NATIONAL BLOOD AUTHORITY
AUSTRALIA

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

Annual Report 2013-14

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Introduction

Immunoglobulins products analysed in this report include intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg). These are referred to as immunoglobulin (Ig). Ig is a blood product derived from donated human blood. It is used to treat a broad range of conditions, with applications in immunoglobulin replacement and immune modulation therapy. This report provides an analysis of national data on national Ig supply in Australia in 2013-14, also considering trends in supply over the last ten years.

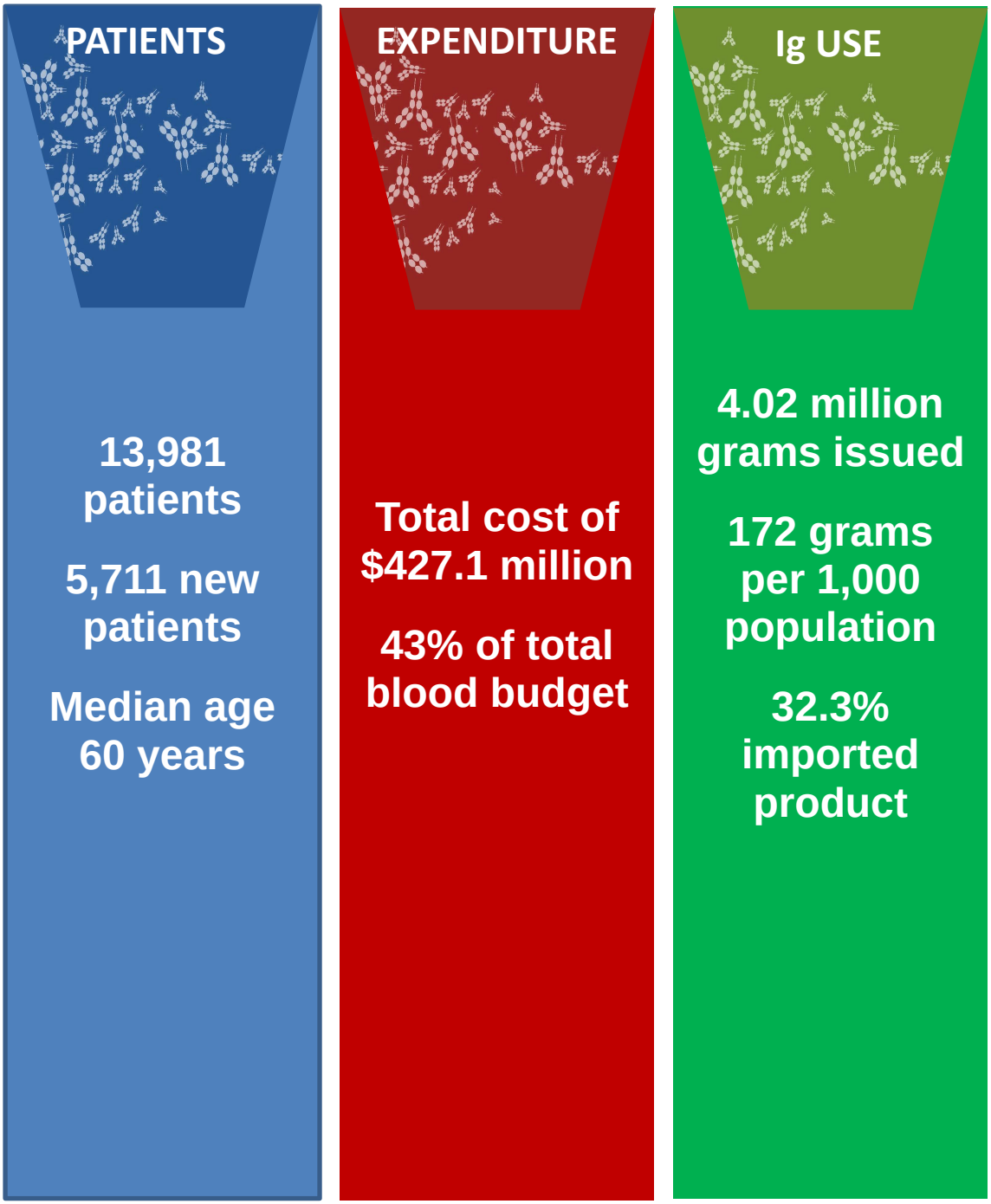
In Australia it is estimated that over 99% of all Ig is supplied under national blood arrangements through contracts administered by the National Blood Authority (NBA). The NBA's role is to coordinate national supply and demand planning for blood and blood products including supply risk management; purchasing 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 immunoglobulin (IVIg) 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, as there is no evidence to support its use in these conditions.

Ig comprises a large proportion of blood expenditure each year. Demand for Ig continues to rise steadily, and Australian per capita use of this product is one of the highest among western countries. Demand for Ig is met through local manufacture of Ig by CSL Behring using plasma collected from voluntary, non-remunerated Australian donors and is supplemented by importation of Ig from overseas manufacturers. Both the 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 88.0% of all Ig supplied, and for this reason specific analysis focuses on these groups.

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 six years between 2008-09 and 2013-14, data has been captured on 36,422 patients. Caveats relating to the quality of this data are outlined below.

This report does not include data on supply of Normal Immunoglobulin (NIg). It includes data on Subcutaneous Immunoglobulin (SCIg) for 2013-14 only as no SCIg product was available in Australia before 2013-14.

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 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 appeared 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 31,304 patients (86%) had weight data entered, but only 6,218 (17%) had their weight data updated following 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 802 (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 3,311 (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 2013-14 a total of 4,021,861 grams of Ig was issued, representing an increase of 399,428 grams (11.0%) over 2012-13. Since 2003-04 there has been an on average 11.4% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

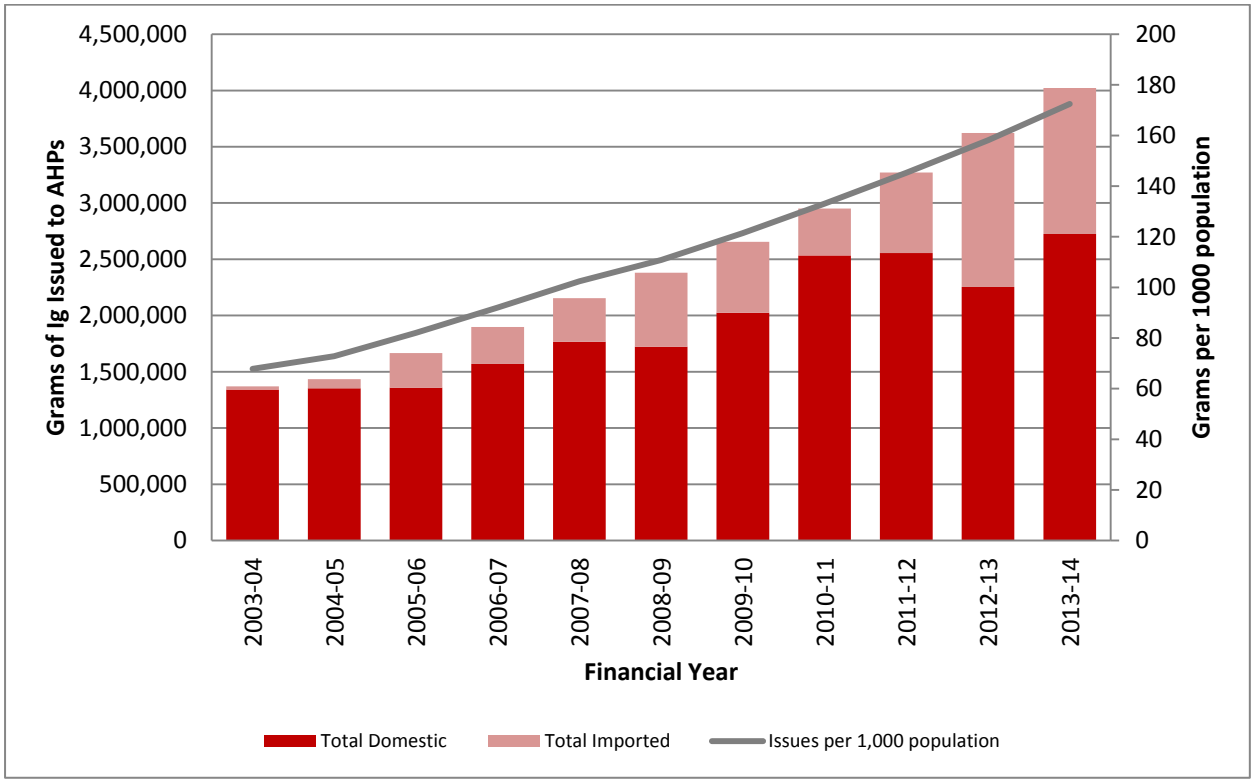


Figure 1 Ten year trends in issues of Ig

Table 1 Growth in Ig grams issued since 2004

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
Growth from previous year	5%	16%	14%	13%	10%	12%	11%	11%	11%	11%
Average Growth from 2003-04	5%	11%	12%	12%	12%	12%	12%	12%	11%	11%
Total grams per 1,000 population	72	82	92	103	111	121	133	145	158	172
Increase in grams per 1,000 population over previous year	7%	13%	12%	11%	8%	10%	10%	9%	9%	9%

There has been a steady increase in demand for Ig over the last ten years, with increases of 10-12% per annum for the last five years. While a small proportion of this increase may be attributable to population increases, there has also been a steady increase of 8-10% per annum in the use of Ig per capita (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	SA	WA	TAS	NT	ACT
2004-05	13%	12%	0%	-5%	19%	14%	23%	3%
2005-06	14%	15%	15%	20%	8%	3%	3%	22%
2006-07	13%	20%	18%	-11%	10%	30%	-16%	12%
2007-08	18%	8%	16%	14%	6%	5%	1%	29%
2008-09	15%	3%	14%	23%	0%	14%	54%	-14%
2009-10	13%	11%	15%	12%	-4%	7%	-18%	20%
2010-11	11%	10%	16%	-4%	10%	8%	7%	28%
2011-12	11%	7%	16%	9%	6%	1%	47%	17%
2012-13	11%	13%	11%	9%	7%	-6%	21%	12%
2013-14	10%	11%	12%	15%	6%	14%	12%	1%

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 in 2013-14 was $244.4 million, an increase of $24.3 million (11.1%) over 2012-13 (Figure 2). The increased expenditure predominately represents increases in demand.

There has also been 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 $427.1 million (excluding hyperimmunes).

There was a concurrent price reduction for some imported Ig products which constrained the overall price increase.

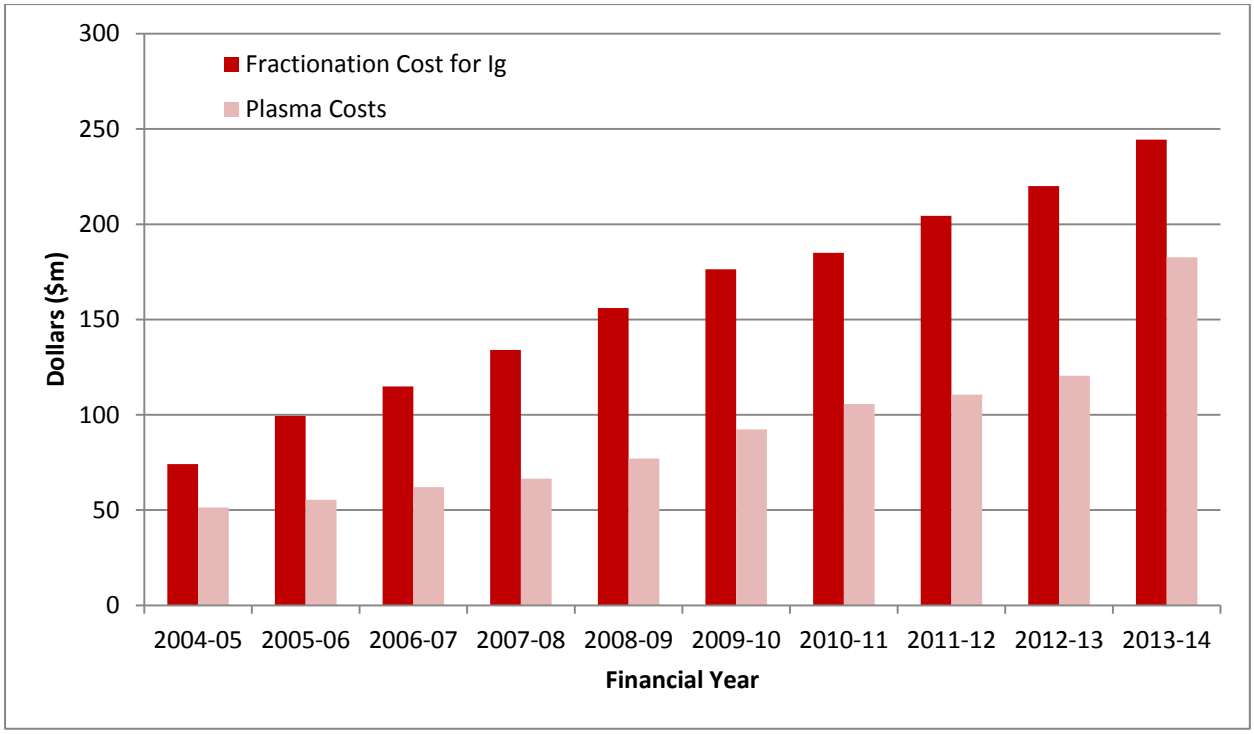


Figure 2 Ten year trends in expenditure on Ig

Demographics

PATIENT NUMBERS

A total of 13,981 patients were issued Ig under national blood arrangements during 2013-14 for 122,791 treatment episodes. This represents a 6.7% increase in the number of patients since 2012-13. A summary of some patient numbers is provided in 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	2,379,967
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

Table 4 Basic numbers

	2012-13	2013-14
Total unique patient IDs	30,840	36,422
Total unique patient IDs with some weight data	25,616	31,304
Total unique patient IDs with an age recorded	26,853	32,504
Total unique patient IDs with a weight change	5,443	6,218
Total unique patient IDs with more than one state or territory	675	802
Total unique patient IDs with two states or territories	620	735
Total unique patient IDs with three or more states or territories	55	67
Total unique patient IDs with more than one condition	2,713	3311
Total unique patient IDs with two conditions	2,405	2887
Total unique patient IDs with three conditions	286	389
Total unique patient IDs with four or more conditions	22	35
Total unique patient IDs aged 93 or older	189	304

GEOGRAPHIC DISTRIBUTION

Nationally, 0.6 patients per 1,000 population received Ig in 2013-14. This varied between states and territories, ranging from 0.3 in Western Australia to 0.8 in Queensland (Figure 3). All states and territories other than the Northern Territory 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.**

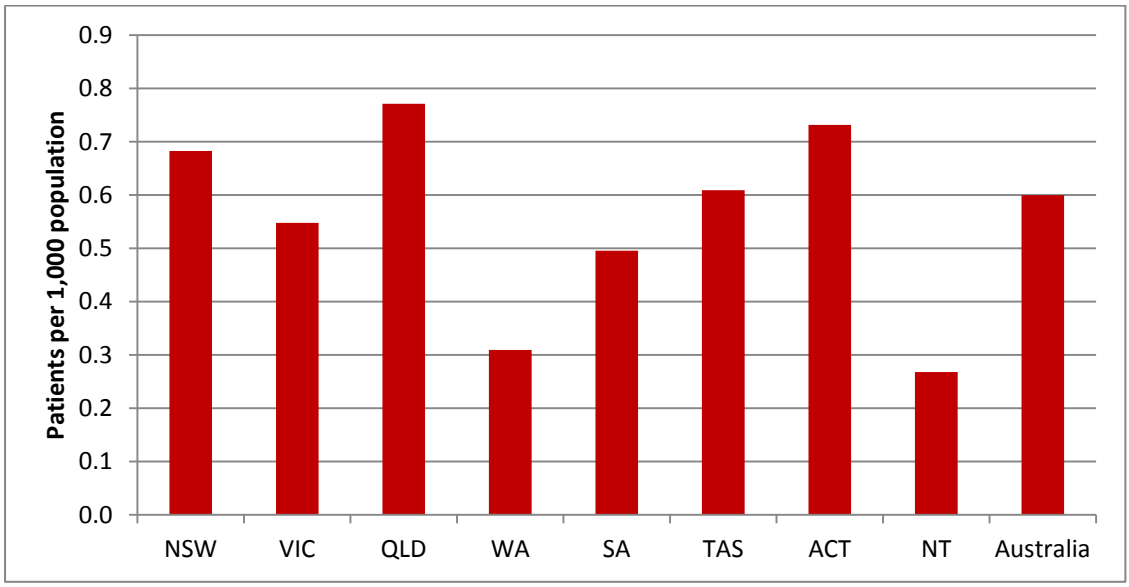


Figure 3 Patients per 1,000 population 2013-14

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 67.9 in the Northern Territory to 226.5 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 93.7 grams per 1,000 population in Western Australia to 226.5 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.

Over time, Western Australia has 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.

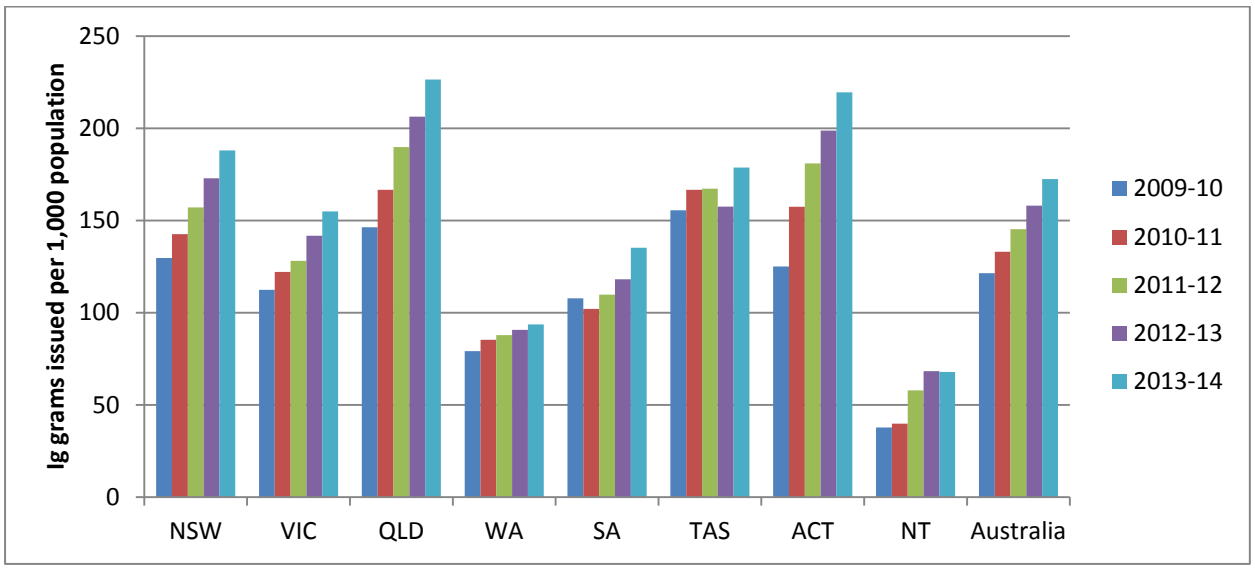


Figure 4 Grams of Ig per 1,000 population by state and territory over time

AGE

The distribution of estimated age is shown in Figure 5 where it is compared with the age distribution of the Australian population at June 2013[1]. A bimodal peak can be seen in the Ig population, with the majority of 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 double between 2000 and 2050[2].

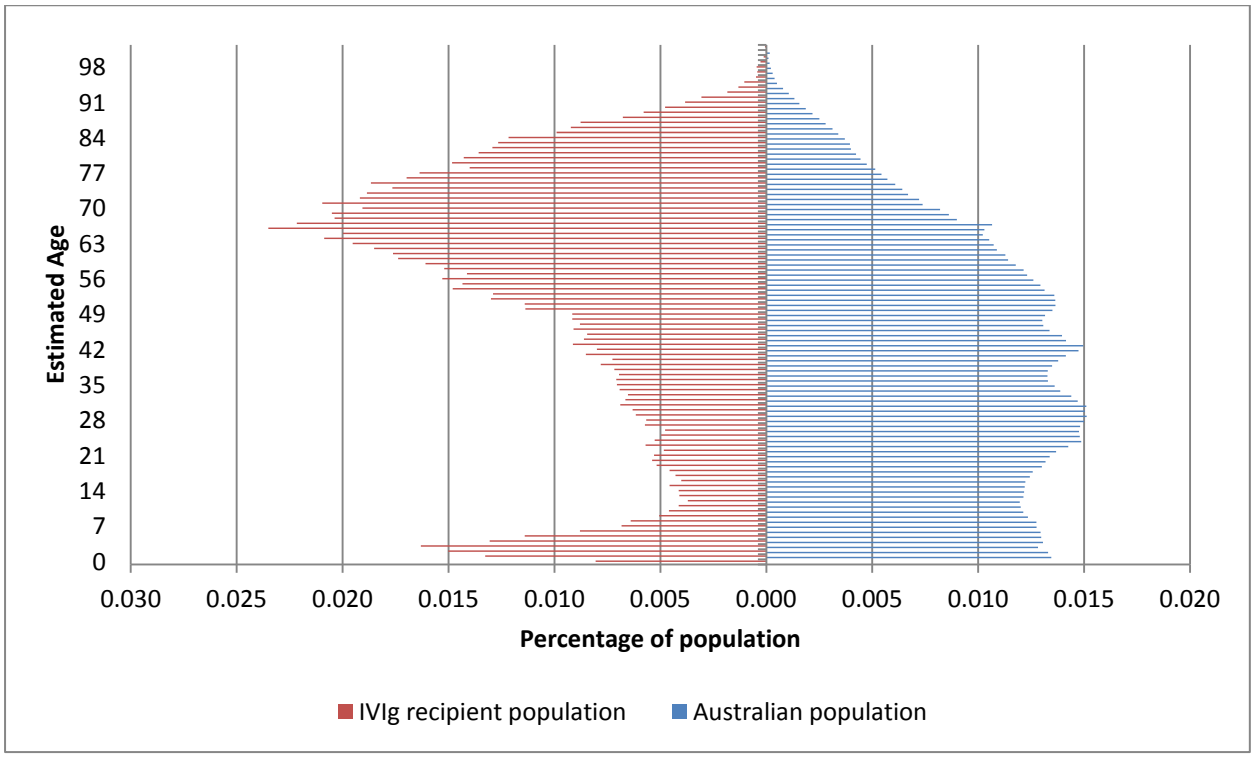


Figure 5 Patient age compared to average Australian age

WEIGHT

Ig dosing is dependent on the weight of the patient. For 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.

[1] ABS 3101.0

[2] World Health Organisation, http://www.who.int/ageing/en/ (Accessed 26 Feb 2014)

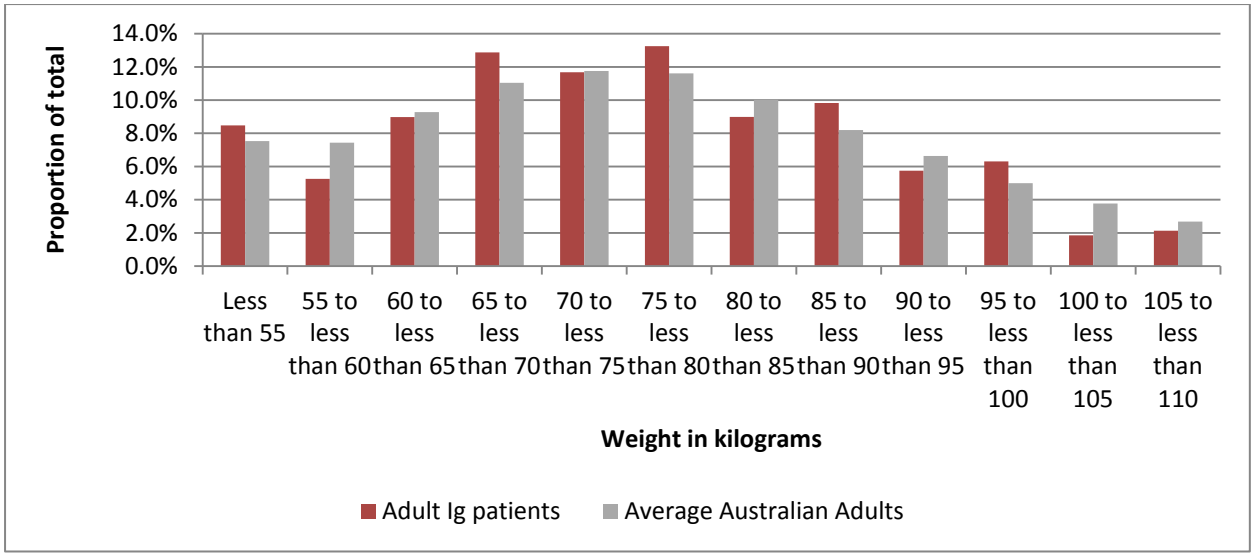


Figure 6 **Patient weights relative to Australian average**

Figure 6 compares the weight of Ig recipients in Australia and the Australian population[3]. There are a higher proportion of patients treated with Ig less than 55kg, between 65kg and 70kg, 75kg and 80kg, 85 and 90kg and 95kg and 100kg relative to the proportion in the Australian population. The average weight of adult Ig patients (77.8 kg) is slightly higher than that of the average weight of an Australian adult (77.7 kg[4]). Given that studies suggest that 63% of Australians are overweight or obese[5], 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[6]. 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 review of the literature relating to lean body mass dosing should be considered for future iterations of the *Criteria.*

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.

[3] ABS 4841.0
[4] ABS 4841.0 (average of male and female)
[5] ABS 4364.0.55.001
[6] 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 2013-14, Australian expenditure on Ig products was $244.4 million, with additional expenditure of $191.2 million on plasma for fractionation (including hyperimmunes) 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 24% of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, Ig accounts for 42.7% of the total blood budget, at a total expenditure of $435.6 million (excluding hyperimmunes).

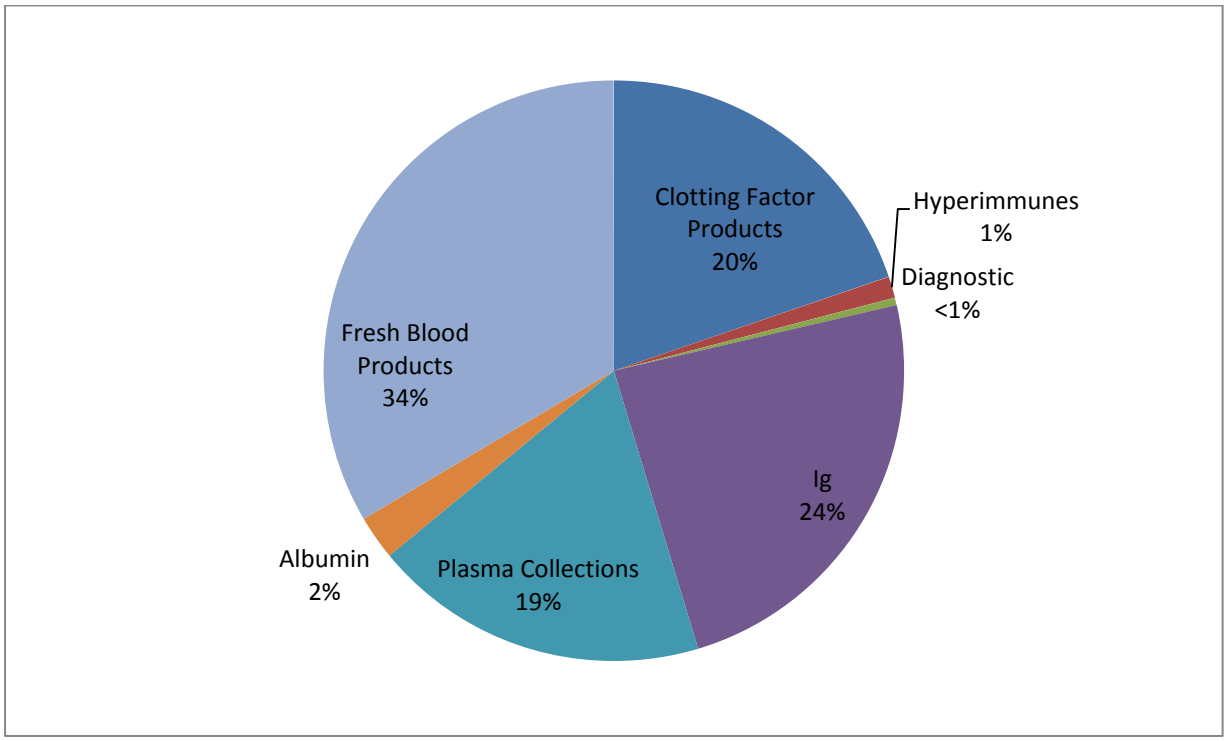


Figure 7 **Ig expenditure as a proportion of the national blood budget**

Of the Ig supplied under national blood arrangements in Australia, 68% (2,724,782 grams) was manufactured domestically and 32% (1,297,079 grams) was imported from overseas. This represents a 5.2% decrease in product importation since 2012-13 (71,190 grams) (Table 5). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 5% in 2013-14 over 2012-13. Intragam P (IVIg) and Evogam (SCIg) are Ig products manufactured domestically in 2013-14. The imported products available were Kiovig (IVIg but can be administered subcutaneously) and Octagam (IVIg) 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 61% 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	932,304	584,439	769,695	166,896	137,364	67,776	53,691	6,036	2,718,201
		$(m)	$58	$37	$48	$10	$9	$4	$3	$<1	$170
	Evogam	g	2,174	122	1,342	1,399	1,512	0	32	0	6,581
		$(m)	$<1	$<1	$<1	$<1	$<1	$0	$<1	$0	$<1
	Total domestic	g	934,478	584,561	771,037	168,295	138,876	67,776	53,723	6,036	2,724,782
		$(m)	$58	$37	$48	$10	$9	$4	$3	$<1	$170
Imported Ig	Kiovig	g	126,660	109,090	108,413	28,144	86,650	2,670	23,918	10,261	495,804
		$(m)	$7	$6	$6	$2	$5	$<1	$1	$1	$28
	Octagam	g	339,020	203,518	183,047	42,542	50	21,399	5,055	168	794,798
		$(m)	$19	$12	$10	$2	$<1	$1	$<1	$<1	$45
	Gammanorm	g	3,495	106	0	23	1,201	0	1,653	0	6,478
		$(m)	$<1	$<1	$0	$<1	$<1	$0	$<1	$0	$<1
	Total imported	g	469,174	312,713	291,460	70,709	87,901	24,069	30,626	10,429	1,297,079
		$(m)	$27	$18	$17	$4	$5	$1	$2	$1	$74
Proportion of domestic to imported Ig		g %	67%	65%	73%	70%	61%	74%	64%	37%	68%
		$(m) %	68%	67%	74%	72%	63%	75%	66%	39%	70%

Note: Price is excluding 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

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
Chapter 5	1,172,728	1,363,847	1,625,246	1,990,586	2,212,914	2,505,332	2,724,809	3,025,452	3,409,100
Chapter 6	400,682	368,458	417,939	345,176	371,832	397,231	444,605	453,352	463,361
Chapter 7	19,518	33,970	45,130	47,275	61,924	76,033	101,287	120,979	148,581
Chapter 8	16,259	15,351	8,888	3,326	2,550	2,574	1,909	39	0
Other	47,730	76,426	37,743	0	0	0	0	0	0
Total	1,656,917	1,858,052	2,134,945	2,386,361	2,649,219	2,981,170	3,272,609	3,599,822	4,021,042

Table 7 Ig issues by *Criteria* chapter (percentage)

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
Chapter 5	71%	73%	76%	83%	84%	84%	83%	84%	85%
Chapter 6	24%	20%	20%	14%	14%	13%	14%	13%	11%
Chapter 7	1%	2%	2%	2%	2%	3%	3%	3%	4%
Chapter 8	1%	1%	<1%	<1%	<1%	<1%	<1%	<1%	0%
Other	3%	4%	2%	0%	0%	0%	0%	0%	0%

For conditions where Ig is used only in exceptional circumstances (Chapter 7), four diagnostic groups accounted for 38.6% of those issues. These conditions were Limbic Encephalitis – nonparaneoplastic (27,787g), Solid organ transplant – lung (10,690g), potassium channel antibody-associated encephalopathy (9,909g) and Pyoderma gangrenosum (8,935g). While use in these conditions represents a small proportion of total Ig use, closer examination may be warranted. For example, approximately 140 lung transplants are performed in Australia every year[7], and 76 patients received Ig for this indication, meaning that approximately half of these patients receive Ig.

Both Limbic Encephalitis – nonparaneoplastic and Pyoderma gangrenosum have doubled in grams issued and also in patients since 2012-13.

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 2013-14 there were no cases 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 88.3% of all Ig supplied, with the top three diagnostic groups accounting for 56.7%.

Acquired hypogammaglobulinaemia secondary to haematological malignancies is the diagnostic group for which the greatest percentage of Ig was issued in 2013-14 (21.5%), closely followed by chronic inflammatory demyelinating polyneuropathy (21.3%). Primary immunodeficiency diseases accounted for 13.9% of total Ig use (Figure 8, Table 8).

Since 2009 there has been a 1.6 fold increase in Ig issues for both acquired hypogammaglobulinaemia secondary to haematological malignancies and chronic inflammatory demyelinating polyneuropathy, and a 1.3 fold increase in issues for primary immunodeficiency diseases. This is compared with the 1.5 fold increase in Ig over this period for all conditions.

[7] 2013, *Lung Transplantation Fact Sheet*, Lung Foundation, Australia.

Secondary hypogammaglobulinaemia falls into the top ten diagnostic groups, in spite of being a condition where the evidence for use is emerging (Chapter 6). Further iterations of the *Criteria* will need to consider whether the recent literature supports continued issues for this diagnostic group. The increase in issues of secondary hypogammaglobulinaemia is largely in New South Wales, where there has been a 284% increase between 2008-09 and 2013-14, associated with a concurrent increase in patient numbers (increase of 128%). The grams issued per patient has increased by 68%. However there has been a large increase in grams per 1,000 population from 2.3 to 5.6. Other states and territories have not had changes as large as New South Wales.

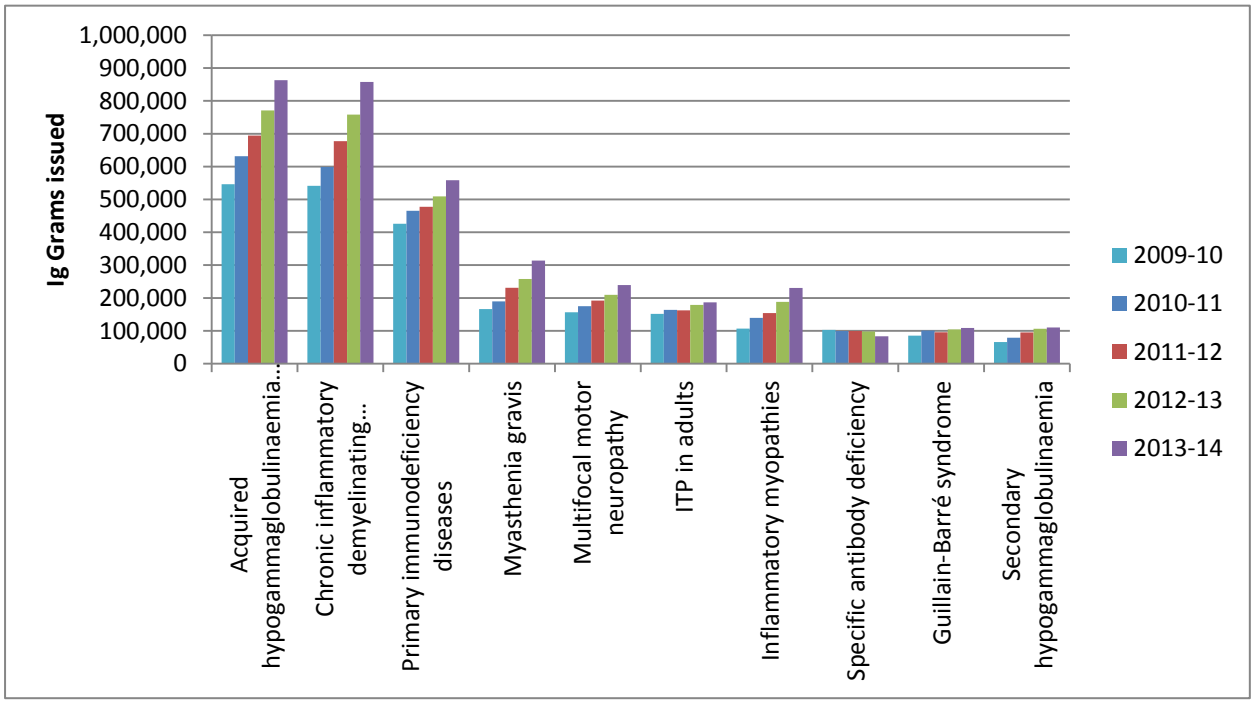


Figure 8 **Ig grams issued by top 10 diagnostic groups**

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

	2009-10	2010-11	2011-12	2012-13	2013-14
Acquired hypogammaglobulinaemia secondary to haematological malignancies	546,391	631,689	694,640	771,071	862,898
Chronic inflammatory demyelinating polyneuropathy	541,206	599,181	677,458	758,271	857,533
Primary immunodeficiency diseases	426,090	465,354	477,461	509,364	558,617
Myasthenia gravis	166,342	189,771	231,064	257,966	313,940
Multifocal motor neuropathy	156,284	175,176	192,109	209,791	239,314
ITP in adults	151,638	163,905	162,098	178,738	186,640
Inflammatory myopathies	106,984	139,195	153,931	188,362	230,473
Specific antibody deficiency	103,042	99,328	99,521	97,749	83,220
Guillain-Barré syndrome	85,344	101,014	95,359	104,360	108,929
Secondary hypogammaglobulinaemia	65,579	79,151	95,183	106,484	110,024

IG ISSUES BY CONDITION

Table 9 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 88.7% of all Ig supplied, with the top ten conditions accounting for 74.7%. This data is also replicated in Figure 9 for the top 10 conditions.

Table 9 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	857,533 (21%)	1,903 (14%)	64
Common variable immunodeficiency disease	487,710 (12%)	1,543 (11%)	54
Myasthenia gravis	313,940 (8%)	747 (5%)	62
Chronic lymphocytic leukaemia	280,076 (7%)	1,179 (8%)	73
Non-Hodgkins lymphoma	245,436 (6%)	1,060 (8%)	68
Multifocal motor neuropathy	239,314 (6%)	438 (3%)	58
Multiple myeloma	229,303 (6%)	1,012 (7%)	71
Polymyositis	131,544 (3%)	340 (2%)	64
Secondary hypogammaglobulinaemia (excludes haem malignancies)	110,024 (3%)	516 (4%)	59
Guillain-Barré syndrome	108,929 (3%)	663 (5%)	55
Kidney transplantation post-transplant	87,913 (2%)	342 (2%)	49
Other relevant haematological malignancies	80,807 (2%)	448 (3%)	62
ITP refractory	78,782 (2%)	497 (4%)	59
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	58,978 (1%)	381 (3%)	62
Specific antibody deficiency	57,596 (1%)	237 (2%)	57
Inclusion body myositis	51,084 (1%)	127 (<1%)	71
Dermatomyositis	47,846 (1%)	139 (1%)	55
ITP with life-threatening haemorrhage	37,853 (1%)	266 (2%)	60
X linked agammaglobulinaemia	33,774 (1%)	105 (<1%)	25
Other primary immunodeficiency	29,339 (1%)	127 (<1%)	49

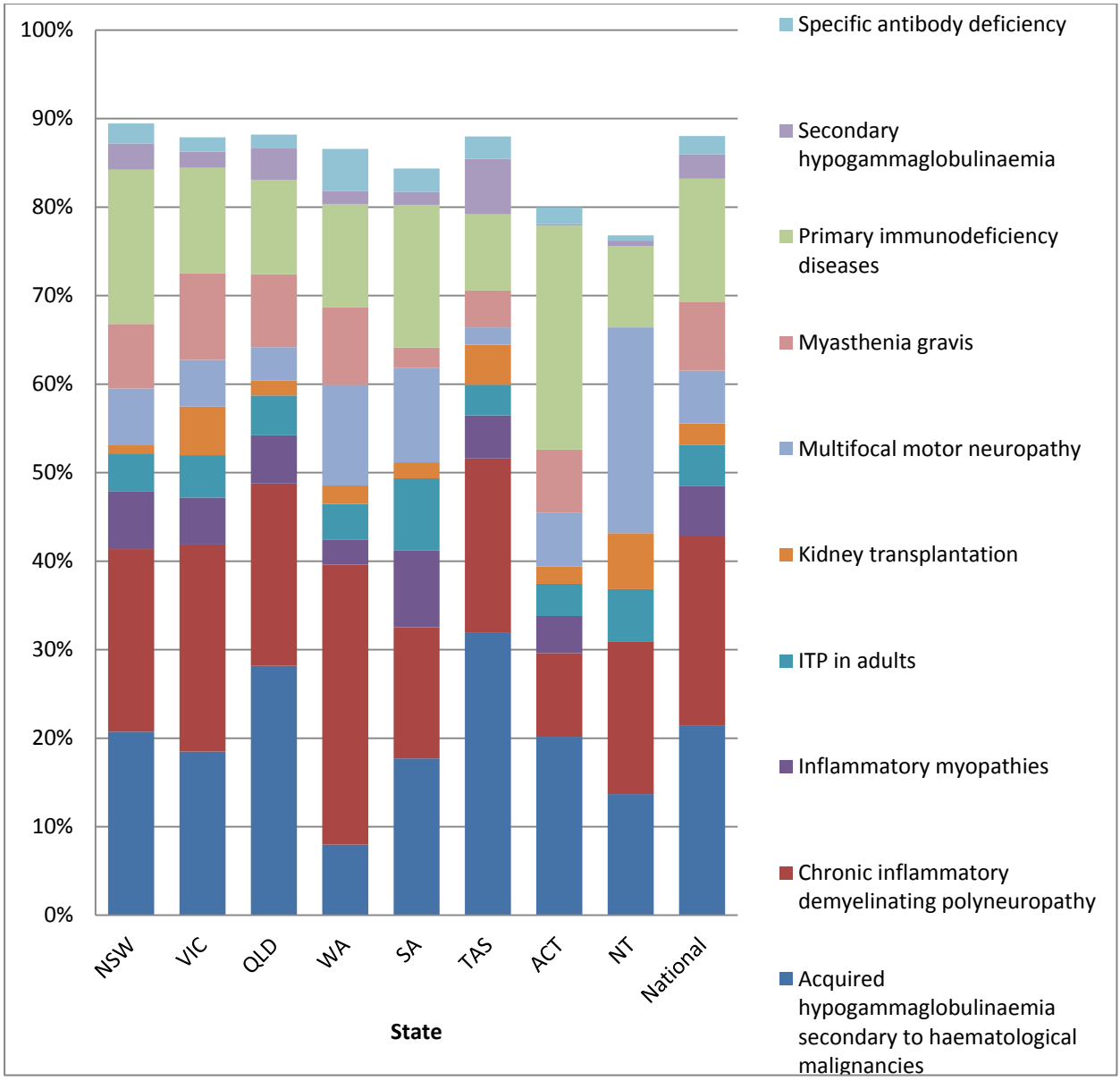


Figure 9 **Proportion of Ig used for top 10 conditions**

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 1,543 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 6.6 per 100,000 population (ranging from 0.4 to 15.6 per 100,000 population across Australian states and territories and 4.6 to 9.7 if ACT, NT, TAS and WA 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

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

estimates is important for health service planning. It should be noted that the prevalence estimate is for diagnosed and treated patients only, and studies suggest that for common variable immunodeficiency disease there is likely to be a large population of undiagnosed patients who would benefit from treatment with Ig.

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 10 replicates this data.

Since 2009, there has been a 1.7 fold increase in Ig issues for neurological conditions, compared with a 1.4 fold increase for haematological conditions and a 1.3 fold increase for immunological conditions.

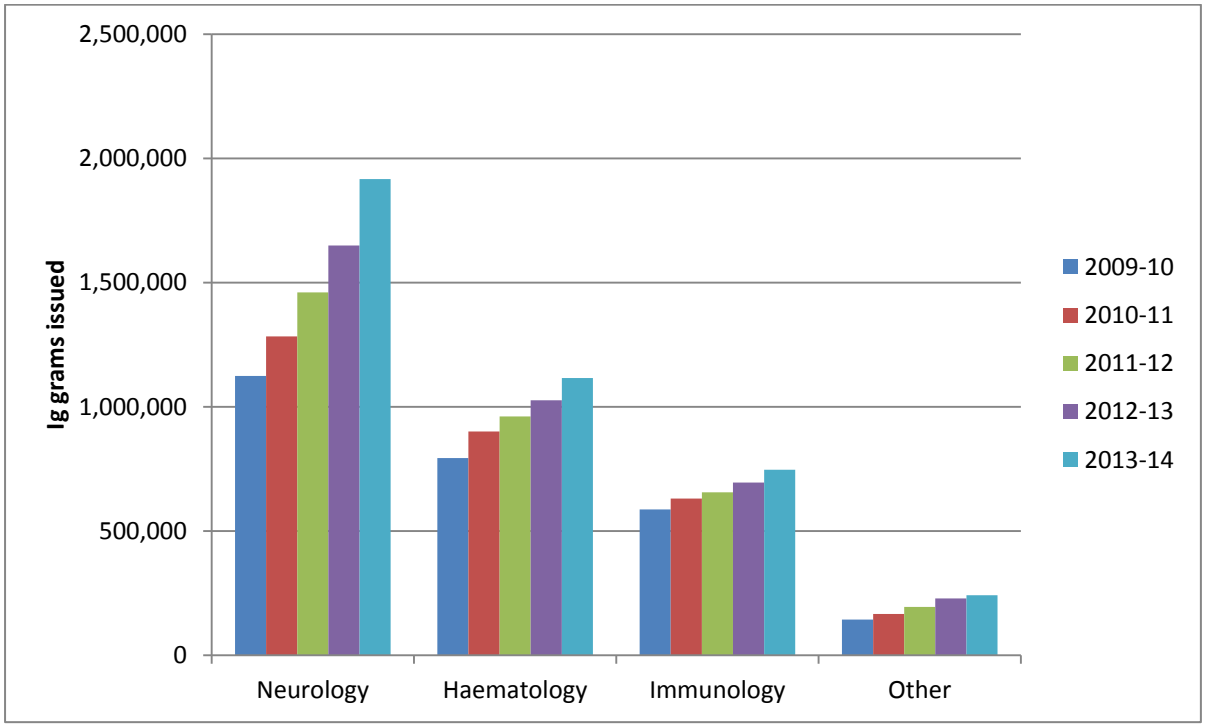


Figure 10 Ig issues by clinical discipline

Table 10 Ig grams issued by clinical discipline

	2009-10	2010-11	2011-12	2012-13	2013-14
Neurology	1,124,604	1,283,190	1,460,702	1,649,358	1,916,792
Haematology	794,098	900,826	961,366	1,026,219	1,116,037
Immunology	586,852	631,076	656,179	695,298	746,828
Other	143,667	166,079	194,363	228,947	241,385

There is significant variation across Australia in Ig use for each clinical discipline. 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 haematological conditions prevailing in these two states. The reason for this inter-state and territory variation is unknown, but it may represent differences in clinician practice, different patient populations or may indicate differences due to availability of specialist services across Australia.

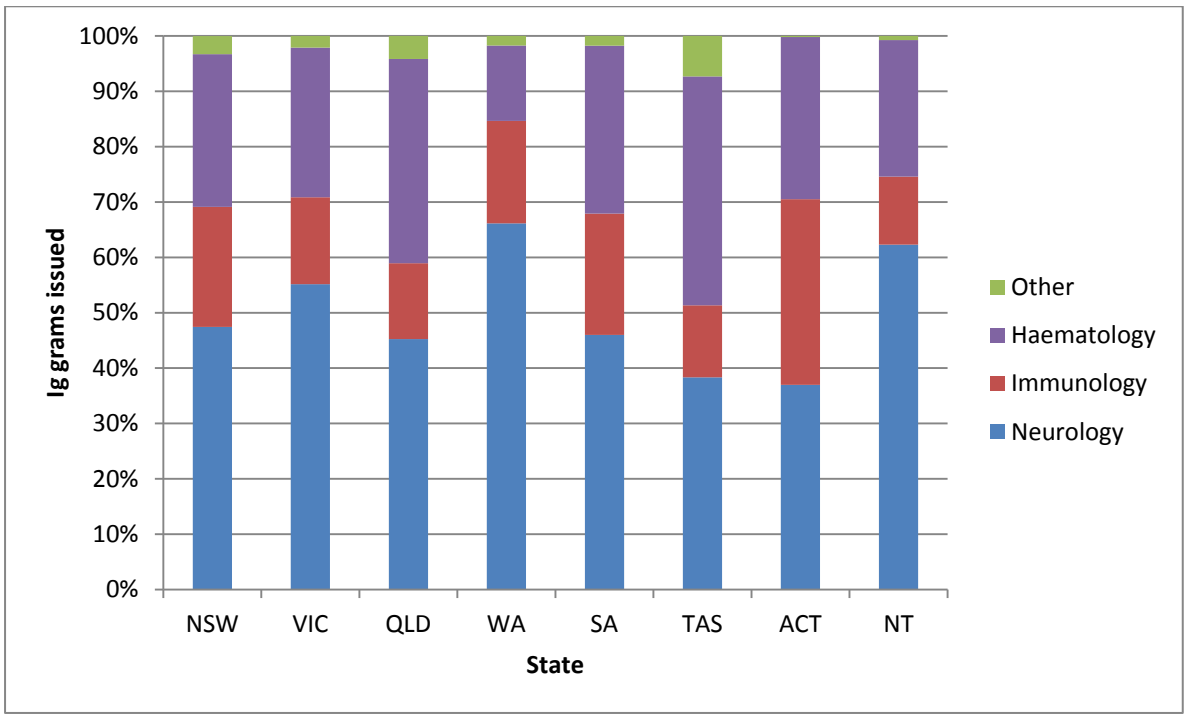


Figure 11 Ig issues by clinical discipline for top 10 conditions by state and territory

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 for each state and territory can be found at **Appendix D** and is summarised in for the conditions using the most Ig. Table 11 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 capita is seen in multiple myeloma followed by Non-Hodgkin's lymphoma. For both these conditions there were a low number of Ig issues per capita in Western Australia, and high use in Queensland. The reason for the significant variation between these two 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 Western Australia being higher than Queensland for both these conditions (**Appendix D)**.

Table 11 Grams of Ig issued by state and territory

2013-14	Ig issued (g)	Proportion of total Ig issued	Proportion of Australian population	Grams per 1,000 population
NSW	1,403,651	35%	32.0%	188
VIC	897,274	22%	24.8%	155
QLD	1,062,497	26%	20.1%	227
WA	239,004	6%	10.9%	94
SA	226,777	6%	7.2%	135
TAS	91,845	2%	2.2%	179
ACT	84,349	2%	1.6%	220
NT	16,465	0%	1.0%	68
Total	4,021,861	100%	100%	172

The following tables (Table 12,Table 13,Table 14,Table 15,Table 16) show the patient numbers for states and territories over time for specific conditions.

Table 12 Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy

Chronic inflammatory demyelinating polyneuropathy	2009-10	2010-11	2011-12	2012-13	2013-14
NSW	524	539	598	652	704
VIC	335	339	372	421	447
QLD	289	312	386	485	529
WA	96	90	99	105	108
SA	63	70	73	80	81
TAS	43	33	30	33	37
ACT	16	14	17	22	28
NT	<5	<5	5	7	<5
Australia	1,341	1,372	1,551	1,753	1,903

Table 13 Patient numbers by state and territory: common variable immunodeficiency disease

Common variable immunodeficiency disease	2009-10	2010-11	2011-12	2012-13	2013-14
NSW	528	562	617	650	721
VIC	207	225	232	241	265
QLD	242	251	276	311	317
WA	74	58	61	67	78
SA	98	107	102	101	110
TAS	18	18	20	21	25
ACT	39	50	54	58	60
NT	<5	5	5	<5	<5
Australia	1,181	1,247	1,323	1,406	1,543

Table 14 Patient numbers by state and territory: myasthenia gravis

Myasthenia gravis	2009-10	2010-11	2011-12	2012-13	2013-14
NSW	170	179	219	235	267
VIC	113	122	141	177	186
QLD	118	142	181	199	212
WA	30	40	36	39	51
SA	22	24	19	17	14
TAS	13	15	17	10	10
ACT	<5	5	10	13	14
NT	0	0	0	0	0
Australia	460	521	609	671	747

Table 15 Patient numbers by state and territory: chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia	2009-10	2010-11	2011-12	2012-13	2013-14
NSW	338	367	381	394	431
VIC	222	233	230	225	271
QLD	275	265	283	297	292
WA	32	35	48	41	45
SA	79	85	79	79	86
TAS	28	32	31	31	34
ACT	16	21	25	29	30
NT	<5	<5	5	5	6
Australia	981	1,023	1,060	1,078	1,179

Table 16 Patient numbers by state and territory: multiple myeloma

Multiple myeloma	2009-10	2010-11	2011-12	2012-13	2013-14
NSW	270	303	324	378	389
VIC	131	159	153	157	176
QLD	281	307	330	346	360
WA	16	16	15	16	20
SA	20	16	17	22	24
TAS	47	58	51	47	42
ACT	11	21	14	10	10
NT	0	<5	<5	<5	<5
Australia	772	875	901	969	1,012

Table 17 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	39	37	46	30	20	35	20	11	37	2
Common variable immunodeficiency disease	30	14	21	9	20	15	54	0	21	3
Myasthenia gravis	14	15	18	8	3	8	15	0	13	6
Chronic lymphocytic leukaemia	13	11	15	3	12	17	21	5	12	5
Non-Hodgkin's lymphoma	8	8	23	2	7	12	13	1	11	12
Multifocal motor neuropathy	12	8	8	11	14	4	13	16	10	2
Multiple myeloma	11	6	19	1	3	23	7	1	10	18
Polymyositis	7	4	8	1	6	3	2	0	6	8
Guillain-Barré syndrome	4	6	5	4	4	4	7	6	5	2
Secondary hypogammaglobulinaemia	6	3	8	1	2	11	0	0	5	6

*The Fold Variation in Table 17 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

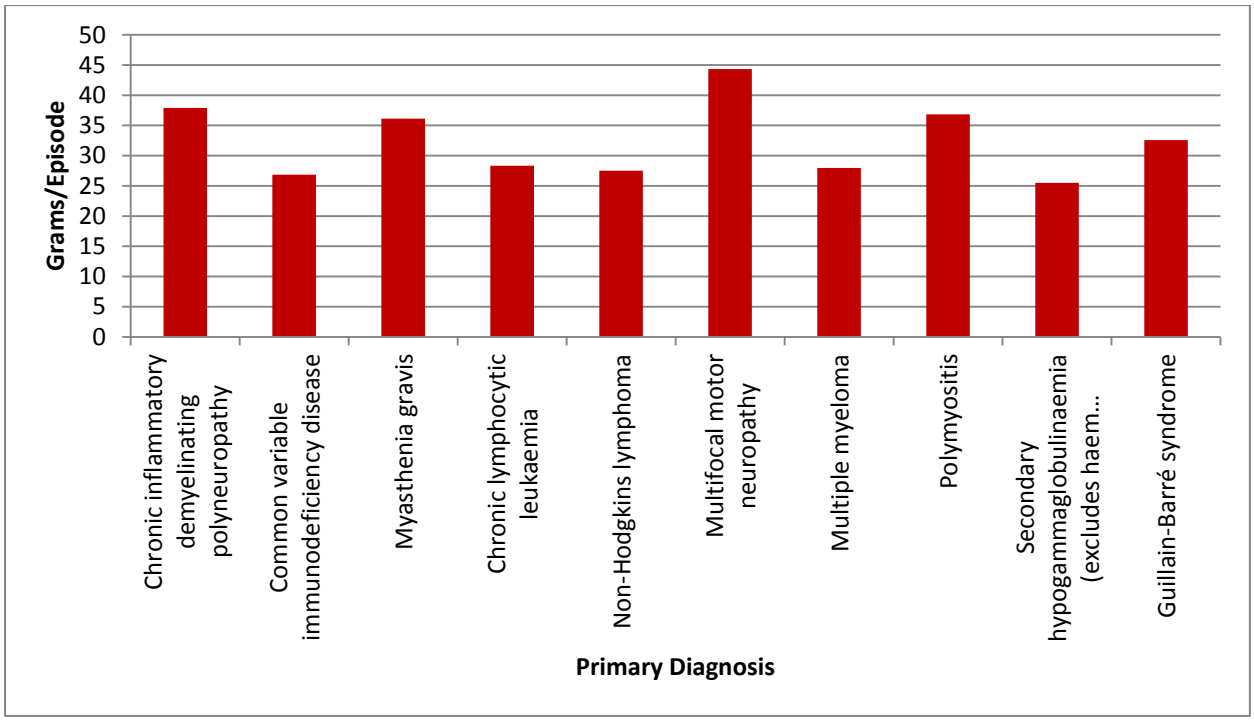


Figure 12 Grams per episode by condition

The data shows that there is significant variance in the dosing of the top 10 conditions; 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 2012-13 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 18). 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 18 Ig grams 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	7,275 (38%)	10,394 (55%)	764 (4%)	24 (0%)	596 (3%)
Common variable immunodeficiency disease	6,857 (41%)	7,741 (46%)	51 (0%)	3 (0%)	1,998 (12%)
Myasthenia gravis	3,048 (43%)	3,745 (53%)	214 (3%)	4 (0%)	118 (2%)
Chronic lymphocytic leukaemia	5,804 (60%)	3,574 (37%)	19 (0%)	0 (0%)	340 (3%)
Multifocal motor neuropathy	1,356 (30%)	2,513 (56%)	458 (10%)	5 (0%)	194 (4%)
Non-Hodgkin lymphoma	5,439 (62%)	3,137 (36%)	5 (0%)	11 (0%)	203 (2%)
Multiple myeloma	5,067 (63%)	2,866 (35%)	6 (0%)	0 (0%)	164 (2%)
Polymyositis	1,166 (39%)	1,633 (55%)	141 (5%)	1 (0%)	52 (2%)
Guillain-Barré syndrome	363 (43%)	403 (47%)	63 (7%)	16 (2%)	4 (0%)
Secondary hypogammaglobulinaemia (excludes haem malignancies)	2,338 (56%)	1,622 (39%)	52 (1%)	3 (0%)	137 (3%)

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 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 criteria have changed, a six month transition period was been allowed to enable treatment strategies to be reviewed, with the exception of IgG subclass deficiency patients, as described above.

Supply of Product

Intravenous immunoglobulin is made from donated human plasma. Australia has not been able to make enough Ig from Australian blood donations for a number of years. While 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 in mid-2007. 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 allow us to fully 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 current 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 are in place for supply of imported Ig under the national blood arrangements. The contracts commenced on 1 January 2012 for a period of three years and have provision for a one year extension. The suppliers are 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 NIg and subcutaneous immunoglobulin (SCIg) in the Ig management framework.

The review identified that there are 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 are to:

- describe the functional model for the current authorisation and clinical governance arrangements, and formally allocate responsibility in each jurisdiction
- introduce new management processes to include NIg 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 current Ig products and arrangements, particularly for junior medical and nursing staff.

Key longer term strategic projects recommended by the review will be considered in 2013-14 for establishing an improved framework for strengthening the clinical governance and authorisation of immunoglobulin in Australia.

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. The first phase of implementation will be 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. Supply of SCIg will commence 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% vial size 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, 5gm/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (imported)

These products are authorised and distributed by the Blood Service in the same manner as IVIg. Since September 2013, 12,228 grams of SCIg have been issued.

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
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
NIg	Normal immunoglobulin
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 donated blood
Blood Service	The Australian Red Cross Blood Service
Clinical Discipline	Classification of the conditions according to the clinical discipline
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 indications for which IVIg is funded under national blood arrangements by all Australian governments
Criteria Met	Circumstances, based on evidence and clinical experience, under which the clinical use of Ig is considered appropriate to be funded in Australia
Criteria Not Met or Qualifying (Q) Criteria Not Met	Circumstances, based on evidence and clinical experience, under which the clinical use of Ig is not considered appropriate to be funded in Australia
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 components
Imprest stock	Health provider orders of product for stock that is maintained at a certain level
Intravenous immunoglobulin	A blood product derived from donated human plasma that is administered intravenously

Term	Description
Jurisdiction	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	A blood product derived from donated 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	A blood 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 each episode occurring every 4 weeks. For example; 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's 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 2013-14

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Chapter 5										
Chronic inflammatory demyelinating polyneuropathy	Patients	704	447	529	108	81	37	28	<5	1,903
	Grams	288,567	213,393	217,350	76,231	33,140	18,245	7,819	2,789	857,533
	Grams/Episode	37	39	34	57	43	45	34	41	38
	Grams per 1,000 pop	39	37	46	30	20	35	20	11	37
Chronic lymphocytic leukaemia	Patients	431	271	292	45	86	34	30	6	1,179
	Grams	100,601	61,902	72,365	7,629	19,699	8,579	8,019	1,282	280,076
	Grams/Episode	30	28	26	27	30	28	31	34	28
	Grams per 1,000 pop	13	11	15	3	12	17	21	5	12
Common variable immunodeficiency disease	Patients	721	265	317	78	110	25	60	<5	1,543
	Grams	221,445	80,682	100,508	23,804	32,998	7,638	20,609	27	487,710
	Grams/Episode	27	29	28	24	22	32	21	27	27
	Grams per 1,000 pop	30	14	21	9	20	15	54	<1	21
Dermatomyositis	Patients	56	33	24	12	9	<5	6	0	139
	Grams	18,067	9,286	8,976	3,760	2,903	2,273	2,582	0	47,846
	Grams/Episode	34	42	37	36	37	65	43	0	38
	Grams per 1,000 pop	2	2	2	1	2	4	7	0	2
Guillain-Barré syndrome	Patients	203	190	133	59	42	12	18	6	663
	Grams	31,700	34,143	21,330	9,441	6,268	1,910	2,638	1,501	108,929
	Grams/Episode	31	34	32	31	35	31	33	30	33
	Grams per 1,000 pop	4	6	5	4	4	4	7	6	5
HSCT - post	Patients	126	47	32	7	6	6	0	<5	223
	Grams	12,408	5,473	6,414	429	562	1,650	0	341	27,277
	Grams/Episode	27	29	29	18	38	32	0	28	28
	Grams per 1,000 pop	2	<1	1	<1	<1	3	0	1	1
Inclusion body myositis	Patients	47	37	22	<5	17	<5	0	0	127
	Grams	17,482	16,081	9,442	144	7,124	812	0	0	51,084

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams/Episode	35	37	32	24	43	31	0	0	36
	Grams per 1,000 pop	2	3	2	<1	4	2	0	0	2
ITP associated with HIV	Patients	<5	<5	0	0	<5	0	0	0	<5
	Grams	340	105	0	0	756	0	0	0	1,201
	Grams/Episode	113	105	0	0	108	0	0	0	109
	Grams per 1,000 pop	<1	<1	0	0	<1	0	0	0	<1
ITP in pregnancy	Patients	19	14	18	9	7	<5	0	0	68
	Grams	3,120	1,492	2,787	1,255	1,011	162	0	0	9,827
	Grams/Episode	41	68	39	63	67	81	0	0	48
	Grams per 1,000 pop	<1	<1	<1	<1	<1	<1	0	0	<1
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic	Patients	112	88	103	28	37	8	<5	<5	381
	Grams	18,373	11,759	18,159	3,674	5,118	927	637	332	58,978
	Grams/Episode	46	57	33	59	58	84	71	83	44
	Grams per 1,000 pop	2	2	4	1	3	2	2	1	3
ITP refractory	Patients	83	152	168	34	38	15	8	<5	497
	Grams	14,800	25,569	24,663	3,740	6,823	2,120	963	105	78,782
	Grams/Episode	37	63	33	75	66	68	64	105	45
	Grams per 1,000 pop	2	4	5	1	4	4	3	<1	3
ITP with life-threatening haemorrhage	Patients	149	47	15	10	31	0	10	<5	266
	Grams	23,802	4,718	1,711	1,128	4,556	0	1,406	533	37,853
	Grams/Episode	41	51	31	59	72	0	70	67	45
	Grams per 1,000 pop	3	<1	<1	<1	3	0	4	2	2
Kawasaki disease	Patients	101	60	39	30	23	<5	5	<5	262
	Grams	4,071	2,574	1,383	1,067	870	123	153	39	10,280
	Grams/Episode	33	28	34	33	32	41	26	20	31
	Grams per 1,000 pop	<1	<1	<1	<1	<1	<1	<1	<1	<1
Lambert-Eaton myasthenic syndrome	Patients	5	<5	10	<5	0	0	0	0	20
	Grams	1,203	1,366	5,545	660	0	0	0	0	8,773
	Grams/Episode	32	41	32	47	0	0	0	0	34
	Grams per 1,000 pop	<1	<1	1	<1	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Multifocal motor neuropathy	Patients	181	88	90	38	27	5	10	5	438
	Grams	89,647	48,044	39,692	27,411	23,910	1,812	5,024	3,775	239,314
	Grams/Episode	43	43	34	67	60	34	49	74	44
	Grams per 1,000 pop	12	8	8	11	14	4	13	16	10
Multiple myeloma	Patients	389	176	360	20	24	42	10	<5	1,012
	Grams	82,054	34,894	89,662	2,767	5,490	11,620	2,601	216	229,303
	Grams/Episode	30	29	26	28	31	31	29	27	28
	Grams per 1,000 pop	11	6	19	1	3	23	7	<1	10
Myasthenia gravis	Patients	267	186	212	51	14	10	14	0	747
	Grams	101,873	89,398	86,669	21,182	5,087	3,871	5,861	0	313,940
	Grams/Episode	35	38	33	47	41	34	45	0	36
	Grams per 1,000 pop	14	15	18	8	3	8	15	0	13
Neonatal haemochromatosis	Patients	<5	<5	<5	<5	0	0	0	0	6
	Grams	1,656	450	6	6	0	0	0	0	2,118
	Grams/Episode	69	90	3	3	0	0	0	0	64
	Grams per 1,000 pop	<1	<1	<1	<1	0	0	0	0	<1
Non-Hodgkins lymphoma	Patients	275	214	455	28	50	29	17	<5	1,060
	Grams	59,516	48,137	110,038	5,047	11,538	6,208	4,802	150	245,436
	Grams/Episode	28	29	26	26	30	29	27	30	28
	Grams per 1,000 pop	8	8	23	2	7	12	13	<1	11
Other Lymphoproliferative / Hypogammaglobulinaemia	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	252	0	0	0	0	0	0	252
	Grams/Episode	0	21	0	0	0	0	0	0	21
	Grams per 1,000 pop	0	<1	0	0	0	0	0	0	<1
Other primary immunodeficiency	Patients	59	38	12	9	6	<5	<5	5	127
	Grams	12,149	10,186	2,193	2,271	941	324	144	1,131	29,339
	Grams/Episode	22	29	17	26	17	9	12	18	23
	Grams per 1,000 pop	2	2	<1	<1	<1	<1	<1	5	1
Other relevant haematological	Patients	216	93	93	23	16	7	6	<5	448
	Grams	35,277	18,209	18,690	3,354	2,334	1,491	1,218	234	80,807
	Grams/Episode	28	29	26	19	24	26	32	18	27

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
malignancies	Grams per 1,000 pop	5	3	4	1	1	3	3	<1	3
Polymyositis	Patients	161	52	91	8	23	<5	<5	0	340
	Grams	55,011	22,939	39,145	2,817	9,326	1,437	870	0	131,544
	Grams/Episode	33	46	37	54	39	45	58	0	37
	Grams per 1,000 pop	7	4	8	1	6	3	2	0	6
Severe combined Immunodeficiency	Patients	7	10	21	<5	<5	0	0	0	40
	Grams	476	1,821	3,942	159	39	0	0	0	6,437
	Grams/Episode	8	19	25	40	2	0	0	0	19
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	0	0	<1
Stiff person syndrome	Patients	19	10	11	0	0	<5	0	0	41
	Grams	11,773	6,493	9,720	0	0	1,349	0	0	29,334
	Grams/Episode	39	49	46	0	0	41	0	0	43
	Grams per 1,000 pop	2	1	2	0	0	3	0	0	1
Wiskott-Aldrich syndrome	Patients	0	<5	<5	<5	0	0	0	0	7
	Grams	0	270	657	429	0	0	0	0	1,356
	Grams/Episode	0	18	31	18	0	0	0	0	23
	Grams per 1,000 pop	0	<1	<1	<1	0	0	0	0	<1
X linked agammaglobulinaemia	Patients	32	45	16	6	8	0	<5	<5	105
	Grams	9,592	15,484	4,908	1,329	1,967	0	158	336	33,774
	Grams/Episode	27	28	28	21	27	0	5	24	27
	Grams per 1,000 pop	1	3	1	<1	1	0	<1	1	1
Chapter 5 Total	Patients	4,263	2,526	3,019	597	638	246	228	43	11,412
	Grams	1,214,99	765,115	895,952	199,732	182,459	72,550	65,502	12,791	3,409,100
	Grams/Episode	32	35	30	41	35	35	29	38	33
	Grams per 1,000 pop	163	132	191	78	109	141	171	53	146
Chapter 6										
Acute disseminated encephalomyelitis	Patients	17	6	8	5	<5	0	<5	<5	41
	Grams	2,907	854	1,203	381	526	0	12	200	6,083
	Grams/Episode	29	31	55	17	31	0	12	20	31
	Grams per 1,000 pop	0	0	0	0	0	0	0	0	0

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	Patients	<5	0	7	0	<5	0	0	0	9
	Grams	192	0	1,339	0	150	0	0	0	1,681
	Grams/Episode	96	0	34	0	30	0	0	0	37
	Grams per 1,000 pop	<1	0	<1	0	<1	0	0	0	<1
Autoimmune haemolytic anaemia	Patients	37	35	30	9	12	<5	0	0	126
	Grams	5,243	3,513	4,720	869	3,253	486	0	0	18,083
	Grams/Episode	36	52	33	67	53	81	0	0	42
	Grams per 1,000 pop	<1	<1	1	<1	2	<1	0	0	<1
Bullous pemphigoid	Patients	10	5	5	<5	0	0	<5	0	22
	Grams	4,890	2,182	3,132	280	0	0	45	0	10,529
	Grams/Episode	47	68	32	23	0	0	45	0	43
	Grams per 1,000 pop	<1	<1	<1	<1	0	0	<1	0	<1
Churg-Strauss syndrome	Patients	0	0	0	<5	0	<5	0	0	<5
	Grams	0	0	0	100	0	1,425	0	0	1,525
	Grams/Episode	0	0	0	100	0	95	0	0	95
	Grams per 1,000 pop	0	0	0	<1	0	3	0	0	<1
Cicatricial pemphigoid	Patients	<5	<5	<5	0	<5	0	<5	0	14
	Grams	4,275	2,280	1,385	0	518	0	4,195	0	12,653
	Grams/Episode	81	54	42	0	35	0	127	0	72
	Grams per 1,000 pop	<1	<1	<1	0	<1	0	11	0	<1
Evans syndrome	Patients	<5	0	<5	<5	0	<5	0	0	5
	Grams	207	0	120	96	0	23	0	0	446
	Grams/Episode	52	0	24	48	0	23	0	0	37
	Grams per 1,000 pop	<1	0	<1	<1	0	<1	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	Patients	<5	<5	<5	<5	<5	0	0	0	13
	Grams	627	405	3,033	4,266	2,379	0	0	0	10,710
	Grams/Episode	45	81	76	91	108	0	0	0	84
	Grams per 1,000 pop	<1	<1	<1	2	1	0	0	0	<1
Foeto-maternal /neonatal	Patients	5	9	<5	<5	<5	<5	0	0	26

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
alloimmune thrombocytopenia (Neonatal)	Grams	30	63	15	9	18	9	0	0	144
	Grams/Episode	3	4	4	3	3	9	0	0	4
	Grams per 1,000 pop	<1	<1	<1	<1	<1	<1	0	0	<1
Haemophagocytic syndrome	Patients	21	8	7	<5	<5	0	<5	0	39
	Grams	3,562	958	1,015	150	280	0	108	0	6,073
	Grams/Episode	45	68	31	75	70	0	9	0	42
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	<1	0	<1
HSCT (for prevention of GvHD in high risk Allogeneic HSCT)	Patients	0	0	<5	0	0	0	0	0	<5
	Grams	0	0	54	0	0	0	0	0	54
	Grams/Episode	0	0	27	0	0	0	0	0	27
	Grams per 1,000 pop	0	0	<1	0	0	0	0	0	<1
IgG subclass deficiency EXISTING patients only	Patients	35	24	7	<5	7	5	0	0	80
	Grams	4,938	8,028	954	885	1,752	1,917	0	0	18,474
	Grams/Episode	29	28	22	28	27	26	0	0	27
	Grams per 1,000 pop	<1	1	<1	<1	1	4	0	0	<1
IgG subclass deficiency. Existing patient with suppurative lung disease	Patients	24	0	<5	0	0	0	0	0	27
	Grams	6,604	0	546	0	0	0	0	0	7,150
	Grams/Episode	28	0	21	0	0	0	0	0	27
	Grams per 1,000 pop	<1	0	<1	0	0	0	0	0	<1
IgM para-proteinaemic neuropathy	Patients	24	15	29	<5	5	0	0	<5	76
	Grams	7,908	4,599	10,374	3,516	1,235	0	0	902	28,534
	Grams/Episode	35	42	35	65	52	0	0	82	40
	Grams per 1,000 pop	1	<1	2	1	<1	0	0	4	1
ITP in children	Patients	27	23	31	<5	26	5	<5	5	123
	Grams	2,616	797	723	66	2,430	183	105	274	7,194
	Grams/Episode	32	27	19	17	32	31	35	34	29
	Grams per 1,000 pop	<1	<1	<1	<1	1	<1	<1	1	<1
Kidney transplantation post-transplant	Patients	67	147	56	27	24	12	7	<5	342
	Grams	10,059	45,879	17,328	4,561	3,290	4,176	1,594	1,027	87,913
	Grams/Episode	22	34	22	32	20	54	39	54	29
	Grams per 1,000 pop	1	8	4	2	2	8	4	4	4

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Kidney transplantation pre-transplant	Patients	42	34	6	<5	7	0	<5	0	91
	Grams	2,984	4,252	675	450	757	0	40	0	9,157
	Grams/Episode	32	20	15	113	24	0	40	0	24
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	<1	0	<1
Microscopic polyangiitis	Patients	0	0	<5	<5	0	0	0	<5	<5
	Grams	0	0	384	363	0	0	0	24	771
	Grams/Episode	0	0	24	26	0	0	0	24	25
	Grams per 1,000 pop	0	0	<1	<1	0	0	0	<1	<1
Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	Patients	5	<5	11	0	0	0	0	0	18
	Grams	1,554	624	2,658	0	0	0	0	0	4,836
	Grams/Episode	38	24	30	0	0	0	0	0	31
	Grams per 1,000 pop	<1	<1	<1	0	0	0	0	0	<1
Multiple sclerosis in pregnancy	Patients	0	0	<5	0	0	0	0	0	<5
	Grams	0	0	273	0	0	0	0	0	273
	Grams/Episode	0	0	21	0	0	0	0	0	21
	Grams per 1,000 pop	0	0	<1	0	0	0	0	0	<1
Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies	Patients	15	<5	6	0	<5	<5	0	0	25
	Grams	3,983	255	1,271	0	183	72	0	0	5,763
	Grams/Episode	33	26	33	0	30	24	0	0	32
	Grams per 1,000 pop	<1	<1	<1	0	<1	<1	0	0	<1
Opsoclonus myoclonus ataxia	Patients	9	8	<5	<5	<5	0	0	0	26
	Grams	1,517	1,683	207	269	1,286	0	0	0	4,961
	Grams/Episode	24	15	23	11	40	0	0	0	20
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	0	0	<1
Pemphigus foliaceus	Patients	<5	0	<5	0	0	0	0	0	<5
	Grams	3,432	0	1,815	0	0	0	0	0	5,247
	Grams/Episode	42	0	55	0	0	0	0	0	46
	Grams per 1,000 pop	<1	0	<1	0	0	0	0	0	<1
Pemphigus vulgaris	Patients	16	<5	6	<5	<5	0	<5	0	31
	Grams	9,414	1,376	4,335	240	910	0	2,340	0	18,615
	Grams/Episode	50	69	43	80	152	0	180	0	56

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams per 1,000 pop	1	<1	<1	<1	<1	0	6	0	<1
Post transfusion purpura	Patients	<5	<5	<5	0	<5	0	0	0	6
	Grams	267	85	180	0	60	0	0	0	592
	Grams/Episode	38	85	45	0	60	0	0	0	46
	Grams per 1,000 pop	<1	<1	<1	0	<1	0	0	0	<1
Secondary hypogammaglobulinaemia (excludes haem malignancies)	Patients	217	88	156	34	13	18	<5	<5	516
	Grams	41,575	16,731	38,629	3,689	3,371	5,810	123	96	110,024
	Grams/Episode	27	27	25	19	14	35	21	48	26
	Grams per 1,000 pop	6	3	8	1	2	11	<1	<1	5
Specific antibody deficiency	Patients	85	28	57	46	18	<5	7	<5	237
	Grams	20,050	6,718	14,083	10,521	4,120	429	1,577	99	57,596
	Grams/Episode	23	27	24	22	21	33	25	9	23
	Grams per 1,000 pop	3	1	3	4	2	<1	4	<1	2
Toxic epidermal necrolysis/Steven Johnson syndrome	Patients	18	19	<5	<5	<5	<5	<5	<5	48
	Grams	2,337	2,805	258	287	426	339	144	171	6,767
	Grams/Episode	71	70	43	48	61	48	72	57	65
	Grams per 1,000 pop	<1	<1	<1	<1	<1	<1	<1	<1	<1
Transplant - Solid Organ	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	21	0	0	0	0	0	0	21
	Grams/Episode	0	21	0	0	0	0	0	0	21
	Grams per 1,000 pop	0	<1	0	0	0	0	0	0	<1
TSS - staphylococcal	Patients	10	23	8	0	5	<5	0	<5	51
	Grams	1,027	3,087	816	0	597	672	0	90	6,289
	Grams/Episode	73	88	74	0	60	112	0	45	81
	Grams per 1,000 pop	<1	<1	<1	0	<1	1	0	<1	<1
TSS - streptococcal	Patients	19	30	30	9	<5	<5	<5	<5	102
	Grams	2,766	4,364	3,447	1,236	502	641	447	230	13,633
	Grams/Episode	84	70	86	77	84	107	75	115	80
	Grams per 1,000 pop	<1	<1	<1	<1	<1	1	1	<1	<1
Wegeners granulomatosis	Patients	<5	<5	0	<5	<5	0	0	0	5
	Grams	288	288	0	675	324	0	0	0	1,575

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams/Episode	36	24	0	135	27	0	0	0	43
	Grams per 1,000 pop	<1	<1	0	<1	<1	0	0	0	<1
Chapter 6 Total	Patients	694	505	478	160	144	58	32	19	2,063
	Grams	145,249	111,844	114,971	32,908	28,366	16,182	10,730	3,113	463,361
	Grams/Episode	31	33	28	30	28	43	59	45	31
	Grams per 1,000 pop	19	19	25	13	17	31	28	13	20

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Chapter 7										
Acute leukaemia in children	Patients	0	<5	0	0	<5	0	0	0	5
	Grams	0	171	0	0	42	0	0	0	213
	Grams/Episode	0	34	0	0	21	0	0	0	30
	Grams per 1,000 pop	0	<1	0	0	<1	0	0	0	<1
Autoimmune neutropenia	Patients	<5	<5	<5	<5	0	0	0	0	10
	Grams	2,694	547	216	308	0	0	0	0	3,765
	Grams/Episode	51	91	27	39	0	0	0	0	50
	Grams per 1,000 pop	<1	<1	<1	<1	0	0	0	0	<1
Autoimmune uveitis	Patients	0	0	<5	0	0	0	0	0	<5
	Grams	0	0	66	0	0	0	0	0	66
	Grams/Episode	0	0	66	0	0	0	0	0	66
	Grams per 1,000 pop	0	0	<1	0	0	0	0	0	<1
Catastrophic antiphospholipid syndrome	Patients	<5	6	12	0	<5	0	0	0	24
	Grams	698	1,866	1,770	0	160	0	0	0	4,493
	Grams/Episode	47	78	36	0	53	0	0	0	49
	Grams per 1,000 pop	<1	<1	<1	0	<1	0	0	0	<1
Coagulation factor inhibitors	Patients	<5	0	<5	<5	<5	0	0	0	10
	Grams	564	0	2,120	132	970	0	0	0	3,786
	Grams/Episode	63	0	85	66	44	0	0	0	65
	Grams per 1,000 pop	<1	0	<1	<1	<1	0	0	0	<1
Devic disease (neuromyelitis optica)	Patients	9	<5	7	<5	<5	0	<5	0	24
	Grams	2,717	573	1,691	1,625	200	0	345	0	7,151
	Grams/Episode	32	34	36	125	40	0	31	0	40
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	<1	0	<1
Diabetic Amyotrophy	Patients	<5	<5	<5	0	0	0	0	0	6
	Grams	1,200	225	375	0	0	0	0	0	1,800
	Grams/Episode	26	38	27	0	0	0	0	0	27
	Grams per 1,000 pop	<1	<1	<1	0	0	0	0	0	<1
Epidermolysis bullosa	Patients	0	0	0	<5	0	<5	<5	0	<5
	Grams	0	0	0	936	0	225	270	0	1,431

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
acquisita	Grams/Episode	0	0	0	72	0	75	68	0	72
	Grams per 1,000 pop	0	0	0	<1	0	<1	<1	0	<1
Epilepsy (rare childhood cases)	Patients	<5	7	10	<5	0	0	<5	0	23
	Grams	612	3,180	3,342	459	0	0	48	0	7,641
	Grams/Episode	31	35	42	46	0	0	24	0	38
	Grams per 1,000 pop	<1	<1	<1	<1	0	0	<1	0	<1
Graves ophthalmopathy	Patients	0	0	<5	0	0	0	0	0	<5
	Grams	0	0	1,665	0	0	0	0	0	1,665
	Grams/Episode	0	0	48	0	0	0	0	0	48
	Grams per 1,000 pop	0	0	<1	0	0	0	0	0	<1
Haemolytic disease of the newborn	Patients	37	31	5	6	13	0	8	<5	101
	Grams	1,088	4,134	941	414	57	0	24	3	6,661
	Grams/Episode	18	48	52	38	3	0	3	3	33
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	<1	<1	<1
Haemolytic transfusion reaction	Patients	0	0	0	0	<5	0	0	0	<5
	Grams	0	0	0	0	3	0	0	0	3
	Grams/Episode	0	0	0	0	3	0	0	0	3
	Grams per 1,000 pop	0	0	0	0	<1	0	0	0	<1
Hashimoto encephalopathy	Patients	<5	<5	<5	<5	0	0	0	0	7
	Grams	43	294	570	480	0	0	0	0	1,387
	Grams/Episode	43	33	25	60	0	0	0	0	34
	Grams per 1,000 pop	<1	<1	<1	<1	0	0	0	0	<1
Limbic Encephalitis (nonparaneoplastic)	Patients	32	22	53	<5	8	<5	<5	<5	122
	Grams	7,903	4,588	11,691	405	1,557	406	908	330	27,787
	Grams/Episode	35	30	32	29	34	34	48	22	33
	Grams per 1,000 pop	1	<1	2	<1	<1	<1	2	1	1
Limbic Encephalitis (Paraneoplastic)	Patients	<5	<5	11	<5	0	0	0	0	19
	Grams	645	825	5,585	225	0	0	0	0	7,280
	Grams/Episode	32	28	35	32	0	0	0	0	34
	Grams per 1,000 pop	<1	<1	1	<1	0	0	0	0	<1
Myocarditis in children	Patients	5	5	<5	<5	<5	0	0	0	15

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams	150	192	51	12	120	0	0	0	525
	Grams/Episode	30	21	10	6	60	0	0	0	23
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	0	0	<1
PANDAS/tic disorders	Patients	0	<5	0	<5	<5	0	0	0	<5
	Grams	0	936	0	183	42	0	0	0	1,161
	Grams/Episode	0	43	0	46	42	0	0	0	43
	Grams per 1,000 pop	0	<1	0	<1	<1	0	0	0	<1
Paraneoplastic cerebellar degeneration (Yo antibodies)	Patients	<5	<5	<5	<5	0	<5	0	0	5
	Grams	33	165	320	960	0	357	0	0	1,835
	Grams/Episode	11	33	32	46	0	33	0	0	37
	Grams per 1,000 pop	<1	<1	<1	<1	0	<1	0	0	<1
Paraneoplastic Subacute Sensory Neuropathy	Patients	<5	<5	<5	0	<5	0	0	0	7
	Grams	729	120	165	0	120	0	0	0	1,134
	Grams/Episode	27	24	33	0	24	0	0	0	27
	Grams per 1,000 pop	<1	<1	<1	0	<1	0	0	0	<1
Paraneoplastic syndromes	Patients	<5	<5	<5	0	<5	0	0	0	6
	Grams	60	279	1,533	0	396	0	0	0	2,268
	Grams/Episode	30	31	36	0	33	0	0	0	34
	Grams per 1,000 pop	<1	<1	<1	0	<1	0	0	0	<1
Potassium channel antibody-associated encephalopathy	Patients	17	6	<5	<5	6	0	<5	0	34
	Grams	4,111	2,283	686	900	1,480	0	450	0	9,909
	Grams/Episode	29	32	34	113	39	0	23	0	33
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	1	0	<1
Pure red cell aplasia	Patients	7	9	8	<5	<5	<5	0	0	30
	Grams	1,031	1,096	2,828	450	1,425	1,569	0	0	8,398
	Grams/Episode	30	41	50	35	89	37	0	0	44
	Grams per 1,000 pop	<1	<1	<1	<1	<1	3	0	0	<1
Pure white cell aplasia	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	126	0	0	0	0	0	0	0	126
	Grams/Episode	42	0	0	0	0	0	0	0	42
	Grams per 1,000 pop	<1	0	0	0	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Pyoderma gangrenosum	Patients	<5	14	<5	<5	6	0	0	0	23
	Grams	120	4,925	180	192	3,518	0	0	0	8,935
	Grams/Episode	40	57	60	192	66	0	0	0	61
	Grams per 1,000 pop	<1	<1	<1	<1	2	0	0	0	<1
Rasmussen Syndrome	Patients	<5	<5	<5	0	<5	<5	<5	0	10
	Grams	1,049	1,041	280	0	610	231	513	0	3,724
	Grams/Episode	44	69	28	0	47	33	32	0	44
	Grams per 1,000 pop	<1	<1	<1	0	<1	<1	1	0	<1
Scleromyxedema	Patients	<5	<5	0	0	<5	0	0	0	6
	Grams	4,847	840	0	0	210	0	0	0	5,897
	Grams/Episode	81	21	0	0	35	0	0	0	56
	Grams per 1,000 pop	<1	<1	0	0	<1	0	0	0	<1
Sjogren's Syndrome	Patients	5	<5	<5	<5	<5	0	<5	0	15
	Grams	1,275	1,017	960	156	1,115	0	2,123	0	6,646
	Grams/Episode	26	33	36	78	56	0	59	0	40
	Grams per 1,000 pop	<1	<1	<1	<1	<1	0	6	0	<1
Solid organ - heart	Patients	11	5	<5	0	0	0	0	0	18
	Grams	935	866	440	0	0	0	0	0	2,241
	Grams/Episode	36	39	34	0	0	0	0	0	37
	Grams per 1,000 pop	<1	<1	<1	0	0	0	0	0	<1
Solid organ - heart/lung	Patients	<5	<5	<5	0	0	0	0	0	6
	Grams	55	910	324	0	0	0	0	0	1,289
	Grams/Episode	55	28	27	0	0	0	0	0	28
	Grams per 1,000 pop	<1	<1	<1	0	0	0	0	0	<1
Solid organ - liver	Patients	<5	<5	0	0	0	0	0	0	<5
	Grams	132	234	0	0	0	0	0	0	366
	Grams/Episode	15	12	0	0	0	0	0	0	13
	Grams per 1,000 pop	<1	<1	0	0	0	0	0	0	<1
Solid organ - lung	Patients	24	26	17	<5	<5	<5	0	0	76
	Grams	2,406	3,214	3,116	526	754	675	0	0	10,690
	Grams/Episode	37	34	31	33	34	32	0	0	34

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams per 1,000 pop	<1	<1	<1	<1	<1	1	0	0	<1
Solid organ - other	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	360	0	0	0	0	0	0	360
	Grams/Episode	0	90	0	0	0	0	0	0	90
	Grams per 1,000 pop	0	<1	0	0	0	0	0	0	<1
Susac syndrome	Patients	6	0	5	0	0	0	0	0	11
	Grams	2,313	0	2,660	0	0	0	0	0	4,973
	Grams/Episode	36	0	47	0	0	0	0	0	41
	Grams per 1,000 pop	<1	0	<1	0	0	0	0	0	<1
Systemic Capillary Leak syndrome	Patients	<5	0	<5	0	0	0	<5	0	<5
	Grams	450	0	429	0	0	0	1,680	0	2,559
	Grams/Episode	64	0	39	0	0	0	80	0	66
	Grams per 1,000 pop	<1	0	<1	0	0	0	4	0	<1
Transplant - Solid Organ	Patients	0	0	0	0	0	<5	0	0	<5
	Grams	0	0	0	0	0	419	0	0	419
	Grams/Episode	0	0	0	0	0	30	0	0	30
	Grams per 1,000 pop	0	0	0	0	0	<1	0	0	<1
Chapter 7 Total	Patients	189	164	158	35	54	11	22	<5	627
	Grams	37,983	34,879	44,002	8,363	12,779	3,882	6,361	333	148,581
	Grams/Episode	36	38	37	55	45	35	46	21	38
	Grams per 1,000 pop	5	6	9	3	8	8	17	1	6
Total	Patients	5,096	3,172	3,617	789	831	313	281	65	13,981
	Grams	1,398,23	911,838	1,054,92	241,003	223,603	92,613	82,593	16,237	4,021,042
	Grams/Episode	32	35	30	40	34	36	32	39	33
	Grams per 1,000 pop	187	157	225	94	133	180	215	67	172

Please note that the totals are recalculated for each category and not sums of the relevant rows above.

Appendix E – Grams Ig Issued by State and Territory

		NSW	VIC	QLD	WA	SA	TAS	ACT	NT
2003-04	Imported Ig		22,200	3,000	144	2,856			
	Domestic Ig	410,505	318,762	306,639	125,094	110,031	40,353	23,895	6,321
2004-05	Imported Ig	41,376	13,860	19,992	144	5,922			
	Domestic Ig	420,858	326,130	284,043	148,200	95,403	46,065	24,615	7,806
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	0
	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

Appendix F – Unique Patients by Quarter and State and Territory

Year	Quarter	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUST
2008-09	Q1	2,216	1,296	1,448	402	331	145	105	13	5,956
	Q2	2,255	1,327	1,466	399	364	151	105	19	6,086
	Q3	2,261	1,313	1,470	357	362	170	99	17	6,049
	Q4	2,383	1,356	1,544	373	395	177	98	31	6,357
2009-10	Q1	2,447	1,377	1,652	385	400	184	112	24	6,581
	Q2	2,499	1,388	1,670	357	440	177	109	20	6,660
	Q3	2,556	1,394	1,682	354	395	183	102	15	6,681
	Q4	2,607	1,460	1,755	373	413	189	121	22	6,940
2010-11	Q1	2,707	1,506	1,839	376	420	197	144	22	7,211
	Q2	2,784	1,545	1,887	395	394	205	132	21	7,363
	Q3	2,761	1,544	1,888	379	397	214	130	15	7,328
	Q4	2,800	1,628	1,947	385	419	200	142	23	7,544
2011-12	Q1	2,933	1,665	2,047	408	421	199	142	27	7,842
	Q2	2,976	1,631	2,115	413	430	206	137	22	7,930
	Q3	2,956	1,594	2,150	403	431	203	150	23	7,910
	Q4	2,961	1,633	2,215	405	459	202	154	29	8,058
2012-13	Q1	3,109	1,751	2,391	449	450	205	168	32	8,497
	Q2	3,140	1,809	2,360	436	463	196	171	26	8,559
	Q3	3,222	1,756	2,299	411	458	183	166	33	8,487
	Q4	3,321	1,826	2,379	430	466	187	170	36	8,763
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

Appendix G – System Source for Tables and Figures