



NATIONAL BLOOD AUTHORITY  
AUSTRALIA

# **NATIONAL REPORT ON THE ISSUE AND USE OF INTRAVENOUS IMMUNOGLOBULIN (IVIg)**

Annual Report 2012-13



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# Contents

LIST OF TABLES .....	4
LIST OF FIGURES .....	4
<b>INTRODUCTION .....</b>	<b>5</b>
<b>REPORT SNAPSHOT.....</b>	<b>6</b>
<b>METHODOLOGY.....</b>	<b>7</b>
DATA QUALITY .....	8
<b>10 YEAR TRENDS .....</b>	<b>9</b>
DEMAND TRENDS.....	9
FINANCIAL TRENDS .....	10
<b>DEMOGRAPHICS .....</b>	<b>12</b>
PATIENT NUMBERS.....	12
GEOGRAPHIC DISTRIBUTION .....	12
AGE.....	14
WEIGHT .....	14
<b>EXPENDITURE .....</b>	<b>16</b>
<b>CLINICAL INDICATIONS .....</b>	<b>18</b>
IVIG ISSUES BY CRITERIA CHAPTER.....	18
IVIG ISSUES BY DIAGNOSTIC GROUPS .....	19
IVIG ISSUES BY CONDITION .....	21
IVIG ISSUES BY CLINICAL DISCIPLINE .....	24
IVIG GRAMS ISSUED PER 1,000 POPULATION .....	25
<b>DOSING.....</b>	<b>30</b>
<b>APPENDIX A – BACKGROUND .....</b>	<b>32</b>
<b>APPENDIX B – ACRONYMS AND GLOSSARY.....</b>	<b>36</b>
ACRONYMS .....	36
GLOSSARY OF TERMS.....	37
<b>APPENDIX C – CLINICAL DISCIPLINE MAPPING TABLE.....</b>	<b>39</b>
<b>APPENDIX D – DATASET OF IVIG SUPPLY BY STATE/TERRITORY 2012-13 .....</b>	<b>45</b>
<b>APPENDIX E – GRAMS IVIG ISSUED BY STATE AND TERRITORY .....</b>	<b>60</b>
<b>APPENDIX F – UNIQUE PATIENTS BY QUARTER AND STATE AND TERRITORY .....</b>	<b>61</b>
<b>APPENDIX G – SOURCE FOR TABLES AND FIGURES .....</b>	<b>62</b>

## LIST OF TABLES

Table 1	Growth in IVIg grams issued since 2004 .....	9
Table 2	Percentage change in grams issued over time by state and territory .....	10
Table 3	Annual numbers of patients, treatment episodes and grams .....	12
Table 4	Basic numbers .....	12
Table 5	Issues of domestic IVIg compared with imported IVIg .....	17
Table 6	IVIg issues (g) by <i>Criteria</i> chapter .....	18
Table 7	IVIg issues by <i>Criteria</i> chapter (percentage) .....	19
Table 8	IVIg grams issued for top 10 diagnostic groups over time .....	21
Table 9	Patient numbers and age for the top 20 conditions .....	22
Table 10	IVIg grams issued by clinical discipline .....	25
Table 11	Grams of IVIg issued by state and territory .....	26
Table 12	Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy .....	26
Table 13	Patient numbers by state and territory: common variable immunodeficiency disease .....	27
Table 14	Patient numbers by state and territory: myasthenia gravis .....	27
Table 15	Patient numbers by state and territory: chronic lymphocytic leukaemia .....	28
Table 16	Patient numbers by state and territory: multiple myeloma .....	28
Table 17	IVIg issued per 1,000 population by state and territory .....	29
Table 18	IVIg grams per episode .....	31

## LIST OF FIGURES

Figure 1	Ten year trends in issues of IVIg .....	9
Figure 2	Ten year trends in expenditure on IVIg .....	11
Figure 3	Patients per 1,000 population 2012-13 .....	13
Figure 4	Grams of IVIg per 1,000 population by state and territory over time .....	13
Figure 5	Patient age compared to average Australian age .....	14
Figure 6	Patient weights relative to Australian average .....	15
Figure 7	IVIg expenditure as a proportion of the national blood budget .....	16
Figure 8	IVIg grams issued by diagnostic group .....	20
Figure 9	Proportion of IVIg used for top 10 conditions .....	23
Figure 10	IVIg issues by clinical discipline .....	24
Figure 11	IVIg issues by clinical discipline for top 10 conditions by state and territory .....	25
Figure 12	Grams per episode by condition .....	30

# Introduction

Intravenous immunoglobulin (IVIg) 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 IVIg supply in Australia in 2012-13, also considering trends in supply over the last ten years.

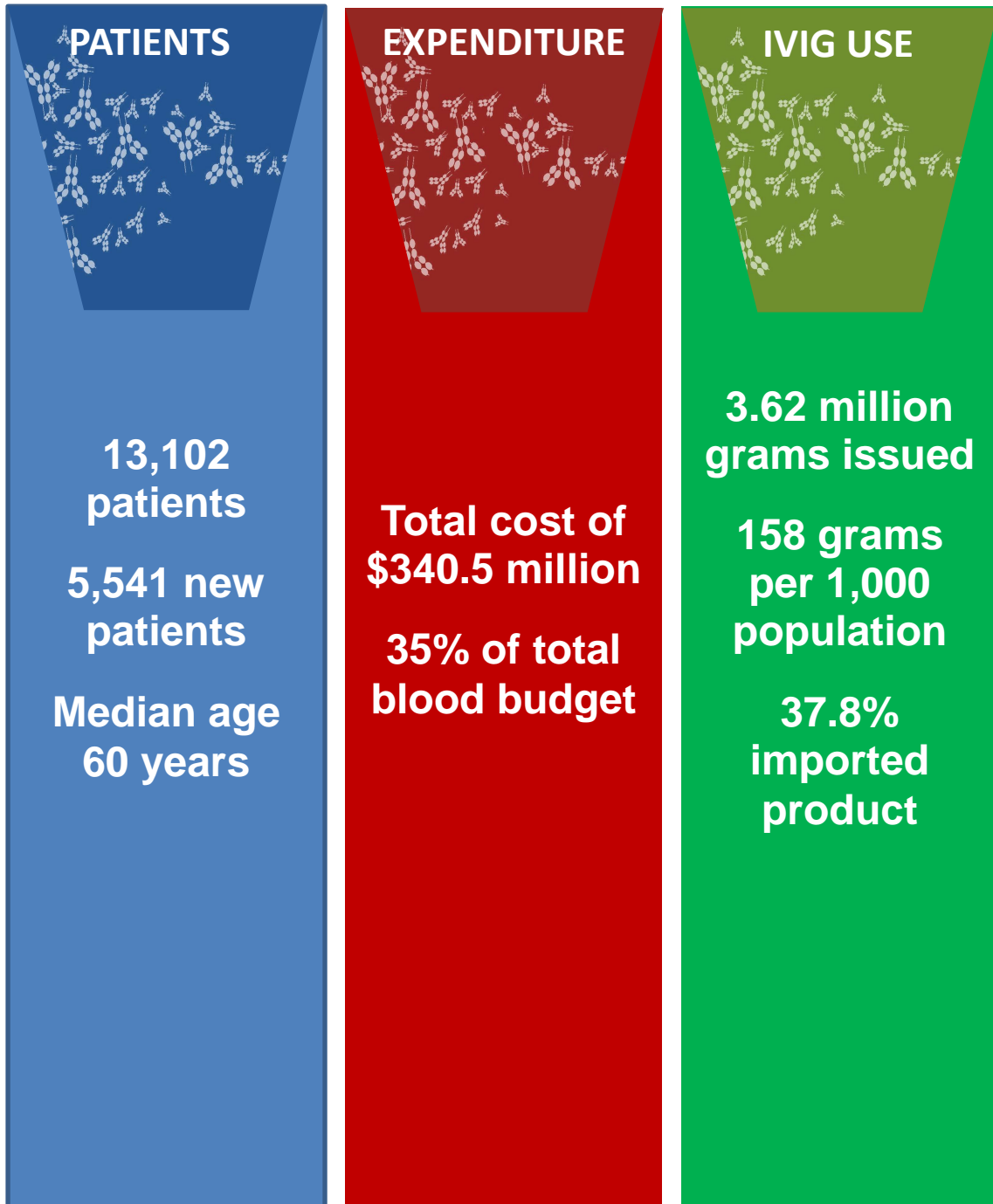
In Australia it is estimated that over 99% of all IVIg is supplied under national blood arrangements through contracts administered by the National Blood Authority (NBA). The NBA's role is to coordinate national supply and demand planning for blood and blood products including supply risk management; 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.

IVIg comprises a large proportion of blood expenditure each year. Demand for IVIg continues to rise steadily, and Australian per capita use of this product is one of the highest among western countries. Demand for IVIg is met through local manufacture of IVIg by CSL Behring using plasma collected from voluntary, non-remunerated Australian donors and is supplemented by importation of IVIg from overseas manufacturers. Both the domestic and imported IVIg 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 IVIg due to national supply arrangements. This report begins with an analysis of IVIg supply over the last ten years, then considers patient demographics, expenditure on IVIg, clinical indications for which IVIg was supplied and finally analyses the dose prescribed for various conditions. The top ten diagnostic groups account for 88.4% of all IVIg 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 IVIg, 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 IVIg issued to Australian Health Providers (AHPs) and purchases from suppliers. This data is held in the NBA Integrated Data Management System (IDMS).

Over the five years between 2008-09 and 2012-13, data has been captured on 30,711 patients. Caveats relating to the quality of this data are outlined below.

This report does not include data on supply of Normal Immunoglobulin (NIg) or Subcutaneous Immunoglobulin (SCIg). No SCIg product was available in Australia in 2012-13.

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 IVIg 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 25,700 patients (83%) had weight data entered, but only 5,509 (18%) 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 IVIg 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 IVIg used in one state or territory for patients residing in a different state or territory.
- A total of 676 (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 1,547 (5%) 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.
- Some data differs to that presented in the National Blood Authority Annual Report 2012-13 due to the annual report not using final acquittal data.



# 10 Year Trends

## DEMAND TRENDS

In 2012-13 a total of 3,622,433 grams of IVIg was issued, representing an increase of 351,124 grams (11%) over 2011-12. Since 2003-04 there has been an on average 11.7% increase in IVIg use, with the greatest proportion of that increase comprising imported products (Figure 1). In 2012-13, there was a decline in the supply of domestic IVIg due to the need for CSL Behring to allocate product to the national reserve following the Octagam recall in 2010-11.

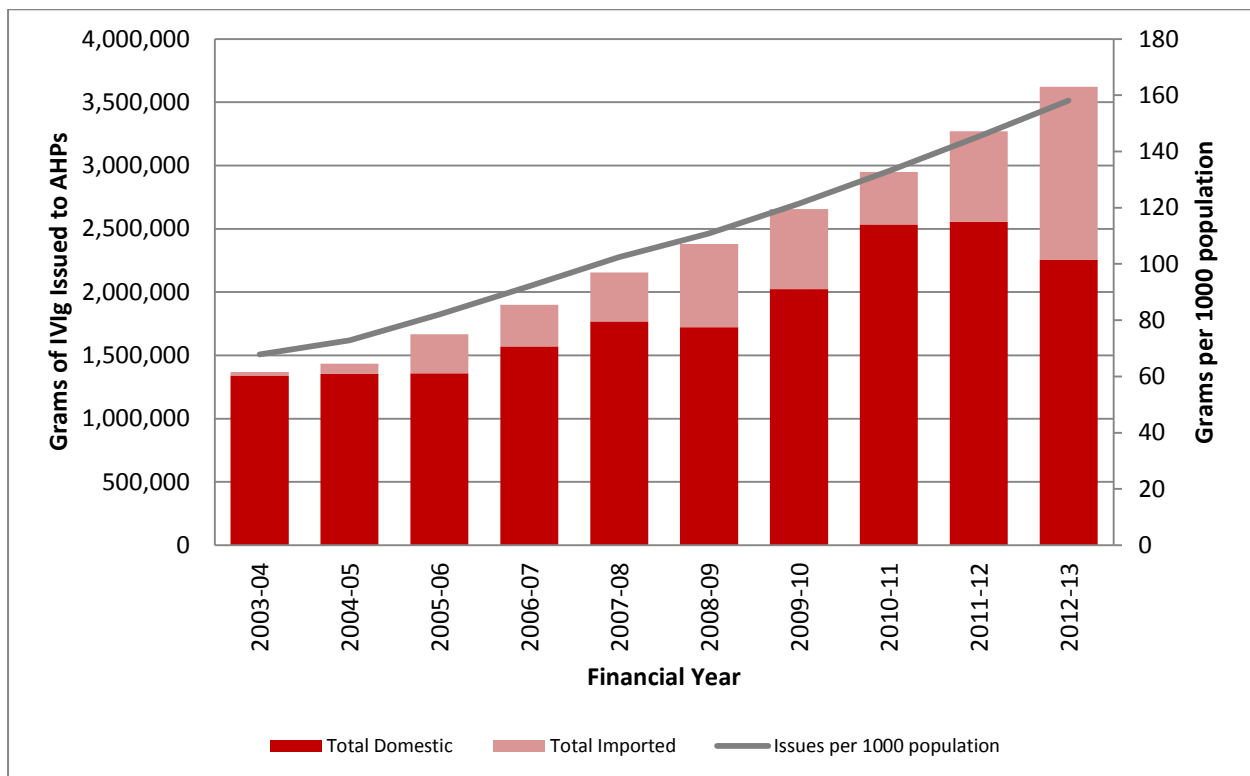


Figure 1 Ten year trends in issues of IVIg

Table 1 Growth in IVIg grams issued since 2004

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

There has been a steady increase in demand for IVIg 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 IVIg 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 New South Wales and Victoria. Further information about the breakdown of domestic and imported IVIg 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%

## FINANCIAL TRENDS

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

Total expenditure on IVIg in 2012-13 was \$220.1 million, an increase of \$15.7 million (7.6%) over 2011-12 (Figure 2). The increased expenditure predominately represents increases in demand.

There has also been an increase in the price of plasma for fractionation over 2011-12; this has resulted in an increase in the cost of domestic IVIg. Combined with expenditure for plasma for fractionation, IVIg accounts for a total expenditure of \$340.5 million (excluding hyperimmunes).

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

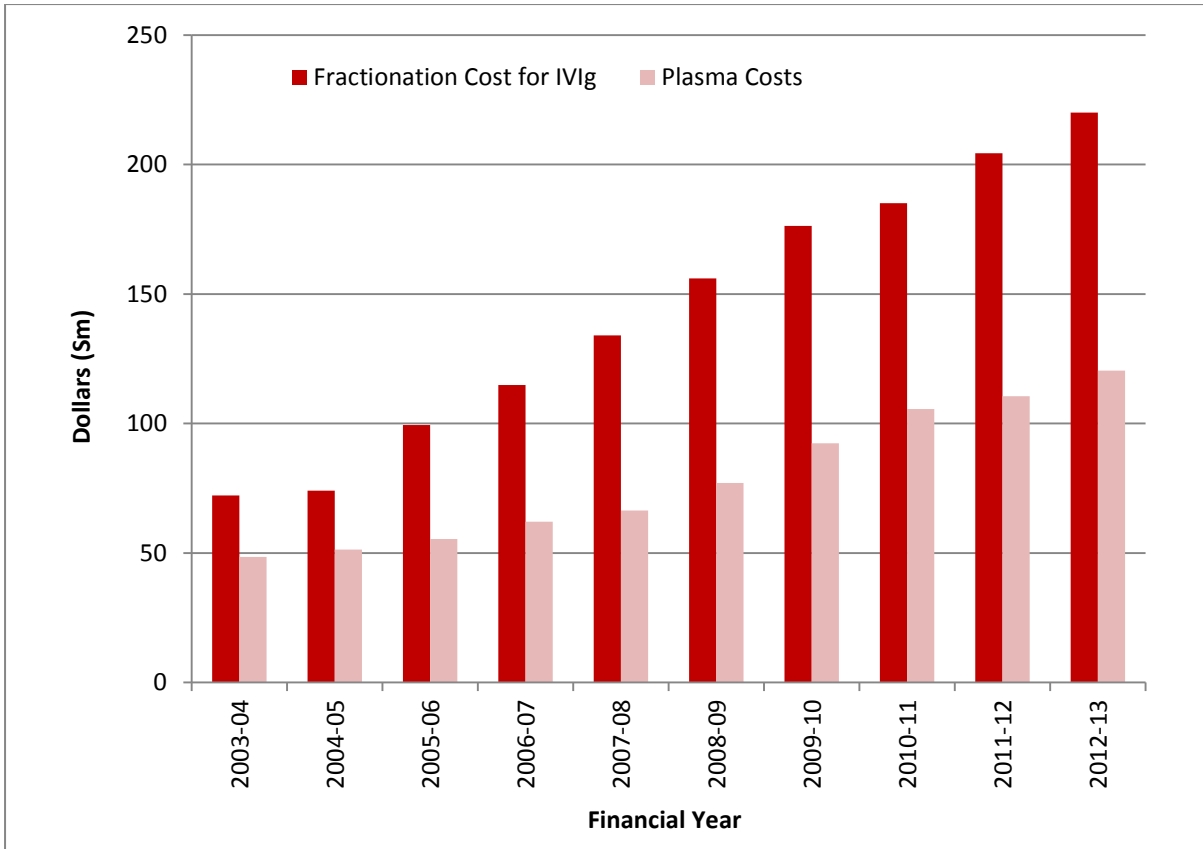


Figure 2 Ten year trends in expenditure on IVIg

# Demographics

## PATIENT NUMBERS

A total of 13,102 patients were issued IVIg under national blood arrangements during 2012-13 for 110,183 treatment episodes. This represents an 8.0% increase in the number of patients since 2011-12. 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

**Table 4** Basic numbers

	2011-12	2012-13
Total unique patient IDs	25,375	30,840
Total unique patient IDs with some weight data	19,965	25,616
Total unique patient IDs with an age recorded	21,317	26,853
Total unique patient IDs with a weight change	3,392	5,443
Total unique patient IDs with more than one state or territory	518	675
Total unique patient IDs with two states or territories	473	620
Total unique patient IDs with three or more states or territories	36	55
Total unique patient IDs with more than one condition	1,547	2,713
Total unique patient IDs with two conditions	1,322	2,405
Total unique patient IDs with three conditions	194	286
Total unique patient IDs with four or more conditions	26	22
Total unique patient IDs aged 93 or older	176	189

## GEOGRAPHIC DISTRIBUTION

Nationally, 0.6 patients per 1,000 population received IVIg in 2012-13. 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 Tasmania 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**.

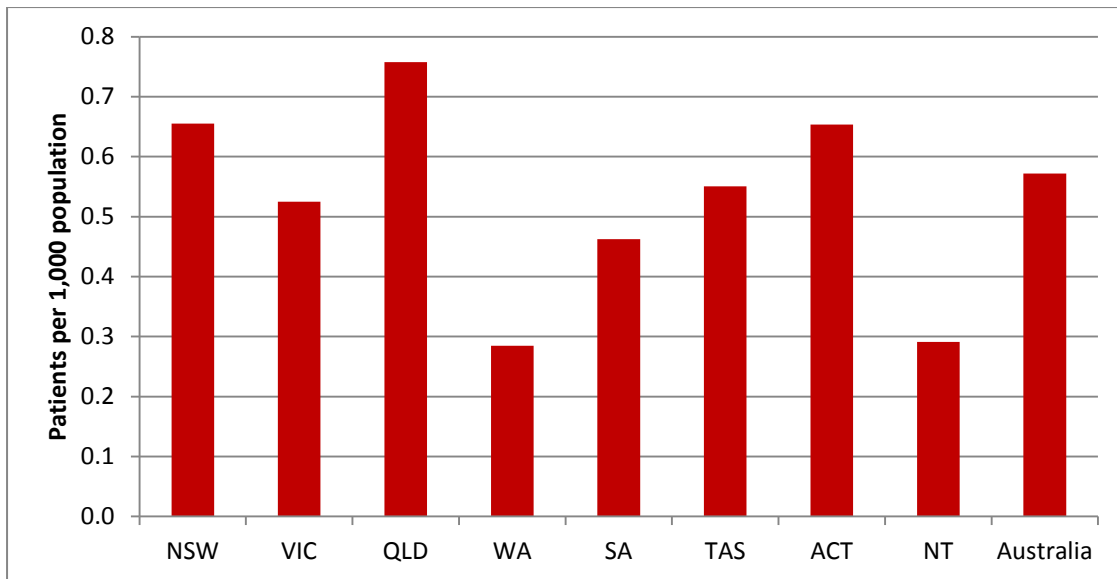


Figure 3 Patients per 1,000 population 2012-13

There is significant variation between jurisdictions in IVIg use in grams per 1,000 population, ranging from 70.7 in the Northern Territory to 205.0 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 IVIg use is 2.3 fold, ranging from 91.1 grams per 1,000 population in Western Australia to 205.0 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 IVIg issued per 1,000 population.

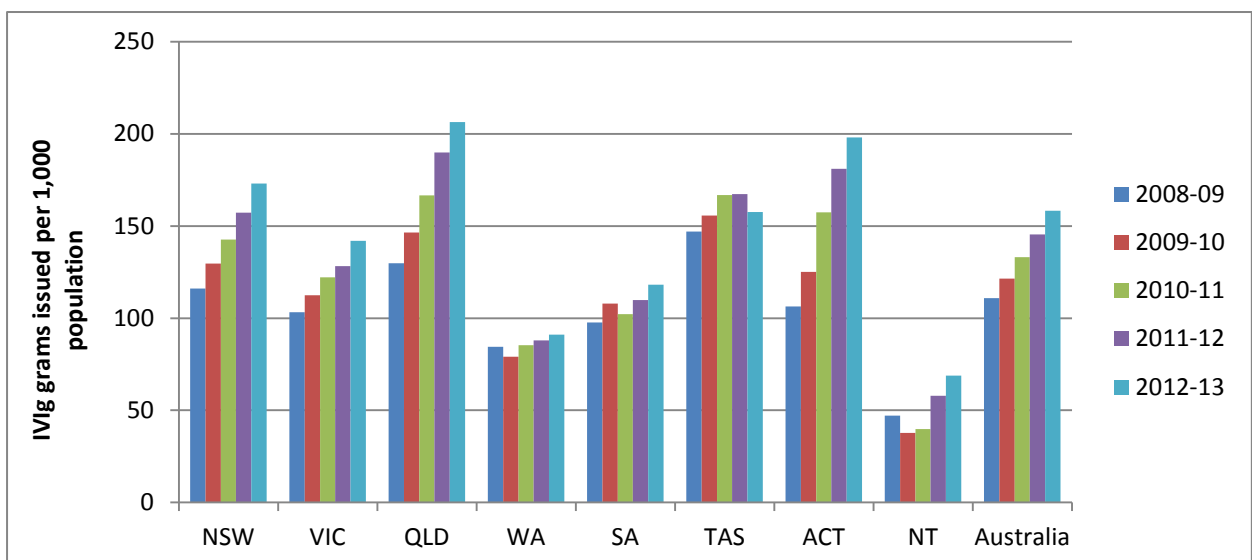


Figure 4 Grams of IVIg per 1,000 population by state and territory over time

## AGE

The distribution of estimated age is shown in Figure 5 where it is compared with the age distribution of the Australian population at December 2012<sup>1</sup>. A bimodal peak can be seen in the IVIg population, with the majority of recipients either being very young, or over 60. The ageing population is expected to place a greater burden on IVIg demand into the future, with the proportion of the world's population over 60 years expected to double between 2000 and 2050<sup>2</sup>.

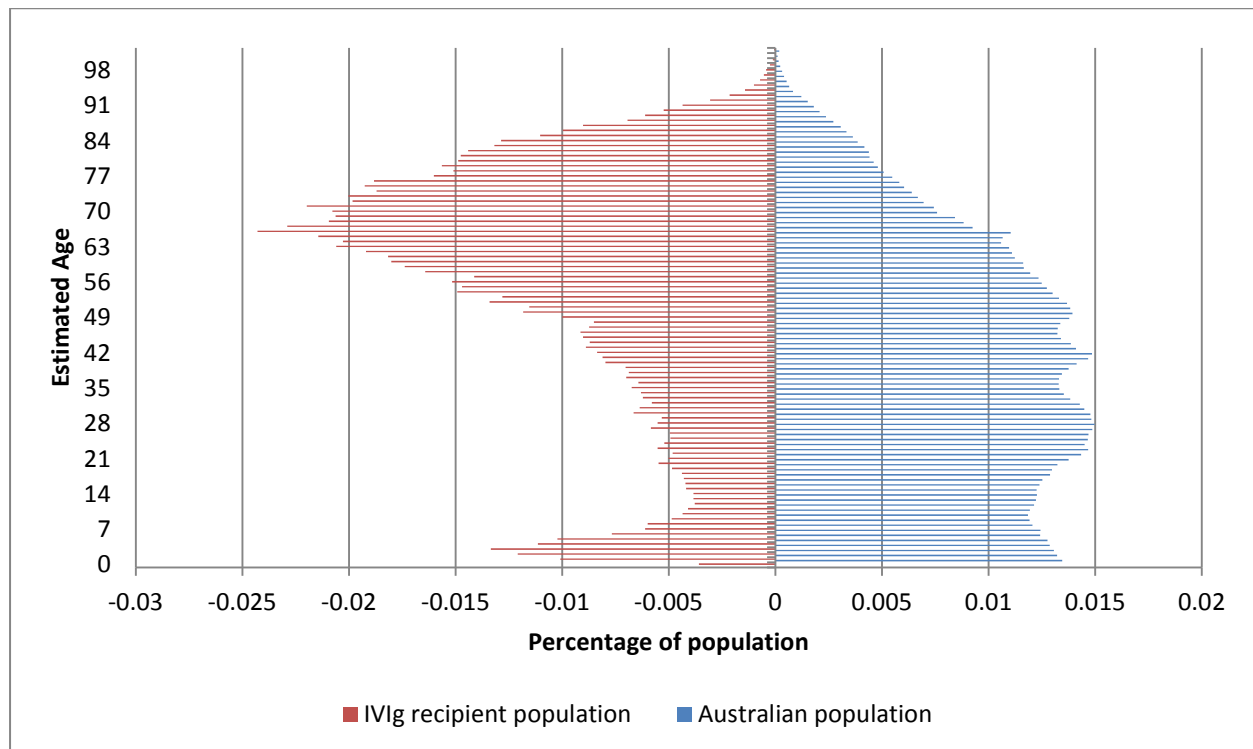


Figure 5 Patient age compared to average Australian age

## WEIGHT

IVIg 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 IVIg is used for its immunomodulatory properties, the *Criteria* limits the dose that can be prescribed based on the patient weight alone.

<sup>1</sup> ABS 4102.0 (average of male and female)

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

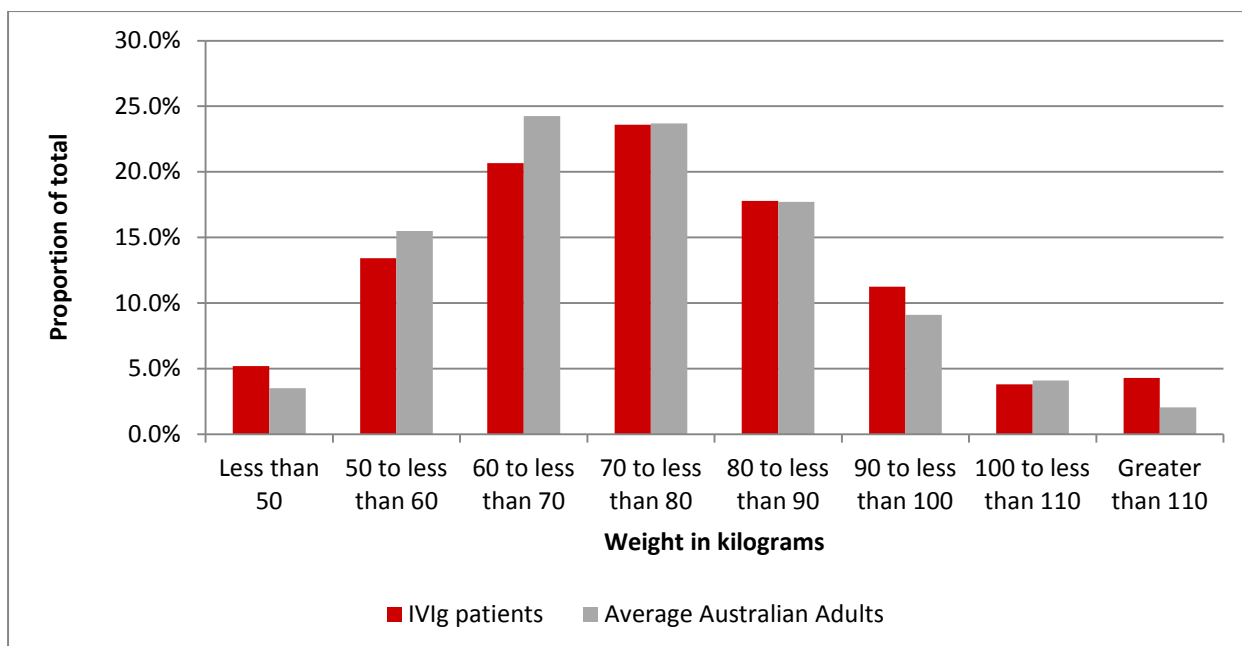


Figure 6 Patient weights relative to Australian average

Figure 6 compares the weight of IVIg recipients in Australia and the Australian population<sup>2</sup>. There are a higher proportion of patients treated with IVIg less than 50kg, between 90 and 100kg and greater than 110 kg relative to the proportion in the Australian population. The average weight of adult IVIg patients (77.5 kg) is slightly lower than that of the average weight of an Australian adult (78.5 kg<sup>3</sup>). Given that studies suggest that 63% of Australians are overweight or obese<sup>4</sup>, the similarity in weight profiles between IVIg recipients and the Australian population suggests that a large proportion of IVIg 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 IVIg dose of between 2.4% and 4.2% were achieved using a lean body dosing methodology.<sup>5</sup> 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.

<sup>2</sup> ABS 4102.0

<sup>3</sup> ABS 4102.0 (average of male and female)

<sup>4</sup> ABS 4364.0.55.001

<sup>5</sup> 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 Australia in 2012-13 expenditure on IVIg products was \$220.1 million, with additional expenditure of \$127.6 million on plasma for fractionation (including hyperimmunes) collected by the Blood Service.

The cost of IVIg as a proportion of the national blood budget is shown at Figure 7. IVIg is the second largest budget item, representing 22.5% of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, IVIg accounts for 35% of the total blood budget, at a total expenditure of \$340.5 million (excluding hyperimmunes).

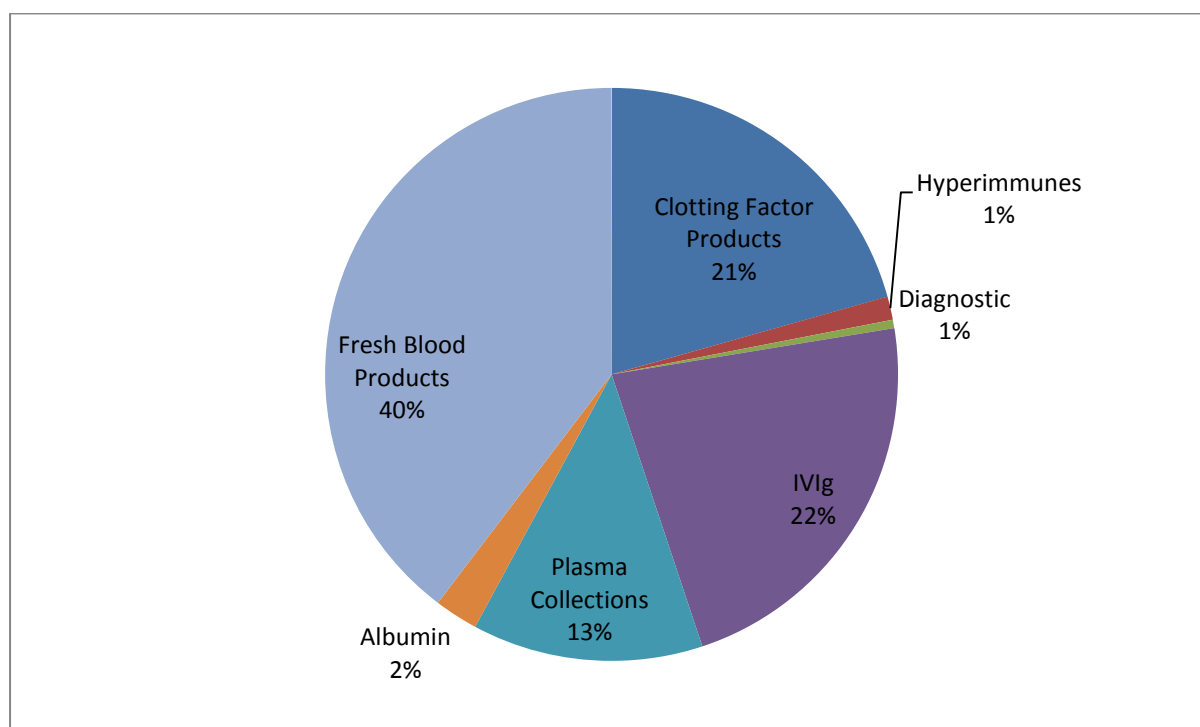


Figure 7 IVIg expenditure as a proportion of the national blood budget

Of the IVIg supplied under national blood arrangements in Australia, 62% (2,254,164 grams) was manufactured domestically and 38% (1,368,269 grams) was imported from overseas. This represents a 91% increase in product importation since 2011-12 (716,163 grams) (Table 5). Intragam P was the only IVIg product manufactured domestically in 2012-13. The two imported products available were Kiovig and Octagam. When a patient is allocated to receive one of the two imported products it is the clinician's choice as to which product they order. Supply of Octagam constituted 64% of the supply of imported IVIg.



Table 5 Issues of domestic IVIg compared with imported IVIg

			NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUS
Domestic IVIg	Intragamma P	g	804,375	484,680	589,662	132,108	123,810	64,305	48,480	6,744	2,254,164
		\$(m)	\$51	\$30	\$37	\$8	\$8	\$4	\$3	\$0	\$142
Imported IVIg	Kiovig	g	110,183	109,720	128,043	40,173	72,728	1,710	23,790	9,551	495,447
		\$(m)	\$6	\$6	\$7	\$2	\$4	\$0	\$1	\$1	\$28
	Octagam	g	357,187	211,365	233,610	52,741	335	14,726	2,858	0	872,822
		\$(m)	\$21	\$12	\$14	\$3	\$0	\$1	\$0	\$0	\$51
	Total imported	g	467,370	321,085	361,652	92,914	72,613	16,436	26,648	9,551	1,368,269
		\$(m)	\$27	\$18	\$21	\$5	\$4	\$1	\$1	\$1	\$78
Proportion of domestic to imported IVIg	g %	63%	60%	62%	59%	63%	80%	65%	41%	62%	
	\$(m) %	65%	62%	64%	61%	66%	81%	67%	44%	64%	

# Clinical Indications

## IVIG ISSUES BY CRITERIA CHAPTER

The *Criteria* classifies conditions into four chapters based on the level of evidence supporting the use of IVIg, 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

IVIg 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 IVIg issues for Chapter 8 conditions (Table 7).

**Table 6** IVIg issues (g) by *Criteria* chapter

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13
Chapter 5	1,005,594	1,172,728	1,363,847	1,625,246	1,990,586	2,212,914	2,505,332	2,724,809	3,025,452
Chapter 6	402,416	400,682	368,458	417,939	345,176	371,832	397,231	444,605	453,352
Chapter 7	17,820	19,518	33,970	45,130	47,275	61,924	76,033	101,287	120,979
Chapter 8	13,110	16,259	15,351	8,888	3,326	2,550	2,574	1,909	39
Other	43,056	47,730	76,426	37,743	0	0	0	0	0
<b>Total</b>	<b>1,481,996</b>	<b>1,656,917</b>	<b>1,858,052</b>	<b>2,134,945</b>	<b>2,386,361</b>	<b>2,649,219</b>	<b>2,981,170</b>	<b>3,272,609</b>	<b>3,599,822</b>

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

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13
Chapter 5	68%	71%	73%	76%	83%	84%	84%	83%	84%
Chapter 6	27%	24%	20%	20%	14%	14%	13%	14%	13%
Chapter 7	1%	1%	2%	2%	2%	2%	3%	3%	3%
Chapter 8	1%	1%	1%	<1%	<1%	<1%	<1%	<1%	<1%
Other	3%	3%	4%	2%	0%	0%	0%	0%	0%

For conditions where IVIg is used only in exceptional circumstances (Chapter 7), four conditions accounted for 35% of those issues. These conditions were potassium channel antibody-associated encephalopathy (13,218g), limbic encephalitis – nonparaneoplastic (10,900g), solid organ transplant – lung (9,802g) and epilepsy (8,291g). While use in these conditions represents a small proportion of total IVIg use, closer examination may be warranted. For example, approximately 140 lung transplants are performed in Australia every year<sup>6</sup>, and 75 patients received IVIg for this indication, meaning that approximately half of these patients receive IVIg.

While IVIg may be issued in life threatening situations prior to diagnosis or in situations where the diagnosis is unclear at the time of treatment, in 2012-13 there were no cases where IVIg 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.

## IVIg ISSUES BY DIAGNOSTIC GROUPS

The top ten diagnostic groups account for 88.4% of all IVIg supplied, with the top three diagnostic groups accounting for 56.6%.

Acquired hypogammaglobulinaemia secondary to haematological malignancies is the diagnostic group for which the greatest percentage of IVIg was issued in 2012-13 (21.4%), closely followed by chronic inflammatory demyelinating polyneuropathy (21.1%). Primary immunodeficiency diseases accounted for 14.2% of total IVIg use (Figure 8, Table 8).

Since 2008 there has been a 1.6 fold increase in IVIg 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 1.4 fold increase in IVIg over this period for all conditions.

<sup>6</sup>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 254% increase between 2008-09 and 2012-13, associated with a concurrent increase in patient numbers (increased of 245%). The grams issued per patient has not increased significantly. However there has been a large increase in grams per 1,000 population from 1.5 to 5.2. Other states and territories have not had changes as large relative to New South Wales.

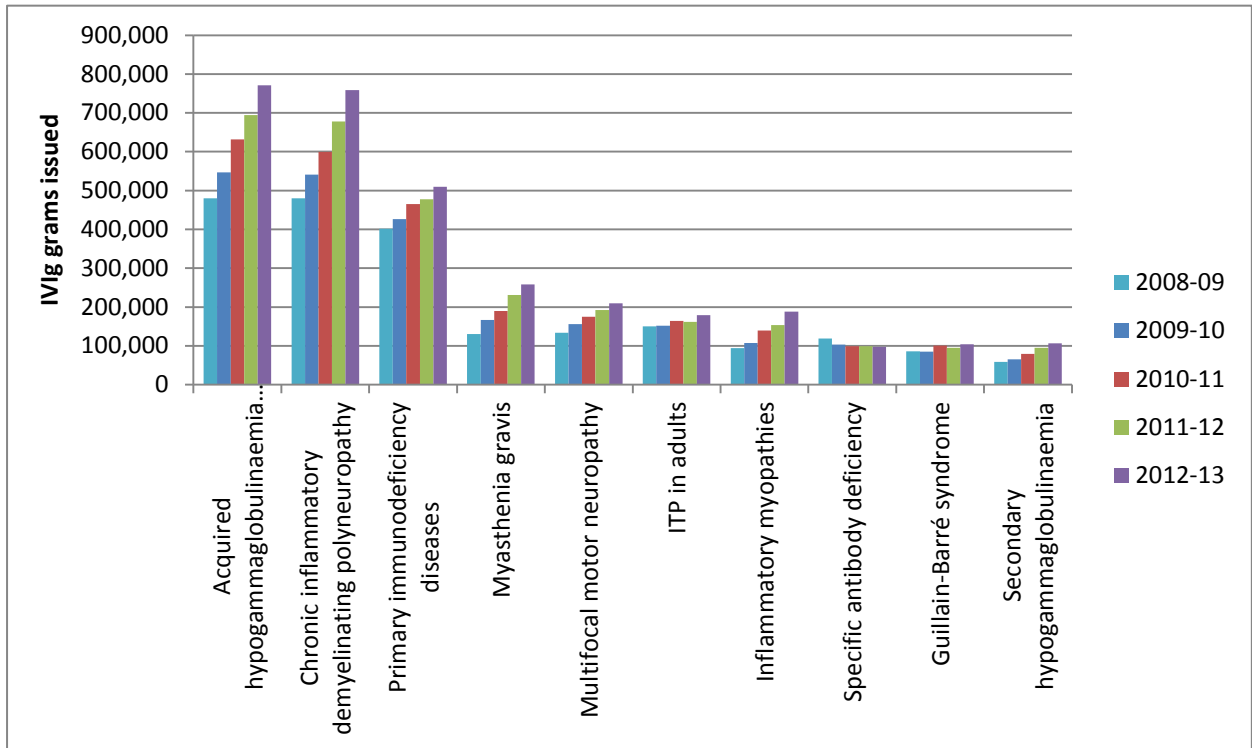


Figure 8 IVIg grams issued by diagnostic group

**Table 8** IVIg grams issued for top 10 diagnostic groups over time

	2008-09	2009-10	2010-11	2011-12	2012-13
Acquired hypogammaglobulinaemia secondary to haematological malignancies	480,204	546,391	631,689	694,640	771,071
Chronic inflammatory demyelinating polyneuropathy	479,968	541,206	599,181	677,458	758,271
Primary immunodeficiency diseases	401,727	426,090	465,354	477,461	509,364
Myasthenia gravis	130,259	166,342	189,771	231,064	257,966
Multifocal motor neuropathy	133,634	156,284	175,176	192,109	209,791
ITP in adults	150,421	151,638	163,905	162,098	178,738
Inflammatory myopathies	94,299	106,984	139,195	153,931	188,362
Specific antibody deficiency	118,538	103,042	99,328	99,521	97,749
Guillain-Barré syndrome	86,005	85,344	101,014	95,359	104,360
Secondary hypogammaglobulinaemia	59,141	65,579	79,151	95,183	106,484

## ***IVIg ISSUES BY CONDITION***

Table 9 provides an overview of the conditions that use the most IVIg, including data on total IVIg use, patient numbers and median birth year. These conditions account for 88.8% of all IVIg supplied, with the top ten conditions accounting for 73.8%. This data is also replicated in Figure 9 for the top 10 conditions.

**Table 9 Patient numbers and age for the top 20 conditions**

<b>Conditions (Top 20)</b>	<b>IVIg g (% of total)</b>	<b>Patients n (% of total)</b>	<b>Median Age</b>
Chronic inflammatory demyelinating polyneuropathy	758,271 (21%)	1,754 (13%)	66
Common variable immunodeficiency disease	436,753 (12%)	1,406 (11%)	56
Myasthenia gravis	257,966 (7%)	671 (5%)	65
Chronic lymphocytic leukaemia	253,763 (7%)	1,080 (8%)	75
Non-Hodgkin's lymphoma	218,655 (6%)	940 (7%)	68
Multifocal motor neuropathy	209,791 (6%)	385 (3%)	58
Multiple myeloma	208,997 (6%)	971 (7%)	71
Secondary hypogammaglobulinaemia	106,484 (3%)	546 (4%)	53
Polymyositis	104,817 (3%)	295 (2%)	63
Guillain-Barré syndrome	104,360 (3%)	622 (5%)	56
ITP refractory	84,250 (2%)	575 (4%)	63
Other relevant haematological malignancies	83,571 (2%)	510 (4%)	56
Kidney transplantation post-transplant	78,337(2%)	299 (2%)	49
ITP in specific circumstances	52,190 (1%)	366 (3%)	64
Specific antibody deficiency	52,173 (1%)	221 (2%)	57
IgG subclass deficiency - existing patients only	44,511 (1%)	163 (1%)	64
Dermatomyositis	43,740 (1%)	133 (1%)	56
Inclusion body myositis	39,806 (1%)	104 (<1%)	73
X linked agammaglobulinaemia	32,725 (1%)	110 (<1%)	24
Other primary immunodeficiency	29,573 (1%)	123 (<1%)	48

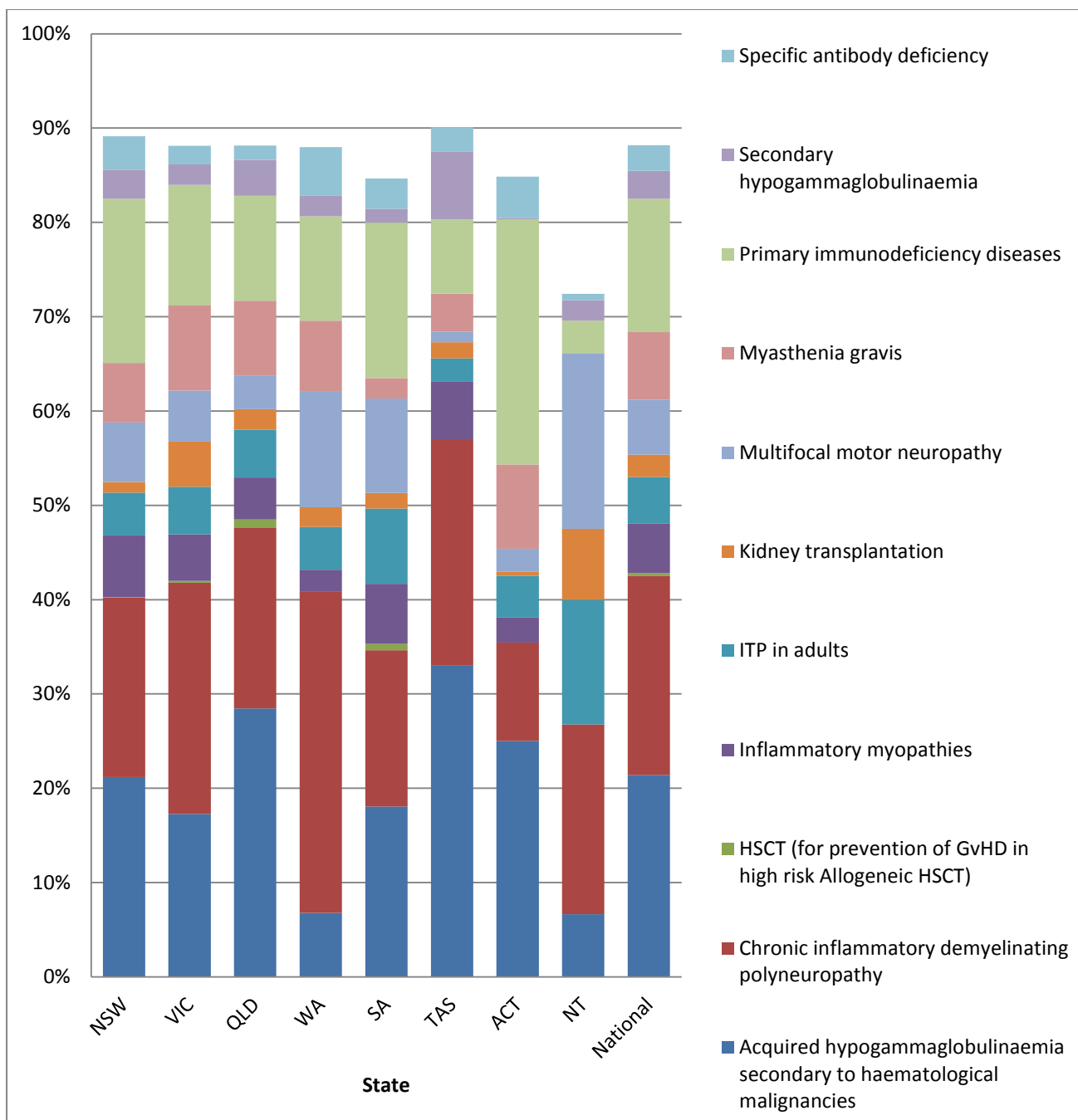


Figure 9 Proportion of IVIg used for top 10 conditions

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

IVIg was supplied for 1,406 patients with common variable immunodeficiency disease. The estimated prevalence of common variable immunodeficiency disease as measured by patients treated with IVIg for this indication is 6.1 per 100,000 population (ranging from 0.8 to 8.8 per 100,000 population across Australian states and territories).

For common variable immunodeficiency disease, this estimate is higher than other studies suggest with estimates between 2 and 4 people per 100,000 population<sup>7</sup>. The ability to calculate accurate prevalence estimates is important for health service planning. It should be noted that the prevalence estimate is for diagnosed and treated patients only, 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 IVIg.

## IVIg ISSUES BY CLINICAL DISCIPLINE

The number of grams of IVIg 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 2008, there has been a 1.6 fold increase in IVIg issues for neurological conditions, compared with a 1.4 fold increase for haematological conditions and a 1.2 fold increase for immunological conditions.

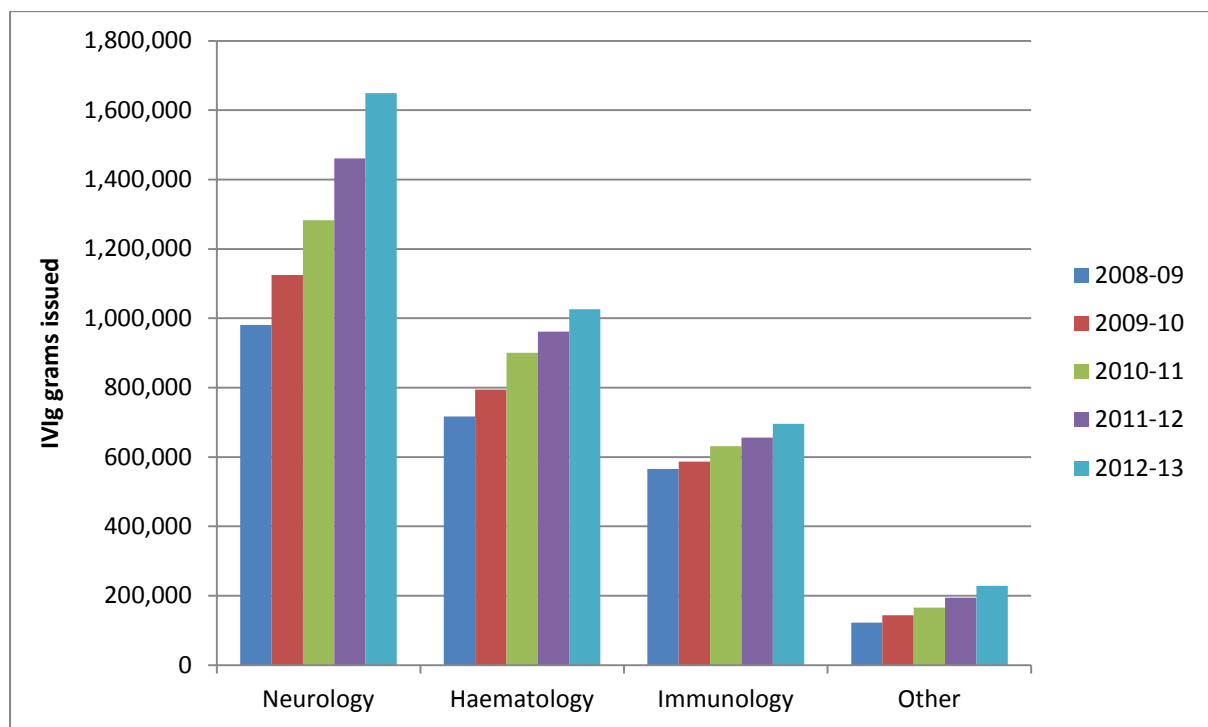


Figure 10 IVIg issues by clinical discipline

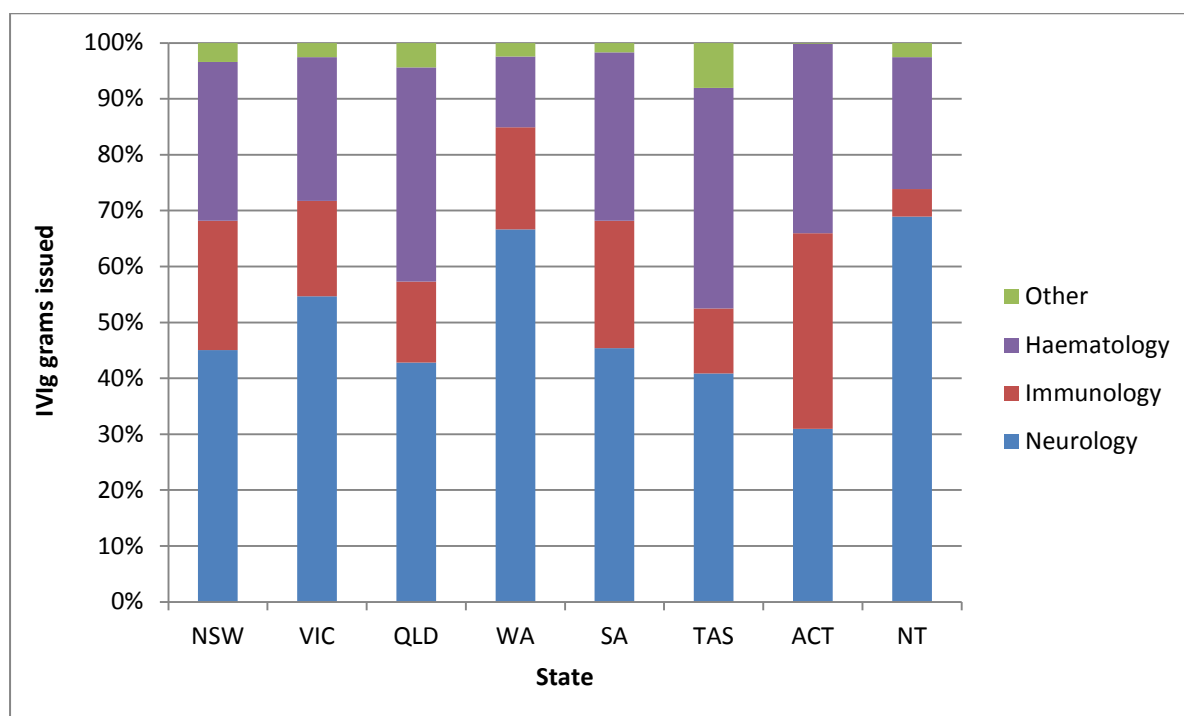
<sup>7</sup> Cunningham-Rundles, C 2012, *The many faces of common variable immunodeficiency*, American Society of Hematology, USA.



**Table 10** IVIg grams issued by clinical discipline

	2008-09	2009-10	2010-11	2011-12	2012-13
Neurology	981,372	1,124,604	1,283,190	1,460,702	1,649,358
Haematology	716,767	794,098	900,826	961,366	1,026,219
Immunology	565,998	586,852	631,076	656,179	695,298
Other	122,226	143,667	166,079	194,363	228,947

There is significant variation across Australia in IVIg 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 IVIg 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** IVIg issues by clinical discipline for top 10 conditions by state and territory

### *IVIg GRAMS ISSUED PER 1,000 POPULATION*

The amount of IVIg 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 Table 17 for the conditions using the most IVIg. Table 11 shows a breakdown of the proportion of IVIg 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 IVIg use per capita is seen in multiple myeloma followed by Non-Hodgkin's lymphoma. For both these conditions there was a low number of IVIg 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 IVIg issued by state and territory**

2012-13	IVIg issued (g)	Proportion of total IVIg issued	Proportion of Australian population	Grams per 1,000 population
NSW	1,271,746	35%	32%	173
VIC	805,765	22%	25%	142
QLD	951,316	27%	20%	206
WA	196,422	6%	11%	79
SA	225,022	6%	7%	135
TAS	80,740	2%	2%	158
ACT	75,128	2%	2%	198
NT	16,294	0%	1%	69
<b>Total</b>	<b>3,622,433</b>	<b>100%</b>	<b>100%</b>	<b>158</b>

The following tables (Table 12, Table 13, Table 14, Table 15, Table 16, Table 17) 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
NSW	524	539	598	652
VIC	335	339	372	422
QLD	289	312	386	485
WA	96	90	99	105
SA	63	70	73	80
TAS	43	33	30	33
ACT	16	14	17	22
NT	<5	<5	5	7
Australia	1,341	1,372	1,551	1,754

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

<b>Common variable immunodeficiency disease</b>	<b>2009-10</b>	<b>2010-11</b>	<b>2011-12</b>	<b>2012-13</b>
NSW	528	563	617	650
VIC	207	226	232	241
QLD	244	251	276	311
WA	74	58	61	67
SA	98	107	102	101
TAS	18	18	20	21
ACT	39	50	54	58
NT	<5	5	5	<5
Australia	1,183	1,249	1,323	1,406

**Table 14 Patient numbers by state and territory: myasthenia gravis**

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

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

<b>Chronic lymphocytic leukaemia</b>	<b>2009-10</b>	<b>2010-11</b>	<b>2011-12</b>	<b>2012-13</b>
NSW	340	371	383	395
VIC	223	234	232	225
QLD	275	265	283	297
WA	32	35	48	42
SA	79	85	79	79
TAS	28	32	31	31
ACT	16	21	25	29
NT	<5	<5	5	5
Australia	984	1,028	1,064	1,080

**Table 16 Patient numbers by state and territory: multiple myeloma**

<b>Multiple myeloma</b>	<b>2009-10</b>	<b>2010-11</b>	<b>2011-12</b>	<b>2012-13</b>
NSW	270	306	327	380
VIC	131	162	153	157
QLD	281	307	330	346
WA	16	16	15	16
SA	20	16	17	22
TAS	47	58	51	47
ACT	11	21	14	10
NT	0	<5	<5	<5
Australia	772	881	904	971

**Table 17** IVIg issued per 1,000 population by state and territory

Condition	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National	Fold Variation*
Chronic inflammatory demyelinating polyneuropathy	32	35	39	31	20	38	20	14	33	2
Common variable immunodeficiency disease	27	13	20	8	18	12	49	0	19	3
Myasthenia gravis	11	13	16	7	3	6	17	0	11	6
Chronic lymphocytic leukaemia	12	9	15	3	11	15	21	3	11	5
Non-Hodgkin's lymphoma	8	7	21	1	6	11	14	1	10	16
Multifocal motor neuropathy	11	8	7	11	12	2	5	13	9	2
Multiple myeloma	10	5	18	1	3	24	8	0	9	23
Polymyositis	7	3	6	1	4	3	2	0	5	7
Guillain-Barré syndrome	4	5	5	3	5	2	5	14	5	2
Secondary hypogammaglobulinaemia	5	3	8	2	2	12	0	2	5	4

\*The Fold Variation in Table 17 is a measure describing difference in the IVIg 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

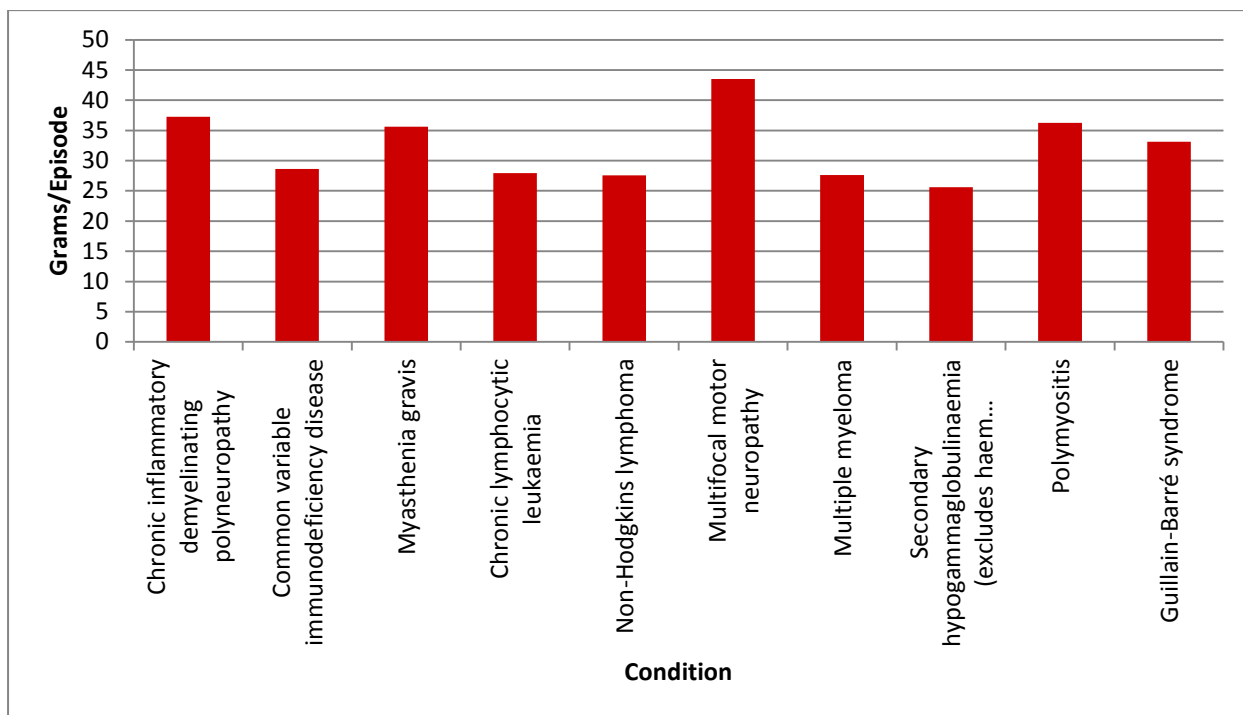


Figure 12 Grams per episode by condition

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.

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 was 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 IVIg grams per episode

Condition	<=0.4	0.4 – 0.99	1 – 2	>2	No weight
	g/kg/episode	g/kg/episode	g/kg/episode	g/kg/episode	Data
	n (%)	n (%)	n (%)	n (%)	n(%)
Chronic inflammatory demyelinating polyneuropathy	7,476 (44%)	7,810 (46%)	407 (3%)	24 (0%)	1,240 (7%)
Common variable immunodeficiency disease	6,710 (44%)	5,339 (35%)	16 (0%)	0 (0%)	3,083 (21%)
Myasthenia gravis	2,780 (48%)	2,650 (46%)	102 (2%)	6 (0%)	255 (4%)
Chronic lymphocytic leukaemia	5,970 (67%)	2,338 (26%)	2 (0%)	0 (0%)	669 (7%)
Non-Hodgkin’s lymphoma	1,175 (30%)	1,988 (50%)	289 (7%)	2 (0%)	513 (13%)
Multifocal motor neuropathy	5,392 (69%)	1,961 (25%)	0 (0%)	0 (0%)	462 (6%)
Multiple myeloma	5,211 (70%)	1,926 (26%)	1 (0%)	0 (0%)	333 (4%)
Secondary hypogammaglobulinaemia (excludes haem malignancies)	2,473 (61%)	1,342 (33%)	21 (1%)	4 (0%)	219 (5%)
Polymyositis	1,148 (47%)	1,038 (43%)	51 (2%)	2 (0%)	183 (8%)
Guillain-Barré syndrome	431 (50%)	317 (37%)	74 (9%)	15 (2%)	22 (2%)

# Appendix A – Background

## Funding for IVIg

IVIg 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 IVIg 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 IVIg was permitted under defined circumstances.

The *Criteria* is a publication that describes the criteria that patients must meet to receive IVIg 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 IVIg is accessed consistently across Australia for the treatment of patients whose health is likely to be improved with IVIg 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 IVIg 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 IVIg 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 IVIg from Australian blood donations for a number of years. While NBA makes sure there is enough IVIg by importing this product, there is a finite international supply.

There are two main ways IVIg is available in Australia:

1. Supply under national blood arrangements

If the IVIg 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 IVIg under national blood arrangements are made to the Blood Service, which is contracted by the NBA as the authoriser and distributor of all IVIg 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 IVIg will continue.

In the role as authoriser of requests for IVIg, 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 IVIg in Australia.

## 2. Direct order and other supply arrangements

If the IVIg 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 IVIg. 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 IVIg). 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 IVIg as a contingency supply if and when needed to supplement shortfalls in the domestic IVIg supply. The IVIg Standing Offer comprised two components, a National Blood Supply component whereby imported IVIg 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 IVIg for all other conditions.

IVIg 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 IVIg, governments purchased imported IVIg (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 IVIg 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 IVIg remained available to all Australians, the NBA negotiated a further 12-month extension to the IVIg 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 IVIg 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 IVIg 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 IVIg 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 IVIg 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 IVIg authorisation and clinical governance arrangements. The aim of the review was to identify options for improvements in the management of IVIg. The review also analysed the issues, benefits and risks of potentially including NIg and subcutaneous immunoglobulin (SCIg) in the IVIg management framework.

The review identified that there are significant variations in IVIg 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 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 IVIg 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 IVIg 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.

# 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
HIV	Human immunodeficiency virus
HSCT	Hematopoietic stem cell transplantation
IDMS	Integrated Data Management System
IgG	Immunoglobulin G
ITP	Idiopathic thrombocytopenic purpura
IVIg	Intravenous immunoglobulin
NBA	National Blood Authority
NIg	Normal immunoglobulin
NSP&B	National Supply Plan and Budget
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 on Health (formerly the Australian Ministers' Health Conference)
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
<b>Blood products</b>	Products manufactured from donated blood
<b>Blood Service</b>	The Australian Red Cross Blood Service
<b>Clinical Discipline</b>	Classification of the conditions according to the clinical discipline
<b>Condition</b>	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.
<b><i>Criteria for the clinical use of intravenous immunoglobulin in Australia (the Criteria)</i></b>	A document describing the indications for which IVIg is funded under national blood arrangements by all Australian governments
<b>Criteria Met</b>	Circumstances, based on evidence and clinical experience, under which the clinical use of IVIg is considered appropriate to be funded in Australia
<b>Criteria Not Met or Qualifying (Q) Criteria Not Met</b>	Circumstances, based on evidence and clinical experience, under which the clinical use of IVIg is not considered appropriate to be funded in Australia
<b>Direct Orders (DO)</b>	Previously known as Jurisdictional Direct Orders (JDO). Arrangements implemented by the NBA with suppliers to facilitate the purchase of IVIg for the treatment of conditions not satisfying the <i>Criteria for the clinical use of IVIg in Australia</i>
<b>Diagnostic Group</b>	A grouping of clinical/medical conditions, as outlined in the <i>Criteria</i> . Also known as disease group
<b>Disease Group</b>	See diagnostic group
<b>Fractionation</b>	A manufacturing process that separates blood plasma into components
<b>Imprest stock</b>	Health provider orders of product for stock that is maintained at a certain level
<b>Intravenous immunoglobulin</b>	A blood product derived from donated human plasma that is administered intravenously

<b>Term</b>	<b>Description</b>
<b>Jurisdiction</b>	The parties to the Australian National Blood Agreement, being the Australian Government and all state and territory governments
<b>Minimum Product Inventory</b>	The minimum inventory of IVIg held by CSL to meet contract obligations
<b>National Blood Agreement</b>	The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the Australian blood sector
<b>National blood arrangements</b>	Arrangements, including funding arrangements, established under the National Blood Agreement
<b>National CSL Reserve</b>	The reserve of inventory of IVIg that CSL Behring manages on behalf of the NBA for contingency purposes.
<b>Normal immunoglobulin</b>	A blood product derived from donated human plasma that is administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection)
<b>Plasma</b>	The liquid part of the blood containing antibodies and other proteins
<b>Primary diagnosis</b>	See 'condition'
<b>Subcutaneous immunoglobulin</b>	A blood product derived from donated human plasma that is administered subcutaneously
<b>Treatment episode</b>	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
Cicatrical 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 Amyotrophy	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 encephalopathy	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 Dysautonomia	NA	Pre 2008 <i>Criteria</i>	Neurology
Alloimmune Neutropenia In Infancy	NA	Pre 2008 <i>Criteria</i>	Haematology
Alloimmune Thrombocytopenia Neonatal	NA	Pre 2008 <i>Criteria</i>	Haematology
Autoimmune Thrombocytopenic	NA	Pre 2008 <i>Criteria</i>	Haematology
Cutaneous Vasculitis	NA	Pre 2008 <i>Criteria</i>	Mixed
Hypogammaglobulinaemia	NA	Pre 2008 <i>Criteria</i>	Immunology
Hypogammaglobulinaemia Unclassified	NA	Pre 2008 <i>Criteria</i>	Immunology
Immunological Miscellaneous, No diagnosis recorded	NA	Pre 2008 <i>Criteria</i>	Immunology
Miscellaneous	NA	Pre 2008 <i>Criteria</i>	Mixed
Myelopathy due to HTLV-1	NA	Pre 2008 <i>Criteria</i>	Immunology
Necrotising Myelitis	NA	Pre 2008 <i>Criteria</i>	Mixed
Other Lymphoproliferative / Hypogammaglobulinaemia	NA	Pre 2008 <i>Criteria</i>	Haematology
Paediatric Myocarditis	NA	Pre 2008 <i>Criteria</i>	Mixed
Sensory neuropathy associated with anti-Hu antibodies	NA	Pre 2008 <i>Criteria</i>	Neurology
Septic thrombocytopenia	NA	Pre 2008 <i>Criteria</i>	Haematology
Stills Disease - Adults	NA	Pre 2008 <i>Criteria</i>	Immunology
Trauma - Burns	NA	Pre 2008 <i>Criteria</i>	Mixed

# Appendix D – Dataset of IVIg supply by state/territory 2012-13

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
<b>Chapter 5</b>										
Chronic inflammatory demyelinating polyneuropathy	Patients	652	422	485	105	80	33	22	7	1,754
	Grams	236,311	200,441	181,288	76,829	32,807	19,686	7,540	3,370	758,271
	Grams/Episode	35	37	34	60	41	48	42	42	37
	Grams per 1,000	32	35	39	31	20	38	20	14	33
Chronic lymphocytic leukaemia	Patients	395	225	297	42	79	31	29	5	1,080
	Grams	87,394	53,754	69,947	7,925	18,510	7,554	7,998	681	253,763
	Grams/Episode	29	28	26	26	30	28	30	27	28
	Grams per 1,000	12	9	15	3	11	15	21	3	11
Common variable immunodeficiency disease	Patients	650	241	311	67	101	21	58	<5	1,406
	Grams	195,933	75,371	90,552	20,401	29,759	6,178	18,476	84	436,753
	Grams/Episode	30	28	28	26	27	27	27	42	29
	Grams per 1,000	27	13	20	8	18	12	49	<1	19
Dermatomyositis	Patients	56	28	23	11	12	<5	<5	0	133
	Grams	17,329	8,027	7,811	2,794	4,430	2,363	987	0	43,740
	Grams/Episode	31	43	34	34	41	54	58	0	36
	Grams per 1,000	2	1	2	1	3	5	3	0	2
Guillain-Barré syndrome	Patients	179	190	127	50	50	8	12	8	622
	Grams	31,517	28,835	22,138	7,387	8,264	1,190	1,794	3,236	104,360
	Grams/Episode	31	33	31	63	34	30	31	28	33
	Grams per 1,000	4	5	5	3	5	2	5	14	5

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Inclusion body myositis	Patients	43	34	20	0	8	<5	0	0	104
	Grams	14,609	14,320	7,753	0	1,814	1,310	0	0	39,806
	Grams/Episode	38	35	34	0	32	37	0	0	36
	Grams per 1,000	2	3	2	0	1	3	0	0	2
ITP associated with HIV	Patients	<5	<5	0	0	0	0	0	0	5
	Grams	406	500	0	0	0	0	0	0	906
	Grams/Episode	102	45	0	0	0	0	0	0	60
	Grams per 1,000	<1	<1	0	0	0	0	0	0	<1
ITP in pregnancy	Patients	29	19	21	8	11	<5	<5	<5	92
	Grams	4,897	1,662	3,135	1,210	1,376	78	423	422	13,202
	Grams/Episode	42	57	40	67	69	39	60	60	47
	Grams per 1,000	<1	<1	<1	<1	<1	<1	1	2	<1
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic	Patients	118	101	81	24	32	7	<5	<5	366
	Grams	17,579	11,846	13,650	3,466	4,614	669	90	278	52,190
	Grams/Episode	45	54	31	63	62	61	90	93	44
	Grams per 1,000	2	2	3	1	3	1	<1	1	2
ITP refractory	Patients	122	148	205	46	33	9	10	5	575
	Grams	17,667	21,708	29,975	5,454	5,509	1,043	1,590	1,306	84,250
	Grams/Episode	37	58	34	63	63	52	66	93	43
	Grams per 1,000	2	4	7	2	3	2	4	6	4
ITP with life-threatening haemorrhage	Patients	112	47	12	<5	30	<5	8	<5	214
	Grams	15,606	5,422	1,246	85	4,323	200	1,102	208	28,190
	Grams/Episode	38	55	32	85	58	100	61	69	44
	Grams per 1,000	2	<1	<1	<1	3	<1	3	<1	1
Kawasaki disease	Patients	91	71	47	21	11	<5	<5	<5	247
	Grams	3,738	2,497	1,638	685	456	147	54	24	9,239
	Grams/Episode	33	25	30	27	33	37	27	12	30
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Lambert-Eaton myasthenic syndrome	Patients	6	<5	10	<5	0	0	0	0	21
	Grams	1,922	1,341	4,371	1,030	0	0	0	0	8,663
	Grams/Episode	34	45	31	36	0	0	0	0	33
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
Multifocal motor neuropathy	Patients	158	78	90	34	22	<5	<5	6	385
	Grams	78,290	44,172	33,930	27,756	19,847	936	1,743	3,119	209,791
	Grams/Episode	40	44	34	68	57	32	41	78	44
	Grams per 1,000	11	8	7	11	12	2	5	13	9
Multiple myeloma	Patients	380	157	346	16	22	47	10	<5	971
	Grams	75,473	29,570	81,995	1,954	4,750	12,207	2,977	72	208,997
	Grams/Episode	30	29	25	26	30	31	30	24	28
	Grams per 1,000	10	5	18	<1	3	24	8	<1	9
Myasthenia gravis	Patients	235	177	199	39	17	10	13	0	671
	Grams	78,563	73,631	74,903	16,807	4,276	3,323	6,465	0	257,966
	Grams/Episode	35	37	33	55	40	33	46	0	36
	Grams per 1,000	11	13	16	7	3	6	17	0	11
Neonatal haemochromatosis	Patients	<5	<5	5	<5	0	0	0	0	10
	Grams	3,267	1,140	1,314	1,450	0	0	0	0	7,171
	Grams/Episode	74	60	53	85	0	0	0	0	68
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
Non-Hodgkin's lymphoma	Patients	285	160	393	20	49	26	19	<5	940
	Grams	60,307	36,938	96,987	3,209	10,228	5,415	5,373	198	218,655
	Grams/Episode	29	29	26	27	28	27	30	50	28
	Grams per 1,000	8	7	21	1	6	11	14	<1	10
Other Lymphoproliferative / Hypogammaglobulinaemia	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	42	0	0	0	0	0	0	42
	Grams/Episode	0	21	0	0	0	0	0	0	21
	Grams per 1,000	0	<1	0	0	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Other primary immunodeficiency	Patients	53	40	13	9	<5	<5	5	<5	123
	Grams	12,009	10,736	1,992	2,535	1,209	312	285	495	29,573
	Grams/Episode	24	28	19	25	32	24	17	20	25
	Grams per 1,000	2	2	<1	1	<1	<1	<1	2	1
Other relevant haematological malignancies	Patients	272	102	88	23	19	10	9	<5	510
	Grams	37,592	19,949	18,021	2,100	2,217	1,761	1,767	165	83,571
	Grams/Episode	27	29	27	18	25	28	30	18	27
	Grams per 1,000	5	4	4	<1	1	3	5	<1	4
Polymyositis	Patients	150	49	67	8	20	<5	<5	0	295
	Grams	49,375	17,947	26,323	2,376	6,389	1,476	932	0	104,817
	Grams/Episode	34	43	35	68	41	45	32	0	36
	Grams per 1,000	7	3	6	<1	4	3	2	0	5
Post-haemopoietic stem cell transplantation (HSCT)	Patients	38	17	24	<5	5	<5	0	0	89
	Grams	2,349	1,020	2,148	99	138	333	0	0	6,086
	Grams/Episode	32	31	27	14	28	33	0	0	29
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1
Severe combined Immunodeficiency	Patients	5	11	22	<5	0	0	0	0	39
	Grams	588	2,562	6,204	3	0	0	0	0	9,357
	Grams/Episode	12	17	25	3	0	0	0	0	21
	Grams per 1,000	<1	<1	1	<1	0	0	0	0	<1
Stiff person syndrome	Patients	14	6	9	0	<5	<5	0	<5	30
	Grams	7,166	5,155	8,937	0	201	822	0	108	22,389
	Grams/Episode	46	53	60	0	22	36	0	22	51
	Grams per 1,000	<1	<1	2	0	<1	2	0	<1	<1
Transplants - Allogeneic stem cell or bone marrow	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	27	0	0	0	0	0	0	0	27
	Grams/Episode	3	0	0	0	0	0	0	0	3
	Grams per 1,000	<1	0	0	0	0	0	0	0	<1



Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Wiskott-Aldrich syndrome	Patients	<5	<5	<5	<5	0	0	0	0	5
	Grams	18	183	348	408	0	0	0	0	957
	Grams/Episode	6	14	25	24	0	0	0	0	20
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
X linked agammaglobulinaemia	Patients	30	49	20	6	7	0	<5	0	110
	Grams	7,548	15,687	6,051	1,627	1,743	0	69	0	32,725
	Grams/Episode	27	28	28	26	26	0	14	0	27
	Grams per 1,000	1	3	1	<1	1	0	<1	0	1
Chapter 5 Total	Patients	3,985	2,347	2,857	530	599	225	207	49	10,577
	Grams	1,057,475	684,452	792,650	187,588	162,858	67,003	59,664	13,765	3,025,452
	Grams/Episode	32	34	30	46	36	35	32	41	33
	Grams per 1,000	144	121	172	76	98	131	157	58	132
<b>Chapter 6</b>										
Acute disseminated encephalomyelitis	Patients	26	8	9	6	<5	<5	0	0	55
	Grams	3,094	1,051	1,159	489	483	153	0	0	6,428
	Grams/Episode	26	32	43	38	37	26	0	0	31
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1
ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	Patients	<5	<5	9	0	<5	0	0	0	12
	Grams	120	187	1,346	0	210	0	0	0	1,863
	Grams/Episode	30	37	33	0	30	0	0	0	33
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Autoimmune haemolytic anaemia	Patients	21	35	28	9	10	<5	<5	0	106
	Grams	3,757	4,013	4,528	1,171	3,976	640	360	0	18,444
	Grams/Episode	34	50	29	62	50	128	90	0	41
	Grams per 1,000	<1	<1	<1	<1	2	1	<1	0	<1
Bullous pemphigoid	Patients	7	<5	<5	<5	0	0	0	0	15
	Grams	6,305	815	1,042	325	0	0	0	0	8,487
	Grams/Episode	61	54	31	25	0	0	0	0	51
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Churg-Strauss syndrome	Patients	0	0	0	<5	0	<5	0	0	<5
	Grams	0	0	0	990	0	153	0	0	1,143
	Grams/Episode	0	0	0	124	0	51	0	0	104
	Grams per 1,000	0	0	0	<1	0	<1	0	0	<1
Cicatrical pemphigoid	Patients	<5	<5	<5	0	0	0	<5	0	10
	Grams	2,118	180	2,509	0	0	0	2,535	0	7,342
	Grams/Episode	76	90	46	0	0	0	69	0	60
	Grams per 1,000	<1	<1	<1	0	0	0	7	0	<1
Evans syndrome	Patients	<5	<5	<5	0	<5	0	0	0	8
	Grams	768	12	288	0	165	0	0	0	1,233
	Grams/Episode	43	12	19	0	41	0	0	0	32
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	Patients	<5	6	6	<5	<5	0	0	0	17
	Grams	1,209	4,513	4,734	1,320	2,489	0	0	0	14,265
	Grams/Episode	64	73	72	60	67	0	0	0	69
	Grams per 1,000	<1	<1	1	<1	1	0	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	Patients	7	10	<5	<5	<5	<5	<5	<5	31
	Grams	33	51	18	9	18	3	3	14	149
	Grams/Episode	3	3	3	3	5	3	2	5	3
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1
Haemophagocytic syndrome	Patients	20	8	7	0	0	0	<5	0	36
	Grams	2,197	1,099	1,278	0	0	0	233	0	4,806
	Grams/Episode	46	46	38	0	0	0	26	0	42
	Grams per 1,000	<1	<1	<1	0	0	0	<1	0	<1
HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	Patients	8	7	37	0	5	0	0	0	57
	Grams	747	1,682	8,127	0	1,345	0	0	0	11,901
	Grams/Episode	34	30	26	0	34	0	0	0	28
	Grams per 1,000	<1	<1	2	0	<1	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
IgG subclass deficiency EXISTING patients only	Patients	98	27	21	<5	11	5	0	0	163
	Grams	26,080	8,928	3,593	1,128	3,099	1,683	0	0	44,511
	Grams/Episode	28	27	21	29	28	26	0	0	27
	Grams per 1,000	4	2	<1	<1	2	3	0	0	2
IgG subclass deficiency. Existing patient with suppurative lung disease	Patients	14	0	<5	0	0	0	0	0	15
	Grams	1,002	0	63	0	0	0	0	0	1,065
	Grams/Episode	29	0	21	0	0	0	0	0	28
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
IgM para-proteinaemic neuropathy	Patients	12	11	23	7	<5	0	0	<5	58
	Grams	4,396	3,621	7,788	3,671	875	0	0	298	20,648
	Grams/Episode	33	45	36	68	49	0	0	99	41
	Grams per 1,000	<1	<1	2	1	<1	0	0	1	<1
ITP in children	Patients	30	17	39	5	24	<5	<5	<5	119
	Grams	1,499	822	1,710	142	1,704	42	51	196	6,165
	Grams/Episode	29	22	26	18	37	11	26	24	28
	Grams per 1,000	<1	<1	<1	<1	1	<1	<1	<1	<1
Kidney transplantation post-transplant	Patients	81	116	56	20	14	7	<5	<5	299
	Grams	11,945	36,470	19,906	4,679	2,333	1,410	330	1,265	78,337
	Grams/Episode	18	33	23	45	19	67	28	38	27
	Grams per 1,000	2	6	4	2	1	3	<1	5	3
Kidney transplantation pre-transplant	Patients	32	15	5	0	5	0	0	0	57
	Grams	2,190	2,797	647	0	961	0	0	0	6,594
	Grams/Episode	30	21	19	0	57	0	0	0	26
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Microscopic polyangiitis	Patients	<5	0	<5	<5	0	0	0	0	<5
	Grams	150	0	816	180	0	0	0	0	1,146
	Grams/Episode	38	0	24	26	0	0	0	0	25
	Grams per 1,000	<1	0	<1	<1	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	Patients	<5	<5	14	0	0	0	0	0	21
	Grams	400	786	2,745	0	0	0	0	0	3,931
	Grams/Episode	20	22	30	0	0	0	0	0	27
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Multiple sclerosis in pregnancy	Patients	<5	0	<5	0	0	0	0	0	<5
	Grams	81	0	444	0	0	0	0	0	525
	Grams/Episode	27	0	32	0	0	0	0	0	31
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies	Patients	9	<5	<5	0	0	0	0	0	16
	Grams	1,748	408	649	0	0	0	0	0	2,805
	Grams/Episode	32	24	34	0	0	0	0	0	31
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Opsoclonus myoclonus ataxia	Patients	5	7	0	0	<5	0	0	0	15
	Grams	1,447	882	0	0	888	0	0	0	3,217
	Grams/Episode	28	13	0	0	31	0	0	0	22
	Grams per 1,000	<1	<1	0	0	<1	0	0	0	<1
Pemphigus foliaceus	Patients	<5	0	<5	0	0	0	0	0	<5
	Grams	2,520	0	1,740	0	0	0	0	0	4,260
	Grams/Episode	41	0	54	0	0	0	0	0	46
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Pemphigus vulgaris	Patients	9	<5	6	<5	<5	0	<5	<5	23
	Grams	9,032	1,455	3,107	150	440	0	2,075	118	16,376
	Grams/Episode	53	77	35	150	88	0	65	24	51
	Grams per 1,000	1	<1	<1	<1	<1	0	5	<1	<1
Post transfusion purpura	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	120	0	0	0	0	0	0	0	120
	Grams/Episode	40	0	0	0	0	0	0	0	40
	Grams per 1,000	<1	0	0	0	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Secondary hypogammaglobulinaemia (excludes haem malignancies)	Patients	214	120	157	35	14	16	<5	<5	546
	Grams	38,382	17,942	35,972	4,867	2,924	5,950	87	361	106,484
	Grams/Episode	27	26	25	18	17	35	22	36	26
	Grams per 1,000	5	3	8	2	2	12	<1	2	5
Specific antibody deficiency	Patients	73	28	49	46	14	<5	12	<5	221
	Grams	16,822	7,208	10,661	10,537	3,228	429	3,175	113	52,173
	Grams/Episode	27	28	22	24	23	33	25	9	25
	Grams per 1,000	2	1	2	4	2	<1	8	<1	2
Toxic epidermal necrolysis/Steven Johnson syndrome	Patients	24	10	5	<5	<5	<5	0	0	47
	Grams	3,249	1,635	430	191	518	447	0	0	6,470
	Grams/Episode	54	74	31	96	58	50	0	0	56
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1
TSS - staphylococcal	Patients	9	30	12	<5	<5	<5	0	<5	60
	Grams	1,272	3,265	1,583	200	579	318	0	85	7,302
	Grams/Episode	67	68	93	200	64	64	0	85	73
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	<1	<1
TSS - streptococcal	Patients	22	36	34	7	9	<5	<5	<5	112
	Grams	2,593	4,782	3,877	657	1,320	120	35	226	13,609
	Grams/Episode	62	70	69	94	55	60	35	75	67
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1
Wegeners granulomatosis	Patients	<5	8	0	0	<5	0	0	0	11
	Grams	342	862	0	0	351	0	0	0	1,555
	Grams/Episode	34	29	0	0	27	0	0	0	29
	Grams per 1,000	<1	<1	0	0	<1	0	0	0	<1
Chapter 6 Total	Patients	709	513	537	149	135	44	27	18	2,101
	Grams	145,615	105,462	120,759	30,705	27,906	11,348	8,884	2,675	453,352
	Grams/Episode	30	33	28	30	31	37	38	34	30
	Grams per 1,000	20	19	26	12	17	22	23	11	20

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
<b>Chapter 7</b>										
Acute leukaemia in children	Patients	0	<5	<5	0	<5	0	0	0	5
	Grams	0	9	24	0	30	0	0	0	63
	Grams/Episode	0	9	12	0	10	0	0	0	11
	Grams per 1,000	0	<1	<1	0	<1	0	0	0	<1
Autoimmune neutropenia	Patients	<5	<5	<5	0	0	0	<5	0	13
	Grams	2,196	294	277	0	0	0	90	0	2,857
	Grams/Episode	46	37	25	0	0	0	45	0	41
	Grams per 1,000	<1	<1	<1	0	0	0	<1	0	<1
Autoimmune uveitis	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	192	0	0	0	0	0	0	0	192
	Grams/Episode	24	0	0	0	0	0	0	0	24
	Grams per 1,000	<1	0	0	0	0	0	0	0	<1
Catastrophic antiphospholipid syndrome	Patients	<5	<5	7	<5	<5	<5	0	<5	17
	Grams	447	568	858	135	370	200	0	106	2,684
	Grams/Episode	30	63	25	27	62	40	0	18	34
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	<1	<1
Coagulation factor inhibitors	Patients	0	<5	<5	0	<5	0	0	0	9
	Grams	0	434	1,255	0	1,470	0	0	0	3,159
	Grams/Episode	0	54	55	0	51	0	0	0	53
	Grams per 1,000	0	<1	<1	0	<1	0	0	0	<1
Devic disease (neuromyelitis optica)	Patients	8	<5	5	<5	<5	0	<5	0	19
	Grams	2,409	342	1,495	375	555	0	210	0	5,385
	Grams/Episode	32	38	30	125	31	0	35	0	33
	Grams per 1,000	<1	<1	<1	<1	<1	0	<1	0	<1
Diabetic Amyotrophy	Patients	<5	5	<5	<5	0	0	0	0	10
	Grams	912	735	610	170	0	0	0	0	2,427
	Grams/Episode	22	39	29	170	0	0	0	0	30
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Epidermolysis bullosa acquisita	Patients	0	0	0	<5	0	<5	0	0	<5
	Grams	0	0	0	936	0	825	0	0	1,761
	Grams/Episode	0	0	0	72	0	75	0	0	73
	Grams per 1,000	0	0	0	<1	0	2	0	0	<1
Epilepsy (rare childhood cases)	Patients	<5	9	11	<5	0	0	<5	0	28
	Grams	1,236	3,054	3,805	141	0	0	45	0	8,281
	Grams/Episode	46	38	39	35	0	0	15	0	39
	Grams per 1,000	<1	<1	<1	<1	0	0	<1	0	<1
Graves ophthalmopathy	Patients	0	0	<5	0	0	0	0	0	<5
	Grams	0	0	500	0	0	0	0	0	500
	Grams/Episode	0	0	50	0	0	0	0	0	50
	Grams per 1,000	0	0	<1	0	0	0	0	0	<1
Haemolytic disease of the newborn	Patients	38	28	14	<5	15	<5	8	0	108
	Grams	2,025	581	3,439	12	53	3	33	0	6,146
	Grams/Episode	27	15	51	3	3	3	2	0	28
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1
Haemolytic transfusion reaction	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	27	0	0	0	0	0	0	0	27
	Grams/Episode	27	0	0	0	0	0	0	0	27
	Grams per 1,000	<1	0	0	0	0	0	0	0	<1
Hashimoto encephalopathy	Patients	<5	<5	<5	<5	<5	0	0	0	8
	Grams	555	200	170	360	513	0	0	0	1,798
	Grams/Episode	33	40	15	60	73	0	0	0	39
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Limbic encephalitis- nonparaneoplastic	Patients	13	20	15	7	<5	<5	<5	<5	61
	Grams	3,101	3,082	3,024	1,009	315	100	70	200	10,900
	Grams/Episode	32	32	31	48	21	20	35	20	32
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Limbic encephalitis- paraneoplastic	Patients	<5	<5	<5	<5	0	0	0	0	9
	Grams	603	225	720	125	0	0	0	0	1,672
	Grams/Episode	27	38	34	125	0	0	0	0	33
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
Myocarditis in children	Patients	11	10	6	<5	0	0	0	<5	31
	Grams	177	486	48	72	0	0	0	12	795
	Grams/Episode	12	23	8	24	0	0	0	12	17
	Grams per 1,000	<1	<1	<1	<1	0	0	0	<1	<1
PANDAS/tic disorders	Patients	<5	<5	<5	0	<5	<5	0	0	6
	Grams	1,850	84	99	0	96	96	0	0	2,225
	Grams/Episode	54	28	99	0	48	48	0	0	53
	Grams per 1,000	<1	<1	<1	0	<1	<1	0	0	<1
Paraneoplastic cerebellar degeneration (Yo antibodies)	Patients	<5	<5	<5	0	0	<5	0	0	11
	Grams	328	550	938	0	0	225	0	0	2,041
	Grams/Episode	30	28	39	0	0	45	0	0	34
	Grams per 1,000	<1	<1	<1	0	0	<1	0	0	<1
Paraneoplastic Subacute Sensory Neuropathy	Patients	0	<5	<5	<5	0	0	0	0	<5
	Grams	0	380	263	150	0	0	0	0	793
	Grams/Episode	0	38	26	150	0	0	0	0	38
	Grams per 1,000	0	<1	<1	<1	0	0	0	0	<1
Paraneoplastic syndromes	Patients	<5	6	<5	<5	<5	0	0	0	17
	Grams	865	1,283	1,440	1,530	411	0	0	0	5,529
	Grams/Episode	26	29	32	128	32	0	0	0	38
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Potassium channel antibody-associated encephalopathy	Patients	23	7	7	<5	<5	<5	0	0	45
	Grams	4,360	4,455	2,022	1,414	842	125	0	0	13,218
	Grams/Episode	27	37	37	109	32	25	0	0	35
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1



Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Pure red cell aplasia	Patients	5	7	10	<5	<5	<5	<5	0	27
	Grams	1,348	1,134	2,420	180	180	1,589	185	0	7,034
	Grams/Episode	34	52	47	36	60	35	93	0	42
	Grams per 1,000	<1	<1	<1	<1	<1	3	<1	0	<1
Pyoderma gangrenosum	Patients	<5	<5	<5	0	<5	0	0	0	10
	Grams	1,552	1,226	540	0	905	0	0	0	4,223
	Grams/Episode	71	44	36	0	82	0	0	0	56
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Rasmussen Syndrome	Patients	<5	<5	5	<5	<5	<5	0	0	11
	Grams	400	1,218	1,167	95	530	33	0	0	3,443
	Grams/Episode	40	68	39	32	44	33	0	0	47
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1
Scleromyxedema	Patients	5	<5	0	0	0	0	<5	0	7
	Grams	4,859	840	0	0	0	0	70	0	5,769
	Grams/Episode	67	21	0	0	0	0	70	0	51
	Grams per 1,000	<1	<1	0	0	0	0	<1	0	<1
Sepsis - neonatal	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	3	0	0	0	0	0	0	3
	Grams/Episode	0	3	0	0	0	0	0	0	3
	Grams per 1,000	0	<1	0	0	0	0	0	0	<1
Sjogren's Syndrome	Patients	<5	<5	<5	<5	<5	0	<5	0	11
	Grams	1,470	118	400	168	744	0	1,518	0	4,418
	Grams/Episode	29	24	31	34	57	0	47	0	37
	Grams per 1,000	<1	<1	<1	<1	<1	0	4	0	<1
Solid organ - heart	Patients	6	6	5	0	0	0	0	0	16
	Grams	925	4,044	516	0	0	0	0	0	5,485
	Grams/Episode	36	156	34	0	0	0	0	0	82
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Solid organ - heart/lung	Patients	<5	<5	<5	<5	0	0	0	0	10
	Grams	642	392	397	100	0	0	0	0	1,531
	Grams/Episode	31	28	26	100	0	0	0	0	30
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
Solid organ - liver	Patients	<5	<5	0	0	<5	0	0	0	6
	Grams	160	204	0	0	245	0	0	0	609
	Grams/Episode	53	16	0	0	20	0	0	0	22
	Grams per 1,000	<1	<1	0	0	<1	0	0	0	<1
Solid organ - lung	Patients	37	19	15	0	<5	<5	0	0	75
	Grams	4,332	1,609	3,113	0	120	629	0	0	9,802
	Grams/Episode	39	30	32	0	30	30	0	0	34
	Grams per 1,000	<1	<1	<1	0	<1	1	0	0	<1
Susac syndrome	Patients	<5	0	<5	0	<5	0	0	0	8
	Grams	1,884	0	2,285	0	125	0	0	0	4,294
	Grams/Episode	47	0	60	0	25	0	0	0	52
	Grams per 1,000	<1	0	<1	0	<1	0	0	0	<1
Systemic Capillary Leak syndrome	Patients	0	0	0	0	0	0	<5	0	<5
	Grams	0	0	0	0	0	0	1,600	0	1,600
	Grams/Episode	0	0	0	0	0	0	133	0	133
	Grams per 1,000	0	0	0	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	319	0	0	319
	Grams/Episode	0	0	0	0	0	40	0	0	40
	Grams per 1,000	0	0	0	0	0	<1	0	0	<1
Chapter 7 Total	Patients	189	153	134	33	42	15	18	<5	583
	Grams	38,851	27,548	31,823	6,972	7,504	4,143	3,821	318	120,979
	Grams/Episode	36	38	37	69	38	38	52	19	38
	Grams per 1,000	5	5	7	3	5	8	10	1	5

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
<b>Chapter 8</b>										
Sepsis (other than neonatal sepsis)	Patients	<5	0	0	0	0	0	0	0	<5
	Grams	0	0	0	0	0	0	0	0	0
	Grams/Episode	0	0	0	0	0	0	0	0	0
	Grams per 1,000	0	0	0	0	0	0	0	0	0
Systemic lupus erythematosus	Patients	0	0	0	<5	0	0	0	0	<5
	Grams	0	0	0	39	0	0	0	0	39
	Grams/Episode	0	0	0	39	0	0	0	0	39
	Grams per 1,000	0	0	0	<1	0	0	0	0	<1
Chapter 8 Total	Patients	<5	0	0	<5	0	0	0	0	<5
	Grams	0	0	0	39	0	0	0	0	39
	Grams/Episode	0	0	0	39	0	0	0	0	39
	Grams per 1,000	0	0	0	<1	0	0	0	0	<1
Total	Patients	4,813	2,982	3,492	704	769	282	248	69	13,102
	Grams	1,241,940	817,461	945,232	225,304	198,268	82,493	72,369	16,757	3,599,822
	Grams/Episode	32	34	30	44	35	35	34	39	33
	Grams per 1,000	169	144	205	91	119	161	191	71	157

# Appendix E – Grams IVlg Issued by State and Territory

		NSW	VIC	QLD	WA	SA	TAS	ACT	NT
<b>2003-04</b>	Imported IVlg		22,200	3,000	144	2,856			
	Domestic IVlg	410,505	318,762	306,639	125,094	110,031	40,353	23,895	6,321
<b>2004-05</b>	Imported IVlg	41,376	13,860	19,992	144	5,922			
	Domestic IVlg	420,858	326,130	284,043	148,200	95,403	46,065	24,615	7,806
<b>2005-06</b>	Imported IVlg	76,368	52,097	134,475	7,765	15,300	13,608	8,165	
	Domestic IVlg	452,565	361,665	219,633	152,127	109,515	33,837	21,774	8,004
<b>2006-07</b>	Imported IVlg	103,270	88,398	79,393	20,577	18,375	11,065	7,170	
	Domestic IVlg	493,172	407,244	337,301	155,821	92,958	50,583	26,470	6,732
<b>2007-08</b>	Imported IVlg	105,633	111,010	85,055	38,445	18,416	11,740	16,875	0
	Domestic IVlg	599,126	423,170	400,144	148,986	108,596	52,755	27,393	6,825
<b>2008-09</b>	Imported IVlg	249,905	131,228	171,367	42,895	27,604	19,965	14,200	
	Domestic IVlg	562,320	417,574	383,865	143,628	128,511	53,745	22,841	10,503
<b>2009-10</b>	Imported IVlg	252,416	101,930	200,264	16,248	31,244	17,110	11,550	
	Domestic IVlg	668,526	507,038	439,089	162,963	143,285	61,686	33,225	8,610
<b>2010-11</b>	Imported IVlg	136,728	93,835	107,798	30,108	27,383	8,843	11,900	80
	Domestic IVlg	887,016	577,260	631,545	167,745	139,296	76,197	45,540	9,099
<b>2011-12</b>	Imported IVlg	265,995	144,284	183,435	59,900	35,775	12,138	14,708	30
	Domestic IVlg	874,995	570,969	674,277	150,294	145,134	73,491	52,446	13,440
<b>2012-13</b>	Imported IVlg	804,375	484,680	589,662	132,108	123,810	64,305	48,480	6,744
	Domestic IVlg	467,370	321,085	361,652	92,914	72,613	16,436	26,648	9,551

## Appendix F – Unique Patients by Quarter and State and Territory

Year	Quarter	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUST
<b>2008-09</b>	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
<b>2009-10</b>	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
<b>2010-11</b>	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
<b>2011-12</b>	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
<b>2012-13</b>	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

# Appendix G – Source for Tables and Figures

Figure 1	Ten year trends in issues of IVIg .....	IDMS
Figure 2	Ten year trends in expenditure on IVIg.....	IDMS
Figure 3	Patients per 1,000 population .....	STARS
Figure 4	Grams of IVIg per 1,000 population by state and territory over time .....	IDMS
Figure 5	Patient age compared to average Australian age.....	STARS
Figure 6	Patient weights relative to Australian average.....	STARS
Figure 7	IVIg expenditure as a proportion of the national blood budget.....	IDMS
Figure 8	IVIg grams issued by diagnostic group.....	STARS
Figure 9	Proportion of IVIg used for top 10 conditions .....	STARS
Figure 10	IVIg issues by clinical discipline .....	STARS
Figure 11	IVIg issues by clinical discipline for top 10 conditions by state and territory.....	STARS
Figure 12	Grams per episode by condition .....	STARS
Table 1	Growth in IVIg issues since 2004.....	IDMS
Table 2	Percentage change in issues over time by state and territory .....	IDMS
Table 3	Annual numbers of patients, treatments and grams.....	STARS & IDMS
Table 4	Basic numbers .....	STARS
Table 5	Issues of domestic IVIg compared with imported IVIg .....	IDMS
Table 6	IVIg issues (g) by <i>Criteria</i> chapter.....	STARS
Table 7	IVIg issues by <i>Criteria</i> chapter (percentage) .....	STARS
Table 8	IVIg grams issued for top 10 diagnostic groups over time.....	STARS
Table 9	Patient numbers and age for the top 20 conditions .....	STARS
Table 10	IVIg grams issued by clinical discipline.....	STARS
Table 11	Grams of IVIg issued by state and territory .....	STARS
Table 12	Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy.....	STARS
Table 13	Patient numbers by state and territory: common variable immunodeficiency disease .....	STARS
Table 14	Patient numbers by state and territory: myasthenia gravis .....	STARS
Table 15	Patient numbers by state and territory: chronic lymphocytic leukaemia .....	STARS
Table 16	Patient numbers by state and territory: multiple myeloma .....	STARS

Table 17 IVIg issued per 1,000 population by state and territory .....IDMS

Table 18 IVIg grams per episode..... STARS

Appendix D – Dataset of IVIg supply by state/territory 2012-13 .....STARS

Appendix E – Grams IVIg Issued by State and Territory .....IDMS

Appendix F – Unique Patients by Quarter and State and Territory .....STARS