Medicare Benefits Schedule Review Taskforce

Report from the Blood Products Working Group

July 2017

Important note

The views and recommendations in this Review 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; and
- Government.

Stakeholders should provide comment on the recommendations via the online consultation tool.

Confidentiality of comments:

If you want 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.

Table of Contents

List of Tables

List of Figures

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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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. 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.

The majority of 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. A complete list of items, including the nature of the recommendations and the page number for each recommendation, can be found in Appendix A (in table summary form).

Recommendations for consultation

The Committee's recommendations for stakeholder consultation are:

- **that two items should be deleted from the MBS;**
- **two items should be changed; and**
- **four items should remain unchanged.**

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.

Δ **Collection and transfusion of blood products.** To reword the descriptor for item 13703 to include the specification that the item be used for intra-operative normovolaemic haemodilution; and to remove items 13706 and 13709 from the MBS.

Δ **Stem cell transplantation.** To reword the descriptor for item 13760 to broaden the list of current indications associated with malignancy; and to specify that the item is for use as part of a treatment program overseen by a multidisciplinary team experienced in the treatment of malignant disorders.

1.4 Consumer engagement

The Committee believes it is important to find out from consumers if they will be impacted by the recommendations outlined in this report. Following public consultation, the Committee will assess the advice from consumers and decide whether any changes are needed to the recommendations.

The Committee will then send the recommendations to the Taskforce. The Taskforce will consider the recommendations as well as the information provided by consumers to make sure all the

important concerns are addressed. The Taskforce will then provide the recommendations to government.

- The Committee brought together practitioners with experience in, and commitment to, the care of people with clinical diseases, to examine how well the description of Medicare items match current clinical practice and meet the needs of Australians. Consumer representatives were on the Committee and in every working group.
- There is also a list of all the reviewed items, written in plain English, in Appendix B – Summary for consumers.
- Changes have been recommended for some items that are no longer up to date. Some items are no longer used, and some should not be used because clinical best practice has changed since they were originally listed. These items have been recommended for deletion.
- Most of the work conducted by the Committee focused on clinical issues and the provision of clinical services. As a result, the consumer representative relied on the advice of the clinicians regarding how consumers would be affected.
- The consumer representative 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 haematology 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

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).

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

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.

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. The framework consists of seven steps:

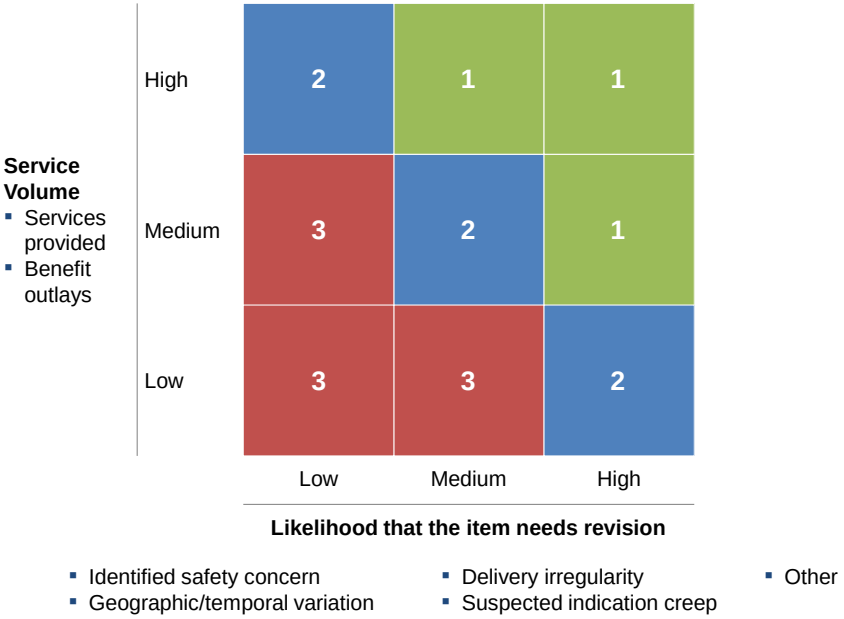
1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.
2. Identify items that are obsolete, are of questionable clinical value, are misused and/or pose a risk to patient safety. This step includes prioritising items as 'priority 1,' 'priority 2'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

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of and time frame 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 haematology-related MBS items.

The Committee consists of 17 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	National Prescribing Service	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 Blood Products Working Group

The Blood Products Working Group is a subgroup of one of six clinical working groups that have been established to support the work of the Pathology Clinical Committee. It was established to review miscellaneous therapeutic procedures subgroup 8 (haematology).

These items (13700 to 13760) cover the administration of blood products, haemapheresis, venesection and stem cell transplantation. The recommendations to the Pathology Clinical Committee are based on rapid evidence review and clinical expertise.

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

Table 2. Blood Products Working Group Members

Name	Position/organisation	Declared conflict of interest
Professor Mark Hertzberg (Chair)	Professor of Haematology, Prince of Wales Hospital, Randwick Conjoint Professor, University of NSW	Provider of MBS-funded services reviewed by this Committee.
Dr Michael Harvey	Director of Haematology, Liverpool Hospital, Liverpool NSW	Provider of MBS-funded services reviewed by this Committee.
Dr Joanne Joseph	Senior staff Specialist in Haematology, Head of Laboratory Haematology, SydPath, St Vincent's Hospital, Sydney; Conjoint Senior Lecturer UNSW Associate	Provider of MBS-funded services reviewed by this Committee.
Professor Glen Kennedy	Acting Executive Director, Cancer Care Services, Metro North Hospital & Health Service, Queensland	Provider of MBS-funded services reviewed by this Committee.
Dr Susan MacCallum	Senior staff specialist in Haematology Prince of Wales Hospital; Conjoint senior lecturer UNSW	Provider of MBS-funded services reviewed by this Committee.
Dr Campbell Tiley	Senior staff Specialist in Haematology, NSW Health Pathology; , Clinical Director of Medicine, Central Coast LHD; Conjoint Senior Lecturer, School of Medicine and Public Health, University of Newcastle	Provider of MBS-funded services reviewed by this Committee.
Mr John Stubbs	Chief Executive Officer, CanSpeak Member, Medical Services Advisory Committee Consumer Representative	Nil

3.3 Areas of responsibility of the Committee

The Committee was assigned 8 MBS blood products items to review. 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 8 blood products items across two meetings, during which it developed the recommendations and rationales outlined in Section 4.

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 are 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 the use of blood products

Introduction

The Committee reviewed 8 assigned blood products 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 Appendix A, and in the consumer summary table in Appendix B.

The Committee's recommendations for public consultation are that two items should be deleted (and their services no longer be provided under the MBS), two items should be changed, and four items should remain unchanged.

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 group.

4.1 Collection and transfusion of blood products—items 13700, 13703, 13706 and 13709

Table 3. Item introduction table for transfusion items 13700, 13703, 13706 and 13709

Item	Long item descriptor	Schedule fee	Benefits FY 2015–16	Services FY 2015–16	Patient count 2015–16	5-year service change % (CAGR)
13700	Harvesting of homologous (including allogeneic) or autologous bone marrow for the purpose of transplantation (Anaes.)	$333.25	$61,923	234	187	13.5%
13703	Transfusion of blood, including collection from donor	$119.50	$359,248	3 486	2 033	11.5%
13706	Transfusion of blood or bone marrow already collected	$48.45	$9,599,849	147 747	32 714	5.5%
13709	Collection of blood for autologous transfusion or when homologous blood is required for immediate transfusion in emergency situation	$48.45	$28,531	708	331	–22.0%

4.1.1 Item 13700

Item 13700 covers bone marrow collection which is a necessary but uncommon MBS funded service. It is recommended that the item be retained with no change.

4.1.2 Item 13703

Use of MBS item 13703 experienced high growth in the period 2010–2014 due to the billing of joint injections using autologous blood products (PRP) under the item. On 1 January 2015 the item descriptor was changed to exclude Medicare rebates for all services relating to autologous blood injections for the treatment of musculoskeletal conditions.

Since changes to the item descriptor were implemented, use has declined and returned to baseline levels (from 19,676 services in the 2014–2015 financial year to 3486 services in FY 2015–2016, a decrease of more than 82%). However, the National Blood Authority's (NBA) Patient Blood Management Steering Committee (PBMSC) has expressed concern that the item may be misused for the purpose of administering discredited ozone therapy.

4.1.3 Item 13706

Both the National Blood Authority and the Jurisdictional Blood Committee have expressed concern about the variable use of item 13706 and the blood product administration items generally.

In a submission to the MBS Review Task Force, the National Blood Authority (NBA) noted that the item does not support the appropriate use of blood and blood products for several reasons, including that subcutaneous administration of gamma globulins is not covered, incentivising the use of intravenous immunoglobulin.[1]

In its submission to the MBS Review Task Force, the PBMSC of the NBA [2] suggested that the item may be claimed by specialist physicians on ward patients when the actual administration of blood products is done by nursing staff or resident medical officers (RMOs) employed by the hospital, potentially serving as an incentive to the inappropriate transfusion of packed red cells.

Use of item 13706 has experienced high growth over the past decade, particularly by haematologists and oncologists (an increase of 154% over the decade 2004–2014) (Figures 2 and 5).

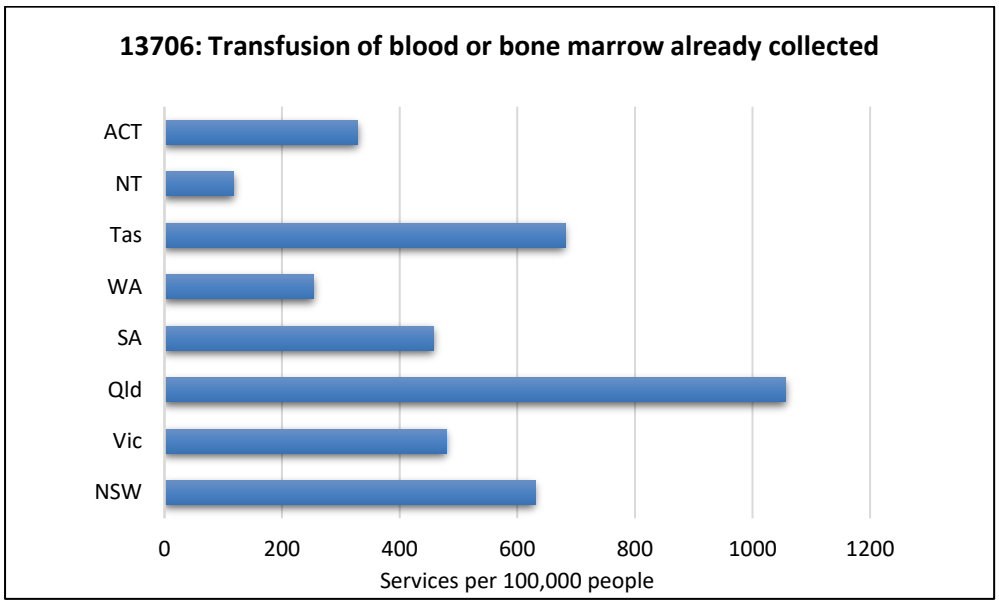
Observations from MBS data show there are significant variations in usage rates among jurisdictions, with a concentration of use in Queensland which has the highest per capita number of overall services provided and a high number of services per patient relative to other states (Figures 3 and 4).

Because of concern that variable use of item 13706 might be associated with variable use of blood products, utilisation data was sought from the National Blood Authority(NBA) .Analysis of NBA data regarding the relative use of blood products by state shows that there is little variation between the states in the per capita use of red blood cells, platelets and fresh frozen plasma . The data do show that there is higher - use of immunoglobulin in Queensland (Table 6 and Figure 6).It is not possible to determine whether the higher use of item 13706 in Queensland is closely associated with the higher use of immunoglobulin nor is it possible to determine any clinical reason that might underpin the higher use of immunoglobulin in Queensland.

It should be noted that the Department of Health will commence a review of immunoglobulin use in 2018.

Analysis of MBS data shows that that 45.5% of claims for item 13706 were claimed with a consultation item 116 on the same day as the 13706 service.

Figure 2. Item 13706: Per capita data by state 2014–2015.



Item 13706 is ordered at much higher rates per 100,000 people in Queensland compared with rates for other states and territories.

Figure 3. Item 13706: number of services per patient by state per financial year, 2009–2010 to 2015–2016.

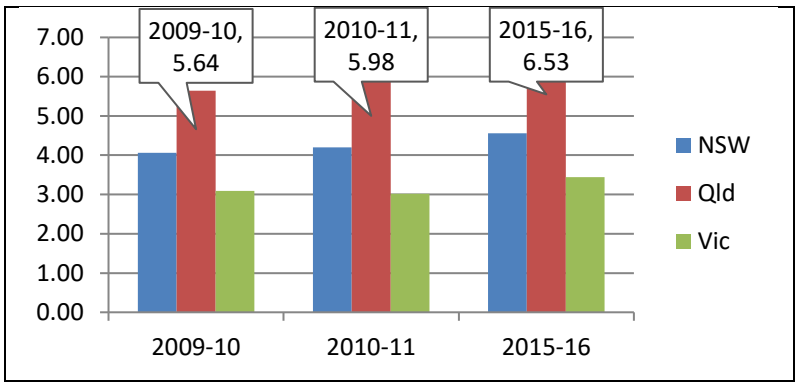


Figure 4. Item 13706: number of services per patient by financial year per state, 2009–2010 to 2015–2016.

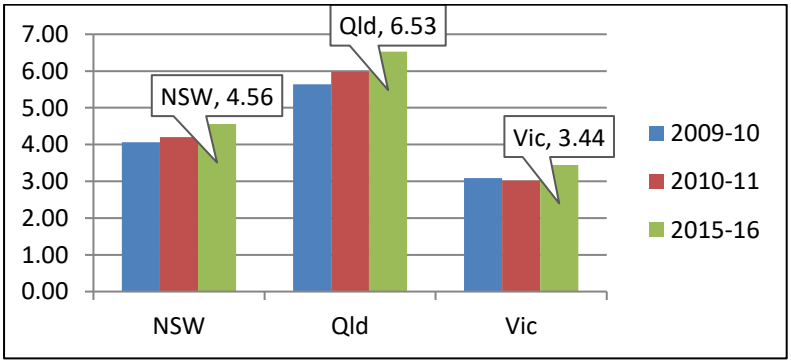


Figure 5. Item 13706: Request by provider type 2014–2015.

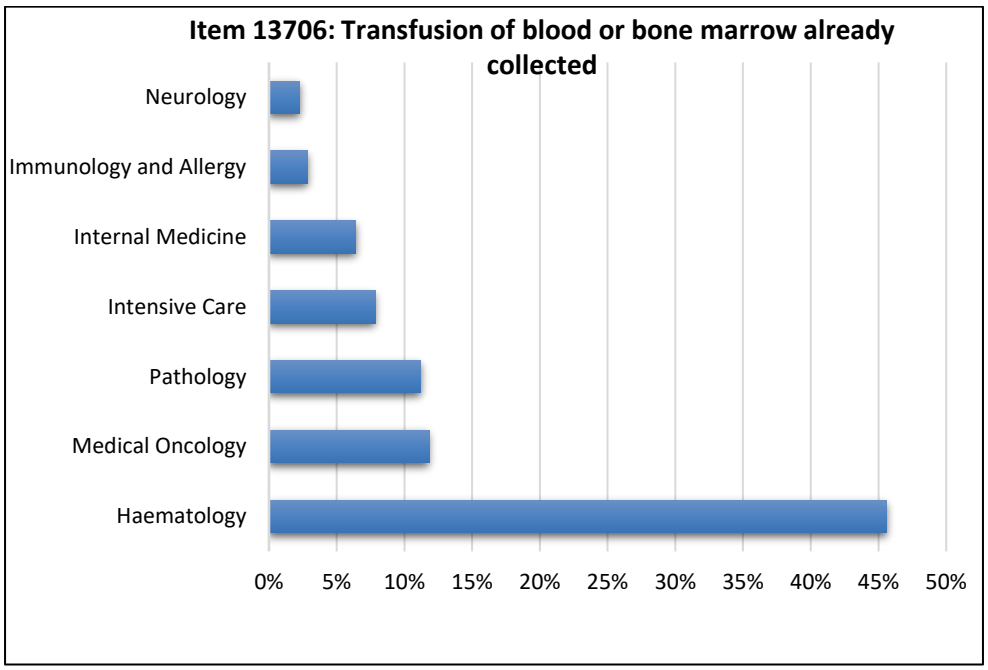


Figure 6. Relative use of blood products by state/100,000 population 2015–2016

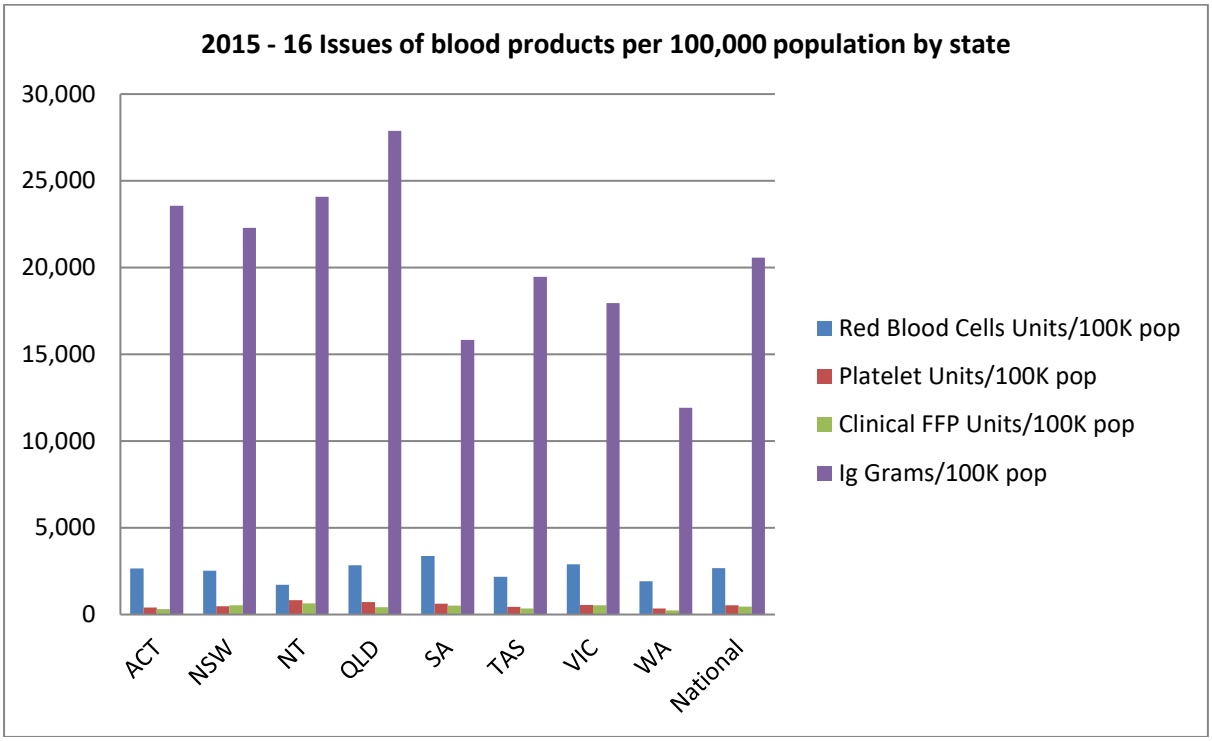


Table 4 shows that individual patients in Queensland receive a high number of multiple 13706 services

Table 4. Item 13706, Number of services per patient by state, 2015–2016

Number of services per person	***NSW***	***Vic***	***Qld***
001	5 241	3 676	3 151
002	1 612	1 405	1 139
003-004	1 275	953	982
005-006	627	411	524
007-008	468	216	365
009-010	521	161	275
011-015	1 293	300	935
016-020	203	100	206
021-030	157	90	214
031-050	59	47	137
051-100	19	7	89
101-200	6	2	24
200+			2
Total	11 481	7 368	8 043

Source: MBS Item 13706, DHS Webstats

Table 5 shows that Queensland patients consistently receive the most 13706 services.

Table 5. Item 13706, number of services by state, 2003–2004 to 2015–2016 (services per 100,000 population)

	NSW	Vic	Qld	SA	WA	Tas	ACT	NT	Total
2003–2004	226	187	501	269	137	293	108	58	262
2004–2005	236	198	633	278	174	306	128	106	299
2005–2006	256	228	703	330	219	394	149	61	338
2006–2007	292	244	698	303	210	426	204	40	352
2007–2008	321	285	765	303	247	415	262	80	390
2008–2009	373	307	766	364	250	448	255	40	419
2009–2010	448	317	837	372	237	463	244	31	459
2010–2011	525	327	928	340	244	541	301	26	507
2011–2012	576	376	1045	385	274	585	361	50	567
2012–2013	609	397	1029	414	286	609	353	55	584
2013–2014	660	432	1116	400	283	620	341	89	625
2014–2015	646	491	1051	451	252	663	348	120	624
2015–2016	650	410	1065	449	257	656	305	67	606

Source: MBS Item 13706, DHS Webstats

Table 6. Relative use of blood products by state/100,000 population 2015–2016

2015–16 issues	Red blood cells	Platelets	Clinical fresh frozen plasma (FFP)	Immuno-globulin
	Units/100 000 population	Units/100 000 population	Units/100 000 population	Grams/100 000 population
ACT	2 654	408	311	23 566
NSW	2 529	479	532	22 294
NT	1 713	822	642	24 078
Qld	2 848	713	418	27 888
SA	3 373	635	521	15 827
Tas	2 184	435	357	19 471
Vic	2 900	561	531	17 950
WA	1 926	352	242	11 914
National	2 667	540	467	20 574

4.1.4 Item 13709

There has been a steady decline in use of item 13709 over 5 years by 22%, with the national average number of services per 100,000 people being 2.01. The Working Group noted the low use of this item overall, having been billed only 654 times in the 2014–2015 financial year. Geographical variation exists, with higher use of item 13709 in Queensland (6.67 services per 100,000 people). The item is mostly used by oncologists (50%).

4.1.5 Recommendation 1

The Working Group proposed the following:

- No changes to item 13700.
- To reword the descriptor for item 13703 (as per Table 7, below) to include the specification that the item be used for intra-operative normovolaemic haemodilution.
- To remove item 13706 from the MBS
- To remove item 13709 from the MBS.

Table 7. Current and proposed item descriptor for item 13703

Item	Current descriptor	Proposed change to descriptor
13703	Transfusion of blood, including collection from donor	Transfusion of blood, including collection from donor, when used for intra-operative normovolaemic haemodilution

4.1.6 Rationale 1

- Changes to item 13700 are not required because, although use has increased over 5 years, this is not of concern, as use is aligned with international practice and the use of this item is not contentious.
- In relation to item 13703, the National Blood Authority's Patient Blood Management Steering Committee (PBMSC) recommended that intra-operative normovolaemic haemodilution is an appropriate and reasonable use of this item within the context of directed donation, and that this addition would disqualify the use of this item for the discredited practice of ozone therapy. The PBMSC was established by the National Blood Authority to provide advice and guidance on strategies to increase the uptake of patient blood management practices in Australia and has representatives from both clinical and government sectors with expertise and knowledge of blood management, the health sector, and quality and safety issues. The Working Group supports the recommendations of the PBMSC and agrees that this addition would make clear the appropriate clinical use of this item.
- In relation to item 13706, the Blood Products Working Group share the concern of the NBA and the PBMSC that the current MBS items for blood transfusion and, in particular, item 13706, may incentivise poor practice and that the variable use of this item around Australia cannot be explained by patient factors. The major use of this item is in haematology.
- The transfusion procedure itself is performed by nursing staff and for this reason is not fundamentally a medical professional service. The Working Group noted that nurse activities are funded though hospital payments which in turn are subsidised through private health insurance facility benefits or public hospital budgets.
  The medical practitioner input comes about from the decision to administer blood products and the overall supervision of a patient who requires this therapy. That activity is subsidised through MBS rebated consultations and indeed, a high proportion of transfusion services are accompanied by same-day billing of a consultation.
- The Working Group considered several options to better align use of item 13706 with clinical need but concluded that the best means to address the identified concern was to recommend that this service be removed from the MBS. This would have the effect of removing any perverse incentive to transfuse patients when it is not clinically reasonable to do so and also address the specific concern the item incentivises use of some other therapies, such as intravenous immunoglobulin, when oral or subcutaneous therapies are suitable; and transfusion over iron supplementation, where supplementation is appropriate.

In making its recommendation, the Working Group notes that appropriate blood transfusions should occur and that this activity is already funded through hospital payments. Medical supervision of the therapy can continue to be funded through MBS rebated consultations (item 116). Removal of item 13706 will not disadvantage patients, as they will continue to receive the necessary blood products without incurring additional out-of-pocket costs.

Δ Autologous transfusion (item 13709) is no longer performed, and collection of blood from a donor for urgent use is a rare circumstance and should not be encouraged.

4.2 Haemapheresis and venesection—items 13750, 13755, and 13757

Table 8. Item introduction table for items 13750, 13755, and 13757

Item	Long item descriptor	Schedule fee	Benefits FY2015–16	Services FY2015–16	Patient count 2015–16	5-year service change % (CAGR)
13750	Therapeutic haemapheresis for the removal of plasma or cellular (or both) elements of blood, utilising continuous or intermittent flow techniques; including morphological tests for cell counts and viability studies, if performed; continuous monitoring of vital signs, fluid balance, blood volume and other parameters with continuous registered nurse attendance under the supervision of a consultant physician, not being a service associated with a service to which item 13755 applies each day	$136.65	$551,670	5 077	902	5.9%
13755	Donor haemapheresis for the collection of blood products for transfusion, utilising continuous or intermittent flow techniques; including morphological tests for cell counts and viability studies; continuous monitoring of vital signs, fluid balance, blood volume and other parameters; with continuous registered nurse attendance under the supervision of a consultant physician; not being a service associated with a service to which item 13750 applies - each day	$136.65	$15,337	136	117	–15.0%
13757	Therapeutic venesection for the management of haemochromatosis, polycythaemia vera or porphyria cutanea tarda	$72.95	$6,205,976	100 558	31 987	2.6%

Blood products item 13750 has undergone an increase in use of 5.9% over the past 5 years. Items 13755 and 13757 are used infrequently, with only 136 services for item 13755 in 2015–2016.

4.2.1 Recommendation 2

The Working Group proposed the following:

- Δ No changes to items 13750, 13755, or 13757.

4.2.2 Rationale 2

- Δ Changes to item 13750 are not required, as the increase in use is moderate. Education programs or audit are appropriate mechanisms to encourage best practice.
- Δ Changes to item 13755 and 13757 are not required, as the items are used infrequently but have a role in haematology and should therefore be retained. Changes to the item 13757 descriptor would not help exclude inappropriate venesection.

4.3 Stem cell transplantation—item 13760

Table 9. Item introduction table for item 13760

Item	Long item descriptor	Schedule fee	Benefits FY2015–16	Services FY2015–16	Patient count 2015–16	5-year service change % (CAGR)
13760	In vitro processing (and cryopreservation) of bone marrow or peripheral blood for autologous stem cell transplantation as an adjunct to high dose chemotherapy for.chemosensitive intermediate or high grade non-Hodgkin's lymphoma at high risk of relapse following first line chemotherapy; or . Hodgkin's disease which has relapsed following, or is refractory to, chemotherapy; or Acute myelogenous leukaemia in first remission, where suitable genotypically matched sibling donor is not available for allogenic bone marrow transplant; or multiple myeloma in remission (complete or partial) following standard dose chemotherapy; or small round cell sarcomas; or primitive neuroectodermal tumour; or germ cell tumours which have relapsed following, or are refractory to, chemotherapy; or germ cell tumours which have had an incomplete response to first line therapy. - performed under the supervision of a consultant physician - each day.	$762.60	$642,616	1047	615	–1.1%

4.3.1 Recommendation 3

The Working Group proposed the following:

- To reword the descriptor for item 13760 (as per Table 10, below) to broaden the list of current indications associated with malignancy; and to specify that the item is for use as part of a treatment program overseen by a multidisciplinary team experienced in the treatment of malignant disorders.

Table 10. Current and proposed item descriptor for item 13760

Item	Current descriptor	New descriptor
13760	In vitro processing (and cryopreservation) of bone marrow or peripheral blood for autologous stem cell transplantation as an adjunct to high dose chemotherapy for: chemosensitive intermediate or high grade non-Hodgkin's lymphoma at high risk of relapse following first line chemotherapy; or Hodgkin's disease which has relapsed following, or is refractory to, chemotherapy; or Acute myelogenous leukaemia in first remission, where suitable genotypically matched sibling donor is not available for allogenic bone marrow transplant; or multiple myeloma in remission (complete or partial) following standard dose chemotherapy; or small round cell sarcomas; or . primitive neuroectodermal tumour; or germ cell tumours which have relapsed following, or are refractory to, chemotherapy; or germ cell tumours which have had an incomplete response to first line therapy. - performed under the supervision of a consultant physician - each day.	In vitro processing and cryopreservation of bone marrow or peripheral blood: 1. for autologous stem cell transplantation in association with high-dose chemotherapy for management of aggressive malignancy; and 2. in a treatment program overseen by a multidisciplinary team experienced in the management of malignant disorders. Explanatory note: MBS rebates for autologous stem cell transplantation are only available for patients with aggressive malignancy who meet the criteria for treatment according to: 1. Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation: Guidelines from the American Society for Blood and Marrow Transplantation (2015) 2. European Society for Blood and Marrow Transplantation: Indications for allo- and auto-SCT for haematological diseases, solid tumours and immune disorders. Current practice in Europe (2015). In addition, the treatment must be authorised and overseen by a multidisciplinary cancer team.

4.3.2 Rationale 3

- The current descriptor for item 13760 is outdated and does not capture the malignant conditions for which there is a good evidence base for stem cell therapies. Rather than developing a more current list for the item descriptor, the Working Group recommend that the item make clear that MBS rebates are only available for malignant conditions and that the specific cancers are set out in relevant US and European guidelines (Sureda et al. 2015 [4] and Majhail et al. 2015 [3] (Table 10).These are agreed international best practice standards. The guidelines should be referenced in the explanatory notes, to allow ready updating as the evidence base changes and standards are revised.
  The Working Group notes too that all patients who receive stem cell therapies should have that therapy authorised by a multidisciplinary cancer team and that this contemporary standard should be a prerequisite for MBS funding of the service.

Δ The Working Group noted that item 13760 is a pathology service but for historical reasons has not been included in the MBS Pathology Services Table. Stem cell services are subject to practice accreditation independent of any MBS pathology laboratory accreditation requirements and for this reason, it remains acceptable for this item to be located in this part of the Schedule.

5. References

[1] National Blood Authority Australia. Submission to the Medical Benefit Schedule Review Taskforce on blood related MBS items. NBAA: Canberra, 2015.

[2] NBAA Patient Blood Management Steering Committee. Submission to the MBS Review Task Force on blood related MBS item numbers. NBAA: Canberra, 2015.

[3] Majhail, NS, SH Farnia, PA Carpenter, RE Champlin, S Crawford, DI Marks, JL Omel, PJ Orchard, J Palmer and W Saber. Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation: Guidelines from the American Society for Blood and Marrow Transplantation. Biology of blood and marrow transplantation: *Journal of the American Society for Blood and Marrow Transplantation*. 2015, vol. 21, no. 11, pp. 1863-1869. doi: 10.1016/j.bbmt.2015.07.032

[4] Sureda, A, P Bader, S Cesaro, P Dreger, RF Duarte, C Dufour, JHF Falkenburg, D Farge-Bancel, A Gennery, N Korger, F Lanza, C Marsh, A Nagler, C Peters, A Velardi, M Mohty and A Madrigal for the European Society for Blood and Marrow Transplantation. Indications for allo- and auto-SCT for haematological diseases, solid tumours and immune disorders: current practice in Europe, 2015. *Bone Marrow Transplantation*. 2015, vol. 50, no. 8, pp. 1037. doi: 10.1038/bmt.2015.6

Appendix A—Assigned items: recommendations list

Item	Current descriptor	Recommendation	Section
13700	Harvesting of homologous (including allogeneic) or autologous bone marrow for the purpose of transplantation (Anaes.)	No change	4.1.5 Recommendation 1
13703	Transfusion of blood, including collection from donor	Change	4.1.5 Recommendation 1
13706	Transfusion of blood or bone marrow already collected	Delete	4.1.5 Recommendation 1
13709	Collection of blood for autologous transfusion or when homologous blood is required for immediate transfusion in emergency situation	Delete	4.1.5 Recommendation 1
13750	Therapeutic haemapheresis for the removal of plasma or cellular (or both) elements of blood, utilising continuous or intermittent flow techniques; including morphological tests for cell counts and viability studies, if performed; continuous monitoring of vital signs, fluid balance, blood volume and other parameters with continuous registered nurse attendance under the supervision of a consultant physician, not being a service associated with a service to which item 13755 applies each day	No change	4.2.1 Recommendation 2
13755	Donor haemapheresis for the collection of blood products for transfusion, utilising continuous or intermittent flow techniques; including morphological tests for cell counts and viability studies; continuous monitoring of vital signs, fluid balance, blood volume and other parameters; with continuous registered nurse attendance under the supervision of a consultant physician; not being a service associated with a service to which item 13750 applies - each day	No change	4.2.1 Recommendation 2
13757	Therapeutic venesection for the management of haemochromatosis, polycythaemia vera or porphyria cutanea tarda	No change	4.2.1 Recommendation 2
13760	In vitro processing (and cryopreservation) of bone marrow or peripheral blood for autologous stem cell transplantation as an adjunct to high dose chemotherapy for.chemosensitive	Change	4.3.1 Recommendation 3

	intermediate or high grade non-Hodgkin's lymphoma at high risk of relapse following first line chemotherapy; or . Hodgkin's disease which has relapsed following, or is refractory to, chemotherapy; or Acute myelogenous leukaemia in first remission, where suitable genotypically matched sibling donor is not available for allogenic bone marrow transplant; or multiple myeloma in remission (complete or partial) following standard dose chemotherapy; or small round cell sarcomas; or primitive neuroectodermal tumour; or germ cell tumours which have relapsed following, or are refractory to, chemotherapy; or germ cell tumours which have had an incomplete response to first line therapy. - performed under the supervision of a consultant physician - each day.		

Appendix B—Summary for consumers

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

Recommendation 1: Collection and transfusion of blood products–items 13700, 13703, 13706 and 13709

Item	What it does	Committee recommendation	What would be different	Why
13700, 13703, 13706 and 13709	Items 13700 and 13709 In these procedures, blood or bone marrow is collected from a patient (known as autologous collection) or from another person or donor (known as homologous collection). Items 13703 and 13706 In these procedures, blood that has been collected from another person or donor is given to a patient who needs a transfusion.	No change to item 13700. To reword the descriptor for item 13703 to include the specification that the item be used for intra-operative normovolaemic haemodilution. Remove item 13706 from the MBS. Remove item 13709 from the MBS.	There will be no impact on patients.	Changes to item 13700 are not needed because, although use has increased over the past 5 years, this is not problematic as the use of this item is consistent with international practice. Changing the descriptor for item 13703 will stop the item being used for practices such as ozone therapy, which has no evidence for use. The practice of intra-operative normovolaemic haemodilution, where blood is removed from a patient just before they have surgery and then infused back into them as a way of conserving blood, is an appropriate and reasonable use of this item. Blood transfusions are done by nurses and not the haematologists themselves, and are paid for through the hospital, which is a separate payment system to the MBS. The ability to claim item 13706 for blood transfusions is a loophole for haematologists to claim for a procedure done by nurses, and might encourage some transfusion procedures that aren't really necessary. The supervision of nurses by specialists to do this procedure is paid for using a different item. The procedure known as autologous transfusion is not performed anymore and should not be done, so removal of this item will stop this practice being done any more.

Recommendation 2: Haemapheresis and venesection– items 13750, 13755, and 13757

Item	What it does	Committee recommendation	What would be different	Why
13750, 13755, and 13757	Apheresis allows for the collection of specific blood components or parts (donor haemapheresis) which are replaced (therapeutic haemapheresis) with similar components received from blood donors. These components are removed and can be stored for later use, or discarded. The blood is put through a machine that separates the blood into the individual parts. This allows parts of the blood that might be causing an illness to be removed, or for donor blood components to be used in the treatment of blood cancers or other blood disorders. Venesection is when blood is removed from circulation to treat blood conditions.	No changes to any of these items. There will be no difference for patients.	There will be no impact on patients.	The increase in the use of item 13750 is moderate. Changing the descriptor is not required. Changes to items 13755 and 13757 are not needed because these items are not used very frequently. However, they do have a role in haematology and should therefore not be deleted from the MBS.

Recommendation 3: Stem cell transplantation– item 13760

Item	What it does	Committee recommendation	What would be different	Why
13760	Autologous stem cell collection is the collection of a patient's own stem cells prior to high dose chemotherapy. These cells are then returned to the patient after their chemotherapy, which is called an 'autologous transplant'. Stem cells are what is known as unspecialised (undifferentiated) cells that can divide and then either stay a stem cell or develop into a different cell type, such as a red blood cell.	To reword the descriptor for item 13760 to broaden the list of current indications associated with malignancy (the presence of cancer); and to specify that the item is for use as part of a treatment program overseen by a multidisciplinary team experienced in the treatment of malignant disorders.	There will be no impact on patients.	As it is currently worded, the descriptor for item 13760 doesn't cover the range of different cancer-related illnesses that stem cell therapies can be used for, according to the evidence. Changing the wording will bring the descriptor into line with the uses set out in current US and European guidelines. Changing the wording will also make sure that this item is only used for the treatment of cancer.