NATIONAL BLOOD AUTHORITY
AUSTRALIA

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

Annual Report 2016-17

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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 (NHIg). Aggregated data for IVIg and SCIg is referred to as immunoglobulin (Ig) unless specifically stated. NHIg 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 2016-17, 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 citeria 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 Intravenous 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, the Criteria identifies the conditions and circumstances for which the use of Ig is funded under national blood arrangements.

The Criteria clearly articulates 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 outlines 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.

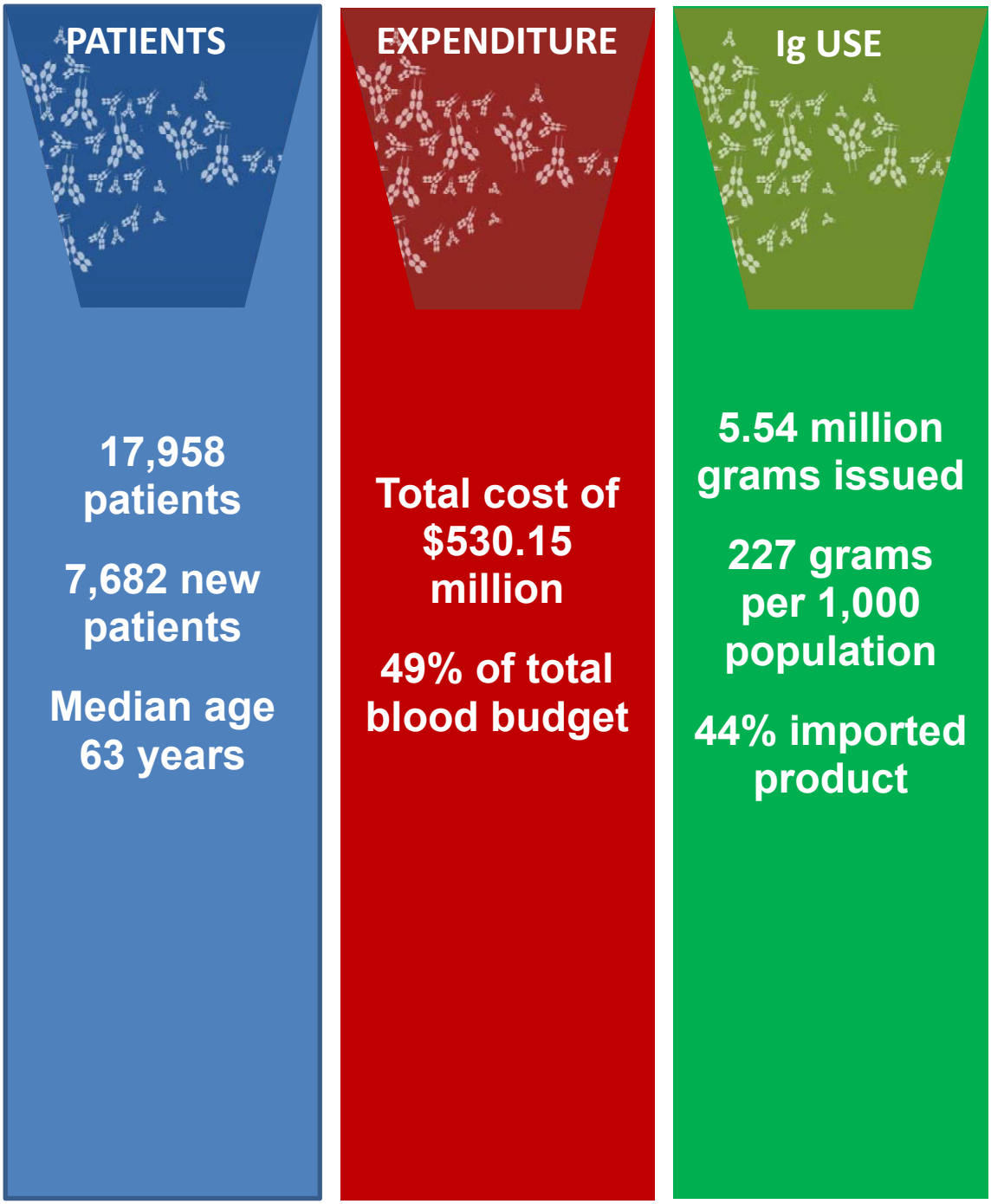
Ig products should be prescribed and dispensed in accordance with any applicable state or territory legislative requirements. In-hospital management of Ig products must also be in accordance with the National Safety and Quality Health Service (NSQHS) Standards, in particular Standards 1, 2 and 7, and 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 49% of total blood expenditure in 2016-17. 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 countries[1]. 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 88.3% of all Ig supplied in 2016-17, 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 2016-17, data has been captured on 56,379 patients. Caveats relating to the quality of this data are outlined below.

This report includes data on the supply of NHIg from 2012-13 and SCIg from 2013-14, as SCIg 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 this 2016-17 report 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 2016-17 a total of 5,542,511 grams of Ig was issued, representing an increase of 560,008 grams (11.2%) over 2015-16. Since 2007-08 there has been an on average 11.3% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

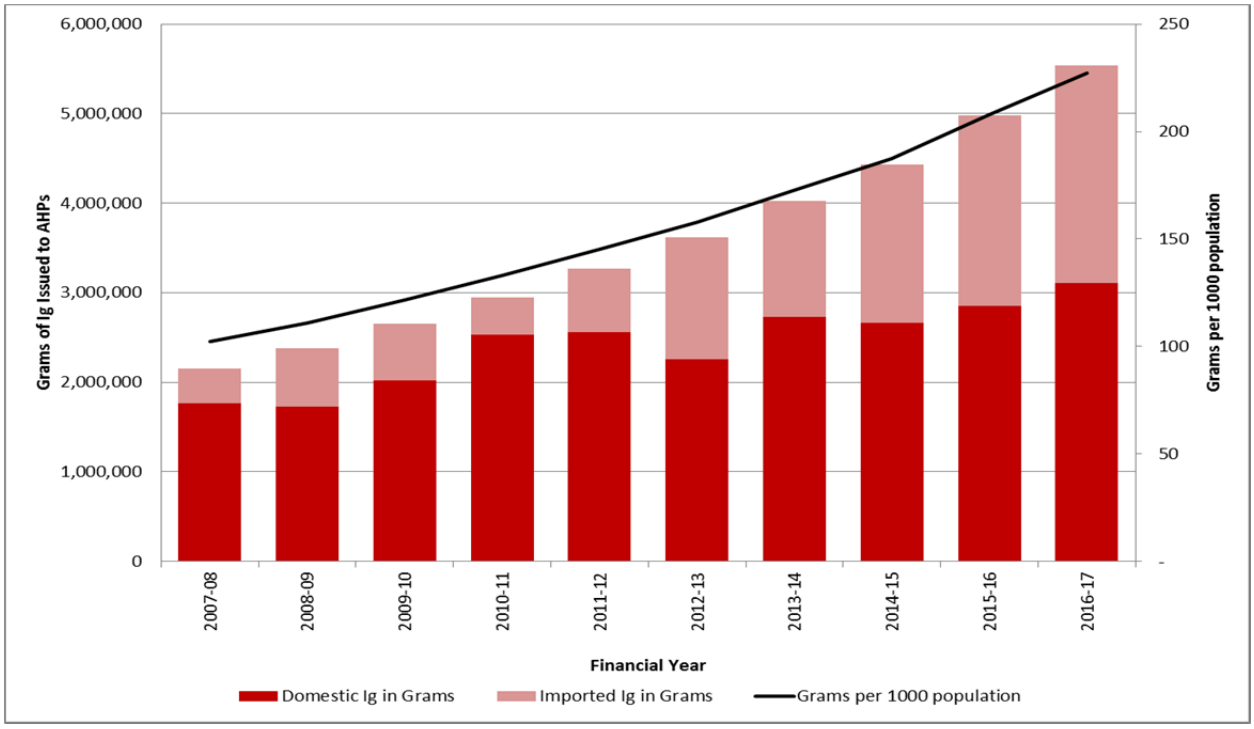


Figure 1 Ten year trends in issues of Ig

Table 1 Growth in Ig grams issued since 2007-08

	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17
Growth from previous year	13%	11%	12%	11%	11%	11%	11%	10%	12%	11%
Average Growth from 2007-08		5%	8%	9%	10%	11%	12%	13%	15%	16%
Total grams per 1,000 population	102	111	121	133	145	158	173	188	208	227
Increase in grams per 1,000 population over previous year	11%	8%	10%	10%	9%	9%	9%	9%	11%	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
2007-08	18%	8%	16%	14%	6%	5%	1%	29%
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%

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 2016-17 was $303.6 million, an increase of $7.2 million (2.4%) over 2015-16 (Figure 2). The increased expenditure predominately represents increases in demand offset by decreases in 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. In 2016-17 this increase was offset by a reduced cost by the Blood Service due to efficiencies recognised. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of $530.2 million (excluding hyperimmune plasma for fractionation).

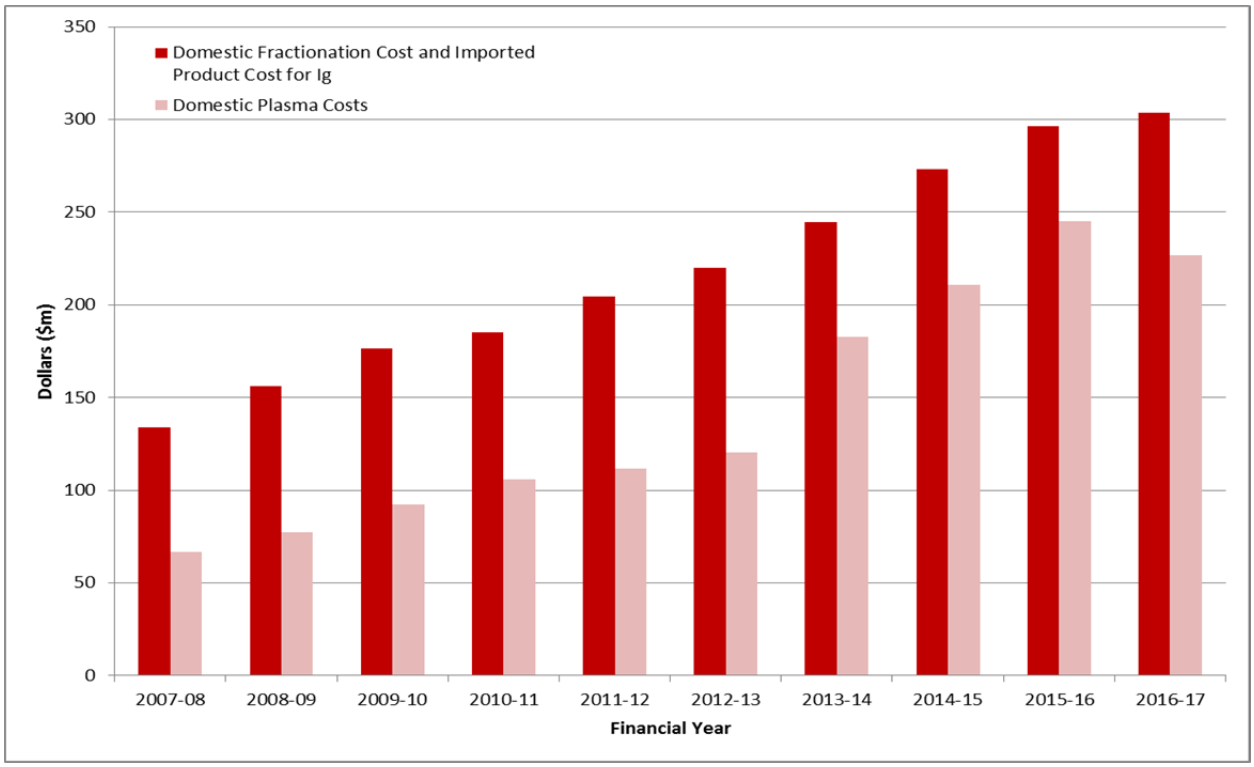


Figure 2 Ten year trends in expenditure on Ig

Demographics

PATIENT NUMBERS

A total of 17,958 patients were issued Ig under the national blood arrangements during 2016-17 for 179,997 treatment episodes. This represents a 10.0% increase in the number of patients since 2015-16. 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
2012-13	13,102	110,183	3,622,433
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

Table 4 Basic numbers

	2016-17
Total unique patient IDs with some weight data	17,744
Total unique patient IDs with an age recorded	17,958
Total unique patient IDs with more than one state or territory	117
Total unique patient IDs with two states or territories	115
Total unique patient IDs with three or more states or territories	<5
Total unique patient IDs with more than one condition	389
Total unique patient IDs with two conditions	370
Total unique patient IDs with three conditions	19
Total unique patient IDs aged 65 and older	8,094
Total unique patient IDs aged 17 and younger	1,669
Total unique new patient IDs	7,682
Average Age	57
Median Age	63
Average Weight (kg)	75

GEOGRAPHIC DISTRIBUTION

Nationally, 0.7 patients per 1,000 population received Ig in 2016-17. This varied between states and territories, ranging from 0.3 in NT to 0.9 in QLD (Figure 3). All states and territories show an increase in the number of patients per 1,000 population over the previous year, except Tasmania (TAS) and the NT.

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

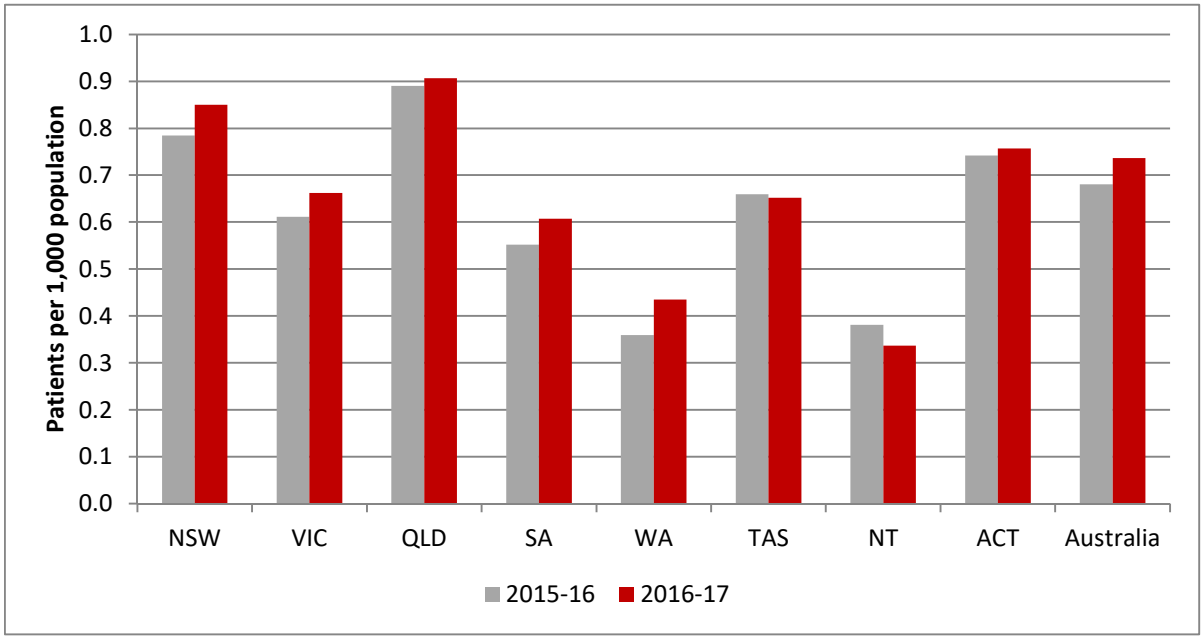


Figure 3 **Patients per 1,000 population 2015-16 and 2016-17**

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 103.3 in the NT to 299.2 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 143.3 grams per 1,000 population in Western Australia (WA) to 299.2 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.

Prior to 2014-15 WA had shown only slight increases in the number of grams issued per 1,000 population, while most states and territories have seen a continued increase in Ig issued per 1,000 population. However, in 2015-16 and 2016-17 WA had the highest increase in growth of Ig issued per 1,000 population as noted in Figure 4, but none the less WA(except NT) remains the lowest Ig issued per 1,000 population.

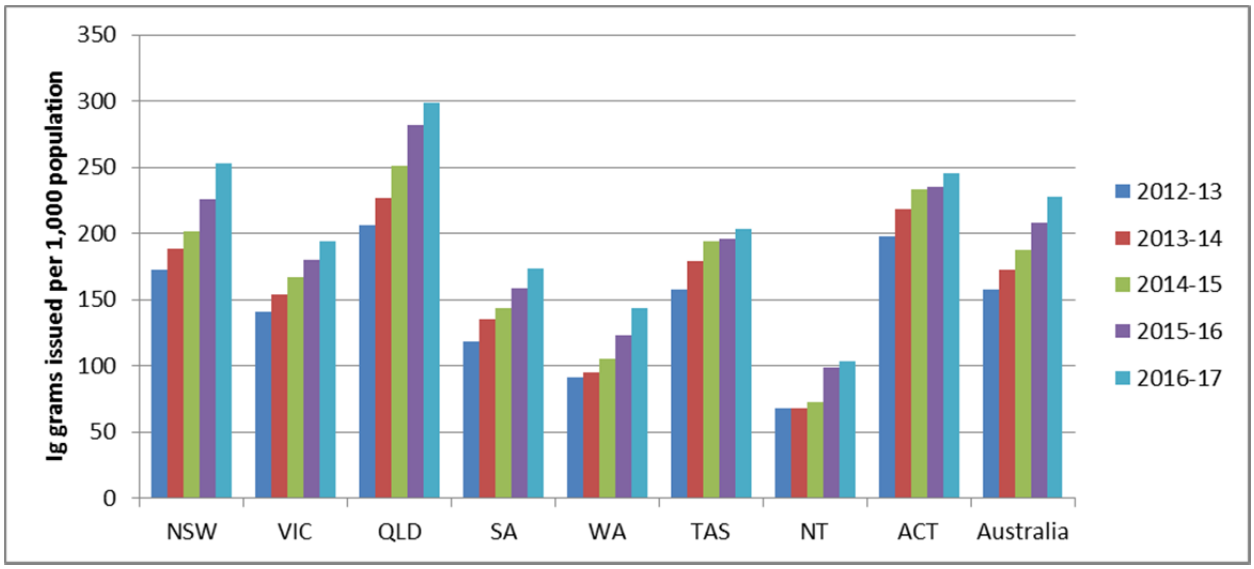


Figure 4 Grams of Ig per 1,000 population by state and territory over time

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 2015[2]. 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 2050[3].

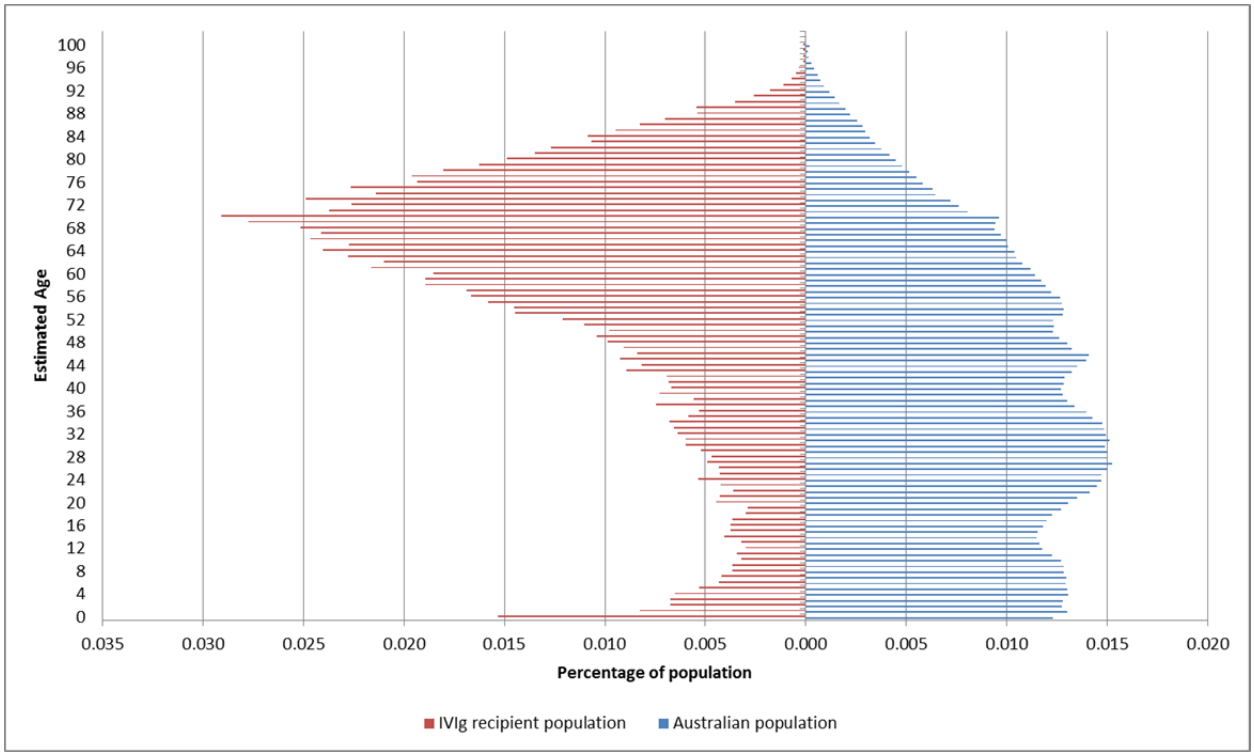


Figure 5 Patient age compared to average Australian age

[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.

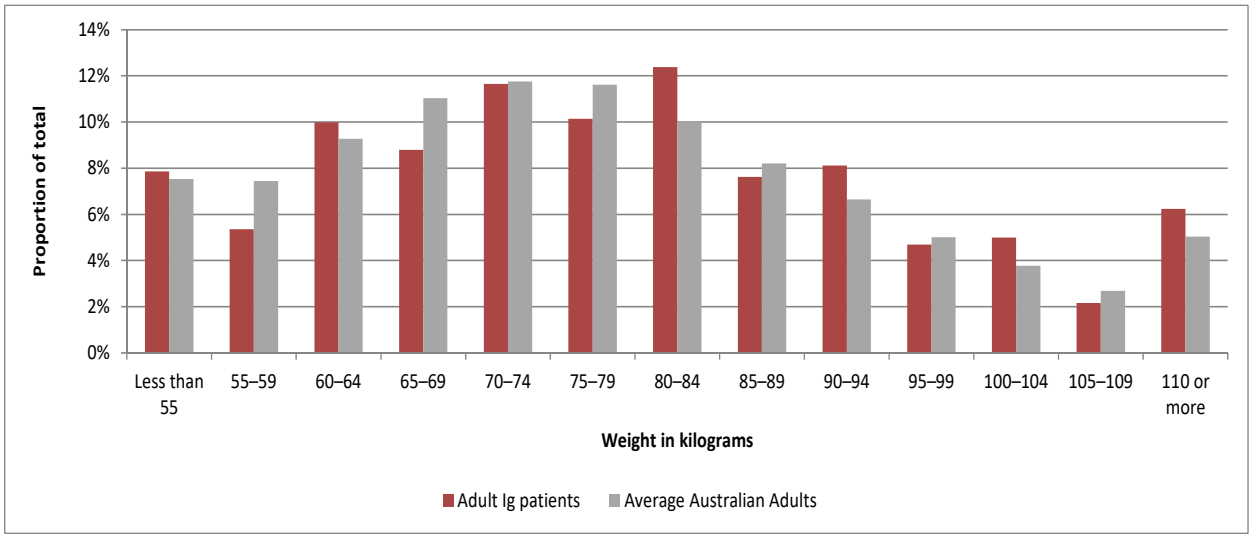


Figure 6 Patient weights relative to Australian average

Note: The above figure calculations relate to only 2016-17 patients.

Figure 6 compares the weight of Ig recipients in Australia in 2016-17 and the Australian population using weight statistics from the ABS in 2011[4]. 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 (78.5 kg) is slightly higher than the average weight of an Australian adult (77.7 kg[5]). This is a change from previous years where it has been lower, suggesting that the Ig population is getting heavier. Given that studies suggest that 63% of Australians are overweight or obese[6], 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 (latest statistics available)
[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 2016-17.

Table 5 Patient numbers and average weight by age range

Age Range	Patient Counts	Average Weight	Treatment Episodes	Grams Dispensed
0-4	782	12	2,539	23,417
5-9	380	25	2,459	34,869
10-14	305	45	2,890	55,421
15-17	200	64	2,374	50,950
18-19	106	69	1,290	26,960
20-24	395	70	4,159	110,540
25-29	420	74	4,109	134,023
30-34	569	78	5,676	172,188
35-39	565	77	6,493	193,308
40-44	674	80	7,182	241,544
45-49	844	81	9,005	299,024
50-54	1,112	83	11,926	407,538
55-59	1,566	81	16,963	562,026
60-64	1,940	82	20,583	651,589
65-69	2,233	80	23,316	732,968
70-74	2,185	80	22,964	716,443
75-79	1,722	77	17,366	533,914
80-84	1,124	74	11,224	333,318
85-89	639	70	5,722	162,986
90-94	174	67	1,585	39,623
95-104	23	63	172	4,862
Total	**17,958**	**75**	**179,997**	**5,487,511**

Expenditure

In 2016-17, Australian expenditure on Ig products was $303.6 million, with additional expenditure of $226.6 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 49% of the total blood budget, at a total expenditure of $530.2 million (excluding hyperimmune plasma for fractionation).

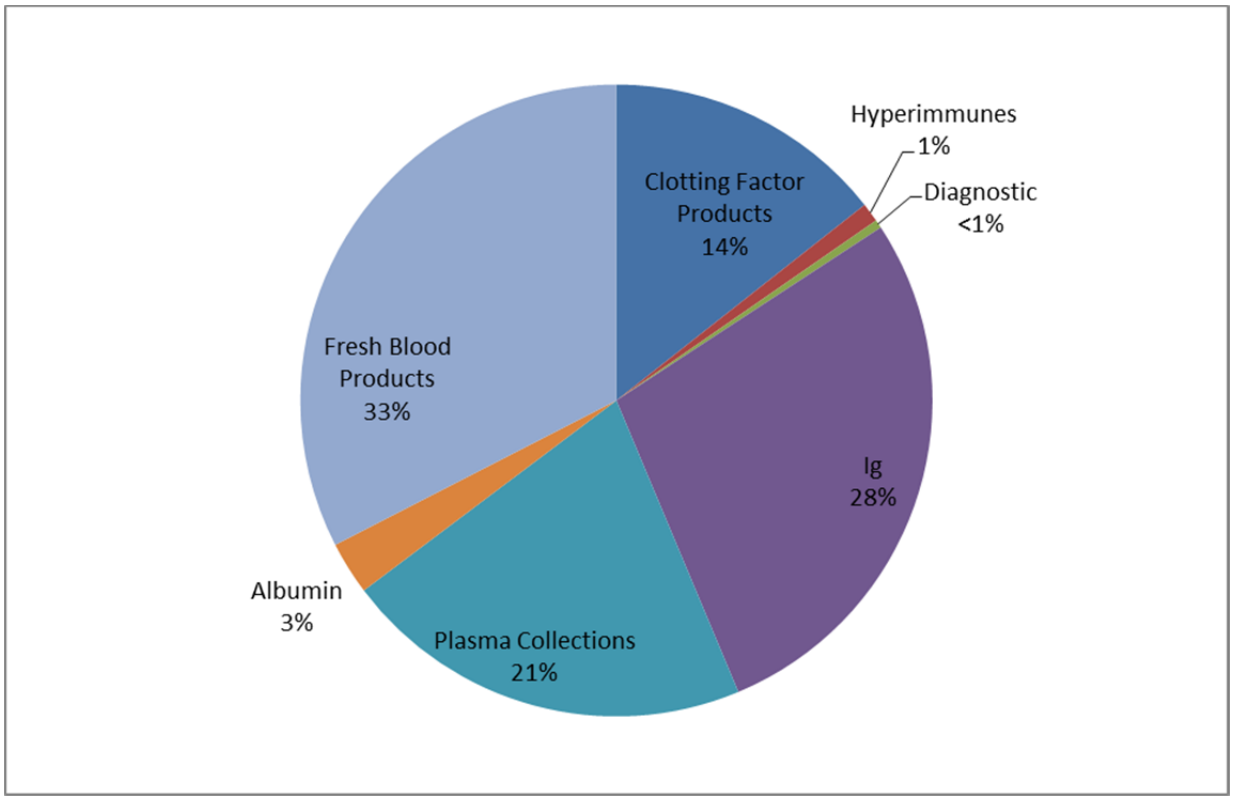


Figure 7 **Ig expenditure as a proportion of the national blood budget**

Of the Ig supplied under national blood arrangements in Australia in 2016-17, 56% (3,105,183 grams) was manufactured domestically and 44% (2,437,328 grams) was imported from overseas (Table 6). This represents a 14.3% increase in product importation from 2015-16 (305,772 grams). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 6.0% in 2016-17 over 2015-16. Intragam P, Intragam 10 (IVIg) and Evogam (SCIg) were Ig products manufactured domestically in 2016-17. The imported products available were Kiovig (IVIg), Octagam (IVIg), Privigen (IVIg), Flebogamma (IVIg), Hizentra (SCIg) and Gammanorm (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 63.7% 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 2016-17.

Table 6 Issues of domestic Ig compared with imported Ig

			NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
Domestic Ig	Intragam P	gm	833,259	515,505	558,645	125,001	129,678	38,748	4,620	40,833	2,246,289
		$(m)	$52	$32	$35	$8	$8	$2	$0	$3	$139
	Intragam 10	gm	202,535	208,198	244,745	52,023	56,665	16,890	2,288	13,628	796,970
		$(m)	$13	$13	$15	$3	$4	$1	$0	$1	$49
	Evogam	gm	21,592	8,822	18,609	5,919	6,094	331	307	250	61,924
		$(m)	$1	$1	$1	$0	$0	$0	$0	$0	$4
	Total Domestic	gm	**1,057,386**	**732,525**	**821,999**	**182,943**	**192,437**	**55,969**	**7,215**	**54,710**	**3,105,183**
		$(m)	**$66**	**$45**	**$51**	**$11**	**$12**	**$3**	**$0**	**$3**	**$193**
Imported Ig	Kiovig	gm	3,582	1,846	1,198	0	0	0	0	0	6,625
		$(m)	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Octagam	gm	6,074	1,373	1,047	0	0	0	0	0	8,494
		$(m)	$0	$0	$0	$0	$0	$0	$0	$0	$1
	Gammanorm	gm	224	0	0	0	0	0	0	3	228
		$(m)	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Flebogamma	gm	371,178	141,616	165,027	39,038	53,998	16,531	790	2,583	790,758
		$(m)	$17	$6	$7	$2	$2	$1	$0	$0	$36
	Privigen	gm	501,585	332,585	449,535	66,195	116,035	30,675	17,415	37,965	1,551,990
		$(m)	$23	$15	$20	$3	$5	$1	$1	$2	$70
	Hizentra	gm	32,100	2,962	22,281	9,756	4,875	2,506	0	4,754	79,234
		$(m)	$2	$0	$1	$1	$0	$0	$0	$0	$5
	Total Imported	gm	**914,742**	**480,381**	**639,087**	**114,989**	**174,908**	**49,712**	**18,205**	**45,305**	**2,437,328**
		$(m)	**$42**	**$22**	**$29**	**$5**	**$8**	**$2**	**$1**	**$2**	**$111**
Proportion of domestic to imported Ig		gm %	54%	60%	56%	61%	52%	53%	28%	55%	56%
		$(m) %	61%	68%	64%	68%	60%	60%	35%	62%	63%

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	772,012	424,069	306,590	153,558	124,418	44,539	7,215	54,710	1,887,111
	Private	gm	285,374	308,456	515,409	29,385	68,019	11,430	-	-	1,218,072
	Total Domestic	gm	**1,057,386**	**732,525**	**821,999**	**182,943**	**192,437**	**55,969**	**7,215**	**54,710**	**3,105,183**
Imported Ig	Public	gm	745,092	304,448	310,356	108,779	128,944	39,668	18,145	45,305	1,700,735
	Private	gm	169,651	175,933	328,732	6,210	45,965	10,044	60	-	736,593
	Total Imported	gm	**914,742**	**480,381**	**639,087**	**114,989**	**174,908**	**49,712**	**18,205**	**45,305**	**2,437,328**
Total Ig	Public	gm	1,517,104	728,517	616,945	262,337	253,361	84,207	25,360	100,015	3,587,845
	Private	gm	455,024	484,389	844,141	35,595	113,983	21,474	60	-	1,954,665
	Total Ig	gm	**1,972,128**	**1,212,905**	**1,461,086**	**297,931**	**367,345**	**105,681**	**25,420**	**100,015**	**5,542,511**
Domestic to Imported	Public	gm%	50.9%	58.2%	49.7%	58.5%	49.1%	52.9%	28.4%	54.7%	52.6%
	Private	gm%	62.7%	63.7%	61.1%	82.6%	59.7%	53.2%	0.0%	0.0%	62.3%
	Total Ig	gm%	**53.6%**	**60.4%**	**56.3%**	**61.4%**	**52.4%**	**53.0%**	**28.4%**	**54.7%**	**56.0%**
Ig as portion of National	Public	gm%	42.3%	20.3%	17.2%	7.3%	7.1%	2.3%	0.7%	2.8%	100.0%
	Private	gm%	23.3%	24.8%	43.2%	1.8%	5.8%	1.1%	0.0%	0.0%	100.0%
	Total Ig	gm%	**35.6%**	**21.9%**	**26.4%**	**5.4%**	**6.6%**	**1.9%**	**0.5%**	**1.8%**	**100.0%**
	Population %		**32.0%**	**25.6%**	**20.0%**	**7.0%**	**10.5%**	**2.1%**	**1.0%**	**1.7%**	**100.0%**
Grams Per 1000 Population	Public		194.5	116.7	126.3	152.8	98.8	162.0	103.0	245.6	147.1
	Private		58.3	77.6	172.9	20.7	44.5	41.3	0.2	-	80.2
	Total Ig		**252.9**	**194.3**	**299.2**	**173.5**	**143.3**	**203.3**	**103.3**	**245.6**	**227.3**

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 837g are mainly for emergency sepsis cases. Refer to **Appendix D** for further information.

Table 8 Ig issues (g) by Criteria chapter

	2012-13	2013-14	2014-15	2015-16	2016-17
Chapter 5	3,025,452	3,409,100	3,785,615	4,223,866	4,620,916
Chapter 6	453,352	463,361	494,489	535,596	645,636
Chapter 7	120,979	148,581	178,221	216,927	220,122
Chapter 8	39	0	0	5	837
Total	**3,599,831**	**4,021,042**	**4,458,326**	**4,976,394**	**5,487,511**

Table 9 Ig issues by Criteria chapter (percentage)

	2012-13	2013-14	2014-15	2015-16	2016-17
Chapter 5	84%	85%	85%	85%	84%
Chapter 6	13%	12%	11%	11%	12%
Chapter 7	3%	4%	4%	4%	4%
Chapter 8	<1%	0%	0%	0%	0%

For conditions where Ig is used only in exceptional circumstances (Chapter 7), five medical conditions accounted for 54.4% of those issues. These medical conditions were Limbic Encephalitis – nonparaneoplastic (66,445g), Paraneoplastic neurological syndromes (18,557g), Devic disease (neuromyelitis optica) (12,597g), Potassium channel antibody-associated encephalopathy (11,312g) and Sjögren's syndrome (10,928g). 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 2016-17 there were only two 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, but has improved with the introduction of BloodSTAR.

IG ISSUES BY MEDICAL CONDITION

The top ten medical conditions account for 88.3% of all Ig supplied, with the top three medical conditions accounting for 56.5%.

Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT is the medical condition for which the greatest percentage of Ig was issued in 2016-17 (22.4%), closely followed by chronic inflammatory demyelinating polyneuropathy (CIDP) (21.3%). Primary immunodeficiency diseases (PID) with antibody deficiency accounted for 12.8% of total Ig use (Figure 8 and Table 10).

Since 2012-13 there has been a greater than 15% increase in Ig issues for both myasthenia gravis (MG) and inflammatory myopathies, a more than 14% increase for secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) and a more than 12% increase in issues for acquired hypogammaglobulinaemia — haematological malignancy and post HSCT, and multifocal motor neuropathy (MMN). This is compared with the 11% increase in Ig over this period for all medical conditions.

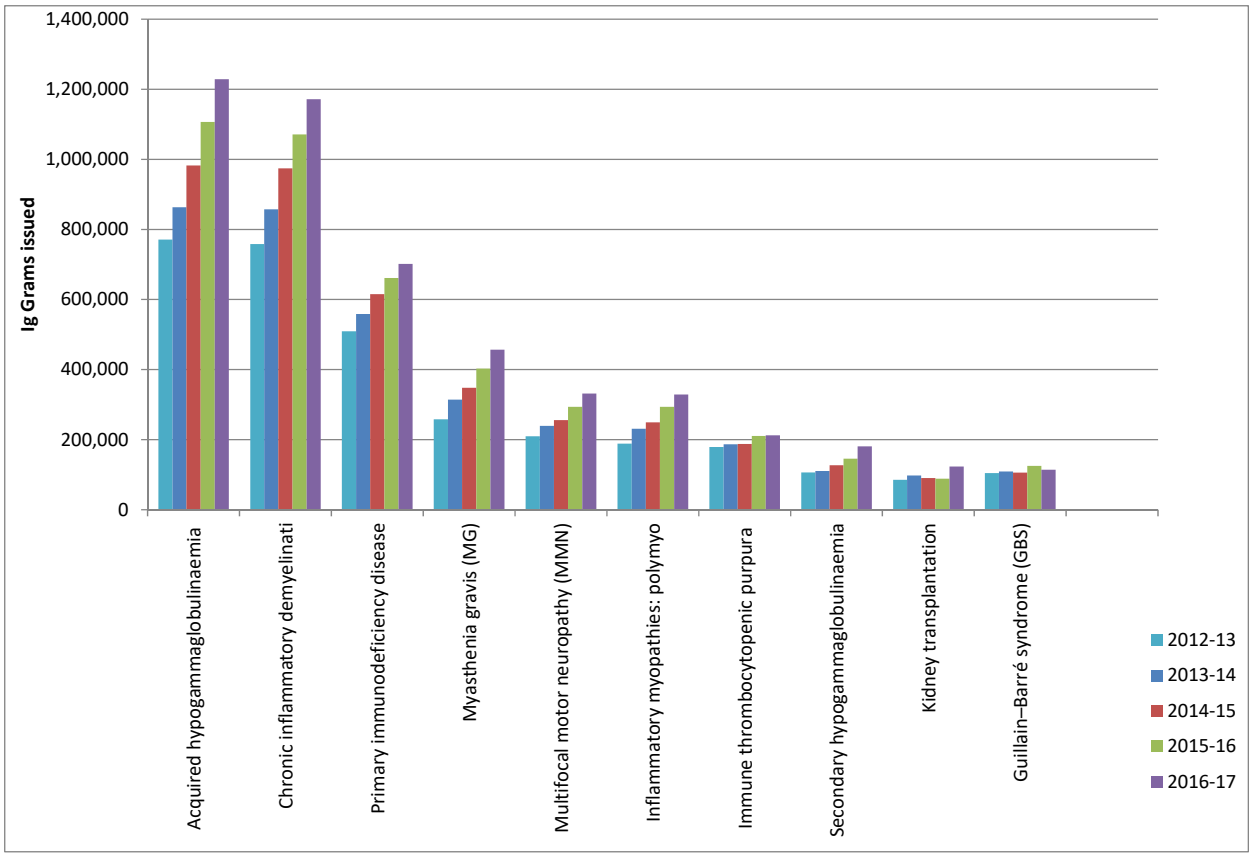


Figure 8 **Ig grams issued by medical condition**

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

	2012-13	2013-14	2014-15	2015-16	2016-17	% Change 2016-17 to 2015-16
Acquired hypogammaglobulinaemia	771,071	862,898	982,773	1,106,721	1,228,405	11.0%
Chronic inflammatory demyelinating polyneuropathy	758,271	857,533	974,258	1,071,135	1,171,581	9.4%
Primary immunodeficiency diseases	509,364	558,617	614,781	660,816	701,547	6.2%
Myasthenia gravis	257,966	313,940	348,336	402,881	456,346	13.3%
Multifocal motor neuropathy	209,791	239,314	256,041	293,458	331,142	12.8%
Inflammatory myopathies)	188,362	230,473	249,229	293,422	329,182	12.2%
Immune thrombocytopenic purpura (ITP) — adult	178,738	186,640	187,621	210,094	211,868	0.8%
Secondary hypogammaglobulinaemia	106,484	110,024	126,561	145,497	180,831	24.3%
Kidney transplantation	84,931	97,070	90,031	88,258	122,994	39.4%
Guillain–Barré syndrome	104,360	108,929	105,567	124,692	114,184	-8.4%

Kidney transplantation grams dispensed falls into the top ten medical conditions in 2016-17, replacing specific antibody deficiency. NSW, Victoria (VIC) and QLD all showed an increase in dispenses of Ig for kidney transplantation in 2016-17 (Table 11). In 2016-17 grams per patient ranged from 112 grams in SA, 110 grams in NT and 128 grams in NSW to 321 grams in QLD and 428 grams in TAS.

Table 11 Difference each year in grams issued for kidney transplantation (percentage)

	2012-13	2013-14	2014-15	2015-16	2016-17
NSW	24%	-8%	-11%	-13%	43%
VIC	-5%	28%	4%	-3%	45%
QLD	71%	-12%	1%	-15%	46%
SA	34%	23%	-57%	66%	-2%
WA	122%	7%	-44%	24%	20%
TAS	-23%	196%	-15%	28%	22%
NT	99%	-19%	-98%	2980%	-61%
ACT	450%	395%	-88%	268%	-63%
Total	**18%**	**14%**	**-7%**	**-2%**	**39%**

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

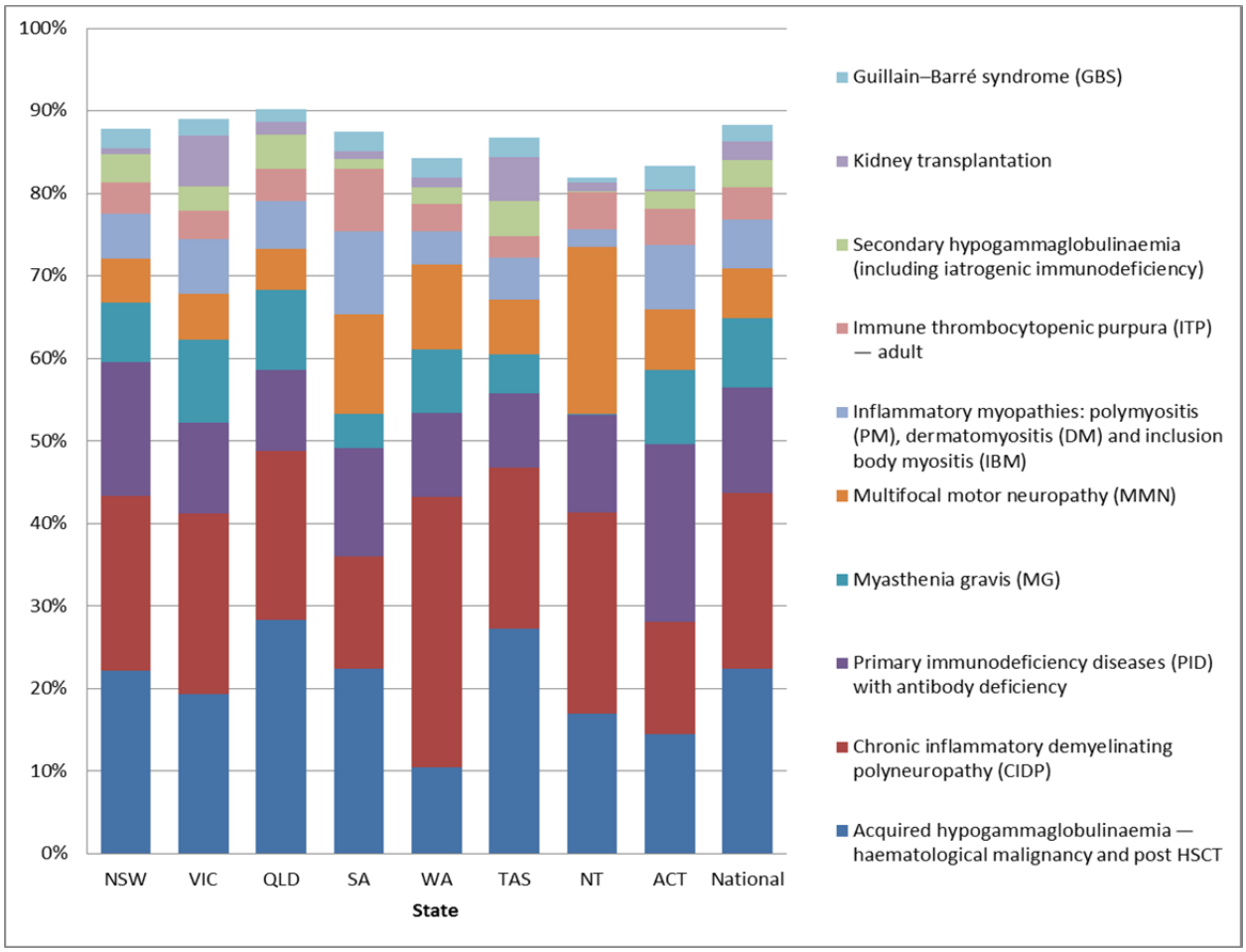


Figure 9 Proportion of Ig used for top 10 medical conditions

IG ISSUES BY SPECIFIC CONDITION

The top twenty specific conditions account for 89% 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 may 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

	Private			Public			Total		
Specific Conditions (Top 20)	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	418,305 (8%)	920 (2%)	64	753,276 (14%)	1,553 (4%)	62	1,171,581 (21%)	2,379 (6%)	63
Common variable immunodeficiency disease	158,688 (3%)	535 (4%)	57	459,940 (8%)	1,346 (4%)	49	618,627 (11%)	1,808 (8%)	51
Myasthenia gravis	157,223 (3%)	384 (5%)	62	299,123 (5%)	753 (4%)	60	456,346 (8%)	1,090 (8%)	61
Chronic lymphocytic leukaemia	184,966 (3%)	784 (1%)	73	198,161 (4%)	801 (2%)	71	383,127 (7%)	1,526 (3%)	72
Non-Hodgkin lymphoma	210,297 (4%)	850 (4%)	69	162,778 (3%)	675 (4%)	65	373,074 (7%)	1,483 (7%)	67
Multifocal motor neuropathy	96,589 (2%)	175 (1%)	59	234,553 (4%)	366 (2%)	58	331,142 (6%)	527 (2%)	58
Multiple myeloma	165,469 (3%)	687 (2%)	71	138,975 (3%)	666 (3%)	68	304,444 (6%)	1,302 (4%)	70
Polymyositis	51,506 (1%)	127 (0%)	62	131,379 (2%)	332 (2%)	60	182,885 (3%)	446 (2%)	61
Secondary hypogammaglobulinaemia	74,824 (1%)	302 (1%)	60	106,008 (2%)	514 (3%)	51	180,831 (3%)	781 (4%)	55
Kidney transplantation post-transplant	10,068 (0%)	34 (1%)	50	107,497 (2%)	421 (2%)	47	117,564 (2%)	442 (3%)	47
Guillain–Barré syndrome	27,347 (0%)	173 (0%)	57	86,837 (2%)	528 (1%)	52	114,184 (2%)	690 (1%)	54
Other relevant haematological malignancies	55,810 (1%)	231 (1%)	66	54,904 (1%)	348 (1%)	49	110,714 (2%)	555 (2%)	56
Dermatomyositis	18,447 (0%)	51 (1%)	61	64,001 (1%)	176 (2%)	47	82,448 (2%)	218 (3%)	50
Specific antibody deficiency	25,865 (0%)	96 (0%)	59	54,886 (1%)	216 (1%)	47	80,751 (1%)	301 (2%)	51

	Private			Public			Total		
Specific Conditions (Top 20)	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
ITP refractory acute	24,493 (0%)	158 (1%)	63	51,156 (1%)	332 (2%)	59	75,648 (1%)	482 (2%)	60
Limbic encephalitis, nonparaneoplastic	16,129 (0%)	67 (0%)	51	50,316 (1%)	215 (1%)	46	66,445 (1%)	279 (1%)	47
ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP)	23,648 (0%)	124 (0%)	65	40,221 (1%)	278 (2%)	59	63,868 (1%)	396 (2%)	61
Inclusion body myositis	22,543 (0%)	58 (1%)	68	41,307 (1%)	99 (2%)	71	63,850 (1%)	152 (2%)	70
Post-haemopoietic stem cell transplantation	18,900 (0%)	90 (0%)	53	38,147 (1%)	299 (1%)	39	57,046 (1%)	375 (1%)	42
ITP with life-threatening haemorrhage	15,861 (0%)	102 (0%)	64	39,851 (1%)	294 (0%)	56	55,712 (1%)	395 (0%)	58

IG ISSUES BY CLINICAL SPECIALITY

The number of grams of Ig issued categorised according to clinical speciality is shown in Figure 10 and Table 13. Some specific conditions prior to 2016-17 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.

Since 2012-13, 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.

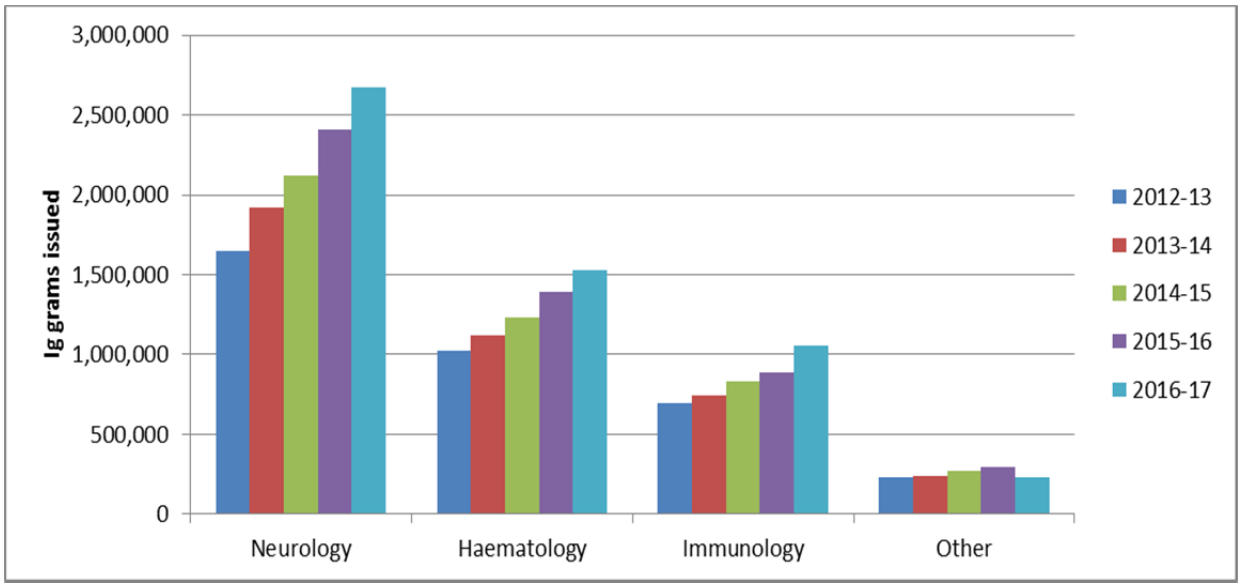


Figure 10 Ig issues by clinical speciality

Table 13 Ig grams issued by clinical speciality

	2012-13	2013-14	2014-15	2015-16	2016-17
Neurology	1,649,358	1,916,792	2,120,111	2,407,995	2,672,261
Haematology	1,026,177	1,116,037	1,234,816	1,390,824	1,530,340
Immunology	695,298	746,828	828,735	885,933	1,053,712
Other	228,947	241,386	274,664	291,643	231,199

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.

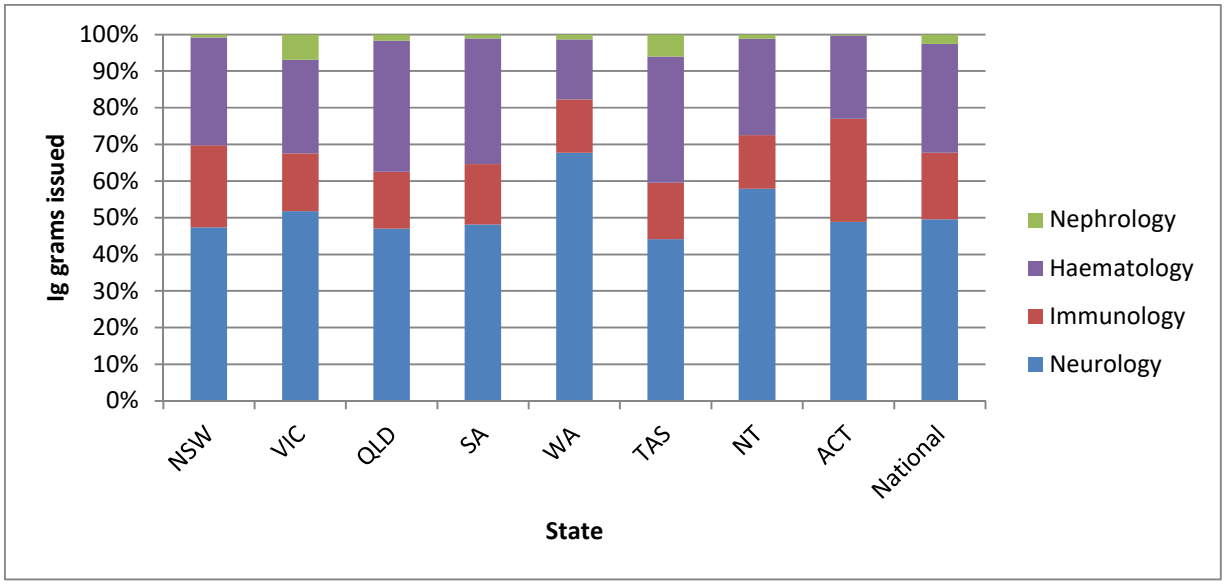


Figure 11 Percentage Ig issues by clinical speciality for top 10 medical conditions

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 kidney transplantation pre-transplant. In total, for the five largest states, there was proportionally low Ig issues per 1,000 population in SA and WA, and proportionally 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	1,972,128	35.6%	32.0%	253
VIC	1,212,905	21.9%	25.6%	194
QLD	1,461,086	26.4%	20.0%	299
SA	297,931	5.4%	7.0%	173
WA	367,345	6.6%	10.5%	143
TAS	105,681	1.9%	2.1%	203
NT	25,420	0.5%	1.0%	103
ACT	100,015	1.8%	1.7%	246
Total	**5,542,511**	**100%**	**100%**	**227**

Table 15 shows the top 10 specific conditions by the Ig grams issued per 1,000 population by state and territory. The fold variation in Table 15 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	54	42	61	23	45	40	24	33	48	2.7
Common variable immunodeficiency disease	38	16	26	19	12	17	6	50	25	3.1
Myasthenia gravis	19	12	21	13	6	13	10	19	16	3.8
Chronic lymphocytic leukaemia	18	19	29	7	11	10	0	22	19	4.2
Non-Hodgkin lymphoma	14	11	31	12	4	18	4	9	15	7.7
Multifocal motor neuropathy	13	10	15	20	14	14	20	18	14	1.9
Multiple myeloma	15	9	21	7	3	18	1	4	12	8.5
Polymyositis	8	6	10	10	3	4	2	8	8	3.1
Secondary hypogammaglobulinaemia	9	6	12	2	3	9	0	5	7	6.4
Kidney transplantation post-transplant	1	12	4	1	1	10	1	1	5	7.9

Dosing

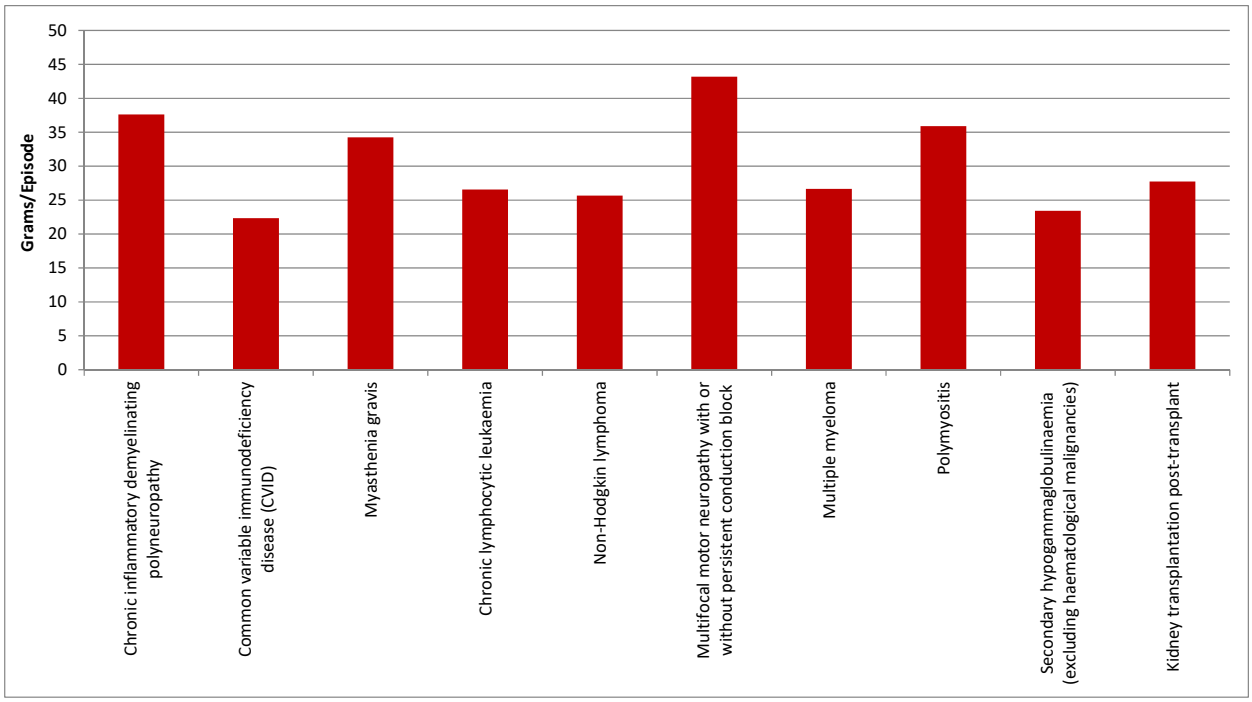


Figure 12 Grams per episode by specific condition

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 an 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 13 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) and may change over time.

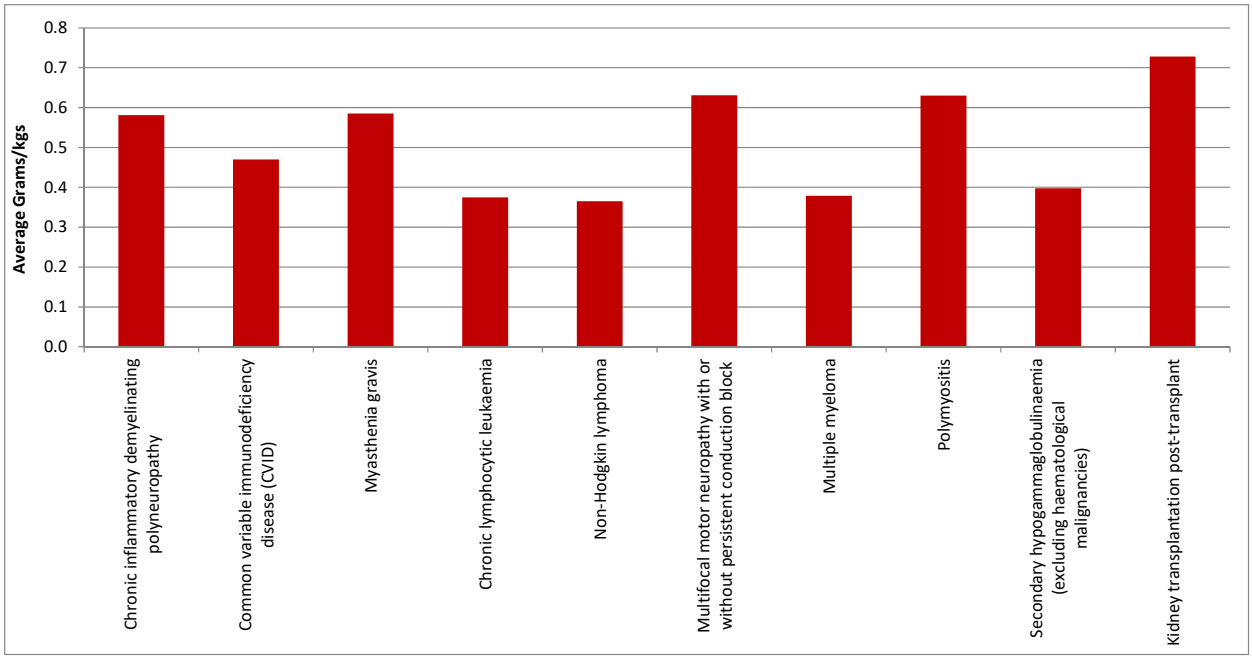


Figure 13 Grams per kg weight by specific condition

Table 16 Ig grams per kg weight per episode

Specific Condition	<=0.4 g/kg/ episode n (%)	0.4 – 0.99 g/kg/ episode n (%)	1 – 2 g/kg/ episode n (%)	>2 g/kg/ episode n (%)	No weight Data n(%)	Ig Average g/kg/ episode
Chronic inflammatory demyelinating polyneuropathy	7,282 (25%)	12,571 (43%)	1,194 (4%)	120 (0%)	8,139 (28%)	0.51
Common variable immunodeficiency disease	6,518 (30%)	7,304 (34%)	73 (0%)	7 (0%)	7,731 (36%)	0.41
Myasthenia gravis	3,462 (28%)	5,341 (43%)	295 (2%)	36 (0%)	3,253 (26%)	0.47
Chronic lymphocytic leukaemia	5,733 (40%)	4,721 (33%)	4 (0%)	0 (0%)	3,731 (26%)	0.38
Non-Hodgkin lymphoma	5,830 (41%)	4,245 (30%)	18 (0%)	4 (0%)	4,172 (29%)	0.37
Multifocal motor neuropathy	1,283 (18%)	3,473 (47%)	549 (8%)	18 (0%)	1,985 (27%)	0.59
Multiple myeloma	4,645 (41%)	3,719 (33%)	2 (0%)	1 (0%)	2,939 (26%)	0.37
Polymyositis	1,097 (23%)	2,205 (46%)	222 (5%)	9 (0%)	1,256 (26%)	0.50
Secondary hypogammaglobulinaemia	2,729 (37%)	2,650 (36%)	50 (1%)	5 (0%)	1,948 (26%)	0.39
Kidney transplantation post-transplant	1,324 (37%)	1,349 (38%)	444 (13%)	58 (2%)	376 (11%)	0.56

Note: n is the number of Treatment Episodes

IVIg and SCIg

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. In 2015-16 the NBA established arrangements for supply of the following SCIg 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 addition to the clinical and diagnostic criteria for access to immunoglobulin products, access to SCIg 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. 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. Further work will be undertaken to support supply of SCIg for other pathways of care.

The medical conditions that SCIg 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 SCIg products in 2016-17. Tables 20-22 show patient numbers, grams issued and treatment episodes by medical conditions for IVIg and SCIg products in 2016-17.

Table 17 Patient numbers for products issued by state and territory in 2016-17

	IVIg								SCIg			
State	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Kiovig 10 percent	Octagam 5 percent	Octagam 10 percent	Privigen 10 per cent	SCIg Evogam	SCIg Gammanorm	SCIg Hizentra	Total
NSW	501	707	3,494	2,420	75	95	81	1,515	80	7	118	**6,627**
VIC	112	400	2,361	568	38	25	16	992	56	0	10	**4,134**
QLD	250	345	2,288	443	37	15	24	1,295	58	0	63	**4,428**
SA	10	103	634	205	22	0	0	161	29	0	18	**1,043**
WA	39	132	572	130	<5	0	<5	276	21	0	31	**1,115**
TAS	8	43	163	35	0	0	7	100	<5	0	8	**339**
NT	0	<5	33	13	0	0	0	42	0	0	0	**83**
ACT	<5	6	170	48	0	0	0	84	<5	<5	18	**308**
AUS	**915**	**1,732**	**9,652**	**3,854**	**173**	**135**	**128**	**4,444**	**246**	**10**	**260**	**17,958**

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 2016-17

	IVIg								SCIg			
State	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Kiovig 10 percent	Octagam 5 percent	Octagam 10 percent	Privigen 10 per cent	SCIg Evogam	SCIg Gammanorm	SCIg Hizentra	Total
NSW	153,229	217,040.00	850,740	185,550	4,619	3,764	4,529	499,990	23,687	267	38,275	**1,981,690**
VIC	39,311	96,465.00	520,668	188,738	3,160	1,459	1,175	324,010	7,755	0	2,669	**1,185,409**
QLD	70,492	89,075.00	572,562	227,238	1,448	780	1,050	446,590	18,275	0	21,877	**1,449,386**
SA	2,945	33,390.00	129,435	43,080	1,985	0	0	63,440	4,610	0	8,506	**287,391**
SA	15,091	37,745.00	128,613	49,360	80	0	30	112,785	5,336	0	4,131	**353,171**
TAS	2,751	14,030.00	40,929	14,860	0	0	284	31,020	216	0	2,332	**106,422**
NT	0	625.00	4,452	1,788	0	0	0	16,980	307	0	0	**24,152**
ACT	33	2,780.00	41,544	12,328	0	0	0	38,480	318	40	4,062	**99,583**
AUS	**283,850**	**491,150.00**	**2,288,943**	**722,940**	**11,291**	**6,003**	**7,068**	**1,533,295**	**60,505**	**307**	**81,852**	**5,487,204**

Note: The use of 307 grams of NHIg for one patient is not included in the above table.

Table 19 Treatment episode numbers for products issued by state and territory in 2016-17

	IVIg								SCIg			
State	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Intragam 10	Kiovig 10 percent	Octagam 5 percent	Octagam 10 percent	Privigen 10 per cent	SCIg Evogam	SCIg Gammanorm	SCIg Hizentra	Total
NSW	4,383	5,423	26,856	5,862	122	115	120	12,357	4,198	50	3,998	**63,484**
VIC	1,142	2,481	17,173	6,503	69	38	25	8,400	880	0	237	**36,948**
QLD	2,658	2,630	21,584	8,504	56	26	32	14,173	861	0	951	**51,475**
SA	89	881	4,509	1,488	42	0	0	1,569	418	0	703	**9,699**
WA	441	942	4,250	1,726	<5	0	<5	2,615	446	0	593	**11,016**
TAS	100	363	1,511	536	0	0	7	839	12	0	159	**3,527**
NT	0	22	136	62	0	0	0	325	5	0	0	**550**
ACT	<5	65	1,514	453	0	0	0	875	42	6	342	**3,298**
AUS	**8,814**	**12,807**	**77,533**	**25,124**	**291**	**179**	**185**	**41,153**	**6,862**	**56**	**6,983**	**179,997**

Table 20 Patient numbers for products issued by medical condition in 2016-17

	IVIg								SCIg			
Medical Condition	**Flebogamma 5 percent**	**Flebogamma 10 percent**	**Intragam P**	**Intragam 10**	**Kiovig 10 percent**	**Octagam 5 percent**	**Octagam 10 percent**	**Privigen 10 per cent**	**SCIg Evogam**	**SCIg Gammanorm**	**SCIg Hizentra**	**Total**
Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	48	61	4,126	1,889	22	9	23	346	31	<5	43	**5,217**
Primary immunodeficiency diseases (PID) with antibody deficiency	28	41	1,656	633	5	5	7	91	162	9	160	**2,120**
Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	27	18	546	260	<5	<5	<5	67	29	0	30	**754**
Specific antibody deficiency (SAD)	7	5	270	88	0	<5	0	7	24	0	28	**343**

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 2016-17

	IVIg								SCIg			
Medical Condition	**Flebogamma 5 percent**	**Flebogamma 10 percent**	**Intragam P**	**Intragam 10**	**Kiovig 10 percent**	**Octagam 5 percent**	**Octagam 10 percent**	**Privigen 10 per cent**	**SCIg Evogam**	**SCIg Gammanorm**	**SCIg Hizentra**	**Total**
Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	11,752	12,830	814,995	267,118	819	269	677	97,700	6,241.6	7	15,999	**1,228,405**
Primary immunodeficiency diseases (PID) with antibody deficiency	5,727	6,910	439,440	123,033	378	178	427	23,380	45,365	300	56,410	**701,547**
Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	7,086	4,940	106,029	35,243	65	110	95	20,035	3,999.2	0	3,230	**180,831**
Specific antibody deficiency (SAD)	1,480	645	62,889	18,335	0	28	0	2,170	4,899.2	0	6,069	**96,515**

Table 22 Treatment episodes for product issued by medical condition in 2016-17

	IVIg								SCIg			
Medical Condition	**Flebogamma 5 percent**	**Flebogamma 10 percent**	**Intragam P**	**Intragam 10**	**Kiovig 10 percent**	**Octagam 5 percent**	**Octagam 10 percent**	**Privigen 10 per cent**	**SCIg Evogam**	**SCIg Gammanorm**	**SCIg Hizentra**	**Total**
Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT	438	468	30,526	10,188	32	9	26	3,841	425	<5	1,389	**47,319**
Primary immunodeficiency diseases (PID) with antibody deficiency	250	260	16,127	4,634	10	5	11	719	5,482	55	4,655	**32,203**
Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)	332	207	4,235	1,507	<5	5	<5	797	351	0	278	**7,719**
Specific antibody deficiency (SAD)	55	23	2,594	793	0	<5	0	102	604	0	643	**4,815**

NHIg

In 2013–14, as a result of the introduction of SCIg 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 SCIg 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.

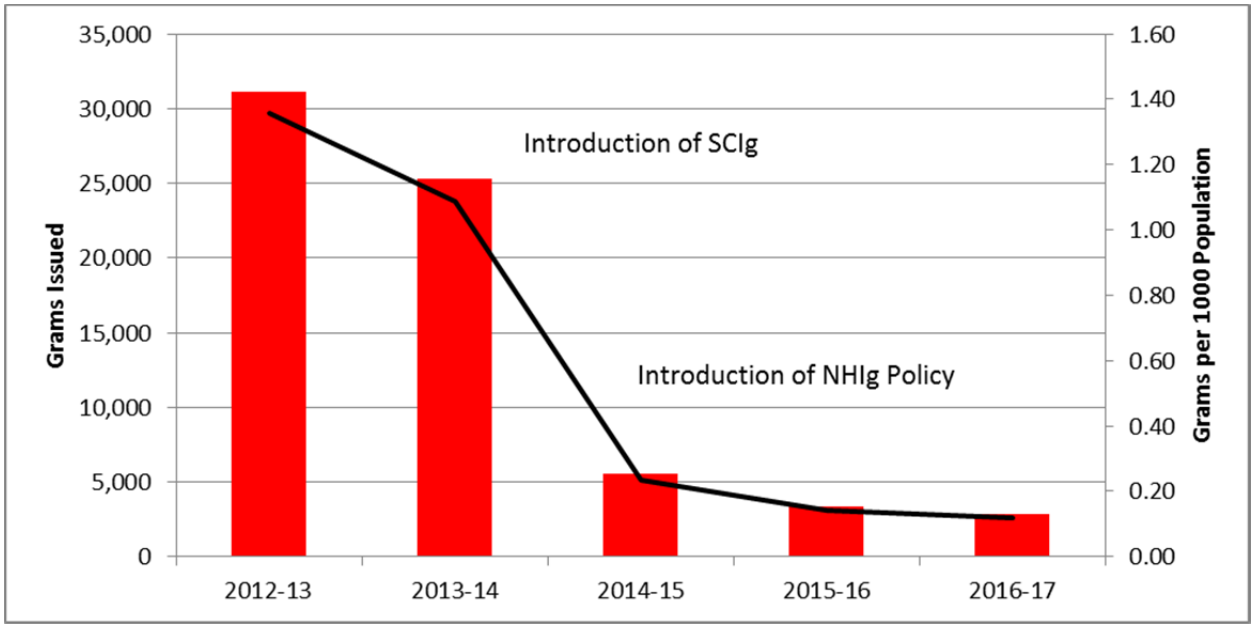


Figure 14 NHIg grams issued and grams issued per 1,000 population

Table 23 NHIg issued from 2012-13 to 2016-17

Product	2012-13	2013-14	2014-15	2015-16	2016-17
Normal Immunoglobulin 2VI - 2ml (grams)	699	654	167	112	43
Normal Immunoglobulin 2VI - 5ml (grams)	30,466	24,649	5,409	3,254	2,806
Total (grams)	**31,165**	**25,303**	**5,576**	**3,366**	**2,849**
Grams Per 1,000 Population	1.36	1.09	0.24	0.14	0.12

Table 24 Grams of NHIg issued by state and territory

	2012-13	2013-14	2014-15	2015-16	2016-17
NSW	9,634	6,915	82	238	351
VIC	6,903	6,747	2,278	489	411
QLD	1,640	2,774	1,472	1,134	401
SA	6,543	4,431	936	980	1,164
WA	5,261	3,458	59	38	48
TAS	344	272	154	43	35
NT	24	191	35	12	15
ACT	816	514	480	432	424
OTHER[7]	0	0	80	0	0
Australia	**31,1655**	**25,302**	**5,576**	**3,366**	**2,849**

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

Per 1,000 Population	2012-13	2013-14	2014-15	2015-16	2016-17
NSW	1.31	0.93	0.01	0.03	0.05
VIC	1.21	1.16	0.38	0.08	0.07
QLD	0.36	0.59	0.31	0.24	0.08
SA	3.93	2.64	0.55	0.57	0.68
WA	2.14	1.38	0.02	0.01	0.02
TAS	0.67	0.53	0.30	0.08	0.07
NT	0.10	0.79	0.14	0.05	0.06
ACT	2.15	1.33	1.22	1.08	1.04
Australia	**1.36**	**1.09**	**0.24**	**0.14**	**0.12**

[7] Other here covers NHIg 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 2016-17	Intragam P (6% 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
2013-14 to 2014-15	Octagam (5% intravenous) Gammanorm (16% subcutaneous) Flebogamma (5% intravenous) Kiovig (10% intravenous[2])	Octapharma Grifols Baxter Healthcare

Year	Imported products supplied	Supplier
2015-16	Octagam (5% intravenous) Gammanorm (16% subcutaneous)	Octapharma
	Kiovig (10% intravenous[2])	Baxter Healthcare
	Flebogamma (5% and 10% intravenous)	Grifols
	Privigen (10% intravenous) Hizentra (20% SCIg)	CSL Behring
2016-17	Flebogamma (5% and 10% intravenous)	Grifols
	Privigen (10% intravenous) Hizentra (20% subcutaneous)	CSL Behring

Notes

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
HSCT	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	Clinical conditions are categorised according to the quality of the available evidence and whether immunoglobulin treatment is considered beneficial. Specific conditions (previously known as primary diagnosis) exist 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
Criteria for the clinical use of intravenous immunoglobulin in Australia (*the *Criteria)	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 *Criteria*
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 2016-17

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
Chapter 5										
Chronic inflammatory demyelinating polyneuropathy	Patients	912	518	644	84	159	38	11	37	2,379
	Average Age	64	63	62	66	61	61	59	63	63
	Average Weight	82	83	84	82	81	84	92	80	83
	Grams	420,647	259,475	296,522	39,123	115,583	20,727	5,876	13,629	1,171,581
	Grams/Episode	41	38	32	37	45	33	67	33	38
	Grams per 1,000 Population	54	42	61	23	45	40	24	33	48
Chronic lymphocytic leukaemia	Patients	581	328	369	105	91	28	10	25	1,526
	Average Age	72	73	72	70	70	68	61	75	72
	Average Weight	78	76	77	80	76	86	73	75	78
	Grams	146,919	77,459	104,910	22,241	14,631	6,750	2,544	7,675	383,127
	Grams/Episode	29	26	24	25	24	29	28	25	27
	Grams per 1,000 Population	19	12	21	13	6	13	10	19	16
Common variable immunodeficiency disease (CVID)	Patients	846	309	355	116	104	29	<5	68	1,808
	Average Age	53	49	54	52	42	50	51	48	51
	Average Weight	73	70	73	69	76	70	86	74	72
	Grams	293,756	101,892	128,790	33,029	30,844	8,670	1,425	20,221	618,627
	Grams/Episode	21	25	26	22	19	24	49	22	22
	Grams per 1,000 Population	38	16	26	19	12	17	6	50	25
Dermatomyositis	Patients	80	53	44	12	12	5		13	218
	Average Age	50	49	52	54	41	49		51	50
	Average Weight	66	64	73	79	96	82		68	70

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	26,538	16,932	20,728	5,665	5,161	3,100		4,325	82,448
	Grams/Episode	35	40	36	33	32	56		34	36
	Grams per 1,000 Population	3	3	4	3	2	6		11	3
Guillain–Barré syndrome	Patients	250	155	150	43	59	16	<5	14	690
	Average Age	54	53	51	64	55	53	7	44	54
	Average Weight	82	79	78	75	74	73	25	87	79
	Grams	47,311	23,777	22,777	6,599	8,174	2,520	150	2,877	114,184
	Grams/Episode	34	42	36	36	31	35	30	39	36
	Grams per 1,000 Population	6	4	5	4	3	5	1	7	5
Inclusion body myositis	Patients	44	55	34	15	<5	<5	<5	<5	152
	Average Age	74	69	66	71	68	78		75	70
	Average Weight	80	82	82	79	77	71		80	81
	Grams	16,642	27,237	13,976	5,208	402	356		30	63,850
	Grams/Episode	35	37	36	31	27	32		30	35
	Grams per 1,000 Population	2	4	3	3	0	1		0	3
ITP associated with HIV	Patients		<5	<5	<5					7
	Average Age		33	54	38					40
	Average Weight		78	73	72					75
	Grams		235	225	189					649
	Grams/Episode		34	38	38					36
	Grams per 1,000 Population		0	0	0					0
ITP in pregnancy	Patients	34	19	22	8	7		<5	<5	92
	Average Age	30	32	29	31	30		19	30	30
	Average Weight	79	76	72	87	67		56	62	76
	Grams	6,514	2,083	4,112	1,447	1,174		57	605	15,992
	Grams/Episode	61	56	53	48	59		57	43	56

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams per 1,000	1	0	1	1	0		0	1	1
ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP, concurrent risk factors)	Patients	115	90	109	28	41	7	<5	<5	396
	Average Age	62	60	63	61	58	63	58	58	61
	Average Weight	81	78	79	77	82	93	87	69	80
	Grams	21,221	10,247	21,261	4,272	4,871	823	387	787	63,868
	Grams/Episode	49	49	41	41	52	69	65	49	46
	Grams per 1,000 Population	3	2	4	2	2	2	2	2	3
ITP refractory acute	Patients	112	150	112	48	41	11	<5	6	482
	Average Age	60	60	60	61	61	70	51	73	60
	Average Weight	75	77	79	82	83	80	73	80	78
	Grams	20,250	18,496	19,691	9,934	4,004	1,049	302	1,924	75,648
	Grams/Episode	50	55	41	51	59	52	76	53	49
	Grams per 1,000 Population	3	3	4	6	2	2	1	5	3
ITP with life-threatening haemorrhage or potential life-threatening haemorrhage	Patients	158	79	82	41	19	8	<5	5	395
	Average Age	56	61	56	58	65	65	64	68	58
	Average Weight	74	74	78	78	82	86	74	84	76
	Grams	25,392	9,395	10,950	6,146	1,575	809	353	1,092	55,712
	Grams/Episode	46	52	38	62	53	62	39	64	47
	Grams per 1,000 Population	3	2	2	4	1	2	1	3	2
Kawasaki disease	Patients	173	123	53	18	31	6	<5	<5	411
	Average Age	4	3	3	2	3	2	5	5	3
	Average Weight	17	17	16	14	16	15	19	25	17
	Grams	6,751	4,748	1,985	532	1,253	265	153	152	15,838
	Grams/Episode	31	24	28	17	26	29	38	51	27
	Grams per 1,000 Population	1	1	0	0	0	1	1	0	1
Lambert–Eaton myasthenic	Patients	6	7	12		<5				26

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
syndrome	Average Age	60	66	69		75				67
	Average Weight	75	88	83		65				82
	Grams	2,962	3,134	4,260		650				11,006
	Grams/Episode	39	40	35		41				38
	Grams per 1,000 Population	0	1	1		0				0
Multifocal motor neuropathy with or without persistent conduction block	Patients	185	101	126	44	46	13	<5	13	527
	Average Age	59	57	58	60	59	61	59	56	58
	Average Weight	80	81	80	85	83	81	91	87	81
	Grams	104,294	65,053	71,225	34,835	36,448	7,053	4,890	7,345	331,142
	Grams/Episode	45	44	35	49	53	34	60	47	43
	Grams per 1,000 Population	13	10	15	20	14	14	20	18	14
Multiple myeloma	Patients	536	259	376	58	38	33	<5	9	1,302
	Average Age	71	70	70	66	66	65	60	72	70
	Average Weight	77	79	76	87	84	84	76	70	78
	Grams	114,933	54,193	104,657	12,733	6,450	9,544	262	1,673	304,444
	Grams/Episode	30	27	24	23	25	27	22	22	27
	Grams per 1,000 Population	15	9	21	7	3	18	1	4	12
Myasthenia gravis	Patients	353	291	311	41	69	13	<5	18	1,090
	Average Age	61	62	61	64	59	49	37	56	61
	Average Weight	81	79	82	82	78	68	80	85	81
	Grams	144,019	119,154	140,148	11,818	27,216	4,992	35	8,966	456,346
	Grams/Episode	37	36	31	29	33	28	35	40	34
	Grams per 1,000 Population	18	19	29	7	11	10	0	22	19
Neonatal haemochromatosis	Patients	<5	<5		<5	<5				11
	Average Age	26	24		0	28				22
	Average Weight	69	62		3	107				60

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	5,119	3,711		8	800				9,638
	Grams/Episode	80	79		4	100				80
	Grams per 1,000 Population	1	1		0	0				0
Non-Hodgkin lymphoma	Patients	453	297	523	107	53	36	5	15	1,483
	Average Age	68	68	67	68	67	66	60	63	67
	Average Weight	76	79	77	77	80	79	83	73	77
	Grams	108,168	70,601	149,876	20,385	10,221	9,384	1,010	3,430	373,074
	Grams/Episode	29	27	24	22	26	23	29	24	26
	Grams per 1,000 Population	14	11	31	12	4	18	4	8	15
Other primary immunodeficiency	Patients	43	34	14	12	9	<5	<5	<5	120
	Average Age	42	47	25	33	49	31	47	26	40
	Average Weight	53	65	48	52	81	57	76	66	60
	Grams	12,221	10,218	2,623	2,722	2,028	869	688	694	32,061
	Grams/Episode	12	21	17	16	16	19	25	12	15
	Grams per 1,000 Population	2	2	1	2	1	2	3	2	1
Other relevant haematological malignancies	Patients	277	81	128	26	33	9	<5	6	555
	Average Age	56	54	60	67	31	66	66	64	56
	Average Weight	70	67	74	71	64	80	83	77	71
	Grams	46,580	14,168	36,122	5,712	4,195	2,356	205	1,376	110,714
	Grams/Episode	27	25	23	19	19	25	29	26	24
	Grams per 1,000 Population	6	2	7	3	2	5	1	3	5
Polymyositis	Patients	186	75	109	43	22	<5	<5	7	446
	Average Age	62	58	61	64	57	79	50	59	61
	Average Weight	77	84	81	77	74	79	91	84	80
	Grams	65,801	35,073	49,528	17,934	8,625	2,010	505	3,410	182,885
	Grams/Episode	35	43	34	35	30	44	63	45	36

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams per 1,000 Population	8	6	10	10	3	4	2	8	8
Post-haemopoietic stem cell transplantation	Patients	164	86	80	22	17	5	<5	<5	375
	Average Age	44	37	46	43	36	40	59	32	42
	Average Weight	70	62	68	73	64	76	50	69	67
	Grams	22,389	12,758	15,733	3,293	1,552	1,020	80	224	57,046
	Grams/Episode	28	21	23	19	20	18	20	32	24
	Grams per 1,000 Population	3	2	3	2	1	2	0	1	2
Severe combined immunodeficiency (SCID)	Patients	11	10	19	<5	<5				43
	Average Age	21	17	20	16	23				20
	Average Weight	38	40	40	41	70				41
	Grams	2,307	2,256	4,213	113	755				9,643
	Grams/Episode	12	15	18	16	31				16
	Grams per 1,000 Population	0	0	1	0	0				0
Stiff person syndrome	Patients	42	7	20	<5	5	<5		<5	77
	Average Age	59	53	58	61	58	36		31	56
	Average Weight	82	72	79	71	77	70		69	78
	Grams	20,361	3,653	11,012	285	2,643	1,989		240	40,182
	Grams/Episode	42	44	36	26	34	49		22	40
	Grams per 1,000 Population	3	1	2	0	1	4		1	2
Wiskott–Aldrich syndrome	Patients	<5	<5			<5				<5
	Average Age	32	15			33				28
	Average Weight	60	52			81				68
	Grams	66	168			713				947
	Grams/Episode	33	24			26				26
	Grams per 1,000 Population	0	0			0				0
X-linked	Patients	39	48	18	6	6	<5	<5	<5	121

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
agammaglobulinaemia	Average Age	32	33	27	20	19	53	29	8	30
	Average Weight	60	60	59	60	52	78	52	25	59
	Grams	12,140	16,544	6,582	2,106	1,659	60	741	437	40,269
	Grams/Episode	26	21	27	29	13	30	23	9	23
	Grams per 1,000 Population	2	3	1	1	1	0	3	1	2
Chapter 5 Total	Patients	5,504	3,131	3,662	866	853	264	57	252	14,488
	Average Age	59	59	61	61	55	60	52	56	60
	Average Weight	75	75	77	77	76	78	75	76	76
	Grams	1,693,297	962,655	1,241,902	246,326	291,624	84,344	19,662	81,108	4,620,916
	Grams/Episode	31	33	28	30	34	30	44	29	31
	Grams per 1,000 Population	217	154	254	143	114	162	80	199	190
Chapter 6										
Acute disseminated encephalomyelitis	Patients	30	15	27	<5	<5	5			81
	Average Age	37	24	24	0	13	29			28
	Average Weight	59	46	57	9	45	68			55
	Grams	5,974	2,469	4,134	20	361	682			13,640
	Grams/Episode	33	31	34	10	18	36			32
	Grams per 1,000 Population	1	0	1	0	0	1			1
Autoimmune haemolytic anaemia	Patients	37	35	22	7	<5	<5	<5		107
	Average Age	53	70	63	73	59	51	65		63
	Average Weight	68	79	74	71	76	91	59		74
	Grams	6,270	4,456	3,048	3,375	518	255	45		17,966
	Grams/Episode	42	48	36	32	18	28	45		38
	Grams per 1,000 Population	1	1	1	2	0	0	0		1
Bullous pemphigoid	Patients	21	6	11	<5	<5	<5			43

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Average Age	70	69	68	75	64	84			69
	Average Weight	84	76	89	132	68	70			83
	Grams	14,149	3,053	7,478	400	542	560			26,182
	Grams/Episode	47	54	46	67	24	62			47
	Grams per 1,000 Population	2	0	2	0	0	1			1
Churg-Strauss syndrome	Patients					<5				<5
	Average Age					63				63
	Average Weight					80				80
	Grams					185				185
	Grams/Episode					23				23
	Grams per 1,000 Population					0				0
Cicatricial pemphigoid/ mucous membrane pemphigoid	Patients	<5	<5	7	<5	<5	<5		<5	21
	Average Age	61	73	70	72	47	45		48	65
	Average Weight	82	87	82	72	87	50		97	83
	Grams	3,665	4,258	3,202	2,295	1,728	470		3,145	18,763
	Grams/Episode	80	71	39	34	22	78		87	50
	Grams per 1,000 Population	0	1	1	1	1	1		8	1
Evans syndrome	Patients	<5	10	<5	<5					15
	Average Age	17	58	62	26					51
	Average Weight	47	78	77	66					74
	Grams	105	1,062	320	181					1,668
	Grams/Episode	26	59	160	26					54
	Grams per 1,000 Population	0	0	0	0					0
Feto-maternal/neonatal alloimmune thrombocytopenia	Patients	5	<5	<5	<5	<5			<5	19
	Average Age	29	32	23	26	34			0	27
	Average Weight	79	78	50	76	86			3	70

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
(Antenatal)	Grams	5,717	2,139	1,278	3,833	1,713			9	14,688
	Grams/Episode	99	53	49	71	82			3	73
	Grams per 1,000 Population	1	0	0	2	1			0	1
Feto-maternal/neonatal alloimmune thrombocytopenia (Neonatal)	Patients	15	5	<5	<5	<5	<5		<5	31
	Average Age	2	0	7	0	0	0		0	2
	Average Weight	8	3	17	3	2	2		2	7
	Grams	691	15	1,209	16	3	3		3	1,940
	Grams/Episode	22	3	47	2	3	3		3	26
	Grams per 1,000 Population	0	0	0	0	0	0		0	0
Haemophagocytic syndrome	Patients	15	14	9	<5	<5		<5		44
	Average Age	42	44	52	46	45		38		45
	Average Weight	60	68	63	80	58		59		64
	Grams	1,971	2,192	1,403	40	417		152		6,175
	Grams/Episode	47	52	31	40	52		15		42
	Grams per 1,000 Population	0	0	0	0	0		1		0
IgG subclass deficiency (existing authorisation)	Patients	11	21	<5	<5	<5	<5			42
	Average Age	68	65	82	65	71	56			65
	Average Weight	99	74	60	77	186	67			84
	Grams	4,491	7,363	51	1,075	1,106	1,679			15,764
	Grams/Episode	31	23	10	24	23	22			25
	Grams per 1,000 Population	1	1	0	1	0	3			1
IgM para-proteinaemic neuropathy	Patients	38	11	34	6	5	6	<5	<5	102
	Average Age	73	69	67	64	72	70	54	70	69
	Average Weight	81	81	83	73	73	82	98	65	81
	Grams	15,511	3,630	12,637	1,350	3,809	1,427	295	155	38,814
	Grams/Episode	38	30	29	30	54	46	74	52	35

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams per 1,000 Population	2	1	3	1	1	3	1	0	2
ITP in children	Patients	25	40	50	19	8	<5	<5	<5	149
	Average Age	6	6	7	8	6	5	13	6	7
	Average Weight	29	29	30	36	29	21	70	26	30
	Grams	3,621	2,192	2,116	2,239	240	252	70	147	10,875
	Grams/Episode	33	21	22	32	24	11	70	16	26
	Grams per 1,000 Population	0	0	0	1	0	0	0	0	0
Kidney transplantation post-transplant	Patients	72	248	64	20	24	12	<5	<5	442
	Average Age	44	48	50	45	40	44	41	24	47
	Average Weight	72	78	81	77	72	78	90	65	78
	Grams	11,539	72,031	21,880	2,561	3,742	5,311	239	263	117,564
	Grams/Episode	23	32	19	27	39	44	27	29	28
	Grams per 1,000 Population	1	12	4	1	1	10	1	1	5
Kidney transplantation pre-transplant	Patients	44	19	7	5	<5	<5			79
	Average Age	48	50	45	57	45	39			49
	Average Weight	75	81	88	85	84	55			78
	Grams	2,965	1,010	563	245	392	255			5,430
	Grams/Episode	39	11	16	41	28	28			23
	Grams per 1,000 Population	0	0	0	0	0	0			0
Microscopic polyangiitis	Patients		<5	<5		<5		<5		7
	Average Age		50	30		35		41		40
	Average Weight		123	70		60		83		91
	Grams		456	146		316		530		1,448
	Grams/Episode		46	24		21		44		34
	Grams per 1,000 Population		0	0		0		2		0
Multiple sclerosis - severe	Patients	7	<5	9						20

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
relapse with no response to high dose methylprednisolone	Average Age	49	52	49						50
	Average Weight	76	70	79						76
	Grams	1,618	777	1,491						3,886
	Grams/Episode	28	32	39						33
	Grams per 1,000 Population	0	0	0						0
Multiple sclerosis in pregnancy and the immediate post-partum period	Patients	<5		<5						<5
	Average Age	34		27						29
	Average Weight	63		77						72
	Grams	125		118						243
	Grams/Episode	25		39						30
	Grams per 1,000	0		0						0
Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed	Patients	19	<5	<5					<5	25
	Average Age	40	42	59					45	43
	Average Weight	84	90	87					60	84
	Grams	7,076	767	835					200	8,878
	Grams/Episode	33	28	38					20	33
	Grams per 1,000 Population	1	0	0					0	0
Opsoclonus myoclonus ataxia	Patients	13	7	<5	<5	<5				28
	Average Age	14	25	2	50	2				16
	Average Weight	30	34	15	71	12				30
	Grams	2,005	1,032	487	1,355	227				5,105
	Grams/Episode	20	19	13	65	8				21
	Grams per 1,000 Population	0	0	0	1	0				0
Pemphigus foliaceus	Patients	<5	<5	<5						6
	Average Age	65	55	55						56
	Average Weight	62	92	85						84

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	320	1,575	1,195						3,090
	Grams/Episode	40	87	33						50
	Grams per 1,000 Population	0	0	0						0
Pemphigus vulgaris	Patients	12	<5	7		<5			<5	24
	Average Age	59	35	59		55			41	56
	Average Weight	88	70	88		111			70	88
	Grams	7,773	1,558	3,490		1,824			278	14,923
	Grams/Episode	61	71	45		47			35	54
	Grams per 1,000 Population	1	0	1		1			1	1
Post-tranfusion purpura	Patients					<5				<5
	Average Age					84				84
	Average Weight					58				58
	Grams					60				60
	Grams/Episode					60				60
	Grams per 1,000 Population					0				0
PR3 or MPO ANCA-positive idiopathic rapidly progressive glomerulonephritis	Patients	<5	<5	6						11
	Average Age	64	47	72						68
	Average Weight	89	200	81						91
	Grams	340	198	2,549						3,087
	Grams/Episode	34	99	45						45
	Grams per 1,000 Population	0	0	1						0
Secondary hypogammaglobulinaemia (excluding haematological malignancies)	Patients	287	180	230	15	47	16		10	781
	Average Age	56	53	57	51	42	61	59	63	55
	Average Weight	72	64	74	56	63	80	100	63	70
	Grams	68,256	34,926	60,414	3,298	7,205	4,646	33	2,055	180,831
	Grams/Episode	27	21	23	20	16	27	33	18	23

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams per 1,000 Population	9	6	12	2	3	9	0	5	7
Solid organ - heart	Patients	10	<5	<5		<5				14
	Average Age	48	13	54		51				44
	Average Weight	81	42	68		65				73
	Grams	1,494	221	445		120				2,279
	Grams/Episode	20	44	23		120				23
	Grams per 1,000 Population	0	0	0		0				0
Solid organ - heart/lung	Patients	5	<5	<5		<5				10
	Average Age	52	19	43		33				36
	Average Weight	70	42	59		84				62
	Grams	1,185	176	54		140				1,555
	Grams/Episode	31	10	27		70				26
	Grams per 1,000 Population	0	0	0		0				0
Solid organ - liver	Patients	<5		<5	<5					6
	Average Age	26		24	60					30
	Average Weight	40		76	74					55
	Grams	207		221	825					1,253
	Grams/Episode	35		6	25					16
	Grams per 1,000 Population	0		0	0					0
Solid organ - lung	Patients	22	66	6	<5	<5	<5			104
	Average Age	44	51	38	51	50	48			49
	Average Weight	58	67	57	58	56	71			64
	Grams	3,123	9,055	531	855	346	735			14,645
	Grams/Episode	27	22	12	20	38	27			23
	Grams per 1,000 Population	0	1	0	0	0	1			1
Solid organ - other	Patients		<5							<5

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Average Age		37							37
	Average Weight		59							59
	Grams		862							862
	Grams/Episode		57							57
	Grams per 1,000 Population		0							0
Specific antibody deficiency	Patients	117	44	49	20	67	<5		7	301
	Average Age	52	55	51	55	46	51	11	40	51
	Average Weight	71	69	71	71	73	84	27	72	71
	Grams	32,161	11,133	13,684	5,421	15,805	214	120	2,213	80,751
	Grams/Episode	18	23	23	19	17	15	10	19	19
	Grams per 1,000 Population	4	2	3	3	6	0	0	5	3
Staphylococcal TSS	Patients	13	11	5	<5	5	<5			39
	Average Age	40	50	41	26	39	8			39
	Average Weight	79	76	64	65	72	43			71
	Grams	1,976	1,330	539	497	550	209			5,101
	Grams/Episode	94	89	67	41	55	52			73
	Grams per 1,000 Population	0	0	0	0	0	0			0
Streptococcal TSS	Patients	42	51	19	10	11	<5	<5	<5	141
	Average Age	46	42	42	38	50	54	45	50	44
	Average Weight	80	73	74	63	72	105	76	100	75
	Grams	6,346	6,114	2,327	881	1,548	200	359	604	18,377
	Grams/Episode	75	68	80	42	77	200	51	151	72
	Grams per 1,000 Population	1	1	0	1	1	0	1	1	1
Toxic epidermal necrolysis/Stevens–Johnson syndrome	Patients	25	22		6	<5	<5	<5	<5	64
	Average Age	51	37		54	59	37	50	34	45
	Average Weight	67	68		75	84	66	65	85	69

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	3,483	3,219		846	290	378	502	341	9,059
	Grams/Episode	54	59		45	73	95	84	43	56
	Grams per 1,000 Population	0	1		0	0	1	2	1	0
Wegener granulomatosis	Patients		<5	<5	<5					<5
	Average Age		73	61	30					49
	Average Weight		65	100	78					80
	Grams		25	180	353					558
	Grams/Episode		25	45	27					31
	Grams per 1,000 Population		0	0	0					0
Chapter 6 Total	Patients	885	812	584	137	203	64	17	35	2,722
	Average Age	50	49	52	46	44	49	43	44	49
	Average Weight	70	69	72	64	70	72	72	66	70
	Grams	214,152	179,289	148,022	31,958	43,184	17,276	2,345	9,411	645,636
	Grams/Episode	30	29	25	28	22	33	37	29	28
	Grams per 1,000 Population	27	29	30	19	17	33	10	23	26
Chapter 7										
Acute leukaemia in children	Patients		9	7		<5				17
	Average Age		9	8		6				9
	Average Weight		32	38		22				33
	Grams		947	112		58				1,117
	Grams/Episode		39	11		10				28
	Grams per 1,000 Population		0	0		0				0
Autoimmune neutropenia	Patients	<5	5	<5		<5		<5	v	14
	Average Age	52	57	48		45		48	59	52
	Average Weight	53	72	73		67		119	41	73

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	665	514	475		130		1,209	90	3,083
	Grams/Episode	39	51	30		22		71	45	45
	Grams per 1,000 Population	0	0	0		0		5	0	0
Autoimmune uveitis	Patients	<5	<5							<5
	Average Age	49	59							57
	Average Weight	95	74							79
	Grams	235	1,012							1,247
	Grams/Episode	34	63							54
	Grams per 1,000 Population	0	0							0
Catastrophic antiphospholipid syndrome	Patients	8	<5	<5		<5				16
	Average Age	37	38	67		45				45
	Average Weight	75	113	74		86				83
	Grams	1,617	579	675		280				3,151
	Grams/Episode	44	53	34		56				43
	Grams per 1,000 Population	0	0	0		0				0
Cerebellar degeneration	Patients	<5	7	6	<5	<5	<5		<5	21
	Average Age	70	60	64	55	65	64		48	62
	Average Weight	63	81	65	75	70	83		74	73
	Grams	310	1,135	1,310	60	1,365	540		148	4,868
	Grams/Episode	28	26	21	30	65	30		30	30
	Grams per 1,000 Population	0	0	0	0	1	1		0	0
Coagulation factor inhibitors	Patients	<5	<5	5	<5	<5				16
	Average Age	71	75	55	68	55				63
	Average Weight	54	65	102	67	50				75
	Grams	1,319	120	3,610	1,075	100				6,224
	Grams/Episode	47	60	74	31	50				54

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams per 1,000 Population	0	0	1	1	0				0
Devic disease (neuromyelitis optica)	Patients	24	<5	5	5	<5	<5	<5		40
	Average Age	50	30	50	57	57	6	45		49
	Average Weight	70	59	66	68	87	18	75		69
	Grams	7,807	790	1,385	475	1,800	125	215		12,597
	Grams/Episode	35	38	20	25	69	16	54		34
	Grams per 1,000 Population	1	0	0	0	1	0	1		1
Diabetic amyotrophy	Patients	<5	6	6						15
	Average Age	63	71	63						65
	Average Weight	78	76	75						76
	Grams	1,191	1,496	1,160						3,847
	Grams/Episode	26	42	31						33
	Grams per 1,000 Population	0	0	0						0
Epidermolysis bullosa acquisita	Patients		<5			<5			<5	5
	Average Age		72			69			47	64
	Average Weight		79			126			81	99
	Grams		474			3,190			1,800	5,464
	Grams/Episode		95			69			58	67
	Grams per 1,000 Population		0			1			4	0
Epilepsy (rare childhood cases)	Patients	5	5	<5		<5	<5			17
	Average Age	15	13	16		8	7			13
	Average Weight	45	51	47		27	30			45
	Grams	843	1,882	941		400	60			4,126
	Grams/Episode	30	38	24		33	30			31
	Grams per 1,000 Population	0	0	0		0	0			0
Graves ophthalmopathy	Patients			<5		<5				<5

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Average Age			52		55				53
	Average Weight			76		47				70
	Grams			1,360		95				1,455
	Grams/Episode			40		32				39
	Grams per 1,000 Population			0		0				0
Haemolytic disease of the newborn	Patients	25	23	<5	10	9	<5	<5	8	80
	Average Age	0	0	22	0	7	0	0	0	1
	Average Weight	3	3	49	3	25	4	2	3	7
	Grams	83	79	81	32	1,400	6	3	45	1,727
	Grams/Episode	3	3	20	3	58	3	3	3	16
	Grams per 1,000 Population	0	0	0	0	1	0	0	0	0
Haemolytic transfusion reaction	Patients	<5			<5					<5
	Average Age	45			0					23
	Average Weight	60			3					32
	Grams	180			3					183
	Grams/Episode	60			3					46
	Grams per 1,000 Population	0			0					0
Hashimoto encephalopathy	Patients	8	<5	<5		5				18
	Average Age	42	44	78		47				46
	Average Weight	77	79	78		65				74
	Grams	2,940	1,050	446		1,993				6,428
	Grams/Episode	30	35	25		34				31
	Grams per 1,000 Population	0	0	0		1				0
Limbic encephalitis	Patients	11	12	16	<5	7	<5	<5	<5	53
	Average Age	48	48	47	72	40	17	73	58	49
	Average Weight	68	86	76	77	62	68	56	56	74

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	2,240	2,179	2,416	495	779	135	110	252	8,605
	Grams/Episode	30	36	32	26	25	135	37	18	31
	Grams per 1,000 Population	0	0	0	0	0	0	0	1	0
Limbic encephalitis, nonparaneoplastic	Patients	87	63	102	7	12	<5	<5	<5	279
	Average Age	49	51	44	39	59	43	43	28	47
	Average Weight	72	70	75	68	70	70	54	67	72
	Grams	19,542	12,006	27,635	967	3,863	952	220	1,261	66,445
	Grams/Episode	30	34	29	26	38	29	22	50	31
	Grams per 1,000 Population	3	2	6	1	2	2	1	3	3
Myocarditis in children	Patients	<5	18	<5	<5	<5		<5		29
	Average Age	3	2	1	5	1		0		2
	Average Weight	11	11	7	18	8		2		11
	Grams	69	444	24	62	30		6		635
	Grams/Episode	14	14	12	21	15		6		14
	Grams per 1,000 Population	0	0	0	0	0		0		0
PANDAS/tic disorders	Patients	13	<5	5	<5	<5				23
	Average Age	9	14	10	18	13				11
	Average Weight	33	48	50	60	60				41
	Grams	2,158	2,196	1,283	125	132				5,893
	Grams/Episode	41	31	31	25	33				34
	Grams per 1,000 Population	0	0	0	0	0				0
Potassium channel antibody-associated encephalopathy	Patients	15	<5	<5	<5	<5	<5			27
	Average Age	47	57	55	60	59	51			52
	Average Weight	75	74	73	53	72	87			75
	Grams	6,098	608	1,104	608	1,470	1,425			11,312
	Grams/Episode	38	32	53	36	36	27			36

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams per 1,000 Population	1	0	0	0	1	3			0
Pure red cell aplasia	Patients	12	13	12		<5	<5			39
	Average Age	56	34	51		88	48			48
	Average Weight	74	51	76		82	88			69
	Grams	3,060	825	3,292		80	1,560			8,816
	Grams/Episode	36	36	38		80	40			38
	Grams per 1,000 Population	0	0	1		0	3			0
Pyoderma gangrenosum	Patients	6	12	<5		<5	<5			23
	Average Age	67	59	60	53	47	28			59
	Average Weight	79	97	68	69	70	100			88
	Grams	2,500	5,978	200	690	670				10,038
	Grams/Episode	69	52	40	57	42	0			54
	Grams per 1,000 Population	0	1	0	0	0				0
Rasmussen Syndrome	Patients	13	<5	<5	<5				<5	22
	Average Age	34	44	39	34				36	37
	Average Weight	72	72	68	137				57	72
	Grams	3,847	1,370	1,146	660				789	7,812
	Grams/Episode	43	31	29	47				25	36
	Grams per 1,000 Population	0	0	0	0				2	0
Scleromyxedema	Patients	5	<5	<5	<5	<5				15
	Average Age	66	64	68	72	36				62
	Average Weight	75	75	80	57	84				73
	Grams	2,731	3,445	960	2,190	280				9,606
	Grams/Episode	45	37	69	35	40				41
	Grams per 1,000 Population	0	1	0	1	0				0
Sjögren's syndrome	Patients	13	<5	5	<5				<5	25

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Average Age	57	81	46	55				52	56
	Average Weight	72	67	72	72				75	72
	Grams	4,510	527	1,460	1,511				2,920	10,928
	Grams/Episode	33	20	18	47				57	34
	Grams per 1,000 Population	1	0	0	1				7	0
Subacute sensory neuropathy	Patients	<5	7	7	<5	<5				21
	Average Age	63	64	55	64	65		49		61
	Average Weight	55	78	86	72	62		80		75
	Grams	955	872	2,260	428	250		320		5,085
	Grams/Episode	26	42	32	27	36		80		33
	Grams per 1,000 Population	0	0	0	0	0		1		0
Susac syndrome	Patients	9		5						13
	Average Age	49		47						48
	Average Weight	87		86						86
	Grams	7,746		2,776						10,522
	Grams/Episode	61		39						53
	Grams per 1,000 Population	1		1						0
Systemic capillary leak syndrome	Patients	7	<5	5				<5	<5	16
	Average Age	39	56	33				0	66	40
	Average Weight	68	82	72				1	80	69
	Grams	1,599	2,200	3,352				3	1,760	8,914
	Grams/Episode	39	71	42				3	88	52
	Grams per 1,000 Population	0	0	1				0	4	0
Chapter 7 Total	Patients	275	202	200	44	61	15	9	21	824
	Average Age	42	42	45	42	44	38	36	34	42
	Average Weight	64	60	73	53	62	68	58	47	64

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams	74,241	42,725	59,462	9,379	18,364	4,802	2,086	9,064	220,122
	Grams/Episode	36	37	31	33	44	31	51	47	35
	Grams per 1,000 Population	10	7	12	5	7	9	8	22	9
Chapter 8										
Aplastic anaemia/pancytopenia	Patients		<5							<5
	Average Age		79							79
	Average Weight		78							78
	Grams		78							78
	Grams/Episode		78							78
	Grams per 1,000 Population		0							0
Sepsis	Patients		<5							<5
	Average Age		41							41
	Average Weight		82							82
	Grams		663							663
	Grams/Episode		133							133
	Grams per 1,000 Population		0							0
Chapter 8 Total	Patients		5							5
	Average Age		49							49
	Average Weight		82							82
	Grams		741							741
	Grams/Episode		124							124
	Grams per 1,000 Population		0							0
chorea	Patients							<5		<5
	Average Age							10		10
	Average Weight							32		32

Specific Condition		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	AUS
	Grams							60		60
	Grams/Episode							60		60
	Grams per 1,000 Population							0		0
contact with a measles patient	Patients				<5					<5
	Average Age				81					81
	Average Weight				92					92
	Grams				36					36
	Grams/Episode				36					36
	Grams per 1,000 Population				0					0
Total	Patients	6,627	4,134	4,428	1,043	1,115	339	83	308	17,958
	Average Age	57	56	60	58	52	57	49	54	57
	Average Weight	74	73	77	74	74	77	73	73	75
	Grams	1,981,690	1,185,409	1,449,386	287,699	353,171	106,422	24,152	99,583	5,487,511
	Grams/Episode	31	32	28	30	32	30	44	30	30
	Grams per 1,000 Population	254	190	297	168	138	205	98	245	225

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
2006-07	Imported Ig	103,270	88,398	79,393	18,375	20,577	11,065		7170
	Domestic Ig	493,172	407,244	337,301	92,958	155,821	50,583	6,732	26,470
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

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

Appendix G – System Source for Tables and Figures