Medicare Benefits Schedule Review Taskforce

Report from the Pathology Clinical Committee—Microbiology

October 2017

Important note

The views and recommendations in this report from the Clinical Committee have been released for the purpose of seeking the views of stakeholders.

This report does not constitute the final position on these items, which is subject to:

- Stakeholder feedback.

Then

- Consideration by the MBS Review Taskforce.

Then, *if endorsed*, consideration by

- The Minister for Health.
- The Government.

Stakeholders should provide comment on the recommendations via mbsreviews@health.gov.au.

Confidentiality of comments:

If you would like your feedback to remain confidential, please mark it as such. It is important to be aware that confidential feedback may still be subject to access under freedom of information law.

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1. Executive summary

The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 5700 items on the MBS can be aligned with contemporary clinical evidence and practice and improve health outcomes for patients. The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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 each of these four 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 program 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 issues identified by the Committee in the course of its deliberations.

The recommendations from the Clinical Committees are released for stakeholder consultation. The Clinical Committees will consider feedback from stakeholders then provide recommendations to the Taskforce in a Review Report. The Taskforce will consider the Review Report from Clinical Committees and stakeholder feedback before making recommendations to the Minister for Health, for consideration by Government.

1.1 MBS Review process

The Taskforce has endorsed a process whereby the necessary clinical review of MBS items is undertaken by Clinical Committees and Working Groups. The Taskforce asked all committees in the second tranche of the Review process to review MBS items using a framework based on Appropriate Use Criteria accepted by the Taskforce. [1] This framework includes the following steps:

- Review data and literature relevant to the items under consideration.
- Identify MBS items that are potentially obsolete, are of questionable clinical value, are misused and/or pose a risk to patient safety.
- Develop and refine recommendations for these items, based on the literature and relevant data, in consultation with relevant stakeholders.

In complex cases, full Appropriate Use Criteria were developed for an item's descriptor and explanatory notes. All second-tranche committees involved in this Review adopted this framework, which is outlined in more detail in Section 2.3.

The recommendations from the Clinical Committees will be released for stakeholder consultation. The Clinical Committees will consider feedback from stakeholders and then provide

recommendations to the Taskforce in Review reports. The Taskforce will consider the Review reports from Clinical Committees, along with stakeholder feedback, before making recommendations to the Minister for Health for consideration by the Government.

1.2 The Pathology Clinical Committee

The Pathology Clinical Committee (the Committee) was established in 2016 to make recommendations to the MBS Review Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise.

Most recommendations relating to these items are included in this report for consultation. The Committee also provided recommendations on items that will be referred to other committees for consultation.

An inclusive set of stakeholders is now engaged in consultation on the recommendations outlined in this report. Following this period of consultation, the recommendations will be finalised and presented to the Taskforce. The Taskforce will consider the report and stakeholder feedback before making recommendations to the Minister for Health for consideration by the Government.

1.3 Recommendations

The Committee has highlighted its most important recommendations below. The complete recommendations (and the accompanying rationales) for all items can be found in Section 4. Recommendations developed for referral to other committees are presented in Section 5.
A complete list of items, including the nature of the recommendations and the page number for each recommendation, can be found in Appendices A and B (in table summary form).

1.3.1 Recommendations for consultation

The Committee's recommendations for stakeholder consultation are that:

- 24 items should be deleted from the MBS
- 20 items should be changed
- 26 items should remain unchanged.

The Committee has proposed 16 new items; with seven expected to be referred to the Medicare Services Advisory Committee (MSAC).

These changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system.

Significant recommendations are summarised below.

- **Anatomical and physiological system framework for microbiology testing using nucleic acid amplification techniques (NAAT).** Split the current generic molecular items (69494, 69495 and 69496) into system-specific MBS items for nucleic acid amplification test (NAAT), allowing for more meaningful data collection on molecular testing.
- **Hepatitis serology.** Propose a new (ideal) model to align with current hepatitis guidelines, noting that this new model will require the development of decision support software, education of requesters and enhanced pathology laboratory information management systems to support implementation. In the interim, an alternative model is also proposed (interim model) which will have one merged item to cover any and all tests for hepatitis viruses A, B and

C, including checking immune status and diagnosing or monitoring acute or chronic hepatitis, three or more tests. New item number for the investigation of hepatitis D or E.

- **Serology items/EBV.** Reinstate the old serology item number 69399 for six or more tests and delete separate Epstein–Barr virus (EBV) items 69472 and 69474 and merge these into the serology items to simplify the Schedule.
- **Site-specific culture and microscopy tests.** Amend the descriptors of items 69303, 69306, 69312 and 69318 to remove the inclusion of microscopy and culture on specimens from other sites.
- **HIV/STI Rule 3 exemption.** Apply Rule 3 exemption to HIV/STI testing (chlamydia and gonorrhoea NAAT testing and HIV serology) in the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine's (ASHM) proposed high-risk population.
- **Complicated hospital specimens.** Revise and separate/split the current item 69321 to recognise the different complexity associated with testing specimens from different sites. Create an item for the microscopy and culture of (a) post-operative wounds or operative or biopsy specimens, and an item for (b) aspirates of body fluids, synovial fluids and CSF.

1.3.2 Recommendations for referral to other committees

The Committee's recommendations to be referred to MSAC Executive for their consideration:

- **Orthopaedic tissues—new service.** The Committee recommends the introduction of a new MBS item for the collection of > 3 and ≤ 5 samples to determine prosthetic joint infections.

The Committee's recommendations to be referred to MSAC for their consideration:

- **Reflex cultures—new service.** The Committee recommends the introduction a new MBS item to fund the reflex culture of a specimen (and, when applicable, sensitivity testing) when culture independent method of identification reveals a microbial pathogen of public health significance.
- **Packaging a microbial isolate of public health significance for transport to a reference laboratory—new service.**
- **Testing for multi-resistant organism (MRO) from appropriate sites—new service.**

1.4 Consumer engagement and impact

The Committee includes experienced and committed health practitioners and consumer representatives. This section summarises the report's key recommendations from a consumer perspective. It aims to make it easier for health consumers and members of the general public to understand the report's recommendations.

A complete list of the recommendations can be found in Appendix C, including a description in plain English of the medical service and the Committee's recommendation, as well as an explanation of why the recommendation has been made.

Consumers rarely engage with MBS item numbers unless they are following up on out-of-pocket expenses. Nevertheless, item descriptions and restrictions are an important part of healthcare accountability. The Committee's recommendations encourage agreed best practice and reflect current clinical evidence.

Both consumers and clinicians are expected to benefit from these recommendations because they address concerns regarding consumer safety and quality of care, and take steps to simplify the MBS

and make it easier to use and understand. Consumer access to services was considered for each recommendation. The Committee also considered the impact of each recommendation on requestor and provider groups to ensure that 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.

The Committee expects these recommendations to support better requesting, with the aim of ensuring that patients are provided with clinically indicated, high-quality care that reflects modern best practice.

The consumer representatives used the following framework to assess recommendations:

Safety: None of the recommendations negatively affects the safety of pathology services.

Quality: Many of the recommended changes are intended to improve quality, primarily by aligning the reimbursement system with evidence-based practice.

Access: The recommendations do not negatively affect appropriate access. However, some patient groups have been receiving services they do not need, which can result in either negative health impacts or unnecessary cost. Inappropriate access was restricted where possible.

Effectiveness: None of the recommendations reduces the effectiveness of pathology services.

Cost-effectiveness: The recommendations will have a positive effect on cost-effectiveness because they make it easier to determine which patient groups should have access to specific tests and treatments.

Accountability: Many of the changes include wording that facilitates future auditing for quality purposes.

Data collection: Data collection for research, monitoring and auditing presents a huge opportunity for a revised MBS, and the recommendations should improve the opportunities to use this data for targeted research in the future.

2. About the Medicare Benefits Schedule (MBS) Review

2.1 Medicare and the MBS

2.1.1 What is Medicare?

Medicare is Australia's universal health scheme, which 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); and subsidised health professional services listed on the Medicare Benefits Schedule (MBS).

2.1.2 What is the MBS?

The MBS is a listing of the health professional services subsidised by the Australian Government. There are more than 5700 MBS items, which provide benefits to patients for a comprehensive range of services including consultations, diagnostic tests and operations.

2.2 The MBS Review Taskforce

2.2.1 What is the MBS Review Taskforce?

The Government established an MBS Review Taskforce (the Taskforce) to review all 5700 MBS items to ensure that they align with contemporary clinical evidence and practice, and to improve health outcomes for patients. The Review is clinician-led, and there are no targets for savings attached to the Review. Following stakeholder feedback, the Taskforce will present its recommendations to the Minister for Health for consideration by the Government.

2.2.2 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-serviced.
- 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.

2.3 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 to review MBS items using a framework based on Appropriate Use Criteria accepted by the Taskforce. [1] The framework consists of seven steps:

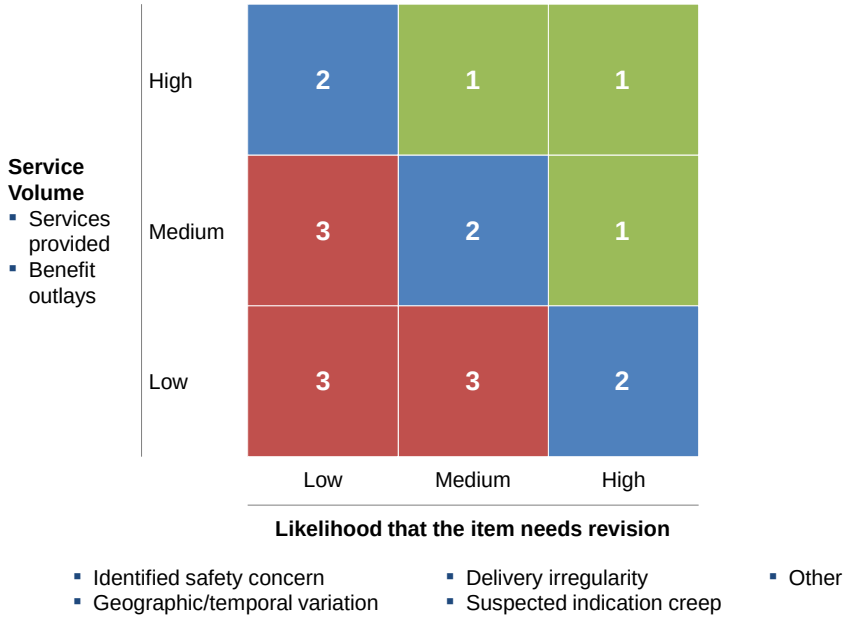
- Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.
- Identify items that are obsolete, are of questionable clinical value, are misused and/or pose a risk to patient safety. This step includes prioritising items as 'priority 1,' 'priority 2' or 'priority 3,' using a prioritisation methodology (described in more detail below).
- Identify any issues, develop hypotheses for recommendations and create a work plan (including establishing Working Groups, when required) to arrive at recommendations for each item.
- 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.
- Review the provisional recommendations and the accompanying rationales, and gather further evidence as required.
- Finalise the recommendations in preparation for broader stakeholder consultation.
- 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:

- 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 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 1 to 3 (where priority 1 items are the highest priority and priority 3 items are the lowest priority for review), using a prioritisation matrix (Figure 1). The Committee used this priority ranking to organise its review of item numbers and apportion the amount of time spent on each item.

Figure 1: Prioritisation matrix.



3. About the Pathology Clinical Committee

The Pathology Clinical Committee (the Committee) was established in April 2016 to make recommendations to the Taskforce on MBS items within its remit, based on rapid evidence review and clinical expertise. The Taskforce asked the Committee to review microbiology-related MBS items.

The Committee consists of 19 members, whose names, positions/organisations and declared conflicts of interest are listed in Section 3.1. 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.

3.1 Committee members

Table 1: Pathology Clinical Committee members

Name	Position/organisation	Declared conflict of interest
Associate Professor Peter Stewart	Royal Prince Alfred Hospital (Public)	None
Professor Rita Horvath	South Eastern Area Laboratory Services (Public)	None
Dr Debra Norris	QML Pathology (Primary)	None
Dr Michael Harrison	Sullivan Nicolaides Pathology (Sonic)	None
Associate Professor Ken Sikaris	Melbourne Pathology (Sonic)	None
Dr Melody Caramins	Specialist Diagnostic Services (Primary)	None
Dr John Rowell	Pathology Queensland	None
Professor Dominic Mallon	PathWest	None
Dr Peter Roberts	Ryde Hospital (AESM)	None
Associate Professor Anthony Landgren	Australian Clinical Labs	None
Associate Professor Mary Jo Waters	St Vincent's Pathology (CHA)	None
Professor Richard MacIsaac	St Vincent's Hospital	None
Dr Emil Djakic	General practitioner	None
Dr Bev Rowbotham	MBS Taskforce	None
Dr Jill Thistlethwaite	General practitioner	None
Ms Valerie Hanrahan	Consumers Health Forum	None
Dr Robyn Lindner	NPS MedicineWise	None
Professor Hans Schneider	Alfred Pathology Service (Melbourne)	None
Associate Professor Adrienne Morey	ACT Pathology	None

It is noted that most Committee and Working Group members share a common conflict of interest in reviewing items that are a source of revenue for them (i.e. Committee members provide the services 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.

3.2 Microbiology Working Group

The Microbiology Working Group is one of six clinical working groups that have been established to support the work of the Pathology Clinical Committee. It was established to review microbiology pathology items and make recommendations to the Pathology Clinical Committee based on rapid evidence review and clinical expertise.

The Microbiology Working Group consists of seven members, whose names, positions/organisations and declared conflicts of interest are listed in Table 2 below.

Table 2: Microbiology Working Group members

Name	Position/Organisation	Declared conflict of interest
A/Professor Mary Jo Waters (Chair)	St Vincent's Pathology (CHA)	Employed by private provider of MBS items under discussion
Dr Jenny Robson	Sullivan Nicolaides Pathology (Sonic)	Employed by private provider of MBS items under discussion
Dr Sasha Jaksic	Dorevitch Pathology (Primary)	Employed by private provider of MBS items under discussion
Dr Rob Hosking	General Practitioner	None
Dr Ian Woolley	Monash Health	None
Dr Stuart McMaster	General Practitioner	None
Ms Diane Walsh	Consumer	None

3.3 Areas of responsibility of the Committee

The Committee was assigned 66 MBS microbiology items and four referred items to review (MBS 2014–15). A complete list of these items can be found in Appendix A.

3.4 Summary of the Committee's review approach

The Committee completed a review of 66 microbiology items and four referred items across eight meetings, during which it developed the recommendations and rationales outlined in Section 4. Recommendations were also developed for referral to other committees. These are outlined in Section 5.

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)
- additional provider and patient-level data, when required.

The review also drew on data presented in the relevant literature and clinical guidelines, all of which are referenced in the report.

An inclusive set of stakeholders is now engaged in consultation on the recommendations resulting from this process, which are outlined in this report. Following this period of consultation, the Committee will consider stakeholder feedback before finalising the recommendations and presenting them to the Taskforce. The Taskforce will consider the report and stakeholder feedback before making recommendations to the Minister for Health for consideration by the Government.

4. Recommendations for consultation

Introduction

The Committee reviewed 66 assigned microbiology items and four referred items and made recommendations based on evidence and clinical expertise, in consultation with relevant stakeholders. The item-level recommendations are described below. A summary list of recommendations can be found in Appendices A and B, and the Consumer Summary table in Appendix C.

The Committee's recommendations for public consultation are that 24 items should be deleted (and their services are no longer provided under the MBS), 20 items should be changed, and 26 items should remain unchanged. The Committee has proposed 16 new items and referred seven items to other Committees.

The changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system. Some of this can be achieved by:

- deleting items that are obsolete
- consolidating or splitting items to reflect contemporary practice
- modernising item descriptors to reflect best practice
- providing clinical guidance for appropriate use through explanatory notes.

The recommendations are presented by item groups, with higher priority groups presented first. In circumstances where the Committee would have preferred to recommend a change, but for various reasons have elected not to, the full discussion has been included for the record.

4.1 System framework for microbiology testing using nucleic acid amplification tests (NAAT)

Table 3: Item introduction table for items 69494—69498

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69494	Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified) 1 test (Item is subject to rule 6 and 26)	$28.65	$5,694,326	234 606	223 039	–0.6%
69495	2 tests described in 69494 (Item is subject to rule 6 and 26)	$35.85	$5,736,362	189 173	180 461	4.8%
69496	3 or more tests described in 69494 (Item is subject to rule 6 and 26)	$43.05	$26,882,403	734 647	648 876	33.9%
69497	A test described in item 69494, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rule 6, 18 and 26)	$28.65	$731,499	30 173	28 561	–8.2%
69498	A test described in item 69494, other than that described in 69497, if rendered by a receiving APP - each test to a maximum of	$7.20	$551,862	90 106	53 183	–0.5%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	2 tests (Item is subject to rule 6, 18 and 26)					

4.1.1 Recommendation 1: Overall recommendation

- Δ Create new MBS items for NAAT in accordance with an anatomical and physiological system framework.
- Δ Retain the generic NAAT item number 69494, with relevant restrictors.
- Δ Delete items 69495 and 69496.

The ability to accurately and quickly identify microbial agents associated with infectious diseases has been a longstanding and continuous goal of diagnostic microbiology laboratories. Over the course of several decades, technology and testing methodologies in this field have gradually evolved from traditional culture-based identification approaches to antigen capture systems and molecular tests. The most commonly used molecular tests are the nucleic acid amplification tests (NAAT), which include the polymerase chain reaction (PCR). With commercial introduction, these tests make up an increasing proportion of the diagnostic workload of microbiology laboratories.

Over recent years NAAT has been augmenting microscopy and/or culture-based methods that require the use of selective agars and enrichment broths. Unlike traditional culture-based methods, NAAT often have a higher sensitivity than culture (which has been considered the 'gold standard') and a shorter turnaround time. Although this testing can be very cost effective and time efficient, the test has its limitations, and NAAT on some specimens are yet to be validated.

Nonetheless, the Committee has acknowledged the move towards molecular testing and has made the recommendation to structure the current microbiology NAAT MBS items to an anatomical and physiological system framework; a model that will recognise that there has been, and will continue to be, a shift towards molecular testing for many organisms. Microscopy and culture testing is still relevant for many organisms and will be required as separate items for many conditions.

Table 3 shows the current item numbers for NAAT. The aim of the anatomical and physiological system framework is to split the current generic molecular items (69494, 69495 and 69496) into system-specific MBS items, allowing for more meaningful data collection on molecular testing. The model will allow for more granular data collection regarding the broad sources for testing and also provides the opportunity to limit the potential to co-claim NAAT and culture testing, as has been observed for testing faeces.

The Committee acknowledged, that while the intent of the proposal is not to increase the net funding of molecular items, it is proposed the restructure will result in some 'savings' through limiting co-claiming, particularly for faeces, which could be redistributed to other system panels within the model. The model will also avoid the practice of over-testing by introducing more specific item descriptors, and promote appropriate testing when NAAT has proven clinical utility.

The Committee proposes several separate MBS items, following a primarily systems-based approach. In summary, the system structure for NAAT is as follows:

- Δ Gastrointestinal, covering bacterial, parasite, viral.
- Δ Urogenital/sexually transmissible infections (STIs), encompassing bacterial, fungal, parasite, viral.

- Respiratory—bacterial, viral.
- Mycobacterial—*Mycobacterium tuberculosis* and antibiotic resistance testing.
- Skin/superficial—bacterial, viral and fungal/dermatophytes.
- Sterile site (e.g. blood/central nervous system/ocular).
- Miscellaneous (not specified elsewhere)—bacterial, fungal, viral and parasites as per current item 69494. Most tests will be covered by the new anatomical and physiological system-based items and this item should be rarely used. It should be rare for more than one test to be required.
- Hepatic (hepatitis C virus [HCV], hepatitis B virus [HBV]), with items to remain as per current MBS Schedule
- HIV, with items to remain as per current MBS Schedule items except for deletion of item 69382.
- The proposed anatomical and physiological system structure provides a framework around which the model could be further developed into a 'syndromic' model in the future. The development of information technology (IT) systems to support integrated decision support will provide opportunities to extend the schedule to a syndromic model.

4.1.2 Rationale 1: Overall rationale

The Committee proposes that an anatomical and physiological system structure of MBS items for molecular tests would provide more meaningful information to health authorities. The recommendations focus on modernising the MBS and encouraging best practice and are based on the following observations.

- Maintaining the current simple 'generic' structure (Table 4) of molecular items within the MBS Schedule may meet short-term objectives but fails to consider the opportunities of inevitable future developments, particularly with the increasingly widespread adoption of culture-independent diagnostic tests (CIDT), potential point of care testing, and whole genome sequencing (WGS)/next generation sequencing (NGS) technology for identifying pathogens and antimicrobial resistance profiles. Since the pandemic flu of 2009, most private and many public laboratories are now performing respiratory NAAT.
- Private pathology laboratory data indicated that molecular testing in microbiology is increasing, with chlamydia/gonorrhoea, respiratory, and faeces molecular testing within the top 10 microbiology tests ordered.
- Many pathology laboratories have developed multiplex panels covering key pathogens; for example, standard viral panels for respiratory illness and additional panels for when more serious illness is suspected (e.g. pertussis, atypical organisms, pneumonias, etc.). In a future syndromic framework, pathology laboratories would be more able to provide targeted guidance to requesters, potentially reducing the ordering of inappropriate and unnecessary tests.
- A syndromic framework of MBS items would enable decision support for electronic pathology ordering, with tests recommended based on a patient's clinical history.
- The following example outlines the proposed systems model and the opportunity for a future syndromic model.

Table 4: Proposed system structure and example of potential future syndromic structure

Current generic item 69494	Proposed item for anatomical and physiological system	Potential syndromic items (examples)
Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified) 1 test (Item is subject to rule 6 and 26)	Respiratory Detection of viral, atypical pneumonia pathogens and *Bordetella* sp. nucleic acid from nasal swabs, throat swabs, nasopharyngeal swabs, nasopharyngeal aspirates and lower respiratory tract samples. Specimens from 1 or more sites. 3 tests or more	Acute upper respiratory tract Acute lower respiratory tract Sinusitis Otitis media Persistent cough Community-acquired pneumonia Hospital-acquired pneumonia Cystic fibrosis and bronchiectasis Pneumonia in the immunocompromised

4.2 Gastrointestinal: Clostridium difficile/faeces

Table 5: Item introduction table for item 69363, 69336, 69339, 69345

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69363	Detection of Clostridium difficile or Clostridium difficile toxin (except if a service described in item 69345 has been performed) - one or more tests	$28.65	$304,513	13 372	11 440	15.0%
69336	Microscopy of faeces for ova, cysts and parasites that must include a concentration technique, and the use of fixed stains or antigen detection for cryptosporidia and giardia - including (if performed) a service mentioned in item 69300 - 1 of this item in any 7 day period	$33.45	$11,995,269	419 544	376 226	8.1%
69339	Microscopy of faeces for ova, cysts and parasites using concentration techniques examined subsequent to item 69336 on a separately collected and identified specimen collected within 7 days of the examination described in 69336 - 1 examination in any 7 day period	$19.10	$519,029	32 302	30 282	1.0%
69345	Culture and (if performed) microscopy without concentration techniques of faeces for faecal pathogens, using at least 2 selective or enrichment media and culture in at least 2 different atmospheres including (if performed): (a) pathogen identification and antibiotic susceptibility testing; and (b) the detection of clostridial toxins; and (c) a service described in item 69300; - 1 examination in any 7 day period	$52.90	$24,919,729	550 526	488 348	7.7%

4.2.1 Recommendation 2

Δ Create a new item for faecal PCR, culture and microscopy—item 693XA.

Δ Merge item 69336 into new item 693XA and delete item 69336.

- Amend item 69339 (subsequent microscopy within 7 days) to make reference to new item 693XA.
- Merge item 69345 into the new combination item 693XA and delete item 69345.
- Amend item 69363 to include NAAT and add guidance on specimen collection in the explanatory notes.
- Refer to section 5.2.2 for recommendation regarding reflex culture for isolates of public health significance.

Table 6: Proposed changes to tests for gastrointestinal pathogens

Item	Current descriptor	Proposed change to descriptor
69363	Detection of Clostridium difficile or Clostridium difficile toxin (except if a service described in item 69345 has been performed) - one or more tests.	Any test for the detection of toxigenic *Clostridium difficile* in unformed stool or bowel tissue including a test for toxin protein detection if positive – one or more tests. Note / Rule: Test is only to be performed on an unformed stool. As per guidelines, if negative do not repeat within 7 days.
693XA		Any combination of tests to detect gastrointestinal pathogen in unformed stool including the detection of bacterial, viral and parasite nucleic acid and/or culture using at least 2 selective or enrichment media in at least 2 different atmospheres including (if performed): (a) pathogen identification and antibiotic susceptibility testing; and (b) a service described in item 69300; - 1 examination in any 7 day period.
69339	Microscopy of faeces for ova, cysts and parasites using concentration techniques examined subsequent to item 69336 on a separately collected and identified specimen collected within 7 days of the examination described in 69336 - 1 examination in any 7 day period.	Microscopy of faeces for ova, cysts and parasites using concentration techniques examined subsequent to item 693XA on a separately collected and identified specimen collected within 7 days of the examination described in 693XA - 1 examination in any 7 day period.

4.2.2 Rationale 2

These recommendations focus on ensuring best practice and are based on the following observations.

- Since 2013, many laboratories in Australia have introduced a more sensitive and time-saving technique (multiplex PCR), which detects *Entamaoeba histolytica, Giardia lamblia, Cryptosporidium spp., Blastocystis* spp and *Dientamoeba fragilis*, to screen for protozoa in faeces, with potential to replace detection by microscopy, which is both subjective and time consuming. After the introduction of PCR the number of positives for these parasites has increased markedly—up to 20% of all faeces specimens received in the laboratory. The increase has predominantly (approximately 75% of total) been due to *Blastocystis spp* and *Dientamoeba fragilis*. Pathogenicity of *Blastocystis* spp and *Dientamoeba fragilis* has not been established in humans. Positive results are predominantly in children and in formed or semi-formed faeces and rarely in loose faeces. [2], [3] This has reportedly resulted in increased medical consultations and unnecessary use of antimicrobials, along with anxiety and uncertainty for families. [2]
- Advice from Australia and New Zealand Paediatric Infectious Diseases (ANZPID) Group of Australasian Society for Infectious Diseases (ASID) and RCPA suggests that *Giardia,*

Cryptosporidium and E. histolytica should be reported, with unnecessary reporting of *Dientamoeba fragilis* or *Blastocystis hominis* avoided. [2], [3]

- The increase in notifications for both parasites and bacterial enteropathogens to the National Notifiable Diseases Surveillance System (NNDSS) is supported by MBS data. Item 69345 faeces culture and item 69496 PCR (three or more tests) have had an annual growth rate of 200% over 2012–2016. Significantly, many notifications for bacterial enteropathogens are by PCR and not culture.
- The rationale behind combining NAAT, microscopy and culture is to encourage pathologists to perform the most appropriate test in accordance with clinical notes of the request and thus to prevent unnecessary testing.
- While NAAT tests may eventually be the first test of choice for many organisms, microscopy and culture still need to be retained within the MBS to allow access to these tests in rural or remote areas where NAAT may not yet be available, and for when a pathogen is not included in the NAAT panel, for example, *Vibrio cholera.*
- Maintaining a specific item for *Clostridium difficile* independent of faeces testing is consistent with 2016 Australian Public Health Laboratory Network laboratory case definition (PHLN LCD) on *C. difficile* testing, which aims to discriminate between clinical disease and colonisation. [4] Testing criteria define the patient groups for which testing is appropriate and outline protocols for repeat testing. The LCD states:
  - Tests for toxigenic *C. difficile* should only be performed on unformed stool specimens (or gut contents from patients with diarrhoea), unless ileus is suspected.
  - All adults and children aged over two years who have been hospitalised for more than 48 hours and develop diarrhoea (more than three unformed stools in a 24-hour period) should be tested for *C. difficile* infection.
  - All adults and children aged over two years in whom diarrhoea has persisted for more than 48 hours and no other enteric pathogen has been identified should be tested for *C. difficile* infection.
  - Repeat testing of faecal specimens during the same episode of diarrhoea is not recommended a) within 4 weeks of a positive test (response to treatment is determined by clinical criteria) or b) after a negative test – unless *C. difficile* infection is strongly suspected and a more sensitive method (e.g. NAAT) is used after a negative immunoassay.
  - Tests for *C. difficile* infection in children less than two years old should be performed in consultation with a paediatrician, specialist microbiologist or approved pathology practitioner (APP).
- The addition of 'unformed stools' in the descriptor of item 69363 is in line with the PHLN LCD and will assist in highlighting that this test is only appropriate if diarrhoea is persisting.
- The Committee acknowledged that the current MBS structure does not limit testing combinations for faeces, but it is expected that the combination of the use of NAAT together with culture and microscopy for many faeces specimens will reduce with the proposed changes. The choice of which tests are most appropriate will be made by the provider.
- MBS items to facilitate referral of isolates of public health significance were recommended in a Health Consult review *Review of culture-independent diagnostic testing*, undertaken at the request of the Department of Health. [5] (See recommendation in Section 5.)

4.3 Urogenital

Table 7: Item introduction table for items 69312, 69316, 69317 and 69319

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69312	Microscopy and culture to detect pathogenic microorganisms from urethra, vagina, cervix or rectum (except for faecal pathogens), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69318; 1 or more tests on 1 or more specimens	$33.75	$23,145,700	800,961	683,298	4.8%
69316	Detection of chlamydia trachomatis by any method - 1 test (Item is subject to rule 26)	$28.65	$4,287,428	175,172	162,785	–9.8%
69317	1 test described in item 69494 and a test described in 69316. (Item is subject to rule 26)	$35.85	$22,175,424	723,841	629,963	12.8%
69319	2 tests described in item 69494 and a test described in 69316. (Item is subject to rule 26)	$42.95	$11,525,384	314,080	269,568	37.4%

4.3.1 Recommendation 3

- Δ Retain microscopy and culture item 69312 with a change to descriptor to include throat swab, and create another duplicate item (693XB) for '2 or more specimens', as multiple sites for testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are recommended in the high-risk groups.
- Δ Create new items, with testing methods not specified, for the detection of pathogenic microorganisms, other than *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, associated with urogenital or sexually transmissible infections (STIs) from urogenital specimens. One specimen (item 693XC), and 2 or more specimens (item 693XD).
- Δ Create new items for NAAT of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* for two or more tests. One specimen (item 693XE), and two or more specimens (item 693XF).
- Δ Delete items 69316, 69317 and 69319.
- Δ Create a new item for screening for carriage of *Streptococcus agalactiae* (group B streptococcus, GBS) from pregnant women at 35–37 weeks' gestation, with NAAT testing at delivery if maternal GBS carriage status is unknown/not known, as per RANZCOG guidelines (item 693XG). [6]
- Δ Refer to section 4.12 for recommendation on rule 3 exemption to HIV/STI testing.
- Δ Refer to section 4.11 for recommendation to remove the inclusion of microscopy and culture on specimens from other sites for item 69312.

  Refer to section 5.2.2 for recommendation regarding reflex culture for isolates of public health significance

Table 8: Proposed changes to tests for urogenital pathogens

Item	Current descriptor	Proposed change to descriptor
69312	Microscopy and culture to detect pathogenic microorganisms from urethra, vagina, cervix or rectum (except for faecal pathogens), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69318; 1 or more tests on 1 or more specimens	Microscopy and culture to detect pathogenic microorganisms from throat (except for respiratory pathogens), urethra, vagina, cervix or rectum (except for faecal pathogens), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; 1 or more tests on 1 or more specimens.
New item 693XB		Microscopy and culture to detect pathogenic microorganisms from throat (except for respiratory pathogens), urethra, vagina, cervix, or rectum (except for faecal pathogens), including (if performed): a) pathogen identification and antibiotic susceptibility testing; b) a service described in item 69300 or 69312; 1 or more tests on 2 or more specimens.
New item 693XC		Detection of pathogenic microorganisms other than *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by any method from urogenital specimens, including (if performed) a service described in 69312. 1 specimen.
New item 693XD		Detection of pathogenic microorganisms other than *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by any method from urogenital specimens, including (if performed) a service described in 69312. 2 or more specimens.
New item 693XE		Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by NAAT. 2 or more tests (Item is subject to rule 26). 1 specimen
New item 693XF		Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by NAAT. 2 or more tests (Item is subject to rule 26). 2 or more specimens.
New item 693XG		Culture for *Streptococcus agalactiae* (GBS) from combined low vaginal swab plus or minus anorectal swab at 35–37 weeks' gestation, or NAAT with reflex culture at delivery and susceptibility testing if performed in women allergic to penicillin.

4.3.2 Rationale 3

The recommendations focus on ensuring best practice and are based on the following observations.

- The *Australian STI Management Guidelines* recommend that specimens are taken from more than one site in certain circumstances for the detection of chlamydia and gonorrhoea, particularly in men or patients in high-risk groups. [7] As such, the Committee recommended to add a new item so pathologists are able to perform microscopy and culture tests on specimens from more than one site through item 693XB.
- Combination items to cover NAAT and microscopy and culture tests for organisms other than chlamydia and gonorrhoea —one specimen (item 693XC), and more than one specimen (item 693XD), are proposed. The descriptor for these does not specify a method and pathologists will determine the most appropriate tests. It is recognised that over time NAAT testing will replace microscopy and culture for many organisms. In the interim, however, the schedule fee for this new item should reflect the current need to use both NAAT and microscopy and culture in a proportion of requests.

- The incidence of gonorrhoea and chlamydia have both increased over the last decade. The requirement for testing for gonorrhoea with chlamydia will help improve the testing rates of gonorrhoea and identify cases earlier. MBS data for items 69316, 69317, and 69319 suggest that fewer than 15% of patients only have chlamydia testing. MBS data do not indicate the current rate of gonorrhoea testing, so it is difficult to estimate how many tests are currently being performed under 69319. Given current concerns regarding the need for widespread testing for gonorrhoea, it was debated whether there should be a new item for combination testing of both gonorrhoea and chlamydia instead of, or as well as, a single test for just chlamydia.
- Advice sought from the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) suggested that chlamydia testing should remain a discrete item, as NAAT for gonorrhoea screening in low-prevalence populations may lead to many false-positive results. The Committee considered this advice but has recommended that testing for both organisms should be encouraged. Concerns regarding false-positive *N. gonorrhoeae* results in low-prevalence populations are less likely, as laboratories adhere to the PHLN guidelines requiring confirmatory testing using an alternative method. [8]
- The items for the detection of chlamydia (items 69316, 69317 and 69319) can be merged to the new items 693XE and 693XF.
- The RANZCOG recommends maternal screening for *Streptococcus agalactiae* at 35–37 weeks' gestation. NAAT testing at delivery has been included in the descriptor, to provide a rapid test for women who have not had screening performed at 35–37 weeks. [9], [10]
- While the Australian Chlamydia Control Effectiveness Pilot (ACCEPt) screening program has been completed, retaining item 69316 was discussed, as there are several platforms that perform single chlamydia test. The Committee decided against this, in preference to encouraging dual testing for both chlamydia and gonorrhoea.
- Chlamydia was the most frequently reported notifiable condition in Australia in 2014, with 86,136 diagnoses; most (78%) of diagnoses were among 15–29-year-olds. [11]
- There were 15,786 cases of gonorrhoea notified in 2014, representing an increased rate in both men (from 62 per 100,000 in 2010 to 99 per 100,000 in 2014) and women (from 30 per 100,000 in 2010 to 38 per 100,000 in 2014). [11]
- Data from NSW show that crude rates of both chlamydia and gonorrhoea have continued to increase steadily since 2014; the number of gonorrhoea notifications was 2608 cases (2166 men, 431 women) in the first quarter of 2017, 58% higher than in the same period in 2015 (1649). The number of chlamydia notifications has also continued to increase in 2017, with 7931 cases (4191 men and 3732 women) in the first quarter, 23% higher than in the same period in 2015 (6455). [12]
- Asymptomatic urethral gonorrhoea in men who have sex with men (MSM) has been reported in a publication from Melbourne Sexual Health. Among men with urethral gonorrhoea (228/5497) the proportions with concurrent pharyngeal or rectal gonorrhoea were 64% (134/210) and 32% (74/235), respectively. [13]
- MBS items to facilitate referral of isolates of public health significance were recommended in a Health Consult review *Review of culture-independent diagnostic testing,* undertaken at the request of the Department of Health. [5] (See recommendation in Section 5.)

4.4 Respiratory

4.4.1 Recommendation 4

Δ Create a new NAAT item for molecular testing of viral, atypical pneumonia pathogens and *Bordetella* species from swabs and lower respiratory tract samples.

Table 9: Proposed changes to tests for respiratory pathogens

Item	Current descriptor	Proposed change to descriptor
New item 693XH		Detection of viral, atypical pneumonia pathogens and *Bordetella* spp. nucleic acid from nasal swabs, throat swabs, nasopharyngeal swabs, nasopharyngeal aspirates and lower respiratory tract samples. Specimens from 1 or more sites. 3 tests or more.

4.4.2 Rationale 4

The recommendations focus on modernising the MBS and are based on the following observations.

Δ The aim is to create a new NAAT item for relevant respiratory tests that have clinical utility and impact on patient management and outcome.

Δ Due to improved accuracy and speed of NAAT in confirming the diagnosis of specific respiratory tract infections such as atypical pneumonia, clinicians are able to instigate earlier targeted treatment of viral or bacterial infections, avoiding inappropriate antibiotic therapy.

Δ Pathogens tested for might include, but not be limited to, influenza viruses A and B, respiratory syncytial virus (RSV) and parainfluenza viruses 1, 2, 3, 4, human metapneumovirus (HMPV), rhinovirus, adenovirus, *B. pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, C. psittaci* and *Legionella*.

Δ Separating and creating a specific item number for respiratory specimens will allow ongoing monitoring of respiratory PCR.

Δ The Committee acknowledged that cost modelling will be required to estimate the impact of these changes and that changes across the MBS should be cost-neutral. Over time there should be a shift away from respiratory pathogen serology testing to molecular testing on respiratory specimens. This is already occurring, with some laboratories promoting more specific and sensitive NAAT for certain respiratory viruses in place of serology testing.

4.5 Mycobacteria

4.5.1 Recommendation 5

Δ Create a new NAAT item for the detection of *M. tuberculosis* (MTB) and antimicrobial molecular resistance markers using NAAT from respiratory or non-pulmonary specimens. This will require an MSAC submission.

Table 10: Proposed changes to tests for *M. tuberculosis*

Item	Current descriptor	Proposed new descriptor
New item 693XI		Detection of *M. tuberculosis* and antimicrobial resistance markers using nucleic acid amplification techniques from respiratory or non-pulmonary specimens where there is high clinical suspicion.

4.5.2 Rationale 5

The recommendation focuses on ensuring best practice and is based on the following observations.

- The Committee identified the clinical need to rapidly confirm the presence of *M. tuberculosis,* as well as rifampicin resistance, as this will alter patient management. The accuracy of NAAT compared with that of culture-based drug susceptibility testing indicates that NAAT can accurately identify patients with rifampicin-resistant *M. tuberculosis* infection. Determining resistance through NAAT could inform the type of antibacterial treatment offered to patients with tuberculosis (TB), thereby avoiding potential side effects such as hepatitis from inappropriate use of rifampicin. Early identification of rifampicin-resistance can influence treatment decisions, ensuring that appropriate anti-TB drugs are given immediately, thus reducing the likelihood of a patient developing multi-drug-resistant TB. [14]
- Current Australian National Tuberculosis Advisory Committee (NTAC) guidelines date from 2006. These state that NAAT is only indicated in particular circumstances (e.g. patients with negative smears, considered at high risk of TB), that these circumstances are the exact instances in which NAAT performance is imperfect (e.g. NAAT detects only one-half to two-thirds of TB patients with negative smears), and that further clinical, public health, and economic research is required to determine the proper indications for TB NAAT testing. [15] As such, a specific MBS item for the detection of *M. tuberculosis* by NAAT was rejected by MSAC in 2015. [14]
- However, the NTAC guidelines are currently being updated and are in draft stage. The new guidelines are likely to provide the most recent evidence update on NAAT testing, which may warrant changes to the MBS.
- In addition, a new Xpert® MTB/RIF Ultra assay with sensitivity to liquid-based culture has become available. The Ultra assay should significantly increase TB detection in patients with negative smears and provide more reliable rifampicin-resistance detection.

4.5.3 Recommendation 5A (amendment) IGRA tests for latent tuberculosis

- In response to a submission from the consultation process, in keeping with contemporary clinical practice and World Health Organization guidance, that interferon gamma release assay (IGRA) tests are valid for the diagnosis of latent tuberculosis and can benefit individual patients. As such, item 69471 has been amended to ensure IGRA tests are MBS funded for latent tuberculosis in all circumstances where such a diagnostic test is clinically isolated.

Table 11: Proposed changes IGRA tests for latent tuberculosis

Item	Current descriptor	Proposed new descriptor
69471	Test of cell-mediated immune response in blood for the detection of latent tuberculosis by interferon gamma release assay (IGRA) in the following people: (a) a person who has been exposed to a confirmed case of active tuberculosis; (b) a person who is infected with human immunodeficiency virus; (c) a person who is to commence, or has commenced, tumour necrosis factor (TNF) inhibitor therapy; (d) a person who is to commence, or has commenced, renal dialysis; (e) a person with silicosis; (f) a person who is, or is about to become, immunosuppressed because of a disease, or a	Test of cell-mediated immune response in blood for the detection of latent tuberculosis by interferon gamma release assay (IGRA), where clinically indicated.

Item	Current descriptor	Proposed new descriptor
	medical treatment, not mentioned in paragraphs (a) to (e)	

4.6 Skin and superficial sites

4.6.1 Recommendation 6

Δ Create a new NAAT item for the detection of pathogenic organisms from skin or superficial site specimens.

Table 12: Proposed changes to tests for skin and superficial site pathogens

Item	Current descriptor	Proposed new descriptor
New item 693XJ		Detection of pathogenic organisms including dermatophyte detection from skin or superficial site specimens using nucleic acid amplification techniques (NAAT).

4.6.2 Rationale 6

The recommendation focuses on modernising and simplifying the MBS and is based on the following observations.

Δ Guidelines recommend culture and microscopy for most skin infections; however, some aetiological agents may require NAAT, including, but not limited to, herpes simplex virus (HSV) 1 and 2, varicella zoster virus (VZV), enterovirus (hand foot and mouth disease), pox viruses, molluscum contagiosum and rickettsial infection. [16]

Δ Currently molecular testing utilises item numbers 69494, 69495 and 69496. Separating and creating a specific PCR item number for skin and superficial sites will allow ongoing monitoring of skin and superficial site PCR.

Δ It is important for patients to know the status of their skin lesions, as the implications for HSV1 and 2 infection will be different to those of VZV. This also has public health implications. The same may be said for enteroviral infection, as some types may be harbingers for epidemics associated with neurological manifestations, such as acute flaccid paralysis or meningoencephalitis.

4.7 NAAT for complicated hospital specimens or sterile sites

4.7.1 Recommendation 7

Δ Create a new NAAT item for the detection of pathogenic organisms from sterile sites such as the central nervous system (CNS) and ocular specimens.

Table 13: Proposed changes to tests for sterile site pathogens

Item	Current descriptor	Proposed new descriptor
New item 693XK		Detection of pathogenic organisms from sterile sites, CNS and ocular specimens using nucleic acid amplification techniques (NAAT).

4.7.2 Rationale 7

The recommendation focuses on modernising the MBS and is based on the following observations.

- There is a clinical need to perform NAAT on complex sterile fluids such as CNS and ocular specimens. The management of viral meningitis and encephalitis differs significantly to that of bacterial meningitis. Rapid detection of viral encephalitis may permit appropriate antiviral therapy, while diagnosis of viral meningitis may limit the use of unnecessary antibiotics. Similar situations apply to ocular infections.

4.8 Miscellaneous NAAT testing for organisms not specified elsewhere

Table 14: Proposed changes to NAAT testing for organisms not elsewhere specified

Item	Current descriptor	Proposed change to descriptor
69494	Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified) 1 test (Item is subject to rule 6 and 26)	Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified) 1 or more tests (Item is subject to rule 6 and 26)
69495	2 tests described in 69494 (Item is subject to rule 6 and 26)	Delete
69496	3 or more tests described in 69494 (Item is subject to rule 6 and 26)	Delete
69497	A test described in item 69494, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rule 6, 18 and 26)	A test described in item 69494, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 or more tests (Item is subject to rule 6, 18 and 26)
69498	A test described in item 69494, other than that described in 69497, if rendered by a receiving APP - each test to a maximum of 2 tests (Item is subject to rule 6, 18 and 26)	Delete

4.8.1 Recommendation 8

- Amend the current item 69494 to cover the testing for bacterial, fungal, viral and parasite organisms not elsewhere specified within the restructured schedule for molecular testing.
- Delete items 69495, 69496 and 69498.

4.8.2 Rationale 8

- The restructure of the current generic molecular items (69494, 69495 and 69496) into system-specific MBS items will accommodate most clinical tests required in most clinical situations. There are, however, testing requirements where tests fall outside the currently proposed system structure and so a generic item will be required, at least in the interim or until the Schedule is further refined.
- The Committee agreed that this should be a restricted item. It is expected that use would be minimal and only in circumstances when the test required is not specified elsewhere in the Schedule. Close monitoring of the use of this item will be required to ensure the appropriate use of the Schedule.
- Such an item could be used for the testing of BK virus in the urine of patients with nephritis after renal transplant and in accessing gastrointestinal biopsies for Whipple's disease (*Tropheryma whipplei* infection) and cytomegalovirus (CMV) infection.
- This may involve low test numbers with high complexity, which would warrant review of the schedule fee for the item.

4.9 Hepatitis serology

Table 15: Item introduction table for items 69475-69484

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69475	One test for hepatitis antigen or antibodies to determine immune status or viral carriage following exposure or vaccination to hepatitis A, hepatitis B, hepatitis C or hepatitis D (item subject to rule 11)	$15.65	$1,822,622	136 688	128 406	4.8%
69478	2 tests described in 69475 (item subject to rule 11)	$29.25	$14,841,389	595 057	555 945	1.6%
69481	Investigation of infectious causes of acute or chronic hepatitis-3 tests for hepatitis antibodies or antigens, (item subject to rule 11)	$40.55	$18,786,763	542 019	503 639	14.7%
69484	Supplementary testing for hepatitis B surface antigen or hepatitis C antibody using a different assay on the specimen which yielded a reactive result on initial testing (Item is subject to rule 18)	$17.10	$689,376	47 439	40 705	3.7%

4.9.1 Recommendation 9a —Ideal model

Δ Propose a new model of MBS items for hepatitis serology (Table 16), noting that this new model will require the development of decision support software, education of requesters and enhanced pathology laboratory information management systems to support implementation.

Table 16: Ideal model—restructure of the hepatitis serology items

Proposed Item	Description	Proposed descriptor
6947A	Check viral hepatitis status (no clinical symptoms). Includes any or all of HBV status,[a] HAV-IgG, and anti-HCV.	Test(s) to determine viral hepatitis status. Includes any or all of HAV-IgG, HBsAg, HBsAb, HBcAb, and HCVAb.
6947B	Investigation of acute hepatitis A, B and C. Includes any or all of HAV-IgM, HBsAg, HBsAb, HBcAb, HBc-IgM, anti-HCVAb.	Test(s) to investigate infectious causes of acute hepatitis A, B or C. Includes any or all of HAV-IgM, HBsAg, HBsAb, HBcAb, HBc-IgM, anti-HCVAb. Notes/restrictions: If there is no record of any HBV serology, the first testing for that pathology practice/network should be HBsAg, HBsAb, and HBcAb to determine HBV status.[a]
6947C	Diagnosis of chronic hepatitis B or C infection. Includes any or all of HBV Status, anti-HCV.	Test(s) to diagnose chronic hepatitis B or C. Includes any or all of HBV Status, anti-HCV.
6947D	Monitoring infectivity and disease phase in a person with chronic hepatitis B or C. Includes any or all of HBeAg and HBeAb.	Test(s) to determine infectious status when HBs positive or the assessment of disease phase in a person with chronic hepatitis B. Includes any or all of HBeAb and HBeAg. Notes: Patient must be HBs positive or be confirmed with chronic hepatitis B.
6947E	Investigation of hepatitis D or E. One test only.	Test(s) to determine viral carriage of hepatitis D virus (in an HBsAg-positive patient) or hepatitis E virus in a patient non-reactive in testing to other hepatitis viruses. One test only.

a If there is no record of any HBV serology, the first testing for that pathology practice/network should be HBs, HBsAb, and HBcAb to determine HBV Status. This will restrict the need for these three tests in the future. It is anticipated that Medicare prevent payment if this item has been already claimed for an individual patient.

4.9.2 Rationale 9a

The recommendation focuses on modernising the MBS and supporting best practice and is based on the following observations.

- Knowledge and management of hepatitis has changed since the introduction of these items to the MBS (2002), therefore a restructure of the existing items is warranted. The ideal model (Table 15) simplifies the Schedule and will require some pushback to requesters to provide adequate clinical information (via decision support, education, guidance and communication). The aim of this model is to:
  - align with national hepatitis B and hepatitis C guidelines [17], [18]
  - avoid a 'ladder' of tests
  - split the items depending on clinical indications for testing (this will require more relevant information from requesters to determine the clinically relevant tests required).
- Requesters will need to indicate the reason for testing, with the pathologist delegate selecting the required relevant tests from a range included under that item number.
- In recommending the ideal model, the Committee acknowledged that a major limitation would be the considerable time involved, in the absence of integrated clinical information systems, to vet all hepatitis requests delivered to a laboratory. For example, large laboratories might process about 1500 requests per day, requiring additional medical staff to review requests and new pathology laboratory IT systems to determine if a request meets the item descriptor. In the future, IT systems or software could be used to perform searches for a patient's previous test results, but this will require support from multiple professional bodies and organisations.
- In recognising the implementation challenges of the ideal model, the Committee proposed an alternative interim model based on reorganising the existing items in the Schedule to better reflect current testing practices.

4.9.3 Recommendation 9b—Interim model

- In view of significant implementation issues with the ideal model, the Committee recommended a short-term alternative approach, as below:
  - Delete items 69475, 69478 and 69481 and merge into one new item to cover any and all tests for all hepatitis viruses, including from checking immune status to diagnosing or monitoring acute or chronic hepatitis, up to three or more tests.
  - Retain current item 69484 and its descriptor
  - Create a new item for investigation of hepatitis D or E—1 test only.
- Provide education, guidance and thorough communication to requesters regarding the changes, and adequate clinical information via decision support.

Table 17: Proposed changes—interim model for hepatitis serology items

Item	Current descriptor	Proposed change to descriptor
New item 694XA		Testing for hepatitis viruses A, B, C to determine immune status, and to diagnose; or monitor acute or chronic hepatitis - up to 3 or more tests.

Item	Current descriptor	Proposed change to descriptor
69484	Supplementary testing for hepatitis B surface antigen or hepatitis C antibody using a different assay on the specimen which yielded a reactive result on initial testing (Item is subject to rule 18)	No change
New item 694XB		Test(s) to determine viral carriage of hepatitis D virus in an HBs-positive patient (antibody and antigen) or hepatitis E virus (antibody only) in a patient non-reactive in testing to other hepatitis viruses.

4.9.4 Rationale 9b

The recommendation focuses on modernising the MBS and supporting best practice and is based on the following observations.

- The current Schedule is difficult to apply due to the lack of clinical information accompanying requests. Members identified that up to 30 per cent of requests had inadequate clinical information to determine which specific tests are required. Unnecessary and/or additional tests may be performed at a cost to the laboratories.
- The current hepatitis items 69475, 69478 and 69481 are used to fund blood tests used to detect current or past infection by the hepatitis A, B, C or D virus. They are used to diagnose suspected acute hepatitis, for sexually transmissible disease screening, determining immunity after immunisation or natural infection and for antenatal screening. However, the hepatitis virus panel can screen blood samples for antibodies and antigens of more than one kind of hepatitis virus at the same time. In addition to these tests, there are also molecular tests to determine the level and activity of the hepatitis B and C viruses.
- National guidelines outline diagnostic strategies for acute and chronic hepatitis B and hepatitis C and identify the priority populations for testing and the associated testing protocols. [17], [18]
- Broader testing will enable improved management of hepatitis B in patients who are hepatitis C positive by identifying those who require hepatitis B immunisation; identifying hepatitis D virus status, which is associated with more severe disease; and improving identification of hepatitis B reactivation in immunosuppressed patients. These changes will be more convenient for patients, as they will limit the need to present to GPs for follow-up tests and will help ensure patients are not lost to follow-up.
- Historically hepatitis E has not been a common infection in Australia and is usually related to overseas travel, but recently non-travel-related cases have been increasing in number. [19] The Committee recommended that this be added to the suite of tests available in the hepatitis serology item, to ensure it is less likely to be overlooked, if clinically indicated. It is a particularly severe infection in pregnant women. Currently hepatitis E testing would be funded via the serology item number 69384.
- Hepatitis testing regimens are complicated and confusing for GPs, and education and information is required to ensure appropriate testing in relevant population groups. The Committee agreed that this is a priority area where decision support would be valuable to guide requesters and ensure guidelines are utilised to encourage best practice.
- It is unlikely the patient population will change significantly as a result of the recommended revisions (i.e. there is no reason that there would be an increase in requests for testing in low-risk populations).

- Δ As hepatitis B immunisation increases in Australia, with currently up to 95% of children immunised by 24 months, there should be lower rates of hepatitis B infection in the community and a consequent reduction in the need to test for the infection. [20]
- Δ There will be an increase in hepatitis E testing in line with guideline recommendations, independent of the Committee's recommendations. Claiming for new items for detection of hepatitis E would be partially counterbalanced by a reduction in current claiming via the serology items.

4.10 Serology items/EBV

Table 18: Item introduction table for items 69384–69401, 69472 and 69474

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69384	Quantitation of 1 antibody to microbial antigens not elsewhere described in the Schedule - 1 test (This fee applies where a laboratory performs the only antibody test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	$15.65	$4,065,863	306 233	286 530	1.5%
69387	2 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 2 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	$29.00	$13,795,061	558 456	509 768	7.2%
69390	3 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 3 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	$42.35	$5,448,447	150 524	145 206	-0.6%
69393	4 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 4 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	$55.70	$12,471,988	262 162	252 822	8.2%
69396	5 or more tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 5 of	$69.10	$11,548,218	196 598	187 762	2.8%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	the antibody tests specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)					
69400	A test described in item 69384, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rules 6 and 18)	$15.65	$534,573	40 122	36 471	–10.7%
69401	A test described in item 69384, other than that described in 69400, if rendered by a receiving APP - each test to a maximum of 4 tests (Item is subject to rule 6, 18 and 18A)	$13.35	$1,843,790	162 836	66 978	4.1%
69472	Detection of antibodies to Epstein Barr Virus using specific serology - 1 test	$15.65	$71,926	5 500	5 122	13.3%
69474	Detection of antibodies to Epstein Barr Virus using specific serology - 2 or more tests	$28.65	$5,440,217	222 774	212 132	1.3%

4.10.1 Recommendation 10

- Δ Re-instate the old serology item number 69399 for six or more tests.
- Δ Delete separate Epstein–Barr virus (EBV) items 69472 and 69474 and merge these into the serology items to simplify the Schedule.
- Δ Amend the descriptor of the serology items 69390, 69363 and 69396 to restrict the number of tests performed for EBV to two tests only.
- Δ No changes to item 69384, 69387, 69400 and 69401.

Table 19: Proposed changes to the serology items 69384-69401, 69472 and 69474

Item	Current descriptor	Proposed change to descriptor
69384	Quantitation of 1 antibody to microbial antigens not elsewhere described in the Schedule - 1 test (This fee applies where a laboratory performs the only antibody test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	No change
69387	2 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 2 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	No change
69390	3 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 3 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	3 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 3 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject

Item	Current descriptor	Proposed change to descriptor
		to rule 6) A maximum of only 2 tests for EBV can be performed.
69393	4 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 4 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	4 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 4 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6) A maximum of only 2 tests for EBV can be performed.
69396	5 or more tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 5 of the antibody tests specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	5 or more tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 5 of the antibody tests specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6) A maximum of only 2 tests for EBV can be performed.
69400	A test described in item 69384, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rules 6 and 18)	No change
69401	A test described in item 69384, other than that described in 69400, if rendered by a receiving APP - each test to a maximum of 4 tests (Item is subject to rule 6, 18 and 18A)	No change
69472	Detection of antibodies to Epstein Barr Virus using specific serology - 1 test	Delete
69474	Detection of antibodies to Epstein Barr Virus using specific serology - 2 or more tests	Delete

4.10.2 Rationale 10

The recommendations focus on modernising and simplifying the MBS and are based on the following observations.

- The serology items were introduced to the MBS in 1996. Since then many new diagnosable diseases have emerged in the Australian community, and it is estimated from member data that it is now not uncommon that at least six immunoassays are required for common clinical scenarios. Member data indicates that between 32 per cent and 51 per cent of requests are for six or more tests. Some tests involve testing for notifiable diseases and have public health ramifications if not performed.
- In modern practice, laboratories are increasingly required to perform multiple tests for the diagnosis of clinical syndromes, for example, fever, rash and arthralgia in returned travellers, or respiratory syndromes. The variety of illnesses and the range of organisms detected causing these syndromes has increased significantly over the last decade. The need to identify the causes and ensure appropriate management is critical. The National Notifiable Diseases Surveillance System report indicates an increase in the number of notifications for all diseases from 82,161 in 1996 to 329,225 in 2016. [21]
- Currently, a maximum of five tests is funded through the MBS. Pathology laboratory data indicate that the number of tests ordered per request has increased significantly, and that 32 per cent of tests performed were for six or more tests, with 5 per cent of requests for between 11 and 27 tests. Based on the growing demand for diagnostic information to inform appropriate treatment options, the Committee recommended reinstating item 69399 for six or more tests. Improved diagnosis and management, including judicious use of antimicrobials, benefits patients and the wider community.

- In serology, syndromic testing has the potential to generate orders for a significant number of serological investigations. Examples include:
  - Fever, rash and arthralgia: parvovirus IgG/IgM; antistreptolysin O titre (ASOT), anti-DNase B; measles IgG/IgM; HIV; dengue IgG/IgM, NS1 antigen; Zika IgG/IgM and chikungunya IgG/IgM. While not all 14 tests would be indicated, frequently at least six would be required in the workup. Tests performed would be dependent on the age of the patient, environmental exposure and underlying immunological status.
  - Mononucleosis syndrome: EBV IgG/IgM, CMV IgG/IgM (frequently add in avidity); *Toxoplasma* IgG/IgM and Q fever IgG/IgM, generating 10 or more tests. Tests performed would be dependent on the age of the patient, environmental exposure and underlying immunological status.
  - Pyrexia of unknown origin in a returned traveller: amoebic; dengue; leptospirosis; other flaviviruses (possibly several depending on the history), and selected arboviruses of importance to Australia. [21]
- As the schedule fee for EBV tests is the same as the fees for the equivalent serology items, the Committee recommended that to simplify the schedule it would be practical to merge these items back into the serology items. Limiting the number of EBV tests to a maximum of two tests will ensure that the utilisation patterns for EBV will not change, although it is noted that there may be changes in claiming patterns and benefits paid due to the effect of coning.
- With respect to impact on other areas of the Schedule, apart from the EBV items whose utilisation will be shifted back into the serology items, the utilisation of other serology items will not be affected.
- Over time, as molecular testing becomes more widely available, utilisation of the serology items for syndromes such as respiratory illness will decrease.
- The recommendation to reinstate the six or more MBS item will result in an overall increase in claims for six or more tests and a consequent increase in MBS benefits paid. This will require modelling and a cost analysis.

4.11 Site-specific culture and microscopy tests 69303, 69306, 69312 and 69318

Table 20: Item introduction table for items 69303, 69306, 69312 and 69318

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69303	Culture and (if performed) microscopy to detect pathogenic microorganisms from nasal swabs, throat swabs, eye swabs and ear swabs (excluding swabs taken for epidemiological surveillance), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; specimens from 1 or more sites	$22.00	$6,511,855	349 234	315 101	7.0%
69306	Microscopy and culture to detect pathogenic microorganisms from skin or other superficial sites, including (if performed): (a)	$33.75	$15,911,548	563 672	449 715	7.2%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69312, 69318; 1 or more tests on 1 or more specimens					
69312	Microscopy and culture to detect pathogenic microorganisms from urethra, vagina, cervix or rectum (except for faecal pathogens), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69318; 1 or more tests on 1 or more specimens	$33.75	$23,145,700	800 961	683 298	4.8%
69318	Microscopy and culture to detect pathogenic microorganisms from specimens of sputum (except when part of items 69324, 69327 and 69330), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69312; 1 or more tests on 1 or more specimens	$33.75	$5,497,366	195 912	150 594	9.4%

4.11.1 Recommendation 11

- Δ Change the descriptors of items 69303, 69306, 69312 and 69318 to remove the inclusion of microscopy and culture on specimens from other sites.
- Δ Refer to section 4.3.1 for the recommendation to amend the descriptor of item 69312 to include 'throat (except for respiratory pathogens)'.

Table 21: Proposed changes to site specific culture and microscopy items

Item	Current descriptor	Proposed change to descriptor
69303	Culture and (if performed) microscopy to detect pathogenic microorganisms from nasal swabs, throat swabs, eye swabs and ear swabs (excluding swabs taken for epidemiological surveillance), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; specimens from 1 or more sites	Culture and (if performed) microscopy to detect pathogenic microorganisms from nasal swabs, throat swabs (excluding STI pathogens), eye swabs and ear swabs (excluding swabs taken for epidemiological surveillance), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; 1 or more tests on 1 or more specimens.
69306	Microscopy and culture to detect pathogenic microorganisms from skin or other superficial sites, including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69312, 69318; 1 or more tests on 1 or more specimens	Microscopy and culture to detect pathogenic microorganisms from skin or other superficial sites, including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; 1 or more tests on 1 or more specimens.
69312	Microscopy and culture to detect pathogenic microorganisms from urethra, vagina, cervix or rectum (except for faecal pathogens), including (if performed): (a) pathogen identification and	Microscopy and culture to detect pathogenic microorganisms from throat (except for respiratory pathogens), urethra, vagina, cervix or rectum (except for faecal pathogens),

Item	Current descriptor	Proposed change to descriptor
	antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69318; 1 or more tests on 1 or more specimens	including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; 1 or more tests on 1 or more specimens.
69318	Microscopy and culture to detect pathogenic microorganisms from specimens of sputum (except when part of items 69324, 69327 and 69330), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69312; 1 or more tests on 1 or more specimens	Microscopy and culture to detect pathogenic microorganisms from specimens of sputum (except when part of items 69324, 69327 and 69330), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300;1 or more tests on 1 or more specimens.

4.11.2 Rationale 11

The recommendations focus on modernising and simplifying the MBS and are based on the following observations.

- Δ The decision to order tests from multiple sites is a clinical decision made by the requester. Each of these items comprise tests performed on specimens derived from independent sites throughout the body to determine the microorganisms that may be causing infection, and the antibiotic sensitivity if treatment is subsequently required. The specimens from each body site are handled, tested and reported separately. Each will potentially involve different site-specific pathogens and the subsequent management may be different for each site.
- Δ Currently the item descriptors include any tests performed on specimens from other sites. As each of these site-specific tests is independent in terms of laboratory processes, consumables and resources the Committee recommended they should be funded separately.
- Δ The MBS data do not provide information on how often specimens from multiple sites are ordered. Currently, a patient presenting with either respiratory symptoms or an eye infection would have a request for either a sputum sample or an eye swab, which would be funded through items 69318 ($33.73) or 69303 ($22.00) respectively. An example of when multiple-site specimens are required is in the testing for sexually transmissible infections, when a request could be for a throat swab together with a urethral and a rectal swab. Currently, only one test would be funded (item 69312 [$33.73]) despite three sets of specimens needing to be collected and tested.
- Δ A costing review considering the redistribution of relevant fees across these items will be required.
- Δ Member data from one large laboratory indicated that the frequency with which cultures from other sites are ordered on the same episode was fairly low, with most associated with item 69303 (3.3% of requests). Similarly, the frequency with which more than one culture is received for the same site was also low, with most associated with item 69306 (3% of requests).

4.12 HIV/STI Rule 3 exemption

4.12.1 Recommendation 12

- Δ Apply Rule 3 exemption to HIV/STI testing (chlamydia and gonorrhoea NAAT testing and HIV serology) in the ASHM's proposed high-risk population. Possible MBS items affected by this exemption are listed in the following table.

Table 22: Existing MBS Items potentially affected by an HIV/STI Rule 3 exemption

Item	Current descriptor	Proposed change to descriptor
69317	1 test described in item 69494 and a test described in 69316. (Item is subject to rule 26)	1 test described in item 69494 and a test described in 69316. (Item is subject to rule 26, and rule 3 exemption.) NB: This Item is recommended for deletion.
69319	2 tests described in item 69494 and a test described in 69316. (Item is subject to rule 26)	2 tests described in item 69494 and a test described in 69316. (Item is subject to rule 26, and rule 3 exemption.) NB: This Item is recommended for deletion.
New item 693XE		Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoea* by NAAT. 2 or more tests (Item is subject to rule 26, and rule 3 exemption). 1 specimen
New item 693XF		Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by NAAT. 2 or more tests (Item is subject to rule 26, and rule 3 exemption). 2 or more specimens
69384	Quantitation of 1 antibody to microbial antigens not elsewhere described in the Schedule – 1 test. (This fee applies where a laboratory performs the only antibody test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	Quantitation of 1 antibody to microbial antigens not elsewhere described in the Schedule – 1 test. (This fee applies where a laboratory performs the only antibody test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA.) (Item is subject to rule 6, and rule 3 exemption.)

4.12.2 Rationale: 12

The Department commissioned an independent review and report to assess the merits of allowing a Rule 3 exemption for HIV and STI testing in high-risk populations, and to ensure that a request for four HIV/STI tests within a six-month period was consistent with clinical best practice. [22] The Committee's recommendations have been drawn from the findings of this report, and are based on the following observations:

- Notification rates for HIV, syphilis, chlamydia and gonorrhoea have increased over the last decade. [23]
- HIV and STI testing are currently covered by global items, with a new GP consultation required for each test. Rule 3 exemptions would allow for up to four tests in a six-month period for HIV and STI testing in high-risk populations, without the requirement of additional GP consultations.
- High-risk populations are defined as:
  - men who have sex with men and who are at high risk of contracting HIV/STIs
  - partners of people living with HIV/AIDS
  - people who inject drugs and report sharing needles.
- The recommendations include STI testing at anatomical sites other than the location of any symptoms that may have prompted a clinical consultation.
- If the Rule 3 exemption for HIV/STI testing is approved, it will allow greater access to testing in the high-risk populations, through removal of the need for a GP visit for each test.
- Testing rates will likely increase in high-risk individuals (estimated increase of 1018 tests in year 5), with an associated decrease in GP consultation rates (estimated decrease of 60 visits in year 5).
- Rule 3 exemption will result in an incremental cost of approximately $296,000 in year 5.

- Δ Potential downstream benefits across the health system will include an increase in detection, an increase in transmission aversion rates, and a decrease in costs to the overall health system associated with HIV and STIs.
- Δ The Committee agreed that, due to the public health consequences and in line with clinical best practice that Rule 3 exemption should apply to HIV and STIs in selected high-risk populations. [22]

4.13 Microscopy and culture of complicated hospital specimens

Table 23: Item introduction table for item 69321

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69321	Microscopy and culture of post-operative wounds, aspirates of body cavities, synovial fluid, CSF or operative or biopsy specimens, for the presence of pathogenic microorganisms involving aerobic and anaerobic cultures and the use of different culture media, and including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300, 69303, 69306, 69312 or 69318; specimens from 1 or more sites	$48.15	$11,677,652	295 484	235 199	8.8%

4.13.1 Recommendation 13

- Δ Revise and separate/split the current item 69321 to recognise the different complexity associated with testing specimens from different sites. Create an item for the microscopy and culture of (a) post-operative wounds or operative or biopsy specimens, and an item for (b) aspirates of body fluids, synovial fluids and cerebrospinal fluid (CSF).
- Δ Remove the inclusion of the less complicated site-specific specimens described in items 69303, 69306, 69312, 69318 (see also section 4.11 for site specific culture)

Table 24: Proposed changes to site specific culture and microscopy items

Item	Current descriptor	Proposed change to descriptor
69321	Microscopy and culture of post-operative wounds, aspirates of body cavities, synovial fluid, CSF or operative or biopsy specimens, for the presence of pathogenic microorganisms involving aerobic and anaerobic cultures and the use of different culture media, and including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300, 69303, 69306, 69312 or 69318; specimens from 1 or more sites	Microscopy and culture of post-operative wounds, or operative or biopsy specimens, or respiratory samples from a cystic fibrosis patient; for the presence of pathogenic microorganisms involving aerobic and anaerobic cultures and the use of different culture media, and including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; specimens from 1 or more sites.
69321-X		Microscopy, cell counts (when indicated) and culture of aspirates of body cavities, synovial fluid, or CSF for the presence of pathogenic microorganisms involving aerobic and anaerobic cultures and the use of different culture media, and including (if performed): (a)

Item	Current descriptor	Proposed change to descriptor
		pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; specimens from 1 or more sites.

4.13.2 Rationale 13

These recommendations focus on modernising the MBS and are based on the following observations.

- The workload and procedures involved in microscopy and culture of fluid samples is more complicated than for samples obtained from anatomical sites. Differential cell counts are performed and microscopy may include the detection of crystals. Specimens may be inoculated into blood culture bottles, which increase the cost of consumables and monitoring.
- Separating this item will enable a review of the costings of both the tissue and fluid specimens and redistribute the funding across the items to better reflect the complexity and costs associated with the fluids.
- Funding should be redistributed between these items to recognise the higher complexity associated with microscopy and culture of aspirates of body fluids, synovial fluids and CSF to better reflect the complexity and costs associated with the fluids.
- The current descriptor and schedule fee for 69321 include any tests performed on specimens from less complicated sites such as throat, ears, sputum, etc., described in items 69303, 69306, 69312 and 69318. As the specimens from each body site are collected, handled, tested and reported separately, the Committee agreed that they should be funded separately and recommended that they be removed from the item descriptors of the complicated specimens.

4.14 Microscopy of wet film

Table 25: Item introduction table for item 69300

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69300	Microscopy of wet film material other than blood, from 1 or more sites, obtained directly from a patient (not cultures) including: (a) differential cell count (if performed); or (b) examination for dermatophytes; or (c) dark ground illumination; or (d) stained preparation or preparations using any relevant stain or stains; 1 or more tests	$12.50	$251,721	24 539	20 370	9.9%

4.14.1 Recommendation 14

- Amend the descriptor to remove the obsolete methods of examination of dermatophytes and dark ground illumination.
- Restrict the co-claiming of this item with the proposed revised item for complicated hospital specimens item 69321 and new item 69321-X (see section 4.13).

Table 26: Proposed changes to item 69300

Item	Current descriptor	Proposed change to descriptor
69300	Microscopy of wet film material other than blood, from 1 or more sites, obtained directly from a patient (not cultures) including: (a) differential cell count (if performed); or (b) examination for dermatophytes; or (c) dark ground illumination; or (d) stained preparation or preparations using any relevant stain or stains; 1 or more tests	Microscopy of wet film material other than blood, from 1 or more sites, obtained directly from a patient (not cultures) including: (a) differential cell count (if performed); or (b) stained preparation or preparations using any relevant stain or stains; 1 or more tests.

4.14.2 Rationale 14

The recommendations focus on modernising the MBS and are based on the following recommendations.

- Δ Dark ground illumination is a microscopy technique rarely performed, as it has been superseded by more contemporary methods such as polymerase chain reaction (PCR).
- Δ Microscopy alone for dermatophytes is very insensitive and usually requires additional culture using either item 69309 or PCR. MBS data do not indicate that this service is being used extensively in remote Australia, so removal would not impact patient care.
- Δ The Committee recommended that this item should not be co-claimed with the proposed revised item for complicated hospital specimens (see section 4.11), as this item is intended for less complicated tissue or fluid samples.
- Δ The change to the descriptor should produce minimal changes to the utilisation of the item.
- Δ There will be little impact on access for patients, as superior, more sensitive test methods are now available.

4.15 Antenatal bundle 69415, 69333

4.15.1 Recommendation 15

- Δ The Committee proposes the development of an antenatal bundle of items to include items 69415 and 69333.
- Δ Delete items 69405, 69408, 69411, 69413 (see section 4.16.2).

Table 27: Proposed descriptor recommended by the Committee

Item	Proposed change to descriptor
New item	First trimester antenatal screen including all of the following: 1) Erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument-generated differential count - not being a service in which haemoglobin only is requested - one or more instrument-generated set of results from a single sample; and (if performed) a morphological assessment of a blood film; and 2) Blood grouping (including back-grouping if performed), and examination of serum for Rh and other blood group antibodies, including identification and quantitation of any antibodies detected; and Urine examination (including serial examination) by any means other than simple culture by dip slide, including: (a) cell count; and (b) culture; and (c) colony count; and (d) (if performed) stained preparations; and (e) (if performed) identification of cultured pathogens; and

Item	Proposed change to descriptor
	(f) (if performed) antibiotic susceptibility testing; and (g) (if performed) examination for pH, specific gravity, blood, protein, urobilinogen, sugar, acetone or bile salts; and Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient with parvovirus infection or varicella during that pregnancy), including the determination of all 5 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody. This item includes (if performed) any test described in 65060, 65070, 65072, 65096, 69333, 69415 and 69384. (Item is subject to rule 25.) Rule 25 would be once per year per pregnancy.

4.15.2 Rationale 15

- The Committee has recommended that there should be one item that includes the basic pathology tests that all pregnant women should have in the first trimester. This will standardise antenatal pathology screening in line with national guidelines and improve health outcomes for pregnant women and their babies. The Obstetrics Clinical Committee have also endorsed this recommendation.
- The tests to be included in this 'panel' are:
  - 65070: Full blood count
  - 65096: Blood grouping and examination of serum for Rh and other blood group antibodies
  - 69333: Urinalysis
  - 69415: Hepatitis B, hepatitis C, HIV, rubella, syphilis (item is for testing all five).
- There are currently five item numbers covering antenatal serology – 69405, 69408, 69411, 69413 and 69415. The inclusion of the five-test item (69415) into the antenatal bundle would mean the items covering one, two, three or four of the serology tests will be redundant. If additional tests are required throughout the pregnancy, the bundle does not exclude the option of claiming for the individual items separately if clinically appropriate. Similarly, the urinalysis item 69333 would be included in this standard set of tests. The option for additional urinalysis requests outside the bundle is available if clinically indicated.

4.16 Items to be removed

4.16.1 Low-volume items 73828, 73834, 73835, 73837

Table 28: Item introduction table for items 73828, 73834, 73835, 73837

Item	Item descriptor	Schedule fee	Services (2014–15)
73828	Semen examination for presence of spermatozoa by a participating nurse practitioner	$6.90	0
73834	Microscopy for wet film other than urine, including any relevant stain by a participating nurse practitioner	$6.90	1
73835	Microscopy of Gram-stained film, including (if performed) a service described in item 73832 or 73834 by a participating nurse practitioner	$6.90	5
73837	Microscopy for fungi in skin, hair or nails by a participating nurse practitioner - 1 or more sites	$6.90	1

4.16.1.1 Recommendation 16.1

- Delete items 73828, 73834, 73835 and 73837.

4.16.1.2 Rationale 16.1

- These items are low-volume services provided by nurse practitioners. MBS data confirm that these are not services being provided exclusively in rural or remote areas. Given the volume of these services is so low, it is recommended that they be removed from the Schedule. The Committee considered that these services are more appropriately performed by laboratories in which staff have experience in doing these types of tests routinely and in significant volumes. Practitioners who only perform these tests occasionally may lack the quality assurance required to ensure best practice. These services will still be available on the Schedule via existing item numbers, albeit at a higher fee. Given the low volume of services provided in 2014–15, the impact of this shift will be negligible.
- Removal will have little impact on access for patients, as these services are still available on the Schedule when provided by laboratories. The quality assurance provided by laboratories routinely providing these types of tests will benefit patients because of the expertise in performing these tests in greater numbers. From the provider's perspective, this will mean that samples will need to be sent to laboratories for review. Given the low volume, this is unlikely to be a disadvantage to the few patients receiving these services.

4.16.2 Obsolete items 69405, 69408, 69411, 69413

Table 29: Item introduction table for items 69405, 69408, 69411, 69413

Item	Item descriptor	Schedule fee	Services (2014–15)
69405	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 1 of the following – rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	$15.65	18 545
69408	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 2 of the following – rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	$29.00	9 977
69411	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 3 of the following – rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	$42.35	17 555
69413	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 4 of the following – rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	$55.70	52 191

4.16.2.1 Recommendation 16.2

Δ Delete items 69405, 69408, 69411 and 69413 after inclusion of the five-test microbiological serology item 65415 in the antenatal bundle recommended by the Obstetrics Clinical Committee.

4.16.2.2 Rationale 16.2

Δ The Committee has recommended the inclusion of the five-test microbiological serology item (69415) for hepatitis B, hepatitis C, HIV, rubella and syphilis into an antenatal bundle. As outlined in section 4.15, the Obstetrics Clinical Committee endorses this recommendation. If the recommendation is accepted by the MBS Review Taskforce, the individual item numbers for fewer than five tests, listed in Table 30, will be redundant. The inclusion of the five tests is in keeping with best practice and will ensure the minimum number of tests for each pregnancy.

Δ Removal of these items is not expected to have a negative impact on providers or patients. The inclusion of the minimum number of appropriate tests in the antenatal bundle will benefit patients and support clinicians to provide evidence-based practice.

4.16.3 HPV items 69418 and 69419

Table 30: Item introduction table for items 69418 and 69419

Item	Item descriptor	Schedule fee	Services (2014–15)
69418	A test for high risk human papillomaviruses (HPV) in a patient who: – has received excisional or ablative treatment for high grade squamous intraepithelial lesions (HSIL) of the cervix within the last two years; or – who within the last two years has had a positive HPV test after excisional or ablative treatment for HSIL of the cervix; or – is already undergoing annual cytological review for the follow-up of a previously treated HSIL – to a maximum of 2 of this item in a 24 month period (Item is subject to rule 25)	$63.55	41 508
69419	A test described in item 69418 if rendered by a receiving APP – 1 test (Item is subject to rule 18 and 25)	$63.55	405

4.16.3.1 Recommendation 16.3

Δ The Committee recommends the deletion of items 69418 and 69419 for follow-up for testing for human papillomaviruses (HPV) after the introduction of the National Cervical Screening Program in December 2017.

4.16.3.2 Rationale 16.3

Δ Recommendations contained within the draft National Cervical Screening Program, due for implementation in December 2017, will render these existing items for testing for high-risk human papillomaviruses (HPV) obsolete. The Program will include a new item for follow-up testing of patients.

4.16.4 HIV viral RNA in cerebrospinal fluid

Table 31: Item introduction table for item 69382

Item	Item descriptor	Schedule fee	Services (2014–15)
69382	Quantitation of HIV viral RNA load in cerebrospinal fluid in a HIV seropositive patient - 1 or more tests on 1 or more specimens	$180.25	1

4.16.4.1 Recommendation 16.4

Δ Delete item 69382.

4.16.4.2 Rationale 16.4

Δ The Committee considered that a separate item for the quantification in cerebrospinal fluid, is an obsolete item, with only one service provided in 2014–15.

Δ Proposed changes to items 69378 and 69381 (see section 4.18.3) will enable this test to be funded if required.

4.16.5 NAAT testing (not specified elsewhere in the Schedule)

Table 32: Item introduction table for items 69495 and 69496

Item	Item descriptor	Schedule fee	Services (2014–15)
69495	2 tests described in 69494 (Item is subject to rule 6 and 26)	$35.85	189 173
69496	3 or more tests described in 69494 (Item is subject to rule 6 and 26)	$43.05	734 647

Item	Item descriptor	Schedule fee	Services (2014–15)
69498	A test described in item 69494, other than that described in 69497, if rendered by a receiving APP - each test to a maximum of 2 tests (Item is subject to rule 6, 18 and 26)	$7.20	90 106

4.16.5.1 Recommendation 16.5

- Delete items 69495 and 69496.
- Delete item 69498.

4.16.5.2 Rationale 16.5

- The introduction of anatomical and physiological system-based items should significantly reduce the need for items to be claimed using the generic items not specified elsewhere (see section 4.8. There may be some circumstances in which one test may be required, but it would be unlikely that two or more tests would be required using this item.
- There will be some circumstances in which tests may need to be referred to another provider, but it is expected that it would be rare for two tests to be required. Most tests should be able to be covered by the anatomical and physiological system-based items.

4.16.6 Urogenital items

Table 33: Item introduction table for items 69316, 69317 and 69319

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
69316	Detection of chlamydia trachomatis by any method – 1 test (Item is subject to rule 26)	$28.65	$4,287,428	175 172	162 785	–9.8%
69317	1 test described in item 69494 and a test described in 69316. (Item is subject to rule 26)	$35.85	$22,175,424	723 841	629 963	12.8%
69319	2 tests described in item 69494 and a test described in 69316. (Item is subject to rule 26)	$42.95	$11,525,384	314 080	269 568	37.4%

4.16.6.1 Recommendation 16.6

- Delete items 69316, 69317and 69319.

4.16.6.2 Rationale 16.6

- The introduction of two new item numbers (693XE and 693XF) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by NAAT—2 tests (Item is subject to rule 26) 1, or 2 or more specimens.
- See section 4.3.

4.17 Minor changes

The Committee has made recommendations for minor changes to the items in the following table. The changes relate to removing restrictions no longer required and simplifying items. Proposed changes are underlined.

4.17.1 Item 69488

- Changes to guidelines for hepatitis C infection have removed the requirement for a specialist or consultant physician to manage treatment. [24] These words should be removed from the descriptor.

4.17.2 Items 69491

- As for the item 69488, above, Australian consensus guidelines for management of hepatitis C infection and PBS recommendations for monitoring of new HCV treatments have removed the requirement for specialist review. [24]
- Item 69491 may become redundant in the future, as the newer drug HCV treatments are not genotype-specific and for these agents this test is not relevant. There will, however, be a transition period in which existing therapies will still be used, and these items still required.
- The Committee acknowledged that this is a changing area of practice, and recommended a regular review of these items using expertise such as ASHM or the ASID Hepatitis Special Interest Group to ensure the Schedule reflects the practice changes.

4.17.3 Items 69378 and 69381, 69379 and 69383

- Merging items 69378 and 69381 will make the Schedule more contemporary. Historically it may have been relevant whether a patient was receiving antiretroviral treatment or not, but now it is not meaningful to keep these items separate. These items have the same fee and also the same allowable frequency of testing.
- The quantification of HIV viral RNA may be done rarely in fluids other than plasma or serum, so it is recommended that the descriptor for merged Items 69378 and 69381 is broadened to encompass 'other body fluids including CSF'. This will negate the need for a separate Item 69382 (see section 4.16.4)
- Changing these items will require changes in the associated approved pathology practitioner (APP) items 69383 and 69379.

Table 34: Minor changes recommended (key changes underlined)

Item	Item descriptor	Proposed amendment
69488	Quantitation of HCV RNA load in plasma or serum in the pre-treatment evaluation or the assessment of efficacy of antiviral therapy of a patient with chronic HCV hepatitis - <u>where any request for the test is made by or on the advice of the specialist or consultant physician who manages the treatment of the patient with chronic HCV hepatitis</u> (including a service in item 69499 or 69445) (Item is subject to rule 18 and 25)	Quantitation of HCV RNA load in plasma or serum in the pre-treatment evaluation or the assessment of efficacy of antiviral therapy of a patient with chronic HCV hepatitis (including a service in item 69499 or 69445.) (Item is subject to rule 18 and 25.)
69491	Nucleic acid amplification and determination of hepatitis C virus (HCV) genotype if: (a) the patient is HCV RNA positive and is being evaluated for antiviral therapy of chronic HCV hepatitis; and (b) <u>the request for the test is made by, or on the advice of, the specialist or consultant physician managing the treatment of the patient;</u> To a maximum of 1 of this item in a <u>12-month</u> period	Nucleic acid amplification and determination of hepatitis C virus (HCV) genotype if: (a) the patient is HCV RNA positive and is being evaluated for antiviral therapy of chronic HCV hepatitis; to a maximum of 1 of this item in a 12-month period.
69378 and	Quantitation of HIV viral RNA load in plasma or serum in the monitoring of a HIV seropositive patient not on antiretroviral therapy - 1 or more tests	Quantitation of HIV viral RNA load in plasma or serum or other body fluids, including CSF in an HIV-seropositive patient - 1 or more tests on 1 or more specimens.

Item	Item descriptor	Proposed amendment
69381 (merge)	and Quantitation of HIV viral RNA load in plasma or serum in the monitoring of antiretroviral therapy in a HIV seropositive patient - 1 or more tests on 1 or more specimens	
69379 and 69383 (merge)	A test described in item 69378 if rendered by a receiving APP -1 or more tests (Item is subject to rule 18); and A test described in item 69381 if rendered by a receiving APP - 1 or more tests on 1 or more specimens (Item is subject to rule 18)	A test described in item (merged 69378 and 69381) if rendered by a receiving APP - 1 or more tests on 1 or more specimens (Item is subject to rule 18)

4.18 No changes

The Committee recommends that the MBS items listed below do not require amendment, as they are clinically appropriate.

Table 35: Item introduction table for items requiring no changes

Item	Item descriptor	Schedule fee	Services (2014–15)
69309	Microscopy and culture to detect dermatophytes and other fungi causing cutaneous disease from skin scrapings, skin biopsies, hair and nails (excluding swab specimens) and including (if performed): (a) the detection of antigens not elsewhere specified in this Table; or (b) a service described in items 69300, 69303, 69306, 69312, 69318; 1 or more tests on 1 or more specimens	$48.15	215 051
69324	Microscopy (with appropriate stains) and culture for mycobacteria - 1 specimen of sputum, urine, or other body fluid or 1 operative or biopsy specimen, including (if performed): (a) microscopy and culture of other bacterial pathogens isolated as a result of this procedure; or (b) pathogen identification and antibiotic susceptibility testing; including a service mentioned in item 69300	$43.00	30 782
69325	A test described in item 69324 if rendered by a receiving APP (Item is subject to rule 18)	$43.00	3 790
69327	Microscopy (with appropriate stains) and culture for mycobacteria - 2 specimens of sputum, urine, or other body fluid or 2 operative or biopsy specimens, including (if performed): (a) microscopy and culture of other bacterial pathogens isolated as a result of this procedure; or (b) pathogen identification and antibiotic susceptibility testing; including a service mentioned in item 69300	$85.00	4 510
69328	A test described in item 69327 if rendered by a receiving APP (Item is subject to rule 18)	$85.00	398
69330	Microscopy (with appropriate stains) and culture for mycobacteria - 3 specimens of sputum, urine, or other body fluid or 3 operative or biopsy specimens, including (if performed): (a) microscopy and culture of other bacterial pathogens isolated as a result of this procedure; or (b) pathogen identification and antibiotic susceptibility testing; including a service mentioned in item 69300	$128.00	7 948
69331	A test described in item 69330 if rendered by a receiving APP (Item is subject to rule 18)	$128.00	208
69333	Urine examination (including serial examination) by any means other than simple culture by dip slide, including: (a) cell count; and (b) culture; and (c) colony count; and (d) (if performed) stained preparations; and (e) (if performed) identification of cultured pathogens; and (f) (if performed) antibiotic susceptibility testing; and (g) (if performed) examination for pH, specific gravity, blood, protein, urobilinogen, sugar, acetone or bile salts	$20.55	4 371 099

Item	Item descriptor	Schedule fee	Services (2014–15)
69354	Blood culture for pathogenic microorganisms (other than viruses), including sub-cultures and (if performed): (a)identification of any cultured pathogen; and (b) necessary antibiotic susceptibility testing; to a maximum of 3 sets of cultures - 1 set of cultures	$30.75	188 443
69357	2 sets of cultures described in item 69354	$61.45	33 262
69360	3 sets of cultures described in item 69354	$92.90	8 595
69380	Genotypic testing for HIV antiretroviral resistance in a patient with confirmed HIV infection if the patient's viral load is greater than 1,000 copies per ml at any of the following times: at presentation; or before antiretroviral therapy: or when treatment with combination antiretroviral agents fails; maximum of 2 tests in a 12 month period	$770.30	782
69387	2 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 2 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	$29.00	558 456
69400	A test described in item 69384, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rules 6 and 18)	$15.65	40 122
69401	A test described in item 69384, other than that described in 69400, if rendered by a receiving APP - each test to a maximum of 4 tests (Item is subject to rule 6, 18 and 18A)	$13.35	162 836
69415	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of all 5 of the following - rubella immune status, specific syphilis serology, carriage of Hepatitis b, Hepatitis c antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	$69.10	182 349
69445	Detection of hepatitis C viral RNA in a patient undertaking antiviral therapy for chronic HCV hepatitis (including a service described in item 69499) - 1 test. To a maximum of 4 of this item in a 12 month period (Item is subject to rule 25)	$92.20	5 633
69451	A test described in item 69445 if rendered by a receiving APP - 1 test. (Item is subject to rule 18 and 25)	$92.20	266
69482	Quantitation of hepatitis B viral DNA in patients who are hepatitis B surface antigen positive and have chronic hepatitis B, but are not receiving antiviral therapy - 1 test (item is subject to rule 25)	$152.10	21 829
69483	Quantitation of hepatitis B viral DNA in patients who are hepatitis B surface antigen positive and who have chronic hepatitis B and are receiving antiviral therapy - 1 test (item is subject to rule 25)	$152.10	24 847
69484	Supplementary testing for hepatitis B surface antigen or hepatitis C antibody using a different assay on the specimen which yielded a reactive result on initial testing (Item is subject to rule 18)	$29.00	47 439
69489	A test described in item 69488 if rendered by a receiving APP (Item is subject to rule 18 and 25)	$180.25	1 624
69492	A test described in item 69491 if rendered by a receiving APP - 1 test (Item is subject to rule 18 and 25)	$204.80	1 232
69499	Detection of hepatitis C viral RNA if at least 1 of the following criteria is satisfied: (a) the patient is hepatitis C seropositive; (b) the patient's serological status is uncertain after testing; (c) the test is performed for the purpose of: (i) determining the hepatitis C status of an immunosuppressed or immunocompromised patient; or (ii) the detection of acute hepatitis C prior to seroconversion where considered necessary for the clinical management of the patient; To a maximum of 1 of this item in a 12 month period (Item is subject to rule 19 and 25)	$92.20	15 599
69500	A test described in item 69499 if rendered by a receiving APP 1 test (Item is subject to rule 18,19 and 25)	$92.20	1 432

5. Recommendations to other committees

5.1 Recommendations to MSAC Executive

5.1.1 Orthopaedic tissues (new items)

5.1.1.1 Recommendation

- Propose three new item numbers for the collection of > 3 and ≤ 5 samples to determine prosthetic joint infection.

- Tissue samples from all intraoperative biopsies should also be referred to anatomical pathology, as a PMN (polymorphonuclear cells) count per high-power field provides additional information relating to determining the likelihood of infection versus loosening of prosthesis.

Table 36: Proposed new items and descriptors for orthopaedic tissues

Item	Proposed descriptor
New item orthopaedic tissues 1	Microscopy and culture of intraoperative biopsies in the assessment of prosthetic joint infections of 3 specimens involving aerobic and anaerobic culture and including if performed: Pathogen identification and antibiotic susceptibility testing to determine the significance based on indistinguishable isolates being detected from 2 or more specimens.
New item orthopaedic tissues 2	Microscopy and culture of intraoperative biopsies in the assessment of prosthetic joint infections of 4 specimens involving aerobic and anaerobic culture and including if performed: (a) Pathogen identification and antibiotic susceptibility testing to determine the significance based on indistinguishable isolates being detected from 2 or more specimens. (b) A service described in new item orthopaedic tissues 1.
New item orthopaedic tissues 3	Microscopy and culture of intraoperative biopsies in the assessment of prosthetic joint infections of 5 or more specimens involving aerobic and anaerobic culture and including if performed: (a) Pathogen identification and antibiotic susceptibility testing to determine the significance based on indistinguishable isolates being detected from 2 or more specimens. (b) A service described in new item orthopaedic tissues 1 and new item orthopaedic tissues 2.

5.1.1.2 Rationale

- International consensus guidelines demonstrate there is clinical benefit in the collection of > 3 and ≤ 5 tissue specimens to monitor and manage infection in orthopaedic joint surgery.

- The number of samples required to be processed and the histology workload required is significant. This is a growing area and increased demand is expected in the future. Preserving prosthetic joints in place is a benefit to the patient and reduces additional costs to health.

- For intraoperative biopsy, guidelines suggest use of multiple samples as part of debridement and retention procedure or when a joint is being revised. Samples may include fluids, pus, synovium, granulation tissue and membrane (tissue that forms at the bone-cement or bone-prosthesis interface). [25]

- There is currently no item in the Schedule that adequately covers this. Services are currently being billed under 69321, which does not recognise the workload and materials required for this procedure. No new technology is involved (with the exclusion of sonication, which is becoming less relevant with improved tissue sampling at time of revisions).

- Data provided by the Department linking Pathology item 69321 to various orthopaedic revision procedures indicate an increase in the number of these services being billed. Members felt that this was a growth area and the changes in practice required to meet best practice were not adequately addressed within the current Schedule.
- Bemer et al demonstrated no impact on clinical effectiveness of microbiological diagnosis of prosthetic joint infection if four rather than five samples were assessed. [26]
- This recommendation is supported by the Orthopaedic Clinical Committee as contemporary best practice. [25], [27], [28], [29]

5.2 Recommendations to MSAC

5.2.1 Testing for multi-resistant organisms (MRO) – new items

5.2.1.1 Recommendation

- Create a new item number to fund the testing for multi-resistant organisms (MRO) from appropriate sites.

Table 37: Proposed new items and descriptors for multi-resistant organisms

Item	Proposed descriptor
New item MRO 1	Culture of specimens (skin; nose, throat, groin, rectal swab, faeces) to determine the presence of multi-resistant organisms. Including (if performed): pathogen identification and antibiotic susceptibility testing.
New item MRO2	Confirmation of antibiotic resistant organisms using NAAT. This test should only be performed after item MRO1.

5.2.1.2 Rationale

- Currently laboratories receive a large number of swabs for determining the presence of methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and carbapenemase-producing Enterobacteriaceae (CPE). These are expensive to process, requiring screening media, identification and susceptibility testing, confirmatory testing by polymerase chain reaction (PCR) or other expensive assays. These investigations are not currently funded.
- Early detection of multi-resistant organisms significantly influences patient management and associated clinical outcomes in healthcare facilities, allowing for preoperative clearance and identifying when differing empirical antimicrobial therapy is required. If a resistant organism is identified in a patient, appropriate treatment and/or infection control measures can be initiated. [30]
- In addition, there are significant public health implications. In May 2017, the Australian Commission on Safety and Quality in Health Care (the Commission) published *Recommendations for the control of carbapenemase-producing Enterobacteriaceae (CPE). A guide for acute care health facilities.* [31] This report, which recommends a range of screening strategies based on risk, notes:
  - Identification of colonised patients on entry to the health facility is important because transfer of colonised patients has been identified as a major risk factor for the introduction and spread of CPE. This has been clearly documented at a global level. [31]

- In June 2015 the Department of Health released its first National Antimicrobial Resistance Strategy (2015–2019), with seven objectives. [32] The third objective relates specifically to screening for multi-resistant organisms:
  - Develop nationally coordinated One Health surveillance of antimicrobial resistance and antimicrobial usage.
- The establishment of national surveillance programs will be guided by seven identified objectives, the second of these being directly relevant to this MSAC recommendation:
  - Active and passive surveillance programs to determine the prevalence of antimicrobial resistance in organisms causing serious health problems in health care and community-acquired infections. [32]
- Priority organisms are listed below.

Table 38: Australia's list of priority organisms

Rationale	Species
Impact in both hospitals and the community	*Enterobacteriaceae (principally* ***Escherichia coli*** *and* ***Klebsiella species****)* *Enterococcus species* *Mycobacterium tuberculosis* ***Neisseria gonorrhoeae*** *Neisseria meningitidis* ***Salmonella species*** ***Shigella species*** ***Streptococcus pneumoniae*** ***Staphylococcus aureus***
Impact largely in hospitals	*Acinetobacter baumannii* complex *Enterobacter cloacae/aerogenes* *Pseudomonas aeruginosa*
Epidemiological and/or antimicrobial usage marker	*Campylobacter jejuni/coli*
Monitored through passive surveillance and elevated to targeted surveillance if threshold exceeded	*Clostridium difficile* *Haemophilus influenzae* type b *Streptococcus agalactiae* *Streptococcus pyogenes*

* WHO priority organisms for surveillance are in **bold.**

- In recognition of the problem, the Department of Health has funded the Commission to coordinate the national surveillance system to guide strategies to reduce the impact of antimicrobial resistance. This national surveillance system will help track the emergence of new drug-resistant organisms and the prevalence of important drug-resistant organisms. The National Alert System for Critical Antimicrobial Resistances: CARAlert, was established by the Commission in March 2016. [30]

5.2.2 Reflex cultures (new items)

- A review by Health Consult, Review of culture-independent diagnostic testing, undertaken at the request of the Department of Health. [5]

5.2.2.1 Recommendation

- To support the proposal outlined in the Health Consult review that new items numbers be introduced for:
  - reflex culture of positive PCR results for pathogens of public health significance as listed in the National Notifiable Disease List (NNDL)

– packaging for transfer of these specimens to public health reference laboratories for phenotypic, genotypic and serological characterisation.

Table 39: Proposed new items and descriptors for reflex cultures

Item	Proposed descriptor
New item reflex culture 1	Reflex culture of specimen where culture independent detection of microbial pathogen of public health significance, with referral of the isolate to a public health laboratory.
New item reflex culture 2	Packaging of an isolate or a specimen of pathogen of public health significance for transfer to a public health reference laboratory for phenotypic, genotypic and serological characterisation.

5.2.2.2 Rationale

- Δ The Committee noted the recommendations from HealthConsult paper referred to above. [5]
- Δ The Committee accepted recommendations for new items for reflex culture for positive PCR results and relevant transfer of specimens (Recommendations R5 and R6 in the report), but recommended removal of the reference to a list of 'pathogens of interest'; instead recommending the descriptor state 'pathogens of public health significance' as listed in the National Notifiable Disease List (NNDL) or similar.
- Δ Linking the descriptor for this item to the NNDL would ensure it always remains current and relevant, whereas a list of pathogens of interest would require regular amendment to ensure currency.
- Δ The Committee recommended that the costs associated with these tests and the appropriate fee as proposed in the Health Consult review should be referred to the Pathology Business Group for consideration.
- Δ The Committee did not accept recommendations R1, R2, R3 and R4 in preference for describing the alternative proposed structure of the molecular items in the schedule (see section 4.1 of this report).

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7. Appendix A—Assigned and referred items: recommendations

Item	Current descriptor	Recommendation	Section reference
69300	Microscopy of wet film material other than blood, from 1 or more sites, obtained directly from a patient (not cultures) including: (a) differential cell count (if performed); or (b) examination for dermatophytes; or (c) dark ground illumination; or (d) stained preparation or preparations using any relevant stain or stains; 1 or more tests	Change	4.14
69303	Culture and (if performed) microscopy to detect pathogenic microorganisms from nasal swabs, throat swabs, eye swabs and ear swabs (excluding swabs taken for epidemiological surveillance), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; specimens from 1 or more sites	Change	4.11
69306	Microscopy and culture to detect pathogenic microorganisms from skin or other superficial sites, including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69312, 69318; 1 or more tests on 1 or more specimens	Change	4.11
69309	Microscopy and culture to detect dermatophytes and other fungi causing cutaneous disease from skin scrapings, skin biopsies, hair and nails (excluding swab specimens) and including (if performed): (a) the detection of antigens not elsewhere specified in this Table; or (b) a service described in items 69300, 69303, 69306, 69312, 69318; 1 or more tests on 1 or more specimens	No change	4.18
69312	Microscopy and culture to detect pathogenic microorganisms from urethra, vagina, cervix or rectum (except for faecal pathogens), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69318; 1 or more tests on 1 or more specimens	Change	4.3.1 & 4.11
69316	Detection of chlamydia trachomatis by any method - 1 test (Item is subject to rule 26)	Delete	4.3.1 & 4.16.6
69317	1 test described in item 69494 and a test described in 69316. (Item is subject to rule 26)	Delete	4.3.1, 4.12 & 4.16.6
69318	Microscopy and culture to detect pathogenic microorganisms from specimens of sputum (except when part of items 69324, 69327 and 69330), including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in items 69300, 69303, 69306 and 69312; 1 or more tests on 1 or more specimens	Change	4.11
69319	2 tests described in item 69494 and a test described in 69316. (Item is subject to rule 26)	Delete	4.3.1, 4.12 & 4.16.6
69321	Microscopy and culture of post-operative wounds, aspirates of body cavities, synovial fluid, CSF or operative or biopsy specimens, for the presence of pathogenic microorganisms involving aerobic and anaerobic cultures and the use of different culture media, and including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300, 69303, 69306, 69312 or 69318; specimens from 1 or more sites	Change	4.13
69324	Microscopy (with appropriate stains) and culture for mycobacteria - 1 specimen of sputum, urine, or other body fluid or 1 operative or biopsy specimen, including	No change	4.18

Item	Current descriptor	Recommendation	Section reference
	(if performed): (a) microscopy and culture of other bacterial pathogens isolated as a result of this procedure; or (b) pathogen identification and antibiotic susceptibility testing; including a service mentioned in item 69300		
69325	A test described in item 69324 if rendered by a receiving APP. (Item is subject to rule 18)	No change	4.18
69327	Microscopy (with appropriate stains) and culture for mycobacteria - 2 specimens of sputum, urine, or other body fluid or 2 operative or biopsy specimens, including (if performed): (a) microscopy and culture of other bacterial pathogens isolated as a result of this procedure; or (b) pathogen identification and antibiotic susceptibility testing; including a service mentioned in item 69300	No change	4.18
69328	A test described in item 69327 if rendered by a receiving APP (Item is subject to rule 18)	No change	4.18
69330	Microscopy (with appropriate stains) and culture for mycobacteria - 3 specimens of sputum, urine, or other body fluid or 3 operative or biopsy specimens, including (if performed): (a) microscopy and culture of other bacterial pathogens isolated as a result of this procedure; or (b) pathogen identification and antibiotic susceptibility testing; including a service mentioned in item 69300	No change	4.18
69331	A test described in item 69330 if rendered by a receiving APP. (Item is subject to rule 18)	No change	4.18
69333	Urine examination (including serial examination) by any means other than simple culture by dip slide, including: (a) cell count; and (b) culture; and (c) colony count; and (d) (if performed) stained preparations; and (e) (if performed) identification of cultured pathogens; and (f) (if performed) antibiotic susceptibility testing; and (g) (if performed) examination for pH, specific gravity, blood, protein, urobilinogen, sugar, acetone or bile salts	No change	4.15 & 4.18
69336	Microscopy of faeces for ova, cysts and parasites that must include a concentration technique, and the use of fixed stains or antigen detection for cryptosporidia and giardia - including (if performed) a service mentioned in item 69300 - 1 of this item in any 7 day period	Delete	4.2
69339	Microscopy of faeces for ova, cysts and parasites using concentration techniques examined subsequent to item 69336 on a separately collected and identified specimen collected within 7 days of the examination described in 69336 - 1 examination in any 7-day period	Change	4.2
69345	Culture and (if performed) microscopy without concentration techniques of faeces for faecal pathogens, using at least 2 selective or enrichment media and culture in at least 2 different atmospheres including (if performed): (a) pathogen identification and antibiotic susceptibility testing; and (b) the detection of clostridial toxins; and (c) a service described in item 69300; - 1 examination in any 7 day period	Delete	4.2
69354	Blood culture for pathogenic microorganisms (other than viruses), including sub-cultures and (if performed): (a) identification of any cultured pathogen; and (b) necessary antibiotic susceptibility testing; to a maximum of 3 sets of cultures - 1 set of cultures	No change	4.2
69357	2 sets of cultures described in item 69354	No change	4.18
69360	3 sets of cultures described in item 69354	No change	4.18

Item	Current descriptor	Recommendation	Section reference
69363	Detection of Clostridium difficile or Clostridium difficile toxin (except if a service described in item 69345 has been performed) - one or more tests	Change	4.2
69378	Quantitation of HIV viral RNA load in plasma or serum in the monitoring of a HIV seropositive patient not on antiretroviral therapy - 1 or more tests	Minor Change	4.17.3
69379	A test described in item 69378 if rendered by a receiving APP -1 or more tests (Item is subject to rule 18)	Minor change	4.17.3
69380	Genotypic testing for HIV antiretroviral resistance in a patient with confirmed HIV infection if the patient's viral load is greater than 1,000 copies per ml at any of the following times: at presentation; or before antiretroviral therapy: or when treatment with combination antiretroviral agents fails; maximum of 2 tests in a 12 month period	No change	4.18
69381	Quantitation of HIV viral RNA load in plasma or serum in the monitoring of antiretroviral therapy in an HIV-seropositive patient - 1 or more tests on 1 or more specimens	Minor Change	4.17.3
69382	Quantitation of HIV viral RNA load in cerebrospinal fluid in a HIV seropositive patient - 1 or more tests on 1 or more specimens	Delete	4.16.4
69383	A test described in item 69381 if rendered by a receiving APP - 1 or more tests on 1 or more specimens (Item is subject to rule 18)	Minor Change	4.17.3
69384	Quantitation of 1 antibody to microbial antigens not elsewhere described in the Schedule - 1 test (This fee applies where a laboratory performs the only antibody test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6, and rule 3 exemption)	Change	4.10 & 4.12
69387	2 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 2 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	No change	4.10 & 4.18
69390	3 tests described in item 69384. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 3 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	Change	4.10
69393	4 tests described in item 69384. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 4 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	Change	4.10
69396	5 or more tests described in item 69384. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 5 of the antibody tests specified on the request form and refers the remainder to the laboratory of a separate APA.) (Item is subject to rule 6)	Change	4.10
69400	A test described in item 69384, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rules 6 and 18)	No change	4.10 & 4.18
69401	A test described in item 69384, other than that described in 69400, if rendered by a receiving APP -	No change	4.10 & 4.18

Item	Current descriptor	Recommendation	Section reference
	each test to a maximum of 4 tests (Item is subject to rule 6, 18 and 18A)		
69405	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 1 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	Delete	4.15 & 4.16.2
69408	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 2 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	Delete	4.15 & 4.16.2
69411	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 3 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	Delete	4.15 & 4.16.2
69413	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of 4 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	Delete	4.15 & 4.16.2
69415	Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient suffering from parvovirus infection or varicella during that pregnancy) including: (a) the determination of all 5 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B, hepatitis C antibody, HIV antibody and (b) (if performed) a service described in 1 or more of items 69384, 69475, 69478 and 69481	No change	4.15 & 4.18
69418	A test for high risk human papillomaviruses (HPV) in a patient who: - has received excisional or ablative treatment for high grade squamous intraepithelial lesions (HSIL) of the cervix within the last two years; or who within the last two years has had a positive HPV test after excisional or ablative treatment for HSIL of the cervix; or - is already undergoing annual cytological review for the follow-up of a previously treated HSIL. - to a maximum of 2 of this item in a 24-month period (Item is subject to rule 25)	Delete	4.16.3
69419	A test described in item 69418 if rendered by a receiving APP - 1 test (Item is subject to rule 18 and 25)	Delete	4.16.3
69445	Detection of hepatitis C viral RNA in a patient undertaking antiviral therapy for chronic HCV hepatitis	No change	4.18

Item	Current descriptor	Recommendation	Section reference
	(including a service described in item 69499) - 1 test. To a maximum of 4 of this item in a 12-month period (Item is subject to rule 25)		
69451	A test described in item 69445 if rendered by a receiving APP - 1 test. (Item is subject to rule 18 and 25)	No change	4.18
69471	Test of cell-mediated immunity in blood for the detection of latent tuberculosis in an immunosuppressed or immunocompromised patient – 1 test	Change	4.5.3
69472	Detection of antibodies to Epstein Barr Virus using specific serology - 1 test	Delete	4.10
69474	Detection of antibodies to Epstein Barr Virus using specific serology - 2 or more tests	Delete	4.10
69475	One test for hepatitis antigen or antibodies to determine immune status or viral carriage following exposure or vaccination to hepatitis A, hepatitis B, hepatitis C or hepatitis D (item subject to rule 11)	Delete	4.9.3
69478	2 tests described in 69475 (item subject to rule 11)	Delete	4.9.3
69481	Investigation of infectious causes of acute or chronic hepatitis - 3 tests for hepatitis antibodies or antigens, (item subject to rule 11)	Delete	4.9.3
69482	Quantitation of hepatitis B viral DNA in patients who are hepatitis B surface antigen positive and have chronic hepatitis B, but are not receiving antiviral therapy - 1 test (item is subject to rule 25)	No change	4.18
69483	Quantitation of hepatitis B viral DNA in patients who are hepatitis B surface antigen positive and who have chronic hepatitis B and are receiving antiviral therapy - 1 test (item is subject to rule 25)	No change	4.18
69484	Supplementary testing for hepatitis B surface antigen or hepatitis C antibody using a different assay on the specimen which yielded a reactive result on initial testing (Item is subject to rule 18)	No change	4.9.3
69488	Quantitation of HCV RNA load in plasma or serum in the pre-treatment evaluation or the assessment of efficacy of antiviral therapy of a patient with chronic HCV hepatitis - where any request for the test is made by, or on the advice of, the specialist or consultant physician who manages the treatment of the patient with chronic HCV hepatitis (including a service in item 69499 or 69445) (Item is subject to rule 18 and 25)	Minor change	4.17.1
69489	A test described in item 69488 if rendered by a receiving APP (Item is subject to rule 18 and 25)	No change	4.18
69491	Nucleic acid amplification and determination of hepatitis C virus (HCV) genotype if: (a) the patient is HCV RNA positive and is being evaluated for antiviral therapy of chronic HCV hepatitis; and (b) the request for the test is made by, or on the advice of, the specialist or consultant physician managing the treatment of the patient; To a maximum of 1 of this item in a 12-month period	Minor change	4.17.2
69492	A test described in item 69491 if rendered by a receiving APP - 1 test (Item is subject to rule 18 and 25)	No change	4.18
69494	Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified) 1 test (Item is subject to rule 6 and 26)	Change	4.1 & 4.8
69495	2 tests described in 69494 (Item is subject to rule 6 and 26)	Delete	4.1,4.8 & 4.16.5

Item	Current descriptor	Recommendation	Section reference
69496	3 or more tests described in 69494 (Item is subject to rule 6 and 26)	Delete	4.1,4.8 & 4.16.5
69497	A test described in item 69494, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rule 6, 18 and 26)	Change	4.8
69498	A test described in item 69494, other than that described in 69497, if rendered by a receiving APP - each test to a maximum of 2 tests (Item is subject to rule 6, 18 and 26)	Delete	4.8 & 4.16.5
69499	Detection of hepatitis C viral RNA if at least 1 of the following criteria is satisfied: (a) the patient is hepatitis C seropositive; (b) the patient's serological status is uncertain after testing; (c) the test is performed for the purpose of: (i) determining the hepatitis C status of an immunosuppressed or immunocompromised patient; or (ii) the detection of acute hepatitis C prior to seroconversion where considered necessary for the clinical management of the patient; To a maximum of 1 of this item in a 12 month period (Item is subject to rule 19 and 25)	No change	4.18
69500	A test described in item 69499 if rendered by a receiving APP 1 test (Item is subject to rule 18,19 and 25)	No change	4.18
73828 referred	Semen examination for presence of spermatozoa by a participating nurse practitioner	Delete	4.16.1
73834 referred	Microscopy for wet film other than urine, including any relevant stain by a participating nurse practitioner	Delete	4.16.1
73835 referred	Microscopy of Gram-stained film, including (if performed) a service described in item 73832 or 73834 by a participating nurse practitioner	Delete	4.16.1
73837 referred	Microscopy for fungi in skin, hair or nails by a participating nurse practitioner – 1 or more sites	Delete	4.16.1

8. Appendix B—New items

Item	Proposed Descriptor	Recommendation	Section
693XA	Any combination of tests to detect gastrointestinal pathogen in unformed stool including the detection of bacterial, viral and parasite nucleic acid and culture using at least 2 selective or enrichment media in at least 2 different atmospheres including (if performed): (a) pathogen identification and antibiotic susceptibility testing; and (b) a service described in item 69300; - 1 examination in any 7-day period	The rationale behind combining NAAT, microscopy and culture is to encourage pathologists to perform the most appropriate test in accordance with clinical notes of the request and to prevent unnecessary testing.	4.2.1
693XB	Microscopy and culture to detect pathogenic microorganisms from throat (except for respiratory pathogens) urethra, vagina, cervix, throat or rectum (except for faecal pathogens), including (if performed): a) pathogen identification and antibiotic susceptibility testing; b) a service described in item 69300 or 69312 1 or more tests on 2 or more specimens	Retain 69312; however, add another duplicate item but for '2 or more specimens,' as multiple sites for testing for *Chlamydia trachomatis* and *Neisseria gonorrhoea* are recommended in the high-risk groups.	4.3.1
693XC	Detection of pathogenic microorganisms other than *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by any method from urogenital specimens, including (if performed) a service described in 69312. 1 specimen	Create a new method free item for the detection of pathogenic microorganisms associated with urogenital/ sexually transmitted disease pathogens from urogenital specimens. 1 specimen	4.3.1
693XD	Detection of pathogenic microorganisms other than *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by any method from urogenital specimens, including (if performed) a service described in 69312. 2 or more specimens	Create a new method free item for the detection of pathogenic microorganisms associated with urogenital/ sexually transmitted disease pathogens from urogenital specimens. 2 or more specimens.	4.3.1
693XE	Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoea* by NAAT. 2 or more tests (Item is subject to rule 26, and rule 3 exemption). 1 specimen	Create a new item for NAAT of *Chlamydia trachomatis* and *Neisseria gonorrhoea* for 2 or more tests. 1 specimen. Rule 3 exemption recommended	4.3.1 & 4.12
693XF	Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by NAAT. 2 or more tests (Item is subject to rule 26, and rule 3 exemption). 2 or more specimens	Create a new item for NAAT of *Chlamydia trachomatis* and *Neisseria gonorrhoea.* 2 or more tests. 2 or more specimens. Rule 3 exemption recommended	4.3.1 & 4.12
693XG	Culture for *Streptococcus agalactiae* (GBS) from combined low vaginal swab plus or minus anorectal swab at 35-37 weeks' gestation and susceptibility testing if performed in women allergic to penicillin	Create a new item for culture of *Streptococcus agalactiae* (GBS) at 35-37 weeks' gestation as per RANZCOG guidelines.	4.3.1
693XH	Detection of viral, atypical pneumonia pathogens and *Bordetella* spp. nucleic acid from nasal swabs, throat swabs, nasopharyngeal aspirates and lower respiratory tract samples. Specimens from 1 or more sites. 3 tests or more	Create a new NAAT item for molecular testing of viral, atypical pneumonia pathogens and *Bordetella* species from swabs and lower respiratory tract samples.	4.4.1
693XI	Detection of *M. tuberculosis* and antimicrobial molecular resistance nucleic acid from respiratory or non-pulmonary	Create a new NAAT item for the detection of *M. tuberculosis* (MTB) antibiotic resistance and antimicrobial molecular	4.5.1

Item	Proposed Descriptor	Recommendation	Section
	specimens where there is high clinical suspicion	resistance nucleic acid from respiratory or non-pulmonary specimens.	
693XJ	Detection of pathogenic organisms from skin or superficial site specimens using nucleic acid amplification techniques (NAAT)	Create a new NAAT item for the detection of pathogenic organisms from skin or superficial site specimens using dermatophyte detection by nucleic acid amplification techniques.	4.6.1
693XK	Detection of pathogenic organisms from sterile sites, CNS and ocular specimens using nucleic acid amplification techniques (NAAT)	Create a new NAAT item for the detection of pathogenic organisms from sterile sites such as the central nervous system (CNS) and ocular specimens.	4.7.1
Interim model item 694XA	Testing for hepatitis viruses A, B & C to determine immune status, and to diagnose; or monitor acute or chronic hepatitis - 3 or more tests	Delete items 69475, 69478, and 69481 and merge into one new item to cover any and all tests for hepatitis viruses A, B & C, including from checking immune status to diagnosing or monitoring acute or chronic hepatitis, up to 3 or more tests.	4.9
694XB	Test(s) to determine viral carriage of hepatitis D virus (in a HBs positive patient) or hepatitis E virus in a patient non-reactive in testing to other hepatitis viruses. One test only.	Create a new Item for the detection of hepatitis D and hepatitis E, with distinct clinical indicators	4.9.3
69321-X	Microscopy, cell counts (when indicated) and culture of aspirates of body cavities, synovial fluid, or CSF for the presence of pathogenic microorganisms involving aerobic and anaerobic cultures and the use of different culture media, and including (if performed): (a) pathogen identification and antibiotic susceptibility testing; or (b) a service described in item 69300; specimens from 1 or more sites.	Revise and separate/split the current item 69321 to recognise the different complexity associated with testing specimens from different sites. Create an item for the microscopy and culture of (a) post-operative wounds or operative or biopsy specimens, and an item for (b) aspirates of body fluids, synovial fluids and CSF.	4.13
Antenatal item	First trimester antenatal screen including all of the following: 1) Erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument generated differential count - not being a service in which haemoglobin only is requested - one or more instrument-generated set of results from a single sample; and (if performed) a morphological assessment of a blood film; and 2) Blood grouping (including back-grouping if performed), and examination of serum for Rh and other blood group antibodies, including identification and quantitation of any antibodies detected; and Urine examination (including serial examination) by any means other than simple culture by dip slide, including: (a) cell count; and (b) culture; and (c) colony count; and (d) (if performed) stained preparations; and (e) (if performed) identification of cultured pathogens; and	The Obstetrics Clinical Committee has recommended that there should be one item that includes the basic pathology tests that all pregnant women should have in the first trimester. This will standardise antenatal pathology screening in line with national guidelines and improve health outcomes for pregnant women and their babies.	4.15

Item	Proposed Descriptor	Recommendation	Section
	(f) (if performed) antibiotic susceptibility testing; and (g) (if performed) examination for pH, specific gravity, blood, protein, urobilinogen, sugar, acetone or bile salts; and Microbiological serology during a pregnancy (except in the investigation of a clinically apparent intercurrent microbial illness or close contact with a patient who has parvovirus infection or varicella during that pregnancy) including the determination of all 5 of the following - rubella immune status, specific syphilis serology, carriage of hepatitis B or hepatitis C antibody or HIV antibody. This item includes (if performed) any test described in 65060, 65070, 65072, 65096, 69333, 69415 and 69384. (Item is subject to rule 25) Rule 25 would be once per year per pregnancy.		
69399		Reinstatement of serology item for 6 or more tests.	4.10
New item orthopaedic tissues 1	Microscopy and culture of intraoperative biopsies in the assessment of prosthetic joint infections of 3 specimens involving aerobic and anaerobic culture and including if performed: Pathogen identification and antibiotic susceptibility testing to determine the significance based on indistinguishable isolates being detected from 2 or more specimens.	Propose three new item numbers for the collection of > 3 and ≤ 5 samples to determine prosthetic joint infection.	5.1.1
New item orthopaedic tissues 2	Microscopy and culture of intraoperative biopsies in the assessment of prosthetic joint infections of 4 specimens involving aerobic and anaerobic culture and including if performed: (a) Pathogen identification and antibiotic susceptibility testing to determine the significance based on indistinguishable isolates being detected from 2 or more specimens. (b) A service described in new item orthopaedic tissues 1.	As above	5.1.1
New item orthopaedic tissues 3	Microscopy and culture of intraoperative biopsies in the assessment of prosthetic joint infections of 5 or more specimens involving aerobic and anaerobic culture and including if performed: (a) Pathogen identification and antibiotic susceptibility testing to determine the significance based on indistinguishable isolates being detected from 2 or more specimens. (b) A service described in new item orthopaedic tissues 1 and new item orthopaedic tissues 2.	As above	5.1.1

Item	Proposed Descriptor	Recommendation	Section
New item MRO 1	Culture of specimens (skin; nose, throat, groin, rectal swab, faeces) to determine the presence of multi-resistant organisms. Including (if performed): pathogen identification and antibiotic susceptibility testing.	Create a new item number to fund the testing for multi-resistant organisms (MRO) from appropriate sites.	5.2.1
New item MRO 2	Confirmation of antibiotic resistant organisms using NAAT. This test should only be performed after item MRO1.	As above	5.2.1
New item reflex culture 1	Reflex culture of specimen where culture independent detection of microbial pathogen of public health significance, with referral of the isolate to a public health laboratory.	Introduce a new item number for reflex culture of positive PCR results for pathogens of public health significance as listed in the National Notifiable Disease List (NNDL)	5.2.2
New item reflex culture 2	Packaging of an isolate or a specimen of pathogen of public health significance for transfer to a public health reference laboratory for phenotypic, genotypic and serological characterisation.	Introduce a new item number for packaging for transfer of these specimens to public health reference laboratories for phenotypic, genotypic and serological characterisation.	5.2.2

9. Appendix C—Summary for consumers

This table describes the pathology services, the recommendation(s) of the clinical experts and why the recommendation(s) has been made.

Recommendations 1 to 8: System framework for microbiology testing using NAAT

This table contains	What they do	Committee recommendation	What would be different	Why
69494-69498 and new items 693XA -693XK	Nucleic acid amplification tests (NAAT) are molecular tests that detect the genetic material (DNA) of organisms. NAAT have significant sensitivity and turnaround time advantages over traditional culture-based methods, potentially returning same-day results. NAAT for viruses are well established and an increasing number of commercial multi-target assays are now available for bacteria and parasites.	Replace the current 'generic' items that covers all molecular tests with a series of new item numbers based on body systems. The new items will specify which body system the tests are being performed on.	In time, these recommendations will have patient benefits. Through the proposed initial changes, requesters will order tests and, depending on where in the body the samples come from, pathologists will use the new specific item number for payment. The information about what sort of tests are being ordered and funded through the MBS will enable further future development of the schedule and information systems to assist requesters to order the most appropriate tests for specific clinical conditions.	NAAT tests will be used for many more organisms and will replace many other traditional methods in the schedule in the future. As this is a growing area, it will be important to know what tests are being ordered for what reasons. By making the schedule more detailed and based on body systems, information can be used to develop processes to assist requesters to order the most appropriate tests for different clinical conditions. At present more than 1.3 million tests are ordered under the general item, with no information available to improved ordering systems around these.

Recommendation 9: Hepatitis serology items

Items	What they do	Committee recommendation	What would be different	Why
69475–69484 and new items 6947A-6947E	Blood tests are used to detect, measure and monitor hepatitis infections. There are different hepatitis viruses that cause different types of hepatitis (A, B, C, D, E) and the national testing guidelines are different for each virus and for different patient populations.	The 'ideal' recommendation is to match the Schedule to the treatment guidelines for the different hepatitis viruses. Unfortunately, this is very complicated and impractical to do without better information systems. In the meantime, the recommendation is to simplify the schedule and, depending on the information provided by the requester, the pathologist will perform the necessary number of tests using the simplified schedule.	There will be no difference for patients. Some patients will require fewer tests performed by the pathologist and others will require more, depending on the national testing guidelines. The 'ideal' model would allow more specific test ordering and provide requesters with more guidance on which tests to order for which patient populations.	Ordering hepatitis tests can be confusing for requesters, and unless enough information is provided, it can be difficult for pathologists to know how many tests to perform. Applying the current Schedule is difficult without the detailed clinical information. Until better information and ordering systems have been developed, it is better to make the Schedule very basic and, depending on the request, the type of hepatitis and the patient's clinical situation, the pathologist will decide which tests are most appropriate.

Recommendation 10: Serology items and Epstein–Barr virus (EBV)

Items	What they do	Committee recommendation	What would be different	Why
69384-69401, 69472 and 69474	A serology blood test is performed to detect and measure the levels of antibodies as a result of exposure to a particular bacteria or virus. When people are exposed to bacteria or viruses their body's immune system produces specific antibodies against the organism. Antibody levels help determine whether an infection occurred recently or years ago.	Increase the number of serology tests that can be claimed from a maximum of 5 to a maximum of 6. Include in the maximum number of tests, the tests required for Epstein–Barr virus, which are currently claimed under separate item numbers.	There would be no difference to patients. This change recognises the shift in testing patterns and the use of results to determine the best treatment methods for infections. It recognises the increase in the types of diseases and changes in organisms in Australia over the past 20 years since these items were introduced to the MBS.	The serology items were introduced to the MBS in 1996. Since then many new diseases have emerged in the Australian community, and it is now not uncommon that at least 6 different tests are required for common clinical situations. This information can improve diagnosis and management of infections, and can indicate whether use of antimicrobials is required. This benefits patients and the wider community.

Recommendation 11: Site specific culture and microscopy tests

Items	What they do	Committee recommendation	What would be different	Why
69303, 69306, 69312, 69318	Samples of body fluids and tissue, come from various sites throughout the body, depending on the suspected source of infection. *Microscopy:* the sample can be viewed under a microscope in the laboratory. This enables a quick initial report, such as 'Gram positive cocci seen', to be telephoned to the clinician if necessary. When combined with an accurate clinical picture this may be enough to initiate targeted treatment. *Culture:* a sample from the original culture is grown to create a pure sample to enable further identification of an organism. This is valuable if the organism is unusual, and may confirm or indicate a change to treatment. Culturing can also enable a bacterial count to be made, which can assist in deciding whether a wound is colonised or infected, and so what the treatment plan would be.	The culture and microscopy tests for different specimen types from different body systems should be separate items.	There will be no difference for patients. This change recognises that different specimens taken from different body systems are collected, handled, tested and reported separately and as such are independent of each other. At the moment, if specimens are taken from 3 separate parts of the body, pathologists can only claim for one item, regardless of the different tests and reports required for different types of specimens.	Currently, the item descriptors include any tests performed on specimens from other sites. As each of these site-specific tests is independent in terms of laboratory processes, consumables and resources, the Committee recommended they should be funded separately.

Recommendation 12: HIV/STI Rule 3 exemption

Item	What it does	Committee recommendation	What would be different	Why
69317, 69319, 69384, 69387,69390,69396, 69494	Rule 3 Exemption provides exemptions to the multiple services rule and has been applied to certain specified tests (e.g. full blood count) for certain conditions or therapies (e.g. chemotherapy for cancer). It is intended to cover seriously or chronically ill patients who require particular tests under specified circumstances It allows for tests to be repeated up to 6 times over a 24-hour period, or tests that are requested up to 6 times on a single request form and performed within 6 months of the date of request, to be eligible for Medicare benefits. It enables patients to have the tests regularly without needing to go to a GP for a request form each time.	Apply Rule 3 exemption to HIV/STI testing (chlamydia and gonorrhoea NAAT testing and HIV serology) in the ASHM proposed high-risk population.	HIV and STI testing are currently covered by separate items, with a new GP consultation required for each test. Rule 3 Exemptions would allow for up to 4 tests in a 6-month period for HIV and STI testing in high-risk populations without the requirement of additional GP consultations.	Clinical guidelines recommend regular testing for HIV and STIs in high-risk populations. Removing the need for these patients to have to go to their GP each time for a request form will make it easier and more practical for them to be tested. Ensuring these patients are tested is an important public health issue that will have benefits across the health system, including an increase in detection, an increase in transmission aversion rates and a decrease in costs to the overall health system from HIV and STIs.

Recommendation 13: Microscopy and culture of complicated hospital specimens

Item	What it does	Committee recommendation	What would be different	Why
Split/ new item 69321 69321-X	Microscopy and culture tests are performed on complicated hospital specimens to identify organisms that may be causing an infection and determine which antibiotics may be suitable if treatment is required. The types of specimens can be either tissues such as post-operative wounds, during an operation or biopsies, or fluids such as samples of body fluids, fluid from joints or the spine.	Revise and separate/split the current item 69321 to recognise the different complexity associated with testing specimens from different sites. Create an item for the microscopy and culture of (a) post-operative wounds or operative or biopsy specimens, and an item for (b) aspirates of body fluids, synovial fluids and cerebrospinal fluid.	There would be no difference to the patient. The time, materials and complexity of testing on complicated fluids is more than that required to test tissues. Splitting this item will enable a review of the costing and to redistribute the fees to recognise that testing the fluids is more complicated and expensive to perform.	The workload and procedures involved in microscopy and culture of fluid samples is more complicated than samples obtained from anatomical sites. Additional tests such as differential cell counts are performed and microscopy may include the detection of crystals in fluids. Specimens may be added into blood culture bottles, which increase the cost of consumables and monitoring.

Recommendation 14: Microscopy of wet film

Item	What it does	Committee recommendation	What would be different	Why
69300	Wet film microscopy involves mixing the specimen with liquid to be viewed under a microscope in the laboratory. It is used to identify organisms causing specific infections.	Amend the descriptor to remove methods that are no longer used—examination of dermatophytes and dark ground illumination.	There will be no difference to patients. This change updates the item to remove methods that are no longer recommended or used.	Over time, laboratory test methods improve, and older methods that were once used are now no longer used and can be deleted from the item descriptor.

Recommendation 15: Antenatal bundle

Item	What it does	Committee recommendation	What would be different	Why
69415, 69333	The Committee has recommended that that all pregnant women should have certain basic pathology tests in the first trimester. This will standardise antenatal pathology screening in line with national guidelines and improve health outcomes for pregnant women and their babies.	The Committee supports the inclusion of item 69333—Urine examination, and item 69415—Hepatitis B, hepatitis C, HIV, rubella, syphilis (item is for testing all 5 infections) into a 'bundle' of tests.	All pregnant women will have the basic tests they need. By having one item number to cover the tests they need, the risk is reduced that one of the tests may be missed.	National guidelines recommend that all Australian women should have a basic set of tests to check the health of themselves and their babies. This change will help reduce the risk of any of these important screening tests being missed.

Recommendation to MSAC Executive 5.1.1: Orthopaedic tissues – new items

Item	What it does	Committee recommendation	What would be different	Why
New item/s	International consensus guidelines demonstrate there is clinical benefit in the collection of > 3 and ≤ 5 tissue specimens to monitor and manage infection in orthopaedic joint surgery.	Propose three new item numbers for the collection of > 3 and ≤ 5 samples to determine prosthetic joint infection.	The number of samples required to be processed and the histology workload required is significant. This is a growing area and increased demand is expected in the future. Preserving prosthetic joints in place is a benefit to the patient and reduces additional costs to health.	There is currently no item in the Schedule that adequately covers this. Services are currently being billed under 69321, which does not recognise the workload and materials required for this procedure.

Recommendation to MSAC 5.2.1: Testing for multi-resistant organisms – new items

Item	What it does	Committee recommendation	What would be different	Why
New item/s	Many organisms are developing resistance to antimicrobial agents. Identifying these significantly influences patient management and their clinical outcomes. Understanding the patterns of resistance and antimicrobial usage across the country is a national priority.	Create new item numbers to fund the testing for multi-resistant organisms (MRO) from appropriate sites.	Currently these tests are not funded. The importance of testing for resistance in important organisms and using antimicrobials appropriately is now well understood. These tests are expensive and the Committee recommends they should be funded. The impact is on individual patients as well as significant public health implications.	These tests are not currently funded and are required to identify resistant organisms and ensure the most appropriate antimicrobials are used. These tests are expensive and are currently provided without reimbursement.

Recommendation to MSAC 5.2.2: Reflex cultures – new items

Item	What it does	Committee recommendation	What would be different	Why
New item/s	For certain organisms identified as 'pathogens of public health significance', laboratories are required to perform additional 'reflex testing' and also send the specimen to another reference laboratory for testing. This surveillance system enables close monitoring of certain infections across Australia and can help identify changes in infection patterns and help avoid spread of diseases.	Support the proposal that new items numbers be introduced for: (a) reflex culture of positive test results (by polymerase chain reaction, PCR) for pathogens of public health significance as listed in the National Notifiable Disease List (NNDL); and (b) packaging for transfer of these specimens to reference laboratories.	Currently these services are not funded and laboratories perform these tests without reimbursement. There would be no difference to patients, but funding of these items would help ensure all the specimens that should be reflex tested and transferred to reference laboratories actually are.	Public health surveillance of infection patterns is essential to avoid the outbreak of diseases. Laboratories are required to perform additional tests and services if certain organisms are identified and currently this is not funded and the costs are borne by the laboratory.

10. Appendix D—Glossary

Term	Description
ABS	Australian Bureau of Statistics
APA	Approved Pathology Authority
APP	Approved Pathology Practitioner
ASHM	Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
CAGR	Compound annual growth rate, or the average annual growth rate over a specified time period.
Change	When referring to an item, 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 (e.g. splitting the current services provided across 2 or more items).
Coning, or episode coning	Episode coning is an arrangement that places an upper limit on the number of services in an episode for which Medicare benefits are payable, and was introduced to prevent over-servicing by doctors. Generally, when more than three items are requested in an episode by a GP for an out-of-hospital service, Medicare only pays for the three most expensive items. Pathology services requested for hospital in-patients, or ordered by specialists, are not subject to these coning arrangements.
Department, The	Australian Government Department of Health
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
FY	Financial year
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.
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.
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.
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 these will need to go through MSAC. It is worth noting that implementation of the recommendation may result in more or fewer item numbers than specifically stated.
No change or unchanged	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

Term	Description
	descriptors (e.g. 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 provided, as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
PBS	Pharmaceutical Benefits Scheme
GPPCCC	General Practice and Primary Care Clinical Committee
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCPA	The Royal College of Pathologists of Australia
Services average annual growth	The average growth per year, over 5 years to FY 2014–15, in utilisation of services. Also known as the compound annual growth rate (CAGR).
Split items	Where an item contains more than 1 test or more than 1 process, a recommendation to split the item means that that part of the test would become a separate item number.
The Committee	The Pathology Clinical Committee
The Taskforce	The MBS Review Taskforce
Total benefits	Total benefits paid in 2014–15 unless otherwise specified.