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

Annual Report 2014-15



With the exception of any logos and registered trademarks, and where otherwise noted, all material presented in this document is provided under a [Creative Commons Attribution 3.0 Australia licence](http://creativecommons.org/licenses/by/3.0/au/).

The details of the relevant licence conditions are available on the Creative Commons website (accessible using the links provided) as is the full legal code for the [CC BY 3.0 AU licence.](http://creativecommons.org/licenses/by/3.0/au/legalcode)

The content obtained from this document or derivative of this work must be attributed as the National Blood Authority National Report on the Issue and Use of Immunoglobulin (Ig) Annual Report 2014-15.

ISSN 1839-1079 (online version)

This report is available online at <http://www.blood.gov.au/data-analysis-reporting>

****

Locked Bag 8430

Canberra ACT 2601

Phone: 13 000 BLOOD (13000 25663)

Email: [data@blood.gov.au](mailto:data@blood.gov.au)

[www.blood.gov.au](http://www.blood.gov.au)

Contents

[List of Tables 4](#_Toc456267402)

[List of Figures 4](#_Toc456267403)

[Introduction 5](#_Toc456267404)

[Report Snapshot 6](#_Toc456267405)

[Methodology 7](#_Toc456267406)

[Data quality 8](#_Toc456267407)

[10 Year Trends 9](#_Toc456267408)

[Demand Trends 9](#_Toc456267409)

[Financial Trends 10](#_Toc456267410)

[Demographics 12](#_Toc456267411)

[Patient Numbers 12](#_Toc456267412)

[Geographic Distribution 12](#_Toc456267413)

[Age 14](#_Toc456267414)

[Weight 14](#_Toc456267415)

[Expenditure 16](#_Toc456267416)

[Clinical Indications 18](#_Toc456267417)

[Ig issues by criteria chapter 18](#_Toc456267418)

[Ig issues by diagnostic groups 19](#_Toc456267419)

[Ig issues by condition 21](#_Toc456267420)

[Ig issues by clinical discipline 24](#_Toc456267421)

[Ig grams issued per 1,000 population 25](#_Toc456267422)

[Dosing 30](#_Toc456267423)

[Products and Use 32](#_Toc456267424)

[Appendix A – Background 35](#_Toc456267425)

[Appendix B – Acronyms and Glossary 39](#_Toc456267426)

[Acronyms 39](#_Toc456267427)

[Glossary of terms 40](#_Toc456267428)

[Appendix C – Clinical Discipline mapping table 42](#_Toc456267429)

[Appendix D – Dataset of Ig supply by state/territory 2014-15 48](#_Toc456267430)

[Appendix E – Grams Ig Issued by State and Territory 62](#_Toc456267431)

[Appendix F – Unique Patients by Quarter and State and Territory 63](#_Toc456267432)

[Appendix G – System Source for Tables and Figures 64](#_Toc456267433)

## List of Tables

[Table 1 Growth in Ig grams issued since 2005 9](#_Toc456266144)

[Table 2 Percentage change in grams issued over time by state and territory 10](#_Toc456266145)

[Table 3 Annual numbers of patients, treatment episodes and grams 12](#_Toc456266146)

[Table 4 Basic numbers 12](#_Toc456266147)

[Table 5 Issues of domestic Ig compared with imported Ig 17](#_Toc456266148)

[Table 6 Ig issues (g) by Criteria chapter 18](#_Toc456266149)

[Table 7 Ig issues by Criteria chapter (percentage) 19](#_Toc456266150)

[Table 8 Ig grams issued for top 10 diagnostic groups over time 21](#_Toc456266151)

[Table 9 Patient numbers and age for the top 20 conditions 22](#_Toc456266152)

[Table 10 Ig grams issued by clinical discipline 24](#_Toc456266153)

[Table 11 Grams of Ig issued by state and territory 26](#_Toc456266154)

[Table 12 Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy 26](#_Toc456266155)

[Table 13 Patient numbers by state and territory: common variable immunodeficiency disease 27](#_Toc456266156)

[Table 14 Patient numbers by state and territory: myasthenia gravis 27](#_Toc456266157)

[Table 15 Patient numbers by state and territory: chronic lymphocytic leukaemia 28](#_Toc456266158)

[Table 16 Patient numbers by state and territory: multiple myeloma 28](#_Toc456266159)

[Table 17 Ig issued per 1,000 population by state and territory for top 10 conditions 29](#_Toc456266160)

[Table 18 Ig grams per episode 31](#_Toc456266161)

[Table 19 Patient numbers for products issued by state and territory in 2014-15 32](#_Toc456266162)

[Table 20 Grams of product issued by state and territory in 2014-15 33](#_Toc456266163)

[Table 21 Patient numbers for products issued by diagnostic group in 2014-15 33](#_Toc456266164)

[Table 22 Grams of product issued by diagnostic group in 2014-15 34](#_Toc456266165)

## List of Figures

[Figure 1 Ten year trends in issues of Ig 9](#_Toc456266166)

[Figure 2 Ten year trends in expenditure on Ig 11](#_Toc456266167)

[Figure 3 Patients per 1,000 population 2014-15 13](#_Toc456266168)

[Figure 4 Grams of Ig per 1,000 population by state and territory over time 13](#_Toc456266169)

[Figure 5 Patient age compared to average Australian age 14](#_Toc456266170)

[Figure 6 Patient weights relative to Australian average 15](#_Toc456266171)

[Figure 7 Ig expenditure as a proportion of the national blood budget 16](#_Toc456266172)

[Figure 8 Ig grams issued by diagnostic group 20](#_Toc456266173)

[Figure 9 Proportion of Ig used for top 10 conditions 23](#_Toc456266174)

[Figure 10 Ig issues by clinical discipline 24](#_Toc456266175)

[Figure 11 Ig issues by clinical discipline for top 10 conditions by state and territory 25](#_Toc456266176)

[Figure 12 Grams per episode by condition 30](#_Toc456266177)

# Introduction

Immunoglobulins products analysed in this report include intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg). These are referred to as immunoglobulin (Ig). Ig is a blood product derived from donated human blood. It is used to treat a broad range of conditions, with applications in immunoglobulin replacement and immune modulation therapy. This report provides an analysis of national data on national Ig supply in Australia in 2014-15, also considering trends in supply over the last ten years.

In Australia it is estimated that over 99% of all Ig is supplied under national blood arrangements through contracts administered by the National Blood Authority (NBA). The NBA’s role is to coordinate national supply and demand planning for blood and blood products including supply risk management; purchasing blood and blood products on behalf of all Australian governments; developing and implementing national strategies to encourage better governance, promoting appropriate use of blood and blood products; and providing expert advice to support government policy development. Further background is at **Appendix A.**

The *Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia* (*Criteria*) identifies the conditions and circumstances for which the use of intravenous immunoglobulin (IVIg) is funded under national blood arrangements. The *Criteria* was first published in 2008, and was updated in 2012. It classifies the 93 diagnostic groups described in the *Criteria* into those for which IVIg has an established therapeutic role (Chapter 5), has an emerging therapeutic role (Chapter 6) and those where IVIg has application in exceptional circumstances only (Chapter 7). IVIg is only supplied for these diagnostic groups unless purchased by a single state, hospital or individual (a Direct Order). Chapter 8 of the *Criteria* outlines those conditions for which IVIg should not be supplied, as there is no evidence to support its use in these conditions.

Ig comprises a large proportion of blood expenditure each year. Demand for Ig continues to rise steadily, and Australian per capita use of this product is one of the highest among western countries. Demand for Ig is met through local manufacture of Ig by CSL Behring using plasma collected from voluntary, non-remunerated Australian donors and is supplemented by importation of Ig from overseas manufacturers. Both the domestic and imported Ig are distributed by the Australian Red Cross Blood Service (Blood Service), with the Blood Service also being responsible for collection of data on behalf of governments for product funded under the national blood arrangements.

Australia is in a unique position to provide analysis and commentary on the use of Ig due to national supply arrangements*.* This report begins with an analysis of Ig supply over the last ten years, then considers patient demographics, expenditure on Ig, clinical indications for which Ig was supplied and finally analyses the dose prescribed for various conditions. The top ten diagnostic groups account for 88.1% of all Ig supplied in 2014-15, and for this reason specific analysis focuses on these groups.

# Report Snapshot

**14,983 patients**

**5,823 new patients**

**Median age 61 years**

**PATIENTS**

**Total cost of $484.1 million**

**48% of total blood budget**

**EXPENDITURE**

**4.43 million grams issued**

**188 grams per 1,000 population**

**40% imported product**

**Ig 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 Ig, or is collected following the treatment where product is issued as imprest stock. The data is collected into the Blood Service’s Supply Tracking Analysis Recording System (STARS) database.
2. Data collected by the NBA on the units Ig issued to Australian Health Providers (AHPs) and purchases from suppliers. This data is held in the NBA Integrated Data Management System (IDMS).

Over the seven years between 2008-09 and 2014-15, data has been captured on 42,245 patients. Caveats relating to the quality of this data are outlined below.

This report does not include data on supply of Normal Immunoglobulin (NIg). It includes data on Subcutaneous Immunoglobulin (SCIg) for 2013-15 only as no SCIg product was available in Australia before 2013-14.

The report includes some language that may be unique to the Australian environment. A list of acronyms and definitions used in this report is at **Appendix B.**

The *Criteria* groups together a number of conditions into one diagnostic group. For example, primary immunodeficiency disease is a diagnostic group in the *Criteria,* with this group incorporating the numerous separate conditions. In some cases the analysis will focus on the diagnostic group, while in other areas it will focus on the condition.

Each condition has been classified according to clinical discipline. It is acknowledged that for some conditions this classification is somewhat arbitrary. For example, there are immunological conditions affecting the blood that could potentially be mapped to either immunology or haematology. Where there appeared to be significant overlap between clinical disciplines, the condition was mapped as mixed. In the majority of cases, the condition was mapped to the speciality most likely to be responsible for patients with that condition, noting that this can vary. **Appendix C** provides the mapping of condition to discipline.

The summary of key items from the data file is provided for each condition at the state and territory level. The summary includes patient numbers, grams of Ig used for the condition, grams per treatment episode and grams per 1,000 population (**Appendix D).** The source used for each figure and table is provided at **Appendix G.**

## Data quality

There are some factors relating to data quality, which need to be considered when reading this report, as follows:

* The reconciliation of data held in STARS and IDMS indicates minor variances at a national level. In some cases these differences can be explained by product being ordered and recorded in STARS the month prior to product actually being issued to a patient.
* Not all data fields are completed for all patients. For example, of the total patients recorded since 2008 37,209 patients (88%) had weight data entered, but only 7,184 (17%) had their weight data change in a treatment following the first entry.
* The ABS population series 3201.0 (Population by Age and Sex, Australian States and Territories) ended in June 2010 and was replaced by Australian Demographic Statistics (cat. No 3101.0). Series 3201.0 was utilised as the denominator for population statistics for Ig annual reports before 2011-12.
* Care should be taken when interpreting the data relating to the smaller states and territories as one or two patients can overly influence the use compared to larger states. The five largest Australian states are New South Wales (NSW), Victoria (VIC), Queensland (QLD), South Australia (SA) and Western Australia (WA).
* There has been no adjustment for Ig used in one state or territory for patients residing in a different state or territory.
* A total of 958 (2%) patients received product in more than one state and territory. For example, if a patient relocated from New South Wales to Victoria, they will be counted as a patient in both states. The national patient count only includes one count for each patient. This may result in the sum of the state and territory totals being greater than the national total.
* Patient numbers were first reported in 2008-09. A small number of patients who did not receive product funded under national blood arrangements have been excluded from the total patient count.
* A total of 3,860 (9%) patients had more than one condition over time. In these cases, a patient may be counted more than once in the data in this report, that is, the patient will be counted in the totals for each condition.
* The STARS data has age and weight data recorded at treatment dates (first reported in 2009-10). This data changes over time. Age data is based on the patient’s age at 1 January each year.
* Diagnosis group and conditions captured prior to the implementation of the Criteria were mapped to ensure that they were meaningfully represented, however information from previous years may not be directly comparable from 2008-09 forward. There is a small variance between disciplines by year due to mapping methodology.

# 10 Year Trends

## Demand Trends

In 2014-15 a total of 4,433,146 grams of Ig was issued, representing an increase of 411,284 grams (10.2%) over 2013-14. Since 2005-06 there has been an on average 12.0% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

Figure 1 Ten year trends in issues of Ig

Table Growth in Ig grams issued since 2005

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2005-06 | 2006-07 | 2007-08 | 2008-09 | 2009-10 | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| Growth from previous year | 16% | 14% | 13% | 11% | 12% | 11% | 11% | 11% | 11% | 10% |
| Average Growth from 2005-06 |  | 14% | 15% | 14% | 15% | 15% | 16% | 17% | 18% | 18% |
| Total grams per 1,000 population | 82 | 92 | 102 | 111 | 121 | 133 | 145 | 158 | 172 | 188 |
| Increase in grams per 1,000 population over previous year | 15% | 12% | 11% | 8% | 10% | 10% | 9% | 9% | 9% | 9% |

There has been a steady increase in demand for Ig over the last ten years, with increases of 10-11% per annum for the last five years. While a small proportion of this increase may be attributable to population increases, there has also been a steady increase of 8-10% per annum in the use of Ig per capita (Table 1) since the introduction of the *Criteria* in 2008. A breakdown of the year on year change in grams issued by state and territory has been provided in Table 2. Queensland has been growing at the fastest rate, closely followed by Victoria and New South Wales. Further information about the breakdown of domestic and imported Ig by state over time can be found in **Appendix E**.

Table Percentage change in grams issued over time by state and territory

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | NSW | VIC | QLD | WA | SA | TAS | NT | ACT |
| 2005-06 | 14% | 15% | 15% | 8% | 20% | 3% | 3% | 22% |
| 2006-07 | 13% | 20% | 18% | 10% | -11% | 30% | -16% | 12% |
| 2007-08 | 18% | 8% | 16% | 6% | 14% | 5% | 1% | 29% |
| 2008-09 | 15% | 3% | 14% | 0% | 23% | 14% | 54% | -14% |
| 2009-10 | 13% | 11% | 15% | -4% | 12% | 7% | -18% | 20% |
| 2010-11 | 11% | 10% | 16% | 10% | -4% | 8% | 7% | 28% |
| 2011-12 | 11% | 7% | 16% | 6% | 9% | 1% | 47% | 17% |
| 2012-13 | 11% | 13% | 11% | 7% | 9% | -6% | 21% | 12% |
| 2013-14 | 10% | 11% | 12% | 15% | 6% | 14% | 12% | 1% |
| 2014-15 | 9% | 11% | 12% | 7% | 12% | 8% | 8% | 8% |

## Financial Trends

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

Total expenditure on Ig (excluding plasma for fractionation) in 2014-15 was $273.1 million, an increase of $28.7 million (11.7%) over 2013-14 (Figure 2). The increased expenditure predominately represents increases in demand.

There has also been an increase in the price of plasma for fractionation due to the increased ratio of apheresis to whole blood plasma for fractionation being supplied, resulting in an increase in the cost of domestic Ig. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of $484.1 million (excluding hyperimmune plasma for fractionation).

Figure 2 Ten year trends in expenditure on Ig

# Demographics

## Patient Numbers

A total of 14,983 patients were issued Ig under national blood arrangements during 2014-15 for 140,855 treatment episodes. This represents a 7.2% increase in the number of patients since 2013-14. 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 Annual numbers of patients, treatment episodes and grams

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Patients** | **Treatment Episodes** | **Total Grams Issued** |
| 2008-09 | 9,870 | 77,212 | 2,380,257 |
| 2009-10 | 10,537 | 85,299 | 2,655,184 |
| 2010-11 | 11,492 | 93,893 | 2,950,371 |
| 2011-12 | 12,127 | 101,388 | 3,271,309 |
| 2012-13 | 13,102 | 110,183 | 3,622,433 |
| 2013-14 | 13,981 | 122,791 | 4,021,861 |
| 2014-15 | 14,983 | 140,855 | 4,433,146 |

Table Basic numbers

|  |  |
| --- | --- |
|  | 2014-15 |
| Total unique patient IDs with some weight data | 14,658 |
| Total unique patient IDs with an age recorded | 14,983 |
| Total unique patient IDs with a weight change | 781 |
| Total unique patient IDs with more than one state or territory | 180 |
| Total unique patient IDs with two states or territories | 170 |
| Total unique patient IDs with three or more states or territories | 10 |
| Total unique patient IDs with more than one condition | 377 |
| Total unique patient IDs with two conditions | 367 |
| Total unique patient IDs with three conditions | 9 |
| Total unique patient IDs with four or more conditions | 1 |
| Total unique patient IDs aged 93 or older | 45 |

Note: The above table calculations relate to only 2014-15 patients unlike previous reports where it included multiple years of data

## Geographic Distribution

Nationally, 0.6 patients per 1,000 population received Ig in 2014-15. This varied between states and territories, ranging from 0.3 in Western Australia to 0.8 in Queensland (Figure 3). All states and territories other than the Australian Capital Territory show an increase in the number of patients per 1,000 population over the previous year.

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

Figure 3 Patients per 1,000 population 2014-15

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 72.6 in the Northern Territory to 251.3 in Queensland (**Figure 4**). Rates for the smaller population states and territories must be viewed with some caution as there are many factors that could contribute to their different use patterns, such as patients travelling to larger states for specialist treatment. Comparing only the five largest Australian states, the variation in Ig use is 2.4 fold, ranging from 103.7 grams per 1,000 population in Western Australia to 251.3 grams per 1,000 population in Queensland. The reason for this inter-state and territory variation is unknown. The lower use may represent appropriate management and prescribing practices, or may represent a level of under-diagnosis.

Over time, Western Australia has shown only slight increases in the number of grams issued per 1,000 population, while most states and territories have seen a continued strong increase in Ig issued per 1,000 population.

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

## Age

The distribution of estimated age is shown in Figure 5 where it is compared with the age distribution of the Australian population at June 2013[[1]](#footnote-1). A bimodal peak can be seen in the Ig population, with the majority of recipients either being very young, or over 55. The ageing population is expected to place a greater burden on Ig demand into the future, with the proportion of the world’s population over 60 years expected to double between 2000 and 2050[[2]](#footnote-2).

Figure 5 Patient age compared to average Australian age

## Weight

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

Figure Patient weights relative to Australian average

Note: The above figure calculations relate to only 2014-15 patients unlike previous reports where it included multiple years of data

Figure 6 compares the weight of Ig recipients in Australia and the Australian population[[3]](#footnote-3). There is a higher proportion of patients treated with Ig less than 55kg relative to the proportion in the Australian population. The average weight of adult Ig patients (77.6 kg) is slightly lower than the average weight of an Australian adult (77.7 kg[[4]](#footnote-4)). Given that studies suggest that 63% of Australians are overweight or obese[[5]](#footnote-5), the similarity in weight profiles between Ig recipients and the Australian population suggests that a large proportion of Ig recipients may also be overweight. While the current *Criteria* provides for dosing based on body weight, some limited studies suggest that dosing on lean body weight (ideal body weight) may be more appropriate. A small pilot study in Western Australia focussing on a narrow range of conditions suggested reductions of Ig dose of between 2.4% and 4.2% were achieved using a lean body dosing methodology[[6]](#footnote-6). However, this has not been published in peer review literature, was not a randomised controlled trial, and did not discuss whether there were differences in clinical outcomes between the two groups. With an increasingly obese population, we can expect increases in demand if total (rather than lean) body weight dosing is continued and review of the literature relating to lean body mass dosing should be considered for future iterations of the *Criteria.*

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

# Expenditure

In 2014-15, Australian expenditure on Ig products was $273.1 million, with additional expenditure of $211.0 million on plasma for fractionation (excluding hyperimmune plasma for fractionation) collected by the Blood Service.

The cost of Ig as a proportion of the national blood budget is shown at Figure 7. Ig is the second largest budget item, representing 26% of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, Ig accounts for 47.9% of the total blood budget, at a total expenditure of $498.9 million (including hyperimmune plasma for fractionation).

Figure Ig expenditure as a proportion of the national blood budget

Of the Ig supplied under national blood arrangements in Australia, 60% (2,659,462 grams) was manufactured domestically and 40% (1,773,683 grams) was imported from overseas. This represents a 36.7% increase in product importation since 2013-14 (476,604 grams) (Table 5). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 4.9% in 2014-15 over 2013-14. Intragam P (IVIg) and Evogam (SCIg) are Ig products manufactured domestically in 2014-15. The imported products available were Kiovig (IVIg but can be administered subcutaneously) and Octagam (IVIg) and Gammanorm (SCIg). When a patient is allocated to receive one of the imported products it is the clinician’s choice as to which product they order. Supply of Octagam constituted 62% of the supply of imported Ig.

Table Issues of domestic Ig compared with imported Ig

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NSW** | | | | | **NSW** | | **VIC** | | **QLD** | | **WA** | | **SA** | | **TAS** | | **ACT** | | **NT** | | **AUS** |
| **Domestic Ig** | Intragam P | g | | | 919,806 | | 573,195 | | 724,434 | | 150,903 | | 130,551 | | 57,453 | | 59,178 | | 4,863 | | 2,620,383 |
| $(m) | | | $58 | | $36 | | $46 | | $10 | | $8 | | $4 | | $4 | | $0 | | $166 |
| Evogam | g | | | 10,606 | | 6,365 | | 11,224 | | 5,074 | | 5,244 | | 534 | | 32 | | 0 | | 39,079 |
| $(m) | | | $1 | | $0 | | $1 | | $0 | | $0 | | $0 | | $0 | | $0 | | $2 |
| **Total Domestic** | g | | | 930,412 | | 579,560 | | 735,658 | | 155,977 | | 135,795 | | 57,987 | | 59,210 | | 4,863 | | 2,659,462 |
| $(m) | | | $59 | | $37 | | $47 | | $10 | | $9 | | $4 | | $4 | | $0 | | $168 |
| **Imported Ig** | Kiovig | g | | | 164,798 | | 144,581 | | 162,867 | | 40,370 | | 103,877 | | 3,920 | | 22,770 | | 12,671 | | 655,853 |
| $(m) | | | $10 | | $9 | | $10 | | $2 | | $6 | | $0 | | $1 | | $1 | | $39 |
| Octagam | g | | | 415,970 | | 272,222 | | 292,752 | | 70,229 | | 75 | | 37,139 | | 6,384 | | 190 | | 1,094,958 |
| $(m) | | | $25 | | $16 | | $17 | | $4 | | $0 | | $2 | | $0 | | $0 | | $65 |
| Gammanorm | g | | | 12,278 | | 66 | | 2,571 | | 972 | | 3,391 | | 549 | | 3,046 | | 0 | | 22,872 |
| $(m) | | | $1 | | $0 | | $0 | | $0 | | $0 | | $0 | | $0 | | $0 | | $1 |
| **Total Imported** | g | | | 593,045 | | 416,868 | | 458,189 | | 111,570 | | 107,343 | | 41,608 | | 32,199 | | 12,861 | | 1,773,683 |
| $(m) | | | $35 | | $25 | | $27 | | $7 | | $6 | | $2 | | $2 | | $1 | | $105 |
| **Proportion of domestic to imported Ig** | | | g % | 61% | | 58% | | 62% | | 58% | | 56% | | 58% | | 65% | | 27% | | 60% | |
| $(m) % | 63% | | 60% | | 63% | | 60% | | 58% | | 60% | | 66% | | 29% | | 62% | |

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

# Clinical Indications

## Ig issues by criteria chapter

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

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

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

Table Ig issues (g) by Criteria chapter

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

Table Ig issues by Criteria chapter (percentage)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2008-09 | 2009-10 | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| Chapter 5 | 83% | 84% | 84% | 83% | 84% | 85% | 85% |
| Chapter 6 | 14% | 14% | 13% | 14% | 13% | 11% | 11% |
| Chapter 7 | 2% | 2% | 3% | 3% | 3% | 4% | 4% |
| Chapter 8 | <1% | <1% | <1% | <1% | <1% | 0% | 0% |

For conditions where Ig is used only in exceptional circumstances (Chapter 7), four diagnostic groups accounted for 57.5% of those issues. These conditions were Limbic Encephalitis – nonparaneoplastic (36,076g), Solid organ transplant – lung (16,311g), Pyoderma gangrenosum (13,256g) and Sjogren’s Syndrome (9,761g). While use in these conditions represents a small proportion of total Ig use, closer examination may be warranted. For example, approximately 140 lung transplants are performed in Australia every year[[7]](#footnote-7), and 94 patients received Ig for this indication, meaning that more than half of these patients received Ig.

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

While Ig may be issued in life threatening situations prior to diagnosis or in situations where the diagnosis is unclear at the time of treatment, in 2014-15 there were no cases where Ig was supplied for a condition not in the *Criteria* (excluding Direct Orders where alignment with the *Criteria* is not required as it is not funded under the national blood arrangements). However, data to support compliance with all aspects of qualifying criteria for each condition is not always collected.

## Ig issues by diagnostic groups

The top ten diagnostic groups account for 88.1% of all Ig supplied, with the top three diagnostic groups accounting for 57.7%.

Acquired hypogammaglobulinaemia secondary to haematological malignancies is the diagnostic group for which the greatest percentage of Ig was issued in 2014-15 (22.0%), closely followed by chronic inflammatory demyelinating polyneuropathy (21.9%). Primary immunodeficiency diseases accounted for 13.8% of total Ig use (Figure 8, Table 8).

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

Secondary hypogammaglobulinaemia falls into the top ten diagnostic groups, in spite of being a condition where the evidence for use is emerging (Chapter 6). Further iterations of the *Criteria* will need to consider whether the recent literature supports continued issues for this diagnostic group. The increase in issues of secondary hypogammaglobulinaemia is largely in New South Wales, where there has been a 361% increase between 2008-09 and 2014-15, associated with a concurrent increase in patient numbers (increase of 153%). The grams issued per patient has increased by 82%. However there has been a large increase in grams per 1,000 population from 1.5 to 6.6. Other states and territories have not had changes as large as New South Wales.

Figure 8 Ig grams issued by diagnostic group

Table Ig grams issued for top 10 diagnostic groups over time

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| Acquired hypogammaglobulinaemia secondary to haematological malignancies | 631,689 | 694,640 | 771,071 | 862,898 | 982,773 |
| Chronic inflammatory demyelinating polyneuropathy | 599,181 | 677,458 | 758,271 | 857,533 | 974,258 |
| Primary immunodeficiency diseases | 465,424 | 477,461 | 509,364 | 558,617 | 614,781 |
| Myasthenia gravis | 189,771 | 231,064 | 257,966 | 313,940 | 348,336 |
| Multifocal motor neuropathy | 175,176 | 192,109 | 209,791 | 239,314 | 256,041 |
| Inflammatory myopathies | 139,195 | 153,931 | 188,362 | 230,473 | 249,229 |
| ITP in adults | 163,905 | 162,098 | 178,738 | 186,640 | 187,621 |
| Secondary hypogammaglobulinaemia | 79,151 | 95,183 | 106,484 | 110,024 | 126,561 |
| Guillain-Barre syndrome | 101,014 | 95,359 | 104,360 | 108,929 | 105,567 |
| Kidney transplantation | 63,480 | 71,922 | 84,931 | 97,070 | 90,031 |

## Ig issues by condition

Table 9 provides an overview of the conditions that use the most Ig, including data on total Ig use, patient numbers and median birth year. These conditions account for 88.4% of all Ig supplied, with the top ten conditions accounting for 75.0%. This data is also replicated in Figure 9 for the top 10 conditions.

Table 9 Patient numbers and age for the top 20 conditions

|  |  |  |  |
| --- | --- | --- | --- |
| Conditions (Top 20) | Ig  g (% of total) | Patients  n (% of total) | Median Age |
| Chronic inflammatory demyelinating polyneuropathy | 974,258 (22%) | 2,054 (14%) | 64 |
| Common variable immunodeficiency disease | 537,584 (12%) | 1,656 (11%) | 54 |
| Myasthenia gravis | 348,336 (8%) | 818 (5%) | 63 |
| Chronic lymphocytic leukaemia | 315,205 (7%) | 1,283 (9%) | 72 |
| Non-Hodgkins lymphoma | 287,900 (6%) | 1,208 (8%) | 68 |
| Multifocal motor neuropathy | 256,041 (6%) | 444 (3%) | 57 |
| Multiple myeloma | 255,962 (6%) | 1,100 (7%) | 71 |
| Polymyositis | 135,102 (3%) | 341 (2%) | 64 |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | 126,561 (3%) | 580 (4%) | 60 |
| Guillain-Barré syndrome | 105,567 (2%) | 628 (4%) | 55 |
| Kidney transplantation post-transplant | 83,131 (2%) | 335 (2%) | 50 |
| Other relevant haematological malignancies | 80,969 (2%) | 428 (3%) | 64 |
| ITP refractory | 74,228 (2%) | 468 (3%) | 64 |
| Specific antibody deficiency | 63,646 (1%) | 252 (2%) | 57 |
| ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 58,430 (1%) | 372 (2%) | 59 |
| Dermatomyositis | 57,451 (1%) | 161 (1%) | 57 |
| Inclusion body myositis | 56,676 (1%) | 140 (1%) | 70 |
| HSCT - post | 42,738 (1%) | 307 (2%) | 52 |
| ITP with life-threatening haemorrhage | 42,394 (1%) | 297 (2%) | 66 |
| X linked agammaglobulinaemia | 36,945 (1%) | 113 (1%) | 24 |

Figure Proportion of Ig used for top 10 conditions

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

Ig was supplied for 1,656 patients with common variable immunodeficiency disease. The estimated prevalence of common variable immunodeficiency disease as measured by patients treated with Ig for this indication is 6.6 per 100,000 population (ranging from 1.2 to 17.0 per 100,000 population across Australian states and territories and 4.7 to 10.5 if ACT, NT, TAS and WA are excluded).

For common variable immunodeficiency disease, this estimate is higher than other studies suggest with estimates between 2 and 4 people per 100,000 population[[8]](#footnote-8). The ability to calculate accurate prevalence estimates is important for health service planning. It should be noted that the prevalence estimate is for diagnosed and treated patients only, and studies suggest that for common variable immunodeficiency disease there is likely to be a large population of undiagnosed patients who would benefit from treatment with Ig.

## Ig issues by clinical discipline

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

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

Figure 10 Ig issues by clinical discipline

Table Ig grams issued by clinical discipline

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| Neurology | 1,283,190 | 1,460,702 | 1,649,358 | 1,916,792 | 2,120,111 |
| Haematology | 900,826 | 961,366 | 1,026,219 | 1,116,037 | 1,234,816 |
| Immunology | 631,076 | 656,179 | 695,298 | 746,828 | 828,735 |
| Other | 166,079 | 194,363 | 228,947 | 241,386 | 274,664 |

There is significant variation across Australia in Ig use for each clinical discipline. Figure 11 shows that in Western Australia issues for neurological conditions represent a greater proportion of total issues than for other states. The proportional use for immunological conditions is much lower in Queensland and Tasmania than other states, with use of Ig for haematological conditions prevailing in these two states. The reason for this inter-state and territory variation is unknown, but it may represent differences in clinician practice, different patient populations or may indicate differences due to availability of specialist services across Australia.

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

## Ig grams issued per 1,000 population

The amount of Ig issued per 1,000 population for each indication varies between state and territory. Complete data for conditions for each state and territory can be found at Appendix D and is summarised in for the conditions using the most Ig. Table 11 shows a breakdown of the proportion of Ig issued in each state and territory with a comparison to the proportion of the population in each state and territory.

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

Table Grams of Ig issued by state and territory

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2013-14 | Ig issued (g) | Proportion of total Ig issued | Proportion of Australian population | Grams per 1,000 population |
| NSW | 1,523,456 | 34% | 32.0% | 201 |
| VIC | 996,428 | 22% | 24.9% | 169 |
| QLD | 1,193,847 | 27% | 20.1% | 251 |
| WA | 267,548 | 6% | 10.9% | 104 |
| SA | 243,138 | 5% | 7.2% | 144 |
| TAS | 99,595 | 2% | 2.2% | 193 |
| ACT | 91,409 | 2% | 1.6% | 236 |
| NT | 17,724 | 0% | 1.0% | 73 |
| **Total** | **4,433,146** | **100%** | **100%** | **188** |

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Chronic inflammatory demyelinating polyneuropathy | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| NSW | 539 | 598 | 652 | 704 | 772 |
| VIC | 339 | 372 | 421 | 447 | 464 |
| QLD | 312 | 386 | 485 | 529 | 580 |
| WA | 90 | 99 | 105 | 108 | 123 |
| SA | 70 | 73 | 80 | 81 | 81 |
| TAS | 33 | 30 | 33 | 37 | 32 |
| ACT | 14 | 17 | 22 | 28 | 27 |
| NT | <5 | 5 | 7 | 4 | 8 |
| **Australia** | **1,372** | **1,551** | **1,753** | **1,903** | **2,054** |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Common variable immunodeficiency disease | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| NSW | 562 | 617 | 650 | 721 | 793 |
| VIC | 225 | 232 | 241 | 265 | 276 |
| QLD | 251 | 276 | 311 | 317 | 338 |
| WA | 58 | 61 | 67 | 78 | 88 |
| SA | 107 | 102 | 101 | 110 | 110 |
| TAS | 18 | 20 | 21 | 25 | 25 |
| ACT | 50 | 54 | 58 | 60 | 66 |
| NT | 5 | 5 | <5 | <5 | <5 |
| **Australia** | **1,247** | **1,323** | **1,406** | **1,543** | **1,656** |

Table Patient numbers by state and territory: myasthenia gravis

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Myasthenia gravis | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| NSW | 179 | 219 | 235 | 267 | 297 |
| VIC | 122 | 141 | 177 | 186 | 199 |
| QLD | 142 | 181 | 199 | 212 | 245 |
| WA | 40 | 36 | 39 | 51 | 41 |
| SA | 24 | 19 | 17 | 14 | 17 |
| TAS | 15 | 17 | 10 | 10 | 11 |
| ACT | 5 | 10 | 13 | 14 | 16 |
| NT |  |  |  |  |  |
| **Australia** | **521** | **609** | **671** | **747** | **818** |

Table Patient numbers by state and territory: chronic lymphocytic leukaemia

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Chronic lymphocytic leukaemia | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| NSW | 368 | 381 | 394 | 431 | 483 |
| VIC | 233 | 230 | 225 | 271 | 290 |
| QLD | 265 | 283 | 297 | 292 | 318 |
| WA | 35 | 48 | 41 | 45 | 64 |
| SA | 85 | 79 | 79 | 86 | 77 |
| TAS | 32 | 31 | 31 | 34 | 34 |
| ACT | 21 | 25 | 29 | 30 | 31 |
| NT | <5 | 5 | 5 | 6 | 9 |
| **Australia** | **1,024** | **1,060** | **1,078** | **1,179** | **1,283** |

Table Patient numbers by state and territory: multiple myeloma

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Multiple myeloma | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 |
| NSW | 304 | 324 | 378 | 389 | 425 |
| VIC | 161 | 153 | 157 | 176 | 215 |
| QLD | 307 | 330 | 346 | 360 | 365 |
| WA | 16 | 15 | 16 | 20 | 23 |
| SA | 16 | 17 | 22 | 24 | 25 |
| TAS | 58 | 51 | 47 | 42 | 39 |
| ACT | 21 | 14 | 10 | 10 | 14 |
| NT | <5 | <5 | <5 | <5 |  |
| **Australia** | **878** | **901** | **969** | **1,012** | **1,100** |

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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Condition | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | National | Fold Variation\* |
| Chronic inflammatory demyelinating polyneuropathy | 44 | 39 | 52 | 37 | 24 | 38 | 23 | 11 | 41 | 2 |
| Common variable immunodeficiency disease | 33 | 15 | 23 | 11 | 20 | 14 | 56 | 1 | 23 | 3 |
| Myasthenia gravis | 16 | 12 | 16 | 4 | 12 | 16 | 20 | 5 | 13 | 4 |
| Chronic lymphocytic leukaemia | 15 | 16 | 21 | 8 | 3 | 8 | 19 | 0 | 15 | 6 |
| Non-Hodgkins lymphoma | 10 | 10 | 26 | 2 | 8 | 16 | 13 | 0 | 12 | 11 |
| Multifocal motor neuropathy | 12 | 9 | 9 | 11 | 16 | 9 | 16 | 27 | 11 | 2 |
| Multiple myeloma | 12 | 8 | 21 | 1 | 3 | 25 | 8 | 0 | 11 | 16 |
| Polymyositis | 7 | 4 | 9 | 1 | 6 | 2 | 3 | 0 | 6 | 8 |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | 7 | 3 | 9 | 2 | 2 | 11 | 2 | 1 | 5 | 6 |
| Guillain-Barré syndrome | 4 | 5 | 5 | 3 | 3 | 4 | 4 | 5 | 4 | 2 |

\*The Fold Variation in Table 17is a measure describing difference in the Ig grams per 1,000 population between the state being issued the least to the state being issued the most, using only data from the five largest states. For example, a low value of 30 and a high value of 60 correspond to a fold variation of 2, or in common terms, a two-fold increase.

# Dosing

Figure 12 Grams per episode by condition

The data shows that there is significant variance in the dosing of the top 10 conditions; where dosing is calculated as number of grams administered in each episode (Figure 12). The definition of episode in the data is not uniform and therefore this data should be interpreted with caution. Variations are expected as the doses and frequency of dose varies as the underlying method for calculating the dose also varies. Also note that the *Criteria* requires the lowest possible dose to achieve the desired clinical outcome, so the ‘dose’ is not ‘mandated’ but rather suggested and guided to the lower end to achieve efficacy which may contribute to the differences in dosing between conditions. The dosing is stable compared to the 2013-14 year.

Dosing in the neurological conditions is higher than for other conditions, as provided for in the *Criteria.* For dosing information for other conditions refer to **Appendix D.**

The grams per kilogram were calculated for each infusion episode (Table 18). From this data it is difficult to assess whether the dosing strategy utilised was in accordance with that provided for under the *Criteria.* This is particularly difficult as the patient weight data is not updated for every episode and may change over time.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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 | 8,198 (38%) | 11,791 (55%) | 906 (4%) | 20 (0%) | 501 (2%) |
| Common variable immunodeficiency disease | 8,352 (46%) | 8,178 (45%) | 64 (0%) | 1 (0%) | 1,697 (9%) |
| Myasthenia gravis | 3,394 (42%) | 4,312 (53%) | 235 (3%) | 5 (0%) | 120 (1%) |
| Chronic lymphocytic leukaemia | 6,272 (58%) | 4,312 (40%) | 8 (0%) | 0 (0%) | 253 (2%) |
| Non-Hodgkin lymphoma | 6,406 (63%) | 3,580 (35%) | 6 (0%) | 0 (0%) | 182 (2%) |
| Multiple myeloma | 5,600 (62%) | 3,219 (36%) | 2 (0%) | 0 (0%) | 150 (2%) |
| Multifocal motor neuropathy | 1,341 (28%) | 2,837 (59%) | 452 (9%) | 3 (0%) | 138 (3%) |
| Polymyositis | 1,195 (38%) | 1,749 (56%) | 150 (5%) | 2 (0%) | 38 (1%) |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | 2,699 (57%) | 1,842 (39%) | 68 (1%) | 5 (0%) | 99 (2%) |
| Guillain-Barré syndrome | 356 (44%) | 370 (46%) | 74 (9%) | 13 (2%) | 0 (0%) |

Table 18 Ig grams per episode

# Products and Use

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. The first phase of implementation was through hospital-based management arrangements, with no additional cost to patients, and further work will be undertaken to support supply of SCIg for other pathways of care. In 2013-14 the NBA established arrangements for supply of the following SCIg products:

* Evogam 16% vial size 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (Australia) Pty Ltd (domestic)
* Gammanorm 16% 1650mg/10ml and 3300mg/20ml supplied by Octapharma Australia Pty Ltd (imported)
* Kiovig 10% 1g/10ml, 2.5g/25ml, 5gm/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (imported)

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

The following tables show the patient numbers, grams issued by states and territories or by condition for IVIg and SCIg products in 2014-15.

Table Patient numbers for products issued by state and territory in 2014-15

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | **SCIg** | | | |  |
| **State** | **Intragam P** | **Kiovig 10%** | **Octagam 5%** | **Octagam 10%** | **Evogam** | **Gammanorm** | **Kiovig 10%** | **Total** |
| NSW | 3,730 | 527 | 758 | 544 | 49 | 60 |  | 5,480 |
| VIC | 2,002 | 461 | 717 | 346 | 44 | <5 |  | 3,447 |
| QLD | 2,334 | 555 | 510 | 607 | 37 | 15 | <5 | <3,905 |
| WA | 550 | 130 | 116 | 61 | 32 | 6 |  | 844 |
| SA | 512 | 319 | <5 |  | 27 | 9 |  | <845 |
| TAS | 182 | 13 | 11 | 136 | <5 | 5 |  | <340 |
| ACT | 210 | 46 | 6 | 8 | <5 | 9 |  | <280 |
| NT | 40 | 39 |  | <5 |  |  |  | <80 |
| **AUS** | **9,422** | **2,071** | **<2,210** | **<1,695** | **<190** | **<105** | **<5** | **<15,010** |

Table Grams of product issued by state and territory in 2014-15

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | **SCIg** | | | |
| **State** | **Intragam P** | **Kiovig 10%** | **Octagam 5%** | **Octagam 10%** | **Evogam** | **Gammanorm** | **Kiovig 10%** | **Total** |
| NSW | 940,329 | 168,172 | 265,945 | 158,492 | 10,598 | 11,788 | 0 | 1,555,324 |
| VIC | 569,970 | 145,379 | 194,366 | 81,424 | 6,491 | 66 | 0 | 997,695 |
| QLD | 716,892 | 161,495 | 151,785 | 137,498 | 10,220 | 2,162 | 180 | 1,180,232 |
| WA | 153,162 | 40,767 | 54,349 | 16,634 | 4,973 | 1,011 | 0 | 270,895 |
| SA | 132,627 | 104,153 | 75 | 0 | 5,398 | 3,493 | 0 | 245,746 |
| TAS | 58,425 | 3,909 | 3,675 | 33,812 | 282 | 574 | 0 | 100,676 |
| ACT | 58,212 | 22,453 | 1,475 | 5,050 | 51 | 2,686 | 0 | 89,927 |
| NT | 4,905 | 12,786 | 0 | 139 | 0 | 0 | 0 | 17,830 |
| **AUS** | **2,634,522** | **659,113** | **671,669** | **433,049** | **38,014** | **21,780** | **180** | **4,458,326** |

Table Patient numbers for products issued by diagnostic group in 2014-15

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | **SCIg** | | | |
| **Diagnostic Group** | **Intragam P** | **Kiovig 10%** | **Octagam 5%** | **Octagam 10%** | **Evogam** | **Gammanorm** | **Kiovig 10%** | **Total** |
| Acquired hypogammaglobulinaemia secondary to haematological malignancies | 3,625 | 282 | 220 | 243 | 12 | 12 |  | 4,307 |
| Chronic inflammatory demyelinating polyneuropathy | 895 | 456 | 529 | 308 |  |  |  | 2,056 |
| Primary immunodeficiency diseases | 1,715 | 53 | 34 | 31 | 146 | 73 | <5 | <1,935 |
| Myasthenia gravis | 234 | 193 | 262 | 166 |  |  |  | 818 |
| Multifocal motor neuropathy | 170 | 125 | 125 | 46 |  |  |  | 444 |
| Inflammatory myopathies | 284 | 145 | 141 | 84 |  |  |  | 638 |
| ITP in adults | 466 | 285 | 217 | 230 |  |  |  | 1,150 |
| Secondary hypogammaglobulinaemia | 468 | 39 | 35 | 35 | 11 | <5 |  | <585 |
| Guillain-Barré syndrome | 143 | 169 | 178 | 149 |  |  |  | 628 |
| Kidney transplantation | 77 | 58 | 117 | 148 |  |  |  | 384 |
| Specific antibody deficiency | 264 | 10 | 14 | 5 | 16 | 13 |  | 309 |

Table Grams of product issued by diagnostic group in 2014-15

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | **SCIg** | | | |
| **Diagnostic Group** | **Intragam P** | **Kiovig 10%** | **Octagam 5%** | **Octagam 10%** | **Evogam** | **Gammanorm** | **Kiovig 10%** | **Total** |
| Acquired hypogammaglobulinaemia secondary to haematological malignancies | 857,700 | 50,759 | 34,282 | 36,189 | 2,158 | 1,686 |  | 982,773 |
| Chronic inflammatory demyelinating polyneuropathy | 441,324 | 185,068 | 235,047 | 112,819 |  |  |  | 974,258 |
| Primary immunodeficiency diseases | 533,871 | 14,490 | 8,903 | 8,812 | 31,909 | 16,617 | 180 | 614,781 |
| Myasthenia gravis | 102,399 | 79,827 | 105,593 | 60,517 |  |  |  | 348,336 |
| Multifocal motor neuropathy | 91,581 | 74,888 | 67,131 | 22,441 |  |  |  | 256,041 |
| Inflammatory myopathies | 113,055 | 59,362 | 51,366 | 25,446 |  |  |  | 249,229 |
| ITP in adults | 68,289 | 48,402 | 34,740 | 36,190 |  |  |  | 187,621 |
| Secondary hypogammaglobulinaemia | 102,942 | 8,040 | 8,346 | 4,537 | 1,261 | 1,436 |  | 126,561 |
| Guillain-Barré syndrome | 19,281 | 28,287 | 31,309 | 26,690 |  |  |  | 105,567 |
| Kidney transplantation | 15,372 | 11,671 | 28,840 | 34,149 |  |  |  | 90,031 |
| Specific antibody deficiency | 73,248 | 1,662 | 2,720 | 1,025 | 2,686 | 2,041 |  | 83,381 |

# Appendix A – Background

**Funding for Ig**

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

**The Criteria**

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

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

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

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

**Supply of Product**

Immunoglobulin is made from donated human plasma. Australia has not been able to make enough Ig from Australian blood donations for a number of years. While NBA makes sure there is enough Ig by importing this product, there is a finite international supply.

There are two main ways Ig is available in Australia:

1. Supply under national blood arrangements

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

Orders for Ig under national blood arrangements are made to the Blood Service, which is contracted by the NBA as the authoriser and distributor of all Ig funded under these arrangements. In seeking authorisation, the requesting clinician will be asked to provide information to the Blood Service to establish that the request meets the *Criteria*. For ongoing conditions, the *Criteria* may specify review criteria to be applied in reviewing the patient to determine whether access to funded Ig will continue.

In the role as authoriser of requests for Ig, the Blood Service maintains a database of requests, and provides data to the NBA which is used as a basis for reporting on the [annual use of Ig in Australia](http://www.blood.gov.au/data-analysis-reporting).

1. Direct order and other supply arrangements

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

**History**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In 2013-14 the NBA established arrangements for supply of the following SCIg products:

* Evogam 16% vial size 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (Australia) Pty Ltd (domestic)
* Gammanorm 16% 1650mg/10ml and 3300mg/20ml supplied by Octapharma Australia Pty Ltd (imported)
* Kiovig 10% 1g/10ml, 2.5g/25ml, 5gm/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (imported)

# 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) |
| AUS | Australia |
| DO  HIV | Direct Order  Human immunodeficiency virus |
| HSCT | Hematopoietic stem cell transplantation |
| IDMS | Integrated Data Management System |
| Ig | Immunoglobulin products including IVIg and SCIg |
| ITP | Idiopathic thrombocytopenic purpura |
| IVIg | Intravenous immunoglobulin |
| JBC  JDO  NBA | Jurisdictional Blood Committee  Jurisdictional Direct Order  National Blood Authority |
| NIg | Normal immunoglobulin |
| NSW | New South Wales |
| NT | Northern Territory |
| PANDAS | Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections |
| QLD | Queensland |
| SA | South Australia |
| SCIg | Subcutaneous Immunoglobulin |
| SCoH  STARS | Standing Council of Health  Supply Tracking Analysis Recording System |
| TAS | Tasmania |
| TGA | Therapeutic Goods Administration |
| TSS | Toxic shock syndrome |
| VIC | Victoria |
| WA | Western Australia |

## Glossary of terms

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

# Appendix C – Clinical Discipline mapping table

| Condition | Chapter | Diagnostic Group | Clinical Discipline |
| --- | --- | --- | --- |
| Chronic lymphocytic leukaemia | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Multiple myeloma | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Non-Hodgkin’s lymphoma | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Other relevant haematological malignancies | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Post-haemopoietic stem cell transplantation (HSCT) | Chapter 5 | Acquired hypogammaglobulinaemia secondary to haematological malignancies | Haematology |
| Chronic inflammatory demyelinating polyneuropathy | Chapter 5 | Chronic inflammatory demyelinating polyneuropathy | Neurology |
| Guillain-Barré syndrome | Chapter 5 | Guillain-Barré syndrome | Neurology |
| Dermatomyositis | Chapter 5 | Inflammatory myopathies | Neurology |
| Inclusion body myositis | Chapter 5 | Inflammatory myopathies | Neurology |
| Polymyositis | Chapter 5 | Inflammatory myopathies | Neurology |
| Idiopathic thrombocytopenic purpura - Adult | Chapter 5 | ITP in adults | Haematology |
| ITP associated with HIV | Chapter 5 | ITP in adults | Haematology |
| ITP in pregnancy | Chapter 5 | ITP in adults | Haematology |
| ITP in Specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | Chapter 5 | ITP in adults | Haematology |
| ITP Refractory | Chapter 5 | ITP in adults | Haematology |
| ITP with life-threatening haemorrhage | Chapter 5 | ITP in adults | Haematology |
| Kawasaki disease | Chapter 5 | Kawasaki disease | Immunology |
| Lambert-Eaton myasthenic syndrome | Chapter 5 | Lambert-Eaton myasthenic syndrome | Neurology |
| Multifocal motor neuropathy | Chapter 5 | Multifocal motor neuropathy | Neurology |
| Multifocal motor neuropathy with persistent conduction block | Chapter 5 | Multifocal motor neuropathy | Neurology |
| Myasthenia gravis | Chapter 5 | Myasthenia gravis | Neurology |
| Neonatal haemochromatosis | Chapter 5 | Neonatal haemochromatosis | Mixed - Haem/Immun |
| Common variable immunodeficiency disease | Chapter 5 | Primary immunodeficiency diseases | Immunology |
| Other Primary 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 Ig supply by state/territory 2014-15

| Condition |  | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | National |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Chapter 5 |  |  |  |  |  |  |  |  |  |  |
| Chronic inflammatory demyelinating polyneuropathy | Patients | 772 | 464 | 580 | 123 | 81 | 32 | 27 | 8 | 2,054 |
| Grams | 330,311 | 229,623 | 247,123 | 96,161 | 39,999 | 19,387 | 8,866 | 2,790 | 974,258 |
| Grams/Episode | 38 | 38 | 34 | 59 | 45 | 39 | 33 | 50 | 38 |
| Grams per 1,000 Population | 44 | 39 | 52 | 37 | 24 | 38 | 23 | 11 | 41 |
| Chronic lymphocytic leukaemia | Patients | 483 | 290 | 318 | 64 | 77 | 34 | 31 | 9 | 1,283 |
| Grams | 118,762 | 70,932 | 76,671 | 10,616 | 20,659 | 8,452 | 7,791 | 1,324 | 315,205 |
| Grams/Episode | 30 | 28 | 26 | 26 | 31 | 30 | 31 | 33 | 28 |
| Grams per 1,000 Population | 16 | 12 | 16 | 4 | 12 | 16 | 20 | 5 | 13 |
| Common variable immunodeficiency disease | Patients | 793 | 276 | 338 | 88 | 110 | 25 | 66 | <5 | 1,656 |
| Grams | 246,707 | 89,346 | 110,887 | 27,399 | 34,270 | 7,052 | 21,588 | 336 | 537,584 |
| Grams/Episode | 22 | 25 | 24 | 18 | 21 | 26 | 19 | 24 | 23 |
| Grams per 1,000 Population | 33 | 15 | 23 | 11 | 20 | 14 | 56 | 1 | 23 |
| Dermatomyositis | Patients | 66 | 39 | 28 | 11 | 10 | <5 | 6 | 0 | 161 |
| Grams | 21,564 | 11,075 | 12,448 | 4,225 | 2,745 | 1,959 | 3,435 | 0 | 57,451 |
| Grams/Episode | 35 | 37 | 41 | 43 | 27 | 65 | 61 | 0 | 38 |
| Grams per 1,000 Population | 3 | 2 | 3 | 2 | 2 | 4 | 9 | 0 | 2 |
| Guillain-Barré syndrome | Patients | 193 | 163 | 154 | 50 | 35 | 14 | 11 | 9 | 628 |
| Grams | 33,094 | 29,377 | 25,209 | 7,424 | 5,266 | 2,260 | 1,677 | 1,262 | 105,567 |
| Grams/Episode | 31 | 35 | 31 | 37 | 34 | 38 | 32 | 35 | 33 |
| Grams per 1,000 Population | 4 | 5 | 5 | 3 | 3 | 4 | 4 | 5 | 4 |
| HSCT - post | Patients | 173 | 62 | 53 | 9 | 5 | 6 | 0 | <5 | 307 |
| Grams | 19,977 | 9,265 | 9,954 | 578 | 1,107 | 1,596 | 0 | 261 | 42,738 |
| Grams/Episode | 27 | 28 | 29 | 19 | 41 | 30 | 0 | 29 | 28 |
| Grams per 1,000 Population | 3 | 2 | 2 | <1 | <1 | 3 | 0 | 1 | 2 |
| Inclusion body myositis | Patients | 49 | 40 | 26 | <5 | 19 | <5 | <5 | <5 | 140 |
| Grams | 16,270 | 18,024 | 12,690 | 227 | 7,616 | 1,242 | 252 | 357 | 56,676 |
| Grams/Episode | 34 | 38 | 34 | 38 | 44 | 31 | 36 | 119 | 36 |
| Grams per 1,000 Population | 2 | 3 | 3 | <1 | 5 | 2 | <1 | 1 | 2 |
| ITP in pregnancy | Patients | 21 | 24 | 28 | 6 | 7 | <5 | 0 | <5 | 89 |
| Grams | 2,490 | 2,496 | 5,214 | 640 | 1,089 | 546 | 0 | 60 | 12,534 |
| Grams/Episode | 46 | 66 | 31 | 64 | 84 | 68 | 0 | 60 | 43 |
| Grams per 1,000 Population | <1 | <1 | 1 | <1 | <1 | 1 | 0 | <1 | <1 |
| ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | Patients | 91 | 92 | 122 | 28 | 29 | 9 | 0 | <5 | 373 |
| Grams | 14,422 | 10,775 | 24,626 | 3,341 | 3,946 | 1,081 | 0 | 275 | 58,465 |
| Grams/Episode | 44 | 55 | 34 | 56 | 60 | 77 | 0 | 92 | 42 |
| Grams per 1,000 | 2 | 2 | 5 | 1 | 2 | 2 | 0 | 1 | 2 |
| ITP refractory | Patients | 50 | 163 | 143 | 36 | 59 | 14 | 0 | <5 | 468 |
| Grams | 12,468 | 24,718 | 20,532 | 3,909 | 10,827 | 1,458 | 0 | 318 | 74,228 |
| Grams/Episode | 40 | 58 | 33 | 69 | 50 | 73 | 0 | 80 | 45 |
| Grams per 1,000 Population | 2 | 4 | 4 | 2 | 6 | 3 | 0 | 1 | 3 |
| ITP with life-threatening haemorrhage | Patients | 200 | 36 | 24 | 11 | 16 | <5 | 6 | <5 | 297 |
| Grams | 29,551 | 3,481 | 4,094 | 1,264 | 2,559 | 417 | 869 | 160 | 42,394 |
| Grams/Episode | 43 | 51 | 39 | 63 | 64 | 52 | 72 | 80 | 45 |
| Grams per 1,000 Population | 4 | <1 | <1 | <1 | 2 | <1 | 2 | <1 | 2 |
| Kawasaki disease | Patients | 108 | 116 | 58 | 29 | 17 | 12 | 5 | 5 | 350 |
| Grams | 4,737 | 4,964 | 2,436 | 1,023 | 834 | 630 | 264 | 222 | 15,110 |
| Grams/Episode | 35 | 31 | 34 | 31 | 44 | 42 | 44 | 32 | 34 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 1 | <1 | <1 | <1 |
| Lambert-Eaton myasthenic syndrome | Patients | 5 | <5 | 13 | <5 | 0 | 0 | <5 | 0 | 24 |
| Grams | 2,054 | 2,087 | 6,262 | 845 | 0 | 0 | 290 | 0 | 11,538 |
| Grams/Episode | 33 | 43 | 34 | 44 | 0 | 0 | 22 | 0 | 35 |
| Grams per 1,000 Population | <1 | <1 | 1 | <1 | 0 | 0 | <1 | 0 | <1 |
| Multifocal motor neuropathy | Patients | 179 | 84 | 90 | 32 | 35 | 12 | 10 | 6 | 444 |
| Grams | 92,731 | 50,260 | 41,519 | 27,479 | 26,615 | 4,643 | 6,222 | 6,573 | 256,041 |
| Grams/Episode | 43 | 43 | 35 | 66 | 57 | 31 | 51 | 58 | 44 |
| Grams per 1,000 Population | 12 | 9 | 9 | 11 | 16 | 9 | 16 | 27 | 11 |
| Multiple myeloma | Patients | 425 | 215 | 365 | 23 | 25 | 39 | 14 | 0 | 1,100 |
| Grams | 89,334 | 44,289 | 97,480 | 3,417 | 5,325 | 13,040 | 3,078 | 0 | 255,962 |
| Grams/Episode | 30 | 29 | 26 | 28 | 33 | 31 | 28 | 0 | 28 |
| Grams per 1,000 Population | 12 | 8 | 21 | 1 | 3 | 25 | 8 | 0 | 11 |
| Myasthenia gravis | Patients | 297 | 199 | 245 | 41 | 17 | 11 | 16 | 0 | 818 |
| Grams | 115,692 | 92,293 | 101,497 | 21,105 | 5,891 | 4,367 | 7,491 | 0 | 348,336 |
| Grams/Episode | 36 | 37 | 33 | 48 | 36 | 30 | 42 | 0 | 36 |
| Grams per 1,000 Population | 15 | 16 | 21 | 8 | 3 | 8 | 19 | 0 | 15 |
| Neonatal haemochromatosis | Patients | <5 | <5 | 7 | <5 | 0 | 0 | <5 | 0 | 15 |
| Grams | 1,569 | 6,213 | 3,810 | 1,080 | 0 | 0 | 3 | 0 | 12,675 |
| Grams/Episode | 65 | 70 | 59 | 83 | 0 | 0 | 3 | 0 | 66 |
| Grams per 1,000 Population | <1 | 1 | <1 | <1 | 0 | 0 | <1 | 0 | <1 |
| Non-Hodgkins lymphoma | Patients | 345 | 247 | 488 | 31 | 64 | 30 | 18 | <5 | 1,208 |
| Grams | 73,136 | 56,685 | 124,770 | 6,010 | 14,079 | 8,177 | 4,973 | 69 | 287,900 |
| Grams/Episode | 29 | 30 | 25 | 26 | 30 | 27 | 31 | 35 | 27 |
| Grams per 1,000 Population | 10 | 10 | 26 | 2 | 8 | 16 | 13 | <1 | 12 |
| Other Lymphoproliferative / Hypogammaglobulinaemia | Patients | 0 | <5 | 0 | 0 | 0 | 0 | 0 | 0 | <5 |
| Grams | 0 | 189 | 0 | 0 | 0 | 0 | 0 | 0 | 189 |
| 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 | 54 | 39 | 12 | 7 | 12 | <5 | <5 | 6 | 130 |
| Grams | 13,269 | 10,469 | 1,977 | 2,073 | 1,402 | 318 | 141 | 1,497 | 31,146 |
| Grams/Episode | 17 | 20 | 16 | 27 | 6 | 6 | 12 | 25 | 16 |
| Grams per 1,000 Population | 2 | 2 | <1 | <1 | <1 | <1 | <1 | 6 | 1 |
| Other relevant haematological malignancies | Patients | 149 | 70 | 113 | 40 | 48 | 7 | <5 | <5 | 428 |
| Grams | 30,674 | 15,972 | 21,316 | 4,468 | 5,680 | 1,488 | 1,245 | 126 | 80,969 |
| Grams/Episode | 29 | 29 | 25 | 19 | 27 | 26 | 29 | 18 | 27 |
| Grams per 1,000 Population | 4 | 3 | 4 | 2 | 3 | 3 | 3 | <1 | 3 |
| Polymyositis | Patients | 154 | 50 | 97 | 9 | 27 | 7 | <5 | 0 | 341 |
| Grams | 52,597 | 26,355 | 40,559 | 2,611 | 10,432 | 1,197 | 1,352 | 0 | 135,102 |
| Grams/Episode | 34 | 47 | 37 | 40 | 46 | 36 | 52 | 0 | 38 |
| Grams per 1,000 Population | 7 | 4 | 9 | 1 | 6 | 2 | 3 | 0 | 6 |
| Severe combined Immunodeficiency | Patients | 11 | 8 | 14 | <5 | <5 | 0 | 0 | <5 | 36 |
| Grams | 1,378 | 2,334 | 3,804 | 120 | 47 | 0 | 0 | 3 | 7,686 |
| Grams/Episode | 12 | 15 | 26 | 40 | 2 | 0 | 0 | 3 | 17 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 0 | 0 | <1 | <1 |
| Stiff person syndrome | Patients | 20 | 11 | 14 | 0 | 0 | <5 | 0 | <5 | 46 |
| Grams | 11,768 | 5,312 | 9,352 | 0 | 0 | 918 | 0 | 150 | 27,500 |
| Grams/Episode | 48 | 44 | 41 | 0 | 0 | 54 | 0 | 30 | 45 |
| Grams per 1,000 Population | 2 | <1 | 2 | 0 | 0 | 2 | 0 | <1 | 1 |
| Wiskott-Aldrich syndrome | Patients | 0 | <5 | <5 | <5 | 0 | 0 | 0 | 0 | 6 |
| Grams | 0 | 580 | 432 | 408 | 0 | 0 | 0 | 0 | 1,420 |
| Grams/Episode | 0 | 19 | 36 | 24 | 0 | 0 | 0 | 0 | 24 |
| Grams per 1,000 Population | 0 | <1 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| X linked agammaglobulinaemia | Patients | 32 | 52 | 16 | 5 | 6 | 0 | <5 | <5 | 113 |
| Grams | 10,543 | 16,538 | 5,154 | 1,698 | 2,154 | 0 | 257 | 600 | 36,945 |
| Grams/Episode | 24 | 21 | 26 | 13 | 30 | 0 | 5 | 24 | 22 |
| Grams per 1,000 Population | 1 | 3 | 1 | <1 | 1 | 0 | <1 | 2 | 2 |
| Chapter 5 Total | Patients | 4,589 | 2,707 | 3275 | 638 | 677 | 263 | 220 | 61 | 12,268 |
| Grams | 1,345,094 | 833,649 | 1,009,814 | 228,118 | 202,538 | 80,227 | 69,793 | 16,383 | 3,785,615 |
| Grams/Episode | 31 | 34 | 29 | 39 | 33 | 32 | 28 | 42 | 32 |
| Grams per 1,000 Population | 178 | 142 | 213 | 88 | 120 | 156 | 180 | 67 | 160 |
| Chapter 6 |  |  |  |  |  |  |  |  |  |  |
| Acute disseminated encephalomyelitis | Patients | 22 | 10 | 12 | <5 | 0 | 0 | <5 | <5 | 50 |
| Grams | 3,416 | 2,108 | 2,883 | 410 | 0 | 0 | 395 | 36 | 9,248 |
| Grams/Episode | 31 | 38 | 42 | 46 | 0 | 0 | 26 | 9 | 35 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 0 | 0 | 1 | <1 | <1 |
| ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis | Patients | <5 | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 10 |
| Grams | 512 | 0 | 885 | 0 | 0 | 0 | 0 | 0 | 1,397 |
| Grams/Episode | 34 | 0 | 37 | 0 | 0 | 0 | 0 | 0 | 36 |
| Grams per 1,000 Population | <1 | 0 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Autoimmune haemolytic anaemia | Patients | 24 | 23 | 35 | 9 | 16 | 6 | <5 | 0 | 115 |
| Grams | 4,580 | 1,952 | 7,536 | 1,427 | 3,762 | 1,008 | 24 | 0 | 20,288 |
| Grams/Episode | 47 | 46 | 42 | 49 | 68 | 67 | 8 | 0 | 48 |
| Grams per 1,000 Population | <1 | <1 | 2 | <1 | 2 | 2 | <1 | 0 | <1 |
| Bullous pemphigoid | Patients | 14 | <5 | 5 | <5 | 0 | 0 | 0 | <5 | 26 |
| Grams | 7,860 | 1,290 | 2,193 | 420 | 0 | 0 | 0 | 198 | 11,961 |
| Grams/Episode | 59 | 76 | 35 | 30 | 0 | 0 | 0 | 66 | 52 |
| Grams per 1,000 Population | 1 | <1 | <1 | <1 | 0 | 0 | 0 | <1 | <1 |
| Churg-Strauss syndrome | Patients | <5 | 0 | 0 | 0 | 0 | <5 | 0 | 0 | <5 |
| Grams | 150 | 0 | 0 | 0 | 0 | 342 | 0 | 0 | 492 |
| Grams/Episode | 30 | 0 | 0 | 0 | 0 | 114 | 0 | 0 | 62 |
| Grams per 1,000 Population | <1 | 0 | 0 | 0 | 0 | <1 | 0 | 0 | <1 |
| Cicatricial pemphigoid | Patients | <5 | 5 | 6 | <5 | <5 | 0 | <5 | 0 | 18 |
| Grams | 4,500 | 5,486 | 4,160 | 270 | 1,890 | 0 | 4,315 | 0 | 20,621 |
| Grams/Episode | 83 | 69 | 50 | 135 | 57 | 0 | 117 | 0 | 71 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 1 | 0 | 11 | 0 | <1 |
| Evans syndrome | Patients | <5 | <5 | <5 | 0 | 0 | 0 | 0 | 0 | 6 |
| Grams | 197 | 310 | 259 | 0 | 0 | 0 | 0 | 0 | 766 |
| Grams/Episode | 22 | 78 | 37 | 0 | 0 | 0 | 0 | 0 | 38 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal) | Patients | <5 | <5 | <5 | <5 | <5 | <5 | 0 | 0 | 16 |
| Grams | 2,427 | 1,743 | 4,056 | 1,197 | 4,320 | 78 | 0 | 0 | 13,821 |
| Grams/Episode | 62 | 70 | 97 | 67 | 105 | 39 | 0 | 0 | 83 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 3 | <1 | 0 | 0 | <1 |
| Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal) | Patients | 7 | 8 | <5 | <5 | 0 | <5 | 0 | 0 | 22 |
| Grams | 30 | 33 | 12 | 6 | 0 | 12 | 0 | 0 | 93 |
| Grams/Episode | 3 | 3 | 3 | 3 | 0 | 4 | 0 | 0 | 3 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 0 | <1 | 0 | 0 | <1 |
| Haemophagocytic syndrome | Patients | 21 | 16 | 5 | <5 | <5 | <5 | <5 | 0 | 48 |
| Grams | 2,788 | 2,679 | 657 | 183 | 225 | 200 | 27 | 0 | 6,758 |
| Grams/Episode | 53 | 52 | 31 | 46 | 56 | 200 | 9 | 0 | 49 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | <1 | <1 | 0 | <1 |
| IgG subclass deficiency EXISTING patients only | Patients | <5 | 24 | <5 | <5 | 5 | 5 | 0 | 0 | 36 |
| Grams | 36 | 7,998 | 42 | 870 | 1,524 | 1,548 | 0 | 0 | 12,018 |
| Grams/Episode | 36 | 28 | 21 | 23 | 29 | 25 | 0 | 0 | 27 |
| Grams per 1,000 Population | <1 | 1 | <1 | <1 | <1 | 3 | 0 | 0 | <1 |
| IgG subclass deficiency. Exisitng patient with suppurative lung disease | Patients | 21 | 0 | <5 | 0 | 0 | 0 | 0 | 0 | 23 |
| Grams | 7,609 | 0 | 108 | 0 | 0 | 0 | 0 | 0 | 7,717 |
| Grams/Episode | 29 | 0 | 27 | 0 | 0 | 0 | 0 | 0 | 29 |
| Grams per 1,000 Population | 1 | 0 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| IgM para-proteinaemic neuropathy | Patients | 27 | 12 | 30 | <5 | 5 | 0 | 0 | 0 | 77 |
| Grams | 9,522 | 3,473 | 11,697 | 2,970 | 1,249 | 0 | 0 | 0 | 28,911 |
| Grams/Episode | 36 | 41 | 34 | 68 | 46 | 0 | 0 | 0 | 38 |
| Grams per 1,000 Population | 1 | <1 | 2 | 1 | <1 | 0 | 0 | 0 | 1 |
| ITP in children | Patients | 24 | 22 | 48 | 10 | 24 | 0 | <5 | <5 | 133 |
| Grams | 1,871 | 761 | 1,587 | 426 | 1,176 | 0 | 93 | 205 | 6,119 |
| Grams/Episode | 32 | 20 | 24 | 22 | 24 | 0 | 47 | 51 | 26 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 0 | <1 | <1 | <1 |
| Kidney transplantation post-transplant | Patients | 66 | 172 | 57 | 16 | 11 | 10 | <5 | <5 | 335 |
| Grams | 9,483 | 48,496 | 16,973 | 2,788 | 1,621 | 3,555 | 195 | 20 | 83,131 |
| Grams/Episode | 23 | 32 | 22 | 50 | 19 | 55 | 14 | 10 | 29 |
| Grams per 1,000 Population | 1 | 8 | 4 | 1 | <1 | 7 | <1 | <1 | 4 |
| Kidney transplantation pre-transplant | Patients | 24 | 28 | <5 | 0 | <5 | 0 | 0 | 0 | 58 |
| Grams | 2,160 | 3,398 | 1,238 | 0 | 105 | 0 | 0 | 0 | 6,901 |
| Grams/Episode | 30 | 17 | 34 | 0 | 35 | 0 | 0 | 0 | 22 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | <1 | 0 | 0 | 0 | <1 |
| Microscopic polyangiitis | Patients | 0 | 0 | <5 | <5 | 0 | 0 | 0 | 0 | <5 |
| Grams | 0 | 0 | 192 | 570 | 0 | 0 | 0 | 0 | 762 |
| Grams/Episode | 0 | 0 | 24 | 34 | 0 | 0 | 0 | 0 | 30 |
| Grams per 1,000 Population | 0 | 0 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| Multiple sclerosis - severe relapse with no response to high dose methylprednisolone | Patients | 9 | <5 | 8 | 0 | 0 | 0 | 0 | 0 | 20 |
| Grams | 1,797 | 784 | 1,990 | 0 | 0 | 0 | 0 | 0 | 4,571 |
| Grams/Episode | 27 | 25 | 26 | 0 | 0 | 0 | 0 | 0 | 26 |
| 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 | 732 | 0 | 318 | 0 | 0 | 0 | 0 | 0 | 1,050 |
| Grams/Episode | 27 | 0 | 23 | 0 | 0 | 0 | 0 | 0 | 26 |
| 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 | 14 | <5 | 7 | 0 | 0 | 0 | 0 | 0 | 22 |
| Grams | 4,399 | 156 | 1,110 | 0 | 0 | 0 | 0 | 0 | 5,665 |
| Grams/Episode | 33 | 78 | 29 | 0 | 0 | 0 | 0 | 0 | 33 |
| Grams per 1,000 | <1 | <1 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Opsoclonus myoclonus ataxia | Patients | 13 | 9 | <5 | <5 | <5 | 0 | 0 | 0 | 26 |
| Grams | 2,721 | 1,311 | 100 | 261 | 1,533 | 0 | 0 | 0 | 5,925 |
| Grams/Episode | 28 | 16 | 20 | 13 | 44 | 0 | 0 | 0 | 25 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 0 | 0 | 0 | <1 |
| Pemphigus foliaceus | Patients | <5 | 0 | <5 | 0 | 0 | 0 | 0 | 0 | <5 |
| Grams | 2,458 | 0 | 418 | 0 | 0 | 0 | 0 | 0 | 2,876 |
| Grams/Episode | 42 | 0 | 28 | 0 | 0 | 0 | 0 | 0 | 39 |
| Grams per 1,000 Population | <1 | 0 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Pemphigus vulgaris | Patients | 17 | 7 | 5 | <5 | <5 | 0 | <5 | 0 | 33 |
| Grams | 11,205 | 2,909 | 3,069 | 1,440 | 1,450 | 0 | 1,980 | 0 | 22,052 |
| Grams/Episode | 51 | 69 | 40 | 120 | 145 | 0 | 180 | 0 | 59 |
| Grams per 1,000 Population | 1 | <1 | <1 | <1 | <1 | 0 | 5 | 0 | <1 |
| Post transfusion purpura | Patients | <5 | <5 | 0 | 0 | 0 | 0 | 0 | 0 | <5 |
| Grams | 55 | 240 | 0 | 0 | 0 | 0 | 0 | 0 | 295 |
| Grams/Episode | 28 | 80 | 0 | 0 | 0 | 0 | 0 | 0 | 59 |
| Grams per 1,000 Population | <1 | <1 | 0 | 0 | 0 | 0 | 0 | 0 | <1 |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | Patients | 240 | 103 | 183 | 27 | 14 | 16 | 8 | <5 | 580 |
| Grams | 49,941 | 18,561 | 44,542 | 3,904 | 3,066 | 5,656 | 681 | 211 | 126,561 |
| Grams/Episode | 26 | 26 | 24 | 15 | 10 | 33 | 18 | 42 | 24 |
| Grams per 1,000 Population | 7 | 3 | 9 | 2 | 2 | 11 | 2 | <1 | 5 |
| Specific antibody deficiency | Patients | 94 | 33 | 57 | 46 | 21 | <5 | <5 | <5 | 252 |
| Grams | 22,260 | 8,553 | 14,168 | 11,065 | 5,387 | 746 | 1,359 | 109 | 63,646 |
| Grams/Episode | 19 | 23 | 25 | 18 | 15 | 26 | 26 | 9 | 20 |
| Grams per 1,000 Population | 3 | 1 | 3 | 4 | 3 | 1 | 4 | <1 | 3 |
| Toxic epidermal necrolysis/Steven Johnson syndrome | Patients | 16 | 20 | <5 | <5 | <5 | <5 | <5 | 0 | 50 |
| Grams | 2,137 | 3,421 | 718 | 449 | 390 | 790 | 237 | 0 | 8,142 |
| Grams/Episode | 55 | 73 | 60 | 75 | 65 | 113 | 79 | 0 | 68 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 2 | <1 | 0 | <1 |
| TSS - staphylococcal | Patients | 10 | 26 | <5 | 6 | <5 | <5 | <5 | 0 | 53 |
| Grams | 1,508 | 4,142 | 509 | 795 | 57 | 395 | 464 | 0 | 7,869 |
| Grams/Episode | 94 | 109 | 64 | 61 | 29 | 56 | 116 | 0 | 89 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | <1 | 1 | 0 | <1 |
| TSS - streptococcal | Patients | 28 | 32 | 12 | 12 | 9 | 6 | <5 | 0 | 103 |
| Grams | 4,402 | 4,281 | 1,151 | 1,645 | 1,095 | 890 | 563 | 0 | 14,027 |
| Grams/Episode | 94 | 73 | 58 | 72 | 64 | 74 | 94 | 0 | 76 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 2 | 1 | 0 | <1 |
| Wegeners granulomatosis | Patients | <5 | <5 | <5 | 0 | <5 | 0 | 0 | 0 | <5 |
| Grams | 135 | 312 | 12 | 0 | 351 | 0 | 0 | 0 | 810 |
| Grams/Episode | 27 | 24 | 12 | 0 | 27 | 0 | 0 | 0 | 25 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | <1 | 0 | 0 | 0 | <1 |
| Chapter 6 Total | Patients | 698 | 555 | 501 | 150 | 123 | 57 | 34 | 10 | 2,103 |
| Grams | 160,886 | 124,394 | 122,582 | 31,094 | 29,201 | 15,220 | 10,333 | 779 | 494,489 |
| Grams/Episode | 30 | 32 | 28 | 26 | 27 | 41 | 55 | 26 | 30 |
| Grams per 1,000 Population | 21 | 21 | 26 | 12 | 17 | 30 | 27 | 3 | 21 |
| Chapter 7 |  |  |  |  |  |  |  |  |  |  |
| Acute leukaemia in children | Patients | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| Grams | 0 | 291 | 0 | 0 | 0 | 0 | 0 | 0 | 291 |
| Grams/Episode | 0 | 24 | 0 | 0 | 0 | 0 | 0 | 0 | 24 |
| Grams per 1,000 Population | 0 | <1 | 0 | 0 | 0 | 0 | 0 | 0 | <1 |
| Autoimmune neutropenia | Patients | 5 | <5 | 5 | 0 | 0 | 0 | 0 | 0 | 12 |
| Grams | 2,103 | 155 | 685 | 0 | 0 | 0 | 0 | 0 | 2,943 |
| Grams/Episode | 57 | 52 | 34 | 0 | 0 | 0 | 0 | 0 | 49 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Autoimmune uveitis | Patients | <5 | <5 | 0 | 0 | <5 | 0 | 0 | 0 | <5 |
| Grams | 475 | 135 | 0 | 0 | 143 | 0 | 0 | 0 | 753 |
| Grams/Episode | 48 | 45 | 0 | 0 | 48 | 0 | 0 | 0 | 47 |
| Grams per 1,000 Population | <1 | <1 | 0 | 0 | <1 | 0 | 0 | 0 | <1 |
| Catastrophic antiphospholipid syndrome | Patients | 5 | <5 | 11 | <5 | 0 | 0 | 0 | 0 | 19 |
| Grams | 813 | 288 | 1,944 | 171 | 0 | 0 | 0 | 0 | 3,216 |
| Grams/Episode | 68 | 96 | 29 | 29 | 0 | 0 | 0 | 0 | 37 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| Coagulation factor inhibitors | Patients | <5 | <5 | <5 | 0 | <5 | 0 | 0 | 0 | 10 |
| Grams | 240 | 132 | 1,699 | 0 | 719 | 0 | 0 | 0 | 2,790 |
| Grams/Episode | 60 | 66 | 94 | 0 | 42 | 0 | 0 | 0 | 68 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | <1 | 0 | 0 | 0 | <1 |
| Devic disease (neuromyelitis optica) | Patients | 16 | <5 | 5 | <5 | <5 | 0 | <5 | 0 | 29 |
| Grams | 4,984 | 885 | 805 | 1,662 | 350 | 0 | 135 | 0 | 8,821 |
| Grams/Episode | 34 | 33 | 28 | 128 | 35 | 0 | 27 | 0 | 38 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 0 | <1 | 0 | <1 |
| Diabetic Amyotrophy | Patients | <5 | 7 | <5 | 0 | 0 | 0 | <5 | 0 | 15 |
| Grams | 1,647 | 1,338 | 705 | 0 | 0 | 0 | 36 | 0 | 3,726 |
| Grams/Episode | 29 | 36 | 29 | 0 | 0 | 0 | 36 | 0 | 31 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | 0 | 0 | <1 | 0 | <1 |
| Epidermolysis bullosa acquisita | Patients | 0 | 0 | 0 | <5 | 0 | 0 | <5 | 0 | <5 |
| Grams | 0 | 0 | 0 | 1,461 | 0 | 0 | 1,170 | 0 | 2,631 |
| Grams/Episode | 0 | 0 | 0 | 86 | 0 | 0 | 90 | 0 | 88 |
| Grams per 1,000 Population | 0 | 0 | 0 | <1 | 0 | 0 | 3 | 0 | <1 |
| Epilepsy (rare childhood cases) | Patients | <5 | 8 | 6 | 7 | <5 | 0 | 0 | 0 | 24 |
| Grams | 360 | 2,480 | 1,217 | 1,324 | 126 | 0 | 0 | 0 | 5,507 |
| Grams/Episode | 36 | 34 | 35 | 53 | 32 | 0 | 0 | 0 | 38 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 0 | 0 | 0 | <1 |
| Graves ophthalmopathy | Patients | 0 | 0 | <5 | 0 | 0 | 0 | 0 | 0 | <5 |
| Grams | 0 | 0 | 2,490 | 0 | 0 | 0 | 0 | 0 | 2,490 |
| Grams/Episode | 0 | 0 | 59 | 0 | 0 | 0 | 0 | 0 | 59 |
| Grams per 1,000 Population | 0 | 0 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Haemolytic disease of the newborn | Patients | 19 | 20 | 9 | 11 | 9 | <5 | 10 | <5 | 82 |
| Grams | 78 | 183 | 1,035 | 609 | 45 | 11 | 45 | 7 | 2,013 |
| Grams/Episode | 3 | 8 | 41 | 29 | 3 | 6 | 3 | 4 | 16 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | <1 | <1 | <1 | <1 |
| Hashimoto encephalopathy | Patients | <5 | <5 | <5 | <5 | 0 | 0 | 0 | 0 | 8 |
| Grams | 627 | 973 | 660 | 1,270 | 0 | 0 | 0 | 0 | 3,530 |
| Grams/Episode | 35 | 35 | 30 | 58 | 0 | 0 | 0 | 0 | 39 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 0 | 0 | 0 | 0 | <1 |
| Limbic Encephalitis (nonparaneoplastic) | Patients | 37 | 34 | 55 | 7 | 6 | <5 | <5 | <5 | 147 |
| Grams | 7,850 | 6,646 | 15,559 | 1,027 | 861 | 410 | 3,438 | 287 | 36,076 |
| Grams/Episode | 35 | 33 | 30 | 29 | 32 | 27 | 55 | 41 | 33 |
| Grams per 1,000 Population | 1 | 1 | 3 | <1 | <1 | <1 | 9 | 1 | 2 |
| Limbic Encephalitis (Paraneoplastic) | Patients | <5 | 9 | 6 | <5 | <5 | <5 | <5 | 0 | 26 |
| Grams | 643 | 1,528 | 3,067 | 510 | 100 | 100 | 132 | 0 | 6,080 |
| Grams/Episode | 27 | 28 | 34 | 30 | 20 | 20 | 26 | 0 | 31 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | <1 | <1 | 0 | <1 |
| Myocarditis in children | Patients | <5 | 17 | 6 | 0 | <5 | 0 | 0 | 0 | 28 |
| Grams | 99 | 273 | 349 | 0 | 57 | 0 | 0 | 0 | 778 |
| Grams/Episode | 25 | 10 | 39 | 0 | 19 | 0 | 0 | 0 | 18 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | <1 | 0 | 0 | 0 | <1 |
| PANDAS/tic disorders | Patients | <5 | <5 | 0 | <5 | 0 | <5 | <5 | 0 | 7 |
| Grams | 718 | 864 | 0 | 288 | 0 | 204 | 87 | 0 | 2,161 |
| Grams/Episode | 27 | 36 | 0 | 72 | 0 | 51 | 87 | 0 | 36 |
| Grams per 1,000 Population | <1 | <1 | 0 | <1 | 0 | <1 | <1 | 0 | <1 |
| Paraneoplastic cerebellar degeneration (Yo antibodies) | Patients | <5 | <5 | <5 | <5 | <5 | <5 | 0 | 0 | 10 |
| Grams | 630 | 85 | 100 | 1,503 | 175 | 512 | 0 | 0 | 3,005 |
| Grams/Episode | 42 | 17 | 20 | 72 | 35 | 32 | 0 | 0 | 45 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | <1 | 0 | 0 | <1 |
| Paraneoplastic Subacute Sensory Neuropathy | Patients | <5 | <5 | <5 | 0 | <5 | <5 | 0 | 0 | 11 |
| Grams | 630 | 812 | 400 | 0 | 208 | 200 | 0 | 0 | 2,249 |
| Grams/Episode | 25 | 41 | 50 | 0 | 26 | 40 | 0 | 0 | 34 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | <1 | <1 | 0 | 0 | <1 |
| Paraneoplastic syndromes | Patients | 0 | 0 | <5 | 0 | <5 | 0 | 0 | 0 | <5 |
| Grams | 0 | 0 | 1,195 | 0 | 363 | 0 | 0 | 0 | 1,558 |
| Grams/Episode | 0 | 0 | 39 | 0 | 33 | 0 | 0 | 0 | 37 |
| Grams per 1,000 Population | 0 | 0 | <1 | 0 | <1 | 0 | 0 | 0 | <1 |
| Potassium channel antibody-associated encephalopathy | Patients | 17 | <5 | <5 | <5 | 5 | <5 | 0 | <5 | 29 |
| Grams | 4,540 | 639 | 426 | 998 | 1,800 | 754 | 0 | 240 | 9,396 |
| Grams/Episode | 29 | 34 | 39 | 111 | 44 | 29 | 0 | 24 | 35 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 1 | 1 | 0 | <1 | <1 |
| Pure red cell aplasia | Patients | 10 | 5 | 12 | <5 | <5 | <5 | 0 | 0 | 31 |
| Grams | 1,790 | 497 | 2,754 | 101 | 1,510 | 1,440 | 0 | 0 | 8,091 |
| Grams/Episode | 35 | 38 | 44 | 51 | 84 | 40 | 0 | 0 | 44 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | 3 | 0 | 0 | <1 |
| Pyoderma gangrenosum | Patients | <5 | 17 | <5 | 0 | <5 | 0 | 0 | <5 | 26 |
| Grams | 1,703 | 7,627 | 1,200 | 0 | 2,592 | 0 | 0 | 135 | 13,256 |
| Grams/Episode | 53 | 59 | 60 | 0 | 72 | 0 | 0 | 45 | 60 |
| Grams per 1,000 Population | <1 | 1 | <1 | 0 | 2 | 0 | 0 | <1 | <1 |
| Rasmussen Syndrome | Patients | 8 | <5 | <5 | <5 | <5 | <5 | <5 | 0 | 16 |
| Grams | 2,451 | 486 | 549 | 90 | 800 | 510 | 363 | 0 | 5,249 |
| Grams/Episode | 45 | 35 | 24 | 90 | 53 | 43 | 33 | 0 | 40 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | <1 | <1 | <1 | 0 | <1 |
| Scleromyxedema | Patients | <5 | <5 | 0 | 0 | <5 | 0 | 0 | 0 | 7 |
| Grams | 4,285 | 1,161 | 0 | 0 | 980 | 0 | 0 | 0 | 6,426 |
| Grams/Episode | 60 | 23 | 0 | 0 | 35 | 0 | 0 | 0 | 43 |
| Grams per 1,000 Population | <1 | <1 | 0 | 0 | <1 | 0 | 0 | 0 | <1 |
| Sjogren's Syndrome | Patients | 9 | <5 | <5 | <5 | <5 | 0 | <5 | 0 | 20 |
| Grams | 1,936 | 1,089 | 1,445 | 100 | 2,476 | 0 | 2,715 | 0 | 9,761 |
| Grams/Episode | 29 | 29 | 41 | 20 | 118 | 0 | 58 | 0 | 46 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 1 | 0 | 7 | 0 | <1 |
| Solid organ - heart | Patients | 5 | 7 | <5 | <5 | 0 | <5 | 0 | 0 | 17 |
| Grams | 461 | 1,340 | 800 | 140 | 0 | 396 | 0 | 0 | 3,137 |
| Grams/Episode | 46 | 45 | 57 | 140 | 0 | 44 | 0 | 0 | 49 |
| Grams per 1,000 Population | <1 | <1 | <1 | <1 | 0 | <1 | 0 | 0 | <1 |
| Solid organ - heart/lung | Patients | <5 | 6 | <5 | 0 | 0 | 0 | 0 | 0 | 8 |
| Grams | 96 | 838 | 324 | 0 | 0 | 0 | 0 | 0 | 1,258 |
| Grams/Episode | 32 | 23 | 27 | 0 | 0 | 0 | 0 | 0 | 25 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Solid organ - liver | Patients | 6 | <5 | 0 | <5 | <5 | 0 | 0 | 0 | 9 |
| Grams | 733 | 93 | 0 | 24 | 65 | 0 | 0 | 0 | 915 |
| Grams/Episode | 37 | 47 | 0 | 24 | 33 | 0 | 0 | 0 | 37 |
| Grams per 1,000 Population | <1 | <1 | 0 | <1 | <1 | 0 | 0 | 0 | <1 |
| Solid organ - lung | Patients | 38 | 36 | 15 | <5 | <5 | <5 | 0 | 0 | 94 |
| Grams | 5,663 | 6,502 | 2,759 | 406 | 559 | 423 | 0 | 0 | 16,311 |
| Grams/Episode | 48 | 29 | 23 | 31 | 29 | 33 | 0 | 0 | 32 |
| Grams per 1,000 Population | <1 | 1 | <1 | <1 | <1 | <1 | 0 | 0 | <1 |
| Solid organ - other | Patients | 0 | 0 | 0 | 0 | <5 | 0 | 0 | 0 | <5 |
| Grams | 0 | 0 | 0 | 0 | 80 | 0 | 0 | 0 | 80 |
| Grams/Episode | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 10 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | <1 | 0 | 0 | 0 | <1 |
| Solid organ - pancreas | Patients | 0 | <5 | 0 | 0 | 0 | 0 | 0 | 0 | <5 |
| Grams | 0 | 335 | 0 | 0 | 0 | 0 | 0 | 0 | 335 |
| Grams/Episode | 0 | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 12 |
| Grams per 1,000 Population | 0 | <1 | 0 | 0 | 0 | 0 | 0 | 0 | <1 |
| Susac syndrome | Patients | 5 | 0 | <5 | 0 | 0 | 0 | 0 | 0 | 9 |
| Grams | 2,274 | 0 | 2,610 | 0 | 0 | 0 | 0 | 0 | 4,884 |
| Grams/Episode | 37 | 0 | 47 | 0 | 0 | 0 | 0 | 0 | 42 |
| Grams per 1,000 Population | <1 | 0 | <1 | 0 | 0 | 0 | 0 | 0 | <1 |
| Systemic Capillary Leak syndrome | Patients | 5 | <5 | <5 | 0 | 0 | 0 | <5 | 0 | 9 |
| Grams | 1,518 | 1,980 | 3,060 | 0 | 0 | 0 | 1,680 | 0 | 8,238 |
| Grams/Episode | 45 | 104 | 113 | 0 | 0 | 0 | 80 | 0 | 82 |
| Grams per 1,000 Population | <1 | <1 | <1 | 0 | 0 | 0 | 4 | 0 | <1 |
| Transplant - Solid Organ | Patients | 0 | 0 | 0 | 0 | 0 | <5 | 0 | 0 | <5 |
| Grams | 0 | 0 | 0 | 0 | 0 | 270 | 0 | 0 | 270 |
| Grams/Episode | 0 | 0 | 0 | 0 | 0 | 15 | 0 | 0 | 15 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | <1 | 0 | 0 | <1 |
| Chapter 7 Total | Patients | 218 | 200 | 163 | 51 | 48 | 16 | 24 | 6 | 716 |
| Grams | 49,344 | 39,652 | 47,836 | 11,683 | 14,008 | 5,229 | 9,801 | 669 | 178,221 |
| Grams/Episode | 38 | 35 | 36 | 55 | 47 | 32 | 55 | 30 | 38 |
| Grams per 1,000 Population | 7 | 7 | 10 | 5 | 8 | 10 | 25 | 3 | 8 |
| Total | Patients | 5,465 | 3,447 | 3901 | 837 | 843 | 336 | 276 | 76 | 14,983 |
| Grams | 1,555,324 | 997,695 | 1,180,232 | 270,895 | 245,746 | 100,676 | 89,927 | 17,830 | 4,458,326 |
| Grams/Episode | 31 | 33 | 30 | 37 | 33 | 33 | 31 | 40 | 32 |
| Grams per 1,000 Population | 206 | 169 | 248 | 105 | 145 | 195 | 232 | 73 | 189 |

# Appendix E – Grams Ig Issued by State and Territory

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | NSW | VIC | QLD | WA | SA | TAS | ACT | NT |
| 2004-05 | Imported Ig |  | 22,200 | 3,000 | 144 | 2,856 |  |  |  |
| Domestic Ig | 410,505 | 318,762 | 306,639 | 125,094 | 110,031 | 40,353 | 23,895 | 6,321 |
| 2005-06 | Imported Ig | 41,376 | 13,860 | 19,992 | 144 | 5,922 |  |  |  |
| Domestic Ig | 420,858 | 326,130 | 284,043 | 148,200 | 95,403 | 46,065 | 24,615 | 7,806 |
| 2006-07 | Imported Ig | 76,368 | 52,097 | 134,475 | 7,765 | 15,300 | 13,608 | 8,165 |  |
| Domestic Ig | 452,565 | 361,665 | 219,633 | 152,127 | 109,515 | 33,837 | 21,774 | 8,004 |
| 2007-08 | Imported Ig | 103,270 | 88,398 | 79,393 | 20,577 | 18,375 | 11,065 | 7,170 |  |
| Domestic Ig | 493,172 | 407,244 | 337,301 | 155,821 | 92,958 | 50,583 | 26,470 | 6,732 |
| 2008-09 | Imported Ig | 105,633 | 111,010 | 85,055 | 38,445 | 18,416 | 11,740 | 16,875 |  |
| Domestic Ig | 599,126 | 423,170 | 400,144 | 148,986 | 108,596 | 52,755 | 27,393 | 6,825 |
| 2009-10 | Imported Ig | 249,905 | 131,228 | 171,367 | 42,895 | 27,604 | 19,965 | 14,200 |  |
| Domestic Ig | 562,320 | 417,574 | 383,865 | 143,628 | 128,511 | 53,745 | 22,841 | 10,503 |
| 2010-11 | Imported Ig | 252,416 | 101,930 | 200,264 | 16,248 | 31,244 | 17,110 | 11,550 |  |
| Domestic Ig | 668,526 | 507,038 | 439,089 | 162,963 | 143,285 | 61,686 | 33,225 | 8,610 |
| 2011-12 | Imported Ig | 136,728 | 93,835 | 107,798 | 30,108 | 27,383 | 8,843 | 11,900 | 80 |
| Domestic Ig | 887,016 | 577,260 | 631,545 | 167,745 | 139,296 | 76,197 | 45,540 | 9,099 |
| 2012-13 | Imported Ig | 265,995 | 144,284 | 183,435 | 59,900 | 35,775 | 12,138 | 14,708 | 30 |
| Domestic Ig | 874,995 | 570,969 | 674,277 | 150,294 | 145,134 | 73,491 | 52,446 | 13,440 |
| 2013-14 | Imported Ig | 467,371 | 321,085 | 361,654 | 92,914 | 72,613 | 16,436 | 26,648 | 9,551 |
| Domestic Ig | 804,375 | 484,680 | 589,662 | 132,108 | 123,810 | 64,305 | 48,480 | 6,744 |
| 2014-15 | Imported Ig | 930,412 | 579,560 | 735,658 | 155,977 | 135,795 | 57,987 | 59,210 | 4,863 |
| Domestic Ig | 593,045 | 416,868 | 458,189 | 111,570 | 107,343 | 41,608 | 32,199 | 12,861 |

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

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

# Appendix G – System Source for Tables and Figures

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

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

[Figure 3 Patients per 1,000 population 2013-14 STARS](#_Toc390098182)

[Figure 4 Grams of Ig 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 Ig expenditure as a proportion of the national blood budget IDMS](#_Toc390098186)

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

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

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

[Figure 11 Ig 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 Ig grams issued since 2005](#_Toc456266980) IDMS

[Table 2 Percentage change in grams issued over time by state and territory](#_Toc456266981) IDMS

[Table 3 Annual numbers of patients, treatment episodes and grams](#_Toc456266982) STARS & IDMS

[Table 4 Basic numbers](#_Toc456266983) STARS

[Table 5 Issues of domestic Ig compared with imported Ig](#_Toc456266984)  IDMS

[Table 6 Ig issues (g) by Criteria chapter](#_Toc456266985)  STARS

[Table 7 Ig issues by Criteria chapter (percentage)](#_Toc456266986)  STARS

[Table 8 Ig grams issued for top 10 diagnostic groups over time](#_Toc456266987)  STARS

[Table 9 Patient numbers and age for the top 20 conditions](#_Toc456266988)  STARS

[Table 10 Ig grams issued by clinical discipline](#_Toc456266989)  STARS

[Table 11 Grams of Ig issued by state and territory](#_Toc456266990)  IDMS

[Table 12 Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy](#_Toc456266991)  STARS

[Table 13 Patient numbers by state and territory: common variable immunodeficiency disease](#_Toc456266992)  STARS

[Table 14 Patient numbers by state and territory: myasthenia gravis](#_Toc456266993)  STARS

[Table 15 Patient numbers by state and territory: chronic lymphocytic leukaemia](#_Toc456266994) STARS

[Table 16 Patient numbers by state and territory: multiple myeloma](#_Toc456266995) STARS

[Table 17 Ig issued per 1,000 population by state and territory for top 10 conditions](#_Toc456266996)  STARS

[Table 18 Ig grams per episode](#_Toc456266997)  STARS

[Table 19 Patient numbers for products issued by state and territory in 2014-15](#_Toc456266998)  STARS

[Table 20 Grams of product issued by state and territory in 2014-15](#_Toc456266999)  STARS

[Table 21 Patient numbers for products issued by diagnostic group in 2014-15](#_Toc456267000)  STARS

[Table 22 Grams of product issued by diagnostic group in 2014-15](#_Toc456267001)  STARS

Appendix D – Dataset of Ig supply by state/territory 2014-14………………………………………………………………………………………………………………………………………..…STARS

Appendix E – Grams Ig Issued by State and Territory …………………………………………………………………………………………………………………………………………….……..…...IDMS

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

1. ABS 3101.0 [↑](#footnote-ref-1)
2. World Health Organisation, <http://www.who.int/ageing/en/> (Accessed 26 Feb 2014) [↑](#footnote-ref-2)
3. ABS 4841.0 [↑](#footnote-ref-3)
4. ABS 4841.0 (average of male and female) [↑](#footnote-ref-4)
5. ABS 4364.0.55.001 [↑](#footnote-ref-5)
6. Aston, L 2012, *The effect of ideal body weight (IBW) adjusted dosing on the use of intravenous immunoglobulin (IVIg) in Western Australia*, Australian Red Cross Blood Service, Australia. [↑](#footnote-ref-6)
7. 2013, *Lung Transplantation Fact Sheet*, Lung Foundation, Australia. [↑](#footnote-ref-7)
8. Cunningham-Rundles, C 2012, *The many faces of common variable immunodeficiency*, American Society of Hematology, USA. [↑](#footnote-ref-8)