



NATIONAL BLOOD AUTHORITY
AUSTRALIA

NATIONAL REPORT ON THE ISSUE AND USE OF IMMUNOGLOBULIN (Ig)

Annual Report 2017-18



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Introduction

Immunoglobulin products, derived from pooled human plasma, are a precious and high cost resource. Strengthening immunoglobulin governance is a priority for the National Blood Authority (NBA), and a number of measures are being developed and implemented to ensure the sustainability of these products into the future.

Immunoglobulin products analysed in this report include intravenous immunoglobulin (IVIg), subcutaneous immunoglobulin (SCIg) and normal human immunoglobulin (NHlg). Aggregated data for IVIg and SCIg is referred to as immunoglobulin (Ig) unless specifically stated. NHlg is reported separately. Ig products are used to treat a broad range of conditions, with applications in replacement and immune modulation therapy. This report provides an analysis of national data on national Ig supply in Australia in 2017-18, also considering trends in supply over the last ten years.

In Australia it is estimated that over 99% of all Ig is supplied under national blood arrangements through contracts administered by the NBA. The NBA's role is to coordinate national supply and demand planning for blood and blood products including supply risk management; to purchase blood and blood products on behalf of all Australian governments; to develop and implement national strategies to encourage better governance; to promote appropriate use of blood and blood products; and to provide expert advice to support government policy development. Further background is at **Appendix A**.

The national Ig Governance Program was introduced in 2014 to pursue governments' objectives for Ig products funded and supplied under the national blood arrangements, namely to:

- ensure Ig product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of government funds, in accordance with relevant national safety and quality standards for health care;
- ensure that access to Ig products is consistent with the criteria for access determined by governments; and
- improve the capture of information of the need for, use of, and outcomes of treatment with Ig products to inform future decisions.

The NBA is responsible for administering the National Ig Governance Program which includes the development and maintenance of a national framework to access government-funded Ig. The current framework comprises a National Policy, the criteria for access, and BloodSTAR (Blood System for Tracking Authorisations and Reviews), a national online system.

The *National Policy: Access to Government-Funded Immunoglobulin Products in Australia* (National Policy) released in November 2016, sets out the process that must be followed and describes the rules and requirements that must be complied with to access government-funded Ig products in Australia. The National Policy supports all those involved in the prescription, use and management of Ig to understand their roles and responsibilities under the governance arrangements.

The *Criteria for the Clinical Use of Immunoglobulin in Australia* (the Criteria) were developed in collaboration with expert specialist clinicians and identify the medical conditions and circumstances for which the use of Ig is considered to be clinically appropriate and where there are no safe, effective and cost-effective alternative treatments. First published in 2007, and revised in 2012 with another revision planned for 2018, the Criteria identifies the conditions and circumstances for which the use of Ig is funded under national blood arrangements.

The Criteria clearly articulate and standardises the qualifying and continuing Ig access requirements. It classifies the 93 conditions described in the Criteria into those for which Ig has an established therapeutic role (Chapter 5), has an emerging therapeutic role (Chapter 6) and those where Ig has application in exceptional circumstances only (Chapter 7). Ig is only supplied for these conditions unless purchased directly by a state or territory, hospital or individual (a Direct Order). Chapter 8 of the Criteria also outline those conditions for which Ig should not be supplied under national blood arrangements.

Introduced in 2016, BloodSTAR was developed by the NBA on behalf of all Australian Governments to serve the needs of health providers and support users to meet their obligations under the National Policy. Through BloodSTAR, Prescribers can request patient authorisation for access to government-funded Ig. Under the governance arrangements, Dispensers may only dispense product to patients with an active authorisation in BloodSTAR. Nurses and Midwives can request product from Dispensers through BloodSTAR. BloodSTAR streamlines the authorisation process, reduces variability and standardises prescribing practices, and increases efficiency and transparency while strengthening decision-making and improving data capture. BloodSTAR was designed, developed, and implemented to all Australian states and territories except New South Wales (NSW).

In addition to the clinical and diagnostic criteria for access to intravenous products, access to SCIg products is provided through an assurance framework for the appropriate use of the product. SCIg access rules are detailed on the NBA website at <https://www.blood.gov.au/SCIg>. Participation in the National SCIg program requires hospitals to establish their capability and capacity to manage a hospital-based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the product within defined governing requirements.

NHIg may only be supplied for two purposes; for the treatment of susceptible contacts of measles, hepatitis A, poliomyelitis and rubella, as directed by public health officials; or for the treatment of immunodeficiency conditions for which the product is indicated for patients for whom IVIg and SCIg are both contraindicated. NHIg access rules are detailed on the NBA website at <https://www.blood.gov.au/NHIg>.

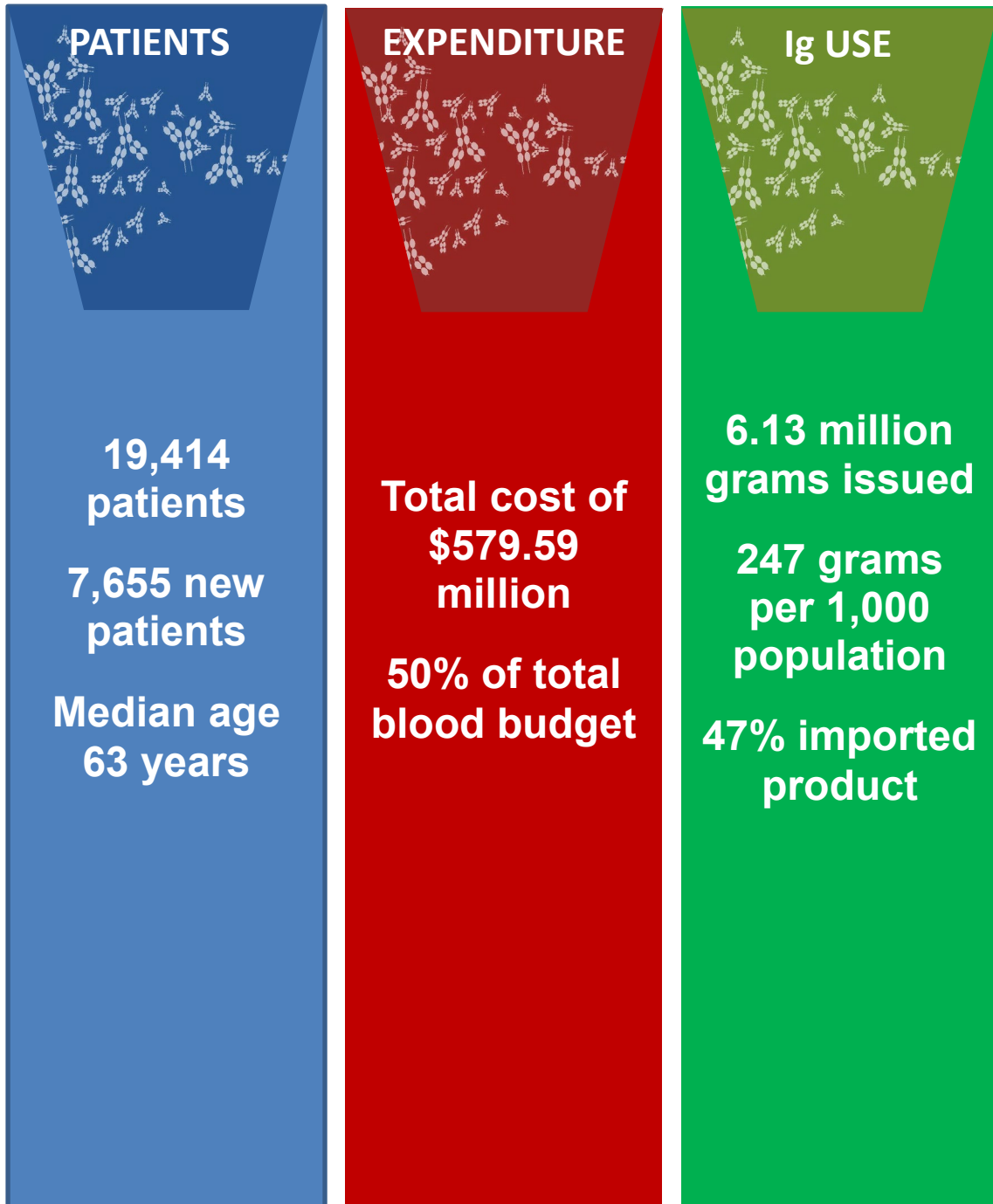
Ig products should be prescribed and dispensed in accordance with any applicable state or territory legislative requirements. In-hospital management of Ig products must also be in accordance with the National Safety and Quality Health Service (NSQHS) Standards, in particular Standards 1, 2 and 7, and the Australian and New Zealand Society of Blood Transfusion (ANZSBT) *Guidelines for the Administration of Blood Products and Guidelines for Transfusion and Immunohaematology Laboratory Practice*.

Ig comprises 50% of total blood expenditure in 2017-18. Demand for Ig continues to rise steadily at around 11% each year, and Australian grams per 1000 population use of this product is one of the highest among western countries¹. Demand for Ig is met through domestic and imported Ig products. Domestic Ig is manufactured by CSL Behring using plasma collected from voluntary, non-remunerated Australian donations. Both domestic and imported Ig are distributed by the Australian Red Cross Blood Service (Blood Service), with the Blood Service also being responsible for collection of data on behalf of governments for product funded under the national blood arrangements.

Australia is in a unique position to provide analysis and commentary on the use of Ig due to national supply arrangements. This report begins with an analysis of Ig supply over the last ten years, then considers patient demographics, expenditure on Ig, clinical indications for which Ig was supplied and finally analyses the dose prescribed for various conditions. The top ten medical conditions account for 88.1% of all Ig supplied in 2017-18, and for this reason specific analysis focuses on these groups.

¹ Robert, Patrick. [Global Use Of Plasma-Derived Medicinal Products](#), 2015

Report Snapshot



Methodology

This report uses data from three primary sources, as follows:

1. Data collected by the Blood Service under contractual arrangements with the NBA on behalf of all Australian governments. This data is collected either when an order is placed for Ig, or where imprest stock is dispensed for treatment. The data is collected into the Blood Service's Supply Tracking Analysis Recording System (STARS) database.
2. Data collected by the NBA on the units dispensed by Australian Health Providers to be administered to the patient. The data is collected into the NBA BloodNet and BloodSTAR systems.
3. Data collected by the NBA on the units of Ig issued to Australian Health Providers (AHPs) and purchases from suppliers. This data is held in the NBA Integrated Data Management System (IDMS).

Prior to 2016-17 authorisation and dispense data was collected by the Blood Service, and in 2016 all jurisdictions transitioned to using BloodSTAR except NSW as shown in the following table. The Blood Service entered information on current patients and authorisations into BloodSTAR using information from STARS. This data is known as *legacy* data.

Jurisdiction	Go Live Date
Northern Territory	14 July 2016
South Australia	1 August 2016
Queensland	22 August 2016
Tasmania	14 September 2016
Victoria	26 September 2016
Australian Capital Territory	24 October 2016
Western Australia	5 December 2016
New South Wales	TBA

Over the nine years between 2008-09 and 2017-18, data has been captured on 64,033 patients. Caveats relating to the quality of this data are outlined below.

This report includes data on the supply of NHlg from 2012-13 and SClg from 2013-14, as SClg products were not available in Australia before 2013-14. The report includes some terminology that may be unique to the Australian environment. A list of acronyms and definitions used in this report is at **Appendix B**.

The Criteria groups together a number of specific conditions into one medical condition. For example, primary immunodeficiency disease is a medical condition in the Criteria, with this group incorporating the numerous separate specific conditions. In some cases the analysis in this report will focus on the medical condition, while in other areas it will focus on the specific condition.

Each specific condition has been classified according to its allocated clinical speciality. It is acknowledged that for some specific conditions this classification could fit into more than one clinical speciality. For example, there are immunological conditions affecting the blood that could potentially be mapped to either immunology or haematology. Where there appears to be significant overlap between clinical specialities, the specific condition was mapped as agreed by the National Immunoglobulin Governance Advisory Committee (NIGAC). In the majority of cases, the specific condition was mapped

to the speciality most likely to be responsible for patients with that specific condition, noting that this can vary. **Appendix C** provides the mapping of specific condition to clinical speciality.

The summary of key items from the data file is provided for each specific condition at the state and territory level. The summary includes patient numbers, average age, average weight, grams of Ig used for the specific condition, grams per treatment episode and grams per 1,000 population (**Appendix D**). The source used for each figure and table is provided at **Appendix G**.

It should be noted that the grams per 1,000 population measure has previously been shown to be a poor indicator for benchmarking. Raw population figures do not take into account the underlying population age structure, hospital usage patterns, and cross-border referrals; nor do total issues take into account varying product wastage rates across time and jurisdictions. A study done by South Australia (SA) in 2010 (Australian Health Review article - "Red alert - a new perspective on patterns of blood use in the SA public sector") shows this and can be found at <https://www.publish.csiro.au/AH/AH10957>.

DATA QUALITY

There are some factors relating to data quality which need to be considered when reading this report, as follows:

- The reconciliation of data held in STARS, BloodSTAR/BloodNet and IDMS indicates minor variances at a national level. In some cases these differences can be explained by product being ordered and recorded in IDMS the month prior to product actually being dispensed to a patient.
- Data is incomplete for some records in both patient and authorisation data. For example data from STARS and BloodSTAR may not include weight. Legacy data entered into BloodSTAR did not include weight.
- The ABS population series 3201.0 (Population by Age and Sex, Australian States and Territories) ended in June 2010 and was replaced by Australian Demographic Statistics (cat. No 3101.0). Series 3201.0 was utilised as the denominator for population statistics for Ig annual reports before 2011-12.
- Care should be taken when interpreting the data relating to the smaller states and territories as one or two patients can overly influence the data compared to larger states.
- There has been no adjustment for Ig dispensed in one state or territory for patients residing in a different state or territory.
- BloodSTAR and STARS jurisdictions or states and territories are based on the state or territory of the facility which dispensed the product, not the treating facility state or territory.
- Patient numbers were first reported in 2008-09. A small number of patients who did not receive product funded under national blood arrangements have been excluded from the total patient count.
- The STARS data has age and weight data recorded at treatment dates (first reported in 2009-10). This data changes over time. Age data is based on the patient's age at 1 January each year for both STARS and BloodSTAR.
- Episodes in STARS were known as Treatment Episodes and in BloodSTAR these are known as Dispense Events. In this document we have used Treatment Episodes for consistency.

- Patient Counts are distinct counts and will not sum for National or Total rows and columns, as patients may have more than one specific condition, have product dispensed in more than one state or territory, have dispense events recorded at a private facility and at a public facility, have received IVIg and SCIg, or have received both domestic and imported product.
- Previous annual reporting for Ig named conditions as Primary Diagnosis or grouped conditions as Disease Category. In BloodSTAR these are known as Specific Conditions or Medical Conditions respectively. Conditions were also grouped to Disciplines previously and these are now known as Specialities in BloodSTAR.
- For 2016-17 and 2017-18 reports, Specific and Medical Conditions are based on the Criteria version 2.
- Dispense data can be entered into BloodSTAR at any time as long as there is a valid and active authorisation. This means that a Dispense Event may be recorded in one month although the actual Dispense Event was in another month, which means data for 2016-17 could be recorded in 2017-18.

10 Year Trends

DEMAND TRENDS

In 2017-18 a total of 6,128,717 grams of Ig was issued, representing an increase of 586,207 grams (10.6%) over 2016-17. Since 2008-09 there has been an on average 11.0% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

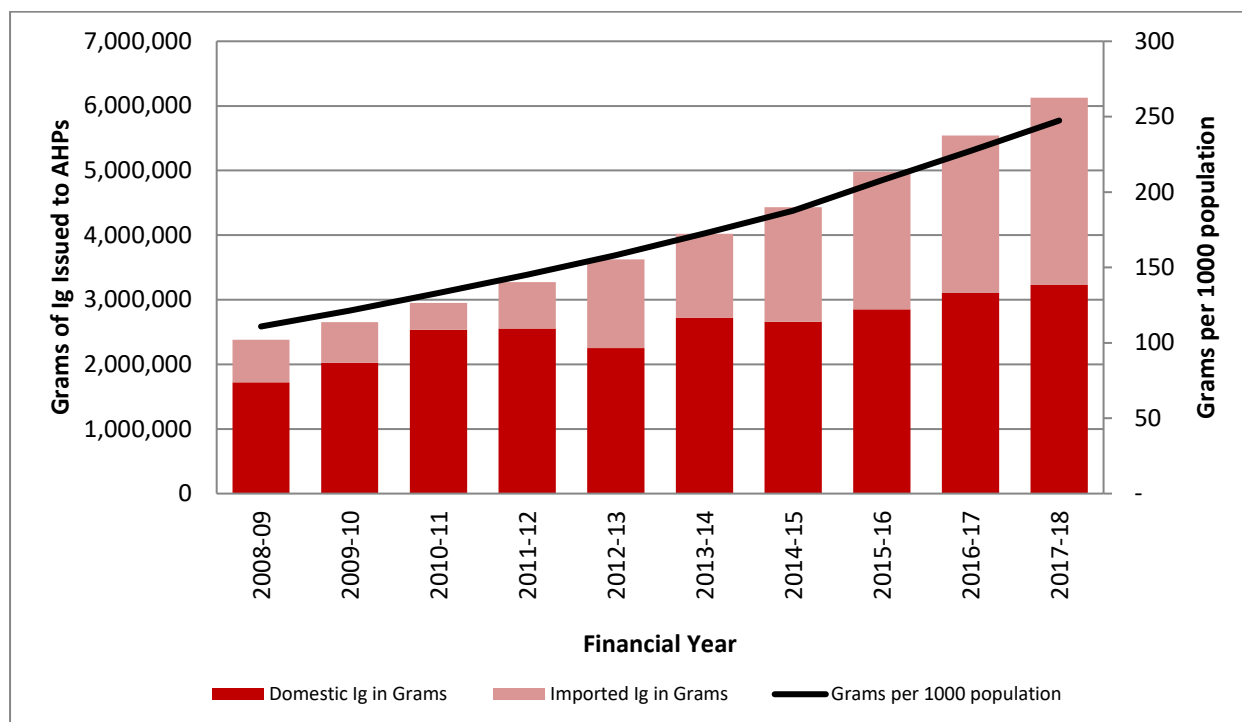


Figure 1 Ten year trends in issues of Ig

Table 1 Growth in Ig grams issued since 2008-09

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Growth from previous year	11%	12%	11%	11%	11%	11%	10%	12%	11%	11%
Average Growth from 2008-09		6%	8%	9%	10%	11%	12%	14%	15%	16%
Total grams per 1,000 population	111	121	133	145	158	173	188	208	227	247
Increase in grams per 1,000 population over previous year	8%	10%	10%	9%	9%	9%	9%	11%	9%	9%

There has been a steady increase in demand for Ig over the last ten years, with increases of 10-12% per annum for the last ten years. While a proportion of this increase may be attributable to population increases, there has also been a steady increase of 8-11% per annum in the use of Ig per 1000 population (Table 1) since the introduction of the Criteria in 2008.

A breakdown of the year on year change in grams issued by state and territory has been provided in Table 2. Over the past ten years the Northern Territory (NT) has been growing at the fastest rate, followed by Queensland (QLD) and NSW. Rates for the smaller population states and territories must be viewed with some caution as there are many factors that could contribute to different use patterns. Further information about the breakdown of domestic and imported Ig by state over time can be found in **Appendix E**.

Table 2 Percentage change in grams issued over time by state and territory

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT
2008-09	15%	3%	14%	23%	0%	14%	54%	-14%
2009-10	13%	11%	15%	12%	-4%	7%	-18%	20%
2010-11	11%	10%	16%	-4%	10%	8%	7%	28%
2011-12	11%	7%	16%	9%	6%	1%	47%	17%
2012-13	11%	13%	11%	9%	7%	-6%	21%	12%
2013-14	10%	11%	12%	15%	6%	14%	1%	12%
2014-15	9%	11%	12%	7%	12%	8%	8%	8%
2015-16	14%	10%	14%	11%	17%	2%	36%	3%
2016-17	14%	11%	8%	10%	18%	4%	6%	7%
2017-18	11%	12%	10%	5%	9%	21%	23%	13%
Average last 10 years	12%	10%	13%	10%	8%	7%	18%	11%

FINANCIAL TRENDS

The increase in demand for Ig places a financial burden on the Australian health system. In Australia, the total cost of domestic Ig supply comprises the cost of the plasma collected by the Blood Service, plus the cost of purchase of the finished Ig product from the supplier (CSL Behring). Imported plasma is purchased at a total product cost only.

Total expenditure on Ig (excluding plasma for fractionation) in 2017-18 was \$327.4 million, an increase of \$23.9 million (7.9%) over 2016-17 (Figure 2). The increased expenditure predominately represents increases in demand offset by lower imported Ig prices.

There also continues to be an increase in the price of plasma for fractionation due to the increased ratio of apheresis to whole blood plasma for fractionation being supplied, resulting in an increase in the cost of domestic Ig. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of \$579.6 million (excluding hyperimmune plasma for fractionation).

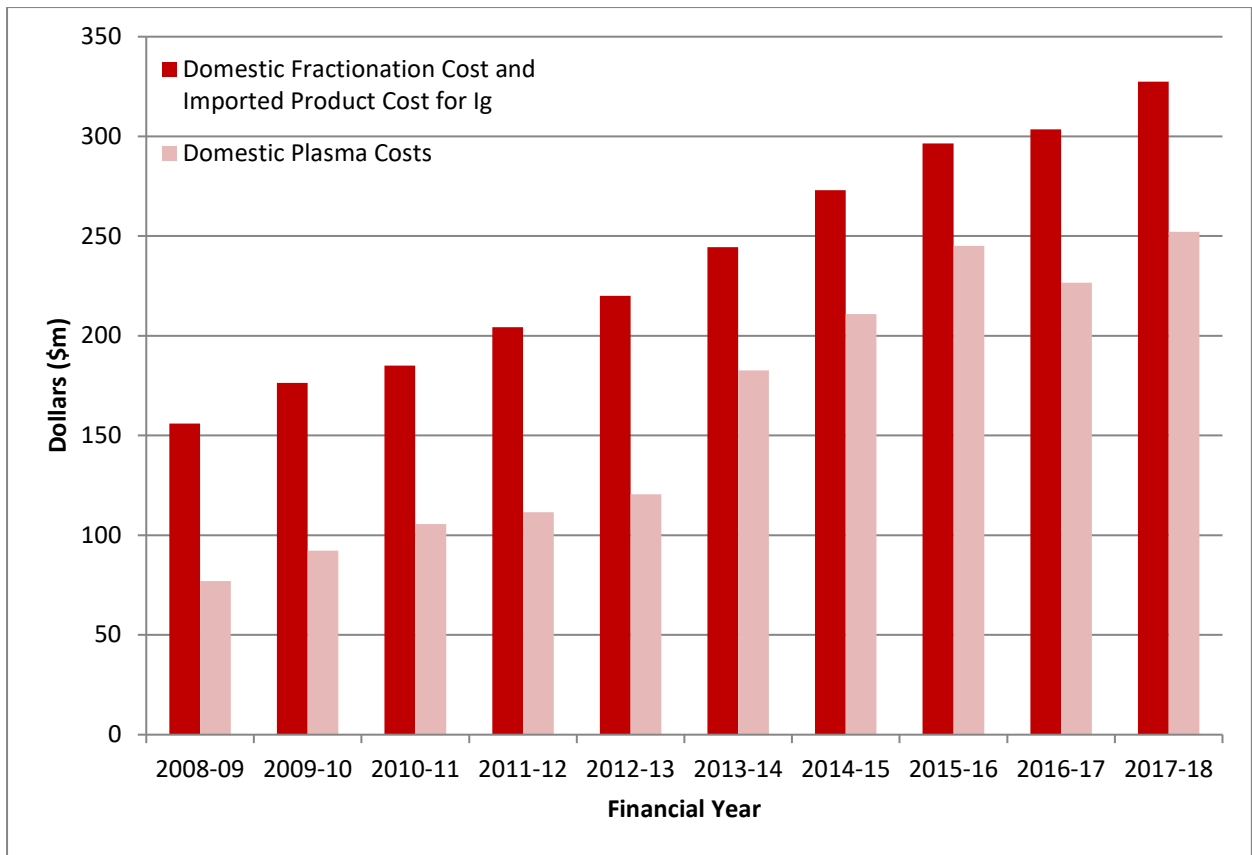


Figure 2 Ten year trends in expenditure on Ig

Demographics

PATIENT NUMBERS

A total of 19,414 patients were issued Ig under the national blood arrangements during 2017-18 for 199,469 treatment episodes. This represents an 8.1% increase in the number of patients since 2016-17. A summary of some patient numbers is provided in Table 3 and Table 4. A breakdown of unique patients by state and territory and quarter is provided in **Appendix F**.

Table 3 Annual numbers of patients, treatment episodes and grams

Year	Patients	Treatment Episodes	Total Grams Issued
2013-14	13,981	122,791	4,021,861
2014-15	14,983	140,855	4,433,146
2015-16	16,331	159,041	4,982,503
2016-17	17,958	179,997	5,542,511
2017-18	19,414	199,449	6,128,717

Table 4 Basic numbers

	2017-18
Total unique patient IDs with some weight data	19,224
Total unique patient IDs with an age recorded	19,414
Total unique patient IDs with more than one state or territory	182
Total unique patient IDs with two states or territories	174
Total unique patient IDs with three or more states or territories	9
Total unique patient IDs with more than one condition	530
Total unique patient IDs with two conditions	496
Total unique patient IDs with three or more conditions	34
Total unique patient IDs aged 65 and older	9,162
Total unique patient IDs aged 17 and younger	1,716
Total unique new patient IDs	7,655
Average Age	57
Median Age	63
Average Weight (kg)	74

GEOGRAPHIC DISTRIBUTION

Nationally, 0.8 patients per 1,000 population received Ig in 2017-18. This varied between states and territories, ranging from 0.4 in WA and NT to 1.0 in QLD (Figure 3). All states and territories show an increase in the number of patients per 1,000 population over the previous year.

Details on the number of patients by specific condition are at **Appendix D**.

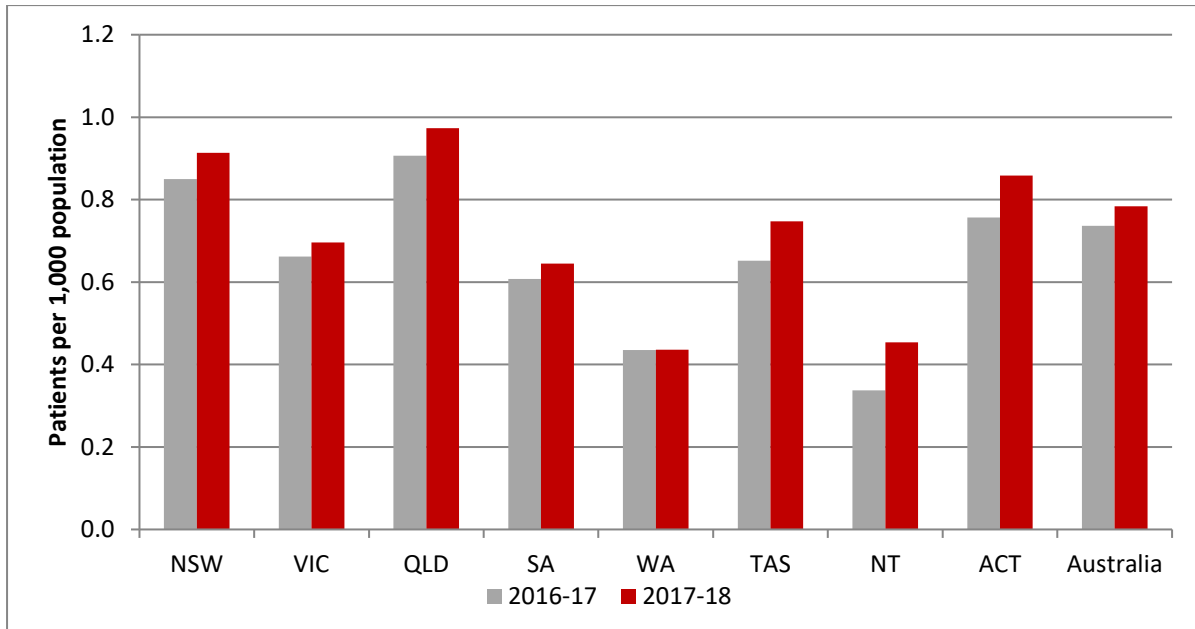


Figure 3 Patients per 1,000 population 2016-17 and 2017-18

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 126.9 in NT to 324.2 in QLD (Figure 4). Rates for the smaller population states and territories must be viewed with some caution as there are many factors that could contribute to their different use patterns. For example, patients may travel to larger states for specialist treatment. At the same time, the ACT services a much broader area. Comparing only the five largest Australian states, the variation in Ig use is 2.1 fold, ranging from 155.0 grams per 1,000 population in Western Australia (WA) to 324.2 grams per 1,000 population in QLD. The reason for this inter-state and territory variation is unknown but it may represent differences in clinical practice, differing patient populations with disease profiles, variable access to alternative therapies, or differences due to the availability of specialist services across Australia.

While most states and territories have seen a continued increase in Ig issued per 1,000 population, TAS and NT increased by 20% and 23% in growth of Ig grams issued per 1,000 population, respectively, while the two largest states NSW and VIC increased by 8%.

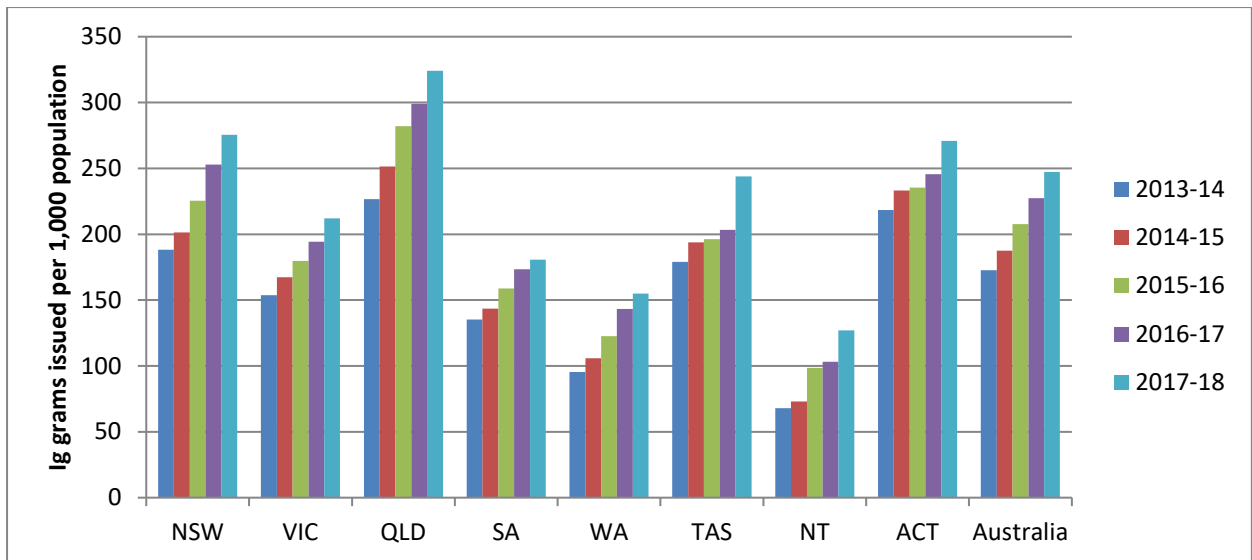


Figure 4 Grams of Ig per 1,000 population by state and territory over time

AGE

The distribution of estimated age is shown in Figure 5 where it is compared with the age distribution of the Australian population at December 2015². A bimodal peak can be seen in the patient population treated with Ig, with the majority of Ig recipients either being very young, or over 55. The ageing population is expected to place a greater burden on Ig demand into the future, with the proportion of the world's population over 60 years expected to more than double between 2015 and 2050³.

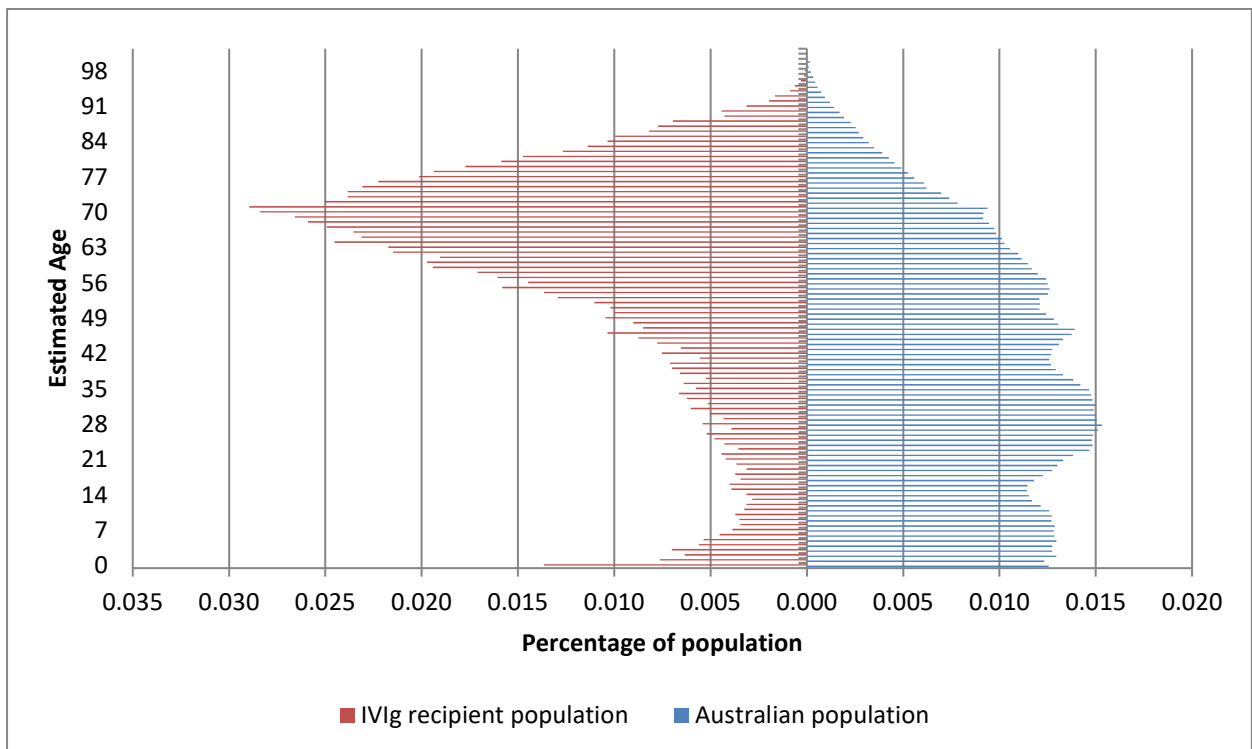


Figure 5 Patient age compared to average Australian age

² ABS 3101.0

³ World Health Organization, <https://www.who.int/features/factfiles/ageing/en/>

WEIGHT

Ig dosing is dependent on the weight of the patient. For many conditions, the patient weight determines the initial dosing, with maintenance therapy titrated against IgG levels and the patient's clinical response to therapy.

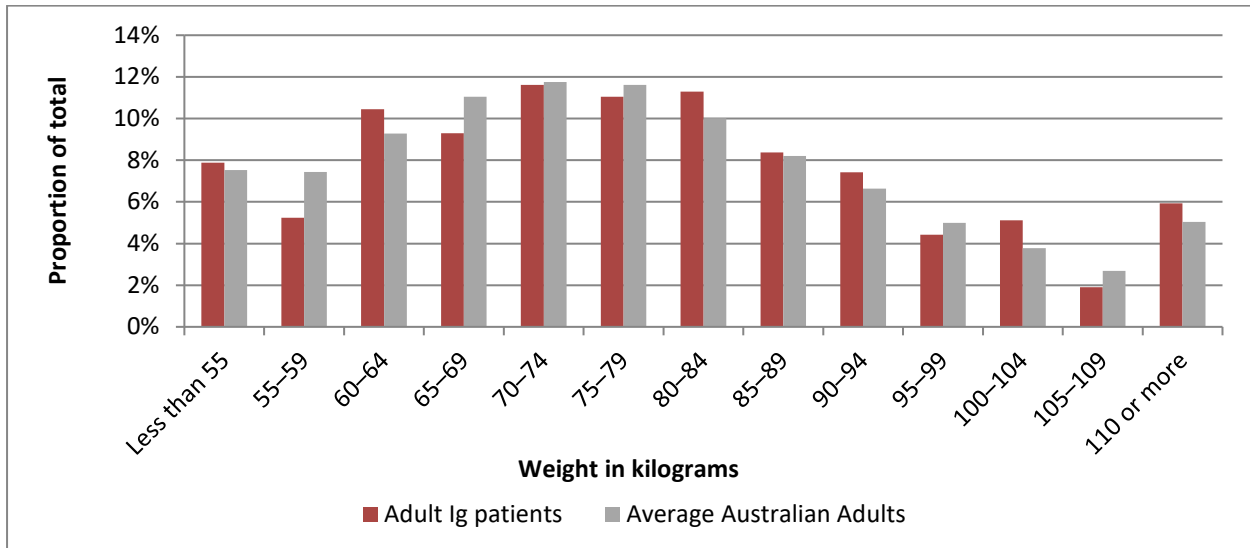


Figure 6 Patient weights relative to Australian average

Note: The above figure calculations relate to only 2017-18 patients.

Figure 6 compares the weight of Ig recipients in Australia in 2017-18 and the Australian population using weight statistics from the ABS in 2011⁴. There is a higher proportion of patients less than 55kg treated with Ig relative to the proportion in the Australian population. The average weight of adult Ig patients (78.8 kg) is slightly higher than the average weight of an Australian adult (77.7 kg⁵). Prior to 2015-16 the average Ig patient weight was slightly lower than the average Australian adult weight, suggesting that the Ig population is getting heavier. Given that studies suggest that 63% of Australians are overweight or obese⁶, the similarity in weight profiles between Ig recipients and the Australian population suggests that a large proportion of Ig recipients may also be overweight. While the current Criteria provides for dosing based on body weight, some limited studies suggest that dosing on lean body weight may be more appropriate.

The amount of Ig prescribed for a patient may vary depending on the indication as well as a patient's weight, as set out in the Criteria. When prescribing Ig, Prescribers should aim to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. The dose may be adjusted for Ideal Body Weight for some patients and a calculator is available in BloodSTAR to facilitate this where appropriate.

Further work needs to be done on ideal body weight dosing and the impacts on patient outcomes.

With an increasingly obese population, increases in demand per patient may be expected if total (rather than lean) body weight dosing is continued. This area should be considered for future research.

Care should be taken when analysing data in this report related to patient weight, as not all patients have weight recorded, and for those that do, the weight recorded may not be current.

⁴ ABS 4841.0

⁵ ABS 4841.0 (average of male and female)

⁶ ABS 4364.0.55.001

Table 5 shows the number of distinct patients and the average weight by age ranges for patients with dispenses in 2017-18.

Table 5 Patient numbers and average weight by age range

Age Range	Patient Counts	Average Weight	Treatment Episodes	Grams Dispensed
0-4	781	11	2,657	23,123
5-9	402	24	2,580	37,389
10-14	312	44	3,005	61,013
15-17	221	64	2,158	54,208
18-19	133	69	1,413	33,961
20-24	391	71	3,934	101,631
25-29	459	75	4,901	148,566
30-34	564	79	6,193	174,508
35-39	603	78	6,244	200,631
40-44	669	80	7,249	240,565
45-49	914	82	10,239	344,094
50-54	1,122	81	12,709	404,975
55-59	1,610	81	17,898	594,561
60-64	2,067	82	23,433	741,246
65-69	2,409	80	25,550	798,340
70-74	2,525	80	26,939	835,297
75-79	1,992	77	20,868	647,839
80-84	1,261	75	12,707	383,079
85-89	720	71	6,543	191,256
90-94	234	69	2,004	53,812
95-104	25	61	227	5,640
Total	19,414	74	199,451	6,075,733

Expenditure

In 2017-18, Australian expenditure on Ig products was \$327.4 million, with additional expenditure of \$252.2 million on plasma for fractionation (excluding hyperimmune plasma for fractionation) collected by the Blood Service, which is primarily directed to manufacture of Ig products.

The cost of Ig as a proportion of the national blood budget is shown at Figure 7. Ig is the second largest budget item, representing 28% of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, Ig accounts for 50% of the total blood budget, at a total expenditure of \$579.6 million (excluding hyperimmune plasma for fractionation).

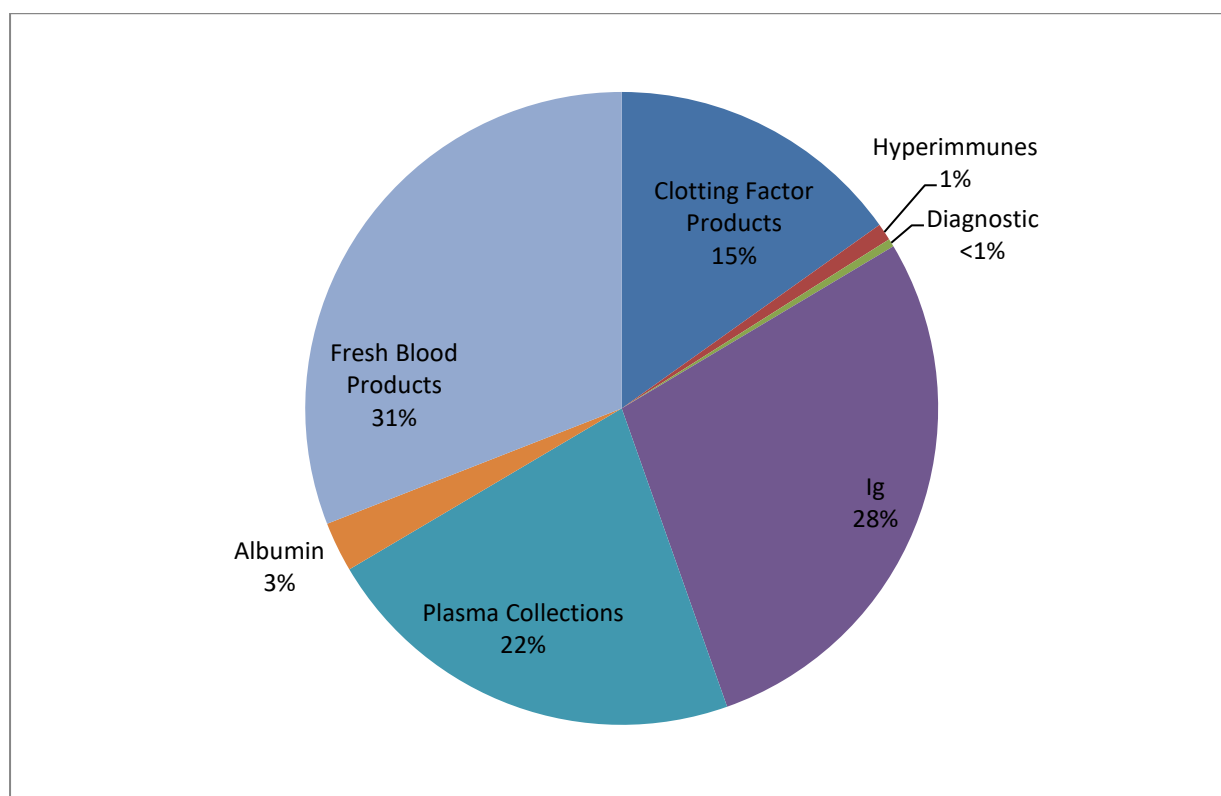


Figure 7 Ig expenditure as a proportion of the national blood budget

Of the Ig supplied under national blood arrangements in Australia in 2017-18, 53% (3,225,722 grams) was manufactured domestically and 47% (2,902,995 grams) was imported from overseas (Table 6). This represents a 19.1% increase in product importation from 2016-17 (465,667 grams). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 6.0% in 2017-18 over 2016-17. Intragam P, Intragam 10 (IVIg) and Evogam (SCIg) were Ig products manufactured domestically in 2017-18. The imported products available were Privigen (IVIg), Flebogamma (IVIg) and Hizentra (SCIg). When a patient is allocated to receive one of the imported products it is the clinician's choice as to which product they order. Supply of Privigen constituted 61.7% of the supply of imported Ig.

Table 7 shows the split between Ig issues for domestic and imported products, by public and private Australian Health Providers (AHPs) for 2017-18.

Table 6 Issues of domestic Ig compared with imported Ig

			NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
Domestic Ig	Intragam P	gm	15,522	609	0	0	0	0	0	0	16,131
		\$(m)	\$1	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$1
	Intragam 10	gm	1,065,420	719,710	858,243	167,880	199,210	65,053	10,690	59,338	3,145,543
		\$(m)	\$64	\$43	\$52	\$10	\$12	\$4	\$1	\$4	\$190
	Evogam	gm	23,278	11,292	16,339	6,663	5,341	288	512	336	64,049
		\$(m)	\$1	\$1	\$1	\$0	\$0	\$0	\$0	\$0	\$4
	Total Domestic	gm	1,104,220	731,611	874,582	174,543	204,551	65,341	11,202	59,674	3,225,722
		\$(m)	\$67	\$44	\$53	\$11	\$12	\$4	\$1	\$4	\$195
Imported Ig	Flebogamma	gm	371,574	211,600	242,555	49,953	66,846	20,365	914	4,820	968,626
		\$(m)	\$17	\$10	\$11	\$2	\$3	\$1	\$0	\$0	\$44
	Privigen	gm	650,825	386,175	461,740	69,530	123,515	38,370	19,190	41,295	1,790,640
		\$(m)	\$29	\$17	\$21	\$3	\$6	\$2	\$1	\$2	\$81
	Hizentra	gm	53,508	24,772	30,757	18,172	5,818	3,864	0	6,838	143,729
		\$(m)	\$3	\$1	\$2	\$1	\$0	\$0	\$0	\$0	\$8
	Total Imported	gm	1,075,907	622,547	735,052	137,655	196,179	62,599	20,104	52,953	2,902,995
		\$(m)	\$49	\$28	\$33	\$6	\$9	\$3	\$1	\$2	\$132
Proportion of domestic to imported Ig	gm %	51%	54%	54%	56%	51%	51%	36%	53%	53%	
	\$(m) %	58%	61%	61%	62%	58%	58%	43%	59%	60%	

Note: \$(m) excludes the costs for plasma for fractionation.

Table 7 Issues of domestic Ig compared with imported Ig and public versus private

			NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
Domestic Ig	Public	gm	789,013	423,166	318,202	140,426	136,400	48,451	11,202	59,674	1,926,531
	Private	gm	315,207	308,445	556,380	34,118	68,151	16,890	-	-	1,299,191
	Total Domestic	gm	1,104,220	731,611	874,582	174,543	204,551	65,341	11,202	59,674	3,225,722
Imported Ig	Public	gm	867,222	401,581	359,462	125,015	147,539	47,756	20,104	52,953	2,021,632
	Private	gm	208,685	220,966	375,591	12,640	48,640	14,843	-	-	881,364
	Total Imported	gm	1,075,907	622,547	735,052	137,655	196,179	62,599	20,104	52,953	2,902,995
Total Ig	Public	gm	1,656,235	824,747	677,663	265,441	283,939	96,207	31,306	112,627	3,948,163
	Private	gm	523,892	529,411	931,971	46,758	116,791	31,733	-	-	2,180,555
	Total Ig	gm	2,180,126	1,354,158	1,609,634	312,198	400,729	127,940	31,306	112,627	6,128,717
Domestic to Imported	Public	gm%	47.6%	51.3%	47.0%	52.9%	48.0%	50.4%	35.8%	53.0%	48.8%
	Private	gm%	60.2%	58.3%	59.7%	73.0%	58.4%	53.2%	0.0%	0.0%	59.6%
	Total Ig	gm%	50.6%	54.0%	54.3%	55.9%	51.0%	51.1%	35.8%	53.0%	52.6%
Ig as portion of National	Public	gm%	41.9%	20.9%	17.2%	6.7%	7.2%	2.4%	0.8%	2.9%	100.0%
	Private	gm%	24.0%	24.3%	42.7%	2.1%	5.4%	1.5%	0.0%	0.0%	100.0%
	Total Ig	gm%	35.6%	22.1%	26.3%	5.1%	6.5%	2.1%	0.5%	1.8%	100.0%
	Population %		32.0%	25.8%	20.0%	7.0%	10.4%	2.1%	1.0%	1.7%	
Grams Per 1000 Population	Public		209.3	129.2	136.5	153.6	109.9	183.4	126.9	270.8	159.4
	Private		66.2	82.9	187.7	27.1	45.2	60.5	-	-	88.0
	Total Ig		275.4	212.1	324.2	180.7	155.0	243.8	126.9	270.8	247.4

Clinical Indications

IG ISSUES BY CRITERIA CHAPTER

The Criteria classifies medical conditions into four chapters based on the level of evidence supporting the use of Ig, as follows:

- Chapter 5, conditions for which Ig has an established therapeutic role
- Chapter 6, conditions for which Ig has an emerging therapeutic role
- Chapter 7, conditions for which Ig has application in exceptional circumstances only
- Chapter 8, conditions for which Ig use is not supported.

Ig was predominately issued for medical conditions within Chapter 5 (Table 8). The relative distribution by chapter has remained relatively stable since 2008 (Table 9). Chapter 8 issues of 313 grams are mainly for emergency sepsis cases. Refer to **Appendix D** for further information.

Table 8 Ig issues (g) by Criteria chapter

	2013-14	2014-15	2015-16	2016-17	2017-18
Chapter 5	3,409,100	3,785,615	4,223,866	4,620,916	5081838
Chapter 6	463,361	494,489	535,596	645,636	721,766
Chapter 7	148,581	178,221	216,927	220,122	271,817
Chapter 8	0	0	5	837	313
Total	4,021,042	4,458,326	4,976,394	5,487,511	6,075,733

Table 9 Ig issues by Criteria chapter (percentage)

	2013-14	2014-15	2015-16	2016-17	2017-18
Chapter 5	85%	85%	85%	84%	93%
Chapter 6	12%	11%	11%	12%	13%
Chapter 7	4%	4%	4%	4%	5%
Chapter 8	0%	0%	0%	0%	0%

For conditions where Ig is used only in exceptional circumstances (Chapter 7), six medical conditions accounted for 62.5% of those issues. These medical conditions were Limbic Encephalitis – nonparaneoplastic (88,621 grams), Paraneoplastic neurological syndromes (27,500 grams), Devic disease (neuromyelitis optica) (14,348 grams), Potassium channel antibody-associated encephalopathy (13,605 grams), Pure red cell aplasia (13,053 grams) and Susac syndrome (12,855 grams). While use in these medical conditions represents a small proportion of total Ig use, closer examination of these medical conditions may be warranted.

While Ig may be issued in life threatening situations prior to diagnosis or in situations where the diagnosis is unclear at the time of treatment, in 2017-18 there were no cases where funded Ig was supplied for a medical condition not supported in the Criteria (excluding Direct Orders where alignment with the Criteria is not required as it is not funded under the national blood arrangements). Refer to **Appendix D** for further information. Data to support compliance with all aspects of qualifying criteria for each specific condition is not always collected in STARS.

IG ISSUES BY MEDICAL CONDITION

The top ten medical conditions account for 88.1% of all Ig supplied, with the top three medical conditions accounting for 56.3%.

Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT is the medical condition for which the greatest percentage of Ig was issued in 2017-18 (23.1%), closely followed by chronic inflammatory demyelinating polyneuropathy (CIDP) (21.2%). Primary immunodeficiency diseases (PID) with antibody deficiency accounted for 11.9% of total Ig use (Figure 8 and Table 10).

Since 2013-14 there has been greater than 16% increase in Ig issues for secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) and a 15% increase in issues for myasthenia gravis (MG) and inflammatory myopathies. This is compared with the 11% increase in Ig over this period for all medical conditions.

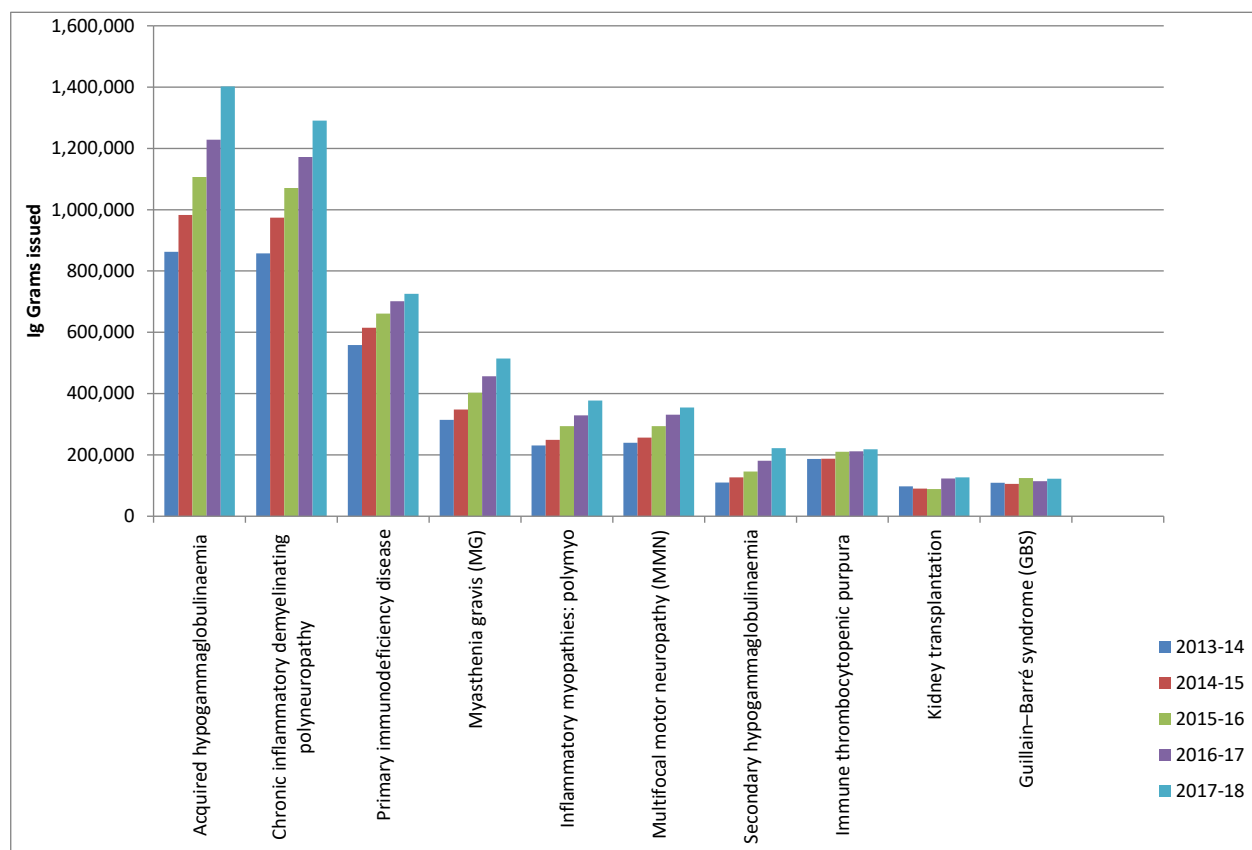


Figure 8 Ig grams issued by medical condition

Table 10 Ig grams issued for top 10 medical conditions over time

	2013-14	2014-15	2015-16	2016-17	2017-18	% Change 2017-18 to 2016-17
Acquired hypogammaglobulinaemia	862,898	982,773	1,106,721	1,228,405	1,401,789	14.1%
Chronic inflammatory demyelinating polyneuropathy	857,533	974,258	1,071,135	1,171,581	1,290,612	10.2%
Primary immunodeficiency diseases	558,617	614,781	660,816	701,547	725,326	3.4%
Myasthenia gravis	313,940	348,336	402,881	456,346	514,017	12.6%
Inflammatory myopathies	230,473	249,229	293,422	329,182	377,479	14.7%
Multifocal motor neuropathy	239,314	256,041	293,458	331,142	354,434	7.0%
Secondary hypogammaglobulinaemia	110,024	126,561	145,497	180,831	222,136	22.8%
Immune thrombocytopenic purpura (ITP) — adult	186,640	187,621	210,094	211,868	218,182	3.0%
Kidney transplantation	97,070	90,031	88,258	122,994	126,587	2.9%
Guillain–Barré syndrome	108,929	105,567	124,692	114,184	122,139	7.0%

Kidney transplantation fell into the top ten medical conditions in 2016-17 with a 39.4% growth over 2015-16; however in 2017-18 the growth was only 2.9%. Further investigation may be warranted for this change year on year. Secondary hypogammaglobulinaemia continued to see the highest increase in use at 22.8% over 2016-17 and is in all states and territories except SA and ACT (Table 11). In 2017-18 grams per patient ranged from 85 grams in NT and 153 grams in SA to 237 grams in NSW and 254 grams in QLD.

Table 11 Difference in grams issued for secondary hypogammaglobulinaemia (percentage)

	2013-14	2014-15	2015-16	2016-17	2017-18
NSW	8%	20%	15%	19%	20%
VIC	-7%	11%	20%	56%	38%
QLD	7%	15%	16%	17%	20%
SA	15%	-9%	-20%	34%	-2%
WA	-24%	6%	38%	33%	12%
TAS	-2%	-3%	-7%	-12%	38%
NT	-73%	120%	-82%	-17%	423%
ACT	41%	454%	22%	146%	-11%
Total	3%	15%	15%	24%	23%

The top ten medical conditions by state and territory by proportion are depicted in Figure 9.

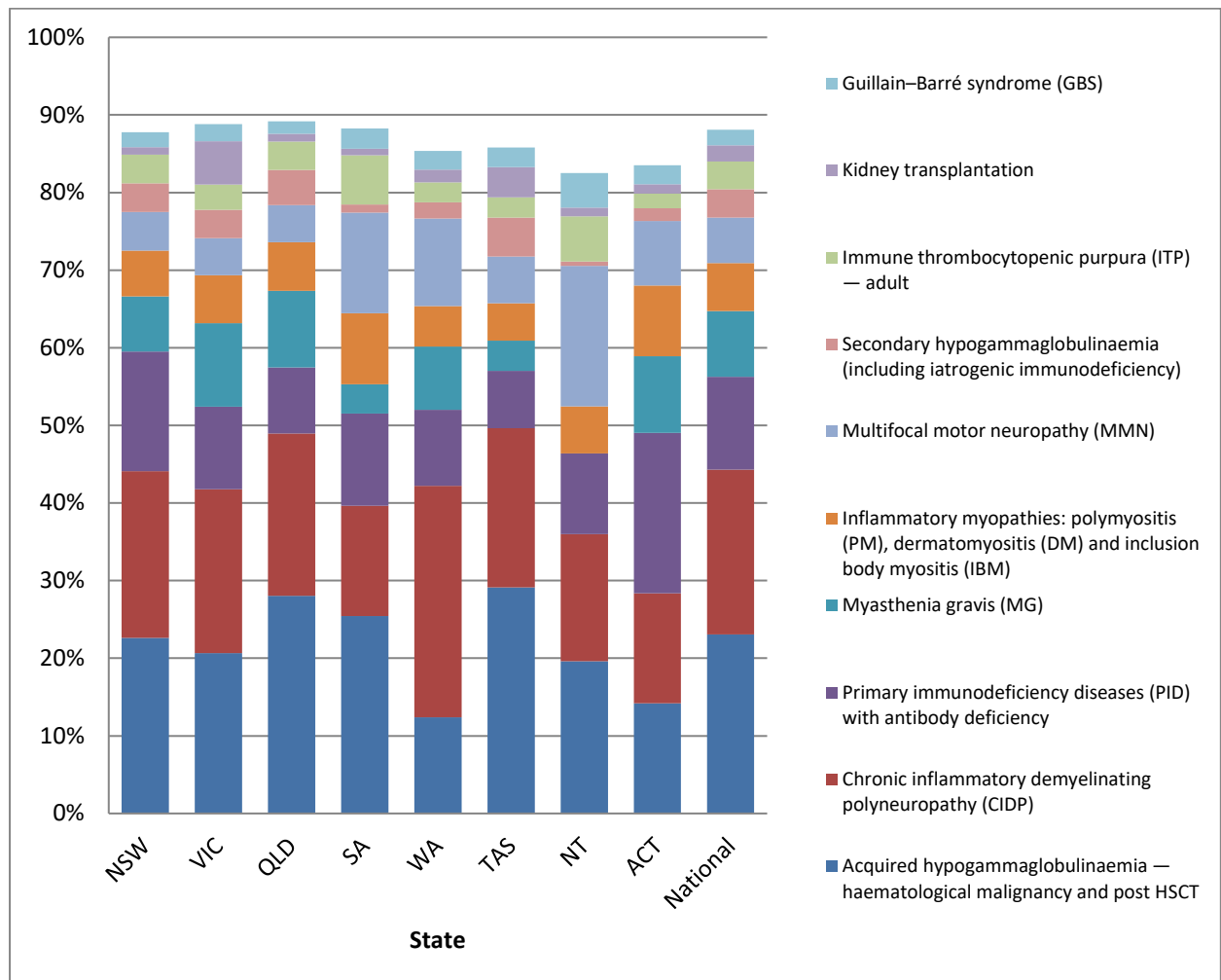


Figure 9 Proportion of Ig used for top 10 medical conditions

IG ISSUES BY SPECIFIC CONDITION

The top twenty specific conditions account for 89.0% of all Ig supplied, with the top ten specific conditions accounting for 75%.

Population based data on Ig issues maybe particularly interesting for specific conditions where the majority of patients receive Ig as it can provide an estimation of disease prevalence.

Table 12 provides an overview of the specific conditions that use the most Ig by private and public dispensing facilities, including data on total Ig use, patient numbers and average age.

Table 12 Patient numbers and age for the top 20 specific conditions by private and public facilities

Specific Conditions (Top 20)	Private			Public			Total		
	Ig g (% of total)	Patients n (% of total)	Average Age	Ig g (% of total)	Patients n (% of total)	Average Age	Ig g (% of total)	Patients n (% of total)	Average Age
Chronic inflammatory demyelinating polyneuropathy	453,940 (7%)	935 (2%)	65	836,672 (14%)	1,772 (4%)	63	1,290,612(21%)	2,595 (6%)	64
Common variable immunodeficiency disease	154,138 (3%)	504 (4%)	57	484,440 (8%)	1,464 (4%)	49	638,578 (11%)	1,876 (8%)	51
Myasthenia gravis	175,046 (3%)	397 (5%)	64	338,972 (6%)	829 (4%)	61	514,017 (8%)	1,174 (8%)	62
Chronic lymphocytic leukaemia	213,115 (4%)	815 (1%)	73	222,108 (4%)	891 (2%)	71	435,223 (7%)	1,632 (3%)	72
Non-Hodgkin lymphoma	242,312 (4%)	961 (4%)	70	180,505 (3%)	756 (4%)	66	422,817 (7%)	1,651 (7%)	68
Multifocal motor neuropathy	106,698 (2%)	176 (2%)	59	247,736 (4%)	406 (3%)	58	354,434 (6%)	560 (5%)	59
Multiple myeloma	187,335 (3%)	746 (1%)	72	166,670 (3%)	790 (2%)	69	354,006 (6%)	1,458 (3%)	70
Secondary hypogammaglobulinaemia	90,184 (1%)	383 (1%)	61	131,953 (2%)	628 (3%)	53	222,136 (4%)	953 (4%)	56
Polymyositis	57,458 (1%)	133 (0%)	63	149,263 (2%)	399 (2%)	61	206,720 (3%)	513 (2%)	62
Guillain–Barré syndrome	24,458 (0%)	149 (1%)	55	97,681 (2%)	610 (2%)	52	122,139 (2%)	754 (3%)	52
Kidney transplantation post-transplant	10,435 (0%)	32 (0%)	53	110,390 (2%)	422 (1%)	48	120,825 (2%)	449 (1%)	48
Other relevant haematological malignancies	61,642 (1%)	263 (0%)	67	55,971 (1%)	387 (1%)	47	117,613 (2%)	625 (2%)	55
Dermatomyositis	19,774 (0%)	50 (1%)	56	76,636 (1%)	208 (1%)	46	96,410 (2%)	250 (2%)	48
Limbic encephalitis, nonparaneoplastic	23,971 (0%)	90 (0%)	51	64,650 (1%)	283 (1%)	45	88,621 (1%)	365 (1%)	46

Specific Conditions (Top 20)	Private			Public			Total		
	Ig g (% of total)	Patients n (% of total)	Average Age	Ig g (% of total)	Patients n (% of total)	Average Age	Ig g (% of total)	Patients n (% of total)	Average Age
Specific antibody deficiency	29,234 (0%)	109 (1%)	60	59,364 (1%)	237 (2%)	48	88,598 (1%)	334 (2%)	52
Inclusion body myositis	24,129 (0%)	52 (1%)	70	50,221 (1%)	125 (2%)	71	74,349 (1%)	170 (2%)	70
Post-haemopoietic stem cell transplantation	24,949 (0%)	124 (1%)	54	47,192 (1%)	349 (2%)	39	72,141 (1%)	443 (2%)	43
ITP with life-threatening haemorrhage	20,298 (0%)	135 (1%)	63	51,160 (1%)	359 (1%)	58	71,457 (1%)	490 (2%)	60
ITP refractory acute	20,358 (0%)	132 (0%)	62	50,122 (1%)	328 (0%)	57	70,479 (1%)	456 (0%)	58
ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP)	23,868 (0%)	133 (0%)	64	41,415 (1%)	279 (1%)	62	65,283 (1%)	407 (1%)	62

IG ISSUES BY CLINICAL SPECIALITY

The number of grams of Ig issued categorised according to clinical speciality is shown in Figure 10. Some specific conditions prior to 2017-18 were classified as mixed, in that they fell across more than one clinical speciality. Other specific conditions fall within a clinical speciality other than neurology, haematology or immunology, such as use in transplant or dermatology. These are considered under 'Other' in Figure 10 and Table 13 replicates this data.

Since 2013-14, there has been a 1.6 fold increase in Ig issues for neurological conditions, compared with a 1.5 fold increase for both haematological conditions and immunological conditions.

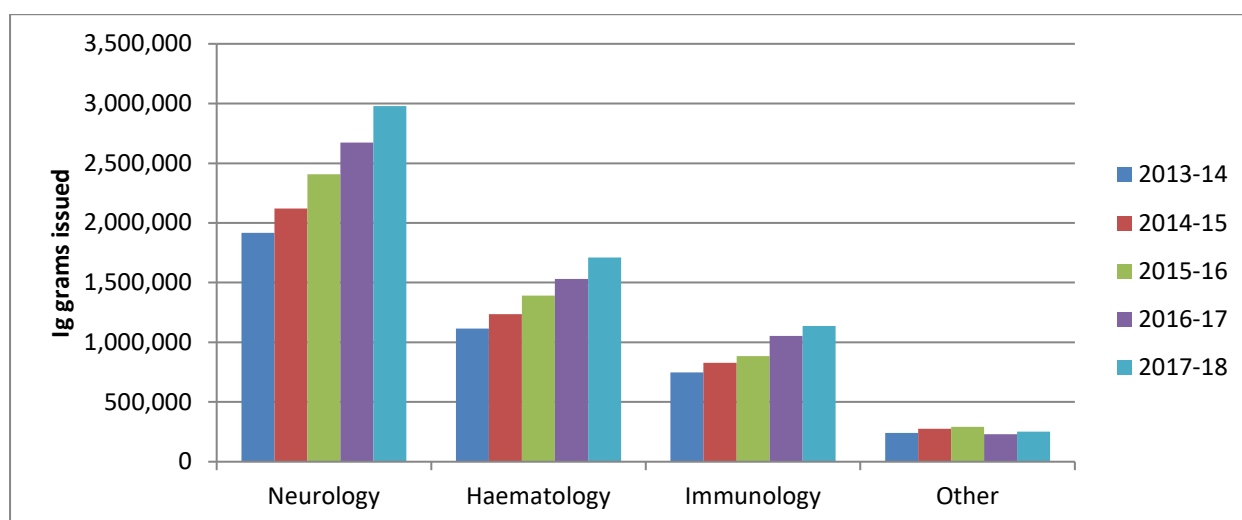


Figure 10 Ig issues by clinical speciality

Table 13 Ig grams issued by clinical speciality

	2013-14	2014-15	2015-16	2016-17	2017-18
Neurology	1,916,792	2,120,111	2,407,995	2,672,261	2,977,065
Haematology	1,116,037	1,234,816	1,390,824	1,530,340	1,710,717
Immunology	746,828	828,735	885,933	1,053,712	1,135,762
Other	241,386	274,664	291,643	231,199	252,189

There is significant variation across Australia in Ig use for each clinical speciality (as allocated). Figure 11 shows that in WA issues for neurological conditions represent a greater proportion of total issues than for other states, and haematological conditions are less than other states and territories. The reason for this inter-state and territory variation is unknown, but it may represent differences in clinical practice, differing disease profiles in the patient populations, variable access to alternative therapies or differences due to the availability of specialist services across Australia.

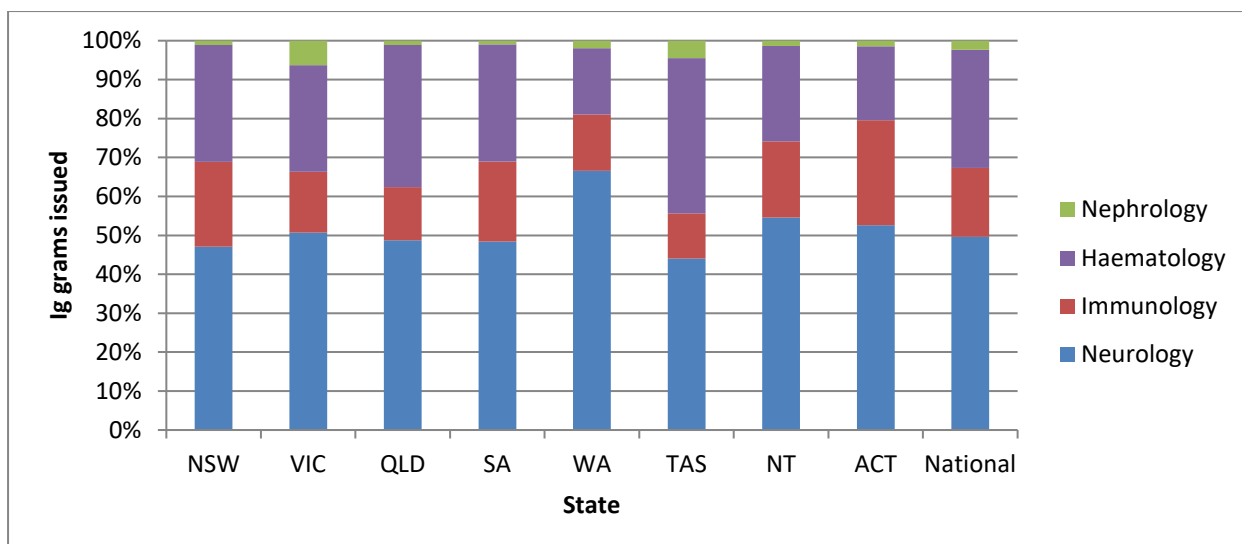


Figure 11 Percentage Ig issues by clinical speciality for top 10 medical conditions

IG GRAMS ISSUED PER 1,000 POPULATION

The amount of Ig issued per 1,000 population for each specific condition varies between state and territory. Complete data for specific conditions by state and territory can be found at **Appendix D**. Table 14 shows a breakdown of the proportion of Ig issued in each state and territory with a comparison to the proportion of the population in each state and territory.

Of the top 10 specific conditions the highest variation between the five largest states and territories in Ig use per 1,000 population is seen in multiple myeloma and secondary hypogammaglobulinaemia. In total, for the five largest states, there was proportionally low Ig issues per 1,000 population in South Australia (SA) and WA respectively, and high in QLD. The reason for the significant variation between these states is unknown, and further studies may be required to ascertain the significance of this finding.

Table 14 Grams of Ig issued by state and territory

	Ig issued (g)	Proportion of total Ig issued	Proportion of Australian population	Grams per 1,000 population
NSW	2,180,126	35.6%	32.0%	275
VIC	1,354,158	22.1%	25.8%	212
QLD	1,609,634	26.3%	20.0%	324
SA	312,198	5.1%	7.0%	181
WA	400,729	6.5%	10.4%	155
TAS	127,940	2.1%	2.1%	244
NT	31,306	0.5%	1.0%	127
ACT	112,627	1.8%	1.7%	271
Total	6,128,717	100%	100%	247

Table 15 shows the top 10 specific conditions by the Ig grams issued per 1,000 population by state and territory. The fold variation Table 15 is a measure describing difference in the Ig grams per 1,000 population between the state being issued the least to the state being issued the most, using only data from the five largest states in Ig use. For example, a low value of 30 and a high value of 60 correspond to a fold variation of 2, or in common terms, a two-fold increase.

Table 15 Grams of Ig issued per 1,000 population by state/ territory for top 10 specific conditions

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS	Fold Variation
Chronic inflammatory demyelinating polyneuropathy	60	44	67	25	45	50	20	38	52	2.7
Common variable immunodeficiency disease	39	17	25	18	12	16	7	52	26	3.2
Myasthenia gravis	21	14	23	13	8	17	11	18	18	3.0
Chronic lymphocytic leukaemia	20	22	32	7	12	9	0	26	21	4.8
Non-Hodgkin lymphoma	16	13	32	13	5	24	6	9	17	6.3
Multifocal motor neuropathy	14	10	15	23	17	15	22	22	14	2.3
Multiple myeloma	16	11	23	12	3	21	3	7	14	8.0
Secondary hypogammaglobulinaemia	10	8	15	2	3	12	1	4	9	7.8
Polymyositis	10	6	12	10	4	8	8	9	8	2.7
Guillain–Barré syndrome	5	5	5	5	4	6	6	7	5	1.5

Dosing

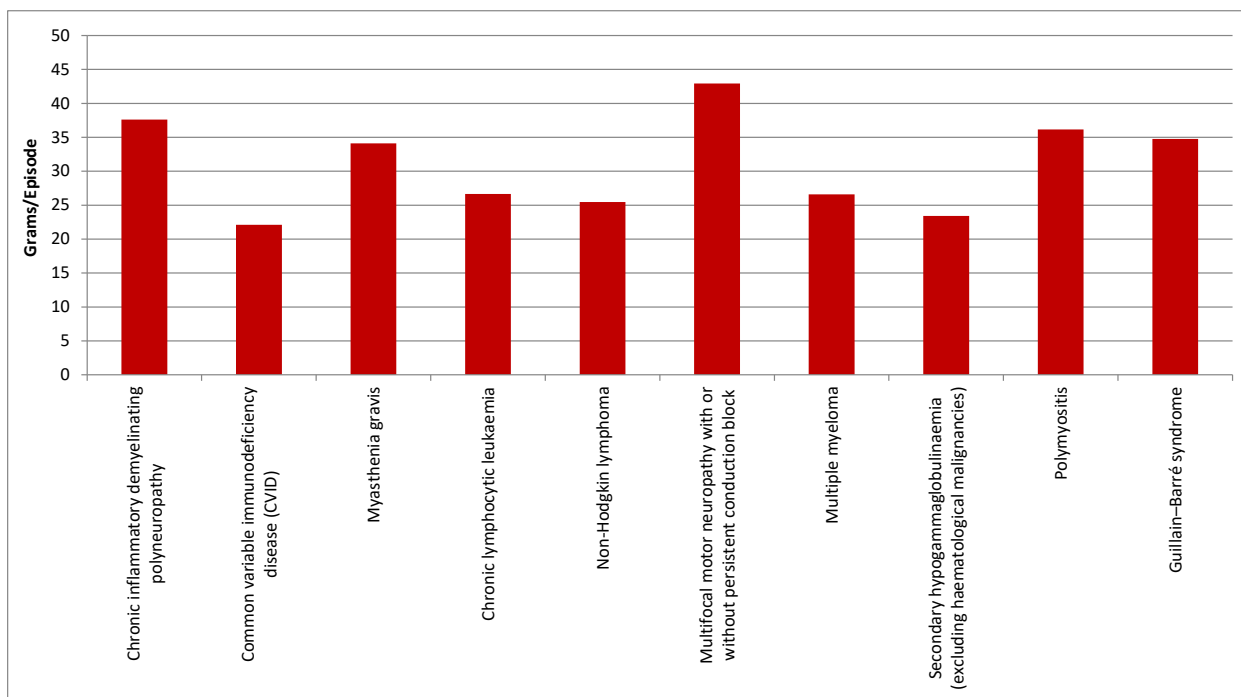


Figure 12 Grams per episode by specific condition

Figure 12 shows that there is significant variance in the dosing of the top 10 specific conditions by grams per episode where dosing is calculated as number of grams administered in each episode. The definition of episode in the data is not uniform and therefore this data should be interpreted with caution. Variations are expected as the dose (g/kg) and frequency of dose also varies. Also note that the Criteria requires the lowest possible dose to achieve the desired clinical outcome, so the dose is not 'mandated' but rather suggested and guided to the lower end to achieve efficacy which may contribute to the differences in dosing between conditions.

Dosing in neurological conditions is higher than for haematological and immunological conditions, as provided for in the Criteria. For dosing information for other conditions refer to **Appendix D**.

The grams per kilogram were calculated for each dispense event (Figure 12 and Table 16). From this data it is difficult to assess whether the dosing strategy utilised was in accordance with that provided for under the Criteria. This is particularly difficult as the patient weight data is not updated or present for every dispense event (particularly for those recorded in STARS and transitioned to BloodSTAR) for every episode and may change over time.

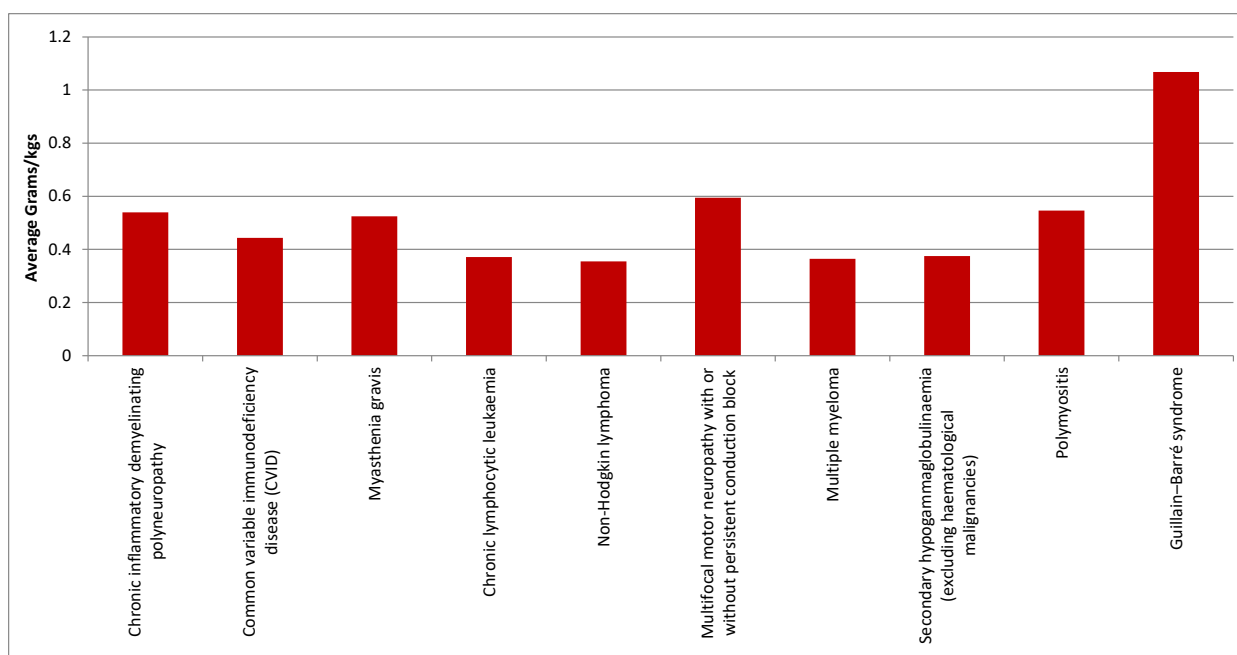


Figure 13 Grams per kg weight by specific condition

Table 16 Ig grams per kg weight per episode

Specific Condition	<=0.4 g/kg/ episode	0.4 – 0.99 g/kg/ episode	1 – 2 g/kg/ episode	>2 g/kg/ episode	No weight Data	Ig Average g/kg/ episode
	n (%)	n (%)	n (%)	n (%)	n(%)	
Chronic inflammatory demyelinating polyneuropathy	10,949 (33%)	19,523 (59%)	1,917 (6%)	160 (0%)	615 (2%)	0.51
Common variable immunodeficiency disease	10,533 (46%)	10,717 (47%)	148 (1%)	34 (0%)	1,231 (5%)	0.43
Myasthenia gravis	5,407 (37%)	8,302 (57%)	616 (4%)	49 (0%)	201 (1%)	0.47
Chronic lymphocytic leukaemia	8,375 (53%)	7,233 (46%)	14 (0%)	2 (0%)	230 (1%)	0.38
Non-Hodgkin lymphoma	9,017 (55%)	7,050 (43%)	19 (0%)	2 (0%)	205 (1%)	0.37
Multifocal motor neuropathy	7,160 (54%)	5,855 (44%)	4 (0%)	0 (0%)	151 (1%)	0.38
Multiple myeloma	1,935 (24%)	5,115 (64%)	777 (10%)	33 (0%)	165 (2%)	0.58
Secondary hypogammaglobulinaemia	4,681 (51%)	4,302 (47%)	35 (0%)	4 (0%)	118 (1%)	0.38
Polymyositis	1,638 (30%)	3,388 (62%)	400 (7%)	19 (0%)	63 (1%)	0.51
Guillain-Barré syndrome	1,076 (42%)	1,152 (45%)	248 (10%)	101 (4%)	8 (0%)	0.55

Note: n is the number of Treatment Episodes

IVIg and SClg

In March 2013, the JBC approved the introduction of SClg under the national blood arrangements. In 2015-16 the NBA established arrangements for supply of the following SClg products:

- Evogam 16% 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (Australia) Pty Ltd (domestic)
- Gammanorm 16% 1650mg/10ml and 3300mg/20ml supplied by Octapharma Australia Pty Ltd (imported)
- Hizentra 5% 1g/5ml, 2g/10ml, 4g/20ml and 10g/50ml supplied by CSL Behring (Australia) Pty Ltd (imported).

In 2017-18 only Evogam and Hizentra were issued to patients for SClg.

In addition to the clinical and diagnostic criteria for access to immunoglobulin products, access to SClg products is provided through an assurance framework for the appropriate use of the product. The first phase of implementation was through hospital-based management arrangements. SClg access rules are detailed on the NBA website at <https://www.blood.gov.au/SClg>. Participation in the National SClg program requires hospitals to establish their capability and capacity to manage a hospital-based SClg program, where the hospital provides access to all resources and takes full accountability for the management and use of the product within defined governing requirements. Further work will be undertaken to support supply of SClg for other pathways of care.

The medical conditions that SClg can be used for are:

- primary immunodeficiency diseases with antibody deficiency
- specific antibody deficiency
- acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
- secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)

These products are authorised and distributed by the Blood Service in the same manner as IVIg.

Tables 17-19 show the patient numbers, grams issued and treatment episodes, by state and territory for IVIg and SClg products in 2017-18. Tables 20-22 show patient numbers, grams issued and treatment episodes by medical conditions for IVIg and SClg products in 2017-18.

Table 17 Patient numbers for products issued by state and territory in 2017-18

State	IVIg					SCIg		Total
	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Privigen 10 percent	SCIg Evogam	SCIg Hizentra	
NSW	395	768	444	2,005	1,997	80	186	7,230
VIC	111	690	17	2,615	1,197	72	110	4,447
QLD	344	546	<5	2,773	1,325	59	111	4,833
SA	14	180	<5	710	220	33	53	1,114
WA	31	175	5	705	232	17	38	1,126
TAS	8	59	<5	215	116	<5	11	392
NT	<5	<5	<5	57	55	<5	0	112
ACT	5	17	0	240	98	<5	25	357
AUS	902	2,424	475	9,212	5,199	262	525	19,414

Note: The national patient count only includes one count for each patient. This may result in the sum of the state and territory totals being greater than the national total. In addition, each patient may have received multiple products, meaning the total number of patients for each state/territory may not match the total of the patient counts for each product.

Table 18 Grams of product issued by state and territory in 2017-18

State	IVIg					SCIg		Total
	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Privigen 10 percent	SCIg Evogam	SCIg Hizentra	
NSW	140,629	242,415	19,245	1,063,803	657,860	26,133	51,878	2,201,962
VIC	34,283	169,325	711	703,848	377,390	9,988	21,389	1,316,934
QLD	93,191	145,630	-15	852,278	457,985	16,502	28,883	1,594,453
SA	2,290	45,705	120	165,603	68,470	5,683	16,456	304,327
SA	9,346	55,265	42	191,388	122,785	4,774	5,559	389,159
TAS	2,655	17,205	39	65,160	38,100	278	3,714	127,151
NT	158	665	39	10,585	18,715	410	0	30,572
ACT	860	3,955	0	58,618	41,410	269	6,066	111,178
AUS	283,411	680,165	20,181	3,111,282	1,782,715	64,036	133,945	6,075,733

Table 19 Treatment episode numbers for products issued by state and territory in 2017-18

State	IVIg					SCIg		Total
	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Privigen 10 percent	SCIg Evogam	SCIg Hizentra	
NSW	3,909	5,880	823	33,480	15,987	3,673	6,462	70,221
VIC	1,069	4,272	33	24,536	9,784	776	1,547	41,968
QLD	3,284	4,719	4	32,314	14,597	488	972	56,349
SA	73	1,184	6	5,813	1,706	366	1,123	10,265
SA	355	1,541	10	6,860	2,990	218	459	12,420
TAS	99	395	5	2,187	1,033	15	128	3,862
NT	5	30	6	301	386	4	0	732
ACT	28	112	0	2,107	993	24	368	3,632
AUS	8,822	18,133	887	107,598	47,476	5,564	11,059	199,449

Table 20 Patient numbers for products issued by medical condition in 2017-18

Medical Condition	IVIg					SCIg		Total
	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Privigen 10 percent	SCIg Evogam	SCIg Hizentra	
Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	49	78	203	5,239	426	38	149	5,766
Primary immunodeficiency diseases (PID) with antibody deficiency	39	29	154	1,731	75	180	297	2,174
Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	36	61	19	742	130	20	35	953
Specific antibody deficiency (SAD)	9	<5	19	309	14	25	46	374

Note: Each patient may have received multiple products per diagnosis, so the total number of patients for each medical condition may not match the total of the patient counts for each product.

Table 21 Grams of product issued by medical condition in 2017-18

Medical Condition	IVIg					SCIg		Total
	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Privigen 10 percent	SCIg Evogam	SCIg Hizentra	
Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	12,038	12,025	6,993	1,234,926	93,800	5,345	36,664	1,401,790
Primary immunodeficiency diseases (PID) with antibody deficiency	10,978	7,145	7,620	547,801	22,985	48,775	80,023	725,325
Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	8,231	7,470	708	168,118	25,085	4,617	7,908	222,136
Specific antibody deficiency (SAD)	1,177	635	585	83,401	2,565	5,299	9,350	103,011

Table 22 Treatment episodes for product issued by medical condition in 2017-18

Medical Condition	IVIg					SCIg		Total
	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Privigen 10 percent	SCIg Evogam	SCIg Hizentra	
Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	432	448	303	46,408	3,703	294	2,936	54,483
Primary immunodeficiency diseases (PID) with antibody deficiency	416	281	392	20,163	780	4,450	6,630	33,106
Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	400	329	32	6,902	1,022	248	562	9,487
Specific antibody deficiency (SAD)	53	28	23	3,484	123	572	929	5,207

NHIg

In 2013–14, as a result of the introduction of SClg as discussed above, demand for NHIg reduced significantly by 18.8 %. CSL Behring (Australia) Pty Ltd produces NHIg from hyperimmune plasma specially collected by the Blood Service. The volume of product is limited by the availability of this specialised plasma, and by production scheduling arrangements in CSL Behring (Australia) Pty Ltd’s manufacturing facility.

Demand for NHIg further declined in 2014-15 by 78% as a result of implementation of the NHIg policy outlining the national position on access and use under the national blood arrangements.

NHIg may only be supplied for two purposes; for the treatment of susceptible contacts of measles, hepatitis A, poliomyelitis and rubella, as directed by public health officials; and for the treatment of immunodeficiency conditions for which the product is indicated for patients for whom IVIg and SClg are both contraindicated. NHIg access rules are detailed on the NBA website at <https://www.blood.gov.au/NHIg>.

Tables 23-25 and Figure 14 show the grams issued and the grams issued per 1,000 population by states and territories for either purpose listed above.

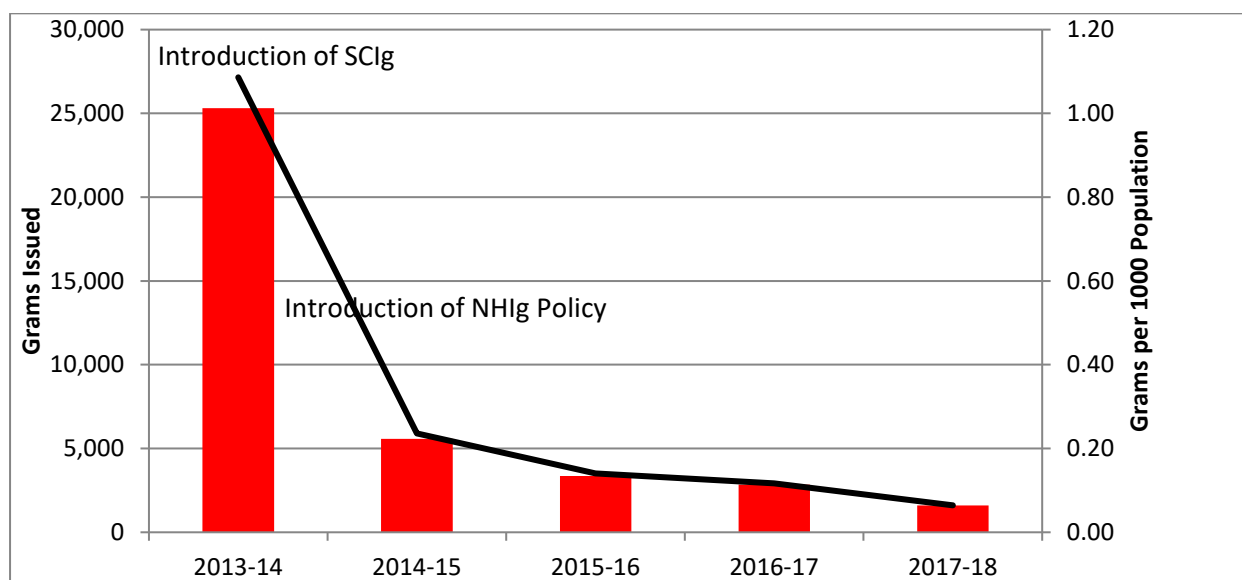


Figure 14 NHIg grams issued and grams issued per 1,000 population

Table 23 NHIg issued from 2013-14 to 2017-18

Product	2013-14	2014-15	2015-16	2016-17	2017-18
Normal Immunoglobulin 2VI - 2ml (grams)	654	167	112	43	110
Normal Immunoglobulin 2VI - 5ml (grams)	24,649	5,409	3,254	2,806	1,484
Total (grams)	25,303	5,576	3,366	2,849	1,594
Grams Per 1,000 Population	1.09	0.24	0.14	0.12	0.06

Table 24 Grams of NHlg issued by state and territory

	2013-14	2014-15	2015-16	2016-17	2017-18
NSW	6,915	82	238	351	345
VIC	6,747	2,278	489	411	465
QLD	2,774	1,472	1,134	401	171
SA	4,431	936	980	1,164	94
WA	3,458	59	38	48	39
TAS	272	154	43	35	39
NT	191	35	12	15	4
ACT	514	480	432	424	437
OTHER ⁷	0	80	0	0	0
Australia	25,302	5,576	3,366	2,849	1,594

Table 25 Grams per 1,000 population of NHlg issued by state and territory

Per 1,000 Population	2013-14	2014-15	2015-16	2016-17	2017-18
NSW	0.93	0.01	0.03	0.05	0.04
VIC	1.16	0.38	0.08	0.07	0.07
QLD	0.59	0.31	0.24	0.08	0.03
SA	2.64	0.55	0.57	0.68	0.05
WA	1.38	0.02	0.01	0.02	0.02
TAS	0.53	0.30	0.08	0.07	0.07
NT	0.79	0.14	0.05	0.06	0.02
ACT	1.33	1.22	1.08	1.04	1.05
Australia					

⁷ Other here covers NHlg sent to the New Zealand Blood Service.

Appendix A – Background

SECURING SUPPLY OF IMMUNOGLOBULIN

Immunoglobulin (Ig) is made from donated human plasma. The supply of Australian donated human plasma is sourced from the Australian Red Cross Blood Service (Blood Service) and sent to CSL Behring Ltd to manufacture domestic Ig. The NBA has contractual arrangements with both the Blood Service and CSL Behring Ltd for these services. In accordance with government policy, the NBA also maintains contractual arrangements with international suppliers to ensure sufficient supply to meet Australian clinical demand within the context of a finite international supply.

The following table shows the domestic and imported products supplied under NBA arrangements (including IgG concentration and method of administration) by financial year.

Year	Domestic products supplied	Supplier
2003-04 to 2012-13	Intragam P (6% intravenous) Normal Human Immunoglobulin (intramuscular ¹)	CSL Behring
2013-14 to 2017-18	Intragam P (6% intravenous) Evogam (16.5% subcutaneous) Normal Human Immunoglobulin (intramuscular ¹)	CSL Behring
From 2017-18	Intragam 10 (10% intravenous) Evogam (16.5% subcutaneous) Normal Human Immunoglobulin (intramuscular ¹)	CSL Behring

Year	Imported products supplied	Supplier
2004-05 to 2009-10	Sandoglobulin (intravenous) Octagam (5% intravenous)	CSL Behring Octapharma
2010-11	Sandoglobulin (intravenous) Octagam (5% intravenous) Flebogamma (5% intravenous)	CSL Behring Octapharma Lateral Grifols
2011-12 to 2012-13	Octagam (5% intravenous) Flebogamma (5% intravenous) Kiovig (10% intravenous ²)	Octapharma Grifols Baxter Healthcare

Year	Imported products supplied	Supplier
2013-14 to 2014-15	Octagam (5% intravenous) Gammanorm (16% subcutaneous) Flebogamma (5% intravenous) Kiovig (10% intravenous ²)	Octapharma Grifols Baxter Healthcare
2015-16	Octagam (5% intravenous) Gammanorm (16% subcutaneous) Kiovig (10% intravenous ²) Flebogamma (5% and 10% intravenous) Privigen (10% intravenous) Hizentra (20% SCIg)	Octapharma Baxter Healthcare Grifols CSL Behring
2016-17 to 2017-18	Flebogamma (5% and 10% intravenous) Privigen (10% intravenous) Hizentra (20% subcutaneous)	Grifols CSL Behring
Notes		
<ol style="list-style-type: none"> 1. The TGA approved Product Information for normal human immunoglobulin provides for intramuscular infusion, but the product is also infused by subcutaneous infusion in some cases. 2. The TGA approved Product Information for these IVIg products provides for subcutaneous infusion as well as intravenous infusion, but the products were supplied under NBA arrangements for intravenous purposes only. 		

In addition to contracting for supply of domestic and imported Ig products, the NBA undertakes annual national supply planning in conjunction with all Australian governments, and continuously monitors demand against approved supply plans. The NBA also undertakes national supply risk assessments and applies staged supply risk management actions as necessary, including under the National Blood Supply Contingency Plan agreed by all Australian governments.

CRITERIA TO ACCESS TO IG UNDER THE NATIONAL BLOOD ARRANGEMENTS

The *Criteria for the Clinical Use of Immunoglobulin in Australia* (the Criteria) was approved by Health Ministers in December 2007 together with a funding policy statement which limited access to Ig funded under the national blood arrangements only to patients who meet the criteria published in the Criteria. Under the national blood arrangements, Ig is funded 63% by the Commonwealth government, with the remaining 37% being funded by the state and territory to which the product is supplied. Patients can access the Ig outside of the Criteria but this is not funded under the national blood arrangements. Further information on how to access Ig can be found here www.blood.gov.au/Intravenous-Ig.

Access to Ig under the Criteria is based on the following principles:

- Ig products should be directed to patients who are most likely to benefit and for whom there are no safe and effective alternative treatments,
- the Criteria should be based on best available evidence, and
- access to Ig should be at the lowest effective dose.

The Criteria for the Clinical Use of Ig in Australia was updated in 2012 and 2016. The first two editions were published in hard copy with Version 2 being adapted for electronic publication in BloodSTAR. The Criteria to determine patient eligibility can be found here <https://www.criteria.blood.gov.au/>.

BLOODSTAR

Since 2016, all authorisation requests for patient-specific access to Ig under the Criteria must be submitted through BloodSTAR.

BloodSTAR standardises and manages access to the supply of immunoglobulin products by enabling authorisation requests to be submitted electronically and work-flowed to an authoriser for assessment and approval. BloodSTAR enables collection of improved national data and enhance the ability to further develop the *Criteria* and provide an improved evidence base for practice improvement and research.

Further information on BloodSTAR is available at <https://www.blood.gov.au/bloodstar> .

THE IG GOVERNANCE PROGRAM

In 2012, on behalf of all Australian Governments, the NBA commissioned a review of the adequacy of the existing intravenous Ig (IVIg) authorisation and clinical governance arrangements, with a view to recommending options for improvements to deliver Governments' goals for the management of IVIg in particular.

The National Ig Governance Program was introduced in 2014 to achieve Governments' objectives for Ig products funded and supplied under the national blood arrangements, namely to:

- ensure Ig product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of Government funds, in accordance with relevant national safety and quality standards for health care;
- ensure that access to Ig products is consistent with the criteria for access determined by Governments; and
- improve the capture of information of the need for, use of, and outcomes of treatment with Ig products to inform future decisions.

An integrated network of National Immunoglobulin Governance Committees has been established, including the National Immunoglobulin Governance Advisory Committee and specialist working groups. The advice and recommendations of this committee network fundamentally informs the development, implementation and ongoing operation of the other governance program measures.

The NBA published the *Ig Governance National Policy* in November 2014 with the second edition released in July 2016 to coincide with the launch of BloodSTAR. The document describes the authorisation arrangements for access to government-funded immunoglobulin products. This includes an explanation of roles, responsibilities, authority and accountability of those involved in requesting authorisation, authorising, supplying, managing and using immunoglobulin products throughout the supply chain within health services.

The Guidelines for Managing Blood and Blood Product Inventory provide better practice processes that can be used by health providers to ensure risks associated with receipt, storage, collection and transport of blood and blood products are mitigated. It also identifies improvement opportunities for implementation. In 2016-17, the NBA developed Module 2 to supplement the overarching inventory management principles and support the implementation of BloodSTAR. The module aims to assist health providers in meeting the requirements of the National Policy by:

- describing how to establish and manage stock levels
- outlining the Ig product ordering models
- identifying different methods to determine ordering requirements/triggers
- providing recommendations for good practice.

For further information on the Ig Governance Program go to the NBA website at <https://www.blood.gov.au/ig-program>.

Appendix B – Acronyms and Glossary

ACRONYMS

ACT	Australian Capital Territory
AHMAC	Australian Health Ministers' Advisory Council
AHP	Australian Health Provider
ANCA	Anti-neutrophil cytoplasmic antibody
AUS	Australia
BloodNet	The national online ordering and inventory management system
BloodSTAR	Blood System for Tracking Authorisations and Reviews
DO	Direct Order
HIV	Human immunodeficiency virus
H SCT	Hematopoietic stem cell transplantation
IDMS	Integrated Data Management System
Ig	Immunoglobulin products including IVIg and SCIg
ITP	Idiopathic thrombocytopenic purpura
IVIg	Intravenous immunoglobulin
JBC	Jurisdictional Blood Committee
JDO	Jurisdictional Direct Order
NBA	National Blood Authority
NHIg	Normal human immunoglobulin
NIGAC	National Immunoglobulin Governance Advisory Committee
NSW	New South Wales
NT	Northern Territory
PANDAS	Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections
QLD	Queensland
SA	South Australia
SCIg	Subcutaneous Immunoglobulin
STARS	Supply Tracking Analysis Recording System
TAS	Tasmania
TGA	Therapeutic Goods Administration
TSS	Toxic shock syndrome
VIC	Victoria
WA	Western Australia

GLOSSARY OF TERMS

Term	Description
Blood products	Products manufactured from human blood
Blood Service	The Australian Red Cross Blood Service
Condition	<p>Clinical conditions are categorised according to the quality of the available evidence and whether immunoglobulin treatment is considered beneficial.</p> <p>Specific conditions (previously known as primary diagnosis) within a medical condition (previous known as disease category). In some instances the medical condition may be the same as the specific condition, for example – Myasthenia gravis is the specific condition and the medical condition</p>
<i>Criteria for the clinical use of immunoglobulin in Australia (the Criteria)</i>	A document describing the conditions, indications and patient qualifying and review criteria for which Ig is funded under national blood arrangements by all Australian governments
Direct Orders (DO)	Previously known as Jurisdictional Direct Orders (JDO). Arrangements implemented by the NBA with suppliers to facilitate the purchase of Ig for the treatment of conditions not satisfying the <i>Criteria for the clinical use of Ig in Australia</i>
Fractionation	A manufacturing process that separates blood plasma into specific protein fractions
Imprest stock	Health provider orders of product for stock that is maintained at a certain level
Intravenous immunoglobulin	An immunoglobulin product derived from donated human plasma that is administered intravenously
Jurisdiction	Any of the parties to the Australian National Blood Agreement, being the Australian Government and all state and territory governments
Minimum Product Inventory	The minimum inventory of Ig held by CSL Behring to meet contract obligations
National Blood Agreement	The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the Australian blood sector
National blood arrangements	Arrangements, including funding arrangements, established under the National Blood Agreement

Term	Description
National CSL Reserve	The reserve of inventory of Ig that CSL Behring manages on behalf of the NBA for contingency purposes
Normal immunoglobulin	An immunoglobulin product derived from human plasma that is administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection)
Plasma	The liquid part of the blood containing antibodies and other proteins
Speciality	Classification of the conditions according to the clinical speciality, previously discipline
Subcutaneous immunoglobulin	An immunoglobulin product derived from donated human plasma that is administered subcutaneously
Treatment episode	One instance or episode of a treatment plan, for example a treatment plan may be made up of 4 episodes over 4 months with an episode occurring every 4 weeks (4 treatment episodes) OR 1 dose of transfused product every two weeks for 6 months would be 13 treatment episodes

Appendix C – Conditions mapping table

Specific Condition	Medical Condition	Chapter	Speciality
Chronic lymphocytic leukaemia	Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	5	Haematology
Multiple myeloma	Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	5	Haematology
Non-Hodgkin lymphoma	Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	5	Haematology
Other relevant haematological malignancies	Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	5	Haematology
Post-haemopoietic stem cell transplantation	Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	5	Haematology
Chronic inflammatory demyelinating polyneuropathy	Chronic inflammatory demyelinating polyneuropathy (CIDP)	5	Neurology
Guillain–Barré syndrome	Guillain–Barré syndrome (GBS)	5	Neurology
ITP associated with HIV	Immune thrombocytopenic purpura (ITP) — adult	5	Haematology
ITP in pregnancy	Immune thrombocytopenic purpura (ITP) — adult	5	Haematology
ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP, concurrent risk factors)	Immune thrombocytopenic purpura (ITP) — adult	5	Haematology
ITP refractory acute	Immune thrombocytopenic purpura (ITP) — adult	5	Haematology
ITP with life-threatening haemorrhage or potential life-threatening haemorrhage	Immune thrombocytopenic purpura (ITP) — adult	5	Haematology
Dermatomyositis	Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM)	5	Neurology
Inclusion body myositis	Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM)	5	Neurology
Polymyositis	Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM)	5	Neurology

Specific Condition	Medical Condition	Chapter	Speciality
Kawasaki disease	Kawasaki disease	5	Immunology
Lambert–Eaton myasthenic syndrome	Lambert–Eaton myasthenic syndrome (LEMS)	5	Neurology
Multifocal motor neuropathy with or without persistent conduction block	Multifocal motor neuropathy (MMN)	5	Neurology
Myasthenia gravis	Myasthenia gravis (MG)	5	Neurology
Neonatal haemochromatosis	Neonatal haemochromatosis (NH)	5	Haematology
Common variable immunodeficiency disease (CVID)	Primary immunodeficiency diseases (PID) with antibody deficiency	5	Immunology
Other primary immunodeficiency	Primary immunodeficiency diseases (PID) with antibody deficiency	5	Immunology
Severe combined immunodeficiency (SCID)	Primary immunodeficiency diseases (PID) with antibody deficiency	5	Immunology
Transient hypogammaglobulinaemia of infancy	Primary immunodeficiency diseases (PID) with antibody deficiency	5	Immunology
Wiskott–Aldrich syndrome	Primary immunodeficiency diseases (PID) with antibody deficiency	5	Immunology
X-linked agammaglobulinaemia	Primary immunodeficiency diseases (PID) with antibody deficiency	5	Immunology
Stiff person syndrome	Stiff person syndrome	5	Neurology
Acute disseminated encephalomyelitis	Acute disseminated encephalomyelitis (ADEM)	6	Neurology
Churg–Strauss syndrome	ANCA-positive systemic necrotising vasculitis	6	Immunology
Microscopic polyangiitis	ANCA-positive systemic necrotising vasculitis	6	Immunology
PR3 or MPO ANCA-positive idiopathic rapidly progressive glomerulonephritis	ANCA-positive systemic necrotising vasculitis	6	Immunology
Wegener granulomatosis	ANCA-positive systemic necrotising vasculitis	6	Immunology
Autoimmune haemolytic anaemia	Autoimmune haemolytic anaemia (AIHA)	6	Haematology
Bullous pemphigoid	Bullous pemphigoid (BP)	6	Dermatology
Cicatricial pemphigoid/ mucous membrane pemphigoid	Cicatricial pemphigoid (CP) or Mucous Membrane Pemphigoid (MMP)	6	Dermatology
Evans syndrome	Evans syndrome	6	Haematology

Specific Condition	Medical Condition	Chapter	Speciality
Feto-maternal/neonatal alloimmune thrombocytopenia (Antenatal)	Feto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT)	6	Haematology
Feto-maternal/neonatal alloimmune thrombocytopenia (Neonatal)	Feto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT)	6	Haematology
Haemophagocytic syndrome	Haemophagocytic syndrome	6	Haematology
IgM para-proteinaemic neuropathy	IgM paraproteinaemic demyelinating neuropathy	6	Neurology
ITP in children	Immune thrombocytopenic purpura (ITP) — in children 15 years and younger	6	Haematology
Kidney transplantation post-transplant	Kidney transplantation	6	Nephrology
Kidney transplantation pre-transplant	Kidney transplantation	6	Nephrology
Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	Multiple sclerosis (MS)	6	Neurology
Multiple sclerosis in pregnancy and the immediate post-partum period	Multiple sclerosis (MS)	6	Neurology
Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed	Multiple sclerosis (MS)	6	Neurology
Opsoclonus myoclonus ataxia	Opsoclonus-myoclonus ataxia (OMA)	6	Neurology
Pemphigus foliaceus	Pemphigus foliaceus (PF)	6	Dermatology
Pemphigus vulgaris	Pemphigus vulgaris (PV)	6	Dermatology
Post-transfusion purpura	Post-transfusion purpura (PTP)	6	Haematology
Secondary hypogammaglobulinaemia (excluding haematological malignancies)	Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	6	Immunology
Solid organ - heart	Solid organ transplantation (other than kidney)	6	Transplant Medicine
Solid organ - heart/lung	Solid organ transplantation (other than kidney)	6	Transplant Medicine
Solid organ - liver	Solid organ transplantation (other than kidney)	6	Transplant

Specific Condition	Medical Condition	Chapter	Speciality
			Medicine
Solid organ - lung	Solid organ transplantation (other than kidney)	6	Transplant Medicine
Solid organ - other	Solid organ transplantation (other than kidney)	6	Transplant Medicine
IgG subclass deficiency (existing authorisation)	Specific antibody deficiency (SAD)	6	Immunology
Specific antibody deficiency	Specific antibody deficiency (SAD)	6	Immunology
Toxic epidermal necrolysis/Stevens–Johnson syndrome	Toxic epidermal necrolysis (TEN)/ Stevens–Johnson syndrome (SJS)	6	Dermatology
Staphylococcal TSS	Toxic shock syndrome (TSS)	6	Immunology
Streptococcal TSS	Toxic shock syndrome (TSS)	6	Immunology
Acute leukaemia in children	Acute leukaemia in children	7	Haematology
Autoimmune congenital heart block	Autoimmune congenital heart block (neonatal lupus)	7	Immunology
Autoimmune neutropenia	Autoimmune neutropenia	7	Immunology
Autoimmune uveitis	Autoimmune uveitis	7	Immunology
Catastrophic antiphospholipid syndrome	Catastrophic antiphospholipid syndrome	7	Immunology
Acquired haemophilia	Coagulation factor inhibitors	7	Haematology
Acquired von Willebrand syndrome	Coagulation factor inhibitors	7	Haematology
Coagulation factor inhibitors	Coagulation factor inhibitors	7	Haematology
Inhibitors to factor IX in haemophilia B	Coagulation factor inhibitors	7	Haematology
Inhibitors to factor VIII in haemophilia A	Coagulation factor inhibitors	7	Haematology
Devic disease (neuromyelitis optica)	Devic disease (neuromyelitis optica)	7	Neurology
Diabetic amyotrophy	Diabetic amyotrophy	7	Neurology
Diabetic lumbosacral radiculoplexus neuropathy	Diabetic amyotrophy	7	Neurology
Epidermolysis bullosa acquisita	Epidermolysis bullosa acquisita	7	Dermatology

Specific Condition	Medical Condition	Chapter	Speciality
Epilepsy (rare childhood cases)	Epilepsy	7	Neurology
Graves ophthalmopathy	Graves ophthalmopathy	7	Neurology
Haemolytic disease of the newborn	Haemolytic disease of the newborn (HDN)	7	Haematology
Haemolytic transfusion reaction	Haemolytic transfusion reaction	7	Haematology
Hashimoto encephalopathy	Hashimoto encephalopathy	7	Neurology
HIV in children	HIV in children	7	Immunology
Limbic encephalitis, nonparaneoplastic	Limbic encephalitis — nonparaneoplastic	7	Neurology
Myocarditis in children	Myocarditis in children	7	Immunology
PANDAS/tic disorders	Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infection (PANDAS)	7	Neurology
Cerebellar degeneration	Paraneoplastic neurological syndromes	7	Neurology
Limbic encephalitis	Paraneoplastic neurological syndromes	7	Neurology
Subacute sensory neuropathy	Paraneoplastic neurological syndromes	7	Neurology
Potassium channel antibody-associated encephalopathy	Potassium channel antibody-associated encephalopathy	7	Neurology
Pure red cell aplasia	Pure red cell aplasia (PRCA)	7	Haematology
Pure white cell aplasia	Pure white cell aplasia (PWCA)	7	Haematology
Pyoderma gangrenosum	Pyoderma gangrenosum	7	Dermatology
Rasmussen syndrome	Rasmussen syndrome	7	Neurology
Scleromyxedema	Scleromyxedema	7	Neurology
Sjögren's syndrome	Sjögren's syndrome	7	Immunology
Susac syndrome	Susac syndrome	7	Immunology
Systemic capillary leak syndrome	Systemic capillary leak syndrome (SCLS)	7	Haematology
Acute optic neuritis	Acute optic neuritis	8	Immunology
Acute rheumatic fever	Acute rheumatic fever	8	Immunology
Adrenoleukodystrophy	Adrenoleukodystrophy	8	Neurology
Amegakaryocytic thrombocytopenia	Amegakaryocytic thrombocytopenia	8	Haematology

Specific Condition	Medical Condition	Chapter	Speciality
Antiphospholipid syndrome (non-obstetric)	Antiphospholipid syndrome (non-obstetric)	8	Haematology
Aplastic anaemia/pancytopenia	Aplastic anaemia/pancytopenia	8	Haematology
Asthma	Asthma	8	Immunology
Atopic dermatitis/eczema — adult	Atopic dermatitis/eczema — adult	8	Dermatology
Autism	Autism	8	Neurology
Autologous haemopoietic stem cell transplantation	Autologous haemopoietic stem cell transplantation	8	Haematology
Behçet’s disease	Behçet’s disease	8	Dermatology
Cardiac surgery with bypass — prophylaxis	Cardiac surgery with bypass — prophylaxis	8	Immunology
Congestive cardiac failure	Congestive cardiac failure	8	Dermatology
Crohn’s disease	Crohn’s disease	8	Immunology
Diamond Blackfan syndrome	Diamond Blackfan syndrome	8	Haematology
Female infertility	Female infertility	8	Immunology
Glomerulonephritis — IgA nephritis	Glomerulonephritis — IgA nephritis	8	Nephrology
Haemolytic uraemic syndrome	Haemolytic uraemic syndrome	8	Haematology
Henoch–Schönlein purpura	Henoch–Schönlein purpura	8	Nephrology
HIV/AIDS — adult	HIV/AIDS — adult	8	Immunology
Idiopathic dilated cardiomyopathy	Idiopathic dilated cardiomyopathy	8	Immunology
Linear IgA disease	Linear IgA disease	8	Dermatology
Lupus cerebritis	Lupus cerebritis	8	Neurology
Lupus nephritis	Lupus nephritis	8	Nephrology
Motor neuron disease/amyotrophic lateral sclerosis	Motor neuron disease/amyotrophic lateral sclerosis	8	Neurology
Myalgic encephalomyelitis	Myalgic encephalomyelitis	8	Neurology
Narcolepsy/cataplexy	Narcolepsy/cataplexy	8	Neurology
Nephrotic syndrome	Nephrotic syndrome	8	Immunology
Obsessive compulsive disorders	Obsessive compulsive disorders	8	Immunology

Specific Condition	Medical Condition	Chapter	Speciality
Polyneuropathy of critical illness	Polyneuropathy of critical illness	8	Neurology
Recurrent fetal loss (with or without antiphospholipid syndrome)	Recurrent fetal loss (with or without antiphospholipid syndrome)	8	Immunology
Rheumatoid arthritis	Rheumatoid arthritis	8	Immunology
Sepsis	Sepsis	8	Immunology
Sickle cell disease	Sickle cell disease	8	Haematology
Systemic lupus erythematosus (SLE)	Systemic lupus erythematosus (SLE)	8	Immunology
Ulcerative colitis	Ulcerative colitis	8	Immunology

Appendix D – Dataset of Ig supply by state/territory 2017-18

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
Chronic inflammatory demyelinating polyneuropathy	Patients	999	568	719	100	150	50	10	47	2,595
	Average Age	65	63	63	65	62	61	60	64	64
	Average Weight	82	82	83	85	85	84	86	83	82
	Grams	472,417	278,432	333,706	43,235	115,967	26,067	5,005	15,785	1,290,612
	Grams/Episode	42	39	31	36	42	37	61	34	38
	Grams per 1,000 Population	61	45	68	25	45	50	20	39	53
Chronic lymphocytic leukaemia	Patients	620	372	400	94	93	39	9	26	1,632
	Average Age	72	74	72	71	72	71	66	75	72
	Average Weight	78	77	77	80	76	80	72	79	77
	Grams	168,090	90,683	114,315	22,642	20,151	9,148	2,829	7,366	435,223
	Grams/Episode	29	26	25	26	24	27	25	25	27
	Grams per 1,000 Population	22	15	23	13	8	18	11	18	18
Common variable immunodeficiency disease (CVID)	Patients	920	320	350	111	100	28	5	69	1,876
	Average Age	53	47	53	51	46	52	42	45	51
	Average Weight	72	72	75	72	101	73	80	74	74
	Grams	311,301	107,889	124,542	30,942	32,192	8,463	1,810	21,440	638,578
	Grams/Episode	20	24	27	22	23	27	50	23	22
	Grams per 1,000 Population	40	17	26	18	13	16	7	53	26
Dermatomyositis	Patients	103	53	50	13	21	<5		11	250
	Average Age	51	44	48	61	41	52		46	48
	Average Weight	67	68	71	80	103	130		66	72
	Grams	33,279	18,838	23,366	5,165	8,850	1,250		5,663	96,410
	Grams/Episode	35	41	32	34	29	74		35	35

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
	Grams per 1,000 Population	4	3	5	3	3	2	14	4	
Guillain–Barré syndrome	Patients	239	194	159	52	67	18	9	16	754
	Average Age	53	51	52	50	51	59	39	59	52
	Average Weight	78	74	77	78	77	82	66	80	77
	Grams	42,690	29,163	25,711	7,955	9,298	3,245	1,363	2,715	122,139
	Grams/Episode	35	39	33	33	26	39	43	55	35
	Grams per 1,000 Population	5	5	5	5	4	6	6	7	5
Inclusion body myositis	Patients	63	47	41	15	<5	<5	<5	<5	170
	Average Age	71	71	68	71	71	81	68	68	70
	Average Weight	80	84	85	79	67	68	82	82	82
	Grams	21,076	25,864	19,615	5,758	338	890	810	810	74,349
	Grams/Episode	35	38	35	29	26	47	30	30	35
	Grams per 1,000 Population	3	4	4	3	0	2	2	2	3
ITP associated with HIV	Patients		<5	<5	<5					<5
	Average Age		64	65	46					61
	Average Weight		70	76	70					71
	Grams		135	225	140					500
	Grams/Episode		27	75	70					50
	Grams per 1,000 Population		0	0	0					0
ITP in pregnancy	Patients	35	11	11	<5	9	<5	<5	<5	73
	Average Age	31	33	28	29	32	31	33	33	31
	Average Weight	77	72	73	69	74	134	89	89	76
	Grams	6,298	1,185	1,375	340	765	90	410	410	10,463
	Grams/Episode	57	42	35	57	51	45	68	68	51
	Grams per 1,000	1	0	0	0	0	0	1	1	0
ITP in specific circumstances (surgery, other therapy)	Patients	128	86	116	41	24	5	<5	<5	407
	Average Age	65	60	61	66	62	49	41	77	62

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
contraindicated, chronic ITP, concurrent risk factors)	Average Weight	78	80	77	76	84	75	89	80	79
	Grams	21,908	10,758	23,165	4,875	3,355	538	340	345	65,283
	Grams/Episode	50	49	41	52	35	90	34	86	46
	Grams per 1,000 Population	3	2	5	3	1	1	1	1	3
ITP refractory acute	Patients	136	123	110	39	34	9	<5	<5	456
	Average Age	61	57	59	55	59	53	38	77	58
	Average Weight	78	78	79	81	78	85	88	68	79
	Grams	23,308	16,102	18,728	5,808	3,835	2,070	360	270	70,479
	Grams/Episode	51	52	39	44	50	83	60	90	47
	Grams per 1,000 Population	3	3	4	3	1	4	1	1	3
ITP with life-threatening haemorrhage or potential life-threatening haemorrhage	Patients	171	111	111	56	19	6	7	9	490
	Average Age	59	64	57	62	49	61	47	61	60
	Average Weight	77	77	76	82	80	95	66	77	77
	Grams	29,962	14,325	14,330	8,083	2,000	600	1,080	1,078	71,457
	Grams/Episode	54	49	36	55	54	67	60	57	49
	Grams per 1,000 Population	4	2	3	5	1	1	4	3	3
Kawasaki disease	Patients	172	96	52	19	44	7	7	5	402
	Average Age	4	4	4	2	3	7	2	3	4
	Average Weight	18	17	19	13	16	26	14	14	18
	Grams	7,633	4,103	2,073	495	1,530	388	218	135	16,573
	Grams/Episode	33	30	21	20	19	39	22	19	28
	Grams per 1,000 Population	1	1	0	0	1	1	1	0	1
Lambert–Eaton myasthenic syndrome	Patients	6	8	8		<5			<5	24
	Average Age	62	55	59		76			73	59
	Average Weight	80	70	75		65			60	73
	Grams	2,843	3,997	3,848		625			600	11,912
	Grams/Episode	38	38	34		37			60	37

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National		
	Grams per 1,000 Population	0	1	1		0		1	0		
Multifocal motor neuropathy with or without persistent conduction block	Patients	214	99	131	53	42	13	7	12	560	
	Average Age	59	58	57	60	61	62	59	58	59	
	Average Weight	79	81	80	86	81	77	96	88	81	
	Grams	109,587	62,926	76,101	39,463	43,938	7,655	5,530	9,235	354,434	
	Grams/Episode	46	43	35	44	48	41	79	58	43	
	Grams per 1,000 Population	14	10	16	23	17	15	22	23	15	
		Patients	547	306	423	90	41	45	<5	13	1,458
Multiple myeloma	Average Age	71	71	70	68	67	66	64	70	70	
	Average Weight	77	79	77	81	80	82	94	79	78	
	Grams	127,518	68,099	114,433	21,533	7,422	11,268	800	2,935	354,006	
	Grams/Episode	30	26	24	23	24	28	31	24	27	
	Grams per 1,000 Population	16	11	23	13	3	22	3	7	15	
		Patients	366	328	352	38	66	12	<5	20	1,174
	Myasthenia gravis	Average Age	61	63	62	63	59	47	62	60	62
Average Weight		82	80	82	79	80	75	88	81	81	
Grams		156,017	141,890	157,030	11,420	31,732	4,965		10,965	514,017	
Grams/Episode		37	38	29	32	31	28	0	39	34	
Grams per 1,000 Population		20	23	32	7	12	10		27	21	
		Patients	<5	<5	<5		<5				9
Neonatal haemochromatosis		Average Age	0	24	0		0				11
	Average Weight	1	53	3		3				25	
	Grams	3	3,083	20		5				3,110	
	Grams/Episode	3	56	3		3				49	
	Grams per 1,000 Population	0	0	0		0				0	
		Patients	524	326	567	110	68	44	6	16	1,651
	Non-Hodgkin lymphoma	Average Age	69	68	68	69	68	66	58	62	68

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
	Average Weight	76	77	76	79	76	79	81	70	76
	Grams	128,298	81,259	159,571	22,721	13,184	12,749	1,490	3,546	422,817
	Grams/Episode	29	25	24	21	23	28	29	21	25
	Grams per 1,000 Population	16	13	33	13	5	25	6	9	17
Other primary immunodeficiency	Patients	44	47	17	11	11	<5	<5	7	141
	Average Age	44	44	25	37	48	31	49	28	41
	Average Weight	56	61	47	59	104	67	76	68	62
	Grams	12,037	12,442	2,876	2,684	2,121	926	675	1,284	35,044
	Grams/Episode	18	21	16	19	18	17	24	15	19
	Grams per 1,000 Population	2	2	1	2	1	2	3	3	1
Other relevant haematological malignancies	Patients	303	94	150	32	39	9	<5	5	625
	Average Age	56	46	61	59	38	67	70	74	55
	Average Weight	69	58	71	72	60	75	75	80	68
	Grams	51,309	14,714	36,343	5,142	5,545	2,678	880	1,003	117,613
	Grams/Episode	27	22	23	23	19	29	31	20	24
	Grams per 1,000 Population	7	2	7	3	2	5	4	2	5
Polymyositis	Patients	206	81	134	43	29	7	5	11	513
	Average Age	63	61	60	67	55	73	56	57	62
	Average Weight	78	83	81	77	80	85	79	80	80
	Grams	75,467	36,469	57,234	16,950	11,113	3,970	1,860	3,658	206,720
	Grams/Episode	36	39	35	39	29	41	45	39	36
	Grams per 1,000 Population	10	6	12	10	4	8	8	9	8
Post-haemopoietic stem cell transplantation	Patients	159	121	112	26	18	6		6	443
	Average Age	45	34	48	50	35	38		46	43
	Average Weight	66	58	68	82	62	62		68	65
	Grams	23,300	17,158	22,177	5,429	1,938	1,213		918	72,131
	Grams/Episode	26	20	21	14	23	24		20	21

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
	Grams per 1,000 Population	3	3	5	3	1	2	2	3	
Severe combined immunodeficiency (SCID)	Patients	9	14	14	<5	<5			41	
	Average Age	23	15	22	6	20			19	
	Average Weight	44	39	47	20	53			42	
	Grams	3,260	2,841	2,985	308	1,316			10,710	
	Grams/Episode	15	18	19	11	36			18	
	Grams per 1,000 Population	0	0	1	0	1			0	
		Patients	51	9	20	<5	<5	<5	<5	88
Stiff person syndrome	Average Age	58	55	59	61	66	37	40	57	
	Average Weight	80	72	79	71	86	70	65	78	
	Grams	26,219	3,450	11,208	390	1,920	2,450	630	46,267	
	Grams/Episode	46	47	35	30	30	45	26	41	
	Grams per 1,000 Population	3	1	2	0	1	5	2	2	
		Patients		<5	<5	<5				7
	Transient hypogammaglobulinaemia of infancy	Average Age		26	48	0				18
Average Weight			39	58	5				27	
Grams			93	135	10				238	
Grams/Episode			23	17	1				11	
Grams per 1,000 Population			0	0	0				0	
		Patients	<5				<5			<5
Wiskott–Aldrich syndrome	Average Age	0				35			21	
	Average Weight	5				65			41	
	Grams	24				745			769	
	Grams/Episode	3				27			21	
	Grams per 1,000 Population	0				0			0	
		Patients	36	47	17	6	6	<5	<5	116
X-linked agammaglobulinaemia	Average Age	30	34	25	22	19	24	9	29	

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
Average Weight	58	62	56	61	170		48	39	66
Grams	13,155	16,410	5,478	2,215	1,779		690	261	39,988
Grams/Episode	25	21	28	26	20		16	12	23
Grams per 1,000 Population	2	3	1	1	1		3	1	2
Chapter 5 Total									
Patients	5,950	3,374	3,990	930	872	306	84	282	15,623
Average Age	60	58	61	60	54	61	49	56	60
Average Weight	75	74	77	77	80	79	74	76	76
Grams	1,866,993	1,062,303	1,350,587	263,698	321,660	100,620	24,929	91,049	5,081,838
Grams/Episode	31	32	28	29	33	32	42	30	31
Grams per 1,000 Population	239	170	277	154	125	194	101	224	208
Chapter 6									
Acute disseminated encephalomyelitis									
Patients	28	10	23		<5	<5	<5	<5	69
Average Age	39	31	19		3	12	11	31	28
Average Weight	57	62	39		18	43	49	56	50
Grams	5,498	2,420	2,958		140	65	878	330	12,288
Grams/Episode	28	21	27		9	33	88	41	27
Grams per 1,000 Population	1	0	1		0	0	4	1	1
Autoimmune haemolytic anaemia									
Patients	33	32	22	8	<5	6		<5	106
Average Age	59	52	59	56	34	74		80	57
Average Weight	74	64	76	65	57	75		50	70
Grams	6,435	3,543	4,080	3,928	505	690		40	19,220
Grams/Episode	47	41	32	50	23	33		40	41
Grams per 1,000 Population	1	1	1	2	0	1		0	1
Bullous pemphigoid									
Patients	18	7	10	<5	<5	<5			40
Average Age	72	68	65	75	68	85			70
Average Weight	87	70	94	60	73	70			83

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Grams	12,173	2,805	11,660	170	518	420			27,745
	Grams/Episode	57	70	53	28	43	53			56
	Grams per 1,000 Population	2	0	2	0	0	1			1
Cicatrical pemphigoid/ mucous membrane pemphigoid	Patients	<5	5	12	<5	<5	<5		<5	28
	Average Age	68	64	66	58	58	60		49	63
	Average Weight	99	102	75	70	89	63		106	83
	Grams	3,150	5,550	6,233	1,400	2,010	2,510		1,590	22,443
	Grams/Episode	90	88	45	40	26	93		66	56
	Grams per 1,000 Population	0	1	1	1	1	5		4	1
Evans syndrome	Patients	<5	<5	<5	<5					11
	Average Age	35	62	40	60					48
	Average Weight	79	41	80	79					72
	Grams	1,175	145	355	1,205					2,880
	Grams/Episode	78	29	39	57					58
	Grams per 1,000 Population	0	0	0	1					0
Feto-maternal/neonatal alloimmune thrombocytopenia (Antenatal)	Patients	<5	<5	<5	<5	<5				16
	Average Age	30	35	32	30	28				31
	Average Weight	68	63	90	58	70				68
	Grams	3,413	1,383	1,670	1,373	1,910				9,748
	Grams/Episode	74	49	52	53	60				59
	Grams per 1,000 Population	0	0	0	1	1				0
Feto-maternal/neonatal alloimmune thrombocytopenia (Neonatal)	Patients	9	6	6	<5		<5		<5	26
	Average Age	3	6	0	15		0		0	4
	Average Weight	11	17	3	48		6		2	13
	Grams	506	1,465	23	1,535		10		10	3,548
	Grams/Episode	23	51	3	81		3		3	41
	Grams per 1,000 Population	0	0	0	1		0		0	0

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
Haemophagocytic syndrome	Patients	22	13	9	<5	<5			50
	Average Age	50	49	42	66	30			48
	Average Weight	69	76	51	74	67			68
	Grams	2,415	1,588	1,250	475	720			6,448
	Grams/Episode	53	69	28	40	72			47
	Grams per 1,000 Population	0	0	0	0	0			0
IgG subclass deficiency (existing authorisation)	Patients	10	20	<5	<5	<5	<5		41
	Average Age	69	67	71	66	72	61		68
	Average Weight	101	73	67	76	174	66		84
	Grams	3,850	6,813	393	1,038	1,213	1,108		14,413
	Grams/Episode	21	24	17	27	23	26		23
	Grams per 1,000 Population	0	1	0	1	0	2		1
IgM para-proteinaemic neuropathy	Patients	34	14	25	<5	<5	5	<5	87
	Average Age	72	74	68	66	74	71	75	71
	Average Weight	81	79	88	87	74	92	66	83
	Grams	13,834	5,040	12,555	970	3,108	2,373	210	38,089
	Grams/Episode	40	33	34	26	43	41	21	36
	Grams per 1,000 Population	2	1	3	1	1	5	1	2
ITP in children	Patients	40	62	39	13	<5	<5	<5	168
	Average Age	9	5	6	6	7	8	12	6
	Average Weight	38	22	26	39	24	31	50	29
	Grams	3,717	3,133	1,565	1,453	80	493	190	493
	Grams/Episode	34	18	24	25	16	26	48	38
	Grams per 1,000 Population	0	1	0	1	0	1	1	1
Kidney transplantation post-transplant	Patients	90	234	54	12	40	13	<5	7
	Average Age	45	50	51	44	44	50	45	52
	Average Weight	72	78	78	75	79	84	78	84

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Grams	16,955	73,045	15,553	2,255	6,400	4,925	348	1,345	120,825
	Grams/Episode	25	31	22	31	38	43	19	37	29
	Grams per 1,000 Population	2	12	3	1	2	9	1	3	5
Kidney transplantation pre-transplant	Patients	55	18	6	<5	<5				85
	Average Age	48	50	55	47	53				49
	Average Weight	73	79	71	75	76				75
	Grams	4,150	750	399	338	125				5,762
	Grams/Episode	38	8	25	28	25				25
	Grams per 1,000 Population	1	0	0	0	0				0
Microscopic polyangiitis	Patients		<5	<5		<5		<5		11
	Average Age		56	26		40		51		43
	Average Weight		95	66		69		64		77
	Grams		670	360		1,600		65		2,695
	Grams/Episode		61	40		34		33		39
	Grams per 1,000 Population		0	0		1		0		0
Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	Patients	5		<5		<5			<5	10
	Average Age	49		35		14			59	42
	Average Weight	72		65		66			100	75
	Grams	1,285		260		80			400	2,025
	Grams/Episode	31		19		16			133	32
	Grams per 1,000 Population	0		0		0			1	0
Multiple sclerosis in pregnancy and the immediate post-partum period	Patients	<5	<5							<5
	Average Age	36	33							34
	Average Weight	100	82							86
	Grams	320	965							1,285
	Grams/Episode	40	64							56
	Grams per 1,000	0	0							0

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed	Patients	22	<5	<5			<5		<5	32
	Average Age	40	37	59			41		43	42
	Average Weight	80	68	87			68		65	78
	Grams	5,873	855	1,375			83		450	8,635
	Grams/Episode	32	31	31			83		28	32
	Grams per 1,000 Population	1	0	0			0		1	0
Opsoclonus myoclonus ataxia	Patients	7	7	<5	<5	<5				24
	Average Age	26	17	18	51	3				22
	Average Weight	43	29	28	72	16				37
	Grams	1,369	883	510	1,290	203				4,254
	Grams/Episode	24	18	15	52	12				23
	Grams per 1,000 Population	0	0	0	1	0				0
Pemphigus foliaceus	Patients	<5	<5	<5						<5
	Average Age	57	52	55						55
	Average Weight	61	84	71						71
	Grams	120	168	1,080						1,368
	Grams/Episode	40	84	37						40
	Grams per 1,000 Population	0	0	0						0
Pemphigus vulgaris	Patients	12	8	<5	<5	<5			<5	31
	Average Age	55	55	54	65	61			67	57
	Average Weight	86	65	99	70	116			66	86
	Grams	11,424	3,040	5,860	280	2,220			1,933	24,756
	Grams/Episode	82	65	43	25	46			41	58
	Grams per 1,000 Population	1	0	1	0	1			5	1
Post-tranfution purpura	Patients	<5								<5
	Average Age	55								55
	Average Weight	83								83

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
	Grams	160							160	
	Grams/Episode	80							80	
	Grams per 1,000 Population	0							0	
PR3 or MPO ANCA-positive idiopathic rapidly progressive glomerulonephritis	Patients	9	<5	<5					15	
	Average Age	61	44	74					61	
	Average Weight	91	123	81					94	
	Grams	3,383	585	3,925					7,893	
	Grams/Episode	50	98	51					53	
	Grams per 1,000 Population	0	0	1					0	
Secondary hypogammaglobulinaemia (excluding haematological malignancies)	Patients	345	223	285	21	47	29	<5	13	953
	Average Age	56	54	60	43	50	56	73	66	56
	Average Weight	72	67	73	50	79	75	76	72	71
	Grams	81,693	48,325	72,413	3,217	8,082	6,401	170	1,837	222,136
	Grams/Episode	26	22	23	18	16	27	19	16	23
	Grams per 1,000 Population	10	8	15	2	3	12	1	5	9
Solid organ - heart	Patients	10	<5	<5		<5				17
	Average Age	53	13	73		46				45
	Average Weight	72	45	66		64				65
	Grams	1,135	308	265		65				1,773
	Grams/Episode	26	51	29		11				27
	Grams per 1,000 Population	0	0	0		0				0
Solid organ - heart/lung	Patients	12				<5				13
	Average Age	44				24				42
	Average Weight	67				48				66
	Grams	2,165				30				2,195
	Grams/Episode	37				10				35
	Grams per 1,000 Population	0				0				0

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
Solid organ - liver	Patients	5			<5					6
	Average Age	17			66					25
	Average Weight	45			65					49
	Grams	1,078			130					1,208
	Grams/Episode	36			65					38
	Grams per 1,000 Population	0			0					0
Solid organ - lung	Patients	27	59	8	5	<5	6			103
	Average Age	46	47	51	48	52	44			47
	Average Weight	62	66	64	63	45	71			65
	Grams	4,165	10,612	635	625	90	1,360			17,487
	Grams/Episode	51	20	12	27	45	22			24
	Grams per 1,000 Population	1	2	0	0	0	3			1
Solid organ - other	Patients		<5							3
	Average Age		49							49
	Average Weight		75							75
	Grams		838							838
	Grams/Episode		52							52
	Grams per 1,000 Population		0							0
Specific antibody deficiency	Patients	142	46	53	25	63	<5	<5	6	334
	Average Age	54	57	53	52	44	44	12	37	52
	Average Weight	69	71	73	67	116	91	27	72	79
	Grams	36,898	12,606	14,680	5,909	15,731	656	40	2,080	88,598
	Grams/Episode	18	22	22	21	19	35	10	17	19
	Grams per 1,000 Population	5	2	3	3	6	1	0	5	4
Staphylococcal TSS	Patients	17	21	6	7	<5	<5		<5	55
	Average Age	53	24	18	24	53	34		16	33
	Average Weight	82	47	57	50	75	95		60	61

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
	Grams	2,173	1,768	550	413	210	190	60	5,363	
	Grams/Episode	84	47	55	52	70	190	60	62	
	Grams per 1,000 Population	0	0	0	0	0	0	0	0	
Streptococcal TSS	Patients	45	68	30	11	11	<5	6	175	
	Average Age	49	42	46	40	40	63	46	45	
	Average Weight	80	78	85	74	72	85	82	79	
	Grams	6,763	8,870	3,833	1,655	1,300	635	883	23,938	
	Grams/Episode	81	67	62	64	62	159	126	71	
	Grams per 1,000 Population	1	1	1	1	1	1	2	1	
Toxic epidermal necrolysis/Stevens–Johnson syndrome	Patients	20	32		<5		<5	9	<5	69
	Average Age	58	50		57		38	47	42	52
	Average Weight	79	71		78		79	76	60	75
	Grams	3,220	5,015		580		255	1,308	120	10,498
	Grams/Episode	70	55		73		32	45	120	57
	Grams per 1,000 Population	0	1		0		0	5	0	0
Wegener granulomatosis	Patients				<5				<5	
	Average Age				31				31	
	Average Weight				70				70	
	Grams				138				138	
	Grams/Episode				28				28	
	Grams per 1,000 Population				0				0	
Chapter 6 Total	Patients	1,004	881	611	132	205	81	19	56	2,963
	Average Age	51	47	52	44	44	53	42	46	49
	Average Weight	71	68	70	63	88	75	69	69	71
	Grams	240,489	203,183	164,436	30,373	46,337	22,172	2,998	11,779	721,766
	Grams/Episode	29	28	27	31	23	35	39	29	28
	Grams per 1,000 Population	31	33	34	18	18	43	12	29	30

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
Chapter 7									
Acute leukaemia in children	Patients		<5	15		<5			18
	Average Age		13	7		0			8
	Average Weight		43	26		7			27
	Grams		250	350		3			603
	Grams/Episode		50	13		3			19
	Grams per 1,000 Population		0	0		0			0
Autoimmune neutropenia	Patients	5	<5	5	<5		<5	<5	15
	Average Age	55	24	54	51		57	49	52
	Average Weight	61	50	64	65		84	116	67
	Grams	615	120	888	130		160	1,430	3,458
	Grams/Episode	32	17	31	65		80	65	42
	Grams per 1,000 Population	0	0	0	0		0	6	0
Autoimmune uveitis	Patients		<5	<5					<5
	Average Age		55	53					54
	Average Weight		87	47					77
	Grams		550	210					760
	Grams/Episode		55	26					42
	Grams per 1,000 Population		0	0					0
Catastrophic antiphospholipid syndrome	Patients	<5	<5	<5	<5		<5		13
	Average Age	50	64	51	55		40		51
	Average Weight	87	60	72	93		50		77
	Grams	1,548	25	689	360		200		2,821
	Grams/Episode	43	25	29	72		50		40
	Grams per 1,000 Population	0	0	0	0		1		0
Cerebellar degeneration	Patients	<5	7	5	<5	<5	<5	<5	26

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Average Age	66	63	76	52	68	69	62	65
	Average Weight	77	77	66	89	69	74	82	76
	Grams	665	2,315	1,275	710	840	510	735	7,050
	Grams/Episode	28	32	28	47	53	27	29	32
	Grams per 1,000 Population	0	0	0	0	0	1	2	0
Coagulation factor inhibitors	Patients	6	<5	7	6				21
	Average Age	50	83	61	60				60
	Average Weight	42	65	85	68				66
	Grams	1,768	200	2,603	1,610				6,180
	Grams/Episode	48	100	54	35				46
	Grams per 1,000 Population	0	0	1	1				0
Devic disease (neuromyelitis optica)	Patients	23	<5	8	<5	<5			40
	Average Age	53	33	54	47	35			50
	Average Weight	73	77	67	66	76			71
	Grams	8,909	1,165	2,314	470	1,490			14,348
	Grams/Episode	35	47	24	34	38			34
	Grams per 1,000 Population	1	0	0	0	1			1
Diabetic amyotrophy	Patients	<5	10	8	<5	<5			24
	Average Age	64	61	61	56	39			61
	Average Weight	61	78	72	85	60			73
	Grams	1,442	2,670	2,690	275	125			7,202
	Grams/Episode	24	35	25	34	18			28
	Grams per 1,000 Population	0	0	1	0	0			0
Epidermolysis bullosa acquisita	Patients	<5				<5		<5	<5
	Average Age	90				71		48	65
	Average Weight	81				116		72	91
	Grams	160				3,063		1,665	4,888

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Grams/Episode	40			75			50	63
	Grams per 1,000 Population	0			1			4	0
Epilepsy (rare childhood cases)	Patients	<5	6	<5	<5	<5			18
	Average Age	12	12	12	3	3			11
	Average Weight	42	51	37	14	19			39
	Grams	1,188	1,365	843		112	40		3,547
	Grams/Episode	37	27	19		10	40		26
	Grams per 1,000 Population	0	0	0		0	0		0
Graves ophthalmopathy	Patients			<5	<5				<5
	Average Age			57	57				57
	Average Weight			82	54				71
	Grams			880	630				1,510
	Grams/Episode			40	21				29
	Grams per 1,000 Population			0	0				0
Haemolytic disease of the newborn	Patients	23	25	5	12	8	<5	<5	77
	Average Age	3	3	6	0	0	0	0	2
	Average Weight	9	8	13	3	3	4	3	7
	Grams	945	2,746	945	40	31	5	18	4,729
	Grams/Episode	24	31	36	3	2	5	3	25
	Grams per 1,000 Population	0	0	0	0	0	0	0	0
Haemolytic transfusion reaction	Patients	<5	<5		<5			<5	6
	Average Age	57	56		0			49	36
	Average Weight	147	70		3			60	59
	Grams	60	230		5			120	415
	Grams/Episode	60	38		3			60	38
	Grams per 1,000 Population	0	0		0			0	0
Hashimoto encephalopathy	Patients	12	5	<5		<5			22

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Average Age	40	40	79		42			42
	Average Weight	76	78	86		60			74
	Grams	4,395	1,210	420		1,574			7,599
	Grams/Episode	38	39	35		26			35
	Grams per 1,000 Population	1	0	0		1			0
Limbic encephalitis	Patients	19	13	11		<5	<5		48
	Average Age	60	61	58		47	22		58
	Average Weight	69	71	67		79	59		70
	Grams	4,620	4,125	2,703		1,413	60		12,920
	Grams/Episode	31	54	25		28	60		34
	Grams per 1,000 Population	1	1	1		1	0		1
Limbic encephalitis, nonparaneoplastic	Patients	139	69	131	7	11	<5	<5	365
	Average Age	45	51	44	50	48	50	48	46
	Average Weight	67	69	77	72	77	78	75	72
	Grams	29,498	12,020	39,478	955	5,200	610	298	88,621
	Grams/Episode	33	31	27	32	43	31	30	30
	Grams per 1,000 Population	4	2	8	1	2	1	1	4
Myocarditis in children	Patients	<5	17	<5	<5	<5			27
	Average Age	4	4	7	0	0			3
	Average Weight	18	19	26	4	6			16
	Grams	68	780	90	30	35			1,003
	Grams/Episode	34	20	18	8	7			18
	Grams per 1,000 Population	0	0	0	0	0			0
PANDAS/tic disorders	Patients	9	<5	9					20
	Average Age	10	12	12					11
	Average Weight	33	48	59					46
	Grams	5,298	1,203	3,343					9,843

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Grams/Episode	65	41	32					46
	Grams per 1,000 Population	1	0	1					0
Potassium channel antibody-associated encephalopathy	Patients	14	5	<5	<5	<5	<5		30
	Average Age	46	52	51	71	56	52		50
	Average Weight	72	83	75	59	64	84		73
	Grams	5,340	1,805	2,025	615	2,575	1,245		13,605
	Grams/Episode	34	48	46	17	40	30		36
	Grams per 1,000 Population	1	0	0	0	1	2		1
Pure red cell aplasia	Patients	15	12	15	<5	<5	<5	<5	48
	Average Age	47	44	55	63	29	36	75	49
	Average Weight	69	71	76	63	65	85	56	72
	Grams	3,543	2,223	5,095	110	293	1,735	55	13,053
	Grams/Episode	38	43	45	37	59	41	55	42
	Grams per 1,000 Population	0	0	1	0	0	3	0	1
Pure white cell aplasia	Patients					<5			<5
	Average Age					12			12
	Average Weight					34			34
	Grams					35			35
	Grams/Episode					35			35
	Grams per 1,000 Population					0			0
Pyoderma gangrenosum	Patients	<5	8	5	<5	<5			20
	Average Age	77	62	60	45	38			62
	Average Weight	87	96	93	82	72			91
	Grams	1,815	4,025	2,805	988	750			10,383
	Grams/Episode	49	59	67	66	27			55
	Grams per 1,000 Population	0	1	1	1	0			0
Rasmussen Syndrome	Patients	12	7	<5	<5			<5	25

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
	Average Age	35	18	30	35			60	30
	Average Weight	71	47	56	131			62	63
	Grams	5,346	3,185	1,030	765			325	10,651
	Grams/Episode	42	34	32	48			19	37
	Grams per 1,000 Population	1	1	0	0			1	0
Scleromyxedema	Patients	<5	<5	<5	<5	<5			14
	Average Age	71	67	66	73	51			66
	Average Weight	73	77	90	57	75			74
	Grams	2,508	2,725	600	1,875	1,500			9,208
	Grams/Episode	52	32	35	38	44			39
	Grams per 1,000 Population	0	0	0	1	1			0
Sjögren's syndrome	Patients	11	<5	<5	<5			<5	19
	Average Age	59	86	37	65			60	59
	Average Weight	77	61	71	71			75	74
	Grams	3,533	125	590	665			2,655	7,568
	Grams/Episode	31	18	28	39			59	37
	Grams per 1,000 Population	0	0	0	0			7	0
Subacute sensory neuropathy	Patients	<5	8	8	<5	<5	<5	<5	29
	Average Age	61	65	65	70	57	62	78	64
	Average Weight	61	63	85	72	81	82	65	73
	Grams	895	1,035	2,920	633	1,135	653	260	7,530
	Grams/Episode	31	24	32	35	57	33	22	32
	Grams per 1,000 Population	0	0	1	0	0	3	1	0
Susac syndrome	Patients	10	<5	6					17
	Average Age	44	33	49					45
	Average Weight	85	75	85					84
	Grams	7,055	2,580	3,220					12,855

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
	Grams/Episode	58	68	49					57	
	Grams per 1,000 Population	1	0	1					1	
Systemic capillary leak syndrome	Patients	7	<5	<5	<5	<5		<5	16	
	Average Age	48	70	37	0	38		67	44	
	Average Weight	76	79	83	5	88		70	71	
	Grams	3,245	2,630	1,343	20	360		1,840	9,438	
	Grams/Episode	43	61	50	10	33		71	51	
	Grams per 1,000 Population	0	0	0	0	0		5	0	
Chapter 7 Total	Patients	329	219	264	55	57	11	8	20	959
	Average Age	44	41	44	38	37	46	44	52	43
	Average Weight	65	60	71	51	57	74	68	62	64
	Grams	94,455	51,306	79,346	10,255	21,161	4,360	2,585	8,350	271,817
	Grams/Episode	37	37	30	35	38	35	45	44	35
	Grams per 1,000 Population	12	8	16	6	8	8	11	21	11
Chapter 8										
Antiphospholipid syndrome (non-obstetric)	Patients								<5	<5
	Average Age								42	42
	Average Weight								60	60
	Grams								60	60
	Grams/Episode								60	60
	Grams per 1,000 Population								0	0
Sepsis	Patients		<5	<5						5
	Average Age		36	41						39
	Average Weight		36	59						49
	Grams		143	85						228
	Grams/Episode		71	17						33

Specific Condition	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National	
Grams per 1,000 Population		0	0						0	
Chapter 8 Total	Patients		<5				<5		6	
	Average Age		36	41			42		39	
	Average Weight		36	59			60		51	
	Grams		143	85			60		288	
	Grams/Episode		71	17			60		36	
	Grams per 1,000 Population		0	0			0		0	
	JDO Issue	Patients	<5							<5
Average Age		3							3	
Average Weight		13							13	
Grams		25							25	
Grams/Episode		25							25	
Grams per 1,000 Population		0							0	
Total	Patients	7,230	4,447	4,833	1,114	1,126	392	112	357	19,414
	Average Age	58	55	59	57	52	59	47	54	57
	Average Weight	74	72	76	74	80	78	73	74	74
	Grams	2,201,962	1,316,934	1,594,453	304,326	389,158	127,151	30,571	111,177	6,075,733
	Grams/Episode	31	31	28	30	31	33	42	31	30
	Grams per 1,000 Population	282	211	326	177	152	245	124	273	249

Note: The national patient count only includes one count for each patient. This may result in the sum of the state and territory totals being greater than the national total.

Appendix E – Grams Ig Issued by State and Territory

		NSW	VIC	QLD	SA	WA	TAS	NT	ACT
2007-08	Imported Ig	105,633	111,010	85,055	18,416	38,445	11,740		16,875
	Domestic Ig	599,126	423,170	400,144	108,596	148,986	52,755	6,825	27,393
2008-09	Imported Ig	249,905	131,228	171,367	27,604	42,895	19,965		14,200
	Domestic Ig	562,320	417,574	383,865	128,511	143,628	53,745	10,503	22,841
2009-10	Imported Ig	252,416	101,930	200,264	31,244	16,248	17,110		11,550
	Domestic Ig	668,526	507,038	439,089	143,285	162,963	61,686	8,610	33,225
2010-11	Imported Ig	136,728	93,835	107,798	27,383	30,108	8,843	80	11,900
	Domestic Ig	887,016	577,260	631,545	139,296	167,745	76,197	9,099	45,540
2011-12	Imported Ig	265,995	144,284	183,435	35,775	59,900	12,138	30	14,708
	Domestic Ig	874,995	570,969	674,277	145,134	150,294	73,491	13,440	52,446
2012-13	Imported Ig	467,371	321,085	361,654	72,613	92,914	16,436	9,551	26,648
	Domestic Ig	804,375	484,680	589,662	123,810	132,108	64,305	6,744	48,480
2013-14	Imported Ig	469,174	312,713	291,460	87,901	70,709	24,069	10,429	30,626
	Domestic Ig	934,478	584,561	771,037	138,876	168,295	67,776	6,036	53,723
2014-15	Imported Ig	593,045	416,868	458,189	107,343	111,570	41,608	12,861	32,199
	Domestic Ig	930,412	579,560	735,658	135,795	155,977	57,987	4,863	59,210
2015-16	Imported Ig	724,960	451,770	584,275	103,165	159,631	48,003	18,489	41,264
	Domestic Ig	1,004,528	643,340	771,182	167,599	152,900	53,207	5,589	52,601
2016-17	Imported Ig	914,742	480,381	639,087	114,989	174,908	49,712	18,205	45,305
	Domestic Ig	1,057,386	732,525	821,999	182,943	192,437	55,969	7,215	54,710
2017-18	Imported Ig	1,075,907	622,547	735,052	137,655	196,179	62,599	20,104	52,953
	Domestic Ig	1,104,220	731,611	874,582	174,543	204,551	65,341	11,202	59,674

Appendix F – Unique Patients by Quarter and State and Territory

Year	Quarter	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUST
2009-10	Q1	2,434	1,367	1,644	400	380	183	23	112	6,508
	Q2	2,496	1,378	1,667	440	356	177	20	109	6,619
	Q3	2,554	1,386	1,682	395	353	183	15	102	6,640
	Q4	2,602	1,451	1,752	413	371	189	22	120	6,889
2010-11	Q1	2,692	1,492	1,839	420	376	197	22	143	7,148
	Q2	2,781	1,533	1,886	394	394	205	21	132	7,315
	Q3	2,752	1,532	1,884	396	376	211	15	130	7,262
	Q4	2,791	1,622	1,946	417	385	197	23	142	7,496
2011-12	Q1	2,921	1,658	2,047	419	407	199	27	142	7,794
	Q2	2,971	1,628	2,115	428	413	206	22	137	7,898
	Q3	2,949	1,590	2,150	430	401	203	23	150	7,860
	Q4	2,961	1,632	2,215	458	405	202	29	154	8,019
2012-13	Q1	3,107	1,751	2,391	449	449	205	32	168	8,494
	Q2	3,139	1,809	2,360	462	436	196	26	171	8,557
	Q3	3,211	1,753	2,298	454	410	183	33	164	8,465
	Q4	3,309	1,821	2,378	463	425	187	36	170	8,737
2013-14	Q1	3,406	1,890	2,472	506	435	204	36	181	9,081
	Q2	3,428	1,971	2,510	481	472	209	36	172	9,237
	Q3	3,440	1,952	2,583	502	454	213	30	188	9,317
	Q4	3,550	2,042	2,660	493	513	215	34	188	9,653
2014-15	Q1	3,713	2,150	2,763	545	518	238	41	189	10,099
	Q2	3,725	2,169	2,719	506	521	228	32	202	10,057
	Q3	3,733	2,161	2,772	530	510	215	25	191	10,096
	Q4	3,846	2,249	2,868	555	514	223	31	202	10,440
2015-16	Q1	4,101	2,354	3,026	587	554	234	46	202	11,033
	Q2	4,103	2,346	3,067	591	583	225	38	198	11,081
	Q3	4,161	2,358	3,073	595	583	226	41	197	11,164
	Q4	4,263	2,400	3,132	601	602	227	50	207	11,424
2016-17	Q1	4,442	2,474	3,202	641	650	226	39	211	11,827
	Q2	4,499	2,516	3,279	651	682	217	40	161	12,022
	Q3	4,622	2,583	3,296	645	663	214	46	221	12,253
	Q4	4,772	2,673	3,403	644	680	228	54	219	12,621
2017-18	Q1	4,972	2,818	3,528	665	742	249	55	235	13,215
	Q2	4,957	2,785	3,576	691	728	256	61	234	13,238
	Q3	5,016	2,848	3,576	699	713	272	55	246	13,387
	Q4	5,171	2,993	3,666	718	775	286	62	268	13,878

Appendix G – System Source for Tables and Figures

Table 1	Growth in Ig grams issued since 2008-09	IDMS
Table 2	Percentage change in grams issued over time by state and territory	IDMS
Table 3	Annual numbers of patients, treatment episodes and grams	STARS and BloodSTAR
Table 4	Basic numbers	STARS and BloodSTAR
Table 5	Patient numbers and average weight by age range	STARS and BloodSTAR
Table 6	Issues of domestic Ig compared with imported Ig.....	IDMS
Table 7	Issues of domestic Ig compared with imported Ig and public versus private	IDMS
Table 8	Ig issues (g) by criteria chapter	STARS and BloodSTAR
Table 9	Ig issues by criteria chapter (percentage).....	STARS and BloodSTAR
Table 10	Ig grams issued for top 10 medical conditions over time.....	STARS and BloodSTAR
Table 11	Difference in grams issued for secondary hypogammaglobulinaemia (percentage).....	STARS and BloodSTAR
Table 12	Patient numbers and age for the top 20 specific conditions by private and public facilities	STARS and BloodSTAR
Table 13	Ig grams issued by clinical speciality	STARS and BloodSTAR
Table 14	Grams of Ig issued by state and territory	IDMS
Table 15	Grams of Ig issued per 1,000 population by state and territory for top 10 specific conditions.....	STARS and BloodSTAR
Table 16	Ig grams per kg weight per episode	STARS and BloodSTAR
Table 17	Patient numbers for products issued by state and territory in 2017-18	STARS and BloodSTAR
Table 18	Grams of product issued by state and territory in 2017-18	35
Table 19	Treatment episode numbers for products issued by state and territory in 2017-18.....	STARS and BloodSTAR
Table 20	Patient numbers for products issued by medical condition in 2017-18.....	STARS and BloodSTAR
Table 21	Grams of product issued by medical condition in 2017-18	STARS and BloodSTAR
Table 22	Treatment episodes for product issued by medical condition in 2017-18	STARS and BloodSTAR
Table 23	NHIg issued from 2013-14 to 2017-18.....	IDMS
Table 24	Grams of NHIg issued by state and territory	IDMS
Table 25	Grams per 1,000 population of NHIg issued by state and territory.....	IDMS

Figure 1	Ten year trends in issues of Ig.....	IDMS
Figure 2	Ten year trends in expenditure on Ig.....	IDMS
Figure 3	Patients per 1,000 population 2016-17 and 2017-18.....	STARS and BloodSTAR
Figure 4	Grams of Ig per 1,000 population by state and territory over time	IDMS
Figure 5	Patient age compared to average Australian age.....	STARS and BloodSTAR
Figure 6	Patient weights relative to Australian average.....	STARS and BloodSTAR
Figure 7	Ig expenditure as a proportion of the national blood budget	IDMS
Figure 8	Ig grams issued by medical condition	STARS and BloodSTAR
Figure 9	Proportion of Ig used for top 10 medical conditions.....	STARS and BloodSTAR
Figure 10	Ig issues by clinical speciality	STARS and BloodSTAR
Figure 11	Percentage Ig issues by clinical speciality for top 10 medical conditions.....	STARS and BloodSTAR
Figure 12	Grams per episode by specific condition	STARS and BloodSTAR
Figure 13	Grams per kg weight by specific condition	STARS and BloodSTAR
Figure 14	NHIg grams issued and grams issued per 1,000 population.....	IDMS
Appendix D – Dataset of Ig supply by state/territory		STARS and BloodSTAR
Appendix E – Grams Ig Issued by State and Territory		IDMS
Appendix F – Unique Patients by Quarter and State and Territory		STARS and BloodSTAR