curettage of, with or without dilatation (including curettage for incomplete miscarriage) under general anaesthesia or under epidural or spinal (intrathecal) nerve block where undertaken in a hospital, including procedures to which item 35626, 35627 or 35630 applies, where performed (Anaes.) - S	\$183.00	13,875	-0.4%	\$1,148,131
35643	Evacuation of the contents of the gravid uterus by curettage or suction curettage not being a service to which item 35639 or 35640 applies, including procedures to which item 35626, 35627 or 35630 applies, where performed (Anaes.)	\$218.00	51,629	-4.0%	\$8,886,494

### Recommendation 29

- Items 35640 and 35643:
  - Change the item descriptors to allow these procedures to be performed under sedation, and outside a hospital setting.
  - The proposed item descriptor for item 35640 is as follows:
    - Uterus, curettage of, with or without dilatation (including curettage for incomplete miscarriage) under general anaesthesia or under epidural or spinal (intrathecal) nerve block, or under sedation, including procedures to which item 35626 or 35630 applies, where performed. (Anaes.)

<sup>6</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations.

<sup>7</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists.



- The proposed item descriptor for item 35643 is as follows:
  - Evacuation of the contents of the gravid uterus by curettage or suction curettage using local anaesthesia, general anaesthesia, epidural or spinal (intrathecal) nerve block, or under sedation, including procedures to which item 35626 or 35630 applies, where performed. (Anaes.)

## Rationale

This recommendation focuses on modernising the MBS to reflect contemporary best practice. It is based on the following.

- Items 35640 and 35643:
  - Sedation is a safe and clinically useful means of anaesthesia for these procedures and it enables service delivery outside a hospital setting. Permitting the use of sedation and removing the in-hospital restriction from the item descriptors will facilitate increased access for patients in rural and metropolitan non-hospital settings without compromising the safety of the procedure.

## 6.6 Removal of ectopic pregnancy (items 35674, 35676, 35677 and 35678)

### 6.6.1 Items 35674, 35676, 35677 and 35678

Table 24: Item introduction table for items 35674, 35676, 35677 and 35678

Item	Descriptor	Schedule fee		Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35674	Ultrasound guided needling and injection of ectopic pregnancy	\$207.85		3	-9.7%	\$592
35676 <sup>8</sup>	Ectopic pregnancy, removal of (Anaes.) (Assist.) - G	\$425.00		4	-4.4%	\$1,275
35677 <sup>9</sup>	Ectopic pregnancy, removal of (Anaes.) (Assist.) - S	\$536.00		17	-13.9%	\$6,400
35678	Ectopic pregnancy, laparoscopic removal of (Anaes.) (Assist.)	\$646.25		271	-6.4%	\$130,820

## Recommendation 30

- Item 35674: No change.
- Item 35677: Consolidate this service into item 35717.

<sup>8</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations.

<sup>9</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists



- Item 35678: Consolidate this service into item 35638.

### Rationale

This recommendation focuses on modernising the MBS to reflect contemporary best practice. It is based on the following.

- These changes will maintain access to laparotomy (where indicated) and simplify the MBS by consolidating several low-volume items.
- It is likely that the overall decline in the volume of services for these items reflects the shift towards medical management options that occurred during the 2011–16 period.
- Item 35674:
  - Although this procedure is seldom used in contemporary practice, it remains a valuable option in rare cases and should not be removed from the MBS.
- Item 35677:
  - There is no need to distinguish between items 35677 and 35712 (laparotomy and removal of a tube). As suggested by the low and declining service volumes for item 35677, open removal of ectopic pregnancies is no longer part of contemporary practice. Access to this service in special situations is maintained through use of item 35717.
- Item 35678:
  - This item is covered under proposed item 35638X.

## 6.7 Hysteroscopic and endometrial procedures (items 35616, 35622, 35623, 35626, 35627, 35630, 35633, 35634, 35635 and 35636)

### 6.7.1 Items 35626, 35627 and 35630

Table 25: Item introduction table for items 35626, 35627 and 35630

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35626	Hysteroscopy, including biopsy, performed by a specialist in the practice of his or her specialty where the patient is referred to him or her for the investigation of suspected intrauterine pathology (with or without local anaesthetic), not being a service associated with a service to which item 35627 or 35630 applies.	\$82.80	270	-7.0%	\$19,634
35627	Hysteroscopy with dilatation of the cervix performed in the operating theatre of a hospital - not being a service associated with a service to which item 35626 or 35630 applies (Anaes.)	\$107.15	989	-1.5%	\$54,512



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35630	Hysteroscopy, with endometrial biopsy, performed in the operating theatre of a hospital - not being a service associated with a service to which item 35626 or 35627 applies (Anaes.)	\$183.00	30,455	1.2%	\$3,292,603

### Recommendation 31

- Item 35626:
  - Change the item descriptor to:
    - Specify that this item is intended for use in outpatient settings.
    - Specify abnormal or postmenopausal uterine bleeding as the indications for use.
    - Remove the co-claiming exclusion for item 35627.
  - The Committee recommended increasing the schedule fee to an amount greater than that of item 35647 (\$203.65 [large loop excision of cervical transitional zone]).
  - The proposed item descriptor is as follows:
    - Outpatient hysteroscopy for the investigation of abnormal uterine bleeding (AUB) or postmenopausal bleeding, with or without local anaesthesia, including any associated endometrial biopsy, not being a service associated with a service to which item 35630 applies.
- Item 35627: Consolidate these services into item 35630. Delete item.
- Item 35630:
  - Change the item descriptor to:
    - Specify that this service is performed under general anaesthesia.
    - Specify abnormal or postmenopausal uterine bleeding as the indications for use.
    - Remove the co-claiming exclusion for item 35627.
  - The proposed item descriptor is as follows:
    - Hysteroscopy, with or without endometrial biopsy, for the investigation of abnormal uterine bleeding (AUB) or postmenopausal bleeding when performed under general anaesthesia – not being a service associated with a service to which item 35626 applies. (Anaes.)



## Rationale

This recommendation focuses on improving the value of care and increasing patient access, particularly for those in rural areas. It is based on the following.

### Context and observations

Hysteroscopic procedures provide another useful alternative to open abdominal surgery for some forms of intrauterine pathology. These procedures can be done either in an operating theatre (usually under general anaesthesia) or in an outpatient setting, such as a clinician's private practice or the outpatient clinic area of a hospital (usually using local anaesthesia).

The Committee made four key observations:

- Diagnostic hysteroscopy may be safely and effectively performed in an outpatient setting, with high grade evidence supporting improved clinical and cost-benefit outcomes for patients.
- High grade evidence demonstrates a higher patient satisfaction rate with outpatient procedures compared with inpatient procedures.
- The current disparity in schedule fee between items 35626 and 35630 does not appropriately reflect the relative complexity, costs to the operator or superior patient care of the outpatient procedure.
- By avoiding both an anaesthetic fee and hospitalisation costs, a net cost-saving would be expected even if the schedule fee for item 35626 was set higher than that of item 35630.
- **Outpatient diagnostic hysteroscopy developments**
  - Over the past decade, a growing base of Australian and international scientific literature has shown that many diagnostic procedures can be performed in an outpatient setting (outside a hospital; for example, at a clinic or clinician's rooms), without general anaesthetic, and still provide equivalent outcomes to in-patient procedures, as well as greater patient satisfaction, convenience, accessibility and value to the healthcare system (24) (25) (26) (27) (28).
  - The Committee noted several potential benefits to performing hysteroscopy on an outpatient basis, including the following:
    - Outpatient hysteroscopy is increasingly favoured in modern clinical practice because it can be performed safely and easily, with or without local anaesthesia, and because it has a high rate of patient acceptability (25) (26) (29) (30).
    - It offers the potential for significant resource savings, both financially and in terms of theatre utilisation (27).



- It reduces anaesthetic-related risk for patients who do not require general anaesthesia.
  - It offers an alternative route of access for rural patients who may not benefit from nearby surgical facilities.
  - Results obtained through outpatient hysteroscopy compare well with those obtained through in-patient hysteroscopy (30).
- **The current situation in Australia**
    - Item 35630 specifies that treatment must occur in the operating theatre of a hospital. It is otherwise equivalent (from a practical perspective) to item 35626.
    - However, MBS data shows that only 270 (0.9 per cent) of the 31,714 diagnostic hysteroscopy services (defined here as items 35626, 35627 and 35630) performed in FY2015–16 took place in an outpatient care setting.
    - The Committee noted that certain disincentives may deter clinicians from performing outpatient hysteroscopy. The Committee believes that factors that currently discourage clinicians from using item 35626 instead of item 35630 include the following:
      - Performing the procedure in an operating theatre allows a clinician to schedule and perform several procedures sequentially, potentially improving the clinician's efficiency.
      - When performing a service in an operating theatre, the clinician does not need to organise or pay for surgical equipment, consumables, nursing assistance or pre- or postoperative care. These expenses are passed on to the patient, the state and private health insurers by the hospital managing the operating theatre. In contrast, performing the procedure on an outpatient in a clinician's rooms requires the clinician to cover the above costs and imposes the additional time burden associated with organising the various aspects of the service.
      - The current schedule fee for item 35626 is \$82.80, which is 45 per cent of the \$183.00 schedule fee for item 35630.

### ***Problems and possible solutions***

- The Committee agreed that the ratio of outpatient to in-patient services was too low, given the relative benefits of outpatient service provision for many patients. In addition, it found that the difference in schedule fees between items 35626 (\$82.80) and 35630 (\$183.00) was inappropriate, given the extra costs a clinician must cover in an outpatient setting and the potentially higher level of inconvenience for clinicians. The Committee feels there are clear and inappropriate disincentives for clinicians to provide outpatient services in the current system.



- Recognising that outpatient hysteroscopy services provide benefits to patients and the healthcare system, the Committee recommended increasing the schedule fees for outpatient procedures to a level above the schedule fee for the current in-patient item in order to address these disincentives. This may result in an increase in total cost for the hysteroscopy item numbers, but this will be offset by savings from decreased general anaesthesia rates and decreased costs associated with hospital facilities. A shift towards outpatient care will also open up surgical theatre capacity for more urgent cases.
- The Committee agreed that it is important to retain current in-patient item 35630 to preserve access to hysteroscopy services because an outpatient service is not appropriate for every patient and may not be available in some areas. This procedure has not changed, and its current schedule fee is an appropriate reflection of its complexity.
- The Committee does not expect the recommended changes to affect the total number of diagnostic hysteroscopy procedures performed. However, the distribution of services performed is expected to shift from item 35630 to item 35626.

#### ***Item-specific rationale***

- Item 35626:
  - Specifying these indications will encourage appropriate item use.
  - Performing care in an outpatient setting should not preclude the use of anaesthesia if a patient requires it and the facilities are available in this setting.
  - Item 35647 (large loop excision of transitional zone) is usually performed in an outpatient setting and requires similar levels of skills, equipment and additional costs. While the level of fee that might be required to meaningfully affect clinician and patient behaviour is unknown, the Committee feels that a higher fee than that of 35647 would help to incentivise better clinical practice.
- Item 35627:
  - The service is already adequately covered by item 35630, which means that there is no need for this item.
- Item 35630:
  - Specifying these indications will encourage appropriate use of this item.

#### **6.7.2 Items 35623, 35634, 35635 and 35636**

**Table 26: Item introduction table for items 35623, 35634, 35635 and 35636**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35623	Hysteroscopic resection of myoma, or myoma and uterine septum resection (where both are performed), followed by endometrial ablation by laser or diathermy (Anaes.)	\$819.25	698	3.9%	\$422,211
35634	Hysteroscopic resection of uterine septum followed by endometrial ablation by laser or diathermy (Anaes.)	\$685.70	45	9.2%	\$20,020
35635	Hysteroscopy involving resection of the uterine septum (Anaes.)	\$299.45	219	5.4%	\$35,371
35636	Hysteroscopy, involving resection of myoma, or resection of myoma and uterine septum (where both are performed) (Anaes.)	\$433.00	1,418	6.8%	\$435,294

### Recommendation 32

- Item 35623:
  - Change the item descriptor to specify that abnormal uterine bleeding (AUB) is the indication for use, and to improve overall clarity.
  - The proposed item descriptor is as follows:
    - Endometrial ablation and resection of myoma and/or uterine septum, using hysteroscopic guided electrosurgery or laser energy for abnormal uterine bleeding (AUB), with or without endometrial sampling. (Anaes.)
- Item 35634: Consolidate service into item 35623. Delete item.
- Item 35635:
  - Change the item descriptor to improve overall clarity.
  - Include division of adhesions ESH Grade 2 or more.
  - The proposed item descriptor is as follows:
    - Hysteroscopy involving division of a uterine septum, or division of intrauterine adhesions ESH Grade 2 or higher (Anaes.)
- Item 35636:
  - Change the item descriptor to improve overall clarity.
  - The proposed item descriptor is as follows:
    - Hysteroscopic resection of myoma, or myoma and uterine septum (where both are performed). (Anaes.)



## Rationale

This recommendation focuses on updating item descriptor terminology and improving the clarity of the MBS. It is based on the following.

- Item 35623:
  - The proposed item descriptor wording will improve the clarity of the MBS and reflect current terminology. Specifying the indications also encourages appropriate use of this item.
  - No further changes are recommended because this high-end hysteroscopic procedure is a valuable alternative to hysterectomy in appropriately selected cases.
- Item 35634:
  - A separate item number is no longer necessary because its services are covered by item 35623.
- Item 35635:
  - This minor wording change more accurately describes the appropriate procedure, as used in contemporary clinical practice.
  - This procedure remains a useful option, especially for patients with infertility and recurrent implantation failure or in recurrent miscarriage (31) (32).
  - The change to the item descriptor aligns this procedure with RANZCOG/AGES training requirements level 4 procedures; therefore, it is appropriate that it have a higher rebate (\$299.45) than item 35633 (\$218.00).
- Item 35636:
  - This minor wording change more accurately describes the appropriate procedure, as used in contemporary clinical practice.

### 6.7.3 Item 35633

**Table 27: Item introduction table for item 35633**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35633	Hysteroscopy with uterine adhesiolysis or polypectomy or tubal catheterisation (including for insertion of device for sterilisation) or removal of IUD which cannot be removed by other means, 1 or more of (Anaes.)	\$218.00	19,609	6.5%	\$2,927,221



### Recommendation 33

- Change the descriptor of item 35633.
  - The proposed item descriptor is as follows:
  - Hysteroscopy with removal of polyps by any method or division of minor adhesions (ESH classification 1) under visual guidance (Anaes.)

#### Rationale

This recommendation focuses on modernising the MBS, reflecting contemporary best practice, and improving transparency to the procedure. It is based on the following.

- The procedures claimed under this item number vary considerably in terms of complexity.
- The Committee used the ESH classification of female genital tract anomalies in order to categorise the complexity of these intrauterine adhesions (33) (34).
- The Committee recommended noting the use of vision guidance for removal of intrauterine pathology in keeping with current published guidelines (34) (35) is best practice for these pathologies.

#### 6.7.4 Items 35616, 35620 and 35622

**Table 28: Item introduction table for items 35616, 35620 and 35622**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35616	Endometrium, endoscopic examination of and ablation of, by microwave or thermal balloon or radiofrequency electrosurgery, for chronic refractory menorrhagia including any hysteroscopy performed on the same day, with or without uterine curettage (Anaes.)	\$449.60	4,593	9.0%	\$1,456,162
35620	Endometrial biopsy where malignancy is suspected in patients with abnormal uterine bleeding or post menopausal bleeding (Anaes.)	\$53.35	7,186	7.8%	\$342,728
35622	Endometrium, endoscopic ablation of, by laser or diathermy, for chronic refractory menorrhagia including any hysteroscopy performed on the same day, with or without uterine curettage, not being a service associated with a service to which item 30390 applies (Anaes.)	\$602.45	1,562	0.7%	\$659,841

### Recommendation 34

- Item 35616:
  - Change the item descriptor to:



- Remove the specification that chronic refractory menorrhagia is the only indication for use.
- Remove the specific inclusion of uterine curettage procedure.
- Remove 'microwave' as a form of energy delivery.
- The proposed item descriptor is as follows:
  - Endometrial ablation by thermal balloon or radiofrequency electrosurgery, for abnormal uterine bleeding with or without endometrial sampling including any hysteroscopy performed on the same day. (Anaes.)
- Item 35620:
  - Change the item descriptor to remove suspicion of malignancy as the only indication for use.
  - The proposed item descriptor is as follows:
    - Endometrial biopsy for pathological assessment in women with abnormal uterine bleeding or post-menopausal bleeding. (Anaes.)
- Item 35622:
  - Change the item descriptor to specify use of hysteroscopy in electrosurgery, refer to AUB in general, and allow endometrial sampling as needed.
  - The proposed item descriptor is as follows:
    - Endometrial ablation, using hysteroscopically guided electrosurgery or laser energy, for abnormal uterine bleeding with or without endometrial sampling, not being a service associated with a service to which item 30390 applies. (Anaes.)

## Rationale

This recommendation focuses on modernising the MBS to reflect contemporary best practice. It is based on the following.

- Item 35616:
  - The revised wording in the proposed item descriptor reflects modern terminology. It also removes the reference to microwave endometrial ablation, which is no longer available in Australia.
- Item 35620:



- There is no need to specify suspicion of malignancy because this is a diagnostic procedure that is often necessary in cases of abnormal bleeding, whether or not the suspected cause is malignancy.
- The revised wording in the proposed item descriptor reflects contemporary clinical practice for the investigation of abnormal bleeding. This should not be limited to cases of suspected malignancy, which form only a small portion of these investigations.
- Item 35622:
  - Minor revisions to the wording in the proposed item descriptor improve overall clarity and more closely reflect modern clinical practice.

## 6.8 IUD procedures (items 35502, 35503 and 35506)

### 6.8.1 Items 35502 and 35503

**Table 29: Item introduction table for items 35502 and 35503**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35502	Intrauterine device, introduction of, for the control of idiopathic menorrhagia, and endometrial biopsy to exclude endometrial pathology, not being a service associated with a service to which another item in this Group applies (Anaes.)	\$80.15	3,339	11.5%	\$252,308
35503	Intra uterine contraceptive device, introduction of, if the service is not associated with a service to which another item in this Group applies (other than a service mentioned in item 30062) (Anaes.)	\$53.55	60,084	8.7%	\$2,857,721

#### Recommendation 35

- Item 35502: Consolidate this service into item 35503. Delete item.
- Item 35503:
  - Change the descriptor to allow endometrial biopsy items to be claimed in addition to item 35503.
  - The Committee recommended increasing the schedule fee for item 35503 (\$53.55) so that it adequately reimburses patients and clinicians for the level of training, skill, equipment and time required to provide the service. The Committee recommended that the schedule fee should be (at least) equivalent to the current schedule fee for item 35502 (\$80.15).
  - The proposed descriptor for item 35503 is as follows:



- Introduction of an intrauterine device for abnormal uterine bleeding or contraception, if the service is not associated with a service to which another item in this Group applies (other than a service mentioned in item 30062). (Anaes.)
- The Committee recommended investigating alternative avenues for increasing the availability and affordability of IUD insertion training for GPs.

### Rationale

This recommendation focuses on improving accessibility, health outcomes and the value of care for the community. It is based on the following.

### Context and observations

The Committee found that IUDs are safe and efficacious as a method for long-term contraception, and insertion of these devices in primary care represents an important and cost-effective service for healthcare providers. There is substantial, high-quality evidence confirming high levels of safety and satisfaction among women who have an IUD for contraceptive purposes. The devices can also be used in almost all women, including women who are nulliparous (have not carried a pregnancy beyond 20 completed weeks' gestation). The development of the levonorgestrel intrauterine system (LNG-IUD, principally marketed in Australia as Mirena®) also offers substantial control of heavy menstrual bleeding (HMB). The efficacy of this device is demonstrated by high-quality evidence, reflected in guidelines and standards around the world. Women of all ages consider IUDs an acceptable method for both contraceptive purposes and HMB control (36). Australian IUD usage for each of these indications is discussed in more detail below.

The Committee made several observations regarding IUD use in Australia, relating to:

- Principal indications and access.
- Barriers to increased insertion by GPs.
- **Principal indications and access**
  - Contraception
    - In Australia, there is limited uptake of long-acting reversible contraceptives (LARCs) such as IUDs, with only 2–6.5 per cent of women who require contraception receiving a LARC, compared with 11–14 per cent in Northern Europe. In 2015, IUD usage among women aged 15–49 who are married or regularly cohabiting was 1.5 per cent in Australia, compared to 5.1 per cent in the United States and 10–12 per cent in Northern and Western Europe (37) (38) (39) (40).



- Greater access to these methods could help to reduce Australia's unintended pregnancy and termination rates (36) (41).
- The 12 per cent year-on-year growth in MBS benefits paid for IUD insertion services is likely to be accounted for by the recent introduction of non-copper IUDs, and it has occurred within the context of continued inadequate access overall.
- HMB
  - The standards for investigating and treating HMB recently proposed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) highlight the importance of the LNG-IUD as the optimal medical treatment for women suffering with HMB (42).
  - In other healthcare systems where LNG-IUD treatment is available (such as in the United Kingdom), its inclusion in public funding schemes has been demonstrated to reduce operative interventions without compromising quality of care, while maintaining high levels of patient satisfaction (43).
  - Medical treatment options for HMB include simple treatments (indicated in approximately 20 per cent of patients) and the LNG-IUD (indicated in approximately 34 per cent of patients). The use of primarily outpatient treatments keeps patients out of hospital, decreasing the operative load on hospitals, increasing the availability of resources in other areas, and potentially increasing the overall value of care provided by the health system.

### Identified problems

- The Committee found that at present, access to IUD insertion services in the Australian primary care setting is inadequate. Increasing the country's capacity to provide both contraceptive services and treatment for HMB in primary care remains a high priority for women's healthcare delivery.
- With input from the General Practice and Primary Care Clinical Committee, the Committee identified two major factors in the published literature that act as barriers to IUD insertion at the primary care level: training and the remuneration of services. These factors may in turn lead to a third barrier: the gradual de-skilling of GPs in the performance of this procedure.
  - Remuneration
    - GPs who had sought training in fitting IUDs cited inadequate remuneration as the most important barrier to fitting more IUDs in primary care (44).



- Health professionals and patients also identified procedure cost, appointment waiting time and distance to a LARC provider as barriers to use. Rural youth in particular mentioned cost barriers and transport difficulties (45).
- Calculations by the Committee suggest that the current schedule fee for insertion of an IUD does not cover the costs borne by the clinician.
  - Current national family planning guidelines suggest that the clinician who introduces the device should have a nurse or assistant available throughout the procedure to manage the rare complication of cervical shock if necessary.
  - Estimated costs for an IUD insertion kit, an assisting nurse and consumables amount to between \$50 and \$100 per procedure, which means that the clinician's time receives limited or no reimbursement from the current schedule fee for item 35503 (\$53.55, or \$45.55 for bulk-billed GP patients).
  - Simple insertions take approximately 30 minutes, but complex insertions take much longer and require both clinician and nursing assistant time. More complex cases do not receive higher schedule fees, increasing the effective cost to the clinician.
- De-skilling of GPs
  - The Committee believes that without an urgent and meaningful effort to introduce change, these barriers may become self-perpetuating. For example, patients and GPs could begin to favour referral to a specialist for the provision of IUD services if primary care access remains inadequate (due to the limited number of GPs willing to provide these services, either because of training or reimbursement concerns). This would exacerbate the de-skilling of GPs because it would prevent them from performing a sufficient number of services to maintain the skill required to (a) have enough confidence to perform the procedure, and (b) minimise the risk of uterine perforation and other adverse events.
  - A recent report in *Australian Family Physician* found that among GPs, low patient numbers was a significant barrier to incorporating IUD insertion into their practice (44).
  - MBS data shows that specialists performed 45 per cent of item 35503 IUD insertions in FY2014–15. Each referral results in an additional specialist consultation fee being claimed through the MBS. The Committee considered many of these referrals to be unnecessary, which decreases accessibility for patients (because there are fewer specialists than generalists) and reduces value for the community (due to the additional consultation fees).



- However, in certain clinical situations it is appropriate to refer a patient requesting an IUD insertion to a specialist. The Committee recommended retaining this option in order to preserve access for such cases, although it should not be used as widely as it is today.
- Training
  - Access to training for GPs may be a significant barrier for some GPs, particularly in remote and rural areas (44).
- Other barriers

Although reimbursement is the most significant barrier, other barriers to primary care provision of IUD services include the following:

- Consumer perceptions and a poorly informed medical community.
  - Pockets of poorly informed specialists and GPs perpetuate ‘medical myths’ that suggest that an IUD is not a high-quality contraceptive or an appropriate treatment for HMB (46) (47).
- Patient persistence and affordability.
  - Two consultations are recommended prior to introduction of the device, and one consultation is recommended following introduction of the device. Specifically, patients receive a long consultation around choice (describing the introduction process), a consultation for introduction of the device and a follow-up consultation. This may be with a specialist, which would then incur the increased cost associated with specialist consultations. In addition, the inconvenience and cost associated with these multiple referrals and consultations may present an unintentional access barrier to consumers.

### **Possible solutions**

Improving IUD insertion rates in Australia stands to deliver notable benefits to Australian women by reducing unnecessarily high rates of unplanned pregnancy, HMB and hysterectomies. The Committee recognised that interventions targeting all of these problems simultaneously are needed in order to meaningfully increase the provision of IUD services by GPs. Indeed, it is difficult to predict the level of effect that addressing training, schedule fees or other barriers in isolation would have on the situation. However, both the Committee and the GGWG felt strongly that failing to address inadequate sub-cost remuneration would render any other interventions ineffective.

The main intervention recommended by this Committee is to modify the schedule fee for item 35503 (\$53.55), with the intention of improving the financial viability of this procedure for clinicians. The Committee agreed that addressing this major barrier would increase GPs’ willingness to provide



IUD services, leading to a virtuous cycle of increased usage, skill and comfort providing the services, and consequent improvements in Australian consumers' health.

The Committee also recommended implementing measures to increase the accessibility of IUD insertion training for GPs, although such measures are likely to be outside the remit of the MBS Review. The Committee believes that increasing the schedule fee for item 35503 (\$53.55) as recommended could positively change the cost-to-benefit ratio of undergoing training for clinicians, as long as training providers do not increase the price of training in parallel with the schedule fee.

Should this recommendation be found to be infeasible in isolation, the Committee strongly supports the creation of a group empowered to intervene across the identified problems in a holistic manner, and/or the implementation of a mechanism for selectively increasing the reimbursement of IUD insertion procedures done by GPs.

### Item-specific rationale

- Item 35502:
  - The same insertion technique is used for insertion of an IUD for both contraceptive and AUB therapeutic indications.
  - Item 35502 includes endometrial biopsy (item 35620), while item 35503 does not. However, the difference in schedule fees between items 35502 and 35503 is equivalent to the schedule fee for a co-claimed endometrial biopsy. This means that if co-claiming of item 35620 is allowed with item 35503, consumer access to the original item 35502 services is effectively maintained, and there is no need to retain 35502 as a separate item.
- Item 35503:
  - Endometrial biopsy will now be co-claimed as a separate procedure, using item 35620. This will incentivise higher value care. Previously, item 35502 IUD insertions assumed that an endometrial biopsy would be taken, but did not require it. Following the recommended changes, clinicians will need to make an explicit decision to perform a biopsy, which means that rebates for biopsies will only be provided when they are actually indicated and performed, rather than by default.

### 6.8.2 Item 35506

Table 30: Item introduction table for item 35506

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35506	Intrauterine contraceptive device, removal of under general anaesthesia, not being a service associated with a service to which another item in this Group applies (Anaes.)	\$53.70	3,215	9.5%	\$145,326



## Recommendation 36

- Item 35506: Change item descriptor to improve clarity
  - The proposed item descriptor is as follows:
    - Intrauterine contraceptive device, removal of under general anaesthesia, for a retained or embedded device, including any hysteroscopy not being a service associated with a service to which another item in this Group applies (Anaes.)

### Rationale

This recommendation focuses on maintaining access to important services. It is based on the following.

- There are two situations where IUD removal requires general anaesthetic. In situations with a simple retained string, IUD removal is quick and simple, and it should be conducted using this item where general anaesthetic is needed. However, IUDs embedded in the uterine wall can be difficult to remove, requiring the use of hysteroscopy to provide visual guidance.

## 6.9 Bartholin's gland procedures (items 35512, 35513, 35516Error! Bookmark not defined., 35517 and 35520)

### 6.9.1 Items 35512, 35513, 35516, 35517 and 35520

Table 31: Item introduction table for items 35512, 35513, 35516, 35517 and 35520

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35512 <sup>10</sup>	Bartholin's cyst, excision of (Anaes.) - G	\$179.40	32	3.5%	\$4,082
35513 <sup>11</sup>	Bartholin's cyst, excision of (Anaes.) - S	\$221.70	259	3.7%	\$39,883
35516Error! Bookmark not defined.	Bartholin's cyst or gland, marsupialisation of (Anaes.) - G	\$116.35	69	1.8%	\$6,106
35517 <sup>11</sup>	Bartholin's cyst or gland, marsupialisation of (Anaes.) - S	\$146.00	786	-0.3%	\$81,521
35520	Bartholin's abscess, incision of (Anaes.)	\$58.30	164	-1.2%	\$7,931

<sup>10</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations.

<sup>11</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists.



### Recommendation 37

- Retain two separate item numbers for these procedures: one for marsupialisation procedures and one for the excision of the Bartholin's gland in its entirety.
- Item 35513:
  - Change the item descriptor to include excision of Bartholin's abscess or gland.
  - The proposed item descriptor is as follows:
    - Bartholin's abscess, cyst or gland, excision of (Anaes.)
- Item 35517:
  - Change the item descriptor to include marsupialisation of Bartholin's abscess.
  - The proposed item descriptor is as follows:
    - Bartholin's abscess, cyst or gland, marsupialisation of (Anaes.)
  - Item 35520: Delete item.

### Rationale

This recommendation focuses on modernising the MBS, encouraging best practice and improving patient health outcomes. It is based on the following.

- Consolidating these items into two item numbers—one for marsupialisation (item 35517) and one for excision (item 35513)—reflects contemporary clinical best practice. The recommended items do not differentiate between a cyst and an abscess in the Bartholin's gland because the treatment approach is identical for both.
- Item 35520:
  - This recommendation reflects clinical best practice. The incision of a Bartholin's gland (either cyst or abscess formation) is not a definitive procedure and is no longer recommended as routine clinical practice.

## 6.10 Vulval and vaginal procedures (items 35507, 35508, 35509, 35533, 35534, 35565, 35566 and 35572)

### 6.10.1 Items 35507 and 35508

**Table 32: Item introduction table for items 35507 and 35508**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35507	Vulval or vaginal warts, removal of under general anaesthesia, or under regional or field nerve block (excluding pudendal block) requiring admission to a hospital, where the time taken is less than or equal to 45 minutes - not being a service associated with a service to which item 32177 or 32180 applies (Anaes.)	\$174.45	258	-1.9%	\$25,598
35508	Vulval or vaginal warts, removal of under general anaesthesia, or under regional or field nerve block (excluding pudendal block) requiring admission to a hospital, where the time taken is greater than 45 minutes - not being a service associated with a service to which item 32177 or 32180 applies (Anaes.) (Assist.)	\$256.95	62	0.0%	\$10,732

### Recommendation 38

- Items 35507 and 35508: No change.

#### Rationale

This recommendation recognises these items' continuing value in Australian gynaecological care. It is based on the following.

- These items accurately reflect contemporary clinical practice.
- Differentiating between procedures based on time is clinically significant and appropriate in this case.

#### 6.10.2 Items 35509, 35565, 35566 and 35572

**Table 33: Item introduction table for items 35509, 35565, 35566 and 35572**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35509	Hymenectomy (Anaes.)	\$89.45	340	8.4%	\$21,032
35565	Vaginal reconstruction for congenital absence, gynatresia or urogenital sinus (Anaes.) (Assist.)	\$683.90	59	8.1%	\$16,374
35566	Vaginal septum, excision of, for correction of double vagina (Anaes.) (Assist.)	\$397.25	73	2.3%	\$19,958
35572	Colpotomy, not being a service to which another item in this Group applies (Anaes.)	\$123.80	28	-17.2%	\$1,837

### Recommendation 39

- Items 35509, 35565 and 35566: No change.
- Item 35572: Delete item.



## Rationale

This recommendation focuses on modernising the MBS to reflect contemporary best practice. It is based on the following.

- Items 35509, 35565 and 35566:
  - These items accurately represent contemporary clinical practice. MBS data suggests that usage levels are appropriate.
- Item 35572:
  - With the advancement of radiological procedures, there is no clinical application for this procedure in modern clinical practice.

### 6.10.3 Items 35533 and 35534

**Table 34: Item introduction table for items 35533 and 35534**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35533	Vulvoplasty or Labioplasty, for repair of: (a) female genital mutilation; or (b) anomalies associated with major congenital anomalies of the uro-gynaecological tract other than a service associated with a service to which item 35536, 37050, 37836, 37842, 37851 or 43882 applies (H) (Anaes.)	\$349.85	701	-13.9%	\$158,332
35534	Vulvoplasty or Labioplasty, for localised gigantism if it can be demonstrated that: (a) the structural abnormality is causing significant functional impairment; and (b) non-surgical treatments have failed (H) (Anaes.)	\$349.85	0	0.0%	\$0

## Recommendation 40

- Item 35533 and 35534: No change.

## Rationale

This recommendation recognises these items' continuing value in Australian gynaecological care. It is based on the following.

- In the years leading up to 2014, there was a sharp increase in use of item 35533 for cosmetic indications. MBS funding is not permitted for cosmetic indications, as indicated in the *Health Insurance Act 1973*. This increase resulted in an investigation of item usage and a change to the item descriptor, as well as the introduction of item 35534.
- Since item 35533 was split into items 35533 and 35534 in November 2014, claims for item 35534 required pre-approval from the Medicare Claims Review Panel (MCRP).



- Following these changes, there has been a decline in the use of item 35533 (with a compound annual growth rate of -13.9 per cent over the past five years). This suggests that the item has been used more responsibly since the descriptor change was made.

Note that the MCRP process was disbanded from 1 November 2018 and changes were made to the explanatory notes applying to the items to outline that a detailed clinical history, which includes the medical need for the surgery, be included in the patients notes, as this may be subject to audit.

## 6.11 Other procedures (items 35518, 35611, 35649, 35658, 35500, 35680 and 35759)

### 6.11.1 Items 35518, 35611, 35649, 35658, 35500, 35680 and 35759

**Table 35: Item introduction table for items 35518, 35611, 35649, 35658, 35500, 35680 and 35759**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35518	Ovarian cyst aspiration, for cysts of at least 4cm in diameter in a premenopausal person and at least 2cm in diameter in a postmenopausal person, by abdominal or vaginal route, using interventional imaging techniques and not associated with services provided for assisted reproductive techniques (Anaes.)	\$207.85	176	-2.6%	\$27,501
35611	Cervix, removal of polyp or polypi, with or without dilatation of cervix, not being a service associated with a service to which item 35608 applies (Anaes.)	\$64.00	5,776	2.6%	\$289,700
35649	Hysterotomy or uterine myomectomy, abdominal (Anaes.) (Assist.)	\$536.00	769	-1.9%	\$253,600
35658	Uterus (at least equivalent in size to a 10 week gravid uterus), debulking of, prior to vaginal removal at hysterectomy (Anaes.) (Assist.)	\$416.05	2,191	3.8%	\$296,172
35500	Gynaecological examination under anaesthesia, not being a service associated with a service to which another item in this Group applies (Anaes.)	\$81.30	1,204	3.6%	\$74,533
35680	Bicornuate uterus, plastic reconstruction for (Anaes.) (Assist.)	\$582.05	4	-10.6%	\$1,854
35759	Procedure for the control of post operative haemorrhage following gynaecological surgery, under general anaesthesia, utilising a vaginal or abdominal and vaginal approach where no other procedure is performed (Anaes.) (Assist.)	\$563.30	194	0.1%	\$81,113

### Recommendation 41

- Item 35518: Delete item.
- Item 35611:



- Change the item descriptor to add the indication of removal of vaginal polyp or polypi.
- The proposed item descriptor is as follows:
  - Removal of cervical or vaginal polyp or polypi, with or without dilatation of cervix, not being a service associated with a service to which item 35608 applies (Anaes.)
- Item 35649:
  - Change the item descriptor to remove the word 'hysterotomy' and specify that this item refers to the removal of one or more myomas.
  - The proposed item descriptor is as follows:
    - Myomectomy, one or more myomas, when undertaken by an open abdominal approach. (Anaes.) (Assist.)
- Item 35658:
  - Change the item the descriptor to specify that:
    - Debulking of the uterus can be by vaginal or laparoscopic routes.
    - Include possibility of co-claiming this item number for removal of a myoma by the laparoscopic route to denote the increased complexity of this procedure by RANZCOG/AGES training requirements levels.
    - Add an explanatory note stating documentation of uterine or myoma size should be obtained on subsequent pathological examination.
  - The proposed item descriptor is as follows:
    - Uterus (at least equivalent in size to 10 week gravid uterus), debulking of, prior to vaginal or laparoscopic removal at hysterectomy or myoma of at least 4cm removed by laparoscopy when retrieved from the abdomen.
- Item 35500: No change.
- Item 35680: Delete item.
- Item 35759:
  - Change the item descriptor to include the use of a laparoscopic approach.
  - The proposed item descriptor is as follows:
    - Procedure for the control of post operative haemorrhage following gynaecological surgery, under general anaesthesia, utilising a vaginal, abdominal or laparoscopic approach where no other procedure is performed. (Anaes.) (Assist.)



## Rationale

This recommendation focuses on modernising the MBS to reflect contemporary best practice. It is based on the following.

- Item 35518:
  - This procedure is no longer considered appropriate in modern practice due to its potential to spread as-yet undiagnosed malignancy. Today, these procedures are more appropriately performed by an interventional radiologist, using that specialty's relevant item number.
  - There may be some concern that deletion of the item would deny access to a potentially useful procedure for selected patients with endometriomas and very high-risk patients who cannot undergo more invasive procedures.
  - Other GGWG and Committee members felt that the risks of these procedures did not outweigh the potential benefits of these changes for the above patient groups.
- Item 35611:
  - The Committee expressed concern that item 35557 (Vagina, removal of simple tumour) might be used inappropriately for the removal of vaginal polyps. The procedure to remove vaginal polypi is similar in technique and complexity to that used to remove cervical polypi. The Committee considers it more appropriate to allow use of item 35611 for either indication, and to restrict use of item 35557 to more complex procedures.
  - The Committee considered limiting use of this item (to a single use on each occasion) due to concerns that multiple claims were being made for the same procedure. However, MBS data suggested that only 0.1 per cent of services were provided to the same patient more than once in FY2015–16, and it is unlikely that these were claimed on the same day.
- Item 35649:
  - The proposed descriptor more accurately describes the procedure, as used in contemporary clinical practice.
- Item 35658:
  - Total or subtotal laparoscopic hysterectomies should largely replace abdominal hysterectomies because they involve less bleeding and less pain, have a faster recovery time and require a shorter hospital stay. The Committee also noted that the uterus is often enlarged and debulking is required. The current item number does not specifically allow for the contemporary best practice of performing the debulking procedure at the time of laparoscopic hysterectomy.



- The addition of myoma retrieval to this descriptor allows for an increased payment for the more complex removal of the pathology from the pelvis subsequent to its laparoscopic removal. This is an advanced laparoscopic procedure that requires additional training with an identified pathway under the RANZCOG/AGES training requirements levels of complexity. Laparoscopic morcellation of a myoma requires increased operative time and specific operative skills to complete efficiently and safely.
- Item 35500:
  - The proposed descriptor reflects clinical practice, and the item appears to be used appropriately.
- Item 35680:
  - This item number reflects outdated clinical practice and should not be used.
- Item 35759:
  - Adding a laparoscopic approach to the item descriptor more accurately reflects the procedure as it is performed in contemporary clinical practice.



## 7. Urogynaecology recommendations

The Committee noted that 31 items described procedures primarily concerned with urinary function and vaginal repair procedures. The UGWG was formed to provide specialist advice on these items and develop the recommendations outlined below. Principal changes include the following:

- Consolidating several urodynamic items into two complete medical service items.
- Allowing MBS funding of vaginal surgery for pelvic organ prolapse only when native tissue without graft (mesh) is used.
- Creating new items to cover the excision of mesh in symptomatic patients.

On 28 November 2017, the Therapeutic Goods Administration (TGA) decided to remove mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG) (48). After a review of the clinical evidence, the TGA found that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients.

In independently reviewing the evidence, the Committee identified problems with MBS items involving the use of mesh and developed recommendations to address patient safety. Following the TGA's announcement regarding regulatory actions in relation to transvaginal mesh products and single incision mini-slings, the Committee revised its recommendations to align with the TGA, as a result there will be no MBS items available that will allow for the use of graft (mesh) material in the treatment of pelvic organ prolapse.

### 7.1 Urogynaecology Working Group membership

The UGWG included the members listed in Table 36.

**Table 36. UGWG members**

Name	Position/Organisation	Interests declared
Associate Professor Malcolm Frazer*	Urogynaecologist	Paid surgical preceptor and occasional lecturer for Johnson and Johnson, and for American Medical Systems with regard to transvaginal mesh kits. No further remunerated contact with these companies for the past five years. Occasional adviser for Clayton Utz Lawyers, relating to the use of transvaginal mesh and suburethral slings in Australia.
Dr Peta Higgs	Urogynaecologist	Claims MBS items.
Associate Professor Christopher Maher	Urogynaecologist	None.
Dr Kris Cvach	Urogynaecologist	Claims MBS items.
Dr Elizabeth Gallagher	General Gynaecologist	Claims MBS items. Board Member, Australian Medical Association-ACT (AMA-ACT Limited).



Name	Position/Organisation	Interests declared
		Member, Australian Medical Association (AMA) Federal Council-ACT Representative. Member, Australasian Gynaecologic Endoscopy Society (AGES). Member, Urogynaecology Society of Australia (UGSA). Member, International Urogynaecology Society (IUGA). Member, Australian Menopause Society (AMS). Has attended sponsored training sessions and workshops on pelvic anatomy and mesh products hosted by American Medical Systems (AMS) and Boston Scientific. Shareholder, Sonic Health Care. Partner, Barton Private Hospital, Barton General Practice and The Barton Specialist Centre.
Dr Alisa Wilson Edwards	Urologist	Claims MBS items. Educational speaker, Astellas, Allergan. Lead investigator on an industry sponsored national randomised controlled trial (Analytica).
Ms Diane Walsh	Consumer representative	None.
Dr Sara Whitburn	General Practitioner	Member, Royal College of General Practitioners. Diplomat, Royal Australian and New Zealand College of Obstetrics and Gynaecology.
Professor Michael Permezal (GCC Chair)*	Committee ex-officio	None.

\*Also a member of the Committee.

It is noted that the majority of members share a common conflict of interest in reviewing items that are a source of revenue for them (that is, members' patients claim the items under review). This conflict is inherent in a clinician-led process, and having been acknowledged by the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.

The UGWG developed the following recommendations, which were unanimously endorsed by the Committee.

## Item-specific recommendations

### 7.2 Urodynamic study items (11900, 11903, 11906, 11909, 11912, 11915, 11917 and 11921)

The Committee reviewed nine items relating to urodynamic studies. These items are still useful as a means of accurately evaluating the structure and function of the urinary tract, but the Committee found that their current structure in the MBS could be improved to simplify claiming and rebates for



clinicians and patients, while also promoting higher value care. This restructure will bring the number of urodynamics items down to four without harming patient access or safety. The Committee also reviewed item 11919 but decided that this item should be referred to the Urology Committee because gynaecologists seldom perform this service. Please see Section 8 (recommendations referred to other Committees) for further detail.

### 7.2.1 Item 11900

**Table 37: Item introduction table for item 11900**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
11900	Urine flow study including peak urine flow measurement, not being a service associated with a service to which item 11919 applies	\$27.55	54,918	7.4%	\$1,324,963

### Recommendation 42

- Change the descriptor to restrict co-claiming with items 11912, 11917 and 11919.
- The proposed item descriptor is as follows:
  - Urine flow study including peak urine flow measurement, not being a service associated with a service to which items 11912, 11917 or 11919 applies.

### Rationale

This recommendation focuses on modernising the MBS and promoting higher value care through the appropriate use and co-claiming of items. It is based on the following observations.

- The Committee agreed that a urine flow study is a required and clinically relevant investigation, and that the item needs no alteration. Its high levels of use are consistent with its standing as a fundamental tool of urogynaecological practice.
- Urine flow studies are now included in complete medical service items 11912 and 11917 recommended by the Committee. As a result, they no longer need to be claimed in addition.

### 7.2.2 Items 11903, 11906, 11909, 11912 and 11915

**Table 38: Item introduction table for items 11903, 11906, 11909, 11912 and 11915**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
11903	Cystometrography, not being a service associated with a service to which any of items 11012 to 11027, 11912, 11915, 11919, 11921 and 36800 or an item in group 13 of the Diagnostic Imaging Services Table applies	\$111.10	123	-3.2%	\$11,691



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
11906	Urethral pressure profilometry, not being a service associated with a service to which any of items 11012 to 11027, 11909, 11919, 11921 and 36800 or an item in group 13 of Diagnostic Imaging Services Table applies	\$111.10	571	-4.6%	\$53,780
11909	Urethral pressure profilometry with simultaneous measurement of urethral sphincter electromyography, not being a service associated with a service to which any of items 11906, 11919, 11921 and 36800 or an item in group 13 of Diagnostic Imaging Services Table applies	\$165.15	69	53.9%	\$9,671
11912	Cystometrography with simultaneous measurement of rectal pressure, not being a service associated with a service to which any of items 11012 to 11027, 11903, 11915, 11919, 11921 and 36800 or an item in group 13 of the Diagnostic Imaging Services Table applies (Anaes.)	\$165.15	1,385	-2.1%	\$190,673
11915	Cystometrography with simultaneous measurement of urethral sphincter electromyography, not being a service associated with a service to which any of items 11012 to 11027, 11903, 11909 11912, 11919, 11921 and 36800 or an item in group 13 of Diagnostic Imaging Services Table applies	\$165.15	5	20.1%	\$686

### Recommendation 43

- Consolidate the services of items 11903, 11906, 11909 and 11915 into item 11912. Delete items 11903, 11906, 11909 and 11915.
- Item 11912:
  - Change the descriptor to:
    - Allow stomal or vaginal pressure to be used where rectal pressure is not possible.
    - Include urine flow studies, urethral pressure profilometry and urethral sphincter electromyography.
    - Remove reference to items 11903, 11915 and 11921 as these numbers will be consolidated into item 11912.
    - Include items 11900 and 11917 as items that cannot be co-claimed.
  - Base the schedule fee on the combination of the current schedule fees for items 11900 (\$27.55), 11912 (\$165.15) and 11906 (\$111.10), taking into account the multiple services rule. This is intended to be a cost-neutral recommendation.
  - The proposed item descriptor is as follows:



- Cystometry with simultaneous measurement of rectal pressure, with measurement of any 1 or more of urine flow rate, urethral pressure profile, urethral sphincter electromyography, not being a service associated with a service to which any of items 11012 to 11027, 11900, 11917, 11919 and 36800 applies. (Anaes.)

## Rationale

This recommendation focuses on encouraging best practice and avoiding unnecessary waste by ensuring that these procedures are performed together, rather than in isolation. It is based on the following observations.

- Clinical best practice supports performing these procedures together because they provide different elements of the full diagnostic picture, which is needed to accurately address many forms of urogynaecological pathology. In practice, these procedures are already performed together (almost exclusively) and constitute a complete medical service for urodynamic studies without imaging. In most cases, there is little clinical utility in performing them in isolation, and the Committee believes that creating a complete medical service item would provide higher value care to patients and the community (49) (50) (51) (52).
- The current absence of abdominal pressure measurement in the item descriptors does not align with the guidelines in the International Continence Society Good Urodynamic Practices and Terms 2016 (ICS-GUP). The ICS-GUP stipulates that measurement of abdominal pressure in cystometry is needed to provide accurate assessment of detrusor pressures (53). This level of detailed information is required in order to make clinically relevant diagnoses.
- Item 11906 is already frequently co-claimed with item 11912 (approximately 94 per cent of item 11906 claims were made with item 11912).
- Item 11909 is infrequently claimed (there were only 69 claims in FY2015–16) but the Committee felt that urethral sphincter electromyography should be retained within newly expanded item 11912 to reflect the breadth of appropriate clinical practice, maintain patient access to a useful service, and align with the supplementary urodynamics tests outlined in the descriptors for items 11917 and 11919.
- Items 11903, 11909 and 11915 are infrequently claimed. Incorporating them into item 11912 will preserve access to their services where needed.
- The services described by items 11900 and 11917 overlap with those of 11912, so where these are performed those items should be claimed instead of, rather than in addition to, 11912.



### 7.2.3 Item 11917

**Table 39: Item introduction table for item 11917**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
11917	Cystometrography in conjunction with ultrasound of 1 or more components of the urinary tract, with measurement of any 1 or more of urine flow rate, urethral pressure profile, rectal pressure, urethral sphincter electromyography; including all imaging associated with cystometrography, not being a service associated with a service to which any of items 11012 to 11027, 11900 to 11915, 11919, 11921 and 36800 applies (Anaes)	\$428.35	17,321	1.3%	\$6,175,097

### Recommendation 44

- Change the item descriptor to:
  - Remove references to item 11915 (which will be consolidated into item 11912) and item 11921 (which is recommended for deletion).
  - Explicitly include rectal pressure measurement so that it is no longer optional.
- The proposed item descriptor is as follows:
  - Cystometrography in conjunction with ultrasound of 1 or more components of the urinary tract, with measurement of any 1 or more of urine flow rate, urethral pressure profile, urethral sphincter electromyography, with simultaneous measurement of rectal pressure; including all imaging associated with cystometrography, not being a service associated with a service to which any of items 11012 to 11027, 11900, 11912, 11919 and 36800 applies. Stomal or vaginal pressure may be used where rectal pressure is not possible. (Anaes.)

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- This item does not require any major changes because it already reflects current clinical practice and appropriate bundling of supplementary urodynamics tests.
- Stipulating that the test should be performed alongside measurement of rectal pressure aligns with the clinical guidelines in the ICS-GUP (53), as outlined in the discussion for items 11903 and 11915.

### 7.2.4 Item 11921

**Table 40: Item introduction table for item 11921**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
11921	Bladder washout test for the localisation of infection	\$75.05	59	-8.9%	\$3,344

## Recommendation 45

- Delete item.

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- A separate item number is unnecessary for this procedure. Although it can be useful to sample urine at the time of cystoscopy or catheterisation for microbial identification or screening for malignancy, the Committee agreed that it is more appropriate to consider this an existing part of items 36800 (bladder catheterisation) and 36812 (cystoscopy).
- This item's schedule fee is higher than the schedule fee for catheterisation, despite the procedures being similar. Although the item is used infrequently, it has the potential for inappropriate claiming and misuse, and it adds no value to clinical care beyond other existing items. Examination of co-claiming data revealed no consistent patterns of use, and use appeared to be limited to only a few clinicians.
- The Committee considered whether this item number is being claimed for services for which there are currently no item numbers. If this is the case, it recommended that clinicians use the appropriate channels to have defined item numbers created for those services.

## 7.3 Urethral caruncle items (35523, 35526 and 35527)

### 7.3.1 Items 35523, 35526 and 35527

**Table 41: Item introduction table for items 35523, 35526 and 35527**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35523	URETHRA OR URETHRAL CARUNCLE, cauterisation of (Anaes.)	\$58.30	82	-3.3%	\$2,276
35526 <sup>12</sup>	URETHRAL CARUNCLE, excision of (Anaes.) – G	\$116.35	10	7.4%	\$608

<sup>12</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35527 <sup>13</sup>	URETHRAL CARUNCLE, excision of (Anaes.) - S	\$146.00	93	-2.9%	\$5,777

## Recommendation 46

- Item 35523: Delete item.
- Item 35527:
  - Change the item descriptor to specify that the caruncle is symptomatic and that conservative management has failed.
  - The proposed item descriptor is as follows:
    - Urethral caruncle, symptomatic, excision of, where conservative management has failed or where there is a suspicion of malignancy. (Anaes.)

## Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- Item 35523:
  - Cautery is no longer considered appropriate in the management of urethral caruncle, and the item is infrequently claimed.
- Item 35527:
  - Published studies indicate a low but definite possibility of malignancy in caruncles (54). For this reason, excision and histological examination is considered preferable to cauterisation. The majority of caruncles are asymptomatic and require no treatment. Symptomatic lesions (for example, bleeding, dysuria, dyspareunia) should receive direct local application of oestrogen cream for two months before excision is considered. All lesions with atypical symptoms, or where there is a suspicion of malignancy, should be biopsied/excised immediately (55). MBS data suggests that caruncles are mostly managed using the optimal treatment of excision. The Committee's suggested changes are unlikely to result in any clinical, financial or patient access disadvantage.

## 7.4 Genital prolapse repair items (35568, 35577, 35578, 35595 and 35597)

### 7.4.1 Items 35568 and 35595

<sup>13</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists

**Table 42: Item introduction table for items 35568 and 35595**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35568	SACROSPINOUS COLPOPEXY FOR MANAGEMENT OF UPPER VAGINAL PROLAPSE (Anaes.) (Assist.)	\$624.60	4,328	0.4%	\$1,034,237
35595	LAPAROSCOPIC OR ABDOMINAL PELVIC FLOOR REPAIR INCORPORATING THE FIXATION OF THE UTEROSACRAL AND CARDINAL LIGAMENTS TO RECTOVAGINAL AND PUBOCERVICAL FASCIA for symptomatic upper vaginal vault prolapse (Anaes.) (Assist.)	\$1,155.00	1,061	13.6%	\$784,508

### Recommendation 47

- Item 35568:
  - Change the item descriptor to add iliococcygeus fixation as an alternative surgical technique for this procedure.
  - The proposed item descriptor is as follows:
    - Procedures for the management of symptomatic upper vaginal (vault or cervical) prolapse by sacrospinous or iliococcygeus fixation. (Anaes.) (Assist.)
- Item 35595:
  - Change the item descriptor to add several additional specifications covering surgical approach and procedural detail, as well as a requirement to check ureteric integrity as part of the procedure.
  - Reduce the schedule fee to align with item 35568 (\$624.60).
  - The proposed item descriptor is as follows:
    - Procedure for the management of symptomatic vaginal vault or cervical prolapse, by uterosacral ligament suspension, by any approach, without graft, where the uterosacral ligaments are separately identified, transfixed and then incorporated into rectovaginal and pubocervical fascia of the vaginal vault, including cystoscopy to check ureteric integrity (Anaes.) (Assist.)

### Rationale

This recommendation focuses on promoting patient safety and appropriate claiming of MBS items. It is based on the following.



- There are a number of surgical procedures designed to elevate the prolapsed vaginal vault or uterus without the use of graft materials. At the time of writing, there is a lack of convincing evidence that one single approach is obviously superior.
- The schedule fee for the laparoscopic/abdominal approach was considered unnecessarily high when compared to the existing vaginal procedures, particularly when taking into account the improvements in laparoscopic technology and skills that have occurred in the last decade.
- Items 35568 and 35595 are intended to specifically cover both vault elevation following prior hysterectomy and hysteropexy procedures where the uterus is preserved. These approaches are becoming more common, and a good deal of comparative scientific work is currently underway.
- Item 35568:
  - Iliococcygeus fixation is considered a valid alternative technique for this procedure, and it requires substantially equivalent skill and time to perform. The Committee felt that this approach should not be excluded from this item number.
- Item 35595:
  - MBS data shows that a total benefit of \$784,508 was paid for item 35595 in FY2015–16, across 1,061 services. The item also saw an average annual growth of 13.6 per cent over the 2011–2016 period, which is considerably higher than the 3.1 per cent increase seen across the UGWG's items as a whole. There was also significant variation in billing, with South Australia accounting for the largest proportion of services.
  - Although the Committee initially considered consolidating item 35595 into item 35568, it decided that item 35595 was still individually relevant as it separates the substantially different (but still valid) vaginal vault or cervical prolapse repair technique of uterosacral ligament suspension from the techniques described in item 35568. MBS data also showed that there is virtually no co-claiming of items 35568 and 35595.
  - In this procedure, ureteric damage is relatively more likely than in item 35568 procedures. For this reason, the Committee has included a mandatory check cystoscopy in the item, which will require clinicians to confirm the presence or absence of ureteric damage. This will improve patient safety and the value of care provided.
  - To discourage misuse of this item, separate identification of the uterosacral ligament is now required.

#### **7.4.2 Items 35577, 35578 and 35597**

**Table 43: Item introduction table for items 35577, 35578 and 35597**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35577	MANCHESTER (DONALD FOTHERGILL) OPERATION for genital prolapse, with or without mesh (Anaes.) (Assist.)	\$674.50	44	-11.0%	\$20,256
35578	LE FORT OPERATION for genital prolapse, not being a service associated with a service to which another item in this Subgroup applies (Anaes.) (Assist.)	\$674.50	101	21.0%	\$50,785
35597	SACRAL COLPOPEXY laparoscopic or open procedure where graft or mesh is secured to vault, anterior and posterior compartment and to sacrum for correction of symptomatic upper vaginal vault prolapse	\$1,473.20	964	6.0%	\$1,013,111

### Recommendation 48

- Item 35577:
  - Change the item descriptor to more accurately describe a ‘Manchester Repair,’ and delete the words ‘with or’ so that it is clear that the procedure should be performed without mesh, and align terminology with that used by the TGA (‘pelvic organ prolapse’).
  - The proposed item descriptor is as follows:
    - Manchester (Donald Fothergill) operation for pelvic organ prolapse (includes cervical amputation, anterior and posterior native tissue vaginal wall repairs without graft) (H) (Anaes.) (Assist.)
    - This recommendation was implemented on 1 July 2018 in order to address urgent safety concerns relating to the use of synthetic mesh.
- Item 35578:
  - Change the item descriptor by deleting the term ‘Le Fort’ and renaming the procedure ‘colpocleisis’, and align terminology with that used by the TGA (‘pelvic organ prolapse’)
  - The proposed item descriptor is as follows:
    - Colpocleisis for pelvic organ prolapse, not being a service associated with a service to which another item in this Subgroup applies, with the exception of 35599. (Anaes.) (Assist.)
- Item 35597:



- Change the item descriptor to clarify that the procedure can be performed using any approach, including laproscopic, open or robotic techniques
- The proposed item descriptor is as follows:
  - Sacral colpopexy by any approach where graft or mesh is secured to vault, anterior and posterior compartment and to sacrum for correction of symptomatic upper vaginal vault prolapse (Anaes.) (Assist.)

## Rationale

This recommendation focuses on modernising and clarifying the MBS. It is based on the following.

- Item 35577:
  - The Manchester Repair was first described in the early 20th century and has since been gradually superseded by combined vaginal hysterectomy and vaginal repairs. Nevertheless, it remains a valid option for some women who may wish to preserve the uterus. There is some confusion over which separate procedures should be included in the term, and for this reason the Committee proposed changing the item descriptor (as outlined above) to clarify the situation.
  - A very recent publication suggests that the Manchester procedure remains an efficient and safe treatment for uterine prolapse (56).
  - The Committee is not aware of published literature that adequately supports the use of mesh in this procedure. Given the evidence that mesh use in primary vaginal compartment repair procedures for pelvic organ prolapse is associated with poorer outcomes than native tissue repairs, the Committee recommended removing the ability to use mesh from this item.
- Item 35578:
  - Colpocleisis is the contemporary term used to describe the modern form of the Le Fort operation.
  - The colpocleisis procedure is still quite commonly used to manage prolapse symptoms in a mostly elderly population (57). This population has a high incidence of associated stress leakage of urine requiring surgical treatment. The current wording of the item descriptor excludes the possibility of performing a simultaneous sling procedure (item 35599, another service within this subgroup), resulting in inadequate care or the need for two separate operations (with the additional anaesthetic risks, morbidity, cost and inconvenience this involves).
- Item 35597:



- Sacral colpopexy is still widely regarded as the ‘gold standard’ procedure for vault support in prolapse. It remains a valuable surgical option for prolapse, whether performed as a laparoscopic or open procedure.
- Robotic surgical techniques are seeing more widespread use for this procedure, and have not been shown to have inferior outcomes to open or laparoscopic methods.
- This procedure involves the insertion of mesh via the abdominal route and is therefore consistent with the TGA’s regulatory actions. Use of mesh via this approach has not been associated with the same level of adverse effects as that via the transvaginal route, and its use in sacral colpopexy is still supported by the academic literature (58).

## 7.5 Vaginal compartment repair items (35570, 35571 and 35573)

### 7.5.1 Items 35570, 35571 and 35573

**Table 44: Item introduction table for items 35570, 35571 and 35573**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35570	ANTERIOR VAGINAL COMPARTMENT REPAIR by vaginal approach (involving repair of urethrocoele and cystocoele) with or without mesh, not being a service associated with a service to which item 35573, 35577 or 35578 applies (Anaes.) (Assist.)	\$553.85	2,385	-2.7%	\$600,503
35571	POSTERIOR VAGINAL COMPARTMENT REPAIR by vaginal approach (involving one or more of the following; repair of perineum, rectocoele or enterocoele) with or without mesh, not being a service associated with a service to which item 35573, 35577 or 35578 applies (Anaes.) (Assist.)	\$553.85	3,332	1.4%	\$944,990
35573	ANTERIOR AND POSTERIOR VAGINAL COMPARTMENT REPAIR by vaginal approach (involving both anterior and posterior compartment defects) with or without mesh, not being a service associated with a service to which item 35577 or 35578 applies (Anaes.) (Assist.)	\$830.90	6,546	-0.2%	\$3,668,220

### Recommendation 49

*Important note: The changes to these items were implemented on 1 July 2018 to address patient safety concerns relating to the use of synthetic mesh.*



- Revise items 35570, 35571 and 35573 to make clear that vaginal surgery for pelvic organ prolapse is MBS funded only when graft (mesh) is not used, and align terminology with that used by the TGA ('pelvic organ prolapse').
- Item 35570:
  - The proposed item descriptor is as follows:
    - Anterior vaginal compartment repair by vaginal approach for pelvic organ prolapse (involving repair of urethrocele and cystocele), using native tissue without graft, other than a service associated with a service to which item 35573, 35577 or 35578 (H) (Anaes.) (Assist.)
- Item 35571:
  - The proposed item descriptor is as follows:
    - Posterior vaginal compartment repair by vaginal approach for pelvic organ prolapse involving repair of one or more of the following:
      - (a) perineum;
      - (b) rectocele;
      - (c) enterocele;using native tissue without graft, other than a service associated with a service to which item 35573, 35577 or 35578 applies (H) (Anaes.) (Assist.)
- Item 35573:
  - The proposed item descriptor is as follows:
    - Anterior and posterior vaginal compartment repair by vaginal approach for pelvic organ prolapse (involving anterior and posterior compartment defects), using native tissue without graft, other than a service associated with a service to which item 35577 or 35578 applies (H) (Anaes.) (Assist.)

### **Rationale**

This recommendation focuses on improving patient safety by taking into account new research and clinical experience. It is based on the following.

### **Context and observations**

- The Committee noted the following contextual points surrounding these procedures.



- The current item descriptors for vaginal compartment repair procedures specify that they can be performed ‘with or without mesh.’
- The TGA decided to remove mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the ARTG in late November, 2017. Following a post-market review of urogynaecological mesh implants the TGA believes the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients.
- ‘Mesh’ can refer to any of several types of organic or synthetic graft material. The Committee elected to divide the principal types into three categories:
  - Native tissue (patient’s own tissue, usually referred to as ‘graft’).
  - Biological (organic tissue of human or other origin, referred to as either ‘mesh’ or ‘graft’).
  - Permanent/composite (synthetic or combination material with a non-resorbable component, referred to as either ‘mesh’ or ‘graft’).

### ***Identified problems***

- The Committee identified several problems that it recommended addressing in the interest of patient safety.
  - In recent years, concern has arisen about the safety profile of transvaginal graft augmented surgery for vaginal prolapse using biological or permanent/composite graft materials, when compared with procedures using native tissue (the patient’s own tissue).
  - Permanent/composite mesh and biological graft repairs are associated with complications that do not occur with native tissue repairs—notably mesh/graft exposure, pain, bleeding and discharge, which can require excision of graft material in some cases.
  - Best clinical practice today would support the performance of primary vaginal repair surgery using native tissue alone.

### **Possible solutions**

- The Committee recommended addressing these problems in the interest of patient safety.
  - The proposed changes to the items’ descriptors are intended to improve patient safety by guiding clinical best practice, in line with the published literature, current guidance from RANZCOG (59) and the regulatory actions of the TGA (48).



## 7.5.2 Proposed new items 3557X, 3557Y and 3557Z

### Recommendation 50

*Important note: These recommendations were implemented on 1 July 2018 in order to address urgent safety concerns relating to the use of synthetic mesh.*

- Create new items to allow excision of non-native tissue graft material in symptomatic patients.
- Require the size of the excised mesh to be histologically confirmed. This is relevant to vaginal procedures only.
- Item 3557X:
  - The proposed item descriptor is as follows:
    - Vaginal procedure for excision of graft material in symptomatic patients with graft related complications, including graft related pain or discharge and bleeding related to graft exposure, less than 2cm<sup>2</sup> in its maximum area, either singly or in multiple pieces. (Not payable more than twice per provider per patient in a 12 month period.) (Anaes.)(Assist.)
- Item 3557Y:
  - The proposed item descriptor is as follows:
    - Vaginal procedure for excision of graft material in symptomatic patients with graft related complications, including graft related pain or discharge and bleeding related to graft exposure, more than 2cm<sup>2</sup> in its maximum area, either singly or in multiple pieces. (Not payable more than twice per provider per patient in a 12 month period.) (Anaes.)(Assist.)
- Item 3557Z:
  - The proposed item descriptor is as follows:
    - Abdominal procedure either open, laparoscopic or robotic, for removal of graft material in patients symptomatic with graft related complications, including graft related pain or discharge and bleeding related to graft exposure or where the graft has penetrated adjacent organs such as the bladder (including urethra) or bowel, including retroperitoneal dissection and mobilisation of bladder and/or bowel. (Not payable more than twice per provider per patient in a 12 month period.) (Anaes.)(Assist.)



## Rationale

This recommendation focuses on improving access and modernising the MBS. It will also support access to a procedure that is currently not reimbursable, but that addresses severe complications that may result from procedures covered by other MBS items. It is based on the following.

- At present, there is no item number for the excision of mesh or graft by the vaginal route. Anecdotal evidence suggests that clinicians are either using inappropriate item numbers when performing such procedures or are declining to perform them at all. Committee members had heard reports of patients feeling compelled to travel abroad to have such procedures done. Due to the lack of any specific MBS item, the number of these procedures performed in Australia is unknown.
- This recommendation will support the performance of mesh or graft excision procedures where clinically appropriate. This will improve patient safety and modernise the MBS by adding necessary procedures that are inappropriately absent from the MBS at present.
- Including three different item numbers recognises the different levels of surgical complexity involved in removing the mesh, depending on the size, approach and complications experienced after mesh insertion.
- It is already standard clinical practice to send excised samples of this type for histological examination. Making this a requirement will facilitate the recording of reliable measurements of excised mesh size, leading to improved compliance with the item descriptors. It should not lead to an unwarranted increase in the use of histology.
- Item 3557X:
  - Given the similarity in complexity with item 35570 (\$553.85 [anterior repair]), the Committee recommended an equivalent schedule fee.
- Item 3557Y:
  - Given the similarity in complexity with item 35573 (\$830.9 [AP repair]), the Committee recommended an equivalent schedule fee.
- Item 3557Z:
  - Given the similarity in complexity with item 35597 (\$1473.2 [sacral colpopexy]), the Committee recommended an equivalent schedule fee.
- There is evidence that patients have better outcomes (particularly with regards to pelvic pain) if the mesh causing their symptoms is removed entirely in one operation rather than in small pieces on separate occasions (60) (61). Therefore, removing all mesh on the first occasion should be encouraged and repeated surgical procedures discouraged due to their association



with worsening of symptoms. This recommendation may also encourage providers to refer the patient to a more experienced surgeon rather than repeating attempts to remove the mesh. There is no limit to the number of times a patient may claim for these items.

- The Government accepted these recommendations and on 1 July 2018, changes were made to the MBS to introduce three new interim items for the surgical removal of mesh in symptomatic patients.

## 7.6 Stress incontinence procedure items (37043, 37044, 35599, 35602 and 35605)

### 7.6.1 Items 37043 and 37044

Table 45: Item introduction table for items 37043 and 37044

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
37043	BLADDER STRESS INCONTINENCE, Stamey or similar type needle colposuspension, with or without mesh, not being a service associated with a service to which item 30405 or 35599 applies (Anaes.) (Assist.)	\$674.50	52	-17.6%	\$23,304
37044	BLADDER STRESS INCONTINENCE, suprapubic procedure for, eg Burch colposuspension, with or without mesh, not being a service associated with a service to which item 30405 or 35599 applies (Anaes.) (Assist.)	\$691.75	232	-8.6%	\$77,088

### Recommendation 51

- Item 37043: Delete item.
- Item 37044:
  - Change the item descriptor by deleting the words ‘with or without mesh.’
  - Include a requirement to perform a diagnostic cystoscopy as part of this procedure (item 36812), and restrict co-claiming of this item.
  - The Committee recommended increasing the schedule fee to reflect the inclusion of item 36812 (\$166.70) in this item. The proposed schedule fee is \$775.10.
  - The proposed item descriptor is as follows:
    - Bladder stress incontinence, suprapubic operation for, eg Burch colposuspension, open or laparoscopic route, using native tissue without graft, with diagnostic cystoscopy to assess the integrity of the lower urinary tract; not being a service associated with a service to which 30405, 35599 or 36812 applies. (Anaes.) (Assist.)



## Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- Item 37043:
  - This procedure has been entirely superseded by other procedures and no longer forms part of mainstream urogynaecological practice. It is preferable to use a sub-urethral sling procedure for these patients (51), and these services should move to another item, such as item 35599.
- Item 37044:
  - This procedure remains a valid option for managing urinary stress incontinence. Given the small reduction in claims for item 35599 (tape procedures) documented in the recent data, use of item 37044 may actually increase. There is no evidence that the laparoscopic route is more effective than the open route.
  - The Committee is not aware of published literature that adequately supports the use of mesh in this procedure. Given the evidence that mesh use in primary vaginal compartment repair procedures is associated with poorer outcomes than native tissue repairs, the Committee recommended removing the ability to use mesh as part of this item.
  - In this situation, performing a diagnostic cystoscopy is considered best practice because the potential adverse effects of accidental damage to the bladder during this procedure can be severe.

### 7.6.2 Items 35599, 35602 and 35605

**Table 46: Item introduction table for items 35599, 35602 and 35605**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35599	STRESS INCONTINENCE, sling operation for, with or without mesh or tape, not being a service associated with a service to which item 30405 applies	\$674.50	5,040	-3.1%	\$1,981,105
35602	STRESS INCONTINENCE, combined synchronous ABDOMINOVAGINAL operation for; abdominal procedure, with or without mesh (including aftercare) not being a service to which item 30405 applies	\$674.50	25	-1.5%	\$9,893
35605	STRESS INCONTINENCE, combined synchronous ABDOMINOVAGINAL operation for; vaginal procedure, with or without mesh (including aftercare) not being a service to which item 30405 applies	\$365.95	23	-4.5%	\$4,261



## Recommendation 52

- Item 35599:
  - Change the item descriptor in the following ways:
    - Specify that the item covers a manufactured mid-urethral sling (for example, tension-free vaginal tape [TVT]) and not the types of mesh used in vaginal compartment repairs.
    - Specify that this procedure is for manufactured female mid-urethral sling systems.
    - Delete the wording 'or without.'
    - Delete the reference to item 30405.
    - Include diagnostic cystoscopy as a part of this procedure, and restrict co-claiming of the diagnostic cystoscopy item (36812).
  - The proposed item descriptor is as follows:
    - Stress incontinence, female synthetic mid-urethral sling operation for, with diagnostic cystoscopy to assess the integrity of the lower urinary tract; not being a service associated with a service to which 30405 or 36812 applies. (Anaes.) (Assist.)
  - The Committee recommended adjusting the schedule fee (\$674.50) to reflect the addition of a diagnostic cystoscopy procedure (by adding 50 per cent of the diagnostic cystoscopy item schedule fee [item 36812]).
- Items 35602 and 35605: Consolidate these services into item 37042.

### Rationale

This recommendation focuses on modernising the MBS and encouraging clinical best practice. It is based on the following.

- Item 35599:
  - Mid-urethral sling procedures using a synthetic non-absorbable material (usually Prolene), presented as an integral kit for insertion, are now the most commonly performed procedures for stress urinary incontinence. This is distinct from item 37042, which is used to describe a sling procedure that utilises the patient's own fascia harvested from the anterior abdominal wall. The item descriptor's reference to excluding item 30405—which refers to 'Ventral or incisional hernia, (excluding recurrent inguinal or femoral hernia), repair of, requiring muscle transposition, mesh hernioplasty or resection of strangulated bowel'—is difficult to explain. It is assumed to refer to a particular circumstance that was relevant when item 35599 was first introduced. The reference is no longer relevant and should be deleted.



- The Committee recommended that item 35599 be reserved for female synthetic sling systems for stress incontinence because the descriptor of item 37040 specifically references male synthetic sling systems for stress incontinence (the anatomical differences between the sexes necessitate different medical products for this procedure). Therefore, the descriptor for item 35599 should be changed to specify female synthetic slings for stress incontinence, to ensure 37040 and 35599 are differentiated as separate procedures.
- The Committee considered the performance of a diagnostic cystoscopy to be an essential part of this procedure, ensuring that no damage has been done to the bladder or urethra.

## 7.7 Vaginal hysterectomy items (35657 and 35673)

### 7.7.1 Items 35657 and 35673

**Table 47: Item introduction table for items 35657 and 35673**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35657	HYSTERECTOMY, VAGINAL with or without uterine curettage, not being a service to which item 35673 applies NOTE: Strict legal requirements apply in relation to sterilisation procedures on minors. Medicare benefits are not payable for services not rendered in accordance with relevant Commonwealth and State and Territory law. Observe the explanatory note before submitting a claim.	\$674.70	3,557	-6.0%	\$1,304,285
35673	Hysterectomy, vaginal, (with or without uterine curettage) with salpingectomy, oophorectomy or excision of ovarian cyst, 1 or more, 1 or both sides (Anaes.) (Assist.)	\$757.80	848	14.0%	\$359,190

### Recommendation 53

- Item 35657:
  - Change the item descriptor to include the term ‘McCall-type culdoplasty.’
  - The proposed item descriptor is as follows:
    - Hysterectomy, vaginal with or without uterine curettage, inclusive of a McCall-type culdoplasty, not being a service to which item 35673 applies. (Anaes.)(Assist.)
  - Item 35673: Change the item descriptor to include the term ‘McCall-type culdoplasty.’
  - The proposed item descriptor is as follows:
    - Hysterectomy, vaginal, with or without uterine curettage, with salpingectomy, oophorectomy or excision of ovarian cyst, 1 or more, 1 or both sides, inclusive of a



McCall-type culdoplasty, not being a service to which item 35657 applies.  
(Anaes.)(Assist.)

### Rationale

This recommendation focuses on modernising the MBS and encouraging clinical best practice. It is based on the following.

- The McCall culdoplasty is properly regarded as a prophylactic procedure to prevent future vaginal vault prolapse. It forms part of an appropriately comprehensive vaginal hysterectomy procedure.
- Including the McCall-type culdoplasty in the item descriptor will improve the clarity of the wording and reduce inappropriate co-claiming of a vault suspension item when only a few simple sutures are placed around the vault during closing of the vaginal incision.

## 7.8 Uterine suspension items (35683 and 35684)

### 7.8.1 Items 35683 and 35684

Table 48: Item introduction table for items 35683 and 35684

Item	Descriptor	Schedule Fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35683 <sup>14</sup>	UTERUS SUSPENSION OR FIXATION OF, as an independent procedure - G	\$351.20	2	0%	\$527
35684 <sup>15</sup>	UTERUS SUSPENSION OR FIXATION OF, as an independent procedure - S	471.15	1	-27.5%	353

### Recommendation 54

- Item 35684: Delete item.

### Rationale

This recommendation focuses on modernising the MBS. It is based on the following.

- MBS data showed that this item is rarely claimed (less than seven episodes during FY2015–16).
- This item is now adequately covered by the expanded descriptor for item 35568 in cases of uterine prolapse. The Committee considered the possibility that these item numbers were

<sup>14</sup> Note this item was deleted from the MBS in November 2017 as part of the 'G' and 'S' changes outlined in the Executive Summary, but has been included in this report as the Committee considered the item as part of its deliberations.

<sup>15</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists.



being used to cover ventrosuspension of the uterus, but it decided that this procedure no longer forms part of mainstream gynaecology.

## 7.9 Fistula repair (item 35596 and proposed new item 35596X)

### 7.9.1 Item 35596

Table 49: Item introduction table for item 35596

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35596	FISTULA BETWEEN GENITAL AND URINARY OR ALIMENTARY TRACTS repair of, not being a service to which items 37029, 37333 or 37336 applies	\$683.90	145	3.0%	\$48,110

### Recommendation 55

- Split this item into two items: 35596 and 35596X.
- Item 35596:
  - Change the item descriptor to refer specifically to a vesicovaginal fistula repaired via the vaginal route.
  - The proposed item descriptor is as follows:
    - Vesicovaginal fistula closure of by the vaginal route, not being a service to which items 37029, 37333 or 37336 applies. (Anaes.) (Assist.)
- Item 35596X:
  - Create a new item to refer specifically to a rectovaginal fistula repaired via the vaginal route.
  - The proposed item descriptor is as follows:
    - Rectovaginal fistula repair of by the vaginal route, not being a service to which items 37029, 37333 or 37336 applies. (Anaes.) (Assist.)
- In addition to these changes, the Gynaecology Clinical Committee supports the recommendations of the Urology Clinical Committee to create new items to allow for MBS funding of repair of fistulae in male patients and the repair of complex fistulae. The Committee stipulates that the changes to fistulae items it has recommended should be implemented at the same time as those recommended by the Urology Clinical Committee to avoid the unintended consequence of limiting access to male patients or those of either sex with other rarer but equally severe urogenital fistulae.



## Rationale

This recommendation focuses on modernising and improving the clarity of the MBS. It is based on the following.

- Existing item 37029 covers closure of a vesicovaginal fistula via the abdominal route. Splitting item 35596 into items for vesicovaginal and rectovaginal fistula repairs makes logical and surgical sense because these are distinct clinical entities with differing aetiologies and potential morbidity profiles. Separating these procedures also more accurately reflects modern clinical practice.
- The Committee recommended increasing the schedule fee for both of these items to the level of item 37029 (\$924.70) change, which is similarly complex and requires similar skill and experience.
  - These rare and complex procedures can take between two and four hours to perform and require a high degree of specialised training and experience in order to ensure a good patient outcome.
- It is extremely rare to encounter patients with both vesicovaginal and rectovaginal fistulae. The occurrence of both would represent an extremely challenging surgical situation, warranting the co-claiming of both items together. For this reason, there is no need to restrict co-claiming.



## 7.10 Plastic repair of vaginal orifice (item 35569)

### 7.10.1 Item 35569

Table 50: Item introduction table for item 35569

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35569	PLASTIC REPAIR TO ENLARGE VAGINAL ORIFICE (Anaes.)	\$160.85	467	-3.6%	\$52,176

### Recommendation 56

- No change.

#### Rationale

This recommendation focuses on maintaining access to important services.

- This remains a useful procedure and is adequately described by this item.



## 8. Gynaecological oncology recommendations

### 8.1 Gynaecological Oncology Working Group membership

The GOWG included the members listed in Table 51.

**Table 51: GOWG members**

Name	Position/Organisation	Interests declared
Dr Rhonda Farrell (GOWG Chair)*	Gynaecologist & Gynaecological Oncologist	Claims MBS items. Member of ASGO (The Australian Society of Gynaecological Oncologists).
Associate Professor Russell Land	Gynaecologist & Gynaecological Oncologist	None
Dr Deborah Neesham		Claims MBS items.
Dr John Miller	Gynaecologist & Gynaecological Oncologist	Claims MBS items.
Dr Stuart Salfinger	Gynaecologist & Gynaecological Oncologist	Claims MBS items. Vice President (Director), Australian Gynaecologic Endoscopy and Surgery Society. Member, Australia Society of Gynaecologic Oncologists. Paid consultant for teaching purposes, Covidien/Medtronic healthcare.
Dr Jonathan Carter	Gynaecologist & Gynaecological Oncologist	None.
Dr Simon Craig	Gynaecologist & Gynaecological Oncologist	Claims MBS items.
Dr Michael Jackson	Radiation Oncologist	None.
Professor Danielle Mazza	Chair, Department of General Practice, Monash University	None.
Dr Vijay Roach*	General Gynaecologist	Claims MBS items.
Ms Helen Mikolaj	Consumer representative	None.
Dr Greg Jenkins	General Gynaecologist	Claims MBS items.
Professor Michael Permezel (Committee Chair)*	Committee ex-officio	None.

\*Also a member of the Committee.

It is noted that the majority of members share a common conflict of interest in reviewing items that are a source of revenue for them (that is, members' patients claim the items under review). This conflict is inherent in a clinician-led process, and having been acknowledged by the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.

The GOWG developed the following recommendations, which were unanimously endorsed by the Committee.



## Item-specific recommendations

### 8.2 Colposcopy (item 35614)

#### 8.2.1 Item 35614

Table 52: Item introduction table for items 35614

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35614	Examination of lower genital tract by a Hinselmann type colposcope in a patient with a previous abnormal cervical smear or a history of maternal ingestion of oestrogen or where a patient, because of suspicious signs of cancer, has been referred by another medical practitioner (Anaes.)	\$63.90	84,951	1.6%	\$3,948,744

#### Recommendation 57

- Change the item descriptor to:
  - Remove the word ‘Hinselmann.’
  - Remove the referral requirement.
- Change the explanatory notes by adding key criteria for care from the recently released National Cervical Screening Program guidelines (62) and the National Framework for Gynaecological Cancer Control (63).
- Review the amended item in the next one to two years to determine whether it still accurately reflects the National Cervical Screening Program guidelines, and whether item usage is appropriate in the context of these guidelines.
- The proposed item descriptor is as follows:
  - Examination of the lower genital tract using a colposcope in a patient who:
    - Has a human papilloma virus (HPV)-related gynaecological indication, or
    - Has symptoms or signs suspicious of lower genital tract malignancy, or
    - Is undergoing follow-up after treatment of lower genital tract malignancy, or
    - Is undergoing assessment or surveillance of a vulvovaginal pre-malignant or malignant disease.
- The proposed explanatory notes are as follows:
  - *This item to be used in a patient who satisfies the criteria for treatment according to the current National Cervical Screening Program: Guidelines for the management of screen-*



*detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Summarised indications and information relating to the use of this item are provided below:*

- *HPV 16/18 positive or HPV not 16/18 positive and LBC shows pHSIL/HSIL abnormality*
- *HPV positive (any type) and LBC prediction of any glandular abnormality, or any suspicion of invasive cancer, should be referred directly to a gynaecological oncologist or colposcopist experienced in assessment of malignancy*
- *HPV not 16/18 positive on consecutive tests 12 months apart*
- *A patient aged 70–74 yrs and on exit testing has HPV (any type) detected*
- *HPV detected (any type) in an immunosuppressed patient*
- *A patient exposed to DES in utero, colposcopy on an annual basis*
- *A patient who has had a hysterectomy for HSIL (CIN2/3), and has HPV (any type) detected on follow up surveillance*
- *Symptoms or signs suspicious of invasive lower genital tract disease include:*
  - *Premenopausal patient with unexplained abnormal bleeding (despite negative HPV or normal LBC)*
  - *Postmenopausal patient with an episode of abnormal bleeding*
  - *Lesion suggestive of lower genital tract pre-cancer or cancer*
- *Patients requiring follow-up colposcopy include:*
  - *Follow up colposcopy is not recommended after treatment of CIN2/3, or adenocarcinoma in situ, but can be performed at the discretion of the treating colposcopist at 6–12 months*
  - *6 months after initial colposcopy of HPV 16/18 or non 16/18 positive and LBC prediction of pHSIL/HSIL, and normal colposcopy, if patient DOES NOT have treatment.*
  - *A patient who is being followed up after treatment of endometrial, cervical, vaginal or vulva cancer if there are abnormal symptoms, signs of a visible suspicious lesion, or if HPV (any type) remains positive and/or LBC is abnormal*
- *Assessment or surveillance of the following vulvovaginal conditions is indicated, where there is a risk of developing pre-invasive or invasive disease:*
  - *Vulval intraepithelial neoplasia*



- *Vaginal intraepithelial neoplasia*
- *Lichen sclerosis*
- *Lichen planus*
- *Pagets Disease*
- *Psoriasis*
- *High risk HPV in immunocompromised patients*

### **Rationale**

This recommendation focuses on modernising the MBS, improving uptake and promoting compliance with clinical best practice. It is based on the following.

- Removal of the word ‘Hinselmann’ acknowledges that other types of colposcopes may be used, improving access without decreasing quality of care.
- The item should clearly reflect the new National Cervical Screening Program guidelines (62), which are expected to come into effect in 2017. This will encourage clinicians to practice in accordance with the guidelines, which were developed specifically to improve the efficacy and safety of care for at-risk patients while managing scarce public resources effectively—all of which promotes high-value care. A review of the item is recommended within one to two years to determine whether it still reflects the guidelines, although these should not substantially change within the first two to three years of adoption.
- The proposed item recognises that colposcopy is also used for the assessment and surveillance of benign vulvovaginal disease (for example, lichen sclerosis, lichen planus) where there is a risk of malignancy.
- Use of this item is currently restricted to patients who have been referred by another clinician.
  - The Committee noted concerns that removing this restriction could lead to the inappropriate performance of colposcopies by inadequately skilled clinicians.
  - However, the Committee felt that this concern was outweighed by the likelihood that the restriction could lead to unnecessary cross-referral and the interruption of care for patients in its current form.
    - For example, a general gynaecologist may have been seeing a patient for obstetric or other reasons, who then suffers bleeding or other symptoms suggestive of possible cancer. In this instance, that gynaecologist could not perform a colposcopy without sending the patient back to her GP for another referral. Alternatively, the gynaecologist could refer the patient to another gynaecologist. Such cross-referrals are wasteful,



inconvenient and have a negative effect on patient care and the patient's experience of the healthcare system.

- The Committee also noted that the new National Cervical Screening Program guidelines provide much more specific guidance on colposcopy, which should reduce inappropriately performed services.

### 8.3 Colposcopically directed laser therapy items (35539, 35542 and 35545)

#### 8.3.1 Items 35539, 35542 and 35545

Table 53: Item introduction table for items 35539, 35542 and 35545

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35539	Colposcopically directed CO2 laser therapy for previously confirmed intraepithelial neoplastic changes of the cervix, vagina, vulva, urethra or anal canal, including any associated biopsies 1 anatomical site (Anaes.)	\$272.95	526	-12.0%	\$108,860
35542	Colposcopically directed CO2 laser therapy for previously confirmed intraepithelial neoplastic changes of the cervix, vagina, vulva, urethra or anal canal, including any associated biopsies - 2 or more anatomical sites (Anaes.) (Assist.)	\$319.60	72	10.4%	\$18,107
35545	Colposcopically directed CO2 laser therapy for condylomata, unsuccessfully treated by other methods (Anaes.)	\$183.00	43	-17.6%	\$6,047

#### Recommendation 58

- Item 35539:
  - Prevent this item from being claimed alongside item 35644 (cervical ablation).
  - Change the item descriptor by:
    - Adding the words 'histologically confirmed' (in reference to high-grade intraepithelial neoplastic change).
    - Removing the words 'CO2' and 'cervix.'
  - The proposed item descriptor is as follows:
    - Colposcopically directed laser therapy for histologically confirmed high grade intraepithelial neoplastic changes of the vagina, vulva, urethra or anal canal, including any associated biopsies, 1 anatomical site. (Anaes.)
- Item 35542: Consolidate ablation of the cervix into item 35645 and delete item 35542.



- Item 35545:
  - Remove 'CO2' from the item descriptor.
  - The proposed item descriptor is as follows:
    - Colposcopically directed laser therapy for condylomata, unsuccessfully treated by other methods. (Anaes.)

### Rationale

This recommendation focuses on modernising and clarifying the MBS. It is based on the following.

- Laser ablation for confirmed high-grade dysplasia of the lower genital tract remains part of normal clinical practice. Although ablative (destructive) in nature, it can be used instead of other, more destructive techniques or excisional treatments.
- In modern clinical care, different types of laser can be used interchangeably. This means that CO<sup>2</sup> (one of the types of laser) does not need to be specified in the item descriptor.
- Item 35539:
  - This item includes ablation of the cervix, so it does not need to be co-claimable with item 35564.
  - Requiring lesions to be histologically confirmed as high-grade will prevent inappropriate use of this item on less suitable lesions.
- Item 35542:
  - In modern clinical practice, cervical ablation can be achieved through the use of either a laser or an electrocoagulation device. Both produce the same outcome, with comparable technical complexity. For this reason, the Committee felt it was appropriate to incorporate laser methods alongside electrocoagulation methods as part of existing item 35645.
- Item 35545:
  - In modern clinical care, different types of laser can be used interchangeably. This means that the descriptor no longer needs to specify CO<sub>2</sub>.
  - Laser therapy remains part of normal clinical practice for condylomata if medical treatment proves unsuccessful.
  - The Committee anticipates that the number of services performed under item 35545 will continue to decline over time, but it felt that the item should be retained in the interim to maintain access. The Committee expects continued decline as the HPV vaccination becomes more commonplace, protecting more people against the low-risk HPV strains responsible



for genital warts/condylomata (types 6 and 11). This trend is already evident: MBS data shows that the number of services performed shrank by an average of over 17 per cent per year from FY2011–2016, while admission to hospital for treatment of genital warts fell by 72.7 per cent in women aged 18 to 26 years between FY2006–7 and FY2010–11 (64).

## 8.4 Cervical ablation procedures (items 35608, 35644, 35645 and 35646)

### 8.4.1 Items 35608 and 35646

Table 54: Item introduction table for items 35608 and 35646

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35608	Cervix, cauterisation (other than by chemical means), ionisation, diathermy or biopsy of, with or without dilatation of cervix (Anaes.)	\$64.00	26,520	0.9%	\$1,542,914
35646	Cervix, colposcopy with radical diathermy of, with or without cervical biopsy, for previously confirmed intraepithelial neoplastic changes of the cervix.	\$203.65	208	-13.2%	\$28,512

### Recommendation 59

- Item 35608:
  - Change the item descriptor by adding the words ‘endocervical curettage’ and moving the word ‘biopsy’ to appear earlier in the descriptor.
  - The proposed item descriptor is as follows:
    - Cervix, one or more of biopsy, cauterisation (other than by chemical means), ionisation, diathermy or endocervical curettage of, with or without dilatation of cervix. (Anaes.)
- Item 35646: Delete item.

### Rationale

This recommendation focuses on modernising the MBS, improving the clarity of item descriptors and aligning MBS items with clinical best practice. It is based on the following.

- Item 35608:
  - Endocervical curettage is used to assess cervical dysplasia and is typically performed with the procedures covered by item 35608 as part of normal clinical practice (that is, it does not incur separate charges). Endocervical curettage was included in the item descriptor so that the item more accurately reflects contemporary clinical practice.
- Item 35646:



- This procedure is considered obsolete in modern practice: radical diathermy is no longer recommended as therapy for confirmed intra-epithelial neoplastic changes of the cervix. Excisional procedures are now preferred because they provide samples for pathological assessment, which allows improved continuing care.
- Where clinicians choose to use an ablative procedure, this should be done using item 35647, in accordance with its descriptor.

#### 8.4.2 Items 35644 and 35645

**Table 55: Item introduction table for items 35644 and 35645**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35644	Cervix, electrocoagulation diathermy with colposcopy, for previously confirmed intraepithelial neoplastic changes of the cervix, including any local anaesthesia and biopsies, not being a service associated with a service to which item 35639, 35640 or 35647 applies (Anaes.)	\$203.65	762	5.3%	\$128,147
35645	Cervix, electrocoagulation diathermy with colposcopy, for previously confirmed intraepithelial neoplastic changes of the cervix, including any local anaesthesia and biopsies, in association with ablative therapy of additional areas of intraepithelial change in 1 or more sites of vagina, vulva, urethra or anus, not being a service associated with a service to which item 35648 applies (Anaes.)	\$318.70	96	2.2%	\$21,824

#### Recommendation 60

- Change the descriptors for these items to:
  - Include laser and cryotherapy as therapeutic techniques.
  - Specify that a second ablative treatment for a high-grade squamous intraepithelial lesion (HSIL) should not be performed (an excisional treatment is indicated in this situation), as per the current National Cervical Screening Program guidelines (62).
  - Include critical indications and contraindications from the National Cervical Screening Program guidelines, in place of the broad specification ‘for previously confirmed intraepithelial neoplastic changes of the cervix.’
- Item 35644:
  - Remove the restriction on co-claiming this item with items 35639 and 35640.
  - Add a restriction on co-claiming this item with item 35648.
  - The proposed item descriptor is as follows:



- Cervix, ablation by electrocoagulation diathermy, laser or cryotherapy, with colposcopy, including any local anaesthetic and biopsies, for previously biopsy confirmed HSIL (CIN 2/3) in a patient with a Type 1 or 2 (completely visible) transformation zone with no evidence of invasive or glandular disease, and no discordance between cytology and previous histology, not being a service associated with a service to which item 35647 or 35648 applies. (Anaes.)
- The proposed explanatory notes are as follows:
  - *Not for use in patients with a type 3 transformation zone.*
  - *A second ablative treatment for a HSIL (CIN 2/3) should NOT be performed (an excisional treatment is indicated in this situation).*
  - *Treatment of high grade lesions (CIN2/3) in an immunocompromised patient should be by excisional methods only.*
- Item 35645:
  - Remove the restriction on co-claiming this item with item 35649.
  - The proposed item descriptor is as follows:
    - Cervix, ablation by electrocoagulation diathermy, laser or cryotherapy, with colposcopy, including any local anaesthesia or biopsies, in conjunction with ablative therapy of additional areas of biopsy proven high grade intraepithelial lesions of 1 or more sites of the vagina, vulva, urethra or anus, for previously biopsy confirmed HSIL (CIN 2/3) in a patient with a Type 1 or 2 (completely visible) transformation zone with no evidence of invasive or glandular disease, and no discordance between cytology and previous histology, not being a service associated with a service to which 35647 or 35648 applies. (Anaes.)
  - The proposed explanatory notes are as follows:
    - *Not for patients with a type 3 transformation zone.*
    - *A second ablative treatment for a HSIL (CIN 2/3) should NOT be performed (an excisional treatment is indicated in this situation).*
    - *Treatment of high grade lesions (CIN2/3) in an immunocompromised patient should be by excisional methods only.*



## Rationale

This recommendation focuses on modernising the MBS to reflect critical aspects of the current National Cervical Screening Program guidelines (62), which will improve patient safety. It is based on the following.

- The Committee amended the criteria for treatment to align with the current National Cervical Screening Program guidelines. These criteria guide the use of ablative treatments such as electrocoagulation diathermy and laser therapy, preventing inappropriate and dangerous use. For example, ablative procedures should not be performed a second time for patients with HSIL, because in such situations there is a higher chance of advanced malignancy and a biopsy should be taken for further examination to rule this out. As ablative procedures destroy tissue instead of providing a suitable sample, electrocoagulation and laser therapy would leave nothing to examine. An excisional procedure (such as those described by items 35647, 35648 or 35618) should be used instead in these cases.
- Item 35644:
  - The Committee included laser therapy of the cervix in this item (having removed its use in cervical indications from item 35539) because the therapeutic outcome of cervical ablation is essentially the same regardless of the modality used.
  - The Committee agreed that the current restriction on co-claiming with items 35639 and 35640 is inappropriate. Although it would be unusual for a patient to undergo both a uterine curettage and ablative cervical therapy as part of the same procedure, it would not be unreasonable if both indications were present. The Committee further considers it unlikely that removing this restriction will lead to misuse of these items, and it seeks to promote access to items when they are needed.
    - Item 35648 refers to a large loop excision of the transitional zone in conjunction with ablation of other biopsy-proven HSIL lesions. The Committee considers it inappropriate to perform this procedure together with item 35644 because there is overlap in the services described. Only one procedure or the other should be performed.
- Item 35645:
  - The Committee included laser treatment in this item (originally covered by item 35542) because both ablative treatments achieve the same result on the cervix.
  - There is no need to exclude co-claiming of item 35649 (hysterotomy/uterine myomectomy). These procedures would normally not be done together, but in the rare cases where both would be needed, there is no need to restrict co-claiming.



## 8.5 Cervical excision biopsy procedures (items 35647, 35648, 35617 and 35618)

### 8.5.1 Items 35647 and 35648

Table 56: Item introduction table for items 35647 and 35648

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35647	Cervix, large loop excision of transformation zone together with colposcopy for previously confirmed intraepithelial neoplastic changes of the cervix, including any local anaesthesia and biopsies, not being a service associated with a service to which item 35644 applies (Anaes.)	\$203.65	5,996	-1.7%	\$907,961
35648	Cervix, large loop excision diathermy for previously confirmed intraepithelial neoplastic changes of the cervix, including any local anaesthesia and biopsies, in conjunction with ablative treatment of additional areas of intraepithelial change of 1 or more sites of vagina, vulva, urethra or anus, not being a service associated with a service to which item 35645 applies (Anaes.)	\$318.70	409	2.2%	\$95,199

### Recommendation 61

- Change the items to specify the criteria for appropriate treatment, as per the current National Cervical Screening Program guidelines (62) for the prevention of cervical cancer.
- Add an explanatory note that outlines that it is expected that the procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology multidisciplinary team (MDT).
- Item 35647:
  - The proposed item descriptor is as follows:
    - Cervix, complete excision of the endocervical transformation zone using large loop or laser therapy, including any local anaesthesia and biopsies; for patients with a possible high grade glandular abnormality, adenocarcinoma in situ, adenocarcinoma, or any other suspected or biopsy proven invasive cervical cancer (including abnormalities in pregnancy) (Anaes.)
  - The proposed explanatory notes are as follows:
    - *This procedure should only be performed in a patient who satisfies the criteria for treatment according to the current National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding, summarised indications from which are provided below:*



- *Biopsy proven CIN2/CIN 3, or adenocarcinoma in situ of the cervix*
  - *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL and normal colposcopy, after cytological review confirming HSIL, and where VAIN has been excluded*
  - *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL and Biopsy showing CIN1 or lesser grade lesion, where cytological review has confirmed HSIL. (Alternatively, if the colposcopist considers a period of observation is preferable to treatment, or the patient wishes to defer excision, follow co-testing with HPV and LBC may be given in 12 months, followed by excisional treatment if repeat HPV (any type) remains positive or LBC predicts pHSIL/HSIL or a glandular abnormality)*
  - *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL after cytological review, and colposcopy showing Type 3 TZ*
  - *Diagnostic excision can be offered to a patient with HPV (any type) and LBC prediction of LSIL, or negative with colposcopy showing unsatisfactory/type 3 TZ ONLY in the following circumstances:*
    - a) *Completed childbearing*
    - b) *Over age 50 years*
    - c) *Anxious about risk of cancer*
    - d) *May be non-compliant with recommended surveillance*
  - *Excisional therapy should aim to remove the entire transformation zone, with a pre-determined length of cervical tissue, ideally in one piece with minimal distortion or artefact to the final histopathological specimen.*
  - *It is expected that this procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology multidisciplinary team (MDT).*
- **Item 35648:**
    - The proposed item descriptor is as follows:
      - Cervix, complete excision of the endocervical transformation zone using large loop or laser therapy, including any local anaesthesia and biopsies, in conjunction with ablative treatment of additional areas of biopsy-proven high grade intraepithelial lesions of 1 or more sites of the vagina, vulva, urethra or anus; for patients with a possible high grade



glandular abnormality, adenocarcinoma in situ, adenocarcinoma, or any other suspected or biopsy proven invasive cervical cancer (including abnormalities in pregnancy) (Anaes.)

- The proposed explanatory notes are as follows:
  - *This procedure should only be performed in a patient who satisfies the criteria for treatment according to the current National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities , screening in specific populations and investigation of abnormal vaginal bleeding, summarised indications from which are provided below:*
    - *Biopsy proven CIN2/CIN 3, or adenocarcinoma in situ of the cervix*
    - *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL and normal colposcopy, after cytological review confirming HSIL, and where VAIN has been excluded*
    - *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL and Biopsy showing CIN1 or lesser grade lesion, where cytological review has confirmed HSIL. (Alternatively, if the colposcopist considers a period of observation is preferable to treatment, or the patient wishes to defer excision, follow co-testing with HPV and LBC may be given in 12 months, followed by excisional treatment if repeat HPV (any type) remains positive or LBC predicts pHSIL/HSIL or a glandular abnormality)*
    - *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL after cytological review, and colposcopy showing Type 3 TZ*
    - *Diagnostic excision can be offered to a patient with HPV (any type) and LBC prediction of LSIL, or negative with colposcopy showing unsatisfactory/type 3 TZ ONLY in the following circumstances:*
      - a) *Completed childbearing*
      - b) *Over age 50 years*
      - c) *Anxious about risk of cancer*
      - d) *May be non-compliant with recommended surveillance*
        - *Excisional therapy should aim to remove the entire transformation zone, with a pre-determined length of cervical tissue, ideally in one piece with minimal distortion or artefact to the final histopathological specimen.*



- *It is expected that this procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology multidisciplinary team (MDT).*

## Rationale

This recommendation focuses on modernising the MBS to reflect critical aspects of the current National Cervical Screening Program guidelines (62), which will improve patient safety. It is based on the following.

- The Committee agreed that the items should reflect current National Cervical Screening Program guidelines in order to promote safe, high-quality treatment, and to discourage unnecessary treatment in patients where there are contraindications or where other procedures would be more appropriate.
- The Committee noted that it is vital that patients with malignancy of the cervix, and those at high risk of malignancy of the cervix, have their procedure performed by an expert gynaecological oncologist, or their case reviewed by a gynaecological oncologist, pathologist and/or a gynaecological oncology MDT before treatment. This expectation should be outlined in the explanatory notes. This will promote safe, high-quality care for patients in all cases. Recognised referral and consultation pathways to tertiary centres with MDTs currently exist for such cases in all states and territories in Australia.
- If current referral and consultation pathways are not followed, it is possible that patients will be harmed. For example, a substandard excision performed by an inexperienced clinician (for example, in multiple segments) can affect the pathologist's interpretation, which can result in incorrect treatment. Pursuing incorrect treatment (for example, an inappropriately shallow loop, a cone biopsy that is too small or too large, or an inappropriate surgical procedure such as a hysterectomy) can result in poorer outcomes or possible loss of fertility.

### 8.5.2 Items 35617 and 35618

**Table 57: Item introduction table for items 35617 and 35618**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35617 <sup>16</sup>	Cervix, cone biopsy, amputation or repair of, not being a service to which item 35577 or 35578 applies (Anaes.) – G	\$173.70	48	-4.7%	\$5,576

<sup>16</sup> Note that items 35617 was deleted from the MBS on 1 November 2017 as part of the 'G' and 'S' changes which are explained in the Executive Summary. This item has been retained in the report as the Committee did review the item prior to deletion and came to the same conclusion that the all services described in the item should have the same rebate, regardless of whether it is performed by a GP or specialist.



Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35618 <sup>17</sup>	Cervix, cone biopsy, amputation or repair of, other than a service to which item 35577 or 35578 applies (Anaes.) – S	\$218.00	935	-3.3%	\$144,374

## Recommendation 62

- Item 35618:
  - Split this item into two new items. Item 35618 should be used for non-invasive lesions, and item 35618X should be used for histologically proven malignant lesions. Remove the co-claiming restrictions for items 35577 and 35584.
  - Change the descriptor to restrict item use to non-malignant cases.
  - Add explanatory notes that align with the new National Cervical Screening Program guidelines (62).
  - Review this item in one to two years to determine whether it still accurately reflects the guidelines, and whether item usage is appropriate in the context of the guidelines.
  - Add an explanatory note that if the procedure is for a high grade glandular abnormality or any other suspected invasive cervical cancer (including abnormalities in pregnancy) the procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - The proposed item descriptor is as follows:
    - Cervix, cone biopsy or amputation, for a non-invasive lesion; for patients with a possible high-grade glandular abnormality, or any other suspected invasive cervical cancer (including abnormalities in pregnancy)(Anaes.)
  - The proposed explanatory notes are as follows:
    - *Patients should meet the criteria for treatment according to the current National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding, summarised indications from which are provided below.*
      - *Biopsy proven CIN2/CIN 3 or adenocarcinoma in situ*

<sup>17</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists.



- *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL and normal colposcopy, after cytological review confirming HSIL, and where VAIN has been excluded*
- *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL and Biopsy showing CIN1 or lesser grade lesion, where cytological review has confirmed HSIL (alternatively, if the colposcopist considers a period of observation is preferable to treatment, or the patient wishes to defer excision, follow-up co-testing with HPV and LBC may be given in 12 months, followed by excisional treatment if repeat HPV (any type) remains positive or LBC predicts pHSIL/HSIL or a glandular abnormality)*
- *A patient with HPV (any type) positive with LBC prediction of pHSIL/HSIL after cytological review, and colposcopy showing Type 3 TZ*
- *Diagnostic excision can be offered in a patient with HPV (any type) positive with LBC prediction of LSIL or negative with colposcopy showing unsatisfactory/type 3 TZ may be performed ONLY in the following circumstances*
  - a) *Completed childbearing*
  - b) *Over age 50 years*
  - c) *Anxious about risk of cancer*
  - d) *May be non-compliant with recommended surveillance*
- *Excisional therapy should aim to remove the entire transformation zone, with a pre-determined length of cervical tissue, ideally in one piece with minimal distortion or artefact to the final histopathological specimen.*
- *If the cone biopsy is for a high grade glandular lesion, it should be performed by:*
  - *A gynaecological oncologist, or;*
  - *After discussion with a gynaecological oncologist or member of a gynaecological cancer MDT.*
- **Item 35618X:**
  - Create a new item to distinguish cone biopsies performed for non-malignant or suspected malignant indications (item 35618) from more complex cone biopsies performed for histologically proven malignancy.
  - An explanatory note that the procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.



- The Committee recommended a schedule fee for this item that is higher than the schedule fee for item 35618 (\$218.00) or item 35647 (\$203.65). The Committee recommended a schedule fee that is 75 per cent higher than the schedule fee for item 35618 (\$218.00).
- When implementing this change it is important to be aware of how it will affect Private Health Insurance payments. The Committee recommended ensuring new item 35618X is classified as a Type A procedure under the Private Health Insurance Rules so that patients are entitled to an overnight stay.
- The proposed item descriptor is as follows:
  - Cervix, cone biopsy for histologically proven malignancy (Anaes.)
- The proposed explanatory notes are as follows:
  - *It is expected that this procedure is performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology multidisciplinary team (MDT).*

## Rationale

This recommendation focuses on modernising the MBS to reflect critical aspects of the current National Cervical Screening Program guidelines (62), which will improve patient safety. It is based on the following.

- Items 35618 and 35618X:
  - Procedures for patients with a possible high-grade glandular abnormality, adenocarcinoma in situ, adenocarcinoma, or any other suspected or biopsy proven invasive cervical cancer (including abnormalities in pregnancy) should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT to promote safer and more effective care for patients.
  - The co-claiming restrictions for items 35577 and 35584 do not apply to contemporary practice. The Committee noted that it is quite reasonable to co-claim this item with a Manchester operation for genital prolapse where this condition coincides. Item 35584 no longer exists in the MBS.
  - The Committee agreed that the items should clearly reflect the new National Cervical Screening Program guidelines, which are expected to come into effect in 2017. This will encourage clinicians to practice in accordance with the guidelines, which were developed specifically to improve the efficacy and safety of care for at-risk patients while managing scarce public resources effectively—all of which promote high-value care.



- Although the guidelines should not substantially change within the first two to three years of adoption, the Committee felt it would be prudent to review these items within one to two years to determine whether they still reflect the guidelines.
- Item 35618X:
  - The Committee agreed that this procedure warrants a separate item with a higher schedule fee because it is more complex than the procedure covered by item 35618 (\$218.00) and requires more intensive peri-operative care.
    - The cone biopsy in these situations is larger and deeper.
    - The procedure is often performed as a second procedure after a previous excisional biopsy, which makes it more technically difficult and time-consuming.
    - This procedure requires a more detailed discussion with the patient at follow-up, and it may require referral to other members of a gynaecological oncology MDT or planning for further treatment.
  - The Committee agreed that failing to perform a large cone biopsy in cases of suspected malignancy could compromise the clinical care of patients and put them at risk of requiring a further procedure to remove the lesion.
  - The Committee's recommended explanatory notes reflect the National Cervical Screening Program guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal bleeding and reinforces the expectation that only suitably qualified and experienced practitioners should be performing the procedure

## 8.6 Cervical stump removal procedures (items 35612 and 35613)

### 8.6.1 Items 35612 and 35613

Table 58: Item introduction table for items 35612 and 35613

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35612	Cervix, residual stump, removal of, by abdominal approach (Anaes.) (Assist.)	\$506.00	28	0.7%	\$6,521
35613	Cervix, residual stump, removal of, by vaginal approach (Anaes.) (Assist.)	\$404.80	21	-6.9%	\$3,854

### Recommendation 63

- Item 35612:



- Change the item descriptor to specify that this item applies to non-malignant lesions only.
- The proposed item descriptor is as follows:
  - Cervix, residual stump, removal of, by abdominal approach, for non-malignant lesions. (Anaes.) (Assist.)
- Item 35613: Consolidate this service into items 35618 and 35618X.

### Rationale

This recommendation focuses on modernising the MBS, maintaining patient access to this procedure and aligning MBS items with clinical best practice. It is based on the following.

- Item 35612:
  - Service volumes are small for this item, but it remains an effective and appropriate procedure where indicated and should be preserved to retain access.
  - Item 35618 should be used for cervical amputation for non-malignant lesions via vaginal approach, as detailed in the National Cervical Screening Program guidelines (62). This constitutes higher value care in the contemporary clinical setting because it represents best clinical practice and is a lower cost alternative to item 35612.
  - The proposed item 35618X implicitly covers cervical stump removal for malignant disease and is considered a more appropriate procedure to perform for this indication in contemporary clinical practice.
- Item 35613:
  - Service volumes are small for this procedure, and the service already forms part of items 35618 and 35618X. For this reason, there is no need for a separate item for this procedure.

## 8.7 Ovarian transposition out of the pelvis (item 35729)

### 8.7.1 Item 35729

Table 59: Item introduction table for item 35729

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35729	Ovarian transposition out of the pelvis, in conjunction with radical hysterectomy for invasive malignancy (Anaes.)	\$217.80	10	-5.1%	\$613

### Recommendation 64

- No change.



## Rationale

This recommendation focuses on maintaining access to necessary services. It is based on the following.

- Although this is a low-volume item, it is an important method for preserving potential fertility in cancer patients who may receive radiation to the pelvis.
- This procedure may be performed at the time of radical hysterectomy or as a separate procedure after histological findings are received from another procedure. MSAC has recently introduced a new item that will promote access for patients in the latter situation, so there is no need to change item 35729 at this stage.

## 8.8 Lymph node dissection items (35551 and 35723)

### 8.8.1 Items 35551 and 35723

Table 60: Item introduction table for items 35551 and 35723

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35551	Pelvic lymph glands, excision of (radical) (Anaes.) (Assist.)	\$683.90	176	0.0%	\$40,714
35723	Retroperitoneal lymph node biopsies from above the level of the aortic bifurcation, for staging or restaging of gynaecological malignancy (Anaes.) (Assist.)	\$483.10	124	-3.9%	\$19,837

### Recommendation 65

- Item 35551:
  - Change the item descriptor to:
    - Align with that of urology item 37607.
    - Specify that the item is intended to cover unilateral procedures.
    - Include sentinel node dissection and biopsy.
  - The Committee recommended a schedule fee that is equivalent to the schedule fee for item 37607 (\$924.70).
  - The proposed item descriptor is as follows:
    - Pelvic lymph nodes, radical excision of (unilateral) for gynaecologic malignancy, or sentinel node dissection (including any pre-operative injection) (Anaes.) (Assist.)



Include an explanatory note to outline that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT

- Create new item 35551X to cover the services described in item 35551 when provided to patients who have had previous dissection, radiation or chemotherapy for the same indication.
  - Align the item descriptor with that of urology item 37610.
  - Specify that the item is intended to cover unilateral procedures following previous similar retroperitoneal dissection, retroperitoneal irradiation or chemotherapy.
  - Include a reference to nerve-sparing surgical techniques in the explanatory notes.
  - The Committee recommended a schedule fee that is equivalent to the schedule fee for item 37610 (\$1,391.15).
  - The proposed item descriptor is as follows:
    - Pelvic lymph nodes, radical excision of (unilateral) for gynaecologic malignancy, following similar previous dissection, radiation or chemotherapy (Anaes.) (Assist.)
  - Include an explanatory note to outline that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT
- Item 35723:
  - Change the item descriptor to align with that of urology item 37607.
  - Specify that the item is intended to cover unilateral procedures.
  - Include in the explanatory notes a reference to nerve-sparing surgical techniques and the expectation that this procedure be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - The Committee recommended a schedule fee that is equivalent to the schedule fee for item 37607 (\$924.70).
  - The proposed item descriptor is as follows:
    - Para-aortic lymph node dissection from above the level of the aortic bifurcation (unilateral), for staging or restaging of gynaecological malignancy (Anaes.) (Assist.)
- Create new item 35723X to cover the services described in item 35723 when provided to patients who have had previous dissection, radiation or chemotherapy for the same indication.
  - Align the item descriptor with that of urology item 37610.



- Specify that the item is intended to cover unilateral procedures following previous similar retroperitoneal dissection, retroperitoneal irradiation or chemotherapy.
- Include in the explanatory notes a reference to nerve-sparing surgical techniques and the expectation that this procedure, be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
- The Committee recommended a schedule fee that is equivalent to the schedule fee for item 37610 (\$1,391.15).
- The proposed item descriptor is as follows:
  - Para-aortic lymph node dissection (pelvic or above the aortic bifurcation) after prior similar dissection, radiotherapy or chemotherapy for malignancy (Anaes.) (Assist.)
- The proposed explanatory note for items 35551, 35551X, 35723 and 35723X is as follows:
  - *Nerve-sparing techniques to be used where clinically feasible.*
  - *It is expected that these procedures should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.*

## Rationale

This recommendation focuses on modernising the MBS, facilitating access to new surgical techniques, and providing patients with more accurate information and rebates for these procedures. It is based on the following.

### Sentinel node dissection

- The Committee included sentinel node dissection as a potential technique for use in these items for the following reasons:
  - Sentinel node dissection is increasingly used to assess the spread of cancers, including cancers of the cervix and endometrium. However, at present, the MBS only recognises its use in procedures for breast cancer, limiting access for patients with gynaecological indications.
  - Sentinel node procedures may replace extensive node dissection in certain situations, potentially reducing morbidity in patients with gynaecological cancer and resulting in improved quality-of-life outcomes in the long term (particularly by reducing lymphoedema) (65) (66).
  - Sentinel node dissection requires a level of surgical skill and an amount of time similar to that required for the other procedures covered by this item. It still requires retroperitoneal



dissection, and although fewer lymph nodes are removed when compared with traditional dissection techniques, the scale of dissection is similar because the required nodes must first be localised.

### **Nerve-sparing techniques**

- The use of nerve-sparing techniques (where indicated) can decrease the chances of decreased urinary and sexual function due to lymph node dissection surgery.
- The Committee agreed that the use of nerve-sparing techniques should be encouraged but not required for these items. Nerve-sparing techniques are preferred in general, but there are situations in which the use of nerve-sparing techniques is contraindicated or does not offer the optimal patient outcome.

### **Schedule fees**

- MBS data showed that gynaecologists regularly used items 37607 and 37610 (originally intended for use in patients with urological disorders) in place of items 35551 and 35723, most likely in cases of lymph node dissection/biopsy before and after previous similar treatment.
- The schedule fee for item 37607 is approximately 35 per cent higher than the schedule fee for item 35551, and 91 per cent higher than the schedule fee for item 35723. The Committee considered this an inappropriate schedule fee differential, given that the procedures are substantially equivalent in terms of complexity and scope. The schedule fee for item 37607 would more appropriately reflect the duration and complexity of these procedures.
- On average, the procedures described by items 35551 and 35723 take between two and three hours to perform and sometimes require mobilisation of bowel mesentery, ureterolysis, and careful dissection of major vascular organs (inferior vena cava and aorta), mesenteric vessels and other crucial structures (lumbar veins, autonomic nerves).
- Bringing the descriptors and schedule fees for items 35551 and 35723 in line with those for item 37607 will permit gynaecological indications to be reported separately from urological ones. It will also maintain gynaecological patients' access to these valuable procedures, even if a future Urology Clinical Committee recommends changes to items 37607 and 37610.

### **New items for use in patients who have undergone similar previous procedures**

- The Committee recommended creating new items 35551X and 35723X for use in more surgically challenging situations, where prior dissection, radiotherapy and/or chemotherapy have caused significant fibrosis, scarring and adhesions, all of which increase the complexity and time required to perform the operation.
- Adding these items will promote access to these procedures, which can in turn reduce the need for other treatments such as further chemotherapy or radiotherapy. Lymph node



dissections represent higher value care in appropriately selected cases because chemotherapy and radiotherapy are often associated with more severe patient morbidity, prolonged recovery times and higher costs to the healthcare system.

- The Committee recommended a schedule fee for these items that is equivalent to the schedule fee for item 37610, which is similarly complex.

## 8.9 Radical hysterectomy items (35664, 35667 and 35670)

### 8.9.1 Items 35664, 35667 and 35670

Table 61: Item introduction table for items 35664, 35667 and 35670

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35664	Radical hysterectomy with radical excision of pelvic lymph glands (with or without excision of uterine adnexae) for proven malignancy including excision of any 1 or more of parametrium, paracolpos, upper vagina or contiguous pelvic peritoneum and involving ureterolysis where performed (Anaes.) (Assist.)	\$1,452.20	439	7.4%	\$463,538
35667	Radical hysterectomy without gland dissection (with or without excision of uterine adnexae) for proven malignancy including excision of any 1 or more of parametrium, paracolpos, upper vagina or contiguous pelvic peritoneum and involving ureterolysis where performed (Anaes.) (Assist.)	\$1,234.25	1,249	6.6%	\$1,014,185
35670	Hysterectomy, abdominal, with radical excision of pelvic lymph glands, with or without removal of uterine adnexae (Anaes.) (Assist.)	\$1,016.30	50	-10.9%	\$32,489

### Recommendation 66

- Item 35664: Consolidate services into item 35667 and delete this item.
- Item 35667:
  - Change the item descriptor to:
    - Include specifications for nerve-sparing surgery and performance of ureterolysis, where performed.
    - Include radical trachelectomy as a procedure.
    - Exclude specificity around surgical approach to allow surgery to be performed by any approach.



- The Committee recommended increasing the schedule fee to align with item 37210 (\$1,593.40 [nerve-sparing radical prostatectomy]), which is a procedure of comparable technique and complexity.
- The proposed item descriptor is as follows:
  - Radical hysterectomy or radical trachelectomy (with or without excision of uterine adnexae) for proven malignancy including excision of any 1 or more of parametrium, paracolpos, upper vagina or contiguous pelvic peritoneum, utilising nerve sparing techniques and involving ureterolysis where performed (Anaes.) (Assist.)
- In the explanatory notes the expectation that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
- Item 35670: Consolidate services into item 35667 and delete this item.

## Rationale

This recommendation focuses on modernising the MBS, facilitating access to new surgical techniques, and providing patients with more accurate information and rebates for these procedures. It is based on the following.

## Context and problems with current items

- The modern radical hysterectomy involves excision of the uterus, as well as one or more of the parametrium, paracolpos, upper vagina and contiguous pelvic peritoneum, with or without ureterolysis and the use of autonomic nerve-sparing techniques. The surgical techniques used to perform these procedures now differ fundamentally from those used when the relevant MBS items were created (63) (67) (68) (69) (70) (71) (72) (73).
- These changes have been associated with improved survival rates and lower morbidity related to surgery (such as lymphedema, infections, and changes in bowel, bladder and sexual function) (74). Today, primary surgical management of early cervical cancer often removes the need for further treatment with chemotherapy or radiation, further improving morbidity profiles and recovery times in a subset of patients. Perioperative mortality when using modern techniques is now very rare.
- The estimated time required for the contemporary procedure is 2.5–3 hours.
- These items' descriptors and schedule fees no longer reflect the complexity or duration of the contemporary procedure.

## Possible solutions

The Committee discussed the following topics:



- Adding radical trachelectomy as a surgical technique.
- Adding nerve-sparing techniques.
- Merging existing items.
- Determining whether procedures need to be performed by an experienced clinician.
- Setting appropriate schedule fees.

#### *Adding radical trachelectomy as a surgical technique*

- In recent years, it has become apparent that some cervical cancers can be safely treated using a more conservative procedure than the standard radical hysterectomy. Many women with cervical cancer in their child-bearing years wish to preserve their child-bearing ability. A new technique has been developed for these patients: radical trachelectomy (removal of the cervix).
- This new fertility-sparing procedure is recommended in a limited number of situations of invasive cervical cancer. It is equivalent to a radical hysterectomy in terms of the complexity and scale of the dissection required, but allows for the retention of the uterine body, which is then reconnected with the vaginal vault. The procedure usually takes about three hours to perform.
- In more technical terms, the radical trachelectomy procedure includes a cervical amputation together with bilateral parametrectomy, a bilateral ureteric dissection/ureterolysis and radical resection of the upper vagina, along with a complex reanastomosis of the vagina to the isthmus of the uterus.
- This procedure has substantial evidence supporting its safety and efficacy and is considered a standard option that should be offered to appropriately selected patients instead of a radical hysterectomy.
- Although radical trachelectomy is not currently recognised in the MBS, it is similar enough in technique to a radical hysterectomy that the Committee believes it is currently being performed and claimed using item 35667. Considering that the indication, complexity and time requirements of these procedures are similar, the Committee felt it was appropriate to make the inclusion of radical trachelectomy in item 35667 explicit.

#### *Adding nerve-sparing techniques*

- Autonomic pelvic nerves innervate the gynaecological organ system and can be injured during standard radical hysterectomy operations. Nerve injury in this area normally leads to a reduction in sensation and function, which may leave patients with a diminished sensation of a full bladder and a compromised ability to urinate normally. This, in turn, may lead to pelvic



pain, infection and bladder rupture (75) (76). Bowel dysfunction following radical hysterectomy often results in chronic constipation (77). Sexual dysfunction due to a loss of natural lubrication and sensation during intercourse is also relatively common (68) (78).

- Although it prolongs the duration of surgery, meticulous preservation of the autonomic pelvic nerves can reduce the incidence of bladder, bowel and sexual dysfunction to the level expected from a non-radical, simple hysterectomy in appropriate cases, without compromising overall survival (79).
- Although many clinicians already use these techniques, the Committee felt it valuable to specifically mention them in the item descriptors in order to encourage clinical best practice.
- The Committee agreed that the use of nerve-sparing techniques should be encouraged but not required for these items. Nerve-sparing techniques are preferred in general, but there are situations in which the use of nerve-sparing techniques is contraindicated or does not offer the optimal patient outcome.

#### *Merging existing items*

- The services described by items 35664 and 35670 are substantially equivalent to the contemporary procedure now described by item 35667. As a result, there is no longer any need for these separate items to exist.
- Given the difference in complexity between different lymph node dissections (for example, pelvic and para-aortic) that may be needed in conjunction with a radical hysterectomy, the Committee felt it was more appropriate to allow co-claiming of the specific lymph node dissection item performed, rather than using a non-specific, inclusive item such as existing item 35564.

#### *Determining whether procedures should be performed by an experienced clinician*

- Contemporary radical hysterectomy is a difficult surgical procedure that requires subspecialty training and experience beyond the scope of general gynaecological practice.
- The National Framework for Gynaecological Cancer Control recommends that an MDT discusses the case before surgery is performed.
- The Committee agreed that procedures for cases of suspected (pre-invasive) or proven malignancy should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.

#### *Setting an appropriate schedule fee*



- Due to the changes in surgical technique described above, the Committee felt that an increase in the rebate would be appropriate in order to reflect the difficulty of the surgery. A nerve-sparing radical prostatectomy (item 37210) is a procedure of comparable complexity.

## 8.10 New radical hysterectomy items

### 8.10.1 Item 35667X

#### Recommendation 67

- Create a new item to cover radical hysterectomy in the context of previous pelvic irradiation or chemotherapy, with specifications for nerve-sparing surgery and performance of ureterolysis where performed.
- The Committee recommended a schedule fee for this item that is 50 per cent higher than the schedule fee for existing item 35667 (\$1234.25).
- The proposed item descriptor is as follows:
  - Radical hysterectomy (with or without excision of uterine adnexae) including excision of any 1 or more of parametrium, paracolpos, upper vagina or contiguous pelvic peritoneum utilising nerve sparing techniques and involving ureterolysis where performed in a patient with malignancy and previous pelvic radiation and/or chemotherapy treatment, (Anaes.) (Assist.)
- Include in the explanatory notes the expectation that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.

#### Rationale

This recommendation focuses on facilitating access to this procedure for patients with complex disease. It is based on the following.

- The Committee recognised that radical hysterectomy conducted after previous radiotherapy or chemotherapy is a valuable intervention, producing meaningful improvements in patient outcomes in complex cases of gynaecological cancer.
- However, it felt that the currently available radical hysterectomy items did not adequately support the risks, time and effort involved in providing adequate treatment for patients in these complex clinical situations. This has the potential to limit patients' access by providing them with an insufficient rebate for these non-standard procedures.



- The use of radiation or chemotherapy in patients with pelvic malignancy often results in scarring, fibrosis and anatomical changes, which make subsequent surgery much more difficult and time-consuming.
  - *During surgery:* These changes increase the risk of damage to pelvic or abdominal viscera. Efforts made to avoid this often result in surgery taking double the time expected for a radical hysterectomy in a patient who has not undergone radiotherapy or chemotherapy.
  - *After surgery:* Radiotherapy can also cause microvascular thrombosis and a compromised blood supply to the pelvic organs, which significantly impairs healing and greatly increases the risk of repair breakdown and fistula formation (80) (81). These factors can markedly increase the time needed for patients to recover and the level of care needed postoperatively.
- Radical hysterectomy in these patients has a significant complication rate but also provides good outcomes for patients in terms of disease-free and overall survival rates.
  - Surgery following neoadjuvant treatment (whether chemotherapy and/or radiotherapy) is associated with a significant complication rate (80) (81), chiefly involving damage to pelvic organs and nerves.
  - However, a Cochrane meta-analysis of available evidence confirms that surgery following chemotherapy is as effective in terms of overall survival and progression-free survival as surgery before chemotherapy (82). Most importantly, there were also significant reductions in some surgically related serious adverse effects in those patients undergoing surgery following chemotherapy for ovarian cancer, including less haemorrhage, venous thromboembolism and infection.
- Surgery in these cases is becoming more frequent.
  - The Committee noted this particularly in cases of sub-optimal initial debulking surgery and following neoadjuvant (before surgery) chemotherapy for advanced ovarian or primary peritoneal cancer. A recent European study suggested that neoadjuvant chemotherapy and an interval debulking was the preferred treatment regime for advanced ovarian cancer (83).
  - Similar multimodality treatment is also being used more frequently for the treatment of cervical cancer in selected patients, especially those with bulky (stage IB1, IB2 and IIA) tumours (84). The rationale for this is that bulky tumours are difficult to completely clear of cancerous cells using radiation and/or chemotherapy, and that patients can benefit from the physical removal of the cervix as part of a radical hysterectomy.
- The development of highly skilled tertiary referral clinicians has done much to improve the outcomes of women undergoing surgery under such complex circumstances. However, the Committee felt that the complexity and duration of these procedures means that they should



be considered separately from the existing radical hysterectomy items, in much the same way as items 37607 and 37610 distinguish between retroperitoneal lymph node dissection procedures done before and after chemotherapy/radiotherapy.

- The schedule fee for item 37610 (retroperitoneal lymph node dissection after previous similar surgery/chemotherapy/radiotherapy) is 50 per cent higher than the schedule fee for item 35607 (retroperitoneal lymph node dissection). The Committee felt that this was an appropriate schedule fee differential, accounting for the differences between items 35667 and 35667X described above.

### **8.10.2 Item 35667Y**

#### **Recommendation 68**

- Create a new item to cover radical hysterectomy for the indications of complicated placenta accreta, increta and percreta.
- This new item is intended for use only in cases where there is histologically proven invasion of the myometrium and/or other structures outside of the uterus (bladder wall, ureters, pelvic side wall structures) by placental tissue, where a second clinician with advanced surgical skills is required to attend to perform the procedure for intractable severe haemorrhage.
- The Committee recommended a schedule fee for this item that is 50 per cent higher than the schedule fee for existing item 35667 (\$1234.25 [radical hysterectomy]).
- The proposed item descriptor is as follows:
  - Peripartum hysterectomy performed for histologically proven placenta increta or percreta, or placenta accreta where the patient has been referred to another practitioner for the management of severe intractable peripartum haemorrhage. (Anaes.)(Assist.)

#### **Rationale**

This recommendation focuses on modernising the MBS and improving access to this procedure for patients with these life-threatening conditions. It is based on the following.

- There is currently no item number that covers this procedure. The Committee believes that clinicians are using item 35667 at present, although this procedure is more complex than the descriptor for item 35667 indicates.
- Placenta accreta, increta and percreta refer to different grades of abnormal placental attachment to or invasion of the myometrium and/or other structures outside of the uterus (bladder wall, ureters, pelvic side wall structures). This condition can result in severe, life-threatening bleeding during and after giving birth. Although the condition can be managed



without the need for hysterectomy in some cases, severe cases often require a caesarian section, blood transfusion and hysterectomy.

- The surgical management of placenta accreta with severe intractable post-partum haemorrhage has a similar complexity to planned surgery for placenta increta or percreta and can be covered using this single item.
- The procedure is uncommon: less than 0.79 per 1000 mothers in Australia required a peripartum hysterectomy for any cause between 2003 and 2013 (85), with approximately 237 procedures performed per year. Of these, 45–73 per cent are estimated to be for placenta accreta, increta or percreta (86).
- The details of the procedure are as follows:
  - This procedure is one of the most difficult and potentially morbid surgical procedures performed in gynaecology, and it is usually referred to a gynaecological oncologist before delivery as a planned procedure, performed in a centre with appropriate facilities (gynaecological oncologist, interventional radiology, massive transfusion protocol, intensive care facilities). The procedure can result in massive blood loss and death if not performed by an appropriately skilled clinician in a tertiary centre, and in a planned fashion. To be performed safely, the procedure requires bilateral ureterolysis and exposure of the pelvic side wall at the time of caesarean section.
  - The procedure can take two to six hours. Longer durations tend to occur in cases of ongoing severe haemorrhage requiring urgent hysterectomy, where radiological embolisation (performed by an interventional radiologist) is often used as well. The clinician is usually required to be present throughout the entire procedure, including after the hysterectomy itself, as a precautionary measure in case of sudden re-bleeding.
  - Rates of morbidity following this procedure are high, and the patient often requires an extended hospital stay and ongoing care.
- The Committee felt that this item warrants a schedule fee that is 50 per cent higher than the schedule fee for item 35667 (\$1234.25), given the significantly increased time and complexity compared with a standard radical hysterectomy.

## **8.11 Adnexal procedures via laparotomy (items 35712, 35713, 35716, 35717 and 35726)**

### **8.11.1 Items 35712, 35713, 35716 and 35717**

**Table 62: Item introduction table for items 35712, 35713, 35716 and 35717**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35712 <sup>18</sup>	Laparotomy, involving oophorectomy, salpingectomy, salpingo-oophorectomy, removal of ovarian, paraovarian, fimbrial or broad ligament cyst-1 such procedure, not being a service associated with hysterectomy (Anaes.) – G	\$362.15	105	16%	\$21,751
35713 <sup>19</sup>	Laparotomy, involving oophorectomy, salpingectomy, salpingo-oophorectomy, removal of ovarian, parovarian, fimbrial or broad ligament cyst - one such procedure, other than a service associated with hysterectomy (H) (Anaes.) (Assist.) - S	\$452.85	897	-1.3%	\$255,271
35716 <sup>18</sup>	Laparotomy, involving oophorectomy, salpingectomy, salpingo-oophorectomy, removal of ovarian, parovarian, fimbrial or broad ligament cyst - 2 or more such procedures, unilateral or bilateral, not being a service associated with hysterectomy (Anaes.) (Assist.) - G	\$434.35	37	18.3%	\$9,935
35717 <sup>19</sup>	Laparotomy, involving oophorectomy, salpingectomy, salpingo-oophorectomy, removal of ovarian, parovarian, fimbrial or broad ligament cyst 2 or more such procedures, unilateral or bilateral, other than a service associated with hysterectomy - S (Anaes.) (Assist.)	\$545.30	787	-4.7%	\$260,867

### Recommendation 69

- Item 35713: Consolidate this service into item 35717 and delete item.
- Item 35717:
  - Change the item descriptor to:
    - Laparotomy, involving oophorectomy, salpingectomy, salpingo-oophorectomy, removal of ovarian, para-ovarian, fimbrial or broad ligament cyst, 1 or more such procedures, unilateral or bilateral, including adhesiolysis, for benign disease, not being a service associated with hysterectomy (Anaes.) (Assist.)
  - The Committee recommended aligning the schedule fee for consolidated item 35717 (\$545.30) with the schedule fee for item 35638Y
  - Add to the explanatory notes that there needs to be histological and/or photographic evidence of a 'complex ovarian mass'.

<sup>18</sup> Note that items 35712 and 35716 were deleted from the MBS on 1 November 2017 as part of the 'G' and 'S' changes which are explained in the Executive Summary. The items have been retained in the report as the Committee did review the items prior to deletion and came to the same conclusion that the all services described in the items should have the same rebate, regardless of whether it is performed by a GP or specialist.

<sup>19</sup> Note that this item was amended on 1 November 2017 to remove the restriction on the item which limited the claiming of the item to services provided by specialists.



## Rationale

This recommendation focuses on simplifying the MBS, as well as improving access to this procedure by setting a schedule fee that accurately reflects its complexity. It is based on the following.

- There is no significant difference in the complexity or time taken to perform one or more procedures of the type described by these items, which means that there are no major differences between items 35713 and 35717. For this reason, there is no need to retain these separate items because their services can be included under a single item number.
- Adding management of pelvic adhesions to this item reflects the necessary restoration of normal anatomy in these cases and removes the need to specify that two or more procedures must take place. It also removes the need to be able to co-claim item 30378 for pelvic adhesiolysis in these procedures.
- Where a bilateral salpingectomy is performed at the time of caesarian section, it is more appropriate to co-claim item 35691 (Sterilisation by interruption of fallopian tubes, when performed in conjunction with Caesarean section), not item 35717.
- The procedure described by this item has become more complex and time-consuming since the item was created, as explained below. It now requires equivalent or greater skill to perform as item 35638Y, which covers similar surgery performed via a laparoscopic route. For this reason, the Committee felt that the schedule fee for item 35717 should align with the schedule fee for item 35638Y.
  - When items for procedures done using laparoscopic surgical techniques (for example, item 35638) were first introduced, they were granted a higher schedule fee than equivalent procedures done via laparotomy because of the increased level of skill and equipment required. However, the increase in laparoscopic training and skill levels among clinicians over the past decade has resulted in a shift towards laparoscopic procedures, with only the most difficult cases still performed via laparotomy. Examples of such cases include large complex cysts, endometriosis with dense adhesions to bowel and cases with a high risk of undetected malignancy.
  - This means that the procedure covered by this item is now more complex and time-consuming than it was when the item was originally created. In addition, patients undergoing a laparotomy require longer postoperative care (three to four days in hospital) than patients undergoing laparoscopic surgery (who usually only need to stay in overnight).

### 8.11.2 Item 35726



Table 63: Item introduction table for item 35726

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35726	Infracolic omentectomy with multiple peritoneal biopsies for staging or restaging of gynaecological malignancy (Anaes.) (Assist.)	\$483.10	832	4.8%	\$127,606

### Recommendation 70

- Change the item descriptor to:
  - Allow the procedure to be performed ‘with or without’ multiple peritoneal biopsies.
  - Restrict co-claiming with items 35720 and 35720X.
- The proposed item descriptor is as follows:
  - Infracolic omentectomy with or without multiple peritoneal biopsies for staging or restaging of gynaecological malignancy, not being a service to which item 35720X applies. (Anaes.) (Assist.)

### Rationale

This recommendation focuses on improving the clarity of the MBS. It is based on the following.

- This item should be retained to allow for staging or restaging of gynaecological malignancy where there is no macroscopic upper abdominal disease requiring debulking. (The appropriate item to use in such a situation would be 35720 or 35720X.)
- However, biopsies are not always necessary, so this need not be a requirement for use of the item. This also removes any unintentional incentive for performing unnecessary biopsies, potentially improving patient safety.

## 8.12 Radical debulking procedures (item 35720)

### 8.12.1 Item 35720

Table 64: Item introduction table for item 35720

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35720	Radical or debulking operation for advanced gynaecological malignancy, with or without omentectomy (Anaes.) (Assist.)	\$674.50	748	3.1%	\$181,487



## Recommendation 71

- Split item 35720 into two new items, reflecting two different levels of complexity for radical debulking procedures. Item 35720 will cover treatment for macroscopically disseminated malignancy limited to the pelvis, and item 35720X will cover treatment for macroscopically disseminated malignancy involving the pelvic and abdominal cavities.
- Prevent the two new items from being co-claimable with each other.
- Include in the explanatory notes that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
- Item 35720:
  - Change the item descriptor to cover treatment for macroscopically disseminated malignancy limited to the pelvis.
  - The proposed item descriptor is as follows:
  - Radical debulking involving the radical excision of a macroscopically disseminated gynaecological malignancy from the pelvic cavity, including resection of peritoneum from the pelvic side wall, pouch of Douglas, and bladder, for macroscopic disease confined to the pelvis (Anaes.) (Assist.)
  - The Committee recommended setting the schedule fee for this procedure between the schedule fees for items 32024 (\$1,364.60) and 32025 (\$1,825.30).
- Item 35720X.
  - Create this new item to cover treatment for macroscopically disseminated malignancy involving the pelvic and abdominal cavities.
  - The Committee recommended a schedule fee that is double the schedule fee for item 35720 (\$674.50).
  - The proposed item descriptor is as follows:
    - Radical debulking involving the radical excision of a macroscopically disseminated gynaecological malignancy from the abdominal and pelvic cavity where the cancer has extended beyond the pelvis, including resection of peritoneum over the diaphragm, the paracolic gutters, the greater or lesser omentum, and porta hepatis; OR cytoreduction of recurrent gynaecological malignancy from the abdominal and/or pelvic cavity following



previous pelvic and/or abdominal surgery, radiation or chemotherapy, not being a service associated with a service to which item 35720 applies.

- The proposed explanatory notes for these items are as follows:
  - *This item does not include resection of bowel, bladder, spleen, pancreas, or liver. It does include the extensive dissection and removal of the peritoneum from these organs in the abdominal/pelvic cavity.*
  - *This number should not be used for staging procedures for gynaecological malignancy.*
  - *This item number should not be used for a lymph node recurrence without involvement of peritoneal surfaces.*
  - *This procedure should be undertaken by a person with appropriate training in line with the National Framework for Gynaecological Cancer. At a minimum, cases should only be performed after review by a gynaecological oncology multidisciplinary team.*

### Rationale

This recommendation focuses on modernising the MBS, as well as improving patient access by providing rebates that reflect the complexity of the procedures. It is based on the following.

### Context

- Debulking surgery describes the removal of tumour tissue from the abdominal and pelvic cavities and organs in cases where malignant ovarian cancer has spread beyond the ovary.
- The treatment of ovarian cancer has evolved more than any other area of gynaecological oncology surgery over the last 20 years. Existing item 35720 was created at a time when debulking surgery for ovarian cancer was relatively standard, regardless of the specific characteristics of a patient's tumour. Today, clinicians have a much better understanding of the optimal treatment techniques for benign and malignant ovarian tumours, which has resulted in the development of different surgical paradigms. The innovations in care for malignant ovarian tumours are summarised below and detailed in the information appended to this report, entitled 'Debulking (cytoreduction) background and evidence.' This also includes additional references.
- There is currently no item number for removing an ovary with a malignant tumour. As a result, clinicians currently use items 35717 or 35713, both of which are designed to cover benign ovarian tumours. This means that patients with malignant tumours are receiving more extensive surgery than the current items describe or provide rebates for, which may limit their access to adequate care. In addition, there is a significant difference in the extent of surgery required in cases where malignancy is confined to the pelvis, compared to when it has spread across both the pelvis and abdomen, or when it is done after a previous similar surgery. To



address this complexity, the Committee recommended changing item 35720 to better describe the contemporary procedure for malignant tumours in the pelvis, and creating a new item to reflect the significantly increased scale of surgery required for malignant tumours involving both the pelvis and abdomen.

### Current treatment paradigms

- Surgery is necessary to obtain tissue to confirm diagnosis and assess the extent of ovarian cancer, and to attempt optimal cytoreduction (removal of tumour tissue). Ovarian cancer often affects the entire peritoneal cavity, each section of which can take a number of hours to debulk in a full debulking procedure, which ideally involves stripping away all of the visible (and surrounding invisible) tumour tissue.
- There is now a body of evidence supporting improved survival and other important outcomes in patients with advanced gynaecological malignancy when the clinician achieves optimal cytoreduction of a tumour. This usually requires the radical removal of not only the gynaecological organs, but also surrounding peritoneal structures. This, in turn, requires extensive mobilisation of other structures such as ureters, bowel and pelvic vessels to be performed safely.
- Patients fall into two categories based on the stage of their cancer:
  - Approximately 25 per cent of patients present with a tumour confined to the ovary (stage 1) or a tumour beyond the ovary but confined to the pelvis (stage 2).
    - These patients are managed initially with a maximal cytoreductive procedure, sometimes referred to as a tier one debulking (87) (88).
    - This procedure frequently takes two to four hours to perform.
  - The other 75 per cent of women present with a tumour that has spread throughout the peritoneal cavity, which involves the para-aortic or inguinal lymph nodes (stage 3), or a tumour that has spread to more distant sites (stage 4).
    - The standard of care for these patients is surgery (a tier 2 debulking procedure) followed by chemotherapy (63) (89).
    - This surgery usually takes four to eight hours to perform.
    - The combination of optimal cytoreductive surgery and effective platinum-based chemotherapy has led to significant improvements in survival for these women (90).
- Cytoreductive surgery remains the cornerstone of therapy for ovarian cancer. Primary surgical management of ovarian cancer has several benefits:



- Optimal response to postoperative systemic chemotherapy is achieved in a setting of minimal disease.
- Removal of bulky disease rapidly improves symptoms and quality of life.
- Removal of tumour bulk improves the functioning of the immune system.
- Although the stage and differentiation of the tumour cannot be changed, the volume of residual disease is amenable to change thanks to the advent of modern aggressive surgical debulking. Studies have consistently shown that the volume of residual disease remaining after cytoreductive surgery inversely correlates with survival, along with stage of disease and grade of tumour differentiation.
  - Women with an optimally resected tumour (less than 1cm residual disease) have, on average, a 20-month improvement in median survival compared with those with suboptimal resection (residual disease >1cm).
  - A meta-analysis of over 53 studies of advanced stage carcinoma treated with platinum-based chemotherapy found a 5.5 per cent increase in median survival for every 10 per cent increase in the proportion of patients achieving maximal cytoreduction (90).
  - There is growing evidence that greater reductions in the remaining maximum tumour diameter lead to greater improvement in chances of survival (91).
- Postoperative care typically continues for 7–10 days following this extensive surgical procedure, and patients undergoing this surgery frequently require intensive care for the first two days post operatively. Postoperative problems include maintaining fluid balance (as there may be many large fluid shifts related to ascites changes and large areas of denuded peritoneum), slow bowel function, deep vein thrombosis, haemorrhage and infection.
- The initial management of women with ovarian/peritoneal cancer is typically done in consultation with an appropriately trained certified gynaecologic oncologist with experience in ovarian cancer surgery.
  - Studies have consistently shown that surgical treatment by non-gynaecologic oncologists and low-volume clinicians contributes to suboptimal surgical management and shorter median survival (88) (92) (93) (94) (95) (96) (97).
  - A certified gynaecologic oncologist experienced in surgical cytoreduction should perform this surgery because achieving optimal cytoreduction depends in part on the clinician's judgment, experience and aggressiveness. An optimal result is achievable in at least 75 per cent of advanced ovarian cases when treated by an experienced, appropriately certified gynaecologic oncologist (63) (93) (98).



- However, the Committee recognised that restricting use of these items to gynaecological oncologists may limit patient access to the procedure. For this reason, it strongly supports a minimum requirement that the patient be managed as part of an MDT, with regular review.

### ***Recurrent disease (relevant to item 35720X)***

- Where suitable, optimal secondary cytoreductive surgery (resulting in no macroscopic residual disease) for recurrent ovarian cancer can achieve significant improvements in overall survival (91).
- This surgery is not frequently performed. However, it can be of significant benefit to the patient in terms of survival, symptom control and quality of life. In selected cases of recurrent gynaecological cancer, secondary cytoreductive surgery would also be cost-saving because it would reduce the need for other adjuvant treatments (such as radiotherapy or chemotherapy).

### ***Schedule fees***

- Item 35720
  - This procedure now differs significantly from the procedure described by original item 35720. As a result, this item's schedule fee no longer reflects contemporary medical practice.
  - Resection of bowel, bladder, spleen, pancreas and liver are excluded because in many cases they are performed by or with a general surgeon, rather than the gynaecological oncologist who would otherwise claim this item.
  - Practice is changing quickly in this area, so the Committee recommended reviewing items 35720 and 35720X in three to five years.
  - This procedure is technically more complex than the procedure covered by item 35641 (stage 4/5 endometriosis), is usually performed via laparotomy, is usually performed on older and more morbid patients than item 35641, and requires a longer postoperative stay and management of the complex peri-operative morbidities found in cancer patients. The schedule fee for item 35641 also does not account for the additional time and skill required to perform a hysterectomy, unlike item 35720.
  - The complexity of the procedure would be more reliably positioned between that of a high and low anterior rectal resection (items 32024 and 32025). An average of the schedule fees for these items is recommended.



- Item 35720X
  - This is an extensive procedure because it involves all of the procedures listed in item 35720, as well as extensive dissection in the upper abdomen. It is estimated that two thirds of the operative time is spent on the upper abdomen, and one third is spent on the pelvis.
  - There is no directly comparable procedure within the abdomen because a multisite procedure is usually required for either primary (first surgery) or secondary (at recurrence) cytoreduction. Both procedures require extensive mobilisation of various structures (including small and large bowel, ureters, bladder and rectum) to enable safe clearance and then removal of the peritoneal tumour.
  - Given the additional time required to perform this procedure, the Committee suggested a schedule fee that is double the schedule fee for item 35720 (the procedure in the pelvis).

## 8.13 Vaginal procedures (items 35554, 35557, 35560, 35561, 35562 and 35564)

### 8.13.1 Items 35554 and 35557

Table 65: Item introduction table for items 35554 and 35557

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35554	Vagina, dilatation of, as an independent procedure including any associated consultation (Anaes.)	\$43.50	25	-2.9%	\$811
35557	Vagina, removal of simple tumour (including Gartner duct cyst) (Anaes.)	\$214.50	980	-0.7%	\$139,664

### Recommendation 72

- Item 35554: No change.
- Item 35557:
  - Change the item descriptor to exclude use of this item for vaginal biopsy. (Item 35615 should be used instead.)
  - The proposed item descriptor is as follows:
    - Vagina, complete excision of benign tumour (including Gartner's duct cyst), with histological documentation (Anaes.)
  - The proposed explanatory notes are as follows:
    - *This item not to be used for the sole purpose of vaginal biopsy, drainage of Gartner duct cysts, cautery of granulation tissue, or removal of vaginal polyps.*
    - *Item 35615 should be used for vaginal biopsies.*



- *Item 35611 should be used for vaginal polyp removal.*

### Rationale

This recommendation focuses on modernising and simplifying the MBS, as well as promoting correct usage of the items. It is based on the following.

- Item 35554:
  - Vaginal dilatation is rarely performed as an independent procedure but is sometimes used in paediatric cases. This item should be retained in order to maintain patient access to this service.
- Item 35557:
  - Service volumes captured in the MBS data for this item were much higher than the Committee expected, based on its clinical experience. The Committee suspects that this item is being used incorrectly for vaginal biopsies and/or removal of vaginal polyps, which should instead be claimed using items 35615 or 35611, respectively.
  - This proposed item descriptor and explanatory notes more accurately describe the correct usage of the item, promoting rational claiming.

### 8.13.2 Items 35560, 35561, 35562 and 35564

**Table 66: Item introduction table for items 35560, 35561, 35562 and 35564**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35560	Vagina, partial or complete removal of (Anaes.) (Assist.)	\$683.90	191	1.0%	\$68,052
35561	Vaginectomy, radical, for proven invasive malignancy - 1 surgeon (Anaes.) (Assist.)	\$1,379.50	85	5.2%	\$72,858
35562	Vaginectomy, radical, for proven invasive malignancy, conjoint surgery - abdominal surgeon (including aftercare) (Anaes.) (Assist.)	\$1,132.60	9	17.6%	\$5,458
35564	Vaginectomy, radical, for proven invasive malignancy, conjoint surgery - perineal surgeon (Assist.)	\$522.85	8	2.7%	\$2,537

### Recommendation 73

- Item 35560:
  - Change the descriptor to include:
    - Use only for partial or complete vaginectomy for removal of lesions that are suspected of being preinvasive or invasive, or for deeply infiltrating endometriosis where accompanied by histological evidence.



- The proposed item descriptor is as follows:
  - Partial or complete vaginectomy, for deeply infiltrating vaginal endometriosis, when accompanied by histological confirmation from excised tissue; not being a service associated with hysterectomy for non-invasive indications, or; for preinvasive or invasive lesions (cases of suspected or proven malignancy) (Anaes.) (Assist.)
- The proposed explanatory notes are as follows:
  - *This item not to be used for vaginal biopsy or polypectomy - use items 35615 or 35611 respectively.*
  - *This service should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.*
- Item 35561:
  - Add an explanatory note for the item that outlines that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - The Committee recommended increasing the schedule fee to align with the schedule fee for an item of similar complexity, such as item 32039 (\$1,535.05 [Rectum and anus, abdominoperineal resection of, 1 surgeon]).
- Item 35562:
  - Add an explanatory note for the item that outlines that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - The Committee recommended increasing the schedule fee to align with an item of similar complexity, such as item 32042 (\$1,293.15 [Rectum and anus, abdominoperineal resection of, combined synchronous operation, abdominal resection]).
- Item 35564:
  - Add an explanatory note for the item that outlines this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - The Committee recommended increasing the schedule fee so that it is equivalent to 50 per cent of the schedule fee for item 35562 (\$1,132.60). This recognises that the second clinician spends approximately half of the total operating time for item 35562 performing this part of the operation.



## Rationale

This recommendation focuses on modernising the MBS and promoting clinical best practice. It is based on the following.

## Context

- The item descriptor for item 35560 is insufficiently detailed, leaving this item open to incorrect interpretation and usage. The new item descriptor addresses this by specifying the intention of the item more clearly.
- The item descriptors for items 35561, 35562 and 35564 still adequately describe the procedures performed. However, the surgical techniques used today differ fundamentally from those used when these MBS items were created. As a result, these items' schedule fees no longer reflect the complexity or duration of the surgery as it is performed in contemporary medical practice, potentially limiting patient access to adequate procedures.

## Current treatment paradigms

- For each of these items, the contemporary procedure involves far more extensive and precise radical removal of malignant tissue than older techniques, and it enables (where feasible) sparing of the autonomic nerves. This reduces morbidity related to bowel, bladder and sexual dysfunction postoperatively (99) (100) (101) (102) (103) (104).
  - The mean operating time required to perform a radical vaginectomy is determined (to a degree) by whether it has to be performed in conjunction with a radical hysterectomy. However, even with a prior hysterectomy, the ureteric dissection required from the abdominal approach, along with preservation of autonomic nerves, makes this an intricate procedure.
  - In the Committee's experience, an average operating time of approximately three to four hours and a mean in-patient stay of 7–10 days is usual for these procedures.
- In the vast majority of cases, one clinician performs both the abdominal and vaginal components of a radical vaginectomy, rather than two clinicians (as was usual in the past).
  - It requires significantly more expertise to perform both the abdominal and vaginal components of the procedure, as well as managing the patient through a significant period of postoperative care.
  - This procedure now requires three years of additional subspecialty training, which are spent learning the necessary advanced surgical techniques, as well as a formal exit examination administered by the RANZCOG for Certification in Gynaecologic Oncology. (This did not exist when this item number was created.)



- Vaginal carcinoma is a rare disease, and all cases should be referred to a tertiary Gynaecological Oncology Unit for management by a specialised MDT. Significant training and expertise are required to successfully complete the surgery with positive functional and cosmetic outcomes and a low rate of complications. The clinician depends on the skills and knowledge of other members of the MDT before and after surgery in order to optimise the quality of care and patient outcomes.

### ***Item-specific information***

- Item 35560:
  - This item is insufficiently specific regarding the correct indications for use, which are limited to gynaecological malignancy and severe infiltrating endometriosis. The recommendation makes these indications explicit in the item descriptor, which will help to reduce possible inappropriate claiming.
  - Vaginal biopsy and polypectomy procedures are more appropriately claimed using items 35615 and 35611, respectively.
  - The Committee agreed that procedures for cases of suspected (pre-invasive) or proven malignancy should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - This specification will also encourage care by an adequately specialised clinician with knowledge of and experience in obtaining clear surgical margins. This will improve patient outcomes and decrease the incidence of recurrent disease.
- Items 35561, 35562 and 35564:
  - Vaginal cancer is rare and requires individualised, expert care to deliver the best outcome for patients.
  - Complex and radical surgery is required to achieve clear margins for vaginal malignancy. Significant training and expertise is required to safely and successfully complete the surgery with a low postoperative complication rate.
  - The contemporary procedure requires more expertise to perform the abdominal and vaginal components, as well as a significant period of postoperative care. In the majority of cases, one clinician performs the procedure and should be remunerated appropriately.
  - Radical vaginectomy is now a more extensive and precise extirpative procedure, which allows the clinician (where feasible) to spare autonomic nerves. This reduces morbidity related to bowel, bladder and sexual function. The contemporary procedure requires an operating time of up to four hours due to the meticulous nature of the surgery.



## 8.14 Vulval procedures (items 35530, 35536, 35548 and 35615)

### 8.14.1 Items 35530, 35536, 35548 and 35615

Table 67: Item introduction table for items 35530, 35536, 35548 and 35615

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
35530	Clitoris, amputation of, where medically indicated (Anaes.) (Assist.)	\$269.85	15	4.6%	\$2,075
35536	Vulva, wide local excision of suspected malignancy or hemivulvectomy, 1 or both procedures (Anaes.) (Assist.)	\$348.45	878	12.6%	\$225,908
35548	Vulvectomy, radical, for malignancy (Anaes.) (Assist.)	\$834.05	137	7.8%	\$76,171
35615	Vulva, biopsy of, when performed in conjunction with a service to which item 35614 applies	\$53.70	4,378	6.9%	\$91,934

### Recommendation 74

- Item 35530: Consolidate this service into items 35536 and 35548.
- Item 35536:
  - Change the item descriptor to include pre-cancerous lesions with a high risk of malignancy, not just malignancy or suspected malignancy.
  - Add an explanatory note for the item that outlines that this procedure should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
  - The proposed item descriptor is as follows:
    - Vulva, wide local excision of suspected malignancy or vulval lesions with a high risk of malignancy (e.g. vulval high-grade intra-epithelial lesion (HSIL), differentiated stage 1 vulval intra-epithelial neoplasia (VIN1), Pagets Disease) or hemivulvectomy, 1 or both procedures. (Anaes.) (Assist.)
- Item 35548:
  - The Committee recommended increasing the schedule fee for this item (\$834.05) by 50 per cent.
  - Change the explanatory notes to specify that co-claiming of flap procedures is permitted, but deep tissue mobilisation is included in this item and that this procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncology MDT.



- The proposed explanatory notes are as follows:
  - *Co-claiming with a relevant flap procedure is permitted. However, deep tissue mobilisation is included in this item.*
  - *This procedure should be performed by a gynaecological oncologist or only after discussion with, or review by, a gynaecological oncology MDT*
- Item 35615:
  - Change the item descriptor to include vulval or vaginal biopsy.
  - The Committee recommended increasing the schedule fee for this item so that it is slightly higher than the schedule fee for item 35608 (\$64.00). Item 35608 is a similarly complex procedure, but item 35615 also requires the administration of local anaesthetic and suturing.
  - The proposed item descriptor is as follows:
    - Vulva or vagina, biopsy of, when performed in conjunction with a service to which item 35614 applies.

## Rationale

This recommendation focuses on modernising the MBS, aligning item descriptors with clinical best practice, and facilitating patient access through appropriately calibrated schedule fees. It is based on the following.

- Item 35530:
  - MBS data shows that this item is rarely performed as a stand-alone procedure, and that it would more appropriately form part of the procedures described in items 35536 and 35548 in order to promote surgery with adequate margins. Item 35530 can be incorporated into these items without limiting patient access.
- Item 35536:
  - This recommendation makes explicit the main indications for this procedure. This is intended to encourage appropriate use of this item, as well as appropriate treatment of conditions such as vulval HSIL, vulvar intraepithelial neoplasm (VIN) and Pagets' disease.
  - Excising these lesions with adequate margins results in a decreased risk of recurrence and progression to cancer, improving patient outcomes.
  - Surgery offers an improved morbidity profile when compared to alternative treatments such as radiotherapy.



- The relatively high growth in the number of services over the past five years probably reflects the current clinical trend towards excision of HPV-related conditions (especially in younger patients). The Committee expects these numbers to decline in the future as a result of more young women receiving the HPV vaccine.
- The Committee agreed that procedures for cases of suspected (pre-invasive) or proven malignancy should be performed by a gynaecological oncologist, or only after discussion with, or review by, a gynaecological oncologist or gynaecological oncology MDT.
- Item 35548:
  - Although the descriptor still reflects the procedure, the surgical technique used to perform the procedure now differs fundamentally from when this item was created. As a result, this item's schedule fee no longer reflects contemporary medical practice and the positive effect this has had on patient outcomes.
  - *Current treatment paradigms*
    - The contemporary procedure involves far more extensive and precise radical removal of cancer tissue compared with the earlier operation, and it requires more operating time to perform. (The Committee estimates 90–120 minutes, compared to 45–60 minutes for the earlier operation.) This is because of the need for extensive mobilisation of lipocutaneous flaps off the deep fascia—particularly of the thigh—across a broad area to affect a tension-free primary closure and reconstruction. These measures are critical to avoid wound breakdown and achieve an aesthetically and functionally satisfactory outcome, decreasing patient disfigurement and psycho-sexual morbidity (105) (106) (107) (108) (109) (110) (111) (112) (113).
    - The contemporary procedure achieves better patient outcomes than older techniques, with a dramatically reduced incidence of wound breakdown (5.2 per cent for the current procedure, compared to 14 per cent for older procedures, as described below). This reduces the amount of time patients spend recovering in hospital (and therefore hospital costs), as well as psychosocial and psychosexual morbidity.
    - Surgical series utilising the original technique report wound breakdown rates of up to 14 per cent (108) (114). A review of all radical vulvectomies from the database of the Queensland Centre for Gynaecologic Cancer from January 2001 to December 2006 revealed a wound breakdown rate of 5.2 per cent in 96 patients using the contemporary surgical technique. These results are reflective of practice across Australia. There are no randomised studies comparing the pre-1985 technique with contemporary techniques, nor would it be ethical to conduct such a study.



- The contemporary procedure requires more expertise to perform than the old procedure. This includes three years of additional subspecialty training, which are spent learning the advanced surgical techniques necessary for this type of surgery. This training culminates in a formal exit examination administered by the RANZCOG for a Certification in Gynaecologic Oncology. This certification did not exist when item 35548 was created.
- Cancer of the vulva is an uncommon cancer. For this reason, general gynaecologists see few patients and get limited experience diagnosing and managing this condition. Experience with this condition and appropriate advanced surgical management rests largely with subspecialty trained gynaecologic oncologists. The Committee therefore recommended that this item should be performed by a gynaecological oncologist, or only after discussion, or review by, a gynaecological oncologist or gynaecological oncology MDT.
- Schedule fee
  - The Committee felt that the increased complexity and duration of the contemporary procedure warrants an increase in the item's schedule fee. It recommended a 50 per cent increase.
  - The Committee would like to note that use of the contemporary procedure supports cost savings in other areas of the MBS and PBS because precise surgery with adequate margins decreases the need for adjuvant therapy, such as radiotherapy and/or chemotherapy.
- Item 35615:
  - Vulval and vaginal dysplasia requires a biopsy to confirm the diagnosis and guide appropriate treatment. This improves patient safety and outcomes.
  - It is important that this item includes both vulval and vaginal biopsies in order to discourage unnecessarily aggressive treatment before a conclusive diagnosis is made, as well as misuse of the vaginectomy item numbers (35561, 35562 and 35564).

## 8.15 Proposed new items

### 8.15.1 Proposed new item: Caesarean hysterectomy

- Create a new item for caesarean hysterectomy.



- This procedure is often performed in dire emergencies and potentially life-threatening circumstances.
- Creation of a new separate item number would allow appropriate audit of the occurrence of this surgery.
- The Committee recommends a schedule fee equivalent to a radical hysterectomy (item 35664; \$1,452.20).
- The Committee agreed that the proposed item 35667Y would cover most difficult cases of hysterectomy at the time of caesarian section. In addition, for intractable haemorrhage but no placenta accreta, a radical hysterectomy item number would be appropriate.
- Therefore, to avoid misuse this proposed new item should be limited only to cases of life-threatening haemorrhage with clear evidence of ongoing bleeding where other techniques (Balloon, B-Lynch sutures) have failed.
- The Committee acknowledges that MSAC evaluation would be required once a suitable sponsor has submitted an application.



## 9. Recommendations for referral to other Committees

### 9.1 To the Diagnostic Imaging Committee: Pelvic MRI (item 63470)

#### 9.1.1 Pelvic MRI for cervical malignancy

Table 68: Item introduction table for item 63470

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
63470	Magnetic resonance imaging performed under the professional supervision of an eligible provider at an eligible location where: (a) the patient is referred by a specialist or by a consultant physician and (b) the request for scan identifies that (i) a histological diagnosis of carcinoma of the cervix has been made and (ii) the patient has been diagnosed with cervical cancer at figo stage 1b or greater Scan of: - Pelvis for the staging of histologically diagnosed cervical cancer at figo stages 1b or greater (r) (Contrast) (Anaes.)	\$403.20	394	10.8%	\$154,385

#### Recommendation 75

- Change the descriptors for item 63470 to:
  - Remove the restriction that states benefits are payable for a service included by subgroup 20 on one occasion only.
  - Add the following indications:
    - Restaging in the event of suspected recurrence of cervical cancer prior to exenterative surgery and/or for planning of vaginal brachytherapy radiation treatment.
    - Staging for endometrial cancer in a woman with a diagnosis of endometrial cancer who wishes to retain her uterus.
    - Pelvic malignancy prior to pelvic exenterative surgery.
  - The proposed item descriptor is as follows:
    - Magnetic resonance imaging performed under the professional supervision of an eligible provider at an eligible location where: (a) the patient is referred by a specialist or by a consultant physician and (b) the request for scan identifies that (i) a histological diagnosis of carcinoma of the cervix has been made and (ii) the patient has been diagnosed with cervical cancer at figo stage 1b or greater; or (iii) for suspected recurrence of cervical cancer prior to exenterative surgery and/or for planning of vaginal brachytherapy radiation treatment; or (iv) for staging for endometrial cancer in



a woman with a diagnosis of endometrial cancer who wishes to retain her uterus; or (v) for pelvic malignancy prior to pelvic exenterative surgery. Scan of: - Pelvis for the staging of histologically diagnosed cervical cancer at figo stages 1b or greater (r) (Contrast) (Anaes.)

- The Committee acknowledges that MSAC evaluation may be required if these indications cannot simply be added to item 63470.

### Rationale

This recommendation focuses on promoting patient safety by improving surgical decision-making in complex gynaecological cancer patients. It is based on the following (115) (116) (117) (118) (119) (120) (121).

- MRI is already funded for the initial staging of cervical cancer, but there are compelling reasons to allow its use in defined situations after initial staging has taken place (122).
  - In the event of a suspected recurrence of cervical cancer, it is critical to be able to accurately assess a patient's anatomy and the extent of cancer infiltration prior to conducting exenterative surgery and/or vaginal brachytherapy radiation treatment. This will allow more precisely targeted surgery or brachytherapy, which can reduce the extent (and related morbidity) of such treatment.
  - In cases where a woman has endometrial cancer but wishes to retain her uterus, MRI can assist in evaluating whether or not it will be possible to perform such fertility-sparing surgery. If such surgery is possible, MRI can assist a surgeon in planning the optimal surgical approach to achieve this.
  - Similarly, it is not always clear whether a patient is suitable for exenterative pelvic surgery. MRI can help to make the best decision on the suitability for, and approach to, these extensive and difficult surgical procedures.
- Performing MRI for these additional indications will improve the provision of high-value and high-quality care to women with gynaecological malignancy by avoiding unnecessary surgery in patients who are unsuitable for surgery (for example, those who are inoperable due to invasion of surrounding bone or pelvic nerves), or where surgery would result in unnecessary harm or avoidable loss of fertility.

## 9.2 To the Urology Committee: Video urodynamics (item 11919)

Item 11919 is rarely claimed by urogynaecologists. Instead, it is overwhelmingly claimed by urologists in their specialist practice. As a result, the Committee felt that it should not make any firm recommendations with regard to this item. It was decided that further consideration should be



within the scope of the Urology Clinical Committee when it is constituted in the future. The work of the Committee on item 11919 will be made available to the Urology Clinical Committee, should it wish to use it as a basis for deliberations.

### 9.2.1 Item 11919

**Table 69: Item introduction table for item 11919**

Item	Descriptor	Schedule fee	Volume of services FY2015/16	Services 5-year-average annual growth	Total benefits FY2015/16
11919	Cystometrography in conjunction with contrast micturating cystourethrography, with measurement of any 1 or more of urine flow rate, urethral pressure profile, rectal pressure, urethral sphincter electromyography; including all imaging associated with cystometrography, not being a service associated with a service to which items 11012, 11027, 11900-11917, 11921 and 36800 apply (Anaes)	\$428.35	4,827	-0.9%	\$1,714,424

### Recommendation 76

- Change the item descriptor to:
  - Remove the words ‘including all imaging.’
  - Include the phrase ‘with simultaneous measurement of rectal pressure’ (making it explicitly included and no longer optional).
  - The proposed item descriptor is as follows:
    - Cystometrography with simultaneous measurement of rectal pressure, in conjunction with contrast micturating cystourethrography, with measurement of any 1 or more of urine flow rate, urethral pressure profile, urethral sphincter electromyography; not being a service associated with a service to which items 11012, 11027, 11900-11917, 11921 and 36800 apply. (Anaes)
- Change the explanatory notes to specify that stomal or vaginal pressure may be used where rectal pressure is not possible.
  - The proposed explanatory notes are as follows:
    - *Stomal or vaginal pressure may be used where rectal pressure is not possible.*
- Consider advising the Private Health Insurance Branch (PHIB) to support a change in this procedure’s classification from Type C to Type B to allow performance at a hospital.



## Rationale

This recommendation focuses on improving patient care, encouraging best practice, optimising patient access to essential services and reducing discrepancies between MBS items. It is based on the following.

### Context and identified problems

- In the original item descriptor, the phrase ‘including all imaging’ implied that the cost of the fluoroscopy radiology service inherent to item 11919 (which a radiographer is mandated to attend by the Radiation Protection Authority legislation) is included in the schedule fee. Radiology services cannot be claimed separately, as is the case with all other item numbers requiring radiology services (including those that use fluoroscopic screening, such as retrograde pyelography).
- When the radiology service charged to the clinician (\$60–100 or more per patient) is deducted from the schedule fee, it creates a disincentive to offer fluoroscopic urodynamics, compared to other urodynamic services (such as item 11917, which relies on ultrasound).

### Clinical paradigms

- Fluoroscopy combined with urodynamics is internationally regarded as the gold standard approach in cases of suspected obstruction in certain patient groups, such as those with neuropathy (49) (50). In Australia, three quarters of imaging-based urodynamics use ultrasound. MBS data shows that item 11917 (using ultrasound) was claimed 17,321 times, compared with item 11919, which was claimed 4827 times. This does not align with international guidelines and patterns of urodynamic practice in countries such as the United Kingdom and the United States (51) (52).
- Rectal placement of the reference catheter to measure abdominal pressure is considered part of the current International Continence Society (ICS) standard (53). Some urodynamics clinicians are claiming items for rectal pressure but are substituting it with vaginal pressure in patients with an intact rectum, due to ease of use or patient preference. The ICS recommends that vaginal or stomal placement of the abdominal pressure catheter should only be used if rectal catheter placement is impossible. Its review concluded that there is insufficient evidence that the vagina is a reliable alternative to rectal catheterisation. Making this explicit in the item descriptor aligns the MBS with international guidelines.
- Adding explanatory notes to the item descriptor to permit the substitution of vagina or stoma for the rectum where rectal placement is impossible will continue to allow clinician discretion while promoting guidelines-based practice.

### Proposed solutions



- Removing imaging services from this item will place it on an equal footing with alternative procedures, such as that described by item 11917. It will also allow clinicians to select the most appropriate investigation for the patient's specific indication without inappropriate incentivisation.

## Other Recommendations

### Assisted Reproductive Technology

#### 9.2.2 Proposed new item – testing for microdeletion of Y chromosome

##### Recommendation 77

- Create a new item for detection of microdeletions of the Y chromosome in non-obstructive azoospermia (NOA).
- The Committee acknowledges that MSAC evaluation would be required once a suitable sponsor has submitted an application.

##### Rationale

- Detection of Y chromosome microdeletions is standard care worldwide for men with non-obstructive azoospermia, idiopathic infertility or sperm densities <5 million/mL.
- This is a standardized Polymerase Chain Reaction Polymerase Chain Reaction (PCR) test that detects microdeletions of the Y chromosome.
- If a particular type of deletion is found (AZFa and/or AZFb) there is effectively no chance of successful sperm recovery using micro-TESE making.
- Such couples can then:
  - Be directed towards donor insemination and avoid the trauma and expense of a futile micro-TESE attempt
  - Elect for sex selection to avoid male offspring with vertical transmission of infertility in adulthood or have the benefit of this information so it may be addressed in the future.
- The current cost of Y chromosome microdeletion testing (~\$240) is a disincentive for patients to undergo testing and will subsequently undergo futile micro-TESE at great costs to themselves and, potentially, the MBS.



## Gynaecology Oncology

### Recommendation 78

#### 9.2.3 Proposed new item: Caesarean hysterectomy

- Create a new item for caesarean hysterectomy.
  - This procedure is often performed in dire emergencies and potentially life-threatening circumstances.
  - Creation of a new separate item number would allow appropriate audit of the occurrence of this surgery.
  - The Committee recommends a schedule fee equivalent to a radical hysterectomy (item 35664; \$1,452.20).
- The Committee agreed that the proposed item 35667Y would cover most difficult cases of hysterectomy at the time of caesarian section. In addition, for intractable haemorrhage but no placenta accreta, a radical hysterectomy item number would be appropriate.
- Therefore, to avoid misuse this proposed new item should be limited only to cases of life-threatening haemorrhage with clear evidence of ongoing bleeding where other techniques (Balloon, B-Lynch sutures) have failed.
- The Committee acknowledges that MSAC evaluation would be required once a suitable sponsor has submitted an application.



## 10. Stakeholder impact statement

Both patients and providers are expected to benefit from these recommendations because they address concerns regarding patient safety and quality of care, and they take steps to simplify the MBS and make it easier to use and understand. Patient access to services was considered for each recommendation. The Committee also considered each recommendation's impact on provider groups to ensure that any changes were reasonable and fair. However, if the Committee identified evidence of potential item misuse or safety concerns, recommendations were made to encourage best practice, in line with the overarching purpose of the MBS Review.



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## 12. Appendix A – Notes on interpretation of selected ART graphs

The following explanations have been transcribed directly from the referenced papers. They are included here for the reader's convenience, to provide context and assist in the interpretation of the statistics referenced in this report. For additional information, including the original graphs and tables, please refer to the papers themselves.

### **Cumulative live-birth rates after repeated assisted reproduction technology treatment cycles in Australian and New Zealand. December 2016. National Perinatal Epidemiology and Statistics Unit, UNSW**

An extract of the 120,930 treatment cycles performed between 2009 and 2014 undertaken by the 56,652 women who embarked on autologous ART (using their oocytes) in Australia and New Zealand between 2009-2012 was obtained from Australian and New Zealand Assisted Reproductive Technology Database (ANZARD). This allowed a minimum of two years and maximum 6 years follow-up. Records of all frozen/thaw treatments were linked to the initial episode of ovarian stimulation for each individual woman. This allowed each 'complete' treatment cycle to be identified, and its reproductive outcome to be measured. Cycles were excluded for women who used donated oocytes or embryos, or surrogacy arrangements, and where the purpose of the treatment was the long-term storage of oocytes or embryos (e.g. onco-fertility preservation).

The follow-up period was chosen to allow sufficient time to achieve at least one live-birth, and to have sufficient number of 'complete' cycles to provide reliable estimates of live-birth rates. A live-birth was defined as the birth of at least one live born infant of 20 weeks or more gestation or 400grams or more birthweight. The birth of twins or triplets was defined as one live-birth. CLBRs were reported based on the women's age at the commencement of treatment (<30 years, 30-34 years, 35-39 years, 40-44 years and 45+ years old).

Descriptive statistics related to women (age, type of infertility) and treatment factors (number of fresh and frozen/thaw cycles, number of embryos transferred, proportions of cycles using intracytoplasmic sperm injection (ICSI) and blastocyst culture) were generated to describe the cohort of women and ART cycles included in the analysis.

To ensure reliable estimates, CLBRs were calculated for complete cycles where at least 50 women attempted a cycle. Two types of CLBRs were calculated based on assumptions around the prognosis of women who discontinued with ART treatment. The conservative CLBRs assumed that women who discontinued with treatment would not have achieved a live-birth if they continued with treatment. The CLBR for each successive complete cycle was calculated as the total number of women who achieved an ART live-birth divided by the total number of women who commenced ART treatment



between 2009 and 2012. The 95% confidence intervals were calculated using standard errors from the binomial distribution. Women were excluded from the analysis once they achieved their first live-birth. Women were considered to have discontinued from ART treatment if they did not have a treatment-dependent live-birth and did not return for further ART treatment before 31 December 2014.

The optimal CLBRs assumed that women who discontinued with treatment would have had the same chance of a live-birth with continued ART as those who did continue with treatment. The Kaplan-Meier method was used to estimate the optimal CLBRs and their 95% confidence intervals. Women discontinue ART treatment for a number of reasons (psychosocial, medical, financial). Given this information is not available in ART registries, the conservative and optimal CLBRs provide a range within which the true CLBRs would be expected to fall. However, a recent systematic review reported that ~60% of patients who had a failed ART cycle discontinued treatment due to reasons other than a poor prognosis, and a more recent study put his figure at ~85%. Assuming similar rates, gives a realistic estimate of between 55.2-57.3% after three complete cycles which is closer to the optimal rate (58.8%) than the conservative rate (49.9%).

In addition to the CLBRs, cycle-specific live-birth rates were calculated as the number of live-births in a particular complete cycle divided by the number of women who commenced ART treatment in that cycle.

**Cumulative live-birth rates after repeated assisted reproduction technology treatment cycles in Australian and New Zealand. February 2017. National Perinatal Epidemiology and Statistics Unit, UNSW**

Analysis 1: Cumulative Live-birth Rates for women commencing ART treatment in 2009-2012

How to interpret the following tables:

An extract of the 120,930 treatment cycles performed between 2009 and 2014 undertaken by the 56,652 women who embarked on autologous ART (using their own oocytes) in Australia and New Zealand between 2009-2012 was obtained from Australian and New Zealand Assisted Reproductive Technology Database (ANZARD). This allowed a minimum of two years and maximum 6 years' follow-up up from commencement of their treatment. Records of all frozen/thaw treatments were linked to the initial episode of ovarian stimulation for each individual woman. This allowed each 'complete' treatment cycle to be identified, and its reproductive outcome to be measured. Cycles were excluded for women who used donated oocytes or embryos, or surrogacy arrangements, and where the purpose of the treatment was the long-term storage of oocytes or embryos (e.g. onco-fertility preservation).

The follow-up period was chosen to allow sufficient time to achieve at least one live-birth, and to have sufficient number of 'complete' cycles to provide reliable estimates of live-birth rates. A 'live-birth' was defined as the birth of at least one live born infant of 20 weeks or more gestation or 400



grams or more birthweight. The birth of twins or triplets was defined as one live-birth. Cumulative live-birth rates (CLBRs) were reported based on the women's age at the commencement of treatment (<30 years, 30-31 years, 32-33 years, 34-35 years, 36-37 years, 38-39 years, 40-41 years, 42-43 years, 44-45 years and 45+ years old).

Descriptive statistics related to women (age, type of infertility) and treatment factors (number of fresh and frozen/thaw cycles, number of embryos transferred, proportions of cycles using intracytoplasmic sperm injection (ICSI) and blastocyst culture) were generated to describe the cohort of women and ART cycles included in the analysis.

To ensure reliable estimates, CLBRs were calculated for complete cycles where at least 50 women attempted a cycle. Two types of CLBRs were calculated based on assumptions around the prognosis of women who discontinued with ART treatment. The conservative CLBRs assumed that women who discontinued with treatment would not have achieved a live-birth if they continued with treatment. The CLBR for each successive complete cycle was calculated as the total number of women who achieved an ART live-birth divided by the total number of women who commenced ART treatment between 2009 and 2012. The 95% confidence intervals were calculated using standard errors from the binomial distribution. Women were excluded from the analysis once they achieved their first live-birth. Women were considered to have discontinued from ART treatment if they did not have a treatment-dependent live-birth and did not return for further ART treatment before 31 December 2014.

The optimal CLBRs assumed that women who discontinued with treatment would have had the same chance of a live-birth with continued ART as those who did continue with treatment. The Kaplan-Meier method was used to estimate the optimal CLBRs and their 95% confidence intervals.

In addition to the CLBRs, cycle-specific live-birth rates were calculated as the number of live-births in a particular complete cycle divided by the number of women who commenced ART treatment in that cycle.

Additional points to consider:

This analysis answers the questions;

1. "What is a woman's chance of achieving her first live-birth following repeated ART treatment cycles?" (CLBR), and
2. "What is a woman's chance of achieving her first live-birth in a particular complete cycle if previous cycles failed"? (cycle specific rates).

Women discontinue ART treatment for a number of reasons (psychosocial, medical, financial), however estimates indicate that ~60% of patients who had a failed ART cycle discontinued treatment due to reasons other than a poor prognosis, indicating that a realistic estimate would be closer to the optimal rates than the conservative rates.



The woman's age groupings are set at the time of her first initiated ART cycle. Therefore, her age at the time of subsequent cycles could be older. For example, all treatment outcomes for a woman who commenced ART at age 40 years of age would appear in the 'Age 40-41 years' table, even if she was aged 42 years for some of her later cycles.

Analysis 2: Cumulative Live-birth rate per fresh cycle performed in 2014

Combined (fresh + thaw) live-birth rates per fresh cycles for cycles performed in 2014

How to interpret the following table:

This analysis was performed on a cross-sectional extract from ANZARD of the 43,579 autologous ART treatment cycles performed in 2014 in Australia and New Zealand. The age groupings are taken at the age a woman performed a fresh or thaw ART cycle in 2014. The ART cycles could be either the first or subsequent cycles a woman underwent. Cycles were excluded for women who used donated oocytes or embryos, or surrogacy arrangements.

The combined (fresh + thaw) live-birth rate per fresh cycle was computed by adding the live-births resulting from all fresh and thaw cycles performed in 2014, and dividing by the number of initiated fresh cycles in 2014.

Additional Points to consider:

This analysis answers the question: 'What was the estimated cumulative live-birth rate per initiated fresh cycle performed in 2014?'

This calculation provides an approximation to the cumulative live-birth rate of a fresh cycle performed in 2014, and the live-birth rate resulting from the consumption of ART resources within a particular year.

This calculation is reported by both the European Society of Human Reproduction and Embryology (ESHRE)<sup>1</sup> and the International Committee for Monitoring Assisted Reproductive Technologies (ICMART)<sup>2</sup>. However, because this measure is computed using a cross-sectional analysis of all cycles performed in 2014, the fresh and thaw cycles are not linked to specific women and the embryos transferred in a thaw cycle may have originated from cycles performed in previous years.

<sup>1</sup> Dyer, S., Chambers, G. M., De Mouzon, J., Nygren, K. G., Zegers-Hochschild, F., Mansour, R., Ishihara, O., Banker, M. & Adamson, G. D. (2016). International committee for monitoring assisted reproductive technologies world report: assisted reproductive technology 2008, 2009 and 2010. *Human Reproduction*, 31(7), 1588-1609.



<sup>2</sup> Kupka, M. S., Hooghe, T. D., Ferraretti, A. P., De Mouzon, J., Erb, K., Castilla, J. A., Geyter, C. D. & Goossens, V. (2016). Assisted reproductive technology in Europe, 2011: results generated from European registers by ESHRE. *Human Reproduction*,29(10), 2099-2113.

**Cycle-specific live-birth rates during repeated assisted reproduction technology treatment cycles in Australian and New Zealand – based on women’s ages at time of treatment. April 2017.**  
**National Perinatal Epidemiology and Statistics Unit, UNSW**

An extract of the 120,930 treatment cycles performed between 2009 and 2014 undertaken by the 56,652 women who embarked on autologous ART (using their own oocytes) in Australia and New Zealand in 2009-2012 was obtained from Australian and New Zealand Assisted Reproductive Technology Database (ANZARD). This allowed a minimum of two years and maximum 6 years’ follow-up from commencement of their treatment. Records of all frozen/thaw treatments were linked to the initial episode of ovarian stimulation for each individual woman. This allowed each ‘complete’ treatment cycle to be identified, and its reproductive outcome to be measured. Cycles were excluded for women who used donated oocytes or embryos, surrogacy arrangements, and where the purpose of the treatment was the long-term storage of oocytes or embryos.

This analysis presents the live birth rate (LBR) per complete cycle by woman’s age group at time of treatment (<30 years, 30-31 years, 32-33 years, 34-35 years, 36-37 years, 38-39 years, 40-41 years, 42-43 years, 44-45 years and >45 years old). This LBR was calculated for each complete cycle number and age group combination as the total number of woman who achieved an ART live-birth divided by the total number of women who underwent ART treatment in that cycle.

A ‘live-birth’ was defined as the birth of at least one live born infant of 20 weeks or more gestation or 400 grams or more birthweight. The birth of twins or triplets was defined as one live-birth. Women were excluded from the analysis once they achieved their first live-birth. Women were considered to have discontinued from ART treatment if they did not have a treatment-dependent live-birth and did not return for further ART treatment before 31 December 2014.

This analysis answers the question; “At a particular age, what is a woman’s chance of achieving her first live-birth given a certain number of previous failed ART cycles?”

For example, the estimated cycle-specific live-birth rate for women aged 43 years old in their fourth complete cycle (after three failed previous complete cycles), is 5.4%.

The woman’s age groupings are set at the time of her ART treatment(s), and consider previous treatment cycles thereby allowing predictions of likely success rates. However, LBRs are population (mean) estimates and caution should be used if applying at an individual level.



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## 14. Appendix C – Consumer summary tables

This section is a summary for consumers of the main recommendations that the Committee will make to the Taskforce regarding the 141 MBS items originally allocated to its area of responsibility. These recommendations are based on a review of MBS data and published evidence. To inform its recommendations, the Committee took into consideration the clinical experience of its specialist and GP members; the expertise of its consumer representatives; MBS data on the quantity, cost, growth, co-claiming and regional variation of item use; and relevant published literature.

The Committee has made recommendations for 166 items in total (organised into 73 item group-level recommendations in the main body of this report), involving 30 item deletions, 111 changes to existing items and the creation of 25 new items. Due to the large volume and highly technical nature of the recommendations, this section will focus on the key recommendations. Broadly, there have been three types of recommendation: change item descriptors, delete items and add new items. The following table details the type of recommendation, the reason for the recommendation and the result of the recommendation. It is suggested that consumers refer to the corresponding section in the report should they require further detail.



## Key recommendations for ART items

Items	Type of recommendation	Reason for recommendation	Result of recommendation
<b>ART stimulated cycle items: 13200, 13201, 13202, new items, and 13251</b>	<p>Split items and change descriptors.</p> <p>Incorporate item 13251 into each of these items.</p>	<p><i>Context</i></p> <p>ART stimulated cycle treatment is sometimes offered to women who are experiencing difficulty achieving a pregnancy. It involves the administration of medicines that stimulate the ovaries to release more eggs (oocytes) in that month than is usual (a 'stimulated cycle'). The clinician and ART team then extract these eggs and combine them with sperm in a laboratory to make embryos. Usually one or more embryos are then placed into the woman's uterus (womb) in the hope that she will become pregnant (a 'fresh' cycle). Any remaining embryos can be frozen and placed into the womb in later months if desired (a 'frozen' or 'thaw' cycle). When the eggs used in a treatment come from the woman herself, the treatment is termed 'autologous'; when another person donates the eggs, they are termed 'donor' oocytes. ART treatment can help a woman to have a baby. However, ART treatment is expensive and involves physical and psychological risks, and the chances of success vary. These factors can put women under financial, physical and emotional stress.</p> <p><i>Observations</i></p> <p>The Committee noted several points regarding stimulated ART cycle treatment:</p> <p>1) Data shows that natural fertility falls with age, particularly from the mid-30s onwards. The chance of having a live birth due to ART treatment similarly decreases with advancing age. There are currently no restrictions on MBS funding for stimulated ART cycles in Australia, and funding is provided even for women with an extremely small chance of having a live birth in a particular ART cycle.</p> <p>(continues on following page)</p>	<p>These changes are intended to encourage women to undergo treatment when it is more likely to be successful, and not to continue treatment when the chances of success are very low.</p>



- 2) Data shows that providing stimulated ART cycles using a woman's own eggs (oocytes) to women aged 44 and over resulted in a low chance of successfully having a baby (less than 5 per cent per cycle). The vast majority of ART births (about 99 per cent) are achieved within six 'complete' stimulated ART cycles—that is, all those cycles (fresh and frozen) arising from a single episode of ovarian stimulation.
- 3) Women who have one pregnancy of 20 completed weeks' gestation or more due to ART treatment with their own eggs are more likely to have successful future ART cycles than those who do not.
- 4) Intracytoplasmic sperm injection (ICSI) is a technique used in some ART treatments, in which a sperm is directly injected into an egg, instead of being allowed to fertilise it by itself. The Committee noted that providers vary widely in how much they actually use ICSI. For example, providers in Victoria used ICSI in approximately 78 per cent of cases (up to 91 per cent in one region), while providers in New South Wales used it in 58 per cent of cases (and as low as 49 per cent).

#### *Recommendations*

The changes recommended by the Committee to the ART stimulated cycle items would:

- 1) Introduce limits so that women under 44 can receive MBS funding for up to six stimulated cycles with their own eggs. MBS funding would not be provided to women aged 44 or over for fresh cycles using their own eggs.
- 2) Allow women who have a pregnancy of 20 completed weeks' or more gestation (as a result of ART stimulated cycle treatment with their own eggs) to receive MBS funding for up to six more ART stimulated cycles with their own eggs. MBS funding will not be provided to women aged 44 or over for fresh cycles using their own eggs.
- 3) Introduce limits so that women can receive MBS funding for up to six stimulated cycles with their own eggs while they are under the age of 40. Between the ages of 40 and 43, women can receive MBS funding for either four stimulated cycles with their own eggs, or the number of MBS-funded stimulated cycles they had left from before they turned 40, if this is less than four. MBS funding will not be provided to women aged 43 or over for fresh cycles using their own eggs.
- 4) Allow women who have a pregnancy of 20 completed weeks' or more gestation (as a result of ART stimulated cycle treatment with their own eggs) to receive MBS funding for up to six more ART stimulated cycles with their own eggs (if they fell pregnant before age 40), or up to four more ART stimulated cycles with their own eggs (if they fell pregnant between the ages of 40 and 43). MBS funding will not be provided to women aged 43 or over for fresh cycles using their own eggs.



5) Delete ICSI item 13251 and include ICSI as part of the ART stimulated cycle items instead. The schedule fee for these items would be increased so that providers are effectively reimbursed for using ICSI in 60 per cent of the ART stimulated cycles they perform.

<p><b>ART stimulated cycle items for altruistic oocyte donors and those engaged in surrogate arrangements (new)</b></p>	<p>Create new items. Remove surrogacy restrictions.</p>	<p><i>Context and observations</i></p> <p><b>Egg donation</b></p> <p>Data shows that if a woman aged 40 or over uses an egg donated by a younger woman, the chances of a successful birth are better than if she had used her own eggs. The chances of a live birth using a donated egg depend on the age of the donor and recipient, with younger donors and recipients generally obtaining better results. MBS funding for altruistic egg donation (the donor may not receive compensation for donating her eggs) is not explicitly permitted or excluded by the existing MBS items.</p> <p><b>Surrogacy</b></p> <p>Some women suffer from medical problems that allow them to produce eggs but make it impossible for them to carry a baby and/or have a live birth. For these women, the only option for having a biological son or daughter is to have an ART stimulated cycle, and to use their eggs to make an embryo that will be carried by another woman (termed a surrogate mother).</p> <p>The current items specifically exclude MBS funding for altruistic surrogacy arrangements. However, altruistic surrogacy arrangements are now legal in all Australian states and territories, and a number of children are born from surrogacy arrangements each year.</p> <p><i>Recommendations</i></p> <p>The Committee recommended that women should have access to MBS funding for ART stimulated cycle items in these situations.</p>	<p>These changes are intended to provide funding for altruistic egg donors under the age of 40 to have up to four stimulated ART cycles, to provide eggs for named recipients who are under 45 years of age.</p> <p>They would also provide funding for women involved in altruistic surrogacy arrangements.</p> <p>This would open access to MBS-funded ART services for women who previously could not obtain them.</p>
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## Key recommendations for general gynaecology items

Items	Type of recommendation	Reason for recommendation	Result of recommendation
<b>Intrauterine device insertion items: 35502 and 35503</b>	Incorporate item 35502 into item 35503. Change the descriptor and increase schedule fee for newly combined item 35503.	<p><i>Context</i></p> <p>Intrauterine devices (IUDs) are small devices that can be inserted into a woman's uterus. Non-hormone-releasing IUDs are used for contraception, while hormone-releasing IUDs can be used for both contraception and to prevent or treat heavy menstrual bleeding (HMB).</p> <p><i>Observations</i></p> <p>Research shows that relatively few Australian women use IUDs compared with, for example, northern Europeans. Low rates of IUD use are associated with higher rates of unplanned pregnancies. There is also a high level of variation between the rates of hysterectomy (surgical removal of the uterus) performed for HMB in different regions of Australia, with more done in rural than urban areas. Insertion of an IUD in these cases can sometimes help women avoid having to have a hysterectomy, along with the pain, risk and inconvenience that comes with major surgery like this.</p> <p>Higher rates of IUD insertion may therefore be expected to lower the rates of unplanned pregnancy and hysterectomy for HMB in Australia. It is likely that many changes will need to be made to improve IUD insertion rates in Australia. Research shows that two major reasons GPs perform so few IUD insertions are:</p> <ol style="list-style-type: none"> <li>1) The schedule fee for item 35503 is too low to cover the costs involved in performing them.</li> <li>2) It is difficult and expensive to obtain adequate training in IUD insertion techniques.</li> </ol> <p><i>Recommendations</i></p> <p>The Committee recommended increasing the schedule fee for item 35503. It recognised that other changes will need to be made to support increased IUD insertion rates.</p>	<p>Increasing the schedule fee is intended to increase GPs' willingness to perform IUD insertions, which should improve their experience and confidence with the procedure, leading to broader access for women to this safe and effective service.</p> <p>This should lead to fewer unwanted pregnancies and terminations, as well as a decline in the number of (and regional variation in) hysterectomies done for abnormal uterine bleeding (AUB).</p> <p>The Committee recognised that other factors such as better GP access to IUD training are important as well, and recommended that these be pursued outside the MBS Review process.</p>



**Diagnostic hysteroscopy items: 35626, 35627 and 35630**

Incorporate item 35627 into 35630, change descriptors and increase the schedule fee for item 35626.

*Context*

Diagnostic hysteroscopy involves inserting a camera into the uterus so that problems can be seen directly by a clinician. At the same time, biopsies (samples) of the endometrium (lining of the uterus) can be taken, which sometimes help in making a diagnosis.

Hysteroscopy can be performed with or without local or general anaesthetic, and can be performed in a hospital operating theatre (item 35630) or in an outpatient setting such as a private practice or clinic (included in item 35626).

*Observations*

Research shows that women prefer to be treated in an outpatient setting, and that the results of the procedure are just as good in that setting as they are when done in an operating theatre. However, MBS data suggests that less than 1 per cent of diagnostic hysteroscopies are performed in an outpatient setting.

Several factors could be causing this. One reason is that performing the procedure outside an operating theatre requires use of item 35626, which has a much lower schedule fee than item 35630 (even though the procedure is the same). In addition, clinicians have to cover more costs themselves (for example, equipment costs) during an outpatient procedure, and they must organise several activities that hospital staff otherwise would.

*Recommendations*

Considering the potential benefits to women and the community, the Committee recommended that more of the diagnostic hysteroscopies currently performed in operating theatres should be performed in outpatient settings instead. To encourage this, it recommended increasing the schedule fee for item 35626, so that clinicians are appropriately incentivised not to use item 35630 where it is not strictly needed.

There is no need to have two separate items for 35627 and 35630 given the similarity of the services they describe.

Increasing the schedule fee for item 35626 is intended to increase the proportion of diagnostic hysteroscopies performed in outpatient settings.

This should improve women's experiences of these procedures, and it should benefit the community by decreasing the load on operating theatres, providing more access for other surgical cases.



**Laparoscopic hysterectomy, operative laparoscopy, and hysteroscopic surgical items**

Restructure and split items according to complexity.  
Change descriptors.

*Context*

These groups of procedures have evolved considerably in the time since their items were created. Laparoscopy involves performing surgery inside the abdomen and pelvis through small ‘keyhole’ incisions, rather than a large incision (open surgery), as was the norm previously. Hysteroscopy is the passage of an instrument up through the neck of the uterus (cervix) in order to see inside the uterus. These procedures can result in fewer surgical side effects, faster recovery times for women and less scarring than open surgery.

*Observations*

Today, these tools and techniques are employed in ever more complex cases, which were previously performed using open surgical techniques. Because of this change over time, the few existing MBS items are not detailed enough to properly account for all the different types and complexities of procedures that are currently performed using these tools. This limits women’s understanding of the procedures performed on them, as well as their ability to receive the right level of rebate that reflects the relative complexity of the surgery.

*Recommendations*

The Committee recommended restructuring and/or splitting the items so that they more accurately reflect the complexity of the surgery performed.

Splitting and rewording the MBS items for these procedures will provide clarity and consistency in clinical practice and reduce variation in billing. These new MBS items should not adversely affect access for women, as these surgeries were previously claimed using the existing items.



## Key recommendations for urogynaecology items

Items	Type of recommendation	Reason for recommendation	Result of recommendation
<b>Vaginal compartment repair items: 35570, 35571 and 35573</b>	Change descriptors.	<p><i>Context</i></p> <p>Advancing age, vaginal birth and other factors can result in the front (anterior) and back (posterior) walls of the vagina weakening, sometimes enough that the wall bulges inward under pressure from adjacent organs (bladder or bowel). Sometimes this bulging can be severe enough that the part of the vaginal wall ‘prolapses,’ bulging inside or outside the vagina.</p> <p>Vaginal compartment repair procedures aim to fix these weaknesses to prevent discomfort and other problems as a consequence of the prolapse. Until recently, these procedures were performed using either the woman’s own tissue (‘native tissue graft’), or implanted materials (‘mesh’ or ‘graft’), which come in several different forms, including biological, permanent and composite (a combination of permanent and non-permanent materials).</p> <p>The Therapeutic Goods Administration (TGA), part of the Australian Government Department of Health responsible for approving and controlling the availability of medicines or medical devices in Australia, recently banned the use of some mesh products for use in the treatment of pelvic organ prolapse. After reviewing the evidence, the TGA found that the benefits of using transvaginal mesh products do not outweigh the risks to patients.</p> <p><i>Observations</i></p> <p>Although mesh products are very safe in some other types of surgery (such as for stress incontinence), research shows that in some cases, the use of mesh for prolapse can have serious adverse consequences in some women. Research suggests that vaginal compartment repair procedures using native tissue techniques are safe.</p> <p><i>Recommendations</i></p> <p>The Committee recommended allowing MBS funding of vaginal surgery for pelvic organ prolapse only when native tissue without graft (mesh) is used, in order to align their recommendations with the actions of the TGA.</p>	This recommendation will improve patient safety by promoting safer surgical practice.


**Graft excision items  
(new)**

Create three new items.

*Context*

Some women who have had vaginal compartment repair surgery with biological or permanent/composite mesh experience serious side effects, such as severe pain, infection and mesh exposure (mesh material protruding through the surface of the tissue, either into the vagina or into bowel, bladder or other internal structures). The main potentially curative treatment for these side effects is to remove the mesh surgically.

*Observations*

Currently, there is no MBS item covering mesh removal surgery, so clinicians are using other inappropriate items instead, or are declining to perform the surgery. These issues limit access for women, who then suffer unnecessarily or seek surgery overseas, sometimes with increased risk to their safety.

*Recommendations*

The Committee recommended creating three new items: two would address different extents of mesh excision surgery done through the vagina, and a third would cover mesh removal surgery done through the abdomen (often more complex cases).

These new items will help women to more easily access high-quality care from Australian clinicians.

They will also allow researchers to use the MBS to monitor the number of women needing surgical removal of mesh products, which could shape policies towards appropriate mesh use in the future.



## Key recommendations for gynaecological oncology items

Items	Type of recommendation	Reason for recommendation	Result of recommendation
<b>Ovarian cancer debulking, radical hysterectomy, lymph node dissection and biopsy, and cone biopsy items</b>	<p>Restructure and split items to reflect differences in procedure complexity.</p> <p>Change descriptors to include new techniques, guidelines and more detailed descriptions of procedures.</p> <p>Change schedule fees accordingly.</p>	<p><i>Context</i></p> <p>These groups of procedures have evolved considerably since their MBS items were created. Today's procedures are more precise, complex and time-consuming but result in better outcomes for women, with shorter recovery times, as well as improved life expectancy and quality of life. New techniques, such as nerve-sparing surgery and fertility-sparing cervical removal, have also been developed and incorporated into the standard procedures.</p> <p>The changes in gynaecological oncology have been important enough that leading clinicians have developed specific clinical guidelines, based on the latest research. These offer expert guidance on the best way to manage particular types of cancer. However, due to the complexity of cancer care, they can be hundreds of pages long and difficult for clinicians to follow diligently.</p> <p><i>Observations</i></p> <p>Because of this change over time, the few existing MBS items are not detailed enough to properly describe the modern procedures or the best forms of treatment for each specific cancer. They also do not account for the difference a cancer's severity makes to a procedure's complexity and duration. Currently, the same item must be used for operations that take anywhere from 4–10 hours. This lack of detail limits women's understanding of the procedures they receive, as well as their ability to receive the right level of rebate that reflects the complexity of their surgery.</p> <p><i>Recommendations</i></p> <p>The Committee recommended splitting these items according to the practical levels of complexity involved in each, and modifying the wording and schedule fees of these items accordingly.</p>	<p>Splitting and rewording the MBS items for these procedures, and adding commonly used new techniques, will provide clarity and consistency in clinical practice and reduce variation in billing.</p> <p>Adding extracts from the latest guidelines to items' descriptors and explanatory notes will assist clinicians in providing high-quality care.</p> <p>Introducing schedule fees that more closely reflect the actual complexity and duration of surgery should allow more appropriate reimbursement for women and clinicians.</p> <p>These new MBS items should not adversely affect access for women, as these surgeries were previously claimed using the existing items.</p>



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**Multiple items**

Change descriptors to include special treatment requirements.

*Context and observations*

Cancer surgery can be among the most technically demanding in medicine, and research has shown that women's results from surgery are better when their procedure is performed by someone who has had specialised training and experience in cancer surgery. Ideally, a woman's condition will first be assessed by a gynaecological cancer multidisciplinary team (MDT) of specialised clinicians, who can combine their expertise to decide on the best treatment plan. MDTs have been formed at many top hospitals around Australia, and referral pathways are in place from healthcare facilities around the country.

*Recommendations*

For procedures where the benefits of seeing an experienced clinician are especially clear, the Committee has recommended that the relevant items should only be claimed if an MDT has reviewed a woman's condition.

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Adding an MDT review requirement to some items is intended to improve women's safety and experience of their treatment, and to encourage clinicians to follow best clinical practice.



## Appendix D – Glossary

Term	Description
AMH	Anti-Mullerian hormone
ANZARD	Australian & New Zealand Assisted Reproduction Database
ART	Assisted reproductive technologies; refers to various clinical and laboratory procedures aimed at allowing subfertile or infertile couples to conceive a baby.
ARTWG	Assisted Reproductive Technologies Working Group
AUB	Abnormal uterine bleeding
BMI	Body Mass Index
CAGR	Compound annual growth rate, or the average annual growth rate over a specified time period.
Change	When referring to an item, 'change' describes when the item and/or its services will be affected by the recommendations. This could result from a range of recommendations, such as: (i) specific recommendations that affect the services provided by changing item descriptors or explanatory notes; (ii) the consolidation of item numbers; and (iii) splitting item numbers (for example, splitting the current services provided across two or more items).
CIN	Cervical intraepithelial neoplasia
CLBR	Cumulative live birth rate (equivalent to cumulative live delivery rate)
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
Department, The	Australian Government Department of Health
Embryo	A collection of living cells resulting from the fertilisation of an egg cell by a sperm cell. Specifically refers to these cells during the period from approximately the second to the eighth week after fertilisation.
ESH	European Society for Hysteroscopy
Fresh cycle	Used to describe an ART cycle in which an embryo is transferred into a woman's uterus without first being frozen and thawed in a laboratory. A fresh transfer usually takes place soon after the ART cycle concerned.
Frozen/thaw cycle	Used to describe an ART cycle in which an embryo is transferred into a woman's uterus only after being frozen and thawed in a laboratory. A frozen/thaw transfer can take place months or years after the ART cycle that produced it was conducted.
FY	Financial year
GGWG	General Gynaecology Working Group
GOWG	Gynaecological Oncology Working Group
GP	General practitioner
High-value care	Services of proven efficacy reflecting current best medical practice, or for which the potential benefit to consumers exceeds the risk and costs.
HMB	Heavy menstrual bleeding
HPV	Human papilloma virus
HSIL	High-grade squamous intraepithelial lesions
ICS	International Continence Society
ICSI	Intracytoplasmic sperm injection; a laboratory procedure in which a sperm cell is directly injected into an egg cell, resulting in fertilisation.
ICS-GUP	International Continence Society Good Urodynamic Practices and Terms 2016



Inappropriate use/misuse	The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.
IUD	Intrauterine device
IVF	In vitro fertilisation; one of the major forms of ART treatment. Technically, this term applies to only a defined portion of the full ART treatment (mixing of sperm and eggs in a laboratory to produce an embryo). However, in practice, this term generally refers to a full stimulated cycle of ART treatment, which involves administering drugs to a woman in order to stimulate the ovaries to release more eggs than usual. Those eggs are then retrieved using a specialised needle and syringe system and mixed with sperm in a laboratory until fertilisation takes place. The resulting embryo(s) are then incubated until they have matured to a suitable level for transfer into a woman's uterus.
LARC	Long-acting reversible contraceptive
LAVH	Laparoscopic assisted vaginal hysterectomy
LNG-IUD	Levonorgestrel intrauterine system, principally marketed in Australia as Mirena®
Low-value care	Services that evidence suggests confer no or very little benefit to consumers; or for which the risk of harm exceeds the likely benefit; or, more broadly, where the added costs of services do not provide proportional added benefits.
MBS	Medicare Benefits Schedule
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, consisting of an item number, service descriptor and supporting information, schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure or test to which the relevant MBS item refers.
MCRP	Medicare Claims Review Panel
MDT	Multidisciplinary team; a team that can consist of clinicians, nurses, ancillary service providers and scientists, and that reviews and discusses complex medical cases with a view to producing and delivering optimally planned and coordinated care plans for patients.
Misuse (of MBS item)	The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.
MSAC	Medical Services Advisory Committee
New service	Describes when a new service has been recommended, with a new item number. In most circumstances, new services will need to go through the MSAC. It is worth noting that implementation of the recommendation may result in more or fewer item numbers than specifically stated.
NHMRC	National Health and Medical Research Council
No change	Describes when the services provided under these items will not be changed or affected by the recommendations. This does not rule out small changes in item descriptors (for example, references to other items, which may have changed as a result of the MBS Review or prior reviews).
Obsolete services/items	Services that should no longer be performed because they do not represent current clinical best practice and have been superseded by superior tests or procedures.
Oocyte	An egg cell (technically also known as the female gamete)
PBS	Pharmaceutical Benefits Scheme
PCOS	Polycystic ovary syndrome
PGD	Pre-implantation genetic diagnosis
PGS	Pre-implantation genetic screening
RANZCOG	The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RTAC	Reproductive Technology Accreditation Committee
Services average annual growth	The average growth per year, over five years to 2014–15, in utilisation of services. Also known as the compound annual growth rate (CAGR).



Stimulated cycle (ART)	A treatment involving the administration of special drugs that cause a woman's ovaries to release more eggs in a given month than is usual.
The Committee	The Gynaecology Clinical Committee of the MBS Review
The Taskforce	The MBS Review Taskforce
TLH	Total laparoscopic hysterectomy
Total benefits	Total MBS benefits paid in the 2015–16 financial year, unless otherwise specified.
TVT	Tension-free vaginal tape
UGWG	Urogynaecology Working Group
VIN	Vulvar intraepithelial neoplasm