NATIONAL BLOOD AUTHORITY
AUSTRALIA

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

Annual Report 2015-16

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Introduction

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 is a blood product derived from donated human blood. 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 2015-16, 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 National Blood Authority (NBA). The NBA's role is to coordinate national supply and demand planning for blood and blood products including supply risk management; purchasing blood and blood products on behalf of all Australian governments; developing and implementing national strategies to encourage better governance, promoting appropriate use of blood and blood products; and providing expert advice to support government policy development. Further background is at **Appendix A.**

The *Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia* (*Criteria*) identifies the conditions and circumstances for which the use of intravenous and subcutaneous immunoglobulin (SCIg) is funded under national blood arrangements. The *Criteria* was first published in 2008, and was updated in 2012. It classifies the 93 diagnostic groups described in the *Criteria* into those for which IVIg has an established therapeutic role (Chapter 5), has an emerging therapeutic role (Chapter 6) and those where IVIg has application in exceptional circumstances only (Chapter 7). IVIg is only supplied for these diagnostic groups unless purchased by a single state, hospital or individual (a Direct Order). Chapter 8 of the *Criteria* outlines those conditions for which IVIg should not be supplied, under national blood arrangements.

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. 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.

Normal human immunoglobulin (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.

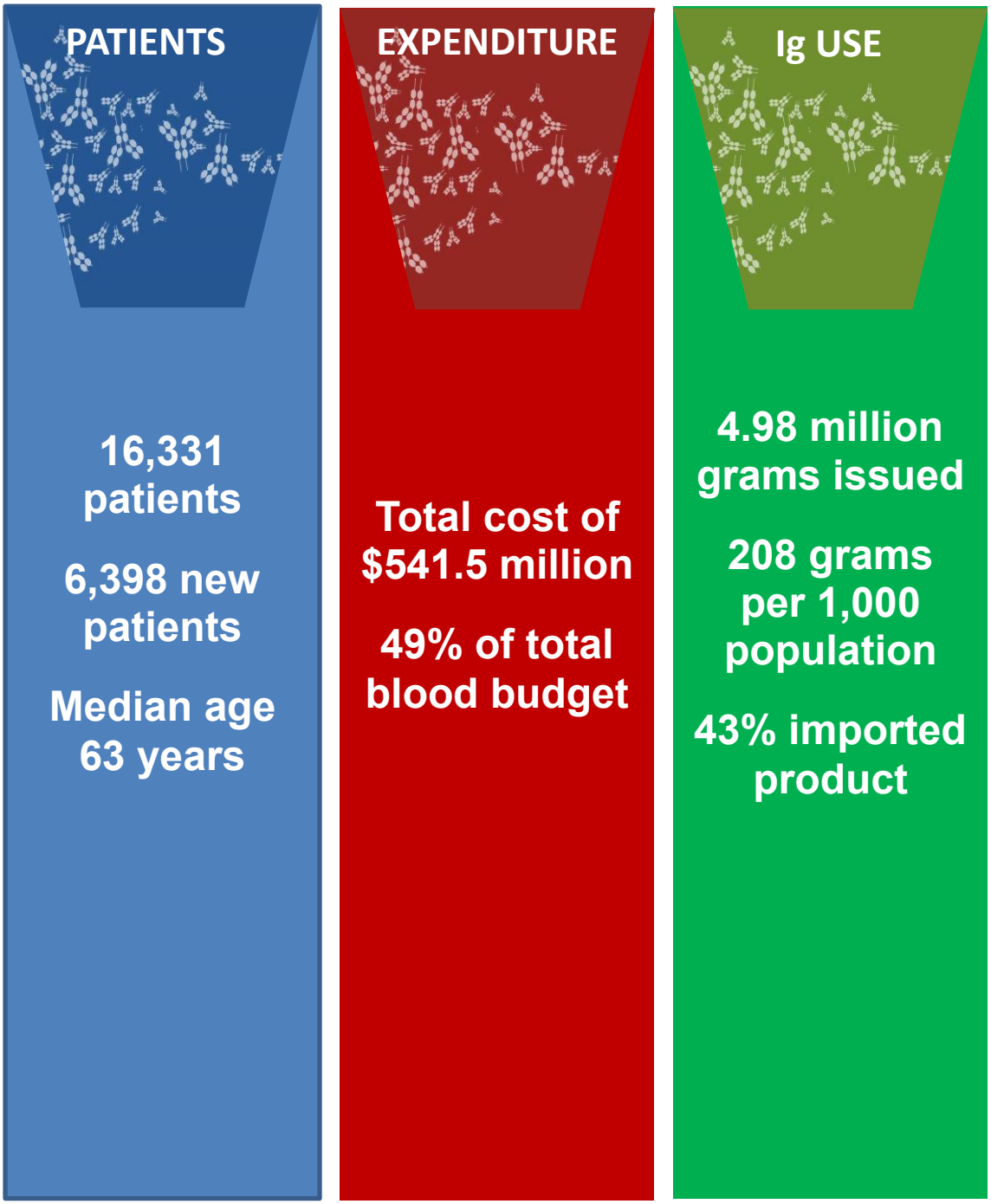
Immunoglobulin products should be prescribed and dispensed in accordance with any applicable state or territory legislative requirements. In-hospital management of immunoglobulin products must also be in accordance with the National Safety and Quality Health Service (NSQHS) Standards, in particular Standards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

Ig comprises a large proportion of blood expenditure each year. Demand for Ig continues to rise steadily, and Australian 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 diagnostic groups account for 88.4% of all Ig supplied in 2015-16, and for this reason specific analysis focuses on these groups.

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

Report Snapshot



Methodology

The report uses data from two 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 is collected following the treatment where product is issued as imprest stock. 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 Ig issued to Australian Health Providers (AHPs) and purchases from suppliers. This data is held in the NBA Integrated Data Management System (IDMS).

Over the eight years between 2008-09 and 2015-16, data has been captured on 48,643 patients. Caveats relating to the quality of this data are outlined below.

This report includes data on the supply of Normal Human Immunoglobulin (NHIg) for the past five years and Subcutaneous Immunoglobulin (SCIg) for 2013-15, as no SCIg product was available in Australia before 2013-14. In this report data for IVIg and SCIg is aggregated and referred to as immunoglobulin (Ig) unless specifically stated. NHIg is reported separately. The report includes some language 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 conditions into one diagnostic group. For example, primary immunodeficiency disease is a diagnostic group in the *Criteria,* with this group incorporating the numerous separate conditions. In some cases the analysis will focus on the diagnostic group, while in other areas it will focus on the condition.

Each condition has been classified according to its allocated clinical discipline. It is acknowledged that for some conditions this classification is somewhat arbitrary. 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 disciplines, the condition was mapped as mixed. In the majority of cases, the condition was mapped to the speciality most likely to be responsible for patients with that condition, noting that this can vary. **Appendix C** provides the mapping of condition to discipline.

The summary of key items from the data file is provided for each condition at the state and territory level. The summary includes patient numbers, grams of Ig used for the 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**.

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 and IDMS indicates minor variances at a national level. In some cases these differences can be explained by product being ordered and recorded in STARS the month prior to product actually being issued to a patient.
- Not all data fields are completed for all patients. For example, of the total patients recorded since 2008 43,661 patients (90%) had weight data entered, but only 8,201 (17%) had their weight data change in a treatment following the first entry.
- 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 use compared to larger states. The five largest Australian states are New South Wales (NSW), Victoria (VIC), Queensland (QLD), South Australia (SA) and Western Australia (WA).
- There has been no adjustment for Ig used in one state or territory for patients residing in a different state or territory.
- A total of 1141 (2%) patients received product in more than one state and territory. For example, if a patient relocated from New South Wales to Victoria, they will be counted as a patient in both states. 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.
- 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.
- A total of 4,423 (9%) patients had more than one condition over time. In these cases, a patient may be counted more than once in the data in this report, that is, the patient will be counted in the totals for each condition.
- 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.
- Diagnosis group and conditions captured prior to the implementation of the Criteria were mapped to ensure that they were meaningfully represented, however information from previous years may not be directly comparable from 2008-09 forward. There is a small variance between disciplines by year due to mapping methodology.

10 Year Trends

DEMAND TRENDS

In 2015-16 a total of 4,982,503 grams of Ig was issued, representing an increase of 549,357 grams (12.4%) over 2014-15. Since 2006-07 there has been an on average 11.6% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

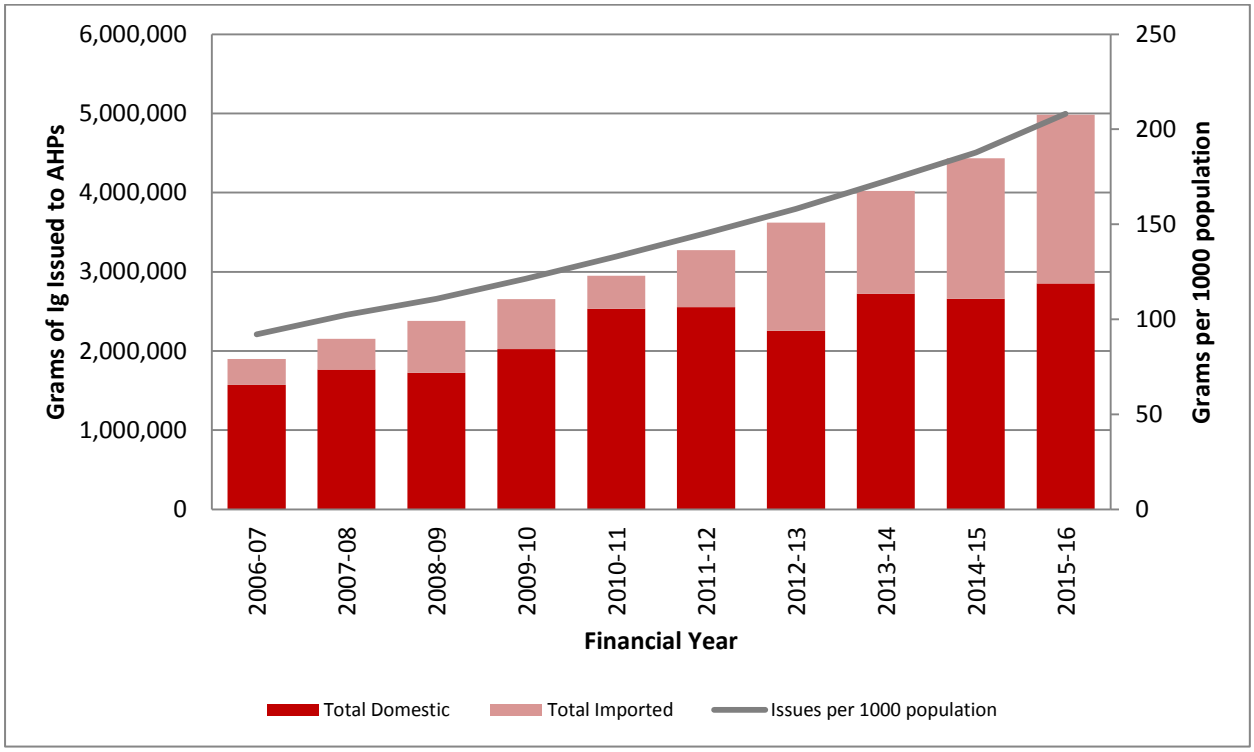


Figure 1 Ten year trends in issues of Ig

Table 1 Growth in Ig grams issued since 2006-07

	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16
Growth from previous year	14%	13%	11%	12%	11%	11%	11%	11%	10%	12%
Average Growth from 2006-07		7%	8%	10%	11%	12%	13%	14%	15%	16%
Total grams per 1,000 population	92	102	111	121	133	145	158	173	188	208
Increase in grams per 1,000 population over previous year	12%	11%	8%	10%	10%	9%	9%	9%	9%	11%

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 five years. While a small 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 '000 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. Queensland has been growing at the fastest rate, closely followed by Victoria and New South Wales. 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	WA	SA	TAS	ACT	NT
2006-07	13%	20%	18%	10%	-11%	30%	12%	-16%
2007-08	18%	8%	16%	6%	14%	5%	29%	1%
2008-09	15%	3%	14%	0%	23%	14%	-14%	54%
2009-10	13%	11%	15%	-4%	12%	7%	20%	-18%
2010-11	11%	10%	16%	10%	-4%	8%	28%	7%
2011-12	11%	7%	16%	6%	9%	1%	17%	47%
2012-13	11%	13%	11%	7%	9%	-6%	12%	21%
2013-14	10%	11%	12%	6%	15%	14%	1%	12%
2014-15	9%	11%	12%	12%	7%	8%	8%	8%
2015-16	14%	10%	14%	17%	11%	2%	3%	36%

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 2015-16 was $296.4 million, an increase of $23.3 million (8.5%) over 2014-15 (Figure 2). The increased expenditure predominately represents increases in demand.

There also continues to be an increase in the price of plasma for fractionation due to the increased ratio of apheresis to whole blood plasma for fractionation being supplied, resulting in an increase in the cost of domestic Ig. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of $541.5 million (excluding hyperimmune plasma for fractionation).

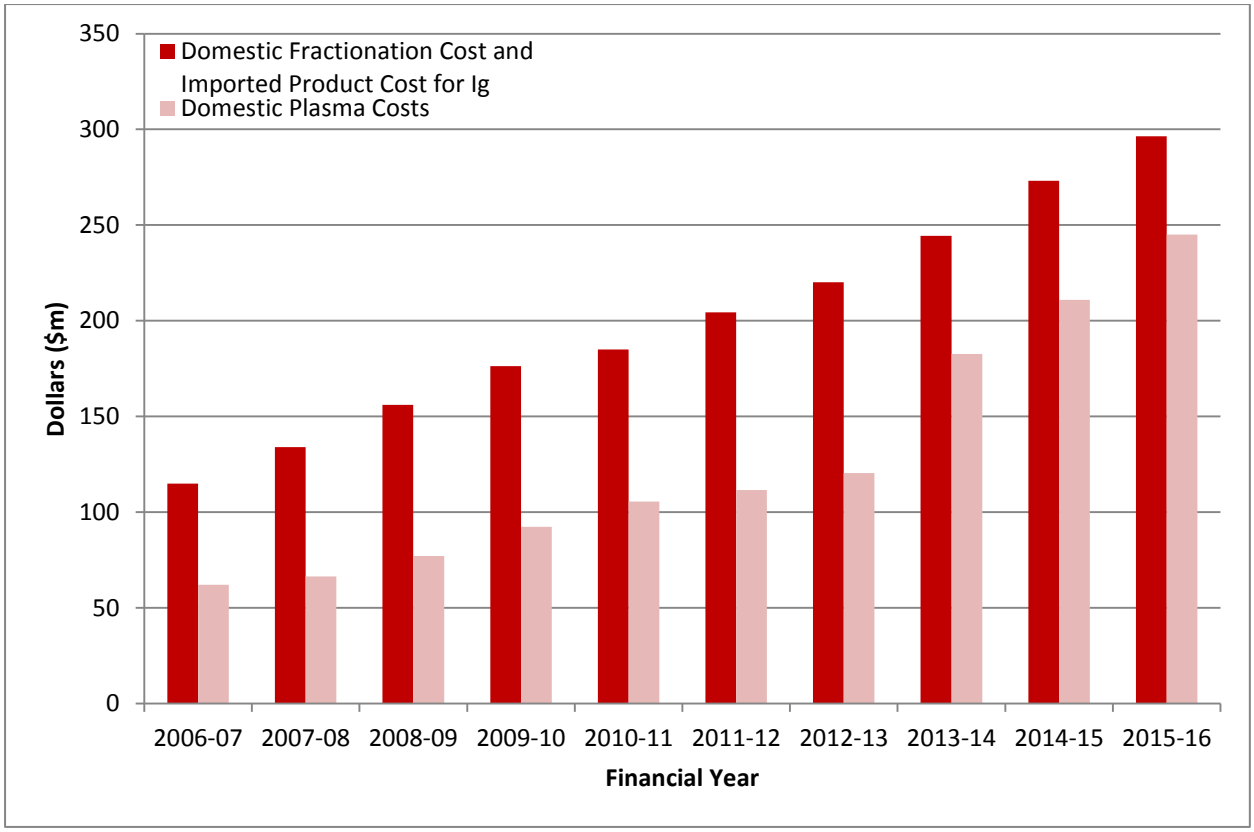


Figure 2 **Ten year trends in expenditure on Ig**

Demographics

PATIENT NUMBERS

A total of 16,331 patients were issued Ig under the national blood arrangements during 2015-16 for 159,041 treatment episodes. This represents a 9.0% increase in the number of patients since 2014-15. 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
2008-09	9,870	77,212	2,380,257
2009-10	10,537	85,299	2,655,184
2010-11	11,492	93,893	2,950,371
2011-12	12,127	101,388	3,271,309
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

Table 4 Basic numbers

	2015-16
Total unique patient IDs with some weight data	16,062
Total unique patient IDs with an age recorded	16,331
Total unique patient IDs with a weight change	918
Total unique patient IDs with more than one state or territory	248
Total unique patient IDs with two states or territories	229
Total unique patient IDs with three or more states or territories	19
Total unique patient IDs with more than one condition	451
Total unique patient IDs with two conditions	441
Total unique patient IDs with three conditions	10
Total unique patient IDs with four or more conditions	0
Total unique patient IDs aged 93 or older	63

Note: The above table calculations relate to only 2015-16 patients unlike previous reports where it included multiple years of data

GEOGRAPHIC DISTRIBUTION

Nationally, 0.7 patients per 1,000 population received Ig in 2015-16. This varied between states and territories, ranging from 0.4 in Western Australia to 0.9 in Queensland (Figure 3). All states and territories show an increase in the number of patients per 1,000 population over the previous year.

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

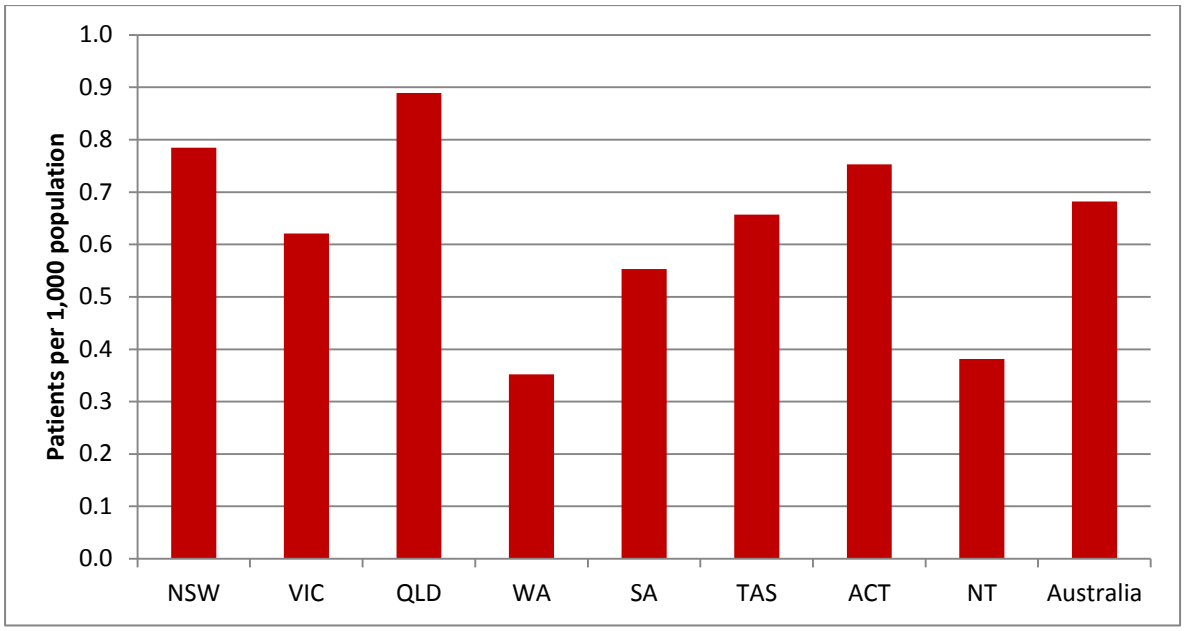


Figure 3 **Patients per 1,000 population 2015-16**

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 98.7 in the Northern Territory to 281.9 in Queensland (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, such as patients travelling to larger states for specialist treatment. Comparing only the five largest Australian states, the variation in Ig use is 2.4 fold, ranging from 120.0 grams per 1,000 population in Western Australia to 281.9 grams per 1,000 population in Queensland. The reason for this inter-state and territory variation is unknown. The lower use may represent appropriate management and prescribing practices, or may represent a level of under-diagnosis.

Prior to 2014-15 Western Australia had shown only slight increases in the number of grams issued per 1,000 population, while most states and territories have seen a continued strong increase in Ig issued per 1,000 population. However, in 2015-16 Western Australia had the highest increase in growth of Ig issued per 1,000 population (excluding NT). Western Australia does remain with the lowest Ig issued per 1,000 population regardless.

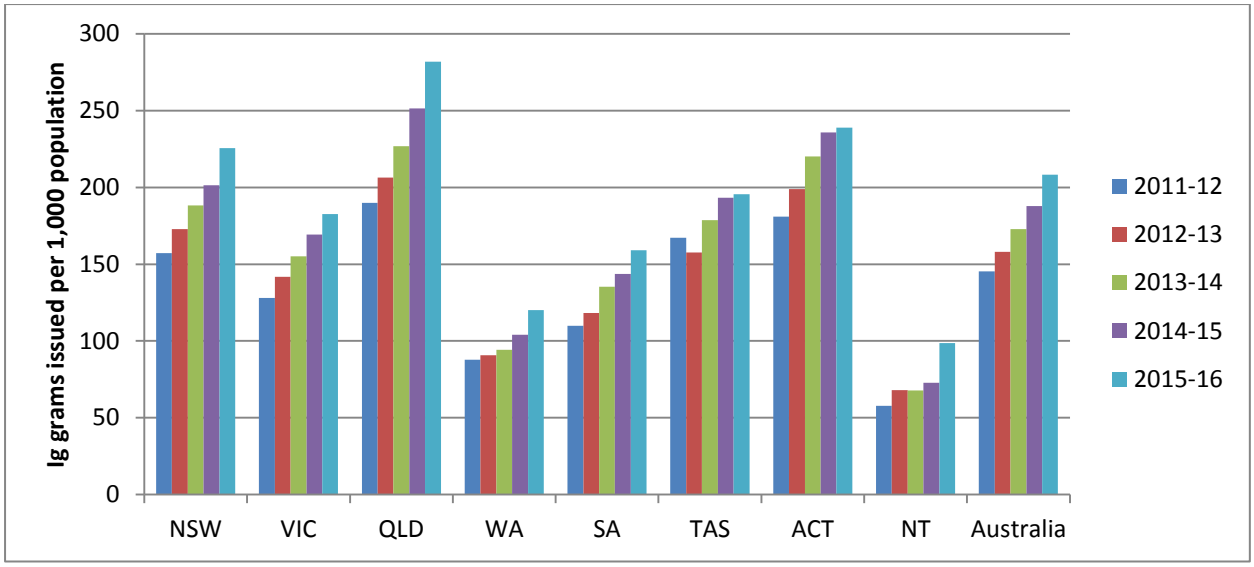


Figure 4 Grams of Ig per 1,000 population by state and territory over time

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].

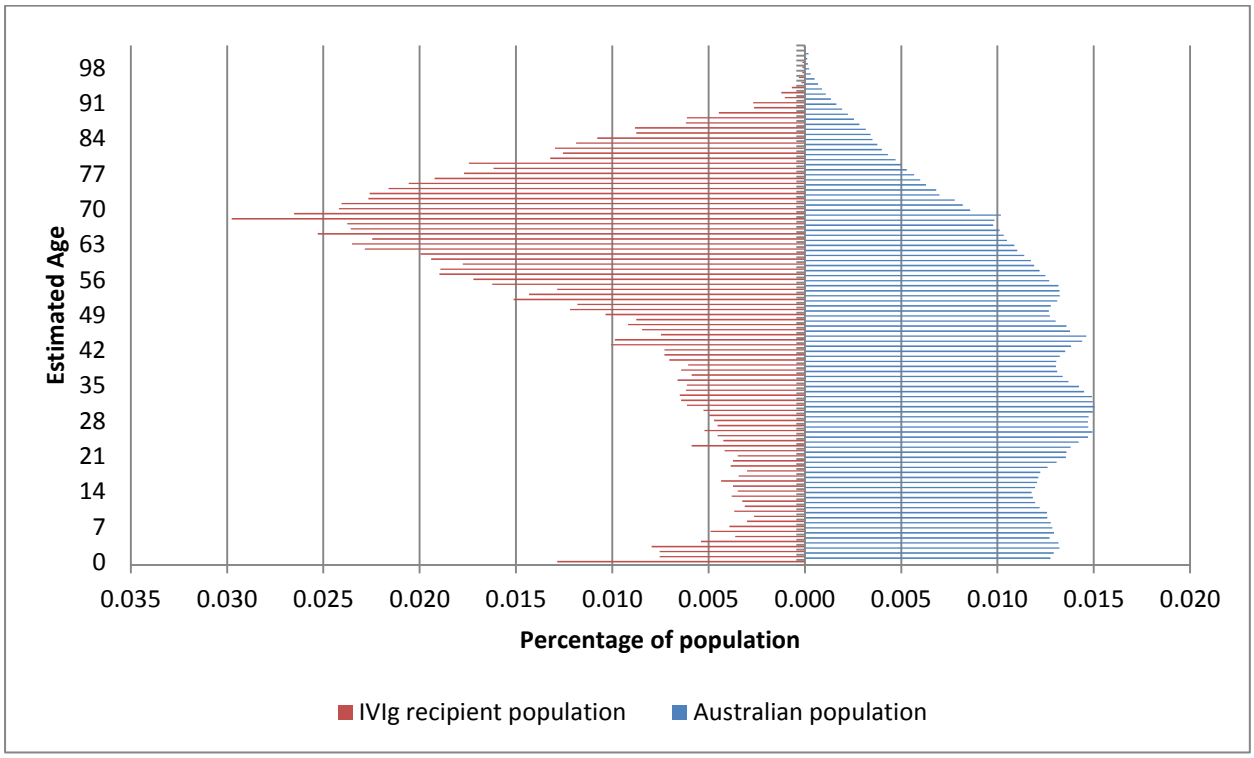


Figure 5 Patient age compared to average Australian age

[2] ABS 3101.0
[3] World Health Organization, http://www.who.int/ageing/en/ (Accessed 16 June 2017)

WEIGHT

Ig dosing is dependent on the weight of the patient. For many immune replacement conditions, the patient weight determines the initial dosing, with maintenance therapy titrated against IgG levels and the patient's clinical response to therapy. However, for conditions where Ig is used for its immunomodulatory properties, the *Criteria* limits the dose that can be prescribed based on the patient weight alone.

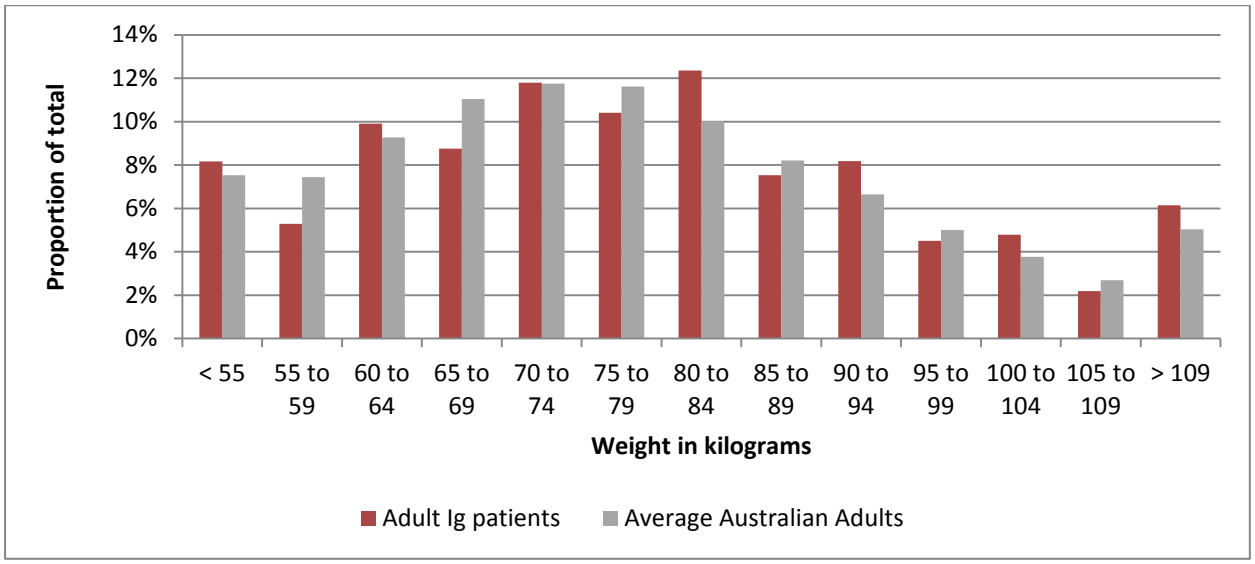


Figure 6 Patient weights relative to Australian average

Note: The above figure calculations relate to only 2015-16 patients.

Figure 6 compares the weight of Ig recipients in Australia and the Australian population[4]. There is a higher proportion of patients treated with Ig less than 55kg relative to the proportion in the Australian population. The average weight of adult Ig patients (78.3 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 (ideal body weight) may be more appropriate. A small pilot study in Western Australia focussing on a narrow range of conditions suggested reductions of Ig dose of between 2.4% and 4.2% were achieved using a lean body dosing methodology[7]. However, this has not been published in peer review literature, was not a randomised controlled trial, and did not discuss whether there were differences in clinical outcomes between the two groups. With an increasingly obese population, we can expect increases in demand if total (rather than lean) body weight dosing is continued and following reviews conducted of the literature relating to lean body mass dosing this area should be considered for future research.

It should be noted that care should be taken when analysing the weights, not all patients have weight recorded and for those that do the weight recorded may not be recent.

[4] ABS 4841.0
[5] ABS 4841.0 (average of male and female)
[6] ABS 4364.0.55.001
[7] Aston, L 2012, *The effect of ideal body weight (IBW) adjusted dosing on the use of intravenous immunoglobulin (IVIg) in Western Australia*, Australian Red Cross Blood Service, Australia.

Expenditure

In 2015-16, Australian expenditure on Ig products was $296.4 million, with additional expenditure of $245.1 million on plasma for fractionation (excluding hyperimmune plasma for fractionation) collected by the Blood Service.

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 27% 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 $541.5 million (excluding hyperimmune plasma for fractionation).

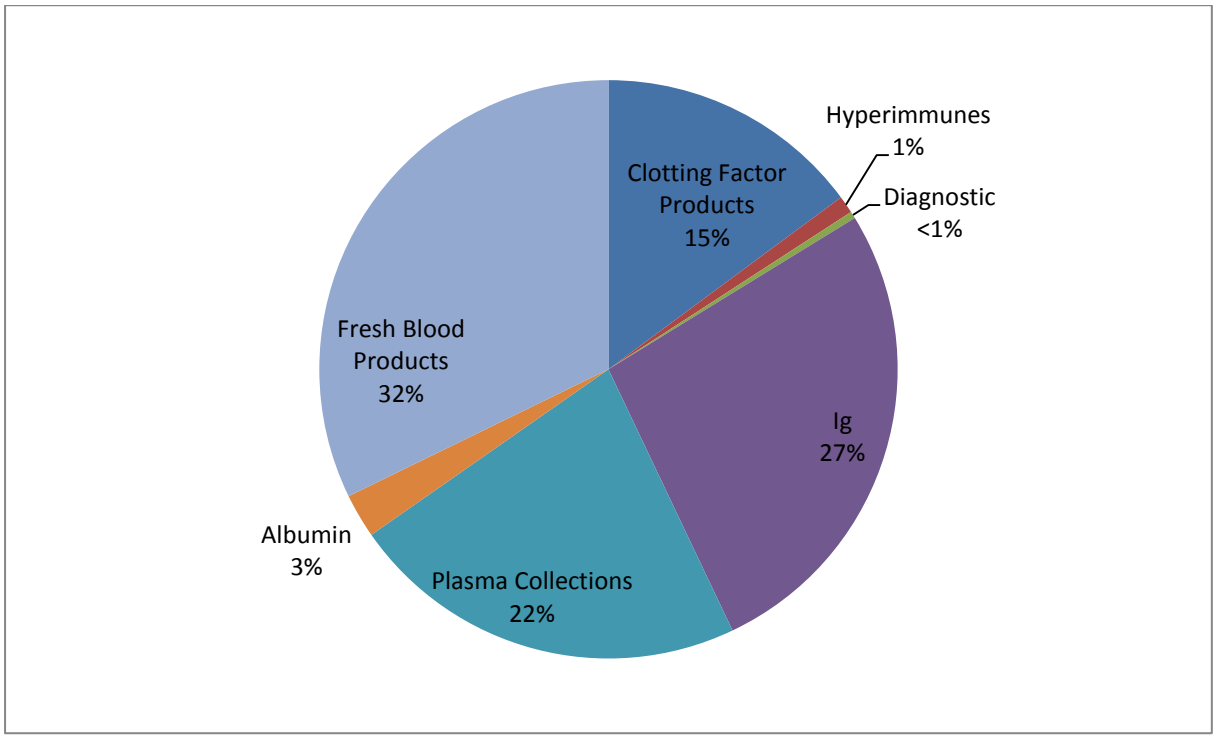


Figure 7 **Ig expenditure as a proportion of the national blood budget**

Of the Ig supplied under national blood arrangements in Australia, 57% (2,850,947 grams) was manufactured domestically and 43% (2,131,556 grams) was imported from overseas. This represents a 20.1% increase in product importation since 2013-14 (476,604 grams) (Table 5). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 5.1% in 2015-16 over 2014-15. Intragam P (IVIg) and Evogam (SCIg) are Ig products manufactured domestically in 2015-16. 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 Octagam constituted 41% of the supply of imported Ig.

Table 5 Issues of domestic Ig compared with imported Ig

			NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUS
Domestic Ig	Intragam P	g	986,685	633,909	754,161	146,661	161,283	52,677	52,518	5,589	2,793,483
		$(m)	$62	$40	$47	$9	$10	$3	$3	$0	$175
	Evogam	g	17,843	9,431	17,021	6,239	6,316	530	83		57,464
		$(m)	$1	$1	$1	$0	$0	$0	$0		$4
	Total Domestic	g	1,004,528	643,340	771,182	152,900	167,599	53,207	52,601	5,589	2,850,947
		$(m)	$63	$40	$48	$10	$11	$3	$3	$0	$179
Imported Ig	Kiovig	g	144,640	112,027	130,704	39,577	65,551	2,068	16,554	8,906	520,025
		$(m)	$9	$7	$8	$2	$4	$0	$1	$1	$31
	Octagam	g	364,569	180,052	237,902	57,246	175	24,778	4,514	137	869,372
		$(m)	$22	$11	$14	$3	$0	$1	$0	$0	$52
	Gammanorm	g	9,268		1,051	587	1,914	1,036	3,614		17,470
		$(m)	$1		$0	$0	$0	$0	$0		$1
	Flebogamma	g	79,296	42,917	42,693	21,308	12,340	5,841	875	35	205,305
		$(m)	$4	$2	$2	$1	$1	$0	$0	$0	$9
	Privigen	g	119,105	116,535	162,265	38,770	21,625	13,630	13,755	9,410	495,095
		$(m)	$5	$5	$7	$2	$1	$1	$1	$0	$22
	Hizentra	g	8,083	239	9,661	2,143	1,560	651	1,952		24,289
		$(m)	$0	$0	$1	$0	$0	$0	$0		$1
	Total Imported	g	724,960	451,770	584,275	159,631	103,165	48,003	41,264	18,489	2,131,556
		$(m)	$41	$25	$32	$9	$6	$3	$2	$1	$117
Proportion of domestic to imported Ig		g %	58%	59%	57%	49%	62%	53%	56%	23%	57%
		$(m) %	61%	62%	60%	53%	65%	56%	59%	27%	61%

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

Clinical Indications

IG ISSUES BY CRITERIA CHAPTER

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

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

Ig was predominately issued for conditions within Chapter 5 (Table 6). The relative distribution by chapter has remained relatively stable since 2008, with a decrease in Ig issues for Chapter 8 conditions (Table 7).

Table 6 Ig issues (g) by Criteria chapter

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16
Chapter 5	1,990,586	2,212,914	2,505,332	2,724,809	3,025,452	3,409,100	3,785,615	4,223,866
Chapter 6	345,176	371,832	397,231	444,605	453,352	463,361	494,489	535,596
Chapter 7	47,275	61,924	76,033	101,287	120,979	148,581	178,221	216,927
Chapter 8	3,326	2,550	2,574	1,909	39	0	0	5
Total	**2,386,361**	**2,649,462**	**2,981,385**	**3,272,930**	**3,599,831**	**4,021,042**	**4,458,326**	**4,976,394**

Table 7 Ig issues by Criteria chapter (percentage)

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16
Chapter 5	84%	84%	83%	84%	85%	85%	85%
Chapter 6	14%	13%	14%	13%	12%	11%	11%
Chapter 7	2%	3%	3%	3%	4%	4%	4%
Chapter 8	<1%	<1%	<1%	<1%	0%	0%	0%

For conditions where Ig is used only in exceptional circumstances (Chapter 7), five diagnostic groups accounted for 54.1% of those issues. These conditions were Limbic Encephalitis – nonparaneoplastic (48,098g), Solid organ transplantation (other than kidney) (24,266g), Pyoderma gangrenosum (16,598g), Paraneoplastic syndromes (16,116g) and Devic disease (neuromyelitis optica) (12,477g). While use in these conditions represents a small proportion of total Ig use, closer examination may be warranted.

Both Limbic Encephalitis – nonparaneoplastic and Pyoderma gangrenosum have approximately quadrupled in grams issued since 2012-13 and tripled in patient count.

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 2015-16 there was one case where Ig was supplied for a condition not in the *Criteria* (excluding Direct Orders where alignment with the *Criteria* is not required as it is not funded under the national blood arrangements). However, data to support compliance with all aspects of qualifying criteria for each condition is not always collected.

IG ISSUES BY DIAGNOSTIC GROUPS

The top ten diagnostic groups account for 88.4% of all Ig supplied, with the top three diagnostic groups accounting for 57.0%.

Acquired hypogammaglobulinaemia secondary to haematological malignancies is the diagnostic group for which the greatest percentage of Ig was issued in 2015-16 (22.2%), closely followed by chronic inflammatory demyelinating polyneuropathy (21.5%). Primary immunodeficiency diseases accounted for 13.3% of total Ig use (Figure 8,

Table 8).

Since 2011-12 there has been a greater than 14% increase in Ig issues for both acquired hypogammaglobulinaemia secondary to haematological malignancies and chronic inflammatory demyelinating polyneuropathy, and a 9.6% increase in issues for primary immunodeficiency diseases. This is compared with the 13% increase in Ig over this period for all conditions. This indicates that while Ig issues for acquired hypogammaglobulinaemia secondary to haematological malignancies and chronic inflammatory demyelinating polyneuropathy are growing at a high rate, primary immunodeficiency diseases are growing at a lower rate while remaining a high use diagnostic group. If these trends continue as they are, we would expect to see myasthenia gravis overtake primary immunodeficiency diseases in the next 7 years.

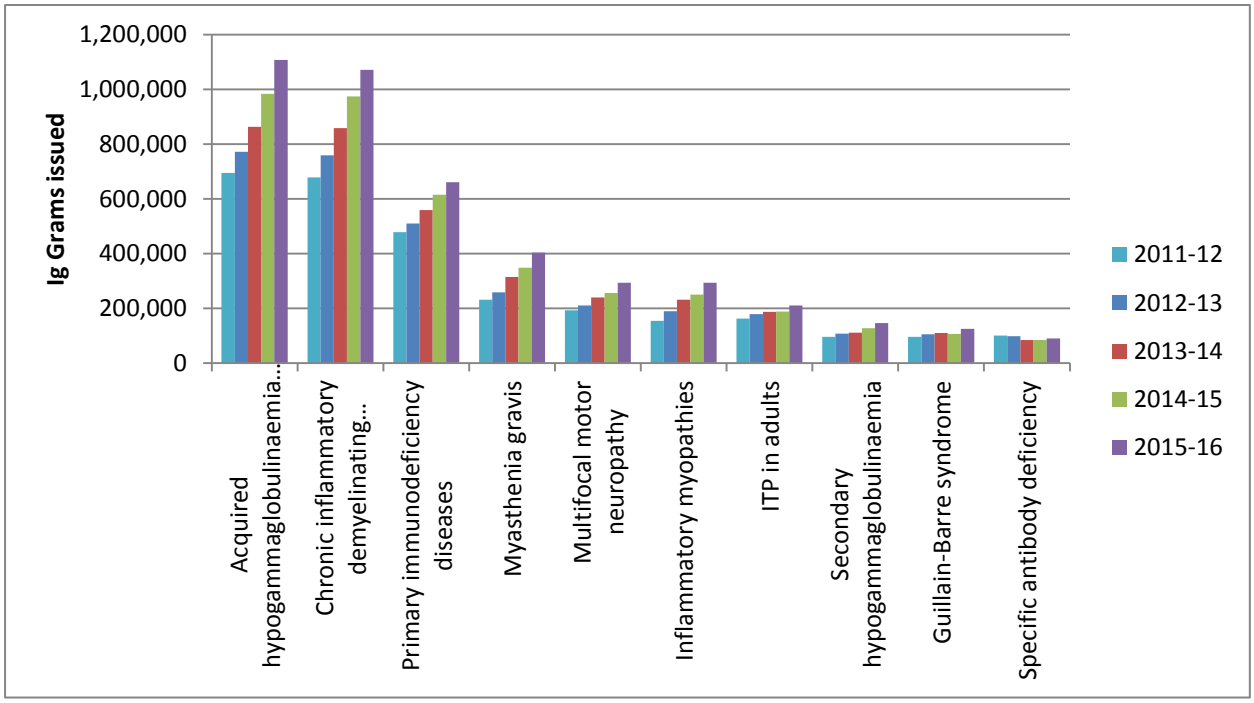


Figure 8 **Ig grams issued by diagnostic group**

Table 8 Ig grams issued for top 10 diagnostic groups over time

	2011-12	2012-13	2013-14	2014-15	2015-16	% Change
Acquired hypogammaglobulinaemia secondary to haematological malignancies	694,640	771,071	862,898	982,773	1,106,721	12.6%
Chronic inflammatory demyelinating polyneuropathy	677,458	758,271	857,533	974,258	1,071,135	9.9%
Primary immunodeficiency diseases	477,461	509,364	558,617	614,781	660,816	7.5%
Myasthenia gravis	231,064	257,966	313,940	348,336	402,881	15.7%
Multifocal motor neuropathy	192,109	209,791	239,314	256,041	293,458	14.6%
Inflammatory myopathies	153,931	188,362	230,473	249,229	293,422	17.7%
ITP in adults	162,098	178,738	186,640	187,621	210,094	12.0%
Secondary hypogammaglobulinaemia	95,183	106,484	110,024	126,561	145,497	15.0%
Guillain-Barre syndrome	95,359	104,360	108,929	105,567	124,692	18.1%
Specific antibody deficiency	99,521	97,749	83,220	83,381	88,994	6.7%

Secondary hypogammaglobulinaemia falls into the top ten diagnostic groups. The increase in issues of secondary hypogammaglobulinaemia was largely in New South Wales between 2009-10 and 2012-13, however in the last 2 years QLD, VIC and WA have also had substantial increases (Table 9). In NSW there has been a 431% increase between 2008-09 and 2015-16, associated with a concurrent increase in patient numbers (increase of 183%). The grams issued per patient has increased by 87%. However there has also been a large increase in grams per 1,000 population from 1.5 to 5.7.

Table 9 Difference in grams issued for secondary hypogammaglobulinaemia (percentage)

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	51%	31%	37%	31%	8%	20%	15%
VIC	17%	35%	30%	4%	-7%	11%	20%
QLD	-6%	13%	12%	1%	7%	15%	16%
WA	-14%	-20%	45%	10%	-24%	6%	38%
SA	88%	0%	-4%	45%	15%	-9%	-20%
TAS	16%	41%	-4%	-8%	-2%	-3%	-7%
ACT	29%	-16%	-66%	-51%	41%	454%	22%
NT	-	1100%	-67%	330%	-73%	119%	-81%
Total	**11%**	**21%**	**20%**	**12%**	**3%**	**15%**	**15%**

IG ISSUES BY CONDITION

Table 10 provides an overview of the conditions that use the most Ig, including data on total Ig use, patient numbers and median birth year. These conditions account for 88.9% of all Ig supplied, with the top ten conditions accounting for 75.1%. This data is also replicated in Figure 9 for the top 10 conditions.

Table 10 Patient numbers and age for the top 20 conditions

Conditions (Top 20)	Ig g (% of total)	Patients n (% of total)	Median Age
Chronic inflammatory demyelinating polyneuropathy	1,071,135 (22%)	2,250 (14%)	64
Common variable immunodeficiency disease	580,964 (12%)	1,724 (11%)	54
Myasthenia gravis	402,881 (8%)	945 (6%)	63
Chronic lymphocytic leukaemia	350,066 (7%)	1,380 (8%)	72
Non-Hodgkin lymphoma	332,148 (7%)	1,308 (8%)	68
Multifocal motor neuropathy	293,458 (6%)	496 (3%)	57
Multiple myeloma	275,685 (6%)	1,177 (7%)	71
Polymyositis	158,414 (3%)	393 (2%)	64
Secondary hypogammaglobulinaemia (excludes haem malignancies)	145,497 (3%)	652 (4%)	60
Guillain-Barré syndrome	124,692 (3%)	727 (4%)	55
Kidney transplantation post-transplant	100,556 (2%)	533 (3%)	50
Other relevant haematological malignancies	94,004 (2%)	574 (4%)	64
ITP refractory	80,807 (2%)	349 (2%)	64
Specific antibody deficiency	72,403 (1%)	268 (2%)	57
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	70,571 (1%)	193 (1%)	59
Dermatomyositis	70,415 (1%)	404 (2%)	57
Inclusion body myositis	64,437 (1%)	142 (1%)	70
HSCT - post	48,266 (1%)	345 (2%)	52
ITP with life-threatening haemorrhage	48,098 (1%)	188 (1%)	66
X linked agammaglobulinaemia	37,968 (1%)	110 (1%)	24

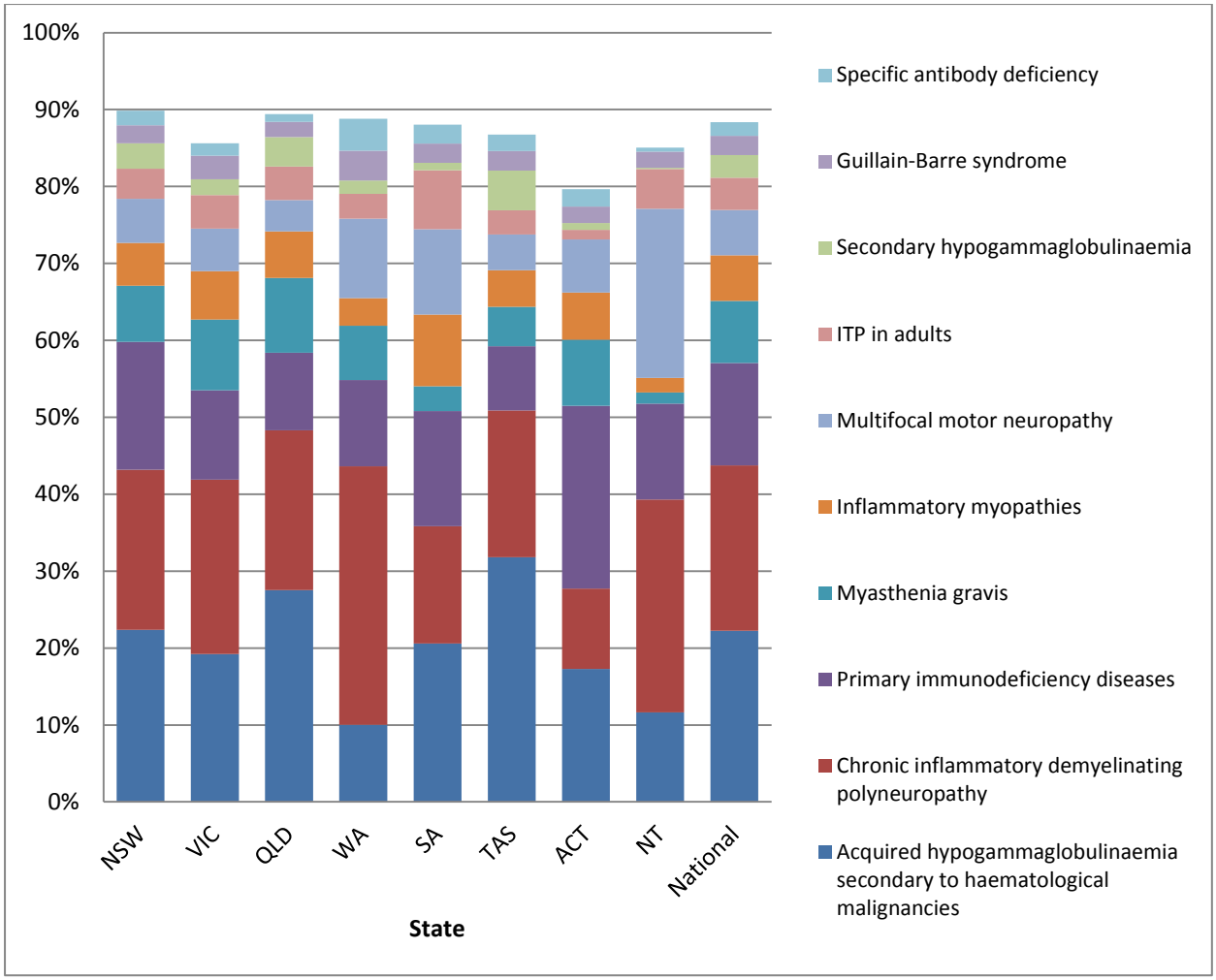


Figure 9 **Proportion of Ig used for top 10 diagnosis group**

Population based data on Ig issues is particularly interesting for conditions where the majority of patients receive Ig as it can provide an estimation of disease prevalence. One condition for which Ig would be prescribed for the vast majority of diagnosed patients is common variable immunodeficiency disease.

Ig was supplied for 1,724 patients with common variable immunodeficiency disease. The estimated prevalence of common variable immunodeficiency disease as measured by patients treated with Ig for this indication is 7.2 per 100,000 population (ranging from 3.7 to 16.0 per 100,000 population across Australian states and territories and 3.7 to 10.6 if ACT, NT and TAS are excluded).

For common variable immunodeficiency disease, this estimate is higher than other studies suggest with estimates between 2 and 4 people per 100,000 population[8]. The ability to calculate accurate prevalence estimates is important for health service planning. It should be noted that the prevalence estimate is for diagnosed and treated patients only.

[8] Cunningham-Rundles, C 2012, *The many faces of common variable immunodeficiency*, American Society of Hematology, USA.

IG ISSUES BY CLINICAL DISCIPLINE

The number of grams of Ig issued categorised according to clinical discipline is shown in Figure 10. Some conditions are classified as mixed, in that they fall across more than one clinical discipline. Other conditions fall within a clinical discipline other than neurology, haematology or immunology, such as use in transplants or dermatology. These are considered under 'Other' in Figure 10. Table 11 replicates this data.

Since 2011-12, there has been a 1.6 fold increase in Ig issues for neurological conditions, compared with a 1.4 fold increase for both haematological conditions and immunological conditions.

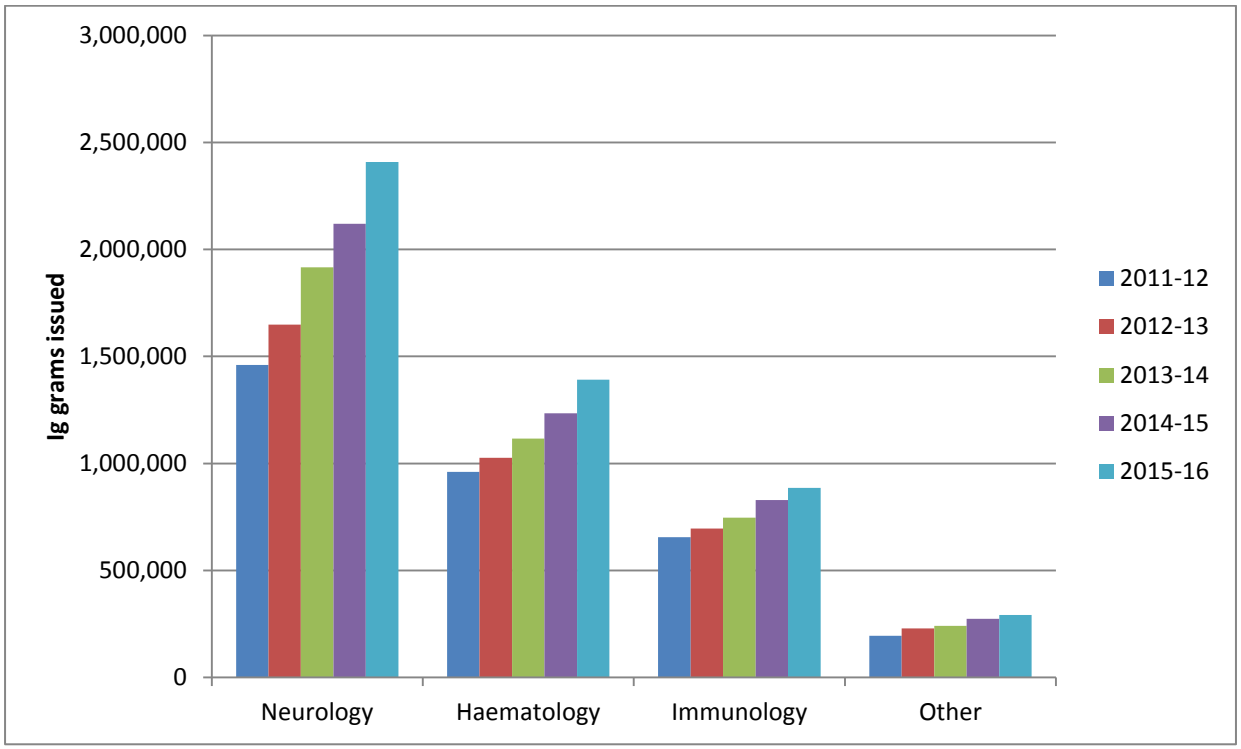


Figure 10 Ig issues by clinical discipline

Table 11 Ig grams issued by clinical discipline

	2011-12	2012-13	2013-14	2014-15	2015-16
Neurology	1,460,702	1,649,358	1,916,792	2,120,111	2,407,995
Haematology	961,366	1,026,177	1,116,037	1,234,816	1,390,824
Immunology	656,179	695,298	746,828	828,735	885,933
Other	194,363	228,947	241,386	274,664	291,643

There is significant variation across Australia in Ig use for each clinical discipline (as allocated). Figure 11 shows that in Western Australia issues for neurological conditions represent a greater proportion of total issues than for other states. The proportional use for immunological conditions is much lower in Queensland and Tasmania than other states, with use of Ig for neurological and haematological conditions prevailing in these two states. 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 and/or differences due to the availability of specialist services across Australia.

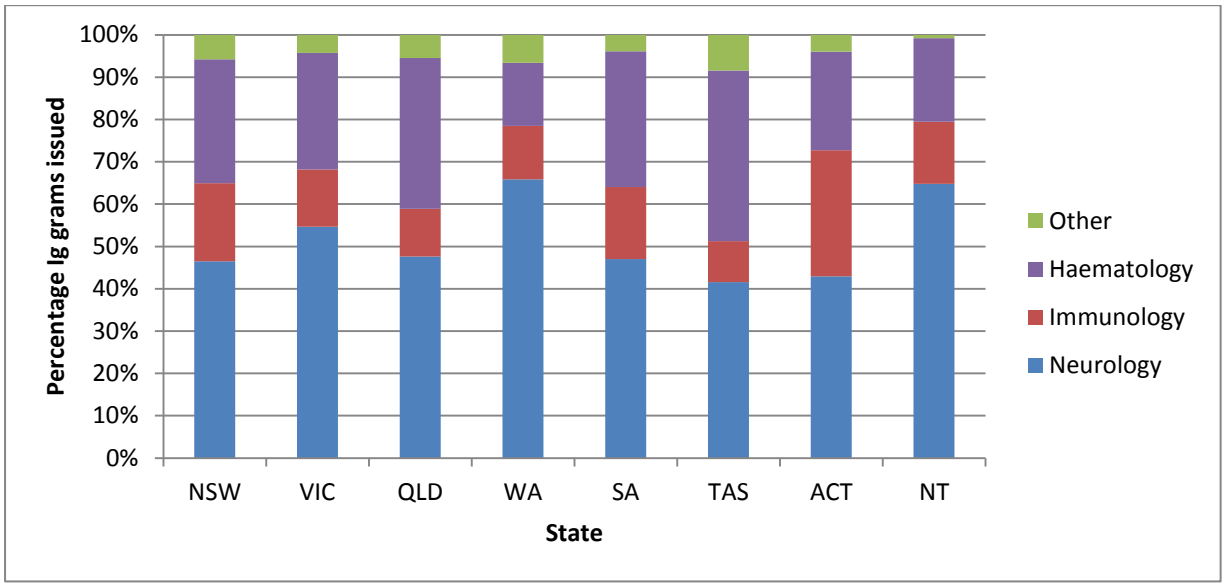


Figure 11 **Percentage Ig issues by clinical discipline for top 10 diagnosis groups by state and territory**

IG GRAMS ISSUED PER 1,000 POPULATION

The amount of Ig issued per 1,000 population for each indication varies between state and territory. Complete data for conditions by state and territory can be found at Appendix D and is summarised for the conditions with the highest usage of Ig. Table 12 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.

The highest variation between states and territories in Ig use per ’000 population is seen in Chronic Inflammatory Demyelinating Polyneuropathy and Non-Hodgkin lymphoma. In total, for the five largest states, there were a low number of Ig issues per ’000 population in South Australia and Western Australia respectively, and high use in Queensland. The reason for the significant variation between these states is unknown, and further studies may be required to ascertain the significance of this finding. Interestingly, the difference appears to be attributed to a greater number of patients, rather than higher dosing, with the dosing in South Australia and Western Australia being higher than Queensland for Chronic Inflammatory Demyelinating Polyneuropathy (**Appendix D**).

Table 12 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	1,729,488	34.7%	32.0%	225
VIC	1,095,110	22%	25.1%	183
QLD	1,355,457	27%	20.1%	282
WA	312,531	6%	10.9%	120
SA	270,764	5%	7.1%	159
TAS	101,210	2%	2.2%	196
ACT	93,865	2%	1.0%	385
NT	24,078	0%	1.6%	61
Total	**4,982,503**	**100%**	**100%**	**208**

The following tables (Table 13, Table 14, Table 15, Table 16 and Table 17) show the patient numbers for states and territories over time for specific conditions.

Table 13 Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy

Chronic inflammatory demyelinating polyneuropathy	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	598	652	704	772	834
VIC	372	421	447	464	507
QLD	386	485	529	580	648
WA	99	105	108	123	130
SA	73	80	81	81	93
TAS	30	33	37	32	36
ACT	17	22	28	27	32
NT	5	7	<5	8	15
Australia	**1,551**	**1,753**	**1,903**	**2,054**	**2,250**

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.

Table 14 Patient numbers by state and territory: common variable immunodeficiency disease

Common variable immunodeficiency disease	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	617	650	721	793	813
VIC	232	241	265	276	288
QLD	276	311	317	338	370
WA	61	67	78	88	95
SA	102	101	110	110	116
TAS	20	21	25	25	29
ACT	54	58	60	66	63
NT	5	<5	<5	<5	10
Australia	**1,323**	**1,406**	**1,543**	**1,656**	**1,724**

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.

Table 15 Patient numbers by state and territory: myasthenia gravis

Myasthenia gravis	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	219	235	267	297	335
VIC	141	177	186	199	215
QLD	181	199	212	245	310
WA	36	39	51	41	46
SA	19	17	14	17	28
TAS	17	10	10	11	16
ACT	10	13	14	16	16
NT					<5
Australia	**609**	**671**	**747**	**818**	**945**

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.

Table 16 Patient numbers by state and territory: chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	381	394	431	483	523
VIC	230	225	271	290	310
QLD	283	297	292	318	347
WA	48	41	45	64	68
SA	79	79	86	77	88
TAS	31	31	34	34	32
ACT	25	29	30	31	27
NT	5	5	6	9	6
Australia	**1,060**	**1,078**	**1,179**	**1,283**	**1,380**

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.

Table 17 Patient numbers by state and territory: multiple myeloma

Multiple myeloma	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	324	378	389	425	466
VIC	153	157	176	215	214
QLD	330	346	360	365	382
WA	15	16	20	23	23
SA	17	22	24	25	40
TAS	51	47	42	39	40
ACT	14	10	10	14	17
NT	<5	<5	<5		<5
Australia	**901**	**969**	**1,012**	**1,100**	**1,177**

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.

Table 18 shows the top 10 conditions by the Ig issued per 1,000 population by state and territory.

Table 18 Ig issued per 1,000 population by state and territory for top 10 conditions

Condition	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National	Fold Variation*
Chronic inflammatory demyelinating polyneuropathy	47	41	58	40	23	38	25	27	45	2.5
Common variable immunodeficiency disease	35	16	25	12	21	15	56	6	24	2.9
Myasthenia gravis	18	12	19	5	12	17	18	8	15	3.8
Chronic lymphocytic leukaemia	17	17	27	8	5	10	21	1	17	5.5
Non-Hodgkin lymphoma	12	11	28	3	9	16	11	1	14	9.4
Multifocal motor neuropathy	13	10	11	12	17	9	17	21	12	1.7
Multiple myeloma	13	8	20	2	4	23	7	0	12	11.9
Polymyositis	7	5	10	2	9	2	5	1	7	5.8
Secondary hypogammaglobulinaemia (excludes haem malignancies)	8	4	11	2	1	10	2	0	6	7.4
Guillain-Barré syndrome	5	6	5	5	4	5	5	2	5	1.5

*The Fold Variation in Table 18 shows the top 10 conditions by the Ig issued per 1,000 population by state and territory.

Table 18 is a measure describing difference in the Ig grams per 1,000 population between the state being issued the least to the state being issued the most, using only data from the five largest states. 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.

Dosing

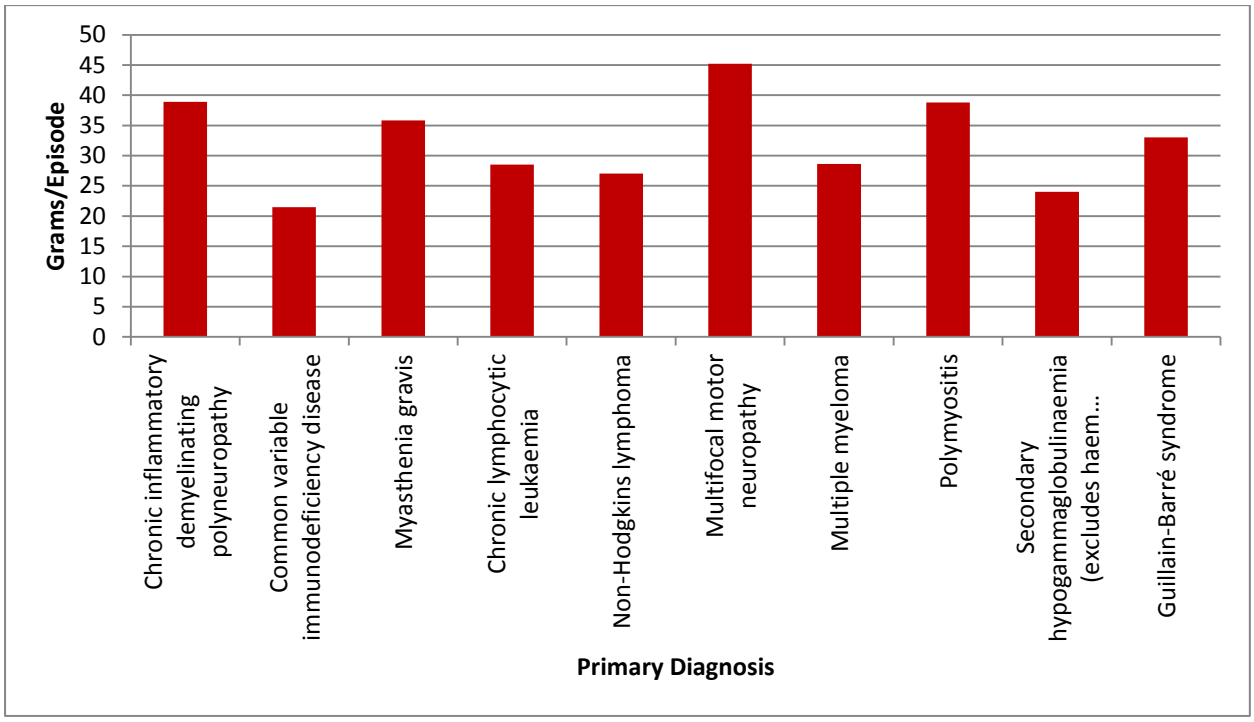


Figure 12 Grams per episode by condition

The data shows that there is significant variance in the dosing of the top 10 conditions by grams per episode; where dosing is calculated as number of grams administered in each episode (Figure 12). The definition of episode in the data is not uniform and therefore this data should be interpreted with caution. Variations are expected as the doses and frequency of dose varies as the underlying method for calculating the 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. The dosing is stable compared to the 2014-15 year.

Dosing in the neurological conditions is higher than for other 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 infusion episode (Table 19). 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 for every episode and may change over time.

Table 19 Ig grams per kg weight per episode

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(%)
Chronic inflammatory demyelinating polyneuropathy	9,151 (39%)	12,766 (55%)	1,101 (5%)	27 (0%)	372 (2%)
Common variable immunodeficiency disease	9,082 (47%)	8,873 (46%)	77 (0%)	3 (0%)	1,389 (7%)
Myasthenia gravis	3,891 (42%)	4,926 (54%)	271 (3%)	5 (0%)	86 (1%)
Chronic lymphocytic leukaemia	6,910 (58%)	4,916 (41%)	4 (0%)	1 (0%)	136 (1%)
Non-Hodgkin lymphoma	1,401 (26%)	3,365 (62%)	558 (10%)	12 (0%)	101 (2%)
Multiple myeloma	7,144 (62%)	4,251 (37%)	13 (0%)	0 (0%)	148 (1%)
Multifocal motor neuropathy	5,744 (61%)	3,533 (38%)	1 (0%)	0 (0%)	137 (1%)
Polymyositis	1,211 (35%)	2,013 (58%)	211 (6%)	4 (0%)	33 (1%)
Secondary hypogammaglobulinaemia (excludes haem malignancies)	419 (46%)	432 (47%)	45 (5%)	21 (2%)	3 (0%)
Guillain-Barré syndrome	2,931 (55%)	2,256 (42%)	72 (1%)	0 (0%)	51 (1%)

IVIg and SCIg

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. The first phase of implementation was through hospital-based management arrangements, with no additional cost to patients, and further work will be undertaken to support supply of SCIg for other pathways of care. 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)
- Kiovig 10% 1g/10ml, 2.5g/25ml, 5g/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (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. 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.

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

Tables 20-22 show the patient numbers, grams issued andtreatment episodes, by state and territory for IVIg and SCIg products in 2015-16. Tables 23-25 show patient numbers, grams issued and treatment episodes by diagnostic group for IVIg and SCIg products in 2015-16.

Table 20 Patient numbers for products issued by state and territory in 2015-16

	IVIg							SCIg				
State	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Kiovig 10 percent	Octagam 5 percent	Octagam 10 percent	Privigen 10 percent	SCIg Evogam	SCIg gammanorm	SCIg Kiovig 10 percent	Hizentra 20 percent	Total
NSW	235	252	3,853	414	610	433	673	70	49		57	6,019
VIC	111	141	2,360	331	430	218	628	58			<5	3,723
QLD	131	129	2,505	437	430	483	904	62	14	<5	51	4,276
WA	48	45	534	108	96	61	151	29	<5		18	916
SA	9	42	665	181	<5		84	33	8		10	942
TAS	7	21	180	9	18	91	72	<5	<5		8	340
ACT		<5	196	48	8	7	68	<5	12		11	296
NT			43	35	<5		31					93
AUS	**538**	**629**	**10,166**	**1,532**	**1,578**	**1,280**	**2,594**	**251**	**90**	**<5**	**156**	**16,331**

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 21 Grams of product issued by state and territory in 2015-16

	IVIg							SCIg				
State	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Kiovig 10 percent	Octagam 5 percent	Octagam 10 percent	Privigen 10 percent	SCIg Evogam	SCIg gammanorm	SCIg Kiovig 10 percent	Hizentra 20 percent	Total
NSW	36,131	40,235	991,716	150,866	221,856	158,411	113,150	18,156	9,230		8,357	1,748,108
VIC	17,562	21,525	633,105	114,407	128,622	58,169	111,990	9,435			231	1,095,046
QLD	17,209	19,125	743,694	134,087	121,763	124,627	149,975	17,436	1,393	120	9,238	1,338,667
WA	9,666	10,800	147,186	39,824	42,030	16,235	37,895	6,045	554		2,121	312,355
SA	1,378	7,050	159,747	67,499	150		16,920	6,286	1,952		1,398	262,379
TAS	1,217	3,975	53,337	2,628	5,659	20,780	12,480	112	1,096		623	101,905
ACT		930	52,803	16,942	2,015	3,489	12,720	77	3,706		1,544	94,226
NT			6,087	9,192	135		8,295					23,709
AUS	**83,162**	**103,640**	**2,787,675**	**535,444**	**522,229**	**381,711**	**463,425**	**57,546**	**17,931**	**120**	**23,512**	**4,976,394**

Table 22 Treatment episode numbers for products issued by state and territory in 2015-16

	IVIg							SCIg				
State	Flebogamma 5 percent	Flebogamma 10 percent	Intragam P	Kiovig 10 percent	Octagam 5 percent	Octagam 10 percent	Privigen 10 percent	SCIg Evogam	SCIg gammanorm	SCIg Kiovig 10 percent	Hizentra 20 percent	Total
NSW	1,058	969	31,400	3,991	6,052	3,798	3,104	3,798	1,668		1,206	57,044
VIC	497	654	19,227	2,811	3,617	1,500	2,866	2,110			39	33,321
QLD	650	523	24,926	3,921	3,796	3,726	4,394	2,255	213	24	1,121	45,549
WA	192	179	4,175	765	748	346	631	944	48		428	8,456
SA	33	158	4,679	1,464	6		358	896	186		105	7,885
TAS	31	75	1,645	66	168	570	359	12	65		80	3,071
ACT		16	1,705	315	59	66	292	16	519		156	3,144
NT			177	218	2		174					571
AUS	**2,461**	**2,574**	**87,934**	**13,551**	**14,448**	**10,006**	**12,178**	**10,031**	**2,699**	**24**	**3,135**	**159,041**

Table 23 Patient numbers for products issued by diagnostic group in 2015-16

	IVIg							SCIg				
Diagnostic Group	**Flebogamma 5 percent**	**Flebogamma 10 percent**	**Intragam P**	**Kiovig 10 percent**	**Octagam 5 percent**	**Octagam 10 percent**	**Privigen 10 percent**	**SCIg Evogam**	**SCIg gammanorm**	**SCIg Kiovig 10 percent**	**Hizentra 20 percent**	**Total**
Acquired hypogammaglobulinaemia secondary to haematological malignancies	33	46	4,123	209	167	175	300	28	10		27	4,711
Chronic inflammatory demyelinating polyneuropathy	129	129	881	401	450	267	608					2,250
Primary immunodeficiency diseases	10	10	1,713	45	28	29	44	186	67	<5	103	1,990
Myasthenia gravis	85	71	272	169	225	150	320					945
Multifocal motor neuropathy	23	27	157	119	102	52	186					496
Inflammatory myopathies	36	57	294	138	129	84	163					726
ITP in adults	62	73	466	127	115	123	296					1,168
Secondary hypogammaglobulinaemia	13	13	519	30	33	31	45	14	<5		10	652
Guillain-Barré syndrome	48	48	219	77	106	85	172					727
Kidney transplantation	31	60	59	42	71	90	116					410
Specific antibody deficiency	<5	<5	272	5	12	<5	9	23	11		16	314

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

Table 24 Grams of product issued by diagnostic group in 2015-16

	IVIg							SCIg				
Diagnostic Group	**Flebogamma 5 percent**	**Flebogamma 10 percent**	**Intragam P**	**Kiovig 10 percent**	**Octagam 5 percent**	**Octagam 10 percent**	**Privigen 10 percent**	**SCIg Evogam**	**SCIg gammanorm**	**SCIg Kiovig 10 percent**	**Hizentra 20 percent**	**Total**
Acquired hypogammaglobulinaemia secondary to haematological malignancies	3,322	3,970	940,026	45,217	35,212	39,143	29,355	4,890	1,927		3,659	1,106,721
Chronic inflammatory demyelinating polyneuropathy	25,040	24,225	438,204	161,461	188,645	109,705	123,855					1,071,135
Primary immunodeficiency diseases	675	1,420	547,440	12,708	7,493	8,697	6,310	45,252	14,235	120	16,467	660,816
Myasthenia gravis	12,183	11,445	119,208	67,993	84,457	52,435	55,160					402,881
Multifocal motor neuropathy	4,135	7,620	96,000	60,154	52,378	24,282	48,890					293,458
Inflammatory myopathies	4,954	9,045	116,037	54,631	46,836	29,105	32,815					293,422
ITP in adults	7,925	11,285	80,886	25,722	19,136	21,840	43,300					210,094
Secondary hypogammaglobulinaemia	893	780	114,966	7,332	7,067	5,364	4,095	3,104	482		1,415	145,497
Guillain-Barré syndrome	7,098	8,795	33,273	13,699	19,184	13,808	28,835					124,692
Kidney transplantation	5,600	7,665	9,174	8,426	17,792	22,566	17,035					88,258
Specific antibody deficiency	228	285	75,777	870	2,729	675	880	4,301	1,287		1,963	88,994

Table 25 Treatment episodes for product issued by diagnostic group in 2015-16

	IVIg							SCIg				
Diagnostic Group	**Flebogamma 5 percent**	**Flebogamma 10 percent**	**Intragam P**	**Kiovig 10 percent**	**Octagam 5 percent**	**Octagam 10 percent**	**Privigen 10 percent**	**SCIg Evogam**	**SCIg gammanorm**	**SCIg Kiovig 10 percent**	**Hizentra 20 percent**	**Total**
Acquired hypogammaglobulinaemia secondary to haematological malignancies	98	131	32,996	1,656	1,237	1,341	982	837	180		463	39,921
Chronic inflammatory demyelinating polyneuropathy	680	569	11,663	3,988	4,897	2,557	3,164					27,518
Primary immunodeficiency diseases	26	42	18,932	360	250	279	174	7,875	2,193	24	2,076	32,231
Myasthenia gravis	338	279	3,305	1,828	2,466	1,442	1,581					11,239
Multifocal motor neuropathy	110	136	2,192	1,278	1,183	537	1,054					6,490
Inflammatory myopathies	144	225	3,011	1,382	1,312	706	846					7,626
ITP in adults	187	195	1,662	555	419	448	888					4,354
Secondary hypogammaglobulinaemia	33	33	4,275	276	247	208	139	510	58		276	6,055
Guillain-Barré syndrome	238	257	1,017	409	570	430	857					3,778
Kidney transplantation	289	294	396	247	663	665	764					3,318
Specific antibody deficiency	9	10	2,915	36	104	22	37	809	268		316	4,526

NHIg

In 2013–14, as a result of the introduction of SCIg as discussed above, demand for Normal Human Immunoglobulin (NHIg) reduced significantly by 18.8 per cent. 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 normal Ig NHIg further declined in 2014-15 as a result of implementation of the NHIg policy outlining the national position on access and use under the national blood arrangements.

Normal human immunoglobulin (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 26-28 and Figure 13 show the grams issued and the issues per 1,000 population by states and territories for either purpose listed above.

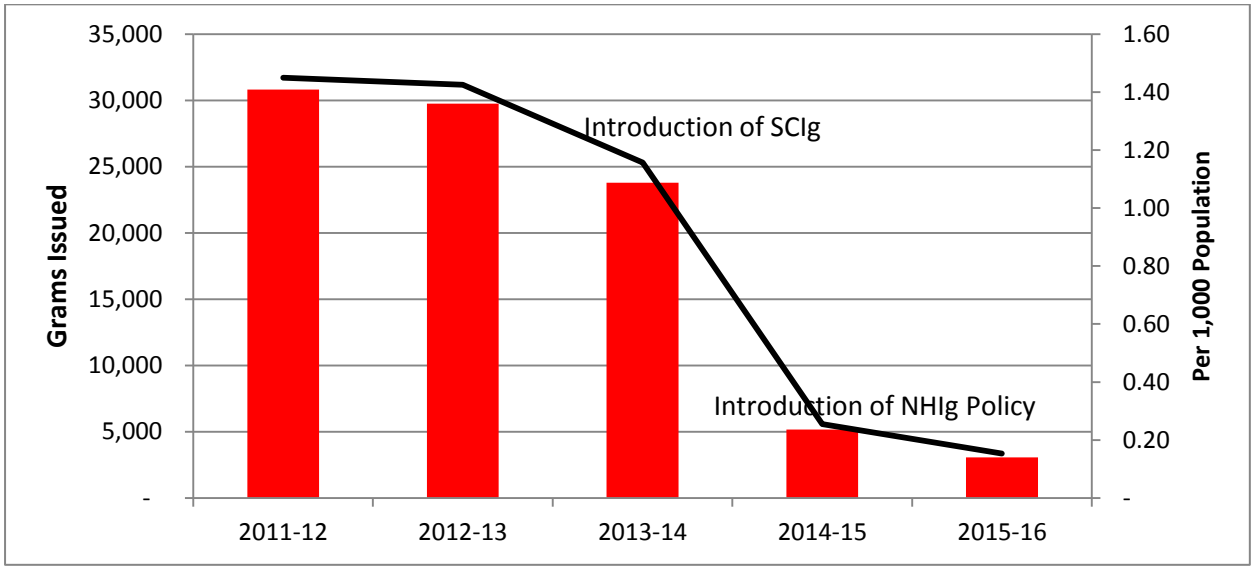


Figure 13 NHIg Grams issued and grams issued per 1,000 population

Table 26 NHIg issued from 2011-12 to 2015-16

Product	2011-12	2012-13	2013-14	2014-15	2015-16
Normal Immunoglobulin 2VI - 2ml (grams)	879	699	654	167	112
Normal Immunoglobulin 2VI - 5ml (grams)	30,836	30,466	24,649	5,409	3,254
Total (grams)	**31,715**	**31,165**	**25,303**	**5,576**	**3,366**
Grams Per 1,000 Population	**1.41**	**1.36**	**1.09**	**0.24**	**0.14**

Table 27 Grams of NHIg issued by state and territory

	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	9,136	9,634	6,915	82	238
VIC	6,323	6,903	6,747	2,278	489
QLD	1,844	1,640	2,774	1,472	1,134
WA	5,258	5,261	3,458	59	38
SA	8,124	6,543	4,431	936	980
TAS	182	344	272	154	43
ACT	797	816	514	480	432
NT	50	24	191	35	12
OTHER[9]	0	0	0	80	0
Australia	**30,867**	**30,325**	**24,597**	**4,981**	**2,922**

Table 28 Grams per 1,000 population of NHIg issued by state and territory

Per 1,000 Population	2011-12	2012-13	2013-14	2014-15	2015-16
NSW	1.26	1.31	0.93	0.01	0.03
VIC	1.13	1.22	1.17	0.39	0.08
QLD	0.41	0.36	0.59	0.31	0.24
WA	2.20	2.12	1.36	0.02	0.01
SA	4.93	3.94	2.64	0.55	0.58
TAS	0.36	0.67	0.53	0.30	0.08
ACT	2.15	2.16	1.34	1.24	1.10
NT	0.22	0.10	0.79	0.14	0.05

[9] Other here covers NHIg sent to the New Zealand Blood Service.

Appendix A – Background

Funding for Ig

Ig supplied under national blood arrangements is funded 63% by the Commonwealth government, with the remaining 37% being funded by the state and territory to which the product is supplied.

The Criteria

A process to review the Australian Health Ministers' Advisory Council (AHMAC) (2000) guidelines commenced in 2004. A result was the approval of the first edition of the *Criteria* by Health Ministers in December 2007. The first edition of the Criteria was made available to clinicians on 3 March 2008 and applied to all new patients from that date. For patients already receiving Ig for an indication not listed as being funded under national blood arrangements, a six month transition period was allowed to enable treatment strategies to be reviewed, with the exception of IgG subclass deficiency, where grandfathering of the use of Ig was permitted under defined circumstances.

The *Criteria* is a publication that describes the eligibility criteria that patients must meet to receive Ig that is funded by all Australian governments. Product is provided free of charge to all patients who have a condition meeting qualifying criteria for supply as outlined in the *Criteria*. The *Criteria* helps to ensure that Ig is accessed consistently across Australia for the treatment of patients whose health is likely to be improved with Ig therapy. The *Criteria* was developed using the best available medical evidence and expertise.

As part of the process to implement the new *Criteria*, the NBA established a clarification process in November 2008. A consultation group was consulted on specific queries that arose in relation to interpretation of the *Criteria.* Consideration of the queries and comments resulted in some amendments to specific indications in the *Criteria*. The revisions were published on the NBA's website in February 2009.

A review of the *Criteria* commenced in 2010. A National Ig Criteria Review Working Group was established to oversee the 2010–11 *Criteria* review process. The *Criteria* second edition was made available to clinicians on 10 August 2012 and applied to all new patients from that date. For patients already receiving Ig for an indication where the specific eligibility criteria had changed, a six month transition period was allowed to enable treatment strategies to be reviewed, with the exception of IgG subclass deficiency patients, as described above.

Supply of Product

Immunoglobulin is made from donated human plasma. The supply of Australian plasma is contracted by the NBA and importation of IVIg is a government policy position to ensure risk mitigation and continuity of supply. While the NBA makes sure there is enough Ig by importing this product, there is a finite international supply.

There are two main ways Ig is available in Australia:

1. Supply under national blood arrangements

If the Ig is ordered to treat a medical condition which is funded under the *Criteria* then the product is supplied and funded under national blood arrangements. In this case the cost of the product is shared between the Commonwealth and the relevant state or territory.

Orders for Ig under national blood arrangements are made to the Blood Service, which is contracted by the NBA as the authoriser and distributor of all Ig funded under these arrangements. In seeking

authorisation, the requesting clinician will be asked to provide information to the Blood Service to establish that the request meets the *Criteria*. For ongoing conditions, the *Criteria* may specify review criteria to be applied in reviewing the patient to determine whether access to funded Ig will continue.

In the role as authoriser of requests for Ig, the Blood Service maintains a database of requests, and provides data to the NBA which is used as a basis for reporting on the annual use of Ig in Australia.

2. Direct order and other supply arrangements

If the Ig is to treat a medical condition that is not funded under the *Criteria*, then the individual state or territory may approve the accessing of product under the Direct Order arrangements established by the NBA, or the product may be ordered directly from a commercial supplier of Ig. In this case the supply of the product is not funded under national blood arrangements, and the cost must be met in some other way.

History

In **2003-04** the NBA coordinated demand management activities for two products in short supply; Biostate (plasma-derived Factor VIII) and Intragam P (plasma-derived Ig). At all times, the NBA successfully met the blood and blood product needs of all Australian states and territories through intensive management of the product, via its contracts with the Blood Service and CSL Limited and the importation of substitutable products from overseas. The NBA arranged for an imported product to be purchased to make up for the shortfall, and this product was made available to patients in March 2004.

In **2004-05** the NBA successfully negotiated a new Plasma Products Agreement with CSL Limited, which came into effect from 1 January 2005.

In December 2004 the NBA also signed a Standing Offer contract with CSL Limited (for the supply of Sandoglobulin ®), as well as with Octapharma Australia Pty Ltd (for the supply of Octagam) for a two-year period in order to allow access to imported Ig as a contingency supply if and when needed to supplement shortfalls in the domestic Ig supply. The Ig Standing Offer comprised two components, a National Blood Supply component whereby imported Ig was procured by the NBA for use under the National Blood Agreement (i.e. for those conditions covered under the nationally agreed cost sharing arrangements) and a Jurisdictional Direct Order component which allowed approved recipients to access imported Ig for all other conditions.

Ig had to be intensively managed again in 2004–05 due to ongoing increases in demand and indications for its clinical use for over 60 clinical syndromes and conditions.

As part of a strategic solution to the shortage of Ig, governments purchased imported Ig (Sandoglobulin®) in 2003 and placed it in the National Reserve of Plasma Products. In order to optimise the use of the stocks in the National Reserve, the NBA in conjunction with states and territories, the Blood Service and CSL Limited, developed and implemented a plan to rotate the Sandoglobulin® stocks out of the National Reserve. This rotation commenced in October 2004.

In **2005–06**, the challenges in supply of domestic Ig required the NBA to adopt the same intensive product management arrangements as it had in 2004-05 with the continued rotation of Sandoglobulin®.

In **2006-07** in order to ensure Ig remained available to all Australians, the NBA negotiated a further 12-month extension to the Ig Standing Offer in December 2006. A procurement process for the renewal of the standing offer arrangements commenced in early 2007.

Intensive product management was successfully undertaken in 2006–07 to avert a number of temporary and longer-term potential shortages, including shortages of Ig and plasma-derived Factor VIII.

In **2007-08** the NBA commenced a procurement process for new contracts. The outcome of the procurement was the finalisation of a new fixed price contract with Octapharma Australia Pty Ltd for the supply of Octagam for three years under the National Blood Supply arrangement. Octagam and a CSL Ltd imported product, Sandoglobulin Liquid, were also supplied under Direct Order arrangements negotiated by the NBA.

In **2008-09** the NBA continued imports of intravenous immunoglobulin to be able to meet domestic clinical demand.

During **2009–10** the plasma fractionation arrangements were governed by the five-year Plasma Products Agreement between the NBA and CSL Limited, which expired on 31 December 2009, and a new CSL Australian Fractionation Agreement which took effect on 1 January 2010.

The contract with Octapharma Australia Pty Ltd for the supply of Octagam was due to expire on 31 December 2010, with the NBA having an option to extend the contract by one year. In May 2010 the NBA moved to exercise the option to extend the contract with Octapharma Australia Pty Ltd, with improved value for money, for a further 12 months.

A contract with CSL Limited for the supply of Sandoglobulin NF (nanofiltration) Liquid under the Direct Order arrangement expired at the end of December 2009.

The NBA entered into a three-year contract with Lateral Grifols Pty Ltd for the supply of Flebogamma 5% DIF (dual inactivation plus nanofiltration) under Direct Orders, which commenced on 1 January 2010.

During **2010-11** imported intravenous immunoglobulin continued to supplement domestic Ig production to meet clinical demand in Australia. In September 2010, Octapharma issued a nationwide voluntary recall of Octagam due to production concerns. To enable domestic demand to be met, the NBA invoked relevant clauses that had been included in the contract with Lateral Diagnostics to allow supply of Flebogamma through national blood arrangements (in addition to the Direct Orders supply). Lateral Diagnostics, working with the Spanish-based manufacturer of Flebogamma, Grifols S.A., responded rapidly and fully to the NBA's additional requirements and this arrangement continued for the remainder of the year. The voluntary recall of Octagam was still in place in Australia at 30 June 2011.

In **2011-12** CSL Limited experienced a decline in its immunoglobulin (IgG) yield. As a result of the reduction in yield, and other logistical factors, CSL Limited was unable to supply Intragam P 200ml from its working inventory against the full annual supply estimate amounts. The NBA also gave approval for CSL Limited to access the Minimum Product Inventory and the National CSL Reserve to augment supply. By the end of June 2012 CSL Limited had fully restocked the Minimum Product Inventory and the National CSL Reserve, although the NBA continued to carefully manage the planned supply of Intragam P in 2012-13.

The Therapeutic Goods Administration (TGA), Australia's national regulator for drugs and regulatory devices, approved the re-introduction of Octagam 5% in October 2011 following the voluntary recall of product in September 2010. The NBA worked with the Blood Service, Octapharma Australia Pty Ltd and Grifols Australia Pty Ltd to manage the transition of patients from Flebogamma 5% DIF under the national supply arrangements; this was achieved by March 2012.

In October 2011 the NBA signed contracts for the supply of imported Ig with Octapharma Australia Pty Ltd for the supply of Octagam 5%. The new contract took effect on 1 January 2012. A 10% formulation of this product became available in July 2012; Baxter Healthcare Pty Ltd for the supply of Kiovig 10% from 1 January 2012 and with Grifols Australia Pty Ltd for a direct order contract operating until 31 December 2012 for the supply of Flebogamma 5% DIF. A new direct order contract for continued supply of Flebogamma 5% commenced on 1 January 2012.

In **2012-13** two contracts were placed for supply of imported Ig under the national blood arrangements. The contracts commenced on 1 January 2012 for a period of three years with provision for a one year extension. The suppliers were Baxter Healthcare Pty Ltd and Octapharma Australia Pty Ltd.

The NBA, on behalf of all Australian governments, completed a review of the adequacy of the current Ig authorisation and clinical governance arrangements. The aim of the review was to identify options for improvements in the management of Ig. The review also analysed the issues, benefits and risks of potentially including NHIg and subcutaneous immunoglobulin (SCIg) in the Ig management framework.

The review identified significant variations in Ig management processes nationally, with process inefficiencies, under investment in integrated data systems and limited evidence of alternative therapies being considered before prescription. It also found variation in dosing, high prescription rates in some conditions compared to international rates of use, limited transparency of price implications and no accountability for cost with the prescriber.

In March 2013, the Jurisdictional Blood Committee (JBC) considered the final report of the review and endorsed the NBA commencing work to implement five short term improvement projects recommended by the review. The five projects were to:

- describe the functional model for the authorisation and clinical governance arrangements, and formally allocate responsibility in each jurisdiction
- introduce new management processes to include NHIg and SCIg in the Ig authorisation process
- improve patient information to ensure patients are aware of the Criteria requirements for eligibility and ongoing therapy
- centralise hospital ordering and product management at the blood bank or pharmacy for improved management, and define when and how emergency stock should be managed
- define and deliver a package of information concerning Ig products and arrangements, particularly for junior medical and nursing staff.

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. The first phase of implementation was through hospital-based management arrangements, with no additional cost to patients, and further work was undertaken to support supply of SCIg for other pathways of care. Supply of SCIg commenced in **September 2013**, including both domestically manufactured and imported SCIg products.

In **2013-14** 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)
- Kiovig 10% 1g/10ml, 2.5g/25ml, 5g/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (imported)

In **2015-16** the NBA established arrangements for supply of the following SCIg product:

- Hizentra 5% 1g/5ml, 2g/10ml, 4g/20ml and 10g/50ml supplied by CSL Behring (Australia) Pty Ltd (imported)

During **2013-14 to 2015-16** the NBA made significant progress to implement new Ig authorisation and clinical governance arrangements. These arrangements aim to address a range of deficiencies identified in the 2012-13 review of the management of Ig, including:

- significant variations and inefficiencies in Ig management processes nationally
- variation in dosing

- high prescription rates in some conditions compared to international rates of use
- limited transparency of price implications
- no accountability for cost with the prescriber.

Key **2013-14** achievements included:

- development and approval by governments of the business cases describing the high level functional model for new authorisation and clinical governance arrangements and the associated supporting national database
- development and implementation of new management processes for NHIg and SCIg
- establishment of the National Ig Governance Advisory Committee.

Key **2014-15** achievements included:

- establishment of a network of new national specialist advisory committees to assess and recommend changes to the arrangements for the supply of Ig in Australia
- publication and implementation of new Ig Governance policies, a standardised patient treatment review process and revised forms
- review of the *Criteria for the clinical use of intravenous immunoglobulin in Australia (Criteria)* for adaptation to the new information management system under development, BloodSTAR.

Key **2015-16** achievements included:

- holding five meetings of the National Immunoglobulin Governance Advisory Committee (NIGAC), and approval by NIGAC of Specialist Working Group three year work plans for achieving key governance outcomes
- implementation of the National Ig Governance framework processes in Western Australia
- publication and implementation of the second edition of the Ig Governance policy to support the implementation of BloodSTAR
- finalisation of the online adaptation of Criteria for BloodSTAR
- commencement of a further review of the Criteria for the clinical use of intravenous immunoglobulin in Australia (the Criteria) with a view to implementing Version Three in 2017
- Specialist Working Groups for Neurology, Immunology, Haematology and Transplantation Medicine finalised the review of the medical conditions in Chapters 5 & 6 of the Criteria through regular teleconference meetings
- Approval of revised Chapter 5 and 6 conditions by the JBC.

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

On **31 December 2015** two contracts for the supply of imported Ig expired. The suppliers were Baxalta Australia Pty Ltd and Octapharma Australia Pty Ltd.

In **June 2015**, the NBA successfully concluded a tender process for new contracts for the national supply of imported Ig to replace the current contracts which expired on 31 December 2015. The new contracts were awarded to CSL Behring Pty Ltd and Grifols Australia Pty Ltd.

Appendix B – Acronyms and Glossary

ACRONYMS

ACT	Australian Capital Territory
AHMAC	Australian Health Ministers' Advisory Council
AHMC	See SCoH
AHP	Australian Health Providers
ANCA	Anti-neutrophil cytoplasmic antibody
AUS	Australia
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
SCoH	Standing Council of Health
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
Clinical Discipline	Classification of the conditions according to the clinical speciality
Condition	Specific diagnoses within a diagnostic group. Also known as the primary diagnosis. In some instances the diagnostic group may be the same as the condition, for example – Myasthenia gravis is the condition and Diagnostic Group
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
Criteria Met	An assessment that the patient eligibility requirements as defined in the *Criteria* for a particular condition have been achieved
Criteria Not Met or Qualifying (Q) Criteria Not Met	An assessment that the patient eligibility requirements as defined in the *Criteria* for a particular condition have not been achieved
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 for the clinical use of IVIg in Australia*
Diagnostic Group	A grouping of clinical/medical conditions, as outlined in the *Criteria.* Also known as disease group
Disease Group	See diagnostic group
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

Term	Description
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 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
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
Primary diagnosis	See 'condition'
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 OR 1 dose of transfused product every two weeks for 6 months would be 13 treatment episodes

Appendix C – Clinical Discipline mapping table

Condition	Chapter	Diagnostic Group	Clinical Discipline
Chronic lymphocytic leukaemia	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Multiple myeloma	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Non-Hodgkin lymphoma	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Other relevant haematological malignancies	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Post-haemopoietic stem cell transplantation (HSCT)	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Chronic inflammatory demyelinating polyneuropathy	Chapter 5	Chronic inflammatory demyelinating polyneuropathy	Neurology
Guillain-Barré syndrome	Chapter 5	Guillain-Barré syndrome	Neurology
Dermatomyositis	Chapter 5	Inflammatory myopathies	Neurology
Inclusion body myositis	Chapter 5	Inflammatory myopathies	Neurology
Polymyositis	Chapter 5	Inflammatory myopathies	Neurology
Idiopathic thrombocytopenic purpura - Adult	Chapter 5	ITP in adults	Haematology
ITP associated with HIV	Chapter 5	ITP in adults	Haematology
ITP in pregnancy	Chapter 5	ITP in adults	Haematology
ITP in Specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	Chapter 5	ITP in adults	Haematology
ITP Refractory	Chapter 5	ITP in adults	Haematology
ITP with life-threatening haemorrhage	Chapter 5	ITP in adults	Haematology
Kawasaki disease	Chapter 5	Kawasaki disease	Immunology
Lambert-Eaton myasthenic syndrome	Chapter 5	Lambert-Eaton myasthenic syndrome	Neurology
Multifocal motor neuropathy	Chapter 5	Multifocal motor neuropathy	Neurology
Multifocal motor neuropathy with persistent conduction block	Chapter 5	Multifocal motor neuropathy	Neurology
Myasthenia gravis	Chapter 5	Myasthenia gravis	Neurology
Neonatal haemochromatosis	Chapter 5	Neonatal haemochromatosis	Mixed - Haem/Immun
Common variable immunodeficiency disease	Chapter 5	Primary immunodeficiency diseases	Immunology
Other Primary	Chapter 5	Primary immunodeficiency diseases	Immunology

Condition	Chapter	Diagnostic Group	Clinical Discipline
Immunodeficiency			
Severe combined Immunodeficiency	Chapter 5	Primary immunodeficiency diseases	Immunology
Transient hypogammaglobulinaemia of infancy	Chapter 5	Primary immunodeficiency diseases	Immunology
Wiskott-Aldrich Syndrome	Chapter 5	Primary immunodeficiency diseases	Immunology
X linked agammaglobulinaemia	Chapter 5	Primary immunodeficiency diseases	Immunology
Stiff person syndrome	Chapter 5	Stiff person syndrome	Neurology
Acute disseminated encephalomyelitis	Chapter 6	Acute disseminated encephalomyelitis	Neurology
ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Churg-Strauss Syndrome	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Microscopic polyangiitis	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Wegener's granulomatosis	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Autoimmune haemolytic anaemia	Chapter 6	Autoimmune haemolytic anaemia	Haematology
Evans syndrome	Chapter 6	Evans syndrome	Haematology
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	Chapter 6	Foeto-maternal /neonatal alloimmune thrombocytopenia	Haematology
Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	Chapter 6	Foeto-maternal /neonatal alloimmune thrombocytopenia	Haematology
Haemophagocytic syndrome	Chapter 6	Haemophagocytic syndrome	Haematology
HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	Chapter 6	HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	Haematology
IgM para-proteinaemic neuropathy	Chapter 6	IgM para-proteinaemic neuropathy	Neurology
ITP in children	Chapter 6	ITP in children	Haematology
Kidney transplantation – post-transplant	Chapter 6	Kidney transplantation	Renal specialist
Kidney transplantation – pre-transplant	Chapter 6	Kidney transplantation	Renal specialist
Kidney transplantation post-transplant	Chapter 6	Kidney transplantation	Renal specialist
Kidney transplantation pre-transplant	Chapter 6	Kidney transplantation	Renal specialist
Multiple sclerosis - Severe relapse with no response to high dose methylprednisolone	Chapter 6	Multiple sclerosis	Neurology
Multiple Sclerosis in Pregnancy	Chapter 6	Multiple sclerosis	Neurology
Multiple Sclerosis in young patients	Chapter 6	Multiple sclerosis	Neurology

Condition	Chapter	Diagnostic Group	Clinical Discipline
severe/relapsing/remitting in whom other therapies have failed			
Opsoclonus myoclonus ataxia	Chapter 6	Opsoclonus myoclonus ataxia	Neurology
Bullous pemphigoid	Chapter 6	Pemphigoid	Immunology
Cicatricial pemphigoid	Chapter 6	Pemphigoid	Immunology
Pemphigus foliaceus	Chapter 6	Pemphigus	Immunology
Pemphigus vulgaris	Chapter 6	Pemphigus	Immunology
Post transfusion purpura	Chapter 6	Post transfusion purpura	Haematology
Secondary hypogammaglobulinaemia (excludes haem malignancies)	Chapter 6	Secondary hypogammaglobulinaemia	Mixed
IgG subclass deficiency EXISTING patients only	Chapter 6	Specific antibody deficiency	Immunology
Specific antibody deficiency	Chapter 6	Specific antibody deficiency	Immunology
IgG subclass deficiency. Existing patient with suppurative lung disease	Chapter 6	Specific antibody deficiency	Immunology
Toxic epidermal necrolysis/Steven Johnson Syndrome	Chapter 6	Toxic epidermal necrolysis/Steven Johnson Syndrome	Immunology
Toxic Shock Syndrome (TSS) - Staphylococcal	Chapter 6	Toxic shock syndrome	Immunology
Toxic Shock Syndrome (TSS) - Streptococcal	Chapter 6	Toxic shock syndrome	Immunology
Acute leukaemia in children	Chapter 7	Acute leukaemia in children	Haematology
Autoimmune congenital heart block	Chapter 7	Autoimmune congenital heart block	Immunology
Autoimmune diabetic neuropathy	Chapter 7	Autoimmune diabetic neuropathy	Neurology
Autoimmune neutropenia	Chapter 7	Autoimmune neutropenia	Haematology
Autoimmune uveitis	Chapter 7	Autoimmune uveitis	Immunology
Catastrophic antiphospholipid syndrome	Chapter 7	Catastrophic antiphospholipid syndrome	Immunology
Coagulation factor inhibitors	Chapter 7	Coagulation factor inhibitors	Haematology
Devic disease (neuromyelitis optica)	Chapter 7	Devic disease (neuromyelitis optica)	Neurology
Diabetic Amyotrophy	Chapter 7	Diabetic Amytrophy	Neurology
Epidermolysis bullosa acquisita	Chapter 7	Epidermolysis bullosa acquisita	Dermatology
Epilepsy (rare childhood cases)	Chapter 7	Epilepsy (rare childhood cases)	Neurology
Graves ophthalmopathy	Chapter 7	Graves ophthalmopathy	Immunology
Haemolytic disease of the newborn	Chapter 7	Haemolytic disease of the newborn	Haematology
Haemolytic transfusion reaction	Chapter 7	Haemolytic transfusion reaction	Haematology
Hashimoto encephalopathy	Chapter 7	Hashimoto enecephalopathy	Neurology

Condition	Chapter	Diagnostic Group	Clinical Discipline
HIV in children	Chapter 7	HIV in children	Immunology
Limbic encephalitis-nonparaneoplastic	Chapter 7	Limbic encephalitis-nonparaneoplastic	Neurology
Myocarditis in children	Chapter 7	Myocarditis in children	Mixed
PANDAS/tic disorders	Chapter 7	PANDAS/tic disorders	Neurology
Limbic encephalitis-paraneoplastic	Chapter 7	Paraneoplastic syndromes	Neurology
Paraneoplastic cerebellar degeneration (Yo antibodies)	Chapter 7	Paraneoplastic syndromes	Neurology
Paraneoplastic Subacute Sensory Neuropathy	Chapter 7	Paraneoplastic syndromes	Neurology
Paraneoplastic syndromes	Chapter 7	Paraneoplastic syndromes	Neurology
Potassium channel antibody-associated encephalopathy	Chapter 7	Potassium channel antibody-associated encephalopathy	Neurology
Pure red cell aplasia	Chapter 7	Pure red cell aplasia	Haematology
Pure white cell aplasia	Chapter 7	Pure white cell aplasia	Haematology
Pyoderma gangrenosum	Chapter 7	Pyoderma gangrenosum	Dermatology
Rasmussen Syndrome	Chapter 7	Rasmussen Syndrome	Neurology
Scleromyxedema	Chapter 7	Scleromyxedema	Mixed
Sepsis - neonatal	Chapter 7	Sepsis - neonatal	Paediatrician
Sjogren’s syndrome	Chapter 7	Sjogren’s syndrome	Immunology
Sjogren's Syndrome	Chapter 7	Sjogren’s syndrome	Immunology
Solid Organ - Heart	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Heart/Lung	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Liver	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Lung	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Other	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Pancreas	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Transplant - Solid Organ	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Transplants - Allogeneic stem cell or bone marrow	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Susac syndrome	Chapter 7	Susac syndrome	Neurology
Systemic Capillary Leak Syndrome	Chapter 7	Systemic Capillary Leak Syndrome	Immunology
Acute optic neuritis	Chapter 8	Acute optic neuritis	Neurology
Acute rheumatic fever	Chapter 8	Acute rheumatic fever	Mixed
Adrenoleukodystrophy	Chapter 8	Adrenoleukodystrophy	Neurology
Amegakaryocytic	Chapter 8	Amegakaryocytic thrombocytopenia	Haematology

Condition	Chapter	Diagnostic Group	Clinical Discipline
thrombocytopenia			
Antiphospholipid syndrome (non obstetric)	Chapter 8	Antiphospholipid syndrome (non obstetric)	Mixed
Aplastic anaemia/pancytopenia	Chapter 8	Aplastic anaemia/pancytopenia	Haematology
Asthma	Chapter 8	Asthma	Mixed
Atopic dermatitis/eczema	Chapter 8	Atopic dermatitis/eczema	Dermatology
Autism – young adults	Chapter 8	Autism – young adults	Mixed
Autologous haemopoietic stem cell transplantation	Chapter 8	Autologous haemopoietic stem cell transplantation	Haematology
Behcet's disease	Chapter 8	Behcet's disease	Immunology
Cardiac surgery with bypass – prophylaxis	Chapter 8	Cardiac surgery with bypass – prophylaxis	Mixed
Congestive cardiac failure	Chapter 8	Congestive cardiac failure	Mixed
Crohn's disease	Chapter 8	Crohn's disease	Mixed
Diamond Blackfan syndrome	Chapter 8	Diamond Blackfan syndrome	Haematology
Female infertility	Chapter 8	Female infertility	Mixed
Glomerulonephritis – IgA nephritis	Chapter 8	Glomerulonephritis – IgA nephritis	Mixed
Haemolytic uraemic syndrome	Chapter 8	Haemolytic uraemic syndrome	Haematology
Henoch-Schonlein purpura	Chapter 8	Henoch-Schonlein purpura	Mixed
HIV/AIDS – adult	Chapter 8	HIV/AIDS – adult	Mixed
Idiopathic dilated cardiomyopathy	Chapter 8	Idiopathic dilated cardiomyopathy	Mixed
Linear IgA disease	Chapter 8	Linear IgA disease	Dermatology
Lupus cerebritis	Chapter 8	Lupus cerebritis	Mixed
Lupus nephritis	Chapter 8	Lupus nephritis	Mixed
Motor neuron disease/amyotrophic lateral sclerosis	Chapter 8	Motor neuron disease/amyotrophic lateral sclerosis	Neurology
Myalgic encephalomyelitis	Chapter 8	Myalgic encephalomyelitis	Neurology
Narcolepsy/cataplexy	Chapter 8	Narcolepsy/cataplexy	Neurology
Nephrotic syndrome	Chapter 8	Nephrotic syndrome	Mixed
Obsessive compulsive disorders	Chapter 8	Obsessive compulsive disorders	Mixed
Polyneuropathy of critical illness	Chapter 8	Polyneuropathy of critical illness	Neurology
Recurrent foetal loss (with or without antiphospholipid syndrome)	Chapter 8	Recurrent foetal loss (with or without antiphospholipid syndrome)	Mixed
Rheumatoid arthritis	Chapter 8	Rheumatoid arthritis	Mixed
Sepsis (other than neonatal sepsis)	Chapter 8	Sepsis (other than neonatal sepsis)	Mixed
Sickle cell disease	Chapter 8	Sickle cell disease	Haematology
Systemic lupus erythematosus	Chapter 8	Systemic lupus erythematosus	Mixed
Ulcerative colitis	Chapter 8	Ulcerative colitis	Mixed

Condition	Chapter	Diagnostic Group	Clinical Discipline
JDO issue	JDO Chapter	JDO	JDO
Acute Idiopathic Dysautomia	NA	Pre 2008 *Criteria*	Neurology
Alloimmune Neutropenia In Infancy	NA	Pre 2008 *Criteria*	Haematology
Alloimmune Thrombocytopenia Neonatal	NA	Pre 2008 *Criteria*	Haematology
Autoimmune Thrombocytopenic	NA	Pre 2008 *Criteria*	Haematology
Cutaneous Vasculitis	NA	Pre 2008 *Criteria*	Mixed
Hypogammaglobulinaemia	NA	Pre 2008 *Criteria*	Immunology
Hypogammaglobulinaemia Unclassified	NA	Pre 2008 *Criteria*	Immunology
Immunological Miscellaneous, No diagnosis recorded	NA	Pre 2008 *Criteria*	Immunology
Miscellaneous	NA	Pre 2008 *Criteria*	Mixed
Myelopathy due to HTLV-1	NA	Pre 2008 *Criteria*	Immunology
Necrotising Myelitis	NA	Pre 2008 *Criteria*	Mixed
Other Lymphoproliferative / Hypogammaglobulinaemia	NA	Pre 2008 *Criteria*	Haematology
Paediatric Myocarditis	NA	Pre 2008 *Criteria*	Mixed
Sensory neuropathy associated with anti-Hu antibodies	NA	Pre 2008 *Criteria*	Neurology
Septic thrombocytopenia	NA	Pre 2008 *Criteria*	Haematology
Stills Disease - Adults	NA	Pre 2008 *Criteria*	Immunology
Trauma - Burns	NA	Pre 2008 *Criteria*	Mixed

Appendix D – Dataset of Ig supply by state/territory 2015-16

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Chapter 5										
Chronic inflammatory demyelinating polyneuropathy	Patients	834	507	648	130	93	36	32	15	2,250
	Grams	363,767	248,735	277,894	104,920	40,008	19,413	9,843	6,557	1,071,135
	Grams/Episode	39	38	34	64	45	39	32	42	39
	Grams per 1,000	47	41	58	40	23	38	25	27	45
Chronic lymphocytic leukaemia	Patients	523	310	347	68	88	32	27	6	1,380
	Grams	134,563	72,774	90,921	12,915	21,203	8,551	7,188	1,953	350,066
	Grams/Episode	30	28	26	26	31	30	31	34	28
	Grams per 1,000	18	12	19	5	12	17	18	8	15
Common variable immunodeficiency disease	Patients	813	288	370	95	116	29	63	10	1,724
	Grams	265,166	96,612	122,267	30,887	34,925	7,645	21,888	1,574	580,964
	Grams/Episode	21	24	22	18	20	28	17	37	21
	Grams per 1,000	35	16	25	12	21	15	56	6	24
Dermatomyositis	Patients	71	49	35	14	12	5	7	0	193
	Grams	21,427	15,056	17,952	6,075	2,994	3,450	3,618	0	70,571
	Grams/Episode	35	41	39	45	37	58	55	0	39
	Grams per 1,000	3	3	4	2	2	7	9	0	3
Guillain-Barré syndrome	Patients	231	196	159	71	41	18	11	<5	727
	Grams	40,830	33,735	26,257	12,171	6,603	2,579	2,017	501	124,692
	Grams/Episode	33	34	32	33	33	34	34	36	33
	Grams per 1,000	5	6	5	5	4	5	5	2	5

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
HSCT - post	Patients	168	79	57	19	17	6	<5	<5	345
	Grams	19,552	10,269	12,346	2,492	1,839	1,535	144	90	48,266
	Grams/Episode	27	19	28	23	32	26	48	30	25
	Grams per 1,000	3	2	3	<1	1	3	<1	<1	2
Inclusion body myositis	Patients	48	48	33	<5	15	<5	0	<5	142
	Grams	18,108	24,929	14,164	543	6,290	312	0	93	64,437
	Grams/Episode	37	37	35	49	41	24	0	47	37
	Grams per 1,000	2	4	3	<1	4	<1	0	<1	3
ITP associated with HIV	Patients	0	0	0	0	0	<5	0	0	<5
	Grams	0	0	0	0	0	275	0	0	275
	Grams/Episode	0	0	0	0	0	92	0	0	92
	Grams per 1,000	0	0	0	0	0	<1	0	0	<1
ITP in pregnancy	Patients	23	18	16	<5	6	<5	0	0	67
	Grams	3,687	2,962	3,555	636	504	480	0	0	11,824
	Grams/Episode	52	74	36	71	72	32	0	0	49
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	Patients	117	90	134	23	32	7	<5	<5	404
	Grams	20,167	12,359	28,026	3,812	5,121	712	80	140	70,415
	Grams/Episode	50	61	38	49	60	65	80	70	46
	Grams per 1,000 Population	3	2	6	1	3	1	<1	<1	3
ITP refractory	Patients	97	204	156	37	64	12	<5	5	574
	Grams	18,567	30,378	24,751	4,405	12,953	1,690	460	802	94,004
	Grams/Episode	49	59	36	69	63	65	51	62	50
	Grams per 1,000	2	5	5	2	8	3	1	3	4
ITP with life-threatening haemorrhage	Patients	141	14	10	13	10	<5	<5	<5	194
	Grams	25,864	2,140	1,803	1,232	1,547	70	638	282	33,576
	Grams/Episode	47	54	36	68	77	35	64	71	48
	Grams per 1,000	3	<1	<1	<1	<1	<1	2	1	1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Kawasaki disease	Patients	140	103	56	30	21	8	8	9	375
	Grams	5,151	4,604	1,791	1,305	1,080	359	459	297	15,046
	Grams/Episode	30	30	28	36	47	45	31	27	31
	Grams per 1,000	<1	<1	<1	<1	<1	<1	1	1	<1
Lambert-Eaton myasthenic syndrome	Patients	7	<5	10	<5	0	0	0	0	20
	Grams	2,721	2,283	4,856	650	0	0	0	0	10,510
	Grams/Episode	45	45	35	50	0	0	0	0	40
	Grams per 1,000	<1	<1	1	<1	0	0	0	0	<1
Multifocal motor neuropathy	Patients	189	98	108	38	43	11	13	5	496
	Grams	100,747	60,204	54,720	32,224	29,136	4,722	6,494	5,213	293,458
	Grams/Episode	44	43	38	67	54	34	53	57	45
	Grams per 1,000	13	10	11	12	17	9	17	21	12
Multiple myeloma	Patients	466	214	382	23	40	40	17	<5	1,177
	Grams	102,726	47,721	98,411	4,460	7,533	11,955	2,814	66	275,685
	Grams/Episode	30	30	26	29	33	32	29	22	29
	Grams per 1,000	13	8	20	2	4	23	7	<1	12
Myasthenia gravis	Patients	335	215	310	46	28	16	16	<5	945
	Grams	128,034	100,633	130,107	22,007	8,418	5,219	8,125	339	402,881
	Grams/Episode	35	36	34	50	35	36	49	57	36
	Grams per 1,000	17	17	27	8	5	10	21	1	17
Neonatal haemochromatosis	Patients	5	<5	0	0	<5	0	<5	0	10
	Grams	353	1,335	0	0	12	0	1,260	0	2,960
	Grams/Episode	32	83	0	0	6	0	60	0	59
	Grams per 1,000	<1	<1	0	0	<1	0	3	0	<1
Non-Hodgkin lymphoma	Patients	388	277	504	38	63	35	15	<5	1,308
	Grams	95,513	63,791	136,216	7,825	15,489	8,456	4,496	363	332,148
	Grams/Episode	29	29	25	27	30	25	30	33	27
	Grams per 1,000	12	11	28	3	9	16	11	1	14

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Other primary immunodeficiency	Patients	48	34	10	8	14	<5	<5	<5	121
	Grams	12,740	10,725	2,474	1,665	2,561	888	228	790	32,072
	Grams/Episode	11	18	16	16	9	15	10	22	13
	Grams per 1,000	2	2	<1	<1	2	2	<1	3	1
Other relevant haematological malignancies	Patients	230	71	150	29	39	12	9	<5	533
	Grams	38,764	15,676	30,678	3,624	7,932	1,934	1,661	288	100,556
	Grams/Episode	28	29	25	19	28	28	21	24	26
	Grams per 1,000	5	3	6	1	5	4	4	1	4
Polymyositis	Patients	163	59	109	10	42	<5	6	<5	393
	Grams	57,093	29,149	48,830	4,571	15,190	1,086	2,137	359	158,414
	Grams/Episode	35	47	38	44	44	37	49	36	39
	Grams per 1,000	7	5	10	2	9	2	5	1	7
Severe combined Immunodeficiency	Patients	7	13	17	<5	<5	0	0	0	39
	Grams	1,743	2,311	4,440	135	6	0	0	0	8,636
	Grams/Episode	9	9	20	17	6	0	0	0	13
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Stiff person syndrome	Patients	25	13	21	<5	0	<5	0	0	62
	Grams	13,487	4,830	11,614	865	0	1,338	0	0	32,134
	Grams/Episode	43	38	37	39	0	37	0	0	40
	Grams per 1,000	2	<1	2	<1	0	3	0	0	1
Wiskott-Aldrich syndrome	Patients	<5	<5	0	<5	0	0	0	0	5
	Grams	33	465	0	678	0	0	0	0	1,176
	Grams/Episode	33	6	0	26	0	0	0	0	11
	Grams per 1,000	<1	<1	0	<1	0	0	0	0	<1
X linked agammaglobulinaemia	Patients	32	50	17	6	5	0	<5	<5	110
	Grams	10,791	16,889	5,933	1,698	1,815	0	241	600	37,968
	Grams/Episode	25	20	17	10	31	0	5	24	19
	Grams per 1,000	1	3	1	<1	1	0	<1	2	2

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Chapter 5 Total	Patients	4,998	2,909	3585	703	771	272	239	76	13,328
	Grams	1,501,589	910,563	1,150,002	261,791	223,157	82,668	73,791	20,306	4,223,866
	Grams/Episode	31	33	29	39	34	33	27	41	31
	Grams per 1,000	196	152	239	101	131	160	188	83	176
Chapter 6										
Acute disseminated encephalomyelitis	Patients	28	20	23	<5	0	<5	0	<5	75
	Grams	5,291	3,557	3,279	20	0	323	0	160	12,630
	Grams/Episode	38	37	37	20	0	27	0	80	37
	Grams per 1,000	<1	<1	<1	<1	0	<1	0	<1	<1
ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	Patients	<5	<5	8	0	0	0	<5	0	14
	Grams	450	1,090	1,907	0	0	0	175	0	3,622
	Grams/Episode	30	44	43	0	0	0	18	0	39
	Grams per 1,000	<1	<1	<1	0	0	0	<1	0	<1
Autoimmune haemolytic anaemia	Patients	45	38	24	7	8	<5	0	0	125
	Grams	7,272	5,825	3,493	936	2,376	180	0	0	20,081
	Grams/Episode	41	58	31	41	77	36	0	0	45
	Grams per 1,000	<1	<1	<1	<1	1	<1	0	0	<1
Bullous pemphigoid	Patients	16	<5	6	<5	0	0	0	0	28
	Grams	11,087	1,820	4,236	660	0	0	0	0	17,803
	Grams/Episode	47	67	36	44	0	0	0	0	45
	Grams per 1,000	1	<1	<1	<1	0	0	0	0	<1
Churg-Strauss syndrome	Patients	0	<5	0	0	<5	0	0	0	<5
	Grams	0	175	0	0	140	0	0	0	315
	Grams/Episode	0	25	0	0	140	0	0	0	39
	Grams per 1,000	0	<1	0	0	<1	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Cicatricial pemphigoid	Patients	<5	<5	7	<5	<5	0	<5	0	21
	Grams	3,684	1,800	2,602	1,880	3,760	0	4,035	0	17,761
	Grams/Episode	88	67	45	134	70	0	122	0	78
	Grams per 1,000	<1	<1	<1	<1	2	0	10	0	<1
Evans syndrome	Patients	0	<5	0	<5	0	0	0	0	<5
	Grams	0	160	0	195	0	0	0	0	355
	Grams/Episode	0	80	0	65	0	0	0	0	71
	Grams per 1,000	0	<1	0	<1	0	0	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	Patients	<5	5	6	<5	<5	<5	0	0	21
	Grams	2,268	4,385	4,683	2,484	2,175	240	0	0	16,235
	Grams/Episode	76	69	78	71	62	60	0	0	71
	Grams per 1,000	<1	<1	<1	<1	1	<1	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	Patients	9	5	<5	5	<5	<5	<5	0	23
	Grams	33	21	3	27	6	3	6	0	99
	Grams/Episode	3	4	3	3	3	3	3	0	3
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1
Haemophagocytic syndrome	Patients	23	13	8	<5	<5	0	0	0	49
	Grams	2,156	1,589	1,165	397	560	0	0	0	5,867
	Grams/Episode	35	44	38	36	93	0	0	0	40
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	48	0	0	0	0	0	0	0	48
	Grams/Episode	24	0	0	0	0	0	0	0	24
	Grams per 1,000	<1	0	0	0	0	0	0	0	<1
IgG subclass deficiency EXISTING patients only	Patients	0	22	<5	<5	<5	<5	0	0	31
	Grams	0	3,207	42	351	549	948	0	0	5,097
	Grams/Episode	0	28	21	23	31	22	0	0	27
	Grams per 1,000	0	<1	<1	<1	<1	2	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
IgG subclass deficiency. Existing patient with suppurative lung disease	Patients	16	19	0	<5	<5	<5	0	0	42
	Grams	5,545	4,221	0	519	477	732	0	0	11,494
	Grams/Episode	30	29	0	23	25	29	0	0	29
	Grams per 1,000	<1	<1	0	<1	<1	1	0	0	<1
IgM para-proteinaemic neuropathy	Patients	39	12	37	<5	6	<5	0	0	98
	Grams	13,102	2,873	14,861	2,874	1,590	767	0	0	36,066
	Grams/Episode	37	35	34	68	32	43	0	0	37
	Grams per 1,000	2	<1	3	1	<1	1	0	0	2
ITP in children	Patients	28	42	48	10	16	<5	5	<5	152
	Grams	2,198	1,842	2,132	249	1,605	435	462	24	8,947
	Grams/Episode	29	32	27	23	31	24	31	12	29
	Grams per 1,000	<1	<1	<1	<1	<1	<1	1	<1	<1
Kidney transplantation post-transplant	Patients	63	175	58	17	22	12	<5	<5	349
	Grams	8,030	47,688	14,352	3,122	2,088	4,383	530	616	80,807
	Grams/Episode	22	30	20	38	22	46	44	77	27
	Grams per 1,000	1	8	3	1	1	8	1	3	3
Kidney transplantation pre-transplant	Patients	32	24	8	<5	5	<5	<5	0	72
	Grams	2,134	2,810	1,052	325	779	165	187	0	7,451
	Grams/Episode	27	14	16	81	31	55	47	0	20
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1
Microscopic polyangiitis	Patients	0	0	<5	<5	0	0	0	0	<5
	Grams	0	0	168	288	0	0	0	0	456
	Grams/Episode	0	0	24	24	0	0	0	0	24
	Grams per 1,000	0	0	<1	<1	0	0	0	0	<1
Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	Patients	5	<5	5	0	<5	0	0	0	13
	Grams	1,354	624	1,309	0	20	0	0	0	3,307
	Grams/Episode	35	24	34	0	20	0	0	0	32
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Multiple sclerosis in pregnancy	Patients	<5	0	<5	0	0	0	0	0	5
	Grams	657	0	267	0	0	0	0	0	924
	Grams/Episode	37	0	30	0	0	0	0	0	34
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Multiple sclerosis in young patients severe/relapsing/remitting in whom other	Patients	17	0	<5	0	0	0	<5	0	19
	Grams	4,028	0	348	0	0	0	150	0	4,526
	Grams/Episode	30	0	35	0	0	0	25	0	30
	Grams per 1,000	<1	0	<1	0	0	0	<1	0	<1
Opsoclonus myoclonus ataxia	Patients	12	6	<5	<5	<5	0	0	0	27
	Grams	2,107	927	255	168	2,008	0	0	0	5,465
	Grams/Episode	27	16	15	13	54	0	0	0	27
	Grams per 1,000	<1	<1	<1	<1	1	0	0	0	<1
Pemphigus foliaceus	Patients	<5	<5	<5	0	0	0	0	0	6
	Grams	2,157	540	1,121	0	0	0	0	0	3,818
	Grams/Episode	49	60	35	0	0	0	0	0	45
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Pemphigus vulgaris	Patients	15	5	8	<5	<5	0	<5	0	34
	Grams	10,404	2,175	6,183	2,238	640	0	1,615	0	23,254
	Grams/Episode	53	70	53	97	160	0	124	0	60
	Grams per 1,000	1	<1	1	<1	<1	0	4	0	<1
Post transfusion purpura	Patients	0	<5	<5	0	0	0	0	0	<5
	Grams	0	69	270	0	0	0	0	0	339
	Grams/Episode	0	69	45	0	0	0	0	0	48
	Grams per 1,000	0	<1	<1	0	0	0	0	0	<1
Secondary hypogammaglobulinaemia (excludes haem malignancies)	Patients	269	125	197	34	14	15	8	<5	652
	Grams	57,591	22,351	51,562	5,405	2,456	5,260	834	39	145,497
	Grams/Episode	26	25	23	16	18	33	22	39	24
	Grams per 1,000	8	4	11	2	1	10	2	<1	6

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Specific antibody deficiency	Patients	105	39	49	50	19	<5	8	<5	268
	Grams	28,037	10,312	13,773	12,056	5,453	503	2,149	122	72,403
	Grams/Episode	18	23	23	15	14	24	24	9	18
	Grams per 1,000	4	2	3	5	3	<1	5	<1	3
Toxic epidermal necrolysis/Steven Johnson syndrome	Patients	19	21	<5	<5	<5	<5	<5	<5	53
	Grams	2,649	2,924	108	510	243	490	60	30	7,014
	Grams/Episode	55	61	9	128	49	163	60	15	57
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1
Transplant - Solid Organ	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	162	0	0	0	0	0	0	162
	Grams/Episode	0	27	0	0	0	0	0	0	27
	Grams per 1,000	0	<1	0	0	0	0	0	0	<1
TSS - staphylococcal	Patients	13	32	8	<5	<5	<5	<5	<5	63
	Grams	1,794	3,851	1,061	369	18	244	192	3	7,532
	Grams/Episode	69	77	66	53	9	81	64	3	70
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1
TSS - streptococcal	Patients	31	27	34	9	<5	<5	<5	0	109
	Grams	4,248	4,354	4,572	1,219	132	90	587	0	15,202
	Grams/Episode	70	93	86	87	33	45	53	0	79
	Grams per 1,000	<1	<1	<1	<1	<1	<1	1	0	<1
Wegeners granulomatosis	Patients	0	<5	<5	0	<5	0	0	0	6
	Grams	0	650	49	0	324	0	0	0	1,023
	Grams/Episode	0	28	25	0	27	0	0	0	28
	Grams per 1,000	0	<1	<1	0	<1	0	0	0	<1
Chapter 6 Total	Patients	790	628	543	168	117	54	38	10	2,315
	Grams	178,320	132,001	134,849	36,290	27,398	14,763	10,982	994	535,596
	Grams/Episode	29	31	27	24	28	36	46	34	29
	Grams per 1,000	23	22	28	14	16	29	28	4	22

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Chapter 7										
Acute leukaemia in children	Patients	0	12	0	0	0	<5	0	0	13
	Grams	0	855	0	0	0	120	0	0	975
	Grams/Episode	0	33	0	0	0	24	0	0	31
	Grams per 1,000	0	<1	0	0	0	<1	0	0	<1
Autoimmune congenital heart block	Patients	<5	0	<5	0	0	0	0	0	<5
	Grams	6	0	6	0	0	0	0	0	12
	Grams/Episode	6	0	6	0	0	0	0	0	6
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Autoimmune neutropenia	Patients	<5	<5	<5	0	0	<5	0	<5	6
	Grams	447	375	150	0	0	80	0	1,116	2,168
	Grams/Episode	50	75	30	0	0	40	0	86	64
	Grams per 1,000	<1	<1	<1	0	0	<1	0	5	<1
Autoimmune uveitis	Patients	<5	0	<5	0	0	0	0	0	<5
	Grams	473	0	175	0	0	0	0	0	648
	Grams/Episode	47	0	35	0	0	0	0	0	43
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Catastrophic antiphospholipid syndrome	Patients	<5	<5	5	<5	0	0	0	<5	13
	Grams	482	181	813	149	0	0	0	80	1,705
	Grams/Episode	40	91	37	21	0	0	0	16	36
	Grams per 1,000	<1	<1	<1	<1	0	0	0	<1	<1
Coagulation factor inhibitors	Patients	<5	<5	6	<5	<5	0	0	0	13
	Grams	635	200	3,120	78	495	0	0	0	4,528
	Grams/Episode	45	100	89	39	33	0	0	0	67
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Devic disease (neuromyelitis optica)	Patients	26	5	6	<5	<5	<5	<5	0	42
	Grams	7,667	1,538	1,137	1,625	260	150	100	0	12,477
	Grams/Episode	32	35	26	125	29	30	20	0	34
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Diabetic Amyotrophy	Patients	<5	<5	<5	0	0	0	0	0	9
	Grams	1,404	485	1,023	0	0	0	0	0	2,912
	Grams/Episode	26	32	28	0	0	0	0	0	28
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Epidermolysis bullosa acquisita	Patients	0	0	0	<5	<5	0	<5	0	<5
	Grams	0	0	0	2,886	90	0	2,006	0	4,982
	Grams/Episode	0	0	0	74	90	0	87	0	79
	Grams per 1,000	0	0	0	1	<1	0	5	0	<1
Epilepsy (rare childhood cases)	Patients	<5	7	<5	6	<5	0	0	0	20
	Grams	696	2,496	894	1,347	252	0	0	0	5,685
	Grams/Episode	41	43	43	36	42	0	0	0	41
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Graves ophthalmopathy	Patients	0	0	<5	<5	0	0	0	0	5
	Grams	0	0	2,360	450	0	0	0	0	2,810
	Grams/Episode	0	0	54	90	0	0	0	0	57
	Grams per 1,000	0	0	<1	<1	0	0	0	0	<1
Haemolytic disease of the newborn	Patients	26	20	11	11	13	0	<5	<5	86
	Grams	1,068	3,962	192	342	51	0	18	3	5,636
	Grams/Episode	23	51	12	24	3	0	3	3	31
	Grams per 1,000	<1	<1	<1	<1	<1	0	<1	<1	<1
Haemolytic transfusion reaction	Patients	<5	<5	0	0	0	0	0	0	<5
	Grams	200	110	0	0	0	0	0	0	310
	Grams/Episode	50	55	0	0	0	0	0	0	52
	Grams per 1,000	<1	<1	0	0	0	0	0	0	<1
Hashimoto encephalopathy	Patients	<5	<5	<5	<5	0	0	0	0	10
	Grams	1,337	946	330	1,655	0	0	0	0	4,268
	Grams/Episode	29	32	30	57	0	0	0	0	37
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Limbic Encephalitis (nonparaneoplastic)	Patients	54	41	70	5	10	<5	6	<5	188
	Grams	12,355	8,166	21,913	970	1,583	368	2,194	550	48,098
	Grams/Episode	34	29	32	46	37	26	56	37	33
	Grams per 1,000	2	1	5	<1	<1	<1	6	2	2
Limbic Encephalitis (Paraneoplastic)	Patients	14	9	15	<5	<5	0	<5	0	46
	Grams	2,313	1,190	2,982	490	687	0	453	0	8,114
	Grams/Episode	27	29	36	38	33	0	24	0	31
	Grams per 1,000	<1	<1	<1	<1	<1	0	1	0	<1
Myocarditis in children	Patients	6	11	6	<5	<5	0	0	0	29
	Grams	48	719	204	54	30	0	0	0	1,055
	Grams/Episode	7	26	20	18	8	0	0	0	20
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
PANDAS/tic disorders	Patients	<5	<5	<5	<5	0	<5	0	0	6
	Grams	244	792	171	120	0	120	0	0	1,447
	Grams/Episode	41	36	171	120	0	60	0	0	45
	Grams per 1,000	<1	<1	<1	<1	0	<1	0	0	<1
Paraneoplastic cerebellar degeneration	Patients	<5	0	<5	<5	<5	<5	0	0	8
	Grams	100	0	180	850	175	274	0	0	1,579
	Grams/Episode	20	0	30	53	35	30	0	0	39
	Grams per 1,000	<1	0	<1	<1	<1	<1	0	0	<1
Paraneoplastic cerebellar degeneration (Yo antibodies)	Patients	<5	0	0	<5	<5	<5	0	0	5
	Grams	160	0	0	665	35	256	0	0	1,116
	Grams/Episode	40	0	0	60	35	32	0	0	47
	Grams per 1,000	<1	0	0	<1	<1	<1	0	0	<1
Paraneoplastic Subacute Sensory Neuropathy	Patients	6	5	0	0	<5	<5	0	<5	17
	Grams	1,307	941	0	0	480	105	0	655	3,488
	Grams/Episode	23	38	0	0	28	35	0	82	32
	Grams per 1,000	<1	<1	0	0	<1	<1	0	3	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Paraneoplastic syndromes	Patients	0	<5	<5	0	<5	0	0	0	<5
	Grams	0	150	1,240	0	429	0	0	0	1,819
	Grams/Episode	0	30	43	0	33	0	0	0	39
	Grams per 1,000	0	<1	<1	0	<1	0	0	0	<1
Potassium channel antibody-associated encephalopathy	Patients	12	5	<5	<5	<5	<5	0	0	25
	Grams	4,516	1,027	640	920	1,148	1,170	0	0	9,421
	Grams/Episode	33	37	40	92	38	33	0	0	37
	Grams per 1,000	<1	<1	<1	<1	<1	2	0	0	<1
Pure red cell aplasia	Patients	10	<5	8	<5	<5	<5	0	0	24
	Grams	2,467	221	3,394	610	170	1,560	0	0	8,422
	Grams/Episode	39	37	45	122	85	40	0	0	44
	Grams per 1,000	<1	<1	<1	<1	<1	3	0	0	<1
Pyoderma gangrenosum	Patients	8	17	0	0	<5	0	0	0	27
	Grams	4,687	10,141	0	0	1,770	0	0	0	16,598
	Grams/Episode	81	58	0	0	68	0	0	0	64
	Grams per 1,000	<1	2	0	0	1	0	0	0	<1
Rasmussen Syndrome	Patients	11	<5	<5	0	<5	0	<5	0	19
	Grams	4,067	551	1,303	0	715	0	495	0	7,131
	Grams/Episode	37	31	36	0	55	0	38	0	38
	Grams per 1,000	<1	<1	<1	0	<1	0	1	0	<1
Scleromyxedema	Patients	6	<5	<5	<5	<5	0	<5	0	14
	Grams	3,367	2,372	240	350	1,505	0	27	0	7,861
	Grams/Episode	47	39	80	35	79	0	27	0	47
	Grams per 1,000	<1	<1	<1	<1	<1	0	<1	0	<1
Sjogren's Syndrome	Patients	10	<5	5	0	<5	0	<5	0	22
	Grams	3,811	489	1,510	0	1,088	0	2,800	0	9,698
	Grams/Episode	31	33	37	0	68	0	58	0	40
	Grams per 1,000	<1	<1	<1	0	<1	0	7	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Solid organ - heart	Patients	9	5	<5	<5	0	<5	0	0	16
	Grams	1,295	999	495	150	0	132	0	0	3,071
	Grams/Episode	24	43	35	75	0	44	0	0	32
	Grams per 1,000	<1	<1	<1	<1	0	<1	0	0	<1
Solid organ - heart/lung	Patients	<5	<5	<5	0	0	0	0	0	7
	Grams	345	547	324	0	0	0	0	0	1,216
	Grams/Episode	58	20	27	0	0	0	0	0	26
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Solid organ - liver	Patients	8	<5	<5	0	0	0	0	0	11
	Grams	777	9	60	0	0	0	0	0	846
	Grams/Episode	43	9	20	0	0	0	0	0	38
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Solid organ - lung	Patients	31	55	13	<5	5	<5	0	0	106
	Grams	4,993	10,473	1,885	564	861	140	0	0	18,915
	Grams/Episode	30	27	20	40	29	35	0	0	27
	Grams per 1,000	<1	2	<1	<1	<1	<1	0	0	<1
Solid organ - other	Patients	0	<5	<5	0	0	0	0	0	<5
	Grams	0	53	51	0	0	0	0	0	104
	Grams/Episode	0	8	7	0	0	0	0	0	7
	Grams per 1,000	0	<1	<1	0	0	0	0	0	<1
Solid organ - pancreas	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	115	0	0	0	0	0	0	0	115
	Grams/Episode	38	0	0	0	0	0	0	0	38
	Grams per 1,000	<1	0	0	0	0	0	0	0	<1
Susac syndrome	Patients	7	0	8	0	0	0	0	0	15
	Grams	6,148	0	3,146	0	0	0	0	0	9,294
	Grams/Episode	51	0	46	0	0	0	0	0	49
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Systemic Capillary Leak syndrome	Patients	<5	<5	<5	0	0	0	<5	0	9
	Grams	672	2,496	3,879	0	0	0	1,360	0	8,407
	Grams/Episode	27	89	90	0	0	0	105	0	77
	Grams per 1,000	<1	<1	<1	0	0	0	3	0	<1
Chapter 7 Total	Patients	270	224	188	49	61	15	21	6	820
	Grams	68,199	52,482	53,816	14,275	11,824	4,475	9,453	2,404	216,927
	Grams/Episode	35	37	37	57	41	35	56	57	38
	Grams per 1,000	9	9	11	5	7	9	24	10	9
Chapter 8										
Sepsis (other than neonatal sepsis)	Patients	0	0	0	0	0	0	0	<5	<5
	Grams	0	0	0	0	0	0	0	5	5
	Grams/Episode	0	0	0	0	0	0	0	5	5
	Grams per 1,000	0	0	0	0	0	0	0	<1	<1
Chapter 8 Total	Patients	0	0	0	0	0	0	0	<5	<5
	Grams	0	0	0	0	0	0	0	5	5
	Grams/Episode	0	0	0	0	0	0	0	5	5
	Grams per 1,000	0	0	0	0	0	0	0	<1	<1
Total	Patients	6,019	3,723	4276	916	942	340	296	93	16,331
	Grams	1,748,108	1,095,046	1,338,667	312,355	262,379	101,905	94,226	23,709	4,976,394
	Grams/Episode	31	33	29	37	33	33	30	42	31
	Grams per 1,000	228	183	278	120	154	197	240	97	208

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	WA	SA	TAS	ACT	NT
2005-06	Imported Ig	76,368	52,097	134,475	7,765	15,300	13,608	8,165	
	Domestic Ig	452,565	361,665	219,633	152,127	109,515	33,837	21,774	8,004
2006-07	Imported Ig	103,270	88,398	79,393	20,577	18,375	11,065	7,170	
	Domestic Ig	493,172	407,244	337,301	155,821	92,958	50,583	26,470	6,732
2007-08	Imported Ig	105,633	111,010	85,055	38,445	18,416	11,740	16,875	
	Domestic Ig	599,126	423,170	400,144	148,986	108,596	52,755	27,393	6,825
2008-09	Imported Ig	249,905	131,228	171,367	42,895	27,604	19,965	14,200	
	Domestic Ig	562,320	417,574	383,865	143,628	128,511	53,745	22,841	10,503
2009-10	Imported Ig	252,416	101,930	200,264	16,248	31,244	17,110	11,550	
	Domestic Ig	668,526	507,038	439,089	162,963	143,285	61,686	33,225	8,610
2010-11	Imported Ig	136,728	93,835	107,798	30,108	27,383	8,843	11,900	80
	Domestic Ig	887,016	577,260	631,545	167,745	139,296	76,197	45,540	9,099
2011-12	Imported Ig	265,995	144,284	183,435	59,900	35,775	12,138	14,708	30
	Domestic Ig	874,995	570,969	674,277	150,294	145,134	73,491	52,446	13,440
2012-13	Imported Ig	467,371	321,085	361,654	92,914	72,613	16,436	26,648	9,551
	Domestic Ig	804,375	484,680	589,662	132,108	123,810	64,305	48,480	6,744
2013-14	Imported Ig	469,174	312,713	291,460	70,709	87,901	24,069	30,626	10,429
	Domestic Ig	934,478	584,561	771,037	168,295	138,876	67,776	53,723	6,036
2014-15	Imported Ig	593,045	416,868	458,189	111,570	107,343	41,608	32,199	12,861
	Domestic Ig	930,412	579,560	735,658	155,977	135,795	57,987	59,210	4,863
2015-16	Imported Ig	724,960	451,770	584,275	159,631	103,165	48,003	41,264	18,489
	Domestic Ig	1,004,528	643,340	771,182	152,900	167,599	53,207	52,601	5,589

Appendix F – Unique Patients by Quarter and State and Territory

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

Appendix G – System Source for Tables and Figures