



Medicare Benefits Schedule Review Taskforce

Taskforce Report for Blood Product Items

2019



Important note

This Report contains the final recommendations from the MBS Review Taskforce following the consultation of the Blood Products Working Group Report with stakeholders. This report has now been forwarded to the Government for consideration.

The Taskforce welcomes ongoing feedback on this or any MBS Review report 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 programme of work that considers how more than 5,700 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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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 (the Minister) 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 recommendations from the clinical committees are released for stakeholder consultation. The clinical committees consider feedback from stakeholders then provide recommendations to the Taskforce in a review report. The Taskforce considers the review reports from clinical committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

1.1 Key recommendations

The Blood Products Working Group (BPWG) review eight items. Changes were made to four items relating to:

- Collection and transfusion of blood products items: the rationale for these changes was to address potential misuse of the items.
- Stem cell transplantation: the rationale for this change was to align the service with international clinical guidelines and contemporary clinical practice.

No changes were made to four items which reflect contemporary clinical practice.

The Review was based on evidence and clinical expertise, in consultation with relevant stakeholders. The recommendations (and the accompanying rationales) for all items can be found in Section 4.



1.2 Consumer impact

The Committee considered the consumer impact of the proposed changes in detail. All recommendations have been summarised for consumers in Appendix A – Summary for consumers. The summary describes the medical service, the recommendation of the clinical experts and the rationale behind the recommendations. A consumer impact statement is available in Section 5.

It is important to find out from consumers if they will be helped or disadvantaged by the recommendations—and how and why. Following targeted consultation, the feedback from consumers will be considered in order to make sure that all the important concerns are addressed. The Taskforce will then provide the recommendations to Government.

Both patients and clinicians are expected to benefit from these recommendations because they address concerns regarding patient safety and quality of care, and because they take steps to simplify the MBS and make it easier to use and understand. In addition, the Committee's recommendations promote the provision of higher value medical care, which can reduce unnecessary procedures and related out-of-pocket fees for patients, while supporting improved access to modern procedures and the responsible operation of the healthcare system as a whole.

The consumer representative on the Committee identified a number of key questions in relation to the Committee's recommendations and their impact on consumers and these are discussed in detail in the consumer impact statement in Section 5 of this Report.

All recommendations have been summarised for consumers in [Appendix A – Summary for Consumers](#). The summary describes the medical service, the recommendation of the clinical experts and the rationale behind the recommendations.



2 About the Medicare Benefits Schedule (MBS) Review

2.1 What is Medicare?

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

Introduced in 1984, Medicare has three components:

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

2.2 What is the MBS?

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

2.3 What is the MBS Review Taskforce?

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

2.4 What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key 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 being particularly under-served.
- Best practice health services—one of the core objectives of the MBS Review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base when 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 MBS Review is to support 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 of the vision will go a long way to 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 benefit and are underused, particularly for patients who cannot readily access those services currently.

2.5 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 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 the committees to review MBS items using a framework based on Professor Adam Elshaug’s appropriate use criteria (1). The framework consists of seven steps:

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



2. Identify items that are obsolete, are of questionable clinical value¹, are misused², 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 the review and its timeframe, each clinical committee has to develop a work plan and assign priorities, keeping in mind the objectives of the review. Committees use 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:

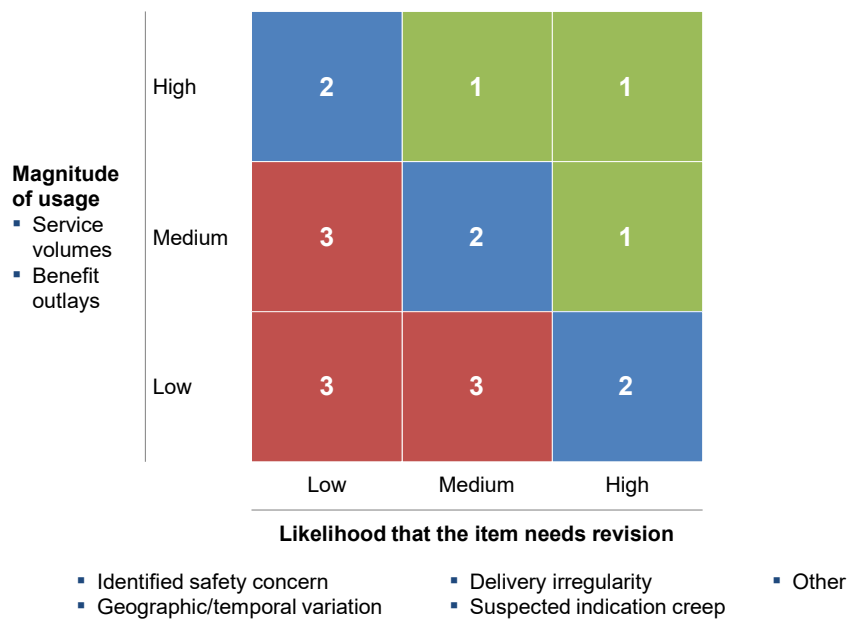
- Service volume.
- The likelihood that the item needed to be revised, determined by indicators such as identified safety concerns, geographic or temporal variation, delivery irregularity, the potential misuse of indications or other concerns raised by the clinical committee (such as inappropriate co-claiming).

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

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



Figure 1: Prioritisation matrix



For each item, these two metrics were ranked high, medium or low. These rankings were then combined to generate a priority ranking ranging from one to three (where priority 1 items are the highest priority and priority 3 items are the lowest priority for review), using a prioritisation matrix (Figure 1). Clinical committees use this priority ranking to organise their review of item numbers and apportion the amount of time spent on each item.

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.

3.1 Membership

The Committee consists of 19 members, whose names, positions/organisations and declared conflicts of interest are listed in Section **Error! Reference source not found..**

**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



Name	Position/organisation	Declared conflict of interest
Dr Robyn Lindner	National Prescribing Service	None
Professor Hans Schneider	Alfred Pathology Service (Melbourne)	None
Associate Professor Adrienne Morey	ACT Pathology	None

3.2 About the Blood Products Working Group

The Blood Products Working Group was established by the Committee's Haematology Working Group to review miscellaneous therapeutic procedures subgroup 8 (haematology) and make recommendations on the administration of blood products 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	None
Dr Michael Harvey	Director of Haematology, Liverpool Hospital, Liverpool NSW	None
Dr Joanne Joseph	Senior staff Specialist in Haematology, Head of Laboratory Haematology, SydPath, St Vincent's Hospital, Sydney; Conjoint Senior Lecturer UNSW Associate	None
Professor Glen Kennedy	Acting Executive Director, Cancer Care Services, Metro North Hospital & Health Service, Queensland	None
Dr Susan MacCallum	Senior staff specialist in Haematology Prince of Wales Hospital; Conjoint senior lecturer UNSW	None



Name	Position/organisation	Declared conflict of interest
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	None
Mr John Stubbs	Chief Executive Officer, CanSpeak Member, Medical Services Advisory Committee Consumer Representative	None

3.3 Conflicts of interest

All members of the Taskforce, clinical committees and working groups are asked to declare any conflicts of interest at the start of their involvement and reminded to update their declarations periodically. A complete list of declared conflicts of interest can be viewed in Table 1 above.

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

3.4 Areas of responsibility

The Committee was assigned eight MBS items to review. A complete list of these items can be found in [Appendix A](#).

3.5 Summary of working group's review approach

The Committee completed a review of eight 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.



Following consultation in July 2017, the Blood Products Working Group considered stakeholder feedback before finalising the recommendations and presenting them to the Taskforce. The Taskforce endorsed the recommendations to the Minister for Health for consideration by the Government.

4 Blood products (Haematology)

The Working Group reviewed eight blood products items.

The item-level recommendations are described below. A summary of recommendations can be found in Appendix A, and in the consumer summary table in Appendix B.

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

4.1 Collection and transfusion of blood products

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

Item	Item descriptor	Schedule fee	Benefits FY 2015–16	Services FY 2015–16	5-year service change % (CAGR)
13703	Transfusion of blood, including collection from donor	\$119.50	\$359,248	3 486	9.9%
13706	Transfusion of blood or bone marrow already collected	\$48.45	\$9,599,849	147 747	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	–22.0%



Important note:

Based on feedback from stakeholders the Taskforce agreed to retain item 13706 but revise the descriptor to read “TRANSFUSION OF BLOOD or bone marrow already collected excluding the transfusion of immunoglobulin”. The Taskforce also agreed to remove the amendment requiring the presence of the treating specialist in the building due to possible unintended consequences for rural and remote patients.

4.1.1 Recommendation 1 – Collection and transfusion of blood products³

- Item 13703: Change the descriptor to include intra-operative normovolaemic haemodilution (NVH) where appropriate. The proposed item descriptor is:
 - *Transfusion of blood, including collection from donor, **when used for intra-operative normovolaemic haemodilution***
- Item 13706: Change the descriptor to exclude the provision of immunoglobulin with blood transfusion services. The proposed item descriptor is:
 - *Transfusion of blood or bone marrow already collect **excluding the transfusion of immunoglobulin***
- Item 13709: This recommendation focuses on promoting evidence based medicine and reducing inappropriate practice. The proposed item descriptor is:
 - **Delete**

4.1.2 Rationale for Recommendation 1

Item 13703

This recommendation focuses on promoting evidence based medicine and reducing inappropriate practice. The recommendation is based on the following:

- △ Intra-operative normovolaemic haemodilution refers to the removal of blood after a patient has been given an anaesthetic to minimise the effect of blood loss during an operation. The blood is infused back into the patient after the operation⁴.
- △ National Blood Authority guidelines recommend that NVH should be considered for ‘adult patients undergoing surgery in which substantial blood loss (blood loss of a volume great enough to induce anaemia that would require therapy)’ (National Blood Authority, 2012).
- △ The Committee noted the risks associated with transfusions include transfusion-associated circulatory overload, haemolytic reactions, anaphylaxis, bacterial sepsis,

³ All proposed changes are highlighted in bold.

⁴ Surgical blood conservation: Intraoperative hemodilution, Avidan M, Silvergleid AJ. 2019UpToDate.



transfusion-related acute lung injury and hepatitis B, in addition to other risks with lower rates of incidence (Authority, 2012) and agreed that any incentive for inappropriate use of the service should be removed.

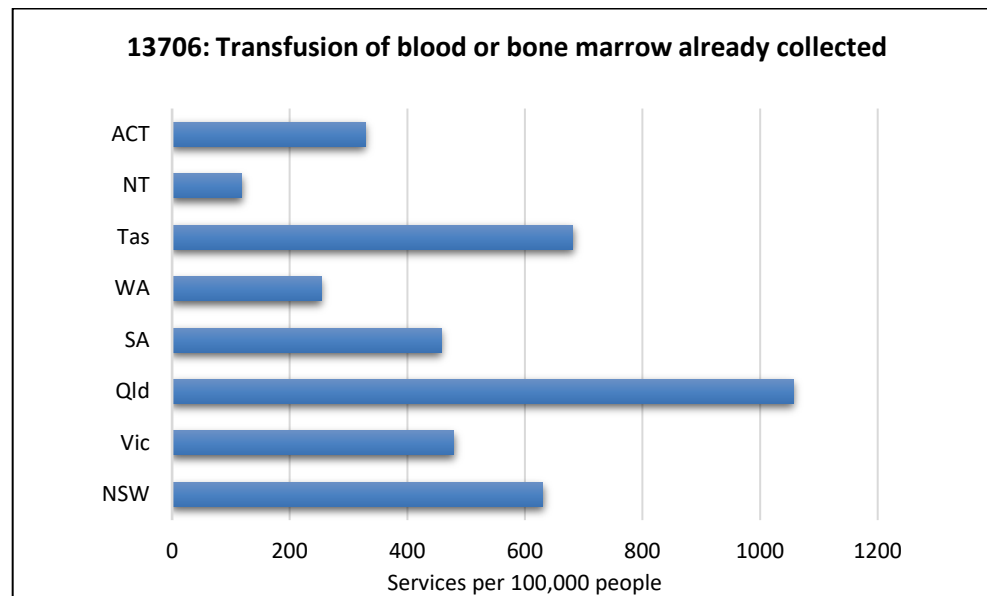
Item 13706

This recommendation focuses on promoting evidence based medicine and reducing inappropriate practice. The recommendation is based on the following:

- △ The Working Group agreed that transfusion of blood or bone marrow is part of normal clinical practice and noted that haematologists provided nearly 50% of all 13706 services in 2014-15.
- △ The Working Group noted that the existing item does not permit the subcutaneous administration of gamma globulins [1]. It was concerned about the potential for the item to incentivise the use of intravenous immunoglobulin, when oral or subcutaneous therapies are more suitable. It may also encourage the use of transfusion over iron supplementation, where supplementation is more appropriate.
- △ 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 exclude transfusion of immunoglobulins from this service. This would have the effect of removing any perverse incentive to transfuse patients when it is not clinically appropriate to do so.
- △ The Working Group noted different claiming patterns between states. In 2015/16, 28 percent of services were provided in Queensland compared to 17 percent in NSW and 11 percent in Victoria. Patients in Queensland received 6.53 services compared to 4.56 in NSW and 3.33 in Victoria.
- △ The Working Group reviewed the data trends, co-claiming patterns and geographical variation. While data indicated a higher use of immunoglobulin in Queensland, the clinical reasons for this use are unknown as the MBS does not collect this information. The Working Group agreed that while the patterns were variable, it is difficult to use the high-level MBS data to interpret with any certainty the clinical appropriateness or otherwise of the service utilisation patterns.



Figure 2. Item 13706: Services per capita 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.

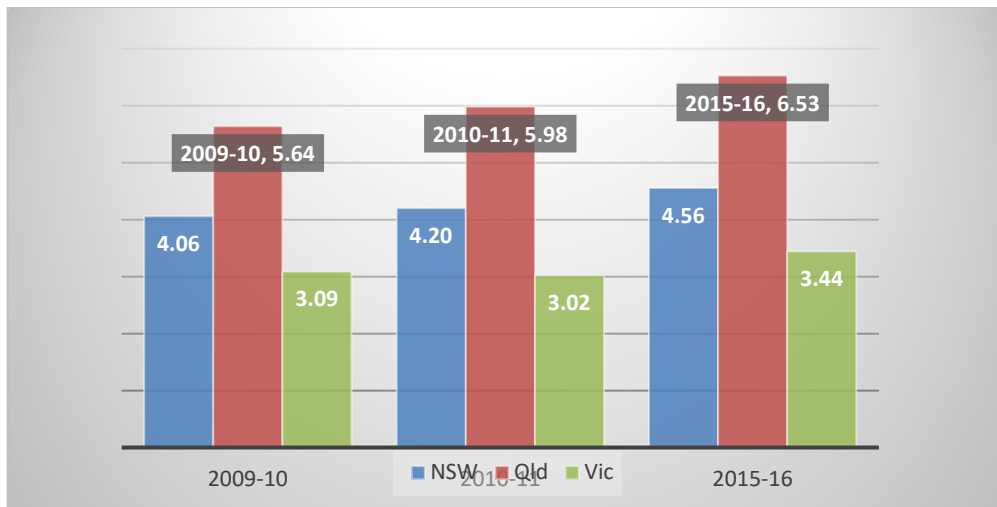


Figure 3.

Item 13706: Services per patient by state per financial year, 2009–2010 to 2015–2016.

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

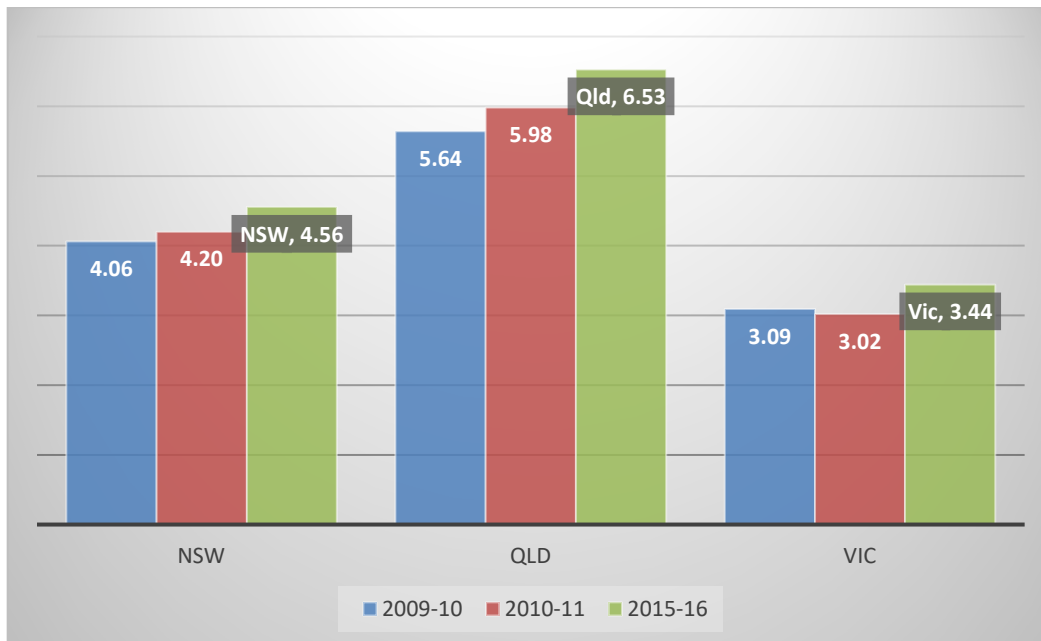


Figure 5. Item 13706: Request by provider type 2014–2015.

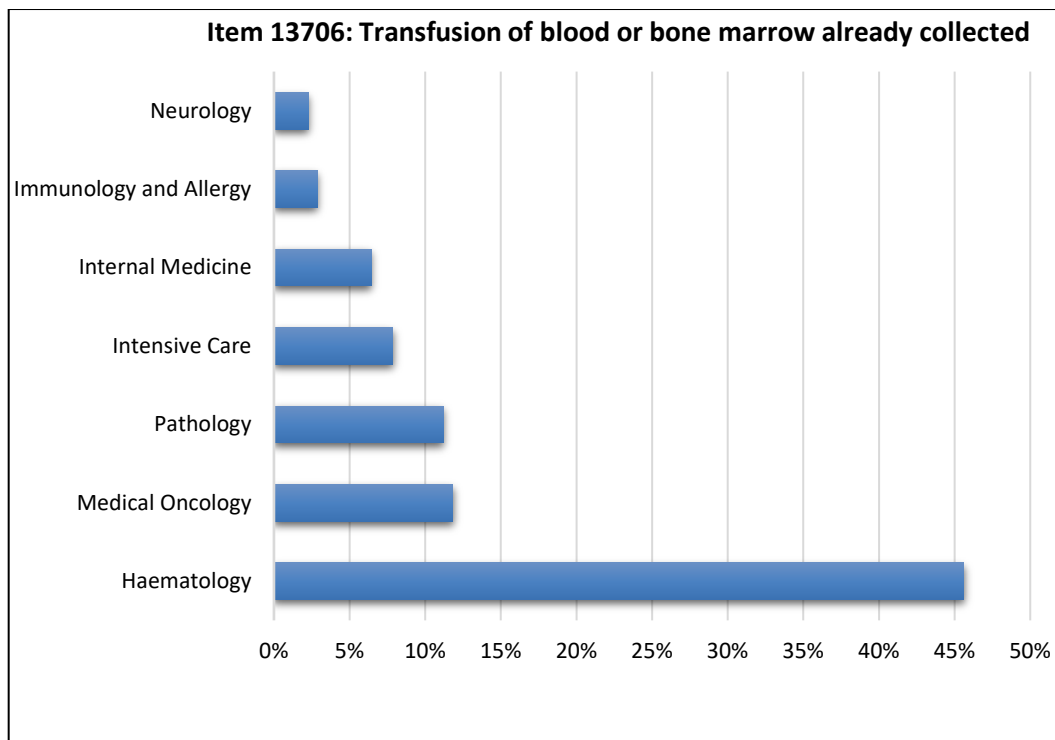


Figure 6. Relative use of blood products by state/100,000 population 2015–2016

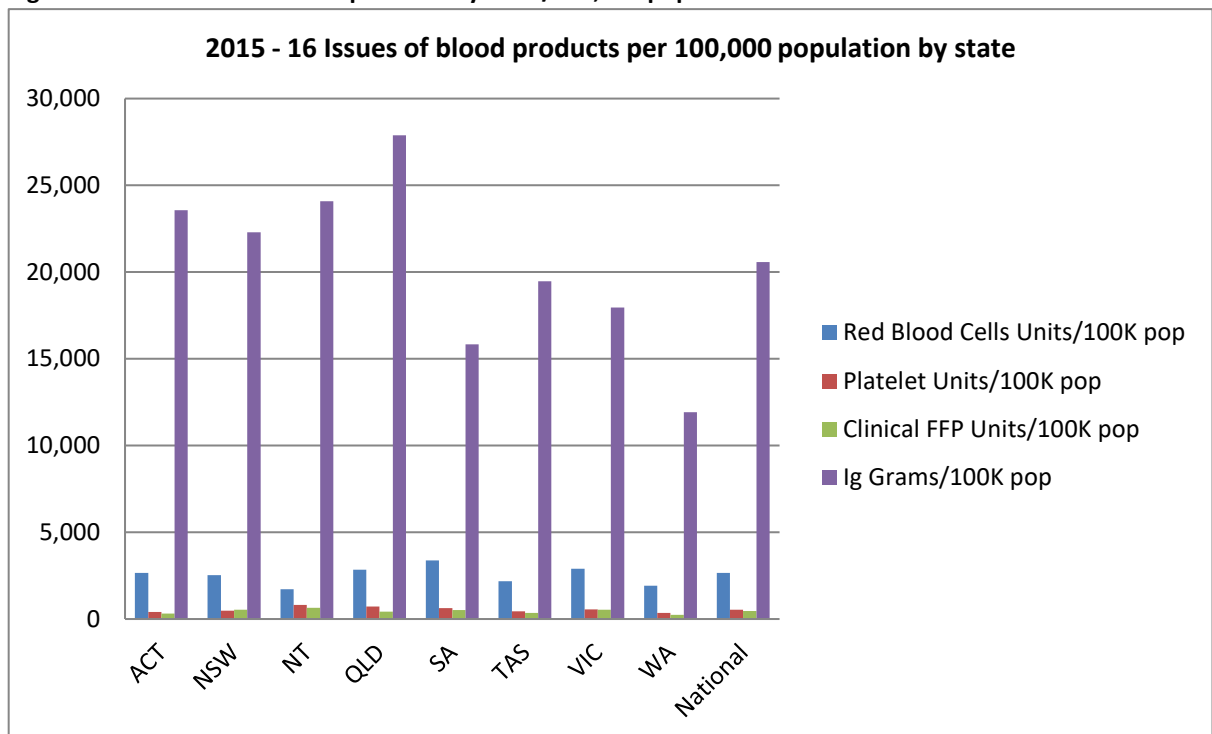


Table 4 shows that individual patients in Queensland receive a higher number of multiple 13706 services.

**Table 4. Item 13706, Services per patient by NSW, VIC, QLD, 2015–2016**

<i>Number of services per person</i>	<i>NSW</i>	<i>Vic</i>	<i>Qld</i>
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, Services by state, 2003–2004 to 2015–2016 (per 100,000 population)

	<i>NSW</i>	<i>Vic</i>	<i>Qld</i>	<i>SA</i>	<i>WA</i>	<i>Tas</i>	<i>ACT</i>	<i>NT</i>	<i>Total</i>
2003–2004	226	187	501	269	137	293	108	58	262
2004–2005	236	198	633	278	174	306	128	106	299



	NSW	Vic	Qld	SA	WA	Tas	ACT	NT	Total
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 (per 100,000 population) 2015–2016

States	Red blood cells	Platelets	Clinical fresh frozen plasma (FFP)	Immuno-globulin
	Units/100,000 pop	Units/100,000 population	Units/100,000 pop	Grams/100,000 pop
ACT	2 654	408	311	23 566



<i>States</i>	<i>Red blood cells</i>	<i>Platelets</i>	<i>Clinical fresh frozen plasma (FFP)</i>	<i>Immuno-globulin</i>
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

Item 13709

The recommendation is based on the following:

- △ 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%).
- △ Autologous transfusion (item 13709) is seldom performed, and collection of blood from a donor for urgent use is a rare circumstance, based on current best practice this therapy should not be encouraged



4.2 Stem cell transplantation

Table 7. Item introduction table for item 13760

Item	Long item descriptor	Schedule fee	Benefits FY2015–16	Services FY2015–16	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	–1.1%



4.2.1 Recommendation 2

- Item 13760: Change the descriptor to reflect clinical best practice. The proposed descriptor is:

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:

Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation: Guidelines from the American Society for Blood and Marrow Transplantation (2015) 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

4.2.2 Rationale for recommendation 2

This recommendation is based on the following:

- △ 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.
- △ This change will broaden the current list of indications associated with malignancy; and 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.
- △ An explanatory note references the list of malignant conditions specified in the US and European guidelines (Sureda et al. 2015 [4] and Majhail et al. 2015 [3] (Table 10). list of malignant conditions which may be claimed under the item. Referencing the international guidelines will allow ready updating as the evidence base changes and standards are revised.
- △ All patients who receive stem cell therapies should have that therapy authorised by a multidisciplinary cancer team and this contemporary standard should be a prerequisite for MBS funding of the service.

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 focuses on improving the understanding of the items and improving efficiency and effectiveness.



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](https://doi.org/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](https://doi.org/10.1038/bmt.2015.6)



6 Glossary

Term	Description
ACT	Australian Capital Territory
CAGR	Compound annual growth rate or the average annual growth rate over a specified time period.
Change	"Change" - when the item and/or its services will be affected by the recommendations. This could result from (i) specific recommendations that affect the services provided by changing item descriptors or explanatory notes; (ii) the consolidation of items; and (iii) splitting item numbers (for example, splitting the current services provided across two or more items).
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
Department, the	Australian Government Department of Health
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 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.
New service	Describes when a new service has been recommended, with a new item number. In most circumstances, new services will need to go through the MSAC. It is worth noting that implementation of the recommendation may result in more or fewer item numbers than specifically stated.
No change or leave 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 descriptors (for example, references to other items, which may have changed as a result of the MBS Review or prior reviews).
Obsolete services / items	Services that should no longer be performed as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
PBS	Pharmaceutical Benefits Scheme
Services average annual growth	The average growth per year, over five years to 2016/17, in utilisation of services. Also known as the compound annual growth rate (CAGR).
Taskforce, the	The MBS Review Taskforce
Total benefits	Total benefits paid in 2016/17 unless otherwise specified.



Appendix A—Assigned items - Changes

Recommendation	Item	Current descriptor	Proposed change (bold text)
1	13703	Transfusion of blood, including collection from donor	Transfusion of blood, including collection from donor, when used for intra-operative normovolaemic haemodilution
	13706	Transfusion of blood or bone marrow already collected	Transfusion of blood or bone marrow already collect excluding the transfusion of immunoglobulin
	13709	Collection of blood for autologous transfusion or when homologous blood is required for immediate transfusion in emergency situation	Delete
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 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 allogeneic bone marrow transplant; or multiple	<p>△ In vitro processing and cryopreservation of bone marrow or peripheral blood:</p> <p>△ 1. for autologous stem cell transplantation in association with high-dose chemotherapy for management of aggressive malignancy; and</p> <p>△ 2. in a treatment program overseen by a multidisciplinary team experienced in the management of malignant disorders</p> <p><i>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:</i></p> <p><i>1. Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation: Guidelines from the American Society for Blood and Marrow Transplantation (2015)</i></p> <p><i>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).</i></p>



Recommendation	Item	Current descriptor	Proposed change (bold text)
		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	<i>In addition, the treatment must be authorised and overseen by a multidisciplinary cancer team</i>

Assigned items - no change

Item	Current descriptor
13700	Harvesting of homologous (including allogeneic) or autologous bone marrow for the purpose of transplantation (Anaes.)
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
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



Item	Current descriptor
13757	Therapeutic venesection for the management of haemochromatosis, polycythaemia vera or porphyria cutanea tarda



Appendix B—Summary for consumers

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

Recommendation 1: items 13703, 13706 and 13709

Item	What it does	Committee recommendation	What would be different	Why
13703 and 13706	Blood and/or bone marrow collected from another person or donor is given to a patient who needs a transfusion.	Change the descriptor to specify that the item includes intra-operative normovolaemic haemodilution.	There will be no impact on patients.	This change will stop the item being used for practices such as ozone therapy, which has no evidence for use.
		Change the descriptor to exclude transfusion of immunoglobulins.	There will be no impact on patients.	The existing descriptor may be encouraging the provision of some transfusion procedures that aren't really necessary.
13709	Blood is collected from a donor (known as autologous collection) to be transfused immediately in an emergency.	Remove item 13709 from the MBS.	There will be no impact on patients.	This service is rarely performed and does not reflect contemporary clinical practice.

Recommendation 2: item 13760

Item	What it does	Committee recommendation	What would be different	Why
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Item	What it does	Committee recommendation	What would be different	Why
13760	A patient's stem cells are collected prior to high dose chemotherapy and are then returned to the patient after their chemotherapy. 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.	Change the descriptor 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.	Patients will benefit as treatment will be required to be overseen by a multi-disciplinary team.	This change will align the service with international clinical guidelines.

No Change: items 13700, 13750, 13755 and 13757

Item	What it does	Committee recommendation	What would be different	Why
13700	Bone marrow is collected from a patient (known as autologous collection) or from another person or donor (known as homologous collection).	No change	There will be no change to the existing service.	This service is aligned with international practice.



Item	What it does	Committee recommendation	What would be different	Why
13750 and 13755	Specific blood components or parts is collected from a patient (donor haemapheresis) and replaced with similar components received from donors (therapeutic haemapheresis). These components are removed and can be stored for later use, or discarded. The blood is put through a machine that separates it 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.	No change	There will be no change to the existing service.	These items remains clinically relevant.
13757	Venesection is when blood is removed from circulation to treat blood conditions.	No Change	There will be no change to the existing service.	These item remains clinically relevant.