nATIONAL REPORT ON THE ISSUE AND USE OF INTRAVENOUS IMMUNOGLOBULIN (IVIg)

Annual Report 2012-13



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# 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

**13,102 patients**

**5,541 new patients**

**Median age 60 years**

**PATIENTS**

**Total cost of $340.5 million**

**35% of total blood budget**

**EXPENDITURE**

**3.62 million grams issued**

**158 grams per 1,000 population**

**37.8% imported product**

**IVIG USE**

# 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[[1]](#footnote-1). 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 20502.

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.

Figure 6 Patient weights relative to Australian average

Figure 6 compares the weight of IVIg recipients in Australia and the Australian population[[2]](#footnote-2). 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[[3]](#footnote-3)). Given that studies suggest that 63% of Australians are overweight or obese[[4]](#footnote-4), 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.[[5]](#footnote-5) 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.

# 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** | Intragam 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 |
| Total | 1,481,996 | 1,656,917 | 1,858,052 | 2,134,945 | 2,386,361 | 2,649,219 | 2,981,170 | 3,272,609 | 3,599,822 |

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[[6]](#footnote-6), 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.

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 decondary 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

|  |  |  |  |
| --- | --- | --- | --- |
| Conditions (Top 20) | IVIg  g (% of total) | Patients  n (% of total) | Median Age |
| 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[[7]](#footnote-7). 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

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 |
| **Total** | 3,622,433 | 100% | 100% | 158 |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Common variable immunodeficiency disease | 2009-10 | 2010-11 | 2011-12 | 2012-13 |
| 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Myasthenia gravis | 2009-10 | 2010-11 | 2011-12 | 2012-13 |
| 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Chronic lymphocytic leukaemia | 2009-10 | 2010-11 | 2011-12 | 2012-13 |
| 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Multiple myeloma | 2009-10 | 2010-11 | 2011-12 | 2012-13 |
| 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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Condition | <=0.4 g/kg/episode  n (%) | 0.4 – 0.99 g/kg/episode  n (%) | 1 – 2 g/kg/episode  n (%) | >2 g/kg/episode  n (%) | No weight Data  n(%) |
| Chronic inflammatory demyelinating polyneuropathy | 7,476 (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%) |

Table 18 IVIg grams per episode

# 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](http://www.blood.gov.au/data-analysis-reporting).

1. 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](http://en.wikipedia.org/wiki/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 |
| --- | --- |
| Blood products | Products manufactured from donated blood |
| Blood Service | The Australian Red Cross Blood Service |
| Clinical Discipline | Classification of the conditions according to the clinical discipline |
| Condition | Specific diagnoses within a diagnostic group. Also known as the primary diagnosis. In some instances the diagnostic group may be the same as the condition, For example – Myasthenia gravis is the condition and Diagnostic Group. |
| *Criteria for the clinical use of intravenous immunoglobulin in Australia (*the *Criteria)* | A document describing the indications for which IVIg is funded under national blood arrangements by all Australian governments |
| Criteria Met | Circumstances, based on evidence and clinical experience, under which the clinical use of IVIg is considered appropriate to be funded in Australia |
| Criteria Not Met or Qualifying (Q) Criteria Not Met | Circumstances, based on evidence and clinical experience, under which the clinical use of IVIg is not considered appropriate to be funded in Australia |
| Direct Orders (DO) | Previously known as Jurisdictional Direct Orders (JDO). Arrangements implemented by the NBA with suppliers to facilitate the purchase of IVIg for the treatment of conditions not satisfying the *Criteria for the clinical use of IVIg in Australia* |
| Diagnostic Group | A grouping of clinical/medical conditions, as outlined in the *Criteria.* Also known as disease group |
| Disease Group | See diagnostic group |
| Fractionation | A manufacturing process that separates blood plasma into components |
| Imprest stock | Health provider orders of product for stock that is maintained at a certain level |
| Intravenous immunoglobulin | A blood product derived from donated human plasma that is administered intravenously |
| Jurisdiction | The parties to the Australian National Blood Agreement, being the Australian Government and all state and territory governments |
| Minimum Product Inventory | The minimum inventory of IVIg held by CSL to meet contract obligations |
| National Blood Agreement | The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the Australian blood sector |
| National blood arrangements | Arrangements, including funding arrangements, established under the National Blood Agreement |
| National CSL Reserve | The reserve of inventory of IVIg that CSL Behring manages on behalf of the NBA for contingency purposes. |
| Normal immunoglobulin | A blood product derived from donated human plasma that is administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection) |
| Plasma | The liquid part of the blood containing antibodies and other proteins |
| Primary diagnosis | See ‘condition’ |
| Subcutaneous immunoglobulin | A blood product derived from donated human plasma that is administered subcutaneously |
| Treatment episode | One instance or episode of a treatment plan, for example a treatment plan may be made up of 4 episodes over 4 months with each episode occurring every 4 weeks. For example; 1 dose of transfused product every two weeks for 6 months would be 13 treatment episodes |

# Appendix C – Clinical Discipline mapping table

| Condition | Chapter | Diagnostic Group | Clinical Discipline |
| --- | --- | --- | --- |
| Chronic lymphocytic leukaemia | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Multiple myeloma | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Non-Hodgkin’s lymphoma | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Other relevant haematological malignancies | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Post-haemopoietic stem cell transplantation (HSCT) | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Chronic inflammatory demyelinating polyneuropathy | Chapter 5 | Chronic inflammatory demyelinating polyneuropathy | Neurology |
| Guillain-Barré syndrome | Chapter 5 | Guillain-Barré syndrome | Neurology |
| Dermatomyositis | Chapter 5 | Inflammatory myopathies | Neurology |
| Inclusion body myositis | Chapter 5 | Inflammatory myopathies | Neurology |
| Polymyositis | Chapter 5 | Inflammatory myopathies | Neurology |
| Idiopathic thrombocytopenic purpura - Adult | Chapter 5 | ITP in adults | Haematology |
| ITP associated with HIV | Chapter 5 | ITP in adults | Haematology |
| ITP in pregnancy | Chapter 5 | ITP in adults | Haematology |
| ITP in Specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | Chapter 5 | ITP in adults | Haematology |
| ITP Refractory | Chapter 5 | ITP in adults | Haematology |
| ITP with life-threatening haemorrhage | Chapter 5 | ITP in adults | Haematology |
| Kawasaki disease | Chapter 5 | Kawasaki disease | Immunology |
| Lambert-Eaton myasthenic syndrome | Chapter 5 | Lambert-Eaton myasthenic syndrome | Neurology |
| Multifocal motor neuropathy | Chapter 5 | Multifocal motor neuropathy | Neurology |
| Multifocal motor neuropathy with persistent conduction block | Chapter 5 | Multifocal motor neuropathy | Neurology |
| Myasthenia gravis | Chapter 5 | Myasthenia gravis | Neurology |
| Neonatal haemochromatosis | Chapter 5 | Neonatal haemochromatosis | Mixed - Haem/Immun |
| Common variable immunodeficiency disease | Chapter 5 | Primary immunodeficiency diseases | Immunology |
| Other Primary Immunodeficiency | Chapter 5 | Primary immunodeficiency diseases | Immunology |
| 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 severe/relapsing/remitting in whom other therapies have failed | Chapter 6 | Multiple sclerosis | Neurology |
| Opsoclonus myoclonus ataxia | Chapter 6 | Opsoclonus myoclonus ataxia | Neurology |
| Bullous pemphigoid | Chapter 6 | Pemphigoid | Immunology |
| Cicatricial pemphigoid | Chapter 6 | Pemphigoid | Immunology |
| Pemphigus foliaceus | Chapter 6 | Pemphigus | Immunology |
| Pemphigus vulgaris | Chapter 6 | Pemphigus | Immunology |
| Post transfusion purpura | Chapter 6 | Post transfusion purpura | Haematology |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | Chapter 6 | Secondary hypogammaglobulinaemia | Mixed |
| IgG subclass deficiency EXISTING patients only | Chapter 6 | Specific antibody deficiency | Immunology |
| Specific antibody deficiency | Chapter 6 | Specific antibody deficiency | Immunology |
| IgG subclass deficiency. Existing patient with suppurative lung disease | Chapter 6 | Specific antibody deficiency | Immunology |
| Toxic epidermal necrolysis/Steven Johnson Syndrome | Chapter 6 | Toxic epidermal necrolysis/Steven Johnson Syndrome | Immunology |
| Toxic Shock Syndrome (TSS) - Staphylococcal | Chapter 6 | Toxic shock syndrome | Immunology |
| Toxic Shock Syndrome (TSS) - Streptococcal | Chapter 6 | Toxic shock syndrome | Immunology |
| Acute leukaemia in children | Chapter 7 | Acute leukaemia in children | Haematology |
| Autoimmune congenital heart block | Chapter 7 | Autoimmune congenital heart block | Immunology |
| Autoimmune diabetic neuropathy | Chapter 7 | Autoimmune diabetic neuropathy | Neurology |
| Autoimmune neutropenia | Chapter 7 | Autoimmune neutropenia | Haematology |
| Autoimmune uveitis | Chapter 7 | Autoimmune uveitis | Immunology |
| Catastrophic antiphospholipid syndrome | Chapter 7 | Catastrophic antiphospholipid syndrome | Immunology |
| Coagulation factor inhibitors | Chapter 7 | Coagulation factor inhibitors | Haematology |
| Devic disease (neuromyelitis optica) | Chapter 7 | Devic disease (neuromyelitis optica) | Neurology |
| Diabetic Amyotrophy | Chapter 7 | Diabetic Amytrophy | Neurology |
| Epidermolysis bullosa acquisita | Chapter 7 | Epidermolysis bullosa acquisita | Dermatology |
| Epilepsy (rare childhood cases) | Chapter 7 | Epilepsy (rare childhood cases) | Neurology |
| Graves ophthalmopathy | Chapter 7 | Graves ophthalmopathy | Immunology |
| Haemolytic disease of the newborn | Chapter 7 | Haemolytic disease of the newborn | Haematology |
| Haemolytic transfusion reaction | Chapter 7 | Haemolytic transfusion reaction | Haematology |
| Hashimoto encephalopathy | Chapter 7 | Hashimoto enecephalopathy | Neurology |
| 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 thrombocytopenia | Chapter 8 | Amegakaryocytic thrombocytopenia | Haematology |
| 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 |
| JDO issue | JDO Chapter | JDO | JDO |
| Acute Idiopathic Dysautomia | NA | Pre 2008 *Criteria* | Neurology |
| Alloimmune Neutropenia In Infancy | NA | Pre 2008 *Criteria* | Haematology |
| Alloimmune Thrombocytopenia Neonatal | NA | Pre 2008 *Criteria* | Haematology |
| Autoimmune Thrombocytopenic | NA | Pre 2008 *Criteria* | Haematology |
| Cutaneous Vasculitis | NA | Pre 2008 *Criteria* | Mixed |
| Hypogammaglobulinaemia | NA | Pre 2008 *Criteria* | Immunology |
| Hypogammaglobulinaemia Unclassified | NA | Pre 2008 *Criteria* | Immunology |
| Immunological Miscellaneous, No diagnosis recorded | NA | Pre 2008 *Criteria* | Immunology |
| Miscellaneous | NA | Pre 2008 *Criteria* | Mixed |
| Myelopathy due to HTLV-1 | NA | Pre 2008 *Criteria* | Immunology |
| Necrotising Myelitis | NA | Pre 2008 *Criteria* | Mixed |
| Other Lymphoproliferative / Hypogammaglobulinaemia | NA | Pre 2008 *Criteria* | Haematology |
| Paediatric Myocarditis | NA | Pre 2008 *Criteria* | Mixed |
| Sensory neuropathy associated with anti-Hu antibodies | NA | Pre 2008 *Criteria* | Neurology |
| Septic thrombocytopenia | NA | Pre 2008 *Criteria* | Haematology |
| Stills Disease - Adults | NA | Pre 2008 *Criteria* | Immunology |
| Trauma - Burns | NA | Pre 2008 *Criteria* | Mixed |

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

| Condition |  | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | National |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Chapter 5 |  |  |  |  |  |  |  |  |  |  |
| 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 Population | 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 Population | 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 Population | 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 Population | 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 Population | 4 | 5 | 5 | 3 | 5 | 2 | 5 | 14 | 5 |
| 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 Population | 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 Population | <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 Population | <1 | <1 | <1 | <1 | <1 | <1 | 1 | 2 | <1 |
| ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 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 Population | 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 Population | 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 Population | 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 Population | <1 | <1 | <1 | <1 | <1 | <1 | <1 | <1 | <1 |
| 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 Population | <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 Population | 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 Population | 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 Population | 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 Population | <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 Population | 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 Population | 0 | <1 | 0 | 0 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | 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 Population | 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 Population | 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 Population | <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 Population | <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 Population | <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 Population | <1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | <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 Population | 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 Population | 144 | 121 | 172 | 76 | 98 | 131 | 157 | 58 | 132 |
| Chapter 6 |  |  |  |  |  |  |  |  |  |  |
| 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 Population | <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 Population | <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 Population | <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 Population | <1 | <1 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | 0 | 0 | 0 | <1 | 0 | <1 | 0 | 0 | <1 |
| Cicatricial 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 Population | <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 Population | <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 Population | <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 Population | <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 Population | <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 Population | <1 | <1 | 2 | 0 | <1 | 0 | 0 | 0 | <1 |
| 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 Population | 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 Population | <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 Population | <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 Population | <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 Population | 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 Population | <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 Population | <1 | 0 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | <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 Population | <1 | 0 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed | 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 Population | <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 Population | <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 Population | <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 Population | 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 Population | <1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | 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 Population | 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 Population | <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 Population | <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 Population | <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 Population | <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 Population | 20 | 19 | 26 | 12 | 17 | 22 | 23 | 11 | 20 |
| Chapter 7 |  |  |  |  |  |  |  |  |  |  |
| 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 Population | 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 Population | <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 Population | <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 Population | <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 Population | 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 Population | <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 Population | <1 | <1 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | 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 Population | <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 Population | 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 Population | <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 Population | <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 Population | <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 Population | <1 | <1 | <1 | <1 | <1 | <1 | <1 | <1 | <1 |
| 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 Population | <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 Population | <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 Population | <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 Population | <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 Population | 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 Population | <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 Population | <1 | <1 | <1 | <1 | <1 | <1 | 0 | 0 | <1 |
| 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 Population | <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 Population | <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 Population | <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 Population | <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 Population | 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 Population | <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 Population | <1 | <1 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| 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 Population | <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 Population | <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 Population | <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 Population | <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 Population | 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 Population | 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 Population | 5 | 5 | 7 | 3 | 5 | 8 | 10 | 1 | 5 |
| Chapter 8 |  |  |  |  |  |  |  |  |  |  |
| 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 Population | 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 Population | 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 Population | 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 Population | 169 | 144 | 205 | 91 | 119 | 161 | 191 | 71 | 157 |

# Appendix E – Grams IVIg Issued by State and Territory

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | NSW | VIC | QLD | WA | SA | TAS | ACT | NT |
| 2003-04 | Imported IVIg |  | 22,200 | 3,000 | 144 | 2,856 |  |  |  |
| Domestic IVIg | 410,505 | 318,762 | 306,639 | 125,094 | 110,031 | 40,353 | 23,895 | 6,321 |
| 2004-05 | Imported IVIg | 41,376 | 13,860 | 19,992 | 144 | 5,922 |  |  |  |
| Domestic IVIg | 420,858 | 326,130 | 284,043 | 148,200 | 95,403 | 46,065 | 24,615 | 7,806 |
| 2005-06 | Imported IVIg | 76,368 | 52,097 | 134,475 | 7,765 | 15,300 | 13,608 | 8,165 |  |
| Domestic IVIg | 452,565 | 361,665 | 219,633 | 152,127 | 109,515 | 33,837 | 21,774 | 8,004 |
| 2006-07 | Imported IVIg | 103,270 | 88,398 | 79,393 | 20,577 | 18,375 | 11,065 | 7,170 |  |
| Domestic IVIg | 493,172 | 407,244 | 337,301 | 155,821 | 92,958 | 50,583 | 26,470 | 6,732 |
| 2007-08 | Imported IVIg | 105,633 | 111,010 | 85,055 | 38,445 | 18,416 | 11,740 | 16,875 | 0 |
| Domestic IVIg | 599,126 | 423,170 | 400,144 | 148,986 | 108,596 | 52,755 | 27,393 | 6,825 |
| 2008-09 | Imported IVIg | 249,905 | 131,228 | 171,367 | 42,895 | 27,604 | 19,965 | 14,200 |  |
| Domestic IVIg | 562,320 | 417,574 | 383,865 | 143,628 | 128,511 | 53,745 | 22,841 | 10,503 |
| 2009-10 | Imported IVIg | 252,416 | 101,930 | 200,264 | 16,248 | 31,244 | 17,110 | 11,550 |  |
| Domestic IVIg | 668,526 | 507,038 | 439,089 | 162,963 | 143,285 | 61,686 | 33,225 | 8,610 |
| 2010-11 | Imported IVIg | 136,728 | 93,835 | 107,798 | 30,108 | 27,383 | 8,843 | 11,900 | 80 |
| Domestic IVIg | 887,016 | 577,260 | 631,545 | 167,745 | 139,296 | 76,197 | 45,540 | 9,099 |
| 2011-12 | Imported IVIg | 265,995 | 144,284 | 183,435 | 59,900 | 35,775 | 12,138 | 14,708 | 30 |
| Domestic IVIg | 874,995 | 570,969 | 674,277 | 150,294 | 145,134 | 73,491 | 52,446 | 13,440 |
| 2012-13 | Imported IVIg | 804,375 | 484,680 | 589,662 | 132,108 | 123,810 | 64,305 | 48,480 | 6,744 |
| Domestic IVIg | 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 |
| 2008-09 | Q1 | 2,216 | 1,296 | 1,448 | 402 | 331 | 145 | 105 | 13 | 5,956 |
| Q2 | 2,255 | 1,327 | 1,466 | 399 | 364 | 151 | 105 | 19 | 6,086 |
| Q3 | 2,261 | 1,313 | 1,470 | 357 | 362 | 170 | 99 | 17 | 6,049 |
| Q4 | 2,383 | 1,356 | 1,544 | 373 | 395 | 177 | 98 | 31 | 6,357 |
| 2009-10 | Q1 | 2,447 | 1,377 | 1,652 | 385 | 400 | 184 | 112 | 24 | 6,581 |
| Q2 | 2,499 | 1,388 | 1,670 | 357 | 440 | 177 | 109 | 20 | 6,660 |
| Q3 | 2,556 | 1,394 | 1,682 | 354 | 395 | 183 | 102 | 15 | 6,681 |
| Q4 | 2,607 | 1,460 | 1,755 | 373 | 413 | 189 | 121 | 22 | 6,940 |
| 2010-11 | Q1 | 2,707 | 1,506 | 1,839 | 376 | 420 | 197 | 144 | 22 | 7,211 |
| Q2 | 2,784 | 1,545 | 1,887 | 395 | 394 | 205 | 132 | 21 | 7,363 |
| Q3 | 2,761 | 1,544 | 1,888 | 379 | 397 | 214 | 130 | 15 | 7,328 |
| Q4 | 2,800 | 1,628 | 1,947 | 385 | 419 | 200 | 142 | 23 | 7,544 |
| 2011-12 | Q1 | 2,933 | 1,665 | 2,047 | 408 | 421 | 199 | 142 | 27 | 7,842 |
| Q2 | 2,976 | 1,631 | 2,115 | 413 | 430 | 206 | 137 | 22 | 7,930 |
| Q3 | 2,956 | 1,594 | 2,150 | 403 | 431 | 203 | 150 | 23 | 7,910 |
| Q4 | 2,961 | 1,633 | 2,215 | 405 | 459 | 202 | 154 | 29 | 8,058 |
| 2012-13 | Q1 | 3,109 | 1,751 | 2,391 | 449 | 450 | 205 | 168 | 32 | 8,497 |
| Q2 | 3,140 | 1,809 | 2,360 | 436 | 463 | 196 | 171 | 26 | 8,559 |
| Q3 | 3,222 | 1,756 | 2,299 | 411 | 458 | 183 | 166 | 33 | 8,487 |
| Q4 | 3,321 | 1,826 | 2,379 | 430 | 466 | 187 | 170 | 36 | 8,763 |

# Appendix G – Source for Tables and Figures

[Figure 1 Ten year trends in issues of IVIg IDMS](#_Toc390098180)

[Figure 2 Ten year trends in expenditure on IVIg IDMS](#_Toc390098181)

[Figure 3 Patients per 1,000 population STARS](#_Toc390098182)

[Figure 4 Grams of IVIg per 1,000 population by state and territory over time IDMS](#_Toc390098183)

[Figure 5 Patient age compared to average Australian age STARS](#_Toc390098184)

[Figure 6 Patient weights relative to Australian average STARS](#_Toc390098185)

[Figure 7 IVIg expenditure as a proportion of the national blood budget IDMS](#_Toc390098186)

[Figure 8 IVIg grams issued by diagnostic group STARS](#_Toc390098187)

[Figure 9 Proportion of IVIg used for top 10 conditions STARS](#_Toc390098188)

[Figure 10 IVIg issues by clinical discipline STARS](#_Toc390098189)

[Figure 11 IVIg issues by clinical discipline for top 10 conditions by state and territory STARS](#_Toc390098190)

[Figure 12 Grams per episode by condition STARS](#_Toc390098191)

[Table 1 Growth in IVIg issues since 2004 IDMS](#_Toc390098315)

[Table 2 Percentage change in issues over time by state and territory IDMS](#_Toc390098316)

[Table 3 Annual numbers of patients, treatments and grams STARS & IDMS](#_Toc390098317)

[Table 4 Basic numbers STARS](#_Toc390098318)

[Table 5 Issues of domestic IVIg compared with imported IVIg IDMS](#_Toc390098319)

[Table 6 IVIg issues (g) by *Criteria* chapter STARS](#_Toc390098320)

[Table 7 IVIg issues by *Criteria* chapter (percentage) STARS](#_Toc390098321)

[Table 8 IVIg grams issued for top 10 diagnostic groups over time STARS](#_Toc390098322)

[Table 9 Patient numbers and age for the top 20 conditions STARS](#_Toc390098323)

[Table 10 IVIg grams issued by clinical discipline STARS](#_Toc390098324)

[Table 11 Grams of IVIg issued by state and territory STARS](#_Toc390098325)

[Table 12 Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy STARS](#_Toc390098326)

[Table 13 Patient numbers by state and territory: common variable immunodeficiency disease STARS](#_Toc390098327)

[Table 14 Patient numbers by state and territory: myasthenia gravis STARS](#_Toc390098328)

[Table 15 Patient numbers by state and territory: chronic lymphocytic leukaemia STARS](#_Toc390098329)

[Table 16 Patient numbers by state and territory: multiple myeloma STARS](#_Toc390098330)

[Table 17 IVIg issued per 1,000 population by state and territory IDMS](#_Toc390098331)

[Table 18 IVIg grams per episode STARS](#_Toc390098332)

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

1. ABS 4102.0 (average of male and female)

   2 World Health Organisation, <http://www.who.int/ageing/en/> (Accessed 26 Feb 2014) [↑](#footnote-ref-1)
2. ABS 4102.0 [↑](#footnote-ref-2)
3. ABS 4102.0 (average of male and female) [↑](#footnote-ref-3)
4. ABS 4364.0.55.001 [↑](#footnote-ref-4)
5. 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. [↑](#footnote-ref-5)
6. 2013, *Lung Transplantation Fact Sheet*, Lung Foundation, Australia. [↑](#footnote-ref-6)
7. Cunningham-Rundles, C 2012, *The many faces of common variable immunodeficiency*, American Society of Hematology, USA. [↑](#footnote-ref-7)