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

Annual Report 2016-17



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# Introduction

Immunoglobulin products, derived from pooled human plasma, are a precious and high cost resource. Strengthening immunoglobulin governance is a priority for the National Blood Authority (NBA), and a number of measures are being developed and implemented to ensure the sustainability of these products into the future.

Immunoglobulin products analysed in this report include intravenous immunoglobulin (IVIg), subcutaneous immunoglobulin (SCIg) and normal human immunoglobulin (NHIg). Aggregated data for IVIg and SCIg is referred to as immunoglobulin (Ig) unless specifically stated. NHIg is reported separately. Ig products are used to treat a broad range of conditions, with applications in replacement and immune modulation therapy. This report provides an analysis of national data on national Ig supply in Australia in 2016-17, 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 NBA. The NBA’s role is to coordinate national supply and demand planning for blood and blood products including supply risk management; to purchase blood and blood products on behalf of all Australian governments; to develop and implement national strategies to encourage better governance; to promote appropriate use of blood and blood products; and to provide expert advice to support government policy development. Further background is at **Appendix A.**

The national Ig Governance Program was introduced in 2014 to pursue governments’ objectives for Ig products funded and supplied under the national blood arrangements, namely to:

* ensure Ig product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of government funds, in accordance with relevant national safety and quality standards for health care;
  + - ensure that access to Ig products is consistent with the criteria for access determined by governments; and
    - improve the capture of information of the need for, use of, and outcomes of treatment with Ig products to inform future decisions.

The NBA is responsible for administering the National Ig Governance Program which includes the development and maintenance of a national framework to access government-funded Ig. The current framework comprises a National Policy, the citeria for access, and BloodSTAR (Blood System for Tracking Authorisations and Reviews), a national online system.

The *National Policy: Access to Government-Funded Immunoglobulin Products in Australia* (National Policy) released in November 2016, sets out the process that must be followed and describes the rules and requirements that must be complied with to access government-funded Ig products in Australia. The National Policy supports all those involved in the prescription, use and management of Ig to understand their roles and responsibilities under the governance arrangements.

The *Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia* (the Criteria) were developed in collaboration with expert specialist clinicians and identify the medical conditions and circumstances for which the use of Ig is considered to be clinically appropriate and where there are no safe, effective and cost-effective alternative treatments. First published in 2007, and revised in 2012, the Criteria identifies the conditions and circumstances for which the use of Ig is funded under national blood arrangements.

The Criteria clearly articulates and standardises the qualifying and continuing Ig access requirements. It classifies the 93 conditions described in the Criteria into those for which Ig has an established therapeutic role (Chapter 5), has an emerging therapeutic role (Chapter 6) and those where Ig has application in exceptional circumstances only (Chapter 7). Ig is only supplied for these conditions unless purchased directly by a state or territory, hospital or individual (a Direct Order). Chapter 8 of the Criteriaoutlines those conditions for which Ig should not be supplied under national blood arrangements.

Introduced in 2016, BloodSTAR was developed by the NBA on behalf of all Australian Governments to serve the needs of health providers and support users to meet their obligations under the National Policy. Through BloodSTAR, Prescribers can request patient authorisation for access to government-funded Ig. Under the governance arrangements, Dispensers may only dispense product to patients with an active authorisation in BloodSTAR. Nurses and Midwives can request product from Dispensers through BloodSTAR. BloodSTAR streamlines the authorisation process, reduces variability and standardises prescribing practices, and increases efficiency and transparency while strengthening decision-making and improving data capture. BloodSTAR was designed, developed, and implemented to all Australian states and territories except New South Wales (NSW).

In addition to the clinical and diagnostic criteria for access to intravenous products, access to SCIg products is provided through an assurance framework for the appropriate use of the product. SCIg access rules are detailed on the NBA website at <https://www.blood.gov.au/SCIg>. Participation in the National SCIg program requires hospitals to establish their capability and capacity to manage a hospital-based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the product within defined governing requirements.

NHIg may only be supplied for two purposes; for the treatment of susceptible contacts of measles, hepatitis A, poliomyelitis and rubella, as directed by public health officials; or for the treatment of immunodeficiency conditions for which the product is indicated for patients for whom IVIg and SCIg are both contraindicated. NHIg access rules are detailed on the NBA website at <https://www.blood.gov.au/NHIg>.

Ig products should be prescribed and dispensed in accordance with any applicable state or territory legislative requirements. In-hospital management of Ig products must also be in accordance with the National Safety and Quality Health Service (NSQHS) Standards, in particular Standards 1, 2 and 7, and the Australian and New Zealand Society of Blood Transfusion (ANZSBT) *Guidelines for the Administration of Blood Products and Guidelines for Transfusion and Immunohaematology Laboratory Practice*.

Ig comprises 49% of total blood expenditure in 2016-17. Demand for Ig continues to rise steadily at around 11% each year, and Australian grams per 1000 population use of this product is one of the highest among western countries[[1]](#footnote-2). Demand for Ig is met through domestic and imported Ig products. Domestic Ig is manufactured by CSL Behring using plasma collected from voluntary, non-remunerated Australian donations. Both domestic and imported Ig are distributed by the Australian Red Cross Blood Service (Blood Service), with the Blood Service also being responsible for collection of data on behalf of governments for product funded under the national blood arrangements.

Australia is in a unique position to provide analysis and commentary on the use of Ig due to national supply arrangements*.* This report begins with an analysis of Ig supply over the last ten years, then considers patient demographics, expenditure on Ig, clinical indications for which Ig was supplied and finally analyses the dose prescribed for various conditions. The top ten medical conditions account for 88.3% of all Ig supplied in 2016-17, and for this reason specific analysis focuses on these groups.

# Report Snapshot

**17,958 patients**

**7,682 new patients**

**Median age 63 years**

**PATIENTS**

**Total cost of $530.15 million**

**49% of total blood budget**

**EXPENDITURE**

**5.54 million grams issued**

**227 grams per 1,000 population**

**44% imported product**

**Ig USE**

# Methodology

This report uses data from three 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 where imprest stock is dispensed for treatment. 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 dispensed by Australian Health Providers to be administered to the patient. The data is collected into the NBA BloodNet and BloodSTAR systems.
3. Data collected by the NBA on the units of Ig issued to Australian Health Providers (AHPs) and purchases from suppliers. This data is held in the NBA Integrated Data Management System (IDMS).

Prior to 2016-17 authorisation and dispense data was collected by the Blood Service, and in 2016 all jurisdictions transitioned to using BloodSTAR except NSW as shown in the following table. The Blood Service entered information on current patients and authorisations into BloodSTAR using information from STARS. This data is known as *legacy* data.

|  |  |
| --- | --- |
| Jurisdiction | Go Live Date |
| Northern Territory | 14 July 2016 |
| South Australia | 1 August 2016 |
| Queensland | 22 August 2016 |
| Tasmania | 14 September 2016 |
| Victoria | 26 September 2016 |
| Australian Capital Territory | 24 October 2016 |
| Western Australia | 5 December 2016 |
| New South Wales | TBA |

Over the nine years between 2008-09 and 2016-17, data has been captured on 56,379 patients. Caveats relating to the quality of this data are outlined below.

This report includes data on the supply of NHIg from 2012-13 and SCIg from 2013-14, as SCIg products were not available in Australia before 2013-14. The report includes some terminology that may be unique to the Australian environment. A list of acronyms and definitions used in this report is at **Appendix B**.

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

Each specific condition has been classified according to its allocated clinical speciality. It is acknowledged that for some specific conditions this classification could fit into more than one clinical speciality. For example, there are immunological conditions affecting the blood that could potentially be mapped to either immunology or haematology. Where there appears to be significant overlap between clinical specialities, the specific condition was mapped as agreed by the National Immunoglobulin Governance Advisory Committee (NIGAC). In the majority of cases, the specific condition was mapped to the speciality most likely to be responsible for patients with that specific condition, noting that this can vary. **Appendix C** provides the mapping of specific condition to clinical speciality.

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

It should be noted that the grams per 1,000 population measure has previously been shown to be a poor indicator for benchmarking. Raw population figures do not take into account the underlying population age structure, hospital usage patterns, and cross-border referrals; nor do total issues take into account varying product wastage rates across time and jurisdictions. A study done by South Australia (SA) in 2010 (Australian Health Review article - "Red alert - a new perspective on patterns of blood use in the SA public sector") shows this and can be found at <https://www.publish.csiro.au/AH/AH10957>.

## 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, BloodSTAR/BloodNet and IDMS indicates minor variances at a national level. In some cases these differences can be explained by product being ordered and recorded in IDMS the month prior to product actually being dispensed to a patient.
* Data is incomplete for some records in both patient and authorisation data. For example data from STARS and BloodSTAR may not include weight. Legacy data entered into BloodSTAR did not include weight.
* 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 data compared to larger states.
* There has been no adjustment for Ig dispensed in one state or territory for patients residing in a different state or territory.
* BloodSTAR and STARS jurisdictions or states and territories are based on the state or territory of the facility which dispensed the product, not the treating facility state or territory.
* 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.
* 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 for both STARS and BloodSTAR.
* Episodes in STARS were known as Treatment Episodes and in BloodSTAR these are known as Dispense Events. In this document we have used Treatment Episodes for consistency.
* Patient Counts are distinct counts and will not sum for National or Total rows and columns, as patients may have more than one specific condition, have product dispensed in more than one state or territory, have dispense events recorded at a private facility and at a public facility, have received IVIg and SCIg, or have received both domestic and imported product.
* Previous annual reporting for Ig named conditions as Primary Diagnosis or grouped conditions as Disease Category. In BloodSTAR these are known as Specific Conditions or Medical Conditions respectively. Conditions were also grouped to Disciplines previously and these are now known as Specialities in BloodSTAR.
* For this 2016-17 report Specific and Medical Conditions are based on the Criteria version 2.
* Dispense data can be entered into BloodSTAR at any time as long as there is a valid and active authorisation. This means that a Dispense Event may be recorded in one month although the actual Dispense Event was in another month, which means data for 2016-17 could be recorded in 2017-18.

# 10 Year Trends

## Demand Trends

In 2016-17 a total of 5,542,511 grams of Ig was issued, representing an increase of 560,008 grams (11.2%) over 2015-16. Since 2007-08 there has been an on average 11.3% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

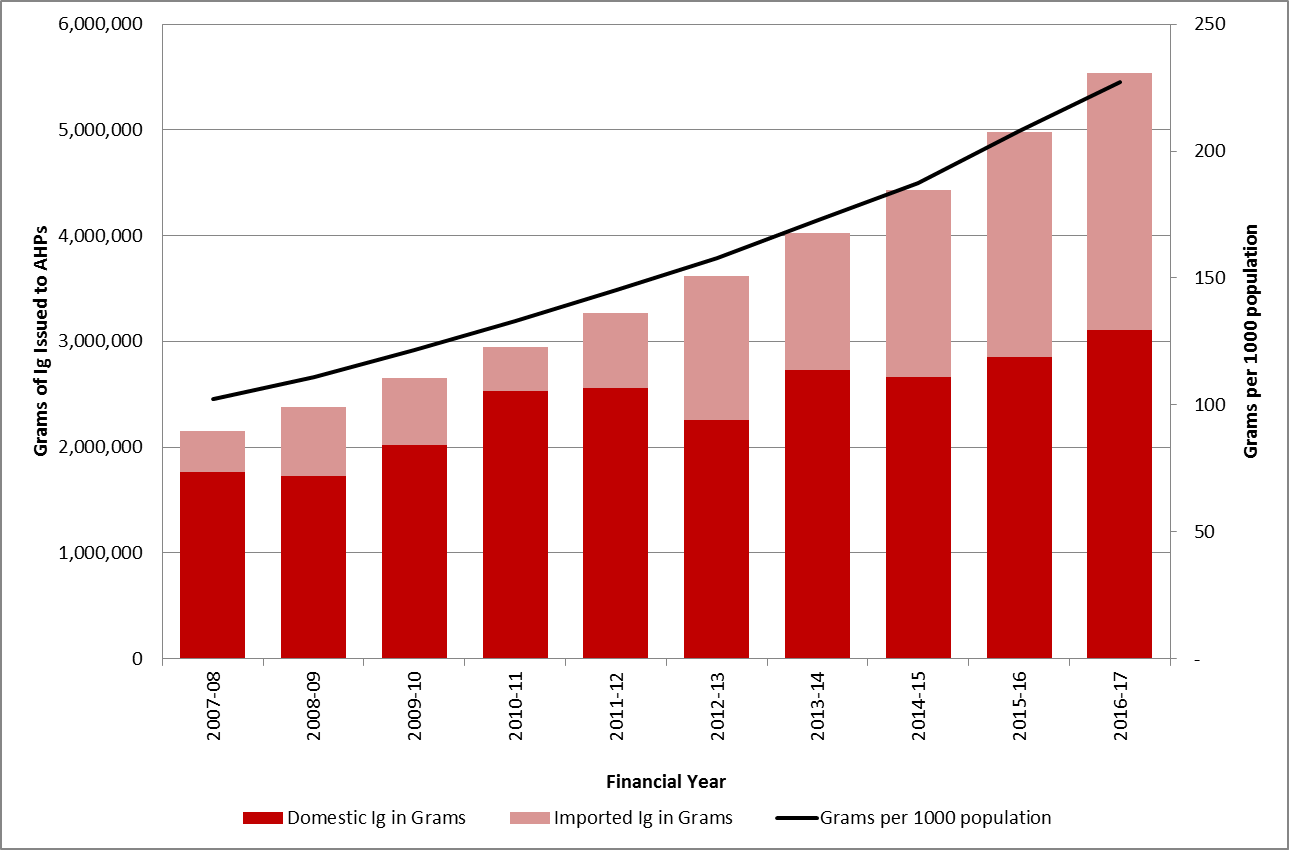


Figure 1 Ten year trends in issues of Ig

Table 1 Growth in Ig grams issued since 2007-08

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2007-08 | 2008-09 | 2009-10 | 2010-11 | 2011-12 | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 |
| Growth from previous year | 13% | 11% | 12% | 11% | 11% | 11% | 11% | 10% | 12% | 11% |
| Average Growth from 2007-08 |  | 5% | 8% | 9% | 10% | 11% | 12% | 13% | 15% | 16% |
| Total grams per 1,000 population | 102 | 111 | 121 | 133 | 145 | 158 | 173 | 188 | 208 | 227 |
| Increase in grams per 1,000 population over previous year | 11% | 8% | 10% | 10% | 9% | 9% | 9% | 9% | 11% | 9% |

There has been a steady increase in demand for Ig over the last ten years, with increases of 10-12% per annum for the last ten years. While a proportion of this increase may be attributable to population increases, there has also been a steady increase of 8-11% per annum in the use of Ig per 1000 population (Table 1) since the introduction of the Criteria in 2008.

A breakdown of the year on year change in grams issued by state and territory has been provided in Table 2. Over the past ten years the Northern Territory (NT) has been growing at the fastest rate, followed by Queensland (QLD) and NSW. Rates for the smaller population states and territories must be viewed with some caution as there are many factors that could contribute to different use patterns. Further information about the breakdown of domestic and imported Ig by state over time can be found in **Appendix E**.

Table 2 Percentage change in grams issued over time by state and territory

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | NSW | VIC | QLD | SA | WA | TAS | NT | ACT |
| 2007-08 | 18% | 8% | 16% | 14% | 6% | 5% | 1% | 29% |
| 2008-09 | 15% | 3% | 14% | 23% | 0% | 14% | 54% | -14% |
| 2009-10 | 13% | 11% | 15% | 12% | -4% | 7% | -18% | 20% |
| 2010-11 | 11% | 10% | 16% | -4% | 10% | 8% | 7% | 28% |
| 2011-12 | 11% | 7% | 16% | 9% | 6% | 1% | 47% | 17% |
| 2012-13 | 11% | 13% | 11% | 9% | 7% | -6% | 21% | 12% |
| 2013-14 | 10% | 11% | 12% | 15% | 6% | 14% | 1% | 12% |
| 2014-15 | 9% | 11% | 12% | 7% | 12% | 8% | 8% | 8% |
| 2015-16 | 14% | 10% | 14% | 11% | 17% | 2% | 36% | 3% |
| 2016-17 | 14% | 11% | 8% | 10% | 18% | 4% | 6% | 7% |

## 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 2016-17 was $303.6 million, an increase of $7.2 million (2.4%) over 2015-16 (Figure 2). The increased expenditure predominately represents increases in demand offset by decreases in imported Ig prices.

There also continues to be an increase in the price of plasma for fractionation due to the increased ratio of apheresis to whole blood plasma for fractionation being supplied, resulting in an increase in the cost of domestic Ig. In 2016-17 this increase was offset by a reduced cost by the Blood Service due to efficiencies recognised. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of $530.2 million (excluding hyperimmune plasma for fractionation).

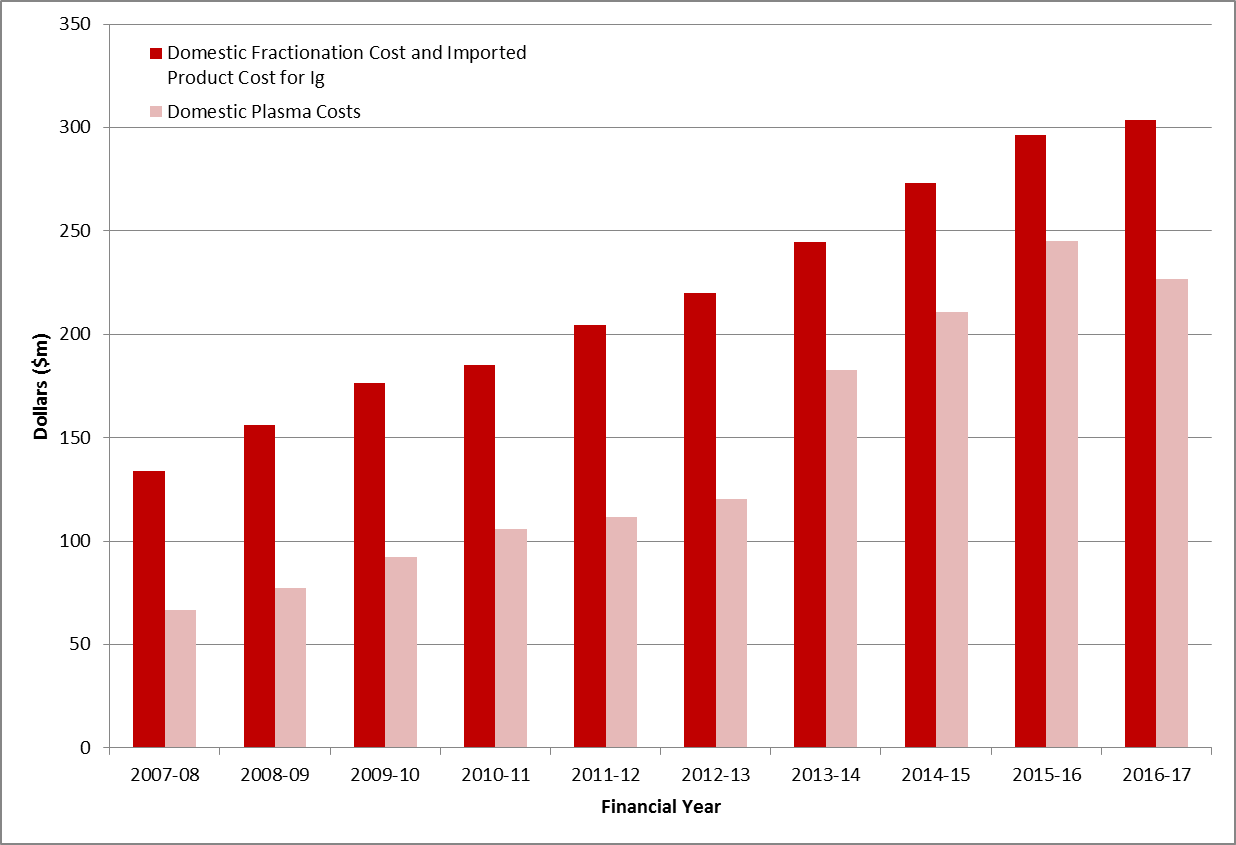


Figure 2 Ten year trends in expenditure on Ig

# Demographics

## Patient Numbers

A total of 17,958 patients were issued Ig under the national blood arrangements during 2016-17 for 179,997 treatment episodes. This represents a 10.0% increase in the number of patients since 2015-16. A summary of some patient numbers is provided in Table 3 and Table 4. A breakdown of unique patients by state and territory and quarter is provided in **Appendix F**.

Table 3 Annual numbers of patients, treatment episodes and grams

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Patients** | **Treatment Episodes** | **Total Grams Issued** |
| 2012-13 | 13,102 | 110,183 | 3,622,433 |
| 2013-14 | 13,981 | 122,791 | 4,021,861 |
| 2014-15 | 14,983 | 140,855 | 4,433,146 |
| 2015-16 | 16,331 | 159,041 | 4,982,503 |
| 2016-17 | 17,958 | 179,997 | 5,542,511 |

Table 4 Basic numbers

|  |  |
| --- | --- |
|  | 2016-17 |
| Total unique patient IDs with some weight data | 17,744 |
| Total unique patient IDs with an age recorded | 17,958 |
| Total unique patient IDs with more than one state or territory | 117 |
| Total unique patient IDs with two states or territories | 115 |
| Total unique patient IDs with three or more states or territories | <5 |
| Total unique patient IDs with more than one condition | 389 |
| Total unique patient IDs with two conditions | 370 |
| Total unique patient IDs with three conditions | 19 |
| Total unique patient IDs aged 65 and older | 8,094 |
| Total unique patient IDs aged 17 and younger | 1,669 |
| Total unique new patient IDs | 7,682 |
| Average Age | 57 |
| Median Age | 63 |
| Average Weight (kg) | 75 |

## Geographic Distribution

Nationally, 0.7 patients per 1,000 population received Ig in 2016-17. This varied between states and territories, ranging from 0.3 in NT to 0.9 in QLD (Figure 3). All states and territories show an increase in the number of patients per 1,000 population over the previous year, except Tasmania (TAS) and the NT.

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



Figure 3 Patients per 1,000 population 2015-16 and 2016-17

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 103.3 in the NT to 299.2 in QLD (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. For example, patients may travel to larger states for specialist treatment. At the same time, the ACT services a much broader area. Comparing only the five largest Australian states, the variation in Ig use is 2.1 fold, ranging from 143.3 grams per 1,000 population in Western Australia (WA) to 299.2 grams per 1,000 population in QLD. The reason for this inter-state and territory variation is unknown, but it may represent differences in clinical practice, differing patient populations with disease profiles, variable access to alternative therapies or differences due to the availability of specialist services across Australia.

Prior to 2014-15 WA had shown only slight increases in the number of grams issued per 1,000 population, while most states and territories have seen a continued increase in Ig issued per 1,000 population. However, in 2015-16 and 2016-17 WA had the highest increase in growth of Ig issued per 1,000 population as noted in Figure 4, but none the less WA(except NT) remains the lowest Ig issued per 1,000 population.

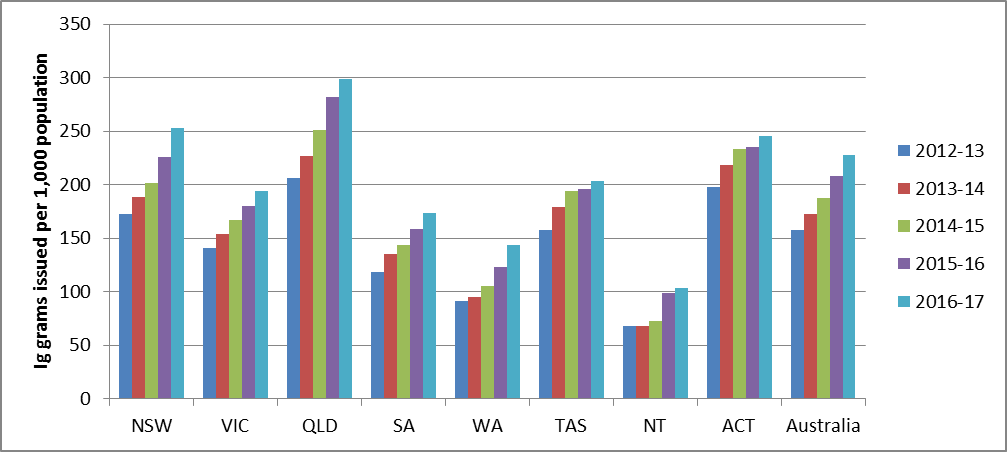


Figure 4 Grams of Ig per 1,000 population by state and territory over time

## Age

The distribution of estimated age is shown in Figure 5 where it is compared with the age distribution of the Australian population at December 2015[[2]](#footnote-3). A bimodal peak can be seen in the patient population treated with Ig, with the majority of Ig recipients either being very young, or over 55. The ageing population is expected to place a greater burden on Ig demand into the future, with the proportion of the world’s population over 60 years expected to more than double between 2015 and 2050[[3]](#footnote-4).

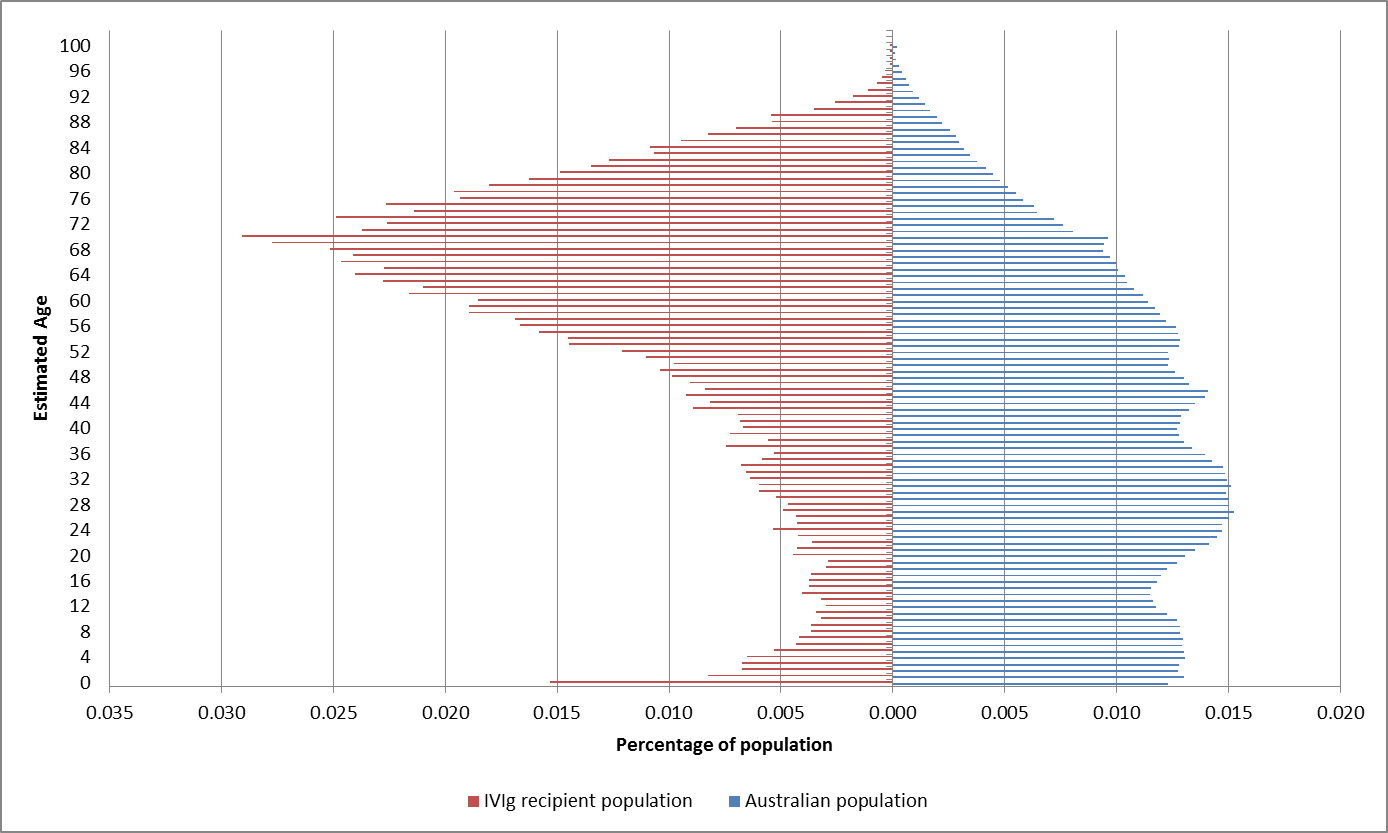


Figure 5 Patient age compared to average Australian age

## Weight

Ig dosing is dependent on the weight of the patient. For many conditions, the patient weight determines the initial dosing, with maintenance therapy titrated against IgG levels and the patient’s clinical response to therapy.



Figure 6 Patient weights relative to Australian average

Note: The above figure calculations relate to only 2016-17 patients.

Figure 6 compares the weight of Ig recipients in Australia in 2016-17 and the Australian population using weight statistics from the ABS in 2011[[4]](#footnote-5). There is a higher proportion of patients less than 55kg treated with Ig relative to the proportion in the Australian population. The average weight of adult Ig patients (78.5 kg) is slightly higher than the average weight of an Australian adult (77.7 kg[[5]](#footnote-6)). This is a change from previous years where it has been lower, suggesting that the Ig population is getting heavier. Given that studies suggest that 63% of Australians are overweight or obese[[6]](#footnote-7), 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 may be more appropriate.

The amount of Ig prescribed for a patient may vary depending on the indication as well as a patient’s weight, as set out in the Criteria. When prescribing Ig, Prescribers should aim to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. The dose may be adjusted for Ideal Body Weight for some patients and a calculator is available in BloodSTAR to facilitate this where appropriate.

Further work needs to be done on ideal body weight dosing and the impacts on patient outcomes.

With an increasingly obese population, increases in demand per patient may be expected if total (rather than lean) body weight dosing is continued. This area should be considered for future research.

Care should be taken when analysing data in this report related to patient weight, as not all patients have weight recorded, and for those that do, the weight recorded may not be current.

Table 5 shows the number of distinct patients and the average weight by age ranges for patients with dispenses in 2016-17.

Table 5 Patient numbers and average weight by age range

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Age Range** | **Patient Counts** | **Average Weight** | **Treatment Episodes** | **Grams Dispensed** |
| 0-4 | 782 | 12 | 2,539 | 23,417 |
| 5-9 | 380 | 25 | 2,459 | 34,869 |
| 10-14 | 305 | 45 | 2,890 | 55,421 |
| 15-17 | 200 | 64 | 2,374 | 50,950 |
| 18-19 | 106 | 69 | 1,290 | 26,960 |
| 20-24 | 395 | 70 | 4,159 | 110,540 |
| 25-29 | 420 | 74 | 4,109 | 134,023 |
| 30-34 | 569 | 78 | 5,676 | 172,188 |
| 35-39 | 565 | 77 | 6,493 | 193,308 |
| 40-44 | 674 | 80 | 7,182 | 241,544 |
| 45-49 | 844 | 81 | 9,005 | 299,024 |
| 50-54 | 1,112 | 83 | 11,926 | 407,538 |
| 55-59 | 1,566 | 81 | 16,963 | 562,026 |
| 60-64 | 1,940 | 82 | 20,583 | 651,589 |
| 65-69 | 2,233 | 80 | 23,316 | 732,968 |
| 70-74 | 2,185 | 80 | 22,964 | 716,443 |
| 75-79 | 1,722 | 77 | 17,366 | 533,914 |
| 80-84 | 1,124 | 74 | 11,224 | 333,318 |
| 85-89 | 639 | 70 | 5,722 | 162,986 |
| 90-94 | 174 | 67 | 1,585 | 39,623 |
| 95-104 | 23 | 63 | 172 | 4,862 |
| **Total** | **17,958** | **75** | **179,997** | **5,487,511** |

# Expenditure

In 2016-17, Australian expenditure on Ig products was $303.6 million, with additional expenditure of $226.6 million on plasma for fractionation (excluding hyperimmune plasma for fractionation) collected by the Blood Service, which is primarily directed to manufacture of Ig products.

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 28% of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, Ig accounts for 49% of the total blood budget, at a total expenditure of $530.2 million (excluding hyperimmune plasma for fractionation).

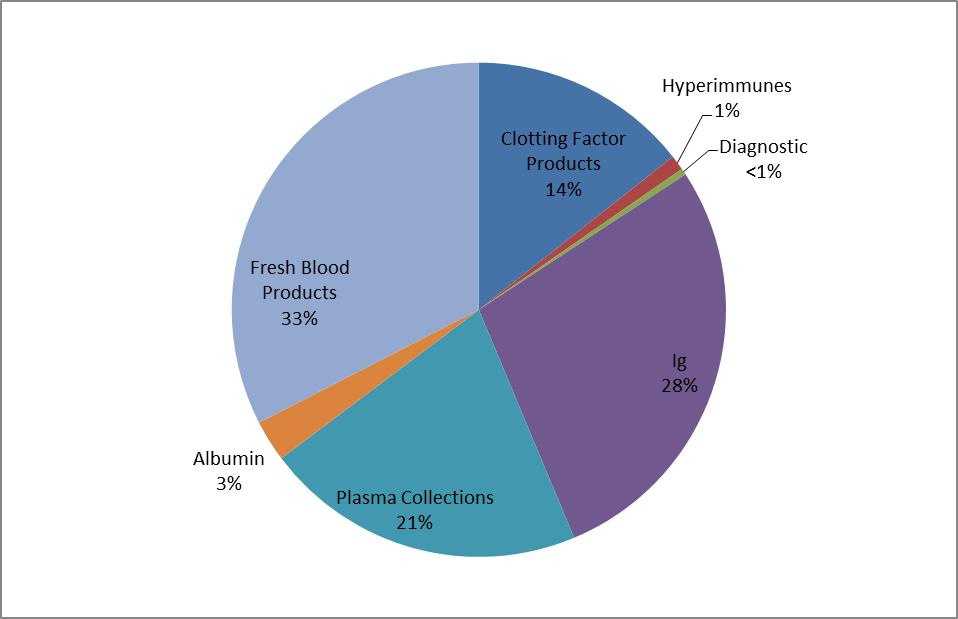


Figure 7 Ig expenditure as a proportion of the national blood budget

Of the Ig supplied under national blood arrangements in Australia in 2016-17, 56% (3,105,183 grams) was manufactured domestically and 44% (2,437,328 grams) was imported from overseas (Table 6). This represents a 14.3% increase in product importation from 2015-16 (305,772 grams). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 6.0% in 2016-17 over 2015-16. Intragam P, Intragam 10 (IVIg) and Evogam (SCIg) were Ig products manufactured domestically in 2016-17. The imported products available were Kiovig (IVIg), Octagam (IVIg), Privigen (IVIg), Flebogamma (IVIg), Hizentra (SCIg) and Gammanorm (SCIg). When a patient is allocated to receive one of the imported products it is the clinician’s choice as to which product they order. Supply of Privigen constituted 63.7% of the supply of imported Ig.

Table 7 shows the split between Ig issues for domestic and imported products, by public and private Australian Health Providers (AHPs) for 2016-17.

Table 6 Issues of domestic Ig compared with imported Ig

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NSW** | | | **NSW** | | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **AUS** |
| **Domestic Ig** | Intragam P | gm | | 833,259 | 515,505 | 558,645 | 125,001 | 129,678 | 38,748 | 4,620 | 40,833 | 2,246,289 |
| $(m) | | $52 | $32 | $35 | $8 | $8 | $2 | $0 | $3 | $139 |
| Intragam 10 | gm | | 202,535 | 208,198 | 244,745 | 52,023 | 56,665 | 16,890 | 2,288 | 13,628 | 796,970 |
| $(m) | | $13 | $13 | $15 | $3 | $4 | $1 | $0 | $1 | $49 |
| Evogam | gm | | 21,592 | 8,822 | 18,609 | 5,919 | 6,094 | 331 | 307 | 250 | 61,924 |
| $(m) | | $1 | $1 | $1 | $0 | $0 | $0 | $0 | $0 | $4 |
| **Total Domestic** | gm | | **1,057,386** | **732,525** | **821,999** | **182,943** | **192,437** | **55,969** | **7,215** | **54,710** | **3,105,183** |
| $(m) | | **$66** | **$45** | **$51** | **$11** | **$12** | **$3** | **$0** | **$3** | **$193** |
| **Imported Ig** | Kiovig | gm | | 3,582 | 1,846 | 1,198 | 0 | 0 | 0 | 0 | 0 | 6,625 |
| $(m) | | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Octagam | gm | | 6,074 | 1,373 | 1,047 | 0 | 0 | 0 | 0 | 0 | 8,494 |
| $(m) | | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1 |
| Gammanorm | gm | | 224 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 228 |
| $(m) | | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Flebogamma | gm | | 371,178 | 141,616 | 165,027 | 39,038 | 53,998 | 16,531 | 790 | 2,583 | 790,758 |
| $(m) | | $17 | $6 | $7 | $2 | $2 | $1 | $0 | $0 | $36 |
| Privigen | gm | | 501,585 | 332,585 | 449,535 | 66,195 | 116,035 | 30,675 | 17,415 | 37,965 | 1,551,990 |
| $(m) | | $23 | $15 | $20 | $3 | $5 | $1 | $1 | $2 | $70 |
| Hizentra | gm | | 32,100 | 2,962 | 22,281 | 9,756 | 4,875 | 2,506 | 0 | 4,754 | 79,234 |
| $(m) | | $2 | $0 | $1 | $1 | $0 | $0 | $0 | $0 | $5 |
| **Total Imported** | gm | | **914,742** | **480,381** | **639,087** | **114,989** | **174,908** | **49,712** | **18,205** | **45,305** | **2,437,328** |
| $(m) | | **$42** | **$22** | **$29** | **$5** | **$8** | **$2** | **$1** | **$2** | **$111** |
| **Proportion of domestic to imported Ig** | | gm % | | 54% | 60% | 56% | 61% | 52% | 53% | 28% | 55% | 56% |
| $(m) % | | 61% | 68% | 64% | 68% | 60% | 60% | 35% | 62% | 63% |

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

Table 7 Issues of domestic Ig compared with imported Ig and public versus private

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NSW** | | | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **AUS** |
| **Domestic Ig** | Public | gm | 772,012 | 424,069 | 306,590 | 153,558 | 124,418 | 44,539 | 7,215 | 54,710 | 1,887,111 |
| Private | gm | 285,374 | 308,456 | 515,409 | 29,385 | 68,019 | 11,430 | - | - | 1,218,072 |
| **Total Domestic** | gm | **1,057,386** | **732,525** | **821,999** | **182,943** | **192,437** | **55,969** | **7,215** | **54,710** | **3,105,183** |
| **Imported Ig** | Public | gm | 745,092 | 304,448 | 310,356 | 108,779 | 128,944 | 39,668 | 18,145 | 45,305 | 1,700,735 |
| Private | gm | 169,651 | 175,933 | 328,732 | 6,210 | 45,965 | 10,044 | 60 | - | 736,593 |
| **Total Imported** | gm | **914,742** | **480,381** | **639,087** | **114,989** | **174,908** | **49,712** | **18,205** | **45,305** | **2,437,328** |
| **Total Ig** | Public | gm | 1,517,104 | 728,517 | 616,945 | 262,337 | 253,361 | 84,207 | 25,360 | 100,015 | 3,587,845 |
| Private | gm | 455,024 | 484,389 | 844,141 | 35,595 | 113,983 | 21,474 | 60 | - | 1,954,665 |
| **Total Ig** | gm | **1,972,128** | **1,212,905** | **1,461,086** | **297,931** | **367,345** | **105,681** | **25,420** | **100,015** | **5,542,511** |
| **Domestic to Imported** | Public | gm% | 50.9% | 58.2% | 49.7% | 58.5% | 49.1% | 52.9% | 28.4% | 54.7% | 52.6% |
| Private | gm% | 62.7% | 63.7% | 61.1% | 82.6% | 59.7% | 53.2% | 0.0% | 0.0% | 62.3% |
| **Total Ig** | gm% | **53.6%** | **60.4%** | **56.3%** | **61.4%** | **52.4%** | **53.0%** | **28.4%** | **54.7%** | **56.0%** |
| **Ig as portion of National** | Public | gm% | 42.3% | 20.3% | 17.2% | 7.3% | 7.1% | 2.3% | 0.7% | 2.8% | 100.0% |
| Private | gm% | 23.3% | 24.8% | 43.2% | 1.8% | 5.8% | 1.1% | 0.0% | 0.0% | 100.0% |
| **Total Ig** | gm% | **35.6%** | **21.9%** | **26.4%** | **5.4%** | **6.6%** | **1.9%** | **0.5%** | **1.8%** | **100.0%** |
|  | **Population %** |  | **32.0%** | **25.6%** | **20.0%** | **7.0%** | **10.5%** | **2.1%** | **1.0%** | **1.7%** | **100.0%** |
| **Grams Per 1000 Population** | Public |  | 194.5 | 116.7 | 126.3 | 152.8 | 98.8 | 162.0 | 103.0 | 245.6 | 147.1 |
| Private |  | 58.3 | 77.6 | 172.9 | 20.7 | 44.5 | 41.3 | 0.2 | - | 80.2 |
| **Total Ig** |  | **252.9** | **194.3** | **299.2** | **173.5** | **143.3** | **203.3** | **103.3** | **245.6** | **227.3** |

# Clinical Indications

## Ig issues by criteria chapter

TheCriteriaclassifies medical conditions into four chapters based on the level of evidence supporting the use of Ig, as follows:

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

Ig was predominately issued for medical conditions within Chapter 5 (Table 8). The relative distribution by chapter has remained relatively stable since 2008 (Table 9). Chapter 8 issues of 837g are mainly for emergency sepsis cases. Refer to **Appendix D** for further information.

Table 8 Ig issues (g) by Criteria chapter

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 |
| Chapter 5 | 3,025,452 | 3,409,100 | 3,785,615 | 4,223,866 | 4,620,916 |
| Chapter 6 | 453,352 | 463,361 | 494,489 | 535,596 | 645,636 |
| Chapter 7 | 120,979 | 148,581 | 178,221 | 216,927 | 220,122 |
| Chapter 8 | 39 | 0 | 0 | 5 | 837 |
| **Total** | **3,599,831** | **4,021,042** | **4,458,326** | **4,976,394** | **5,487,511** |

Table 9 Ig issues by Criteria chapter (percentage)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 |
| Chapter 5 | 84% | 85% | 85% | 85% | 84% |
| Chapter 6 | 13% | 12% | 11% | 11% | 12% |
| Chapter 7 | 3% | 4% | 4% | 4% | 4% |
| Chapter 8 | <1% | 0% | 0% | 0% | 0% |

For conditions where Ig is used only in exceptional circumstances (Chapter 7), five medical conditions accounted for 54.4% of those issues. These medical conditions were Limbic Encephalitis – nonparaneoplastic (66,445g), Paraneoplastic neurological syndromes (18,557g), Devic disease (neuromyelitis optica) (12,597g), Potassium channel antibody-associated encephalopathy (11,312g) and Sjögren’s syndrome (10,928g). While use in these medical conditions represents a small proportion of total Ig use, closer examination of these medical conditions may be warranted.

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 2016-17 there were only two cases where funded Ig was supplied for a medical condition not supported in the Criteria (excluding Direct Orders where alignment with the Criteria is not required as it is not funded under the national blood arrangements).Refer to **Appendix D** for further information. Data to support compliance with all aspects of qualifying criteria for each specific condition is not always collected in STARS, but has improved with the introduction of BloodSTAR.

## Ig issues by medical condition

The top ten medical conditions account for 88.3% of all Ig supplied, with the top three medical conditions accounting for 56.5%.

Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT is the medical condition for which the greatest percentage of Ig was issued in 2016-17 (22.4%), closely followed by chronic inflammatory demyelinating polyneuropathy (CIDP) (21.3%). Primary immunodeficiency diseases (PID) with antibody deficiency accounted for 12.8% of total Ig use (Figure 8 and Table 10).

Since 2012-13 there has been a greater than 15% increase in Ig issues for both myasthenia gravis (MG) and inflammatory myopathies, a more than 14% increase for secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) and a more than 12% increase in issues for acquired hypogammaglobulinaemia — haematological malignancy and post HSCT, and multifocal motor neuropathy (MMN). This is compared with the 11% increase in Ig over this period for all medical conditions.



Figure 8 Ig grams issued by medical condition

Table 10 Ig grams issued for top 10 medical conditions over time

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 | % Change 2016-17 to  2015-16 |
| Acquired hypogammaglobulinaemia | 771,071 | 862,898 | 982,773 | 1,106,721 | 1,228,405 | 11.0% |
| Chronic inflammatory demyelinating polyneuropathy | 758,271 | 857,533 | 974,258 | 1,071,135 | 1,171,581 | 9.4% |
| Primary immunodeficiency diseases | 509,364 | 558,617 | 614,781 | 660,816 | 701,547 | 6.2% |
| Myasthenia gravis | 257,966 | 313,940 | 348,336 | 402,881 | 456,346 | 13.3% |
| Multifocal motor neuropathy | 209,791 | 239,314 | 256,041 | 293,458 | 331,142 | 12.8% |
| Inflammatory myopathies) | 188,362 | 230,473 | 249,229 | 293,422 | 329,182 | 12.2% |
| Immune thrombocytopenic purpura (ITP) — adult | 178,738 | 186,640 | 187,621 | 210,094 | 211,868 | 0.8% |
| Secondary hypogammaglobulinaemia | 106,484 | 110,024 | 126,561 | 145,497 | 180,831 | 24.3% |
| Kidney transplantation | 84,931 | 97,070 | 90,031 | 88,258 | 122,994 | 39.4% |
| Guillain–Barré syndrome | 104,360 | 108,929 | 105,567 | 124,692 | 114,184 | -8.4% |

Kidney transplantation grams dispensed falls into the top ten medical conditions in 2016-17, replacing specific antibody deficiency. NSW, Victoria (VIC) and QLD all showed an increase in dispenses of Ig for kidney transplantation in 2016-17 (Table 11). In 2016-17 grams per patient ranged from 112 grams in SA, 110 grams in NT and 128 grams in NSW to 321 grams in QLD and 428 grams in TAS.

Table 11 Difference each year in grams issued for kidney transplantation (percentage)

|  | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 |
| --- | --- | --- | --- | --- | --- |
| NSW | 24% | -8% | -11% | -13% | 43% |
| VIC | -5% | 28% | 4% | -3% | 45% |
| QLD | 71% | -12% | 1% | -15% | 46% |
| SA | 34% | 23% | -57% | 66% | -2% |
| WA | 122% | 7% | -44% | 24% | 20% |
| TAS | -23% | 196% | -15% | 28% | 22% |
| NT | 99% | -19% | -98% | 2980% | -61% |
| ACT | 450% | 395% | -88% | 268% | -63% |
| **Total** | **18%** | **14%** | **-7%** | **-2%** | **39%** |

The top ten medical conditions by state and territory by proportion of all conditions are depicted in Figure 9.

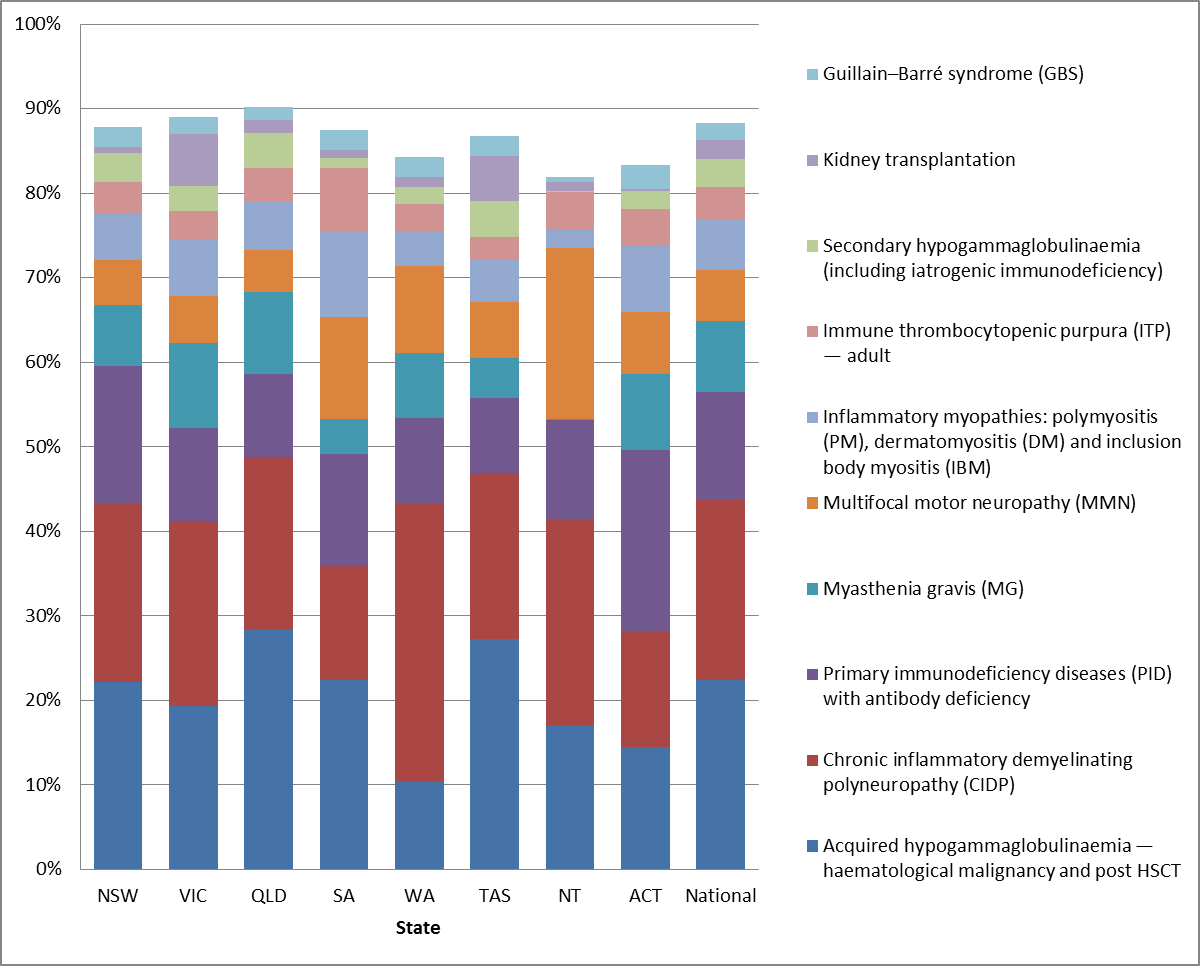
**

Figure 9 Proportion of Ig used for top 10 medical conditions

## Ig issues by specific condition

The top twenty specific conditions account for 89% of all Ig supplied, with the top ten specific conditions accounting for 75%.

Population based data on Ig issues maybe particularly interesting for specific conditions where the majority of patients receive Ig as it may provide an estimation of disease prevalence.

Table 12 provides an overview of the specific conditions that use the most Ig by private and public dispensing facilities, including data on total Ig use, patient numbers and average age.

Table 12 Patient numbers and age for the top 20 specific conditions by private and public facilities

|  | Private | | | Public | | | Total | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Specific Conditions (Top 20) | Ig  g (% of total) | Patients  n (% of total) | Average Age | Ig  g (% of total) | Patients  n (% of total) | Average Age | Ig  g (% of total) | Patients  n (% of total) | Average Age |
| Chronic inflammatory demyelinating polyneuropathy | 418,305 (8%) | 920 (2%) | 64 | 753,276 (14%) | 1,553 (4%) | 62 | 1,171,581 (21%) | 2,379 (6%) | 63 |
| Common variable immunodeficiency disease | 158,688 (3%) | 535 (4%) | 57 | 459,940 (8%) | 1,346 (4%) | 49 | 618,627 (11%) | 1,808 (8%) | 51 |
| Myasthenia gravis | 157,223 (3%) | 384 (5%) | 62 | 299,123 (5%) | 753 (4%) | 60 | 456,346 (8%) | 1,090 (8%) | 61 |
| Chronic lymphocytic leukaemia | 184,966 (3%) | 784 (1%) | 73 | 198,161 (4%) | 801 (2%) | 71 | 383,127 (7%) | 1,526 (3%) | 72 |
| Non-Hodgkin lymphoma | 210,297 (4%) | 850 (4%) | 69 | 162,778 (3%) | 675 (4%) | 65 | 373,074 (7%) | 1,483 (7%) | 67 |
| Multifocal motor neuropathy | 96,589 (2%) | 175 (1%) | 59 | 234,553 (4%) | 366 (2%) | 58 | 331,142 (6%) | 527 (2%) | 58 |
| Multiple myeloma | 165,469 (3%) | 687 (2%) | 71 | 138,975 (3%) | 666 (3%) | 68 | 304,444 (6%) | 1,302 (4%) | 70 |
| Polymyositis | 51,506 (1%) | 127 (0%) | 62 | 131,379 (2%) | 332 (2%) | 60 | 182,885 (3%) | 446 (2%) | 61 |
| Secondary hypogammaglobulinaemia | 74,824 (1%) | 302 (1%) | 60 | 106,008 (2%) | 514 (3%) | 51 | 180,831 (3%) | 781 (4%) | 55 |
| Kidney transplantation post-transplant | 10,068 (0%) | 34 (1%) | 50 | 107,497 (2%) | 421 (2%) | 47 | 117,564 (2%) | 442 (3%) | 47 |
| Guillain–Barré syndrome | 27,347 (0%) | 173 (0%) | 57 | 86,837 (2%) | 528 (1%) | 52 | 114,184 (2%) | 690 (1%) | 54 |
| Other relevant haematological malignancies | 55,810 (1%) | 231 (1%) | 66 | 54,904 (1%) | 348 (1%) | 49 | 110,714 (2%) | 555 (2%) | 56 |
| Dermatomyositis | 18,447 (0%) | 51 (1%) | 61 | 64,001 (1%) | 176 (2%) | 47 | 82,448 (2%) | 218 (3%) | 50 |
| Specific antibody deficiency | 25,865 (0%) | 96 (0%) | 59 | 54,886 (1%) | 216 (1%) | 47 | 80,751 (1%) | 301 (2%) | 51 |
| ITP refractory acute | 24,493 (0%) | 158 (1%) | 63 | 51,156 (1%) | 332 (2%) | 59 | 75,648 (1%) | 482 (2%) | 60 |
| Limbic encephalitis, nonparaneoplastic | 16,129 (0%) | 67 (0%) | 51 | 50,316 (1%) | 215 (1%) | 46 | 66,445 (1%) | 279 (1%) | 47 |
| ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP) | 23,648 (0%) | 124 (0%) | 65 | 40,221 (1%) | 278 (2%) | 59 | 63,868 (1%) | 396 (2%) | 61 |
| Inclusion body myositis | 22,543 (0%) | 58 (1%) | 68 | 41,307 (1%) | 99 (2%) | 71 | 63,850 (1%) | 152 (2%) | 70 |
| Post-haemopoietic stem cell transplantation | 18,900 (0%) | 90 (0%) | 53 | 38,147 (1%) | 299 (1%) | 39 | 57,046 (1%) | 375 (1%) | 42 |
| ITP with life-threatening haemorrhage | 15,861 (0%) | 102 (0%) | 64 | 39,851 (1%) | 294 (0%) | 56 | 55,712 (1%) | 395 (0%) | 58 |

## Ig issues by clinical speciality

The number of grams of Ig issued categorised according to clinical speciality is shown in Figure 10 and Table 13. Some specific conditions prior to 2016-17 were classified as mixed, in that they fell across more than one clinical speciality. Other specific conditions fall within a clinical speciality other than neurology, haematology or immunology, such as use in transplant or dermatology. These are considered under ‘Other’ in Figure 10.

Since 2012-13, there has been a 1.6 fold increase in Ig issues for neurological conditions, compared with a 1.5 fold increase for both haematological conditions and immunological conditions.

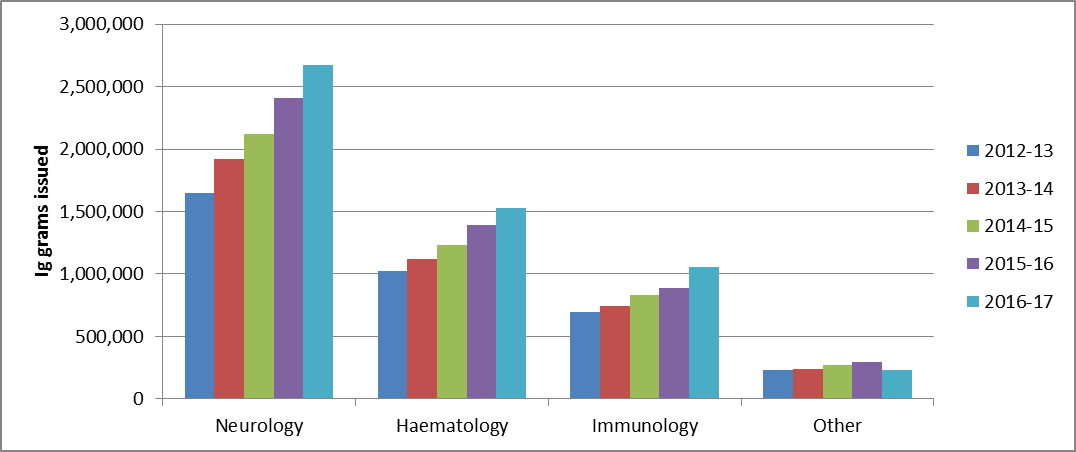


Figure 10 Ig issues by clinical speciality

Table 13 Ig grams issued by clinical speciality

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 |
| Neurology | 1,649,358 | 1,916,792 | 2,120,111 | 2,407,995 | 2,672,261 |
| Haematology | 1,026,177 | 1,116,037 | 1,234,816 | 1,390,824 | 1,530,340 |
| Immunology | 695,298 | 746,828 | 828,735 | 885,933 | 1,053,712 |
| Other | 228,947 | 241,386 | 274,664 | 291,643 | 231,199 |

There is significant variation across Australia in Ig use for each clinical speciality (as allocated). Figure 11 shows that in WA issues for neurological conditions represent a greater proportion of total issues than for other states, and haematological conditions are less than other states and territories. The reason for this inter-state and territory variation is unknown, but it may represent differences in clinical practice, differing disease profiles in the patient populations, variable access to alternative therapies or differences due to the availability of specialist services across Australia.



Figure 11 Percentage Ig issues by clinical speciality for top 10 medical conditions

## Ig grams issued per 1,000 population

The amount of Ig issued per 1,000 population for each specific condition varies between state and territory. Complete data for specific conditions by state and territory can be found at **Appendix D**. Table 14 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.

Of the top 10 specific conditions the highest variation between the five largest states and territories in Ig use per 1,000 population is seen in multiple myeloma and kidney transplantation pre-transplant. In total, for the five largest states, there was proportionally low Ig issues per 1,000 population in SA and WA, and proportionally high in QLD. The reason for the significant variation between these states is unknown, and further studies may be required to ascertain the significance of this finding.

Table 14 Grams of Ig issued by state and territory

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Ig issued (g) | Proportion of total Ig issued | Proportion of Australian population | Grams per 1,000 population |
| NSW | 1,972,128 | 35.6% | 32.0% | 253 |
| VIC | 1,212,905 | 21.9% | 25.6% | 194 |
| QLD | 1,461,086 | 26.4% | 20.0% | 299 |
| SA | 297,931 | 5.4% | 7.0% | 173 |
| WA | 367,345 | 6.6% | 10.5% | 143 |
| TAS | 105,681 | 1.9% | 2.1% | 203 |
| NT | 25,420 | 0.5% | 1.0% | 103 |
| ACT | 100,015 | 1.8% | 1.7% | 246 |
| **Total** | **5,542,511** | **100%** | **100%** | **227** |

Table 15 shows the top 10 specific conditions by the Ig grams issued per 1,000 population by state and territory. The fold variation in Table 15 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 in Ig use. 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.

Table 15 Grams of Ig issued per 1,000 population by state/territory for top 10 specific conditions

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Specific Condition | NSW | VIC | QLD | SA | WA | TAS | NT | ACT | AUS | Fold Variation |
| Chronic inflammatory demyelinating polyneuropathy | 54 | 42 | 61 | 23 | 45 | 40 | 24 | 33 | 48 | 2.7 |
| Common variable immunodeficiency disease | 38 | 16 | 26 | 19 | 12 | 17 | 6 | 50 | 25 | 3.1 |
| Myasthenia gravis | 19 | 12 | 21 | 13 | 6 | 13 | 10 | 19 | 16 | 3.8 |
| Chronic lymphocytic leukaemia | 18 | 19 | 29 | 7 | 11 | 10 | 0 | 22 | 19 | 4.2 |
| Non-Hodgkin lymphoma | 14 | 11 | 31 | 12 | 4 | 18 | 4 | 9 | 15 | 7.7 |
| Multifocal motor neuropathy | 13 | 10 | 15 | 20 | 14 | 14 | 20 | 18 | 14 | 1.9 |
| Multiple myeloma | 15 | 9 | 21 | 7 | 3 | 18 | 1 | 4 | 12 | 8.5 |
| Polymyositis | 8 | 6 | 10 | 10 | 3 | 4 | 2 | 8 | 8 | 3.1 |
| Secondary hypogammaglobulinaemia | 9 | 6 | 12 | 2 | 3 | 9 | 0 | 5 | 7 | 6.4 |
| Kidney transplantation post-transplant | 1 | 12 | 4 | 1 | 1 | 10 | 1 | 1 | 5 | 7.9 |

# Dosing



Figure 12 Grams per episode by specific condition

Figure 12 shows that there is significant variance in the dosing of the top 10 specific conditions by grams per episode, where dosing is calculated as number of grams administered in each episode. The definition of an episode in the data is not uniform and therefore this data should be interpreted with caution. Variations are expected as the dose (g/kg) and frequency of dose also varies. Also note that the Criteria requires the lowest possible dose to achieve the desired clinical outcome, so the dose is not ‘mandated’ but rather suggested and guided to the lower end to achieve efficacy which may contribute to the differences in dosing between conditions.

Dosing in neurological conditions is higher than for haematological and immunological 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 dispense event (Figure 13 and Table 16). 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 or present for every dispense event (particularly for those recorded in STARS and transitioned to BloodSTAR) and may change over time.



Figure 13 Grams per kg weight by specific condition

Table 16 Ig grams per kg weight per episode

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Specific 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(%) | Ig  Average g/kg/  episode |
| Chronic inflammatory demyelinating polyneuropathy | 7,282 (25%) | 12,571 (43%) | 1,194 (4%) | 120 (0%) | 8,139 (28%) | | 0.51 |
| Common variable immunodeficiency disease | 6,518 (30%) | 7,304 (34%) | 73 (0%) | 7 (0%) | 7,731 (36%) | | 0.41 |
| Myasthenia gravis | 3,462 (28%) | 5,341 (43%) | 295 (2%) | 36 (0%) | 3,253 (26%) | | 0.47 |
| Chronic lymphocytic leukaemia | 5,733 (40%) | 4,721 (33%) | 4 (0%) | 0 (0%) | 3,731 (26%) | | 0.38 |
| Non-Hodgkin lymphoma | 5,830 (41%) | 4,245 (30%) | 18 (0%) | 4 (0%) | 4,172 (29%) | | 0.37 |
| Multifocal motor neuropathy | 1,283 (18%) | 3,473 (47%) | 549 (8%) | 18 (0%) | 1,985 (27%) | | 0.59 |
| Multiple myeloma | 4,645 (41%) | 3,719 (33%) | 2 (0%) | 1 (0%) | 2,939 (26%) | | 0.37 |
| Polymyositis | 1,097 (23%) | 2,205 (46%) | 222 (5%) | 9 (0%) | 1,256 (26%) | | 0.50 |
| Secondary hypogammaglobulinaemia | 2,729 (37%) | 2,650 (36%) | 50 (1%) | 5 (0%) | 1,948 (26%) | | 0.39 |
| Kidney transplantation post-transplant | 1,324 (37%) | 1,349 (38%) | 444 (13%) | 58 (2%) | 376 (11%) | | 0.56 |

Note: n is the number of Treatment Episodes

# IVIg and SCIg

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. In 2015-16 the NBA established arrangements for supply of the following SCIg products:

* Evogam 16% 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (Australia) Pty Ltd (domestic)
* Gammanorm 16% 1650mg/10ml and 3300mg/20ml supplied by Octapharma Australia Pty Ltd (imported)
* Hizentra 5% 1g/5ml, 2g/10ml, 4g/20ml and 10g/50ml supplied by CSL Behring (Australia) Pty Ltd (imported)

In addition to the clinical and diagnostic criteria for access to immunoglobulin products, access to SCIg products is provided through an assurance framework for the appropriate use of the product. The first phase of implementation was through hospital-based management arrangements. SCIg access rules are detailed on the NBA website at <https://www.blood.gov.au/SCIg>. Participation in the National SCIg program requires hospitals to establish their capability and capacity to manage a hospital-based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the product within defined governing requirements. Further work will be undertaken to support supply of SCIg for other pathways of care.

The medical conditions that SCIg can be used for are:

* primary immunodeficiency diseases with antibody deficiency
* specific antibody deficiency
* acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
* secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)

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

Tables 17-19 show the patient numbers, grams issued and treatment episodes, by state and territory for IVIg and SCIg products in 2016-17. Tables 20-22 show patient numbers, grams issued and treatment episodes by medical conditions for IVIg and SCIg products in 2016-17.

Table 17 Patient numbers for products issued by state and territory in 2016-17

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | | **SCIg** | | |  |
| **State** | **Flebogamma 5 percent** | **Flebogamma 10 percent** | **Intragam P** | **Intragam 10** | **Kiovig 10 percent** | **Octagam 5 percent** | **Octagam 10 percent** | **Privigen 10 per cent** | **SCIg Evogam** | **SCIg Gammanorm** | **SCIg Hizentra** | **Total** |
| NSW | 501 | 707 | 3,494 | 2,420 | 75 | 95 | 81 | 1,515 | 80 | 7 | 118 | **6,627** |
| VIC | 112 | 400 | 2,361 | 568 | 38 | 25 | 16 | 992 | 56 | 0 | 10 | **4,134** |
| QLD | 250 | 345 | 2,288 | 443 | 37 | 15 | 24 | 1,295 | 58 | 0 | 63 | **4,428** |
| SA | 10 | 103 | 634 | 205 | 22 | 0 | 0 | 161 | 29 | 0 | 18 | **1,043** |
| WA | 39 | 132 | 572 | 130 | <5 | 0 | <5 | 276 | 21 | 0 | 31 | **1,115** |
| TAS | 8 | 43 | 163 | 35 | 0 | 0 | 7 | 100 | <5 | 0 | 8 | **339** |
| NT | 0 | <5 | 33 | 13 | 0 | 0 | 0 | 42 | 0 | 0 | 0 | **83** |
| ACT | <5 | 6 | 170 | 48 | 0 | 0 | 0 | 84 | <5 | <5 | 18 | **308** |
| **AUS** | **915** | **1,732** | **9,652** | **3,854** | **173** | **135** | **128** | **4,444** | **246** | **10** | **260** | **17,958** |

Note: The national patient count only includes one count for each patient. This may result in the sum of the state and territory totals being greater than the national total. In addition, each patient may have received multiple products, meaning the total number of patients for each state/territory may not match the total of the patient counts for each product.

Table 18 Grams of product issued by state and territory in 2016-17

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | | **SCIg** | | |  |
| **State** | **Flebogamma 5 percent** | **Flebogamma 10 percent** | **Intragam P** | **Intragam 10** | **Kiovig 10 percent** | **Octagam 5 percent** | **Octagam 10 percent** | **Privigen 10 per cent** | **SCIg Evogam** | **SCIg Gammanorm** | **SCIg Hizentra** | **Total** |
| NSW | 153,229 | 217,040.00 | 850,740 | 185,550 | 4,619 | 3,764 | 4,529 | 499,990 | 23,687 | 267 | 38,275 | **1,981,690** |
| VIC | 39,311 | 96,465.00 | 520,668 | 188,738 | 3,160 | 1,459 | 1,175 | 324,010 | 7,755 | 0 | 2,669 | **1,185,409** |
| QLD | 70,492 | 89,075.00 | 572,562 | 227,238 | 1,448 | 780 | 1,050 | 446,590 | 18,275 | 0 | 21,877 | **1,449,386** |
| SA | 2,945 | 33,390.00 | 129,435 | 43,080 | 1,985 | 0 | 0 | 63,440 | 4,610 | 0 | 8,506 | **287,391** |
| SA | 15,091 | 37,745.00 | 128,613 | 49,360 | 80 | 0 | 30 | 112,785 | 5,336 | 0 | 4,131 | **353,171** |
| TAS | 2,751 | 14,030.00 | 40,929 | 14,860 | 0 | 0 | 284 | 31,020 | 216 | 0 | 2,332 | **106,422** |
| NT | 0 | 625.00 | 4,452 | 1,788 | 0 | 0 | 0 | 16,980 | 307 | 0 | 0 | **24,152** |
| ACT | 33 | 2,780.00 | 41,544 | 12,328 | 0 | 0 | 0 | 38,480 | 318 | 40 | 4,062 | **99,583** |
| **AUS** | **283,850** | **491,150.00** | **2,288,943** | **722,940** | **11,291** | **6,003** | **7,068** | **1,533,295** | **60,505** | **307** | **81,852** | **5,487,204** |

Note: The use of 307 grams of NHIg for one patient is not included in the above table.

Table 19 Treatment episode numbers for products issued by state and territory in 2016-17

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | | **SCIg** | | |  |
| **State** | **Flebogamma 5 percent** | **Flebogamma 10 percent** | **Intragam P** | **Intragam 10** | **Kiovig 10 percent** | **Octagam 5 percent** | **Octagam 10 percent** | **Privigen 10 per cent** | **SCIg Evogam** | **SCIg Gammanorm** | **SCIg Hizentra** | **Total** |
| NSW | 4,383 | 5,423 | 26,856 | 5,862 | 122 | 115 | 120 | 12,357 | 4,198 | 50 | 3,998 | **63,484** |
| VIC | 1,142 | 2,481 | 17,173 | 6,503 | 69 | 38 | 25 | 8,400 | 880 | 0 | 237 | **36,948** |
| QLD | 2,658 | 2,630 | 21,584 | 8,504 | 56 | 26 | 32 | 14,173 | 861 | 0 | 951 | **51,475** |
| SA | 89 | 881 | 4,509 | 1,488 | 42 | 0 | 0 | 1,569 | 418 | 0 | 703 | **9,699** |
| WA | 441 | 942 | 4,250 | 1,726 | <5 | 0 | <5 | 2,615 | 446 | 0 | 593 | **11,016** |
| TAS | 100 | 363 | 1,511 | 536 | 0 | 0 | 7 | 839 | 12 | 0 | 159 | **3,527** |
| NT | 0 | 22 | 136 | 62 | 0 | 0 | 0 | 325 | 5 | 0 | 0 | **550** |
| ACT | <5 | 65 | 1,514 | 453 | 0 | 0 | 0 | 875 | 42 | 6 | 342 | **3,298** |
| **AUS** | **8,814** | **12,807** | **77,533** | **25,124** | **291** | **179** | **185** | **41,153** | **6,862** | **56** | **6,983** | **179,997** |

Table 20 Patient numbers for products issued by medical condition in 2016-17

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | | **SCIg** | | |  |
| **Medical Condition** | **Flebogamma 5 percent** | **Flebogamma 10 percent** | **Intragam P** | **Intragam 10** | **Kiovig 10 percent** | **Octagam 5 percent** | **Octagam 10 percent** | **Privigen 10 per cent** | **SCIg Evogam** | **SCIg Gammanorm** | **SCIg Hizentra** | **Total** |
| Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 48 | 61 | 4,126 | 1,889 | 22 | 9 | 23 | 346 | 31 | <5 | 43 | **5,217** |
| Primary immunodeficiency diseases (PID) with antibody deficiency | 28 | 41 | 1,656 | 633 | 5 | 5 | 7 | 91 | 162 | 9 | 160 | **2,120** |
| Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | 27 | 18 | 546 | 260 | <5 | <5 | <5 | 67 | 29 | 0 | 30 | **754** |
| Specific antibody deficiency (SAD) | 7 | 5 | 270 | 88 | 0 | <5 | 0 | 7 | 24 | 0 | 28 | **343** |

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

Table 21 Grams of product issued by medical condition in 2016-17

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | | **SCIg** | | |  |
| **Medical Condition** | **Flebogamma 5 percent** | **Flebogamma 10 percent** | **Intragam P** | **Intragam 10** | **Kiovig 10 percent** | **Octagam 5 percent** | **Octagam 10 percent** | **Privigen 10 per cent** | **SCIg Evogam** | **SCIg Gammanorm** | **SCIg Hizentra** | **Total** |
| Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 11,752 | 12,830 | 814,995 | 267,118 | 819 | 269 | 677 | 97,700 | 6,241.6 | 7 | 15,999 | **1,228,405** |
| Primary immunodeficiency diseases (PID) with antibody deficiency | 5,727 | 6,910 | 439,440 | 123,033 | 378 | 178 | 427 | 23,380 | 45,365 | 300 | 56,410 | **701,547** |
| Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | 7,086 | 4,940 | 106,029 | 35,243 | 65 | 110 | 95 | 20,035 | 3,999.2 | 0 | 3,230 | **180,831** |
| Specific antibody deficiency (SAD) | 1,480 | 645 | 62,889 | 18,335 | 0 | 28 | 0 | 2,170 | 4,899.2 | 0 | 6,069 | **96,515** |

Table 22 Treatment episodes for product issued by medical condition in 2016-17

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | | **SCIg** | | |  |
| **Medical Condition** | **Flebogamma 5 percent** | **Flebogamma 10 percent** | **Intragam P** | **Intragam 10** | **Kiovig 10 percent** | **Octagam 5 percent** | **Octagam 10 percent** | **Privigen 10 per cent** | **SCIg Evogam** | **SCIg Gammanorm** | **SCIg Hizentra** | **Total** |
| Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 438 | 468 | 30,526 | 10,188 | 32 | 9 | 26 | 3,841 | 425 | <5 | 1,389 | **47,319** |
| Primary immunodeficiency diseases (PID) with antibody deficiency | 250 | 260 | 16,127 | 4,634 | 10 | 5 | 11 | 719 | 5,482 | 55 | 4,655 | **32,203** |
| Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | 332 | 207 | 4,235 | 1,507 | <5 | 5 | <5 | 797 | 351 | 0 | 278 | **7,719** |
| Specific antibody deficiency (SAD) | 55 | 23 | 2,594 | 793 | 0 | <5 | 0 | 102 | 604 | 0 | 643 | **4,815** |

# NHIg

In 2013–14, as a result of the introduction of SCIg as discussed above, demand for NHIg reduced significantly by 18.8%. CSL Behring (Australia) Pty Ltd produces NHIg from hyperimmune plasma specially collected by the Blood Service. The volume of product is limited by the availability of this specialised plasma, and by production scheduling arrangements in CSL Behring (Australia) Pty Ltd’s manufacturing facility.

Demand for NHIg further declined in 2014-15 by 78% as a result of implementation of the NHIg policy outlining the national position on access and use under the national blood arrangements.

NHIg may only be supplied for two purposes; for the treatment of susceptible contacts of measles, hepatitis A, poliomyelitis and rubella, as directed by public health officials; and for the treatment of immunodeficiency conditions for which the product is indicated for patients for whom IVIg and SCIg are both contraindicated. NHIg access rules are detailed on the NBA website at <https://www.blood.gov.au/NHIg>.

Tables 23-25 and Figure 14 show the grams issued and the grams issued per 1,000 population by states and territories for either purpose listed above.

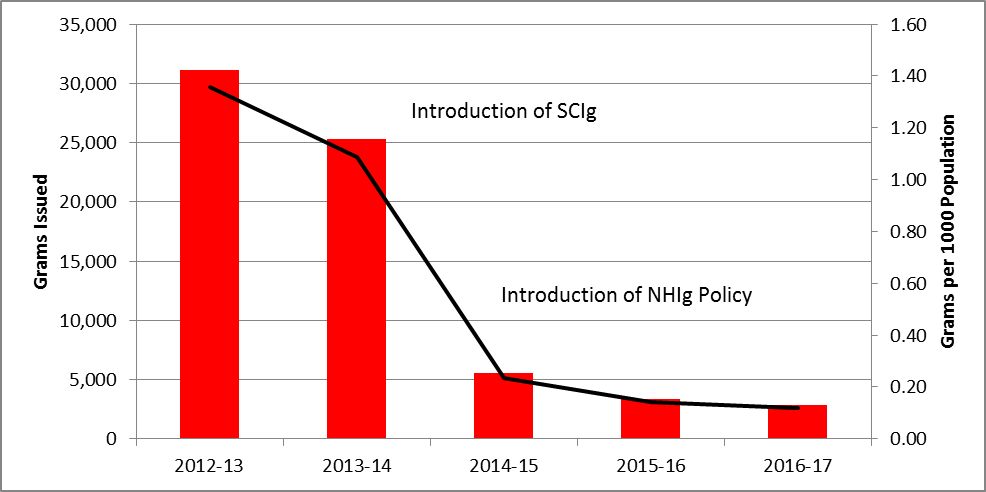


Figure 14 NHIg grams issued and grams issued per 1,000 population

Table 23 NHIg issued from 2012-13 to 2016-17

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **2012-13** | **2013-14** | **2014-15** | **2015-16** | **2016-17** |
| Normal Immunoglobulin 2VI - 2ml (grams) | 699 | 654 | 167 | 112 | 43 |
| Normal Immunoglobulin 2VI - 5ml (grams) | 30,466 | 24,649 | 5,409 | 3,254 | 2,806 |
| **Total (grams)** | **31,165** | **25,303** | **5,576** | **3,366** | **2,849** |
| **Grams Per 1,000 Population** | 1.36 | 1.09 | 0.24 | 0.14 | 0.12 |

Table 24 Grams of NHIg issued by state and territory

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **2012-13** | **2013-14** | **2014-15** | **2015-16** | **2016-17** |
| NSW | 9,634 | 6,915 | 82 | 238 | 351 |
| VIC | 6,903 | 6,747 | 2,278 | 489 | 411 |
| QLD | 1,640 | 2,774 | 1,472 | 1,134 | 401 |
| SA | 6,543 | 4,431 | 936 | 980 | 1,164 |
| WA | 5,261 | 3,458 | 59 | 38 | 48 |
| TAS | 344 | 272 | 154 | 43 | 35 |
| NT | 24 | 191 | 35 | 12 | 15 |
| ACT | 816 | 514 | 480 | 432 | 424 |
| OTHER[[7]](#footnote-8) | 0 | 0 | 80 | 0 | 0 |
| **Australia** | **31,1655** | **25,302** | **5,576** | **3,366** | **2,849** |

Table 25 Grams per 1,000 population of NHIg issued by state and territory

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Per 1,000 Population** | **2012-13** | **2013-14** | **2014-15** | **2015-16** | **2016-17** |
| NSW | 1.31 | 0.93 | 0.01 | 0.03 | 0.05 |
| VIC | 1.21 | 1.16 | 0.38 | 0.08 | 0.07 |
| QLD | 0.36 | 0.59 | 0.31 | 0.24 | 0.08 |
| SA | 3.93 | 2.64 | 0.55 | 0.57 | 0.68 |
| WA | 2.14 | 1.38 | 0.02 | 0.01 | 0.02 |
| *TAS* | 0.67 | 0.53 | 0.30 | 0.08 | 0.07 |
| NT | 0.10 | 0.79 | 0.14 | 0.05 | 0.06 |
| ACT | 2.15 | 1.33 | 1.22 | 1.08 | 1.04 |
| **Australia** | **1.36** | **1.09** | **0.24** | **0.14** | **0.12** |

# Appendix A – Background

Securing supply of Immunoglobulin

Immunoglobulin (Ig) is made from donated human plasma. The supply of Australian donated human plasma is sourced from the Australian Red Cross Blood Service (Blood Service) and sent to CSL Behring Ltd to manufacture domestic Ig. The NBA has contractual arrangements with both the Blood Service and CSL Behring Ltd for these services. In accordance with government policy, the NBA also maintains contractual arrangements with international suppliers to ensure sufficient supply to meet Australian clinical demand within the context of a finite international supply.

The following table shows the domestic and imported products supplied under NBA arrangements (including IgG concentration and method of administration) by financial year.

|  |  |  |
| --- | --- | --- |
| Year | Domestic products supplied | Supplier |
| 2003-04 to 2012-13 | Intragam P (6% intravenous)  Normal Human Immunoglobulin (intramuscular1) | CSL Behring |
| 2013-14 to 2016-17 | Intragam P (6% intravenous)  Evogam (16.5% subcutaneous)  Normal Human Immunoglobulin (intramuscular1) | CSL Behring |

| Year | Imported products supplied | Supplier |
| --- | --- | --- |
| 2004-05  to  2009-10 | Sandoglobulin (intravenous)  Octagam (5% intravenous) | CSL Behring  Octapharma |
| 2010-11 | Sandoglobulin (intravenous)  Octagam (5% intravenous)  Flebogamma (5% intravenous) | CSL Behring  Octapharma  Lateral Grifols |
| 2011-12  to  2012-13 | Octagam (5% intravenous)  Flebogamma (5% intravenous)  Kiovig (10% intravenous2) | Octapharma  Grifols  Baxter Healthcare |
| 2013-14  to  2014-15 | Octagam (5% intravenous)  Gammanorm (16% subcutaneous)  Flebogamma (5% intravenous)  Kiovig (10% intravenous2) | Octapharma  Grifols  Baxter Healthcare |
| 2015-16 | Octagam (5% intravenous)  Gammanorm (16% subcutaneous)  Kiovig (10% intravenous2)  Flebogamma (5% and 10% intravenous)  Privigen (10% intravenous)  Hizentra (20% SCIg) | Octapharma  Baxter Healthcare  Grifols  CSL Behring |
| 2016-17 | Flebogamma (5% and 10% intravenous)  Privigen (10% intravenous)  Hizentra (20% subcutaneous) | Grifols  CSL Behring |
| Notes  1. The TGA approved Product Information for normal human immunoglobulin provides for intramuscular infusion, but the product is also infused by subcutaneous infusion in some cases.  2. The TGA approved Product Information for these IVIg products provides for subcutaneous infusion as well as intravenous infusion, but the products were supplied under NBA arrangements for intravenous purposes only. | | |

In addition to contracting for supply of domestic and imported Ig products, the NBA undertakes annual national supply planning in conjunction with all Australian governments, and continuously monitors demand against approved supply plans. The NBA also undertakes national supply risk assessments and applies staged supply risk management actions as necessary, including under the National Blood Supply Contingency Plan agreed by all Australian governments.

Criteria to access to Ig under the national blood arrangements

The *Criteria for the Clinical Use of Immunoglobulin in Australia* (the Criteria) was approved by Health Ministers in December 2007 together with a funding policy statement which limited access to Ig funded under the national blood arrangements only to patients who meet the criteria published in the Criteria. Under the national blood arrangements, Ig is funded 63% by the Commonwealth government, with the remaining 37% being funded by the state and territory to which the product is supplied. Patients can access the Ig outside of the Criteria but this is not funded under the national blood arrangements. Further information on how to access Ig can be found here [www.blood.gov.au/Intravenous-Ig](http://www.blood.gov.au/Intravenous-Ig) .

Access to Ig under the Criteria is based on the following principles:

* Ig products should be directed to patients who are most likely to benefit and for whom there are no safe and effective alternative treatments,
* the Criteria should be based on best available evidence, and
* access to Ig should be at the lowest effective dose.

The Criteria for the Clinical Use of Ig in Australia was updated in 2012 and 2016. The first two editions were published in hard copy with Version 2 being adapted for electronic publication in BloodSTAR. The Criteria to determine patient eligibility can be found here https://www.criteria.blood.gov.au/.

BloodSTAR

Since 2016, all authorisation requests for patient-specific access to Ig under the Criteria must be submitted through BloodSTAR.

BloodSTAR standardises and manages access to the supply of immunoglobulin products by enabling authorisation requests to be submitted electronically and work-flowed to an authoriser for assessment and approval. BloodSTAR enables collection of improved national data and enhance the ability to further develop the *Criteria* and provide an improved evidence base for practice improvement and research.

Further information on BloodSTAR is available at <https://www.blood.gov.au/bloodstar> .

The Ig Governance Program

In 2012, on behalf of all Australian Governments, the NBA commissioned a review of the adequacy of the existing intravenous Ig (IVIg) authorisation and clinical governance arrangements, with a view to recommending options for improvements to deliver Governments’ goals for the management of IVIg in particular.

The National Ig Governance Program was introduced in 2014 to achieve Governments’ objectives for Ig products funded and supplied under the national blood arrangements, namely to:

* ensure Ig product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of Government funds, in accordance with relevant national safety and quality standards for health care;
* ensure that access to Ig products is consistent with the criteria for access determined by Governments; and
* improve the capture of information of the need for, use of, and outcomes of treatment with Ig products to inform future decisions.

An integrated network of National Immunoglobulin [Governance Committees](https://www.blood.gov.au/Ig-committees) has been established, including the National Immunoglobulin Governance Advisory Committee and specialist working groups. The advice and recommendations of this committee network fundamentally informs the development, implementation and ongoing operation of the other governance program measures.

The NBA published the *Ig Governance National Policy* in November 2014 with the second edition released in July 2016 to coincide with the launch of BloodSTAR. The document describes the authorisation arrangements for access to government-funded immunoglobulin products. This includes an explanation of roles, responsibilities, authority and accountability of those involved in requesting authorisation, authorising, supplying, managing and using immunoglobulin products throughout the supply chain within health services.

*The Guidelines for Managing Blood and Blood Product Inventory* provide better practice processes that can be used by health providers to ensure risks associated with receipt, storage, collection and transport of blood and blood products are mitigated. It also identifies improvement opportunities for implementation. In 2016-17, the NBA developed Module 2 to supplement the overarching inventory management principles and support the implementation of BloodSTAR. The module aims to assist health providers in meeting the requirements of the National Policy by:

* describing how to establish and manage stock levels
* outlining the Ig product ordering models
* identifying different methods to determine ordering requirements/triggers
* providing recommendations for good practice.

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

# Appendix B – Acronyms and Glossary

Acronyms

|  |  |
| --- | --- |
| ACT | Australian Capital Territory |
| AHMAC | Australian Health Ministers’ Advisory Council |
| AHP | Australian Health Provider |
| ANCA | [Anti-neutrophil cytoplasmic antibody](http://en.wikipedia.org/wiki/Anti-neutrophil_cytoplasmic_antibody) |
| AUS | Australia |
| BloodNet | The national online ordering and inventory management system |
| BloodSTAR | Blood System for Tracking Authorisations and Reviews |
| DO | Direct Order |
| HIV | Human immunodeficiency virus |
| HSCT | Hematopoietic stem cell transplantation |
| IDMS | Integrated Data Management System |
| Ig | Immunoglobulin products including IVIg and SCIg |
| ITP | Idiopathic thrombocytopenic purpura |
| IVIg | Intravenous immunoglobulin |
| JBC | Jurisdictional Blood Committee |
| JDO | Jurisdictional Direct Order |
| NBA | National Blood Authority |
| NHIg | Normal human immunoglobulin |
| NIGAC | National Immunoglobulin Governance Advisory Committee |
| NSW | New South Wales |
| NT | Northern Territory |
| PANDAS | Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections |
| QLD | Queensland |
| SA | South Australia |
| SCIg | Subcutaneous Immunoglobulin |
| STARS | Supply Tracking Analysis Recording System |
| TAS | Tasmania |
| TGA | Therapeutic Goods Administration |
| TSS | Toxic shock syndrome |
| VIC | Victoria |
| WA | Western Australia |

Glossary of terms

| Term | Description |
| --- | --- |
| Blood products | Products manufactured from human blood |
| Blood Service | The Australian Red Cross Blood Service |
| Condition | Clinical conditions are categorised according to the quality of the available evidence and whether immunoglobulin treatment is considered beneficial.  Specific conditions (previously known as primary diagnosis) exist within a medical condition (previous known as disease category). In some instances the medical condition may be the same as the specific condition, for example – Myasthenia gravis is the specific condition and the medical condition |
| *Criteria for the clinical use of intravenous immunoglobulin in Australia (*the *Criteria)* | A document describing the conditions, indications and patient qualifying and review criteria for which Ig is funded under national blood arrangements by all Australian governments |
| 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* |
| Fractionation | A manufacturing process that separates blood plasma into specific protein fractions |
| Imprest stock | Health provider orders of product for stock that is maintained at a certain level |
| Intravenous immunoglobulin | An immunoglobulin product derived from donated human plasma that is administered intravenously |
| Jurisdiction | Any of the parties to the Australian National Blood Agreement, being the Australian Government and all state and territory governments |
| Minimum Product Inventory | The minimum inventory of Ig held by CSL Behring to meet contract obligations |
| National Blood Agreement | The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the Australian blood sector |
| National blood arrangements | Arrangements, including funding arrangements, established under the National Blood Agreement |
| National CSL Reserve | The reserve of inventory of Ig that CSL Behring manages on behalf of the NBA for contingency purposes |
| Normal immunoglobulin | An immunoglobulin product derived from human plasma that is administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection) |
| Plasma | The liquid part of the blood containing antibodies and other proteins |
| Speciality | Classification of the conditions according to the clinical speciality, previously discipline |
| Subcutaneous immunoglobulin | An immunoglobulin product derived from donated human plasma that is administered subcutaneously |
| Treatment episode | One instance or episode of a treatment plan, for example a treatment plan may be made up of 4 episodes over 4 months with an episode occurring every 4 weeks (4 treatment episodes) OR 1 dose of transfused product every two weeks for 6 months would be 13 treatment episodes |

# Appendix C – Conditions mapping table

| Specific Condition | Medical Condition | Chapter | Speciality |
| --- | --- | --- | --- |
| Chronic lymphocytic leukaemia | Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 5 | Haematology |
| Multiple myeloma | Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 5 | Haematology |
| Non-Hodgkin lymphoma | Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 5 | Haematology |
| Other relevant haematological malignancies | Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 5 | Haematology |
| Post-haemopoietic stem cell transplantation | Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT | 5 | Haematology |
| Chronic inflammatory demyelinating polyneuropathy | Chronic inflammatory demyelinating polyneuropathy (CIDP) | 5 | Neurology |
| Guillain–Barré syndrome | Guillain–Barré syndrome (GBS) | 5 | Neurology |
| ITP associated with HIV | Immune thrombocytopenic purpura (ITP) — adult | 5 | Haematology |
| ITP in pregnancy | Immune thrombocytopenic purpura (ITP) — adult | 5 | Haematology |
| ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP, concurrent risk factors) | Immune thrombocytopenic purpura (ITP) — adult | 5 | Haematology |
| ITP refractory acute | Immune thrombocytopenic purpura (ITP) — adult | 5 | Haematology |
| ITP with life-threatening haemorrhage or potential life-threatening haemorrhage | Immune thrombocytopenic purpura (ITP) — adult | 5 | Haematology |
| Dermatomyositis | Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM) | 5 | Neurology |
| Inclusion body myositis | Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM) | 5 | Neurology |
| Polymyositis | Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM) | 5 | Neurology |
| Kawasaki disease | Kawasaki disease | 5 | Immunology |
| Lambert–Eaton myasthenic syndrome | Lambert–Eaton myasthenic syndrome (LEMS) | 5 | Neurology |
| Multifocal motor neuropathy with or without persistent conduction block | Multifocal motor neuropathy (MMN) | 5 | Neurology |
| Myasthenia gravis | Myasthenia gravis (MG) | 5 | Neurology |
| Neonatal haemochromatosis | Neonatal haemochromatosis (NH) | 5 | Haematology |
| Common variable immunodeficiency disease (CVID) | Primary immunodeficiency diseases (PID) with antibody deficiency | 5 | Immunology |
| Other primary immunodeficiency | Primary immunodeficiency diseases (PID) with antibody deficiency | 5 | Immunology |
| Severe combined immunodeficiency (SCID) | Primary immunodeficiency diseases (PID) with antibody deficiency | 5 | Immunology |
| Transient hypogammaglobulinaemia of infancy | Primary immunodeficiency diseases (PID) with antibody deficiency | 5 | Immunology |
| Wiskott–Aldrich syndrome | Primary immunodeficiency diseases (PID) with antibody deficiency | 5 | Immunology |
| X-linked agammaglobulinaemia | Primary immunodeficiency diseases (PID) with antibody deficiency | 5 | Immunology |
| Stiff person syndrome | Stiff person syndrome | 5 | Neurology |
| Acute disseminated encephalomyelitis | Acute disseminated encephalomyelitis (ADEM) | 6 | Neurology |
| Churg-Strauss syndrome | ANCA-positive systemic necrotising vasculitis | 6 | Immunology |
| Microscopic polyangiitis | ANCA-positive systemic necrotising vasculitis | 6 | Immunology |
| PR3 or MPO ANCA-positive idiopathic rapidly progressive glomerulonephritis | ANCA-positive systemic necrotising vasculitis | 6 | Immunology |
| Wegener granulomatosis | ANCA-positive systemic necrotising vasculitis | 6 | Immunology |
| Autoimmune haemolytic anaemia | Autoimmune haemolytic anaemia (AIHA) | 6 | Haematology |
| Bullous pemphigoid | Bullous pemphigoid (BP) | 6 | Dermatology |
| Cicatricial pemphigoid/ mucous membrane pemphigoid | Cicatricial pemphigoid (CP) or Mucous Membrane Pemphigoid (MMP) | 6 | Dermatology |
| Evans syndrome | Evans syndrome | 6 | Haematology |
| Feto-maternal/neonatal alloimmune thrombocytopenia (Antenatal) | Feto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT) | 6 | Haematology |
| Feto-maternal/neonatal alloimmune thrombocytopenia (Neonatal) | Feto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT) | 6 | Haematology |
| Haemophagocytic syndrome | Haemophagocytic syndrome | 6 | Haematology |
| IgM para-proteinaemic neuropathy | IgM paraproteinaemic demyelinating neuropathy | 6 | Neurology |
| ITP in children | Immune thrombocytopenic purpura (ITP) — in children 15 years and younger | 6 | Haematology |
| Kidney transplantation post-transplant | Kidney transplantation | 6 | Nephrology |
| Kidney transplantation pre-transplant | Kidney transplantation | 6 | Nephrology |
| Multiple sclerosis - severe relapse with no response to high dose methylprednisolone | Multiple sclerosis (MS) | 6 | Neurology |
| Multiple sclerosis in pregnancy and the immediate post-partum period | Multiple sclerosis (MS) | 6 | Neurology |
| Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed | Multiple sclerosis (MS) | 6 | Neurology |
| Opsoclonus myoclonus ataxia | Opsoclonus-myoclonus ataxia (OMA) | 6 | Neurology |
| Pemphigus foliaceus | Pemphigus foliaceus (PF) | 6 | Dermatology |
| Pemphigus vulgaris | Pemphigus vulgaris (PV) | 6 | Dermatology |
| Post-transfusion purpura | Post-transfusion purpura (PTP) | 6 | Haematology |
| Secondary hypogammaglobulinaemia (excluding haematological malignancies) | Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | 6 | Immunology |
| Solid organ - heart | Solid organ transplantation (other than kidney) | 6 | Transplant Medicine |
| Solid organ - heart/lung | Solid organ transplantation (other than kidney) | 6 | Transplant Medicine |
| Solid organ - liver | Solid organ transplantation (other than kidney) | 6 | Transplant Medicine |
| Solid organ - lung | Solid organ transplantation (other than kidney) | 6 | Transplant Medicine |
| Solid organ - other | Solid organ transplantation (other than kidney) | 6 | Transplant Medicine |
| IgG subclass deficiency (existing authorisation) | Specific antibody deficiency (SAD) | 6 | Immunology |
| Specific antibody deficiency | Specific antibody deficiency (SAD) | 6 | Immunology |
| Toxic epidermal necrolysis/Stevens–Johnson syndrome | Toxic epidermal necrolysis (TEN)/ Stevens–Johnson syndrome (SJS) | 6 | Dermatology |
| Staphylococcal TSS | Toxic shock syndrome (TSS) | 6 | Immunology |
| Streptococcal TSS | Toxic shock syndrome (TSS) | 6 | Immunology |
| Acute leukaemia in children | Acute leukaemia in children | 7 | Haematology |
| Autoimmune congenital heart block | Autoimmune congenital heart block (neonatal lupus) | 7 | Immunology |
| Autoimmune neutropenia | Autoimmune neutropenia | 7 | Immunology |
| Autoimmune uveitis | Autoimmune uveitis | 7 | Immunology |
| Catastrophic antiphospholipid syndrome | Catastrophic antiphospholipid syndrome | 7 | Immunology |
| Acquired haemophilia | Coagulation factor inhibitors | 7 | Haematology |
| Acquired von Willebrand syndrome | Coagulation factor inhibitors | 7 | Haematology |
| Coagulation factor inhibitors | Coagulation factor inhibitors | 7 | Haematology |
| Inhibitors to factor IX in haemophilia B | Coagulation factor inhibitors | 7 | Haematology |
| Inhibitors to factor VIII in haemophilia A | Coagulation factor inhibitors | 7 | Haematology |
| Devic disease (neuromyelitis optica) | Devic disease (neuromyelitis optica) | 7 | Neurology |
| Diabetic amyotrophy | Diabetic amyotrophy | 7 | Neurology |
| Diabetic lumbosacral radiculoplexus neuropathy | Diabetic amyotrophy | 7 | Neurology |
| Epidermolysis bullosa acquisita | Epidermolysis bullosa acquisita | 7 | Dermatology |
| Epilepsy (rare childhood cases) | Epilepsy | 7 | Neurology |
| Graves ophthalmopathy | Graves ophthalmopathy | 7 | Neurology |
| Haemolytic disease of the newborn | Haemolytic disease of the newborn (HDN) | 7 | Haematology |
| Haemolytic transfusion reaction | Haemolytic transfusion reaction | 7 | Haematology |
| Hashimoto encephalopathy | Hashimoto encephalopathy | 7 | Neurology |
| HIV in children | HIV in children | 7 | Immunology |
| Limbic encephalitis, nonparaneoplastic | Limbic encephalitis — nonparaneoplastic | 7 | Neurology |
| Myocarditis in children | Myocarditis in children | 7 | Immunology |
| PANDAS/tic disorders | Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infection (PANDAS) | 7 | Neurology |
| Cerebellar degeneration | Paraneoplastic neurological syndromes | 7 | Neurology |
| Limbic encephalitis | Paraneoplastic neurological syndromes | 7 | Neurology |
| Subacute sensory neuropathy | Paraneoplastic neurological syndromes | 7 | Neurology |
| Potassium channel antibody-associated encephalopathy | Potassium channel antibody-associated encephalopathy | 7 | Neurology |
| Pure red cell aplasia | Pure red cell aplasia (PRCA) | 7 | Haematology |
| Pure white cell aplasia | Pure white cell aplasia (PWCA) | 7 | Haematology |
| Pyoderma gangrenosum | Pyoderma gangrenosum | 7 | Dermatology |
| Rasmussen syndrome | Rasmussen syndrome | 7 | Neurology |
| Scleromyxedema | Scleromyxedema | 7 | Neurology |
| Sjögren’s syndrome | Sjögren’s syndrome | 7 | Immunology |
| Susac syndrome | Susac syndrome | 7 | Immunology |
| Systemic capillary leak syndrome | Systemic capillary leak syndrome (SCLS) | 7 | Haematology |
| Acute optic neuritis | Acute optic neuritis | 8 | Immunology |
| Acute rheumatic fever | Acute rheumatic fever | 8 | Immunology |
| Adrenoleukodystrophy | Adrenoleukodystrophy | 8 | Neurology |
| Amegakaryocytic thrombocytopenia | Amegakaryocytic thrombocytopenia | 8 | Haematology |
| Antiphospholipid syndrome (non-obstetric) | Antiphospholipid syndrome (non-obstetric) | 8 | Haematology |
| Aplastic anaemia/pancytopenia | Aplastic anaemia/pancytopenia | 8 | Haematology |
| Asthma | Asthma | 8 | Immunology |
| Atopic dermatitis/eczema — adult | Atopic dermatitis/eczema — adult | 8 | Dermatology |
| Autism | Autism | 8 | Neurology |
| Autologous haemopoietic stem cell transplantation | Autologous haemopoietic stem cell transplantation | 8 | Haematology |
| Behçet’s disease | Behçet’s disease | 8 | Dermatology |
| Cardiac surgery with bypass — prophylaxis | Cardiac surgery with bypass — prophylaxis | 8 | Immunology |
| Congestive cardiac failure | Congestive cardiac failure | 8 | Dermatology |
| Crohn’s disease | Crohn’s disease | 8 | Immunology |
| Diamond Blackfan syndrome | Diamond Blackfan syndrome | 8 | Haematology |
| Female infertility | Female infertility | 8 | Immunology |
| Glomerulonephritis — IgA nephritis | Glomerulonephritis — IgA nephritis | 8 | Nephrology |
| Haemolytic uraemic syndrome | Haemolytic uraemic syndrome | 8 | Haematology |
| Henoch–Schönlein purpura | Henoch–Schönlein purpura | 8 | Nephrology |
| HIV/AIDS — adult | HIV/AIDS — adult | 8 | Immunology |
| Idiopathic dilated cardiomyopathy | Idiopathic dilated cardiomyopathy | 8 | Immunology |
| Linear IgA disease | Linear IgA disease | 8 | Dermatology |
| Lupus cerebritis | Lupus cerebritis | 8 | Neurology |
| Lupus nephritis | Lupus nephritis | 8 | Nephrology |
| Motor neuron disease/amyotrophic lateral sclerosis | Motor neuron disease/amyotrophic lateral sclerosis | 8 | Neurology |
| Myalgic encephalomyelitis | Myalgic encephalomyelitis | 8 | Neurology |
| Narcolepsy/cataplexy | Narcolepsy/cataplexy | 8 | Neurology |
| Nephrotic syndrome | Nephrotic syndrome | 8 | Immunology |
| Obsessive compulsive disorders | Obsessive compulsive disorders | 8 | Immunology |
| Polyneuropathy of critical illness | Polyneuropathy of critical illness | 8 | Neurology |
| Recurrent fetal loss (with or without antiphospholipid syndrome) | Recurrent fetal loss (with or without antiphospholipid syndrome) | 8 | Immunology |
| Rheumatoid arthritis | Rheumatoid arthritis | 8 | Immunology |
| Sepsis | Sepsis | 8 | Immunology |
| Sickle cell disease | Sickle cell disease | 8 | Haematology |
| Systemic lupus erythematosus (SLE) | Systemic lupus erythematosus (SLE) | 8 | Immunology |
| Ulcerative colitis | Ulcerative colitis | 8 | Immunology |

# Appendix D – Dataset of Ig supply by state/territory 2016-17

| **Specific Condition** |  | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **AUS** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Chapter 5** |  |  |  |  |  |  |  |  |  |  |
| Chronic inflammatory demyelinating polyneuropathy | Patients | 912 | 518 | 644 | 84 | 159 | 38 | 11 | 37 | 2,379 |
| Average Age | 64 | 63 | 62 | 66 | 61 | 61 | 59 | 63 | 63 |
| Average Weight | 82 | 83 | 84 | 82 | 81 | 84 | 92 | 80 | 83 |
| Grams | 420,647 | 259,475 | 296,522 | 39,123 | 115,583 | 20,727 | 5,876 | 13,629 | 1,171,581 |
| Grams/Episode | 41 | 38 | 32 | 37 | 45 | 33 | 67 | 33 | 38 |
| Grams per 1,000 Population | 54 | 42 | 61 | 23 | 45 | 40 | 24 | 33 | 48 |
| Chronic lymphocytic leukaemia | Patients | 581 | 328 | 369 | 105 | 91 | 28 | 10 | 25 | 1,526 |
| Average Age | 72 | 73 | 72 | 70 | 70 | 68 | 61 | 75 | 72 |
| Average Weight | 78 | 76 | 77 | 80 | 76 | 86 | 73 | 75 | 78 |
| Grams | 146,919 | 77,459 | 104,910 | 22,241 | 14,631 | 6,750 | 2,544 | 7,675 | 383,127 |
| Grams/Episode | 29 | 26 | 24 | 25 | 24 | 29 | 28 | 25 | 27 |
| Grams per 1,000 Population | 19 | 12 | 21 | 13 | 6 | 13 | 10 | 19 | 16 |
| Common variable immunodeficiency disease (CVID) | Patients | 846 | 309 | 355 | 116 | 104 | 29 | <5 | 68 | 1,808 |
| Average Age | 53 | 49 | 54 | 52 | 42 | 50 | 51 | 48 | 51 |
| Average Weight | 73 | 70 | 73 | 69 | 76 | 70 | 86 | 74 | 72 |
| Grams | 293,756 | 101,892 | 128,790 | 33,029 | 30,844 | 8,670 | 1,425 | 20,221 | 618,627 |
| Grams/Episode | 21 | 25 | 26 | 22 | 19 | 24 | 49 | 22 | 22 |
| Grams per 1,000 Population | 38 | 16 | 26 | 19 | 12 | 17 | 6 | 50 | 25 |
| Dermatomyositis | Patients | 80 | 53 | 44 | 12 | 12 | 5 |  | 13 | 218 |
| Average Age | 50 | 49 | 52 | 54 | 41 | 49 |  | 51 | 50 |
| Average Weight | 66 | 64 | 73 | 79 | 96 | 82 |  | 68 | 70 |
| Grams | 26,538 | 16,932 | 20,728 | 5,665 | 5,161 | 3,100 |  | 4,325 | 82,448 |
| Grams/Episode | 35 | 40 | 36 | 33 | 32 | 56 |  | 34 | 36 |
| Grams per 1,000 Population | 3 | 3 | 4 | 3 | 2 | 6 |  | 11 | 3 |
| Guillain–Barré syndrome | Patients | 250 | 155 | 150 | 43 | 59 | 16 | <5 | 14 | 690 |
| Average Age | 54 | 53 | 51 | 64 | 55 | 53 | 7 | 44 | 54 |
| Average Weight | 82 | 79 | 78 | 75 | 74 | 73 | 25 | 87 | 79 |
| Grams | 47,311 | 23,777 | 22,777 | 6,599 | 8,174 | 2,520 | 150 | 2,877 | 114,184 |
| Grams/Episode | 34 | 42 | 36 | 36 | 31 | 35 | 30 | 39 | 36 |
| Grams per 1,000 Population | 6 | 4 | 5 | 4 | 3 | 5 | 1 | 7 | 5 |
| Inclusion body myositis | Patients | 44 | 55 | 34 | 15 | <5 | <5 | <5 | <5 | 152 |
| Average Age | 74 | 69 | 66 | 71 | 68 | 78 |  | 75 | 70 |
| Average Weight | 80 | 82 | 82 | 79 | 77 | 71 |  | 80 | 81 |
| Grams | 16,642 | 27,237 | 13,976 | 5,208 | 402 | 356 |  | 30 | 63,850 |
| Grams/Episode | 35 | 37 | 36 | 31 | 27 | 32 |  | 30 | 35 |
| Grams per 1,000 Population | 2 | 4 | 3 | 3 | 0 | 1 |  | 0 | 3 |
| ITP associated with HIV | Patients |  | <5 | <5 | <5 |  |  |  |  | 7 |
| Average Age |  | 33 | 54 | 38 |  |  |  |  | 40 |
| Average Weight |  | 78 | 73 | 72 |  |  |  |  | 75 |
| Grams |  | 235 | 225 | 189 |  |  |  |  | 649 |
| Grams/Episode |  | 34 | 38 | 38 |  |  |  |  | 36 |
| Grams per 1,000 Population |  | 0 | 0 | 0 |  |  |  |  | 0 |
| ITP in pregnancy | Patients | 34 | 19 | 22 | 8 | 7 |  | <5 | <5 | 92 |
| Average Age | 30 | 32 | 29 | 31 | 30 |  | 19 | 30 | 30 |
| Average Weight | 79 | 76 | 72 | 87 | 67 |  | 56 | 62 | 76 |
| Grams | 6,514 | 2,083 | 4,112 | 1,447 | 1,174 |  | 57 | 605 | 15,992 |
| Grams/Episode | 61 | 56 | 53 | 48 | 59 |  | 57 | 43 | 56 |
| Grams per 1,000 | 1 | 0 | 1 | 1 | 0 |  | 0 | 1 | 1 |
| ITP in specific circumstances (surgery, other therapy contraindicated, chronic ITP, concurrent risk factors) | Patients | 115 | 90 | 109 | 28 | 41 | 7 | <5 | <5 | 396 |
| Average Age | 62 | 60 | 63 | 61 | 58 | 63 | 58 | 58 | 61 |
| Average Weight | 81 | 78 | 79 | 77 | 82 | 93 | 87 | 69 | 80 |
| Grams | 21,221 | 10,247 | 21,261 | 4,272 | 4,871 | 823 | 387 | 787 | 63,868 |
| Grams/Episode | 49 | 49 | 41 | 41 | 52 | 69 | 65 | 49 | 46 |
| Grams per 1,000 Population | 3 | 2 | 4 | 2 | 2 | 2 | 2 | 2 | 3 |
| ITP refractory acute | Patients | 112 | 150 | 112 | 48 | 41 | 11 | <5 | 6 | 482 |
| Average Age | 60 | 60 | 60 | 61 | 61 | 70 | 51 | 73 | 60 |
| Average Weight | 75 | 77 | 79 | 82 | 83 | 80 | 73 | 80 | 78 |
| Grams | 20,250 | 18,496 | 19,691 | 9,934 | 4,004 | 1,049 | 302 | 1,924 | 75,648 |
| Grams/Episode | 50 | 55 | 41 | 51 | 59 | 52 | 76 | 53 | 49 |
| Grams per 1,000 Population | 3 | 3 | 4 | 6 | 2 | 2 | 1 | 5 | 3 |
| ITP with life-threatening haemorrhage or potential life-threatening haemorrhage | Patients | 158 | 79 | 82 | 41 | 19 | 8 | <5 | 5 | 395 |
| Average Age | 56 | 61 | 56 | 58 | 65 | 65 | 64 | 68 | 58 |
| Average Weight | 74 | 74 | 78 | 78 | 82 | 86 | 74 | 84 | 76 |
| Grams | 25,392 | 9,395 | 10,950 | 6,146 | 1,575 | 809 | 353 | 1,092 | 55,712 |
| Grams/Episode | 46 | 52 | 38 | 62 | 53 | 62 | 39 | 64 | 47 |
| Grams per 1,000 Population | 3 | 2 | 2 | 4 | 1 | 2 | 1 | 3 | 2 |
| Kawasaki disease | Patients | 173 | 123 | 53 | 18 | 31 | 6 | <5 | <5 | 411 |
| Average Age | 4 | 3 | 3 | 2 | 3 | 2 | 5 | 5 | 3 |
| Average Weight | 17 | 17 | 16 | 14 | 16 | 15 | 19 | 25 | 17 |
| Grams | 6,751 | 4,748 | 1,985 | 532 | 1,253 | 265 | 153 | 152 | 15,838 |
| Grams/Episode | 31 | 24 | 28 | 17 | 26 | 29 | 38 | 51 | 27 |
| Grams per 1,000 Population | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 1 |
| Lambert–Eaton myasthenic syndrome | Patients | 6 | 7 | 12 |  | <5 |  |  |  | 26 |
| Average Age | 60 | 66 | 69 |  | 75 |  |  |  | 67 |
| Average Weight | 75 | 88 | 83 |  | 65 |  |  |  | 82 |
| Grams | 2,962 | 3,134 | 4,260 |  | 650 |  |  |  | 11,006 |
| Grams/Episode | 39 | 40 | 35 |  | 41 |  |  |  | 38 |
| Grams per 1,000 Population | 0 | 1 | 1 |  | 0 |  |  |  | 0 |
| Multifocal motor neuropathy with or without persistent conduction block | Patients | 185 | 101 | 126 | 44 | 46 | 13 | <5 | 13 | 527 |
| Average Age | 59 | 57 | 58 | 60 | 59 | 61 | 59 | 56 | 58 |
| Average Weight | 80 | 81 | 80 | 85 | 83 | 81 | 91 | 87 | 81 |
| Grams | 104,294 | 65,053 | 71,225 | 34,835 | 36,448 | 7,053 | 4,890 | 7,345 | 331,142 |
| Grams/Episode | 45 | 44 | 35 | 49 | 53 | 34 | 60 | 47 | 43 |
| Grams per 1,000 Population | 13 | 10 | 15 | 20 | 14 | 14 | 20 | 18 | 14 |
| Multiple myeloma | Patients | 536 | 259 | 376 | 58 | 38 | 33 | <5 | 9 | 1,302 |
| Average Age | 71 | 70 | 70 | 66 | 66 | 65 | 60 | 72 | 70 |
| Average Weight | 77 | 79 | 76 | 87 | 84 | 84 | 76 | 70 | 78 |
| Grams | 114,933 | 54,193 | 104,657 | 12,733 | 6,450 | 9,544 | 262 | 1,673 | 304,444 |
| Grams/Episode | 30 | 27 | 24 | 23 | 25 | 27 | 22 | 22 | 27 |
| Grams per 1,000 Population | 15 | 9 | 21 | 7 | 3 | 18 | 1 | 4 | 12 |
| Myasthenia gravis | Patients | 353 | 291 | 311 | 41 | 69 | 13 | <5 | 18 | 1,090 |
| Average Age | 61 | 62 | 61 | 64 | 59 | 49 | 37 | 56 | 61 |
| Average Weight | 81 | 79 | 82 | 82 | 78 | 68 | 80 | 85 | 81 |
| Grams | 144,019 | 119,154 | 140,148 | 11,818 | 27,216 | 4,992 | 35 | 8,966 | 456,346 |
| Grams/Episode | 37 | 36 | 31 | 29 | 33 | 28 | 35 | 40 | 34 |
| Grams per 1,000 Population | 18 | 19 | 29 | 7 | 11 | 10 | 0 | 22 | 19 |
| Neonatal haemochromatosis | Patients | <5 | <5 |  | <5 | <5 |  |  |  | 11 |
| Average Age | 26 | 24 |  | 0 | 28 |  |  |  | 22 |
| Average Weight | 69 | 62 |  | 3 | 107 |  |  |  | 60 |
| Grams | 5,119 | 3,711 |  | 8 | 800 |  |  |  | 9,638 |
| Grams/Episode | 80 | 79 |  | 4 | 100 |  |  |  | 80 |
| Grams per 1,000 Population | 1 | 1 |  | 0 | 0 |  |  |  | 0 |
| Non-Hodgkin lymphoma | Patients | 453 | 297 | 523 | 107 | 53 | 36 | 5 | 15 | 1,483 |
| Average Age | 68 | 68 | 67 | 68 | 67 | 66 | 60 | 63 | 67 |
| Average Weight | 76 | 79 | 77 | 77 | 80 | 79 | 83 | 73 | 77 |
| Grams | 108,168 | 70,601 | 149,876 | 20,385 | 10,221 | 9,384 | 1,010 | 3,430 | 373,074 |
| Grams/Episode | 29 | 27 | 24 | 22 | 26 | 23 | 29 | 24 | 26 |
| Grams per 1,000 Population | 14 | 11 | 31 | 12 | 4 | 18 | 4 | 8 | 15 |
| Other primary immunodeficiency | Patients | 43 | 34 | 14 | 12 | 9 | <5 | <5 | <5 | 120 |
| Average Age | 42 | 47 | 25 | 33 | 49 | 31 | 47 | 26 | 40 |
| Average Weight | 53 | 65 | 48 | 52 | 81 | 57 | 76 | 66 | 60 |
| Grams | 12,221 | 10,218 | 2,623 | 2,722 | 2,028 | 869 | 688 | 694 | 32,061 |
| Grams/Episode | 12 | 21 | 17 | 16 | 16 | 19 | 25 | 12 | 15 |
| Grams per 1,000 Population | 2 | 2 | 1 | 2 | 1 | 2 | 3 | 2 | 1 |
| Other relevant haematological malignancies | Patients | 277 | 81 | 128 | 26 | 33 | 9 | <5 | 6 | 555 |
| Average Age | 56 | 54 | 60 | 67 | 31 | 66 | 66 | 64 | 56 |
| Average Weight | 70 | 67 | 74 | 71 | 64 | 80 | 83 | 77 | 71 |
| Grams | 46,580 | 14,168 | 36,122 | 5,712 | 4,195 | 2,356 | 205 | 1,376 | 110,714 |
| Grams/Episode | 27 | 25 | 23 | 19 | 19 | 25 | 29 | 26 | 24 |
| Grams per 1,000 Population | 6 | 2 | 7 | 3 | 2 | 5 | 1 | 3 | 5 |
| Polymyositis | Patients | 186 | 75 | 109 | 43 | 22 | <5 | <5 | 7 | 446 |
| Average Age | 62 | 58 | 61 | 64 | 57 | 79 | 50 | 59 | 61 |
| Average Weight | 77 | 84 | 81 | 77 | 74 | 79 | 91 | 84 | 80 |
| Grams | 65,801 | 35,073 | 49,528 | 17,934 | 8,625 | 2,010 | 505 | 3,410 | 182,885 |
| Grams/Episode | 35 | 43 | 34 | 35 | 30 | 44 | 63 | 45 | 36 |
| Grams per 1,000 Population | 8 | 6 | 10 | 10 | 3 | 4 | 2 | 8 | 8 |
| Post-haemopoietic stem cell transplantation | Patients | 164 | 86 | 80 | 22 | 17 | 5 | <5 | <5 | 375 |
| Average Age | 44 | 37 | 46 | 43 | 36 | 40 | 59 | 32 | 42 |
| Average Weight | 70 | 62 | 68 | 73 | 64 | 76 | 50 | 69 | 67 |
| Grams | 22,389 | 12,758 | 15,733 | 3,293 | 1,552 | 1,020 | 80 | 224 | 57,046 |
| Grams/Episode | 28 | 21 | 23 | 19 | 20 | 18 | 20 | 32 | 24 |
| Grams per 1,000 Population | 3 | 2 | 3 | 2 | 1 | 2 | 0 | 1 | 2 |
| Severe combined immunodeficiency (SCID) | Patients | 11 | 10 | 19 | <5 | <5 |  |  |  | 43 |
| Average Age | 21 | 17 | 20 | 16 | 23 |  |  |  | 20 |
| Average Weight | 38 | 40 | 40 | 41 | 70 |  |  |  | 41 |
| Grams | 2,307 | 2,256 | 4,213 | 113 | 755 |  |  |  | 9,643 |
| Grams/Episode | 12 | 15 | 18 | 16 | 31 |  |  |  | 16 |
| Grams per 1,000 Population | 0 | 0 | 1 | 0 | 0 |  |  |  | 0 |
| Stiff person syndrome | Patients | 42 | 7 | 20 | <5 | 5 | <5 |  | <5 | 77 |
| Average Age | 59 | 53 | 58 | 61 | 58 | 36 |  | 31 | 56 |
| Average Weight | 82 | 72 | 79 | 71 | 77 | 70 |  | 69 | 78 |
| Grams | 20,361 | 3,653 | 11,012 | 285 | 2,643 | 1,989 |  | 240 | 40,182 |
| Grams/Episode | 42 | 44 | 36 | 26 | 34 | 49 |  | 22 | 40 |
| Grams per 1,000 Population | 3 | 1 | 2 | 0 | 1 | 4 |  | 1 | 2 |
| Wiskott–Aldrich syndrome | Patients | <5 | <5 |  |  | <5 |  |  |  | <5 |
| Average Age | 32 | 15 |  |  | 33 |  |  |  | 28 |
| Average Weight | 60 | 52 |  |  | 81 |  |  |  | 68 |
| Grams | 66 | 168 |  |  | 713 |  |  |  | 947 |
| Grams/Episode | 33 | 24 |  |  | 26 |  |  |  | 26 |
| Grams per 1,000 Population | 0 | 0 |  |  | 0 |  |  |  | 0 |
| X-linked agammaglobulinaemia | Patients | 39 | 48 | 18 | 6 | 6 | <5 | <5 | <5 | 121 |
| Average Age | 32 | 33 | 27 | 20 | 19 | 53 | 29 | 8 | 30 |
| Average Weight | 60 | 60 | 59 | 60 | 52 | 78 | 52 | 25 | 59 |
| Grams | 12,140 | 16,544 | 6,582 | 2,106 | 1,659 | 60 | 741 | 437 | 40,269 |
| Grams/Episode | 26 | 21 | 27 | 29 | 13 | 30 | 23 | 9 | 23 |
| Grams per 1,000 Population | 2 | 3 | 1 | 1 | 1 | 0 | 3 | 1 | 2 |
| **Chapter 5 Total** | Patients | 5,504 | 3,131 | 3,662 | 866 | 853 | 264 | 57 | 252 | 14,488 |
| Average Age | 59 | 59 | 61 | 61 | 55 | 60 | 52 | 56 | 60 |
| Average Weight | 75 | 75 | 77 | 77 | 76 | 78 | 75 | 76 | 76 |
| Grams | 1,693,297 | 962,655 | 1,241,902 | 246,326 | 291,624 | 84,344 | 19,662 | 81,108 | 4,620,916 |
| Grams/Episode | 31 | 33 | 28 | 30 | 34 | 30 | 44 | 29 | 31 |
| Grams per 1,000 Population | 217 | 154 | 254 | 143 | 114 | 162 | 80 | 199 | 190 |
| **Chapter 6** |  |  |  |  |  |  |  |  |  |  |
|
| Acute disseminated encephalomyelitis | Patients | 30 | 15 | 27 | <5 | <5 | 5 |  |  | 81 |
| Average Age | 37 | 24 | 24 | 0 | 13 | 29 |  |  | 28 |
| Average Weight | 59 | 46 | 57 | 9 | 45 | 68 |  |  | 55 |
| Grams | 5,974 | 2,469 | 4,134 | 20 | 361 | 682 |  |  | 13,640 |
| Grams/Episode | 33 | 31 | 34 | 10 | 18 | 36 |  |  | 32 |
| Grams per 1,000 Population | 1 | 0 | 1 | 0 | 0 | 1 |  |  | 1 |
| Autoimmune haemolytic anaemia | Patients | 37 | 35 | 22 | 7 | <5 | <5 | <5 |  | 107 |
| Average Age | 53 | 70 | 63 | 73 | 59 | 51 | 65 |  | 63 |
| Average Weight | 68 | 79 | 74 | 71 | 76 | 91 | 59 |  | 74 |
| Grams | 6,270 | 4,456 | 3,048 | 3,375 | 518 | 255 | 45 |  | 17,966 |
| Grams/Episode | 42 | 48 | 36 | 32 | 18 | 28 | 45 |  | 38 |
| Grams per 1,000 Population | 1 | 1 | 1 | 2 | 0 | 0 | 0 |  | 1 |
| Bullous pemphigoid | Patients | 21 | 6 | 11 | <5 | <5 | <5 |  |  | 43 |
| Average Age | 70 | 69 | 68 | 75 | 64 | 84 |  |  | 69 |
| Average Weight | 84 | 76 | 89 | 132 | 68 | 70 |  |  | 83 |
| Grams | 14,149 | 3,053 | 7,478 | 400 | 542 | 560 |  |  | 26,182 |
| Grams/Episode | 47 | 54 | 46 | 67 | 24 | 62 |  |  | 47 |
| Grams per 1,000 Population | 2 | 0 | 2 | 0 | 0 | 1 |  |  | 1 |
| Churg-Strauss syndrome | Patients |  |  |  |  | <5 |  |  |  | <5 |
| Average Age |  |  |  |  | 63 |  |  |  | 63 |
| Average Weight |  |  |  |  | 80 |  |  |  | 80 |
| Grams |  |  |  |  | 185 |  |  |  | 185 |
| Grams/Episode |  |  |  |  | 23 |  |  |  | 23 |
| Grams per 1,000 Population |  |  |  |  | 0 |  |  |  | 0 |
| Cicatricial pemphigoid/ mucous membrane pemphigoid | Patients | <5 | <5 | 7 | <5 | <5 | <5 |  | <5 | 21 |
| Average Age | 61 | 73 | 70 | 72 | 47 | 45 |  | 48 | 65 |
| Average Weight | 82 | 87 | 82 | 72 | 87 | 50 |  | 97 | 83 |
| Grams | 3,665 | 4,258 | 3,202 | 2,295 | 1,728 | 470 |  | 3,145 | 18,763 |
| Grams/Episode | 80 | 71 | 39 | 34 | 22 | 78 |  | 87 | 50 |
| Grams per 1,000 Population | 0 | 1 | 1 | 1 | 1 | 1 |  | 8 | 1 |
| Evans syndrome | Patients | <5 | 10 | <5 | <5 |  |  |  |  | 15 |
| Average Age | 17 | 58 | 62 | 26 |  |  |  |  | 51 |
| Average Weight | 47 | 78 | 77 | 66 |  |  |  |  | 74 |
| Grams | 105 | 1,062 | 320 | 181 |  |  |  |  | 1,668 |
| Grams/Episode | 26 | 59 | 160 | 26 |  |  |  |  | 54 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 |  |  |  |  | 0 |
| Feto-maternal/neonatal alloimmune thrombocytopenia (Antenatal) | Patients | 5 | <5 | <5 | <5 | <5 |  |  | <5 | 19 |
| Average Age | 29 | 32 | 23 | 26 | 34 |  |  | 0 | 27 |
| Average Weight | 79 | 78 | 50 | 76 | 86 |  |  | 3 | 70 |
| Grams | 5,717 | 2,139 | 1,278 | 3,833 | 1,713 |  |  | 9 | 14,688 |
| Grams/Episode | 99 | 53 | 49 | 71 | 82 |  |  | 3 | 73 |
| Grams per 1,000 Population | 1 | 0 | 0 | 2 | 1 |  |  | 0 | 1 |
| Feto-maternal/neonatal alloimmune thrombocytopenia (Neonatal) | Patients | 15 | 5 | <5 | <5 | <5 | <5 |  | <5 | 31 |
| Average Age | 2 | 0 | 7 | 0 | 0 | 0 |  | 0 | 2 |
| Average Weight | 8 | 3 | 17 | 3 | 2 | 2 |  | 2 | 7 |
| Grams | 691 | 15 | 1,209 | 16 | 3 | 3 |  | 3 | 1,940 |
| Grams/Episode | 22 | 3 | 47 | 2 | 3 | 3 |  | 3 | 26 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  | 0 | 0 |
| Haemophagocytic syndrome | Patients | 15 | 14 | 9 | <5 | <5 |  | <5 |  | 44 |
| Average Age | 42 | 44 | 52 | 46 | 45 |  | 38 |  | 45 |
| Average Weight | 60 | 68 | 63 | 80 | 58 |  | 59 |  | 64 |
| Grams | 1,971 | 2,192 | 1,403 | 40 | 417 |  | 152 |  | 6,175 |
| Grams/Episode | 47 | 52 | 31 | 40 | 52 |  | 15 |  | 42 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  | 1 |  | 0 |
| IgG subclass deficiency (existing authorisation) | Patients | 11 | 21 | <5 | <5 | <5 | <5 |  |  | 42 |
| Average Age | 68 | 65 | 82 | 65 | 71 | 56 |  |  | 65 |
| Average Weight | 99 | 74 | 60 | 77 | 186 | 67 |  |  | 84 |
| Grams | 4,491 | 7,363 | 51 | 1,075 | 1,106 | 1,679 |  |  | 15,764 |
| Grams/Episode | 31 | 23 | 10 | 24 | 23 | 22 |  |  | 25 |
| Grams per 1,000 Population | 1 | 1 | 0 | 1 | 0 | 3 |  |  | 1 |
| IgM para-proteinaemic neuropathy | Patients | 38 | 11 | 34 | 6 | 5 | 6 | <5 | <5 | 102 |
| Average Age | 73 | 69 | 67 | 64 | 72 | 70 | 54 | 70 | 69 |
| Average Weight | 81 | 81 | 83 | 73 | 73 | 82 | 98 | 65 | 81 |
| Grams | 15,511 | 3,630 | 12,637 | 1,350 | 3,809 | 1,427 | 295 | 155 | 38,814 |
| Grams/Episode | 38 | 30 | 29 | 30 | 54 | 46 | 74 | 52 | 35 |
| Grams per 1,000 Population | 2 | 1 | 3 | 1 | 1 | 3 | 1 | 0 | 2 |
| ITP in children | Patients | 25 | 40 | 50 | 19 | 8 | <5 | <5 | <5 | 149 |
| Average Age | 6 | 6 | 7 | 8 | 6 | 5 | 13 | 6 | 7 |
| Average Weight | 29 | 29 | 30 | 36 | 29 | 21 | 70 | 26 | 30 |
| Grams | 3,621 | 2,192 | 2,116 | 2,239 | 240 | 252 | 70 | 147 | 10,875 |
| Grams/Episode | 33 | 21 | 22 | 32 | 24 | 11 | 70 | 16 | 26 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| Kidney transplantation post-transplant | Patients | 72 | 248 | 64 | 20 | 24 | 12 | <5 | <5 | 442 |
| Average Age | 44 | 48 | 50 | 45 | 40 | 44 | 41 | 24 | 47 |
| Average Weight | 72 | 78 | 81 | 77 | 72 | 78 | 90 | 65 | 78 |
| Grams | 11,539 | 72,031 | 21,880 | 2,561 | 3,742 | 5,311 | 239 | 263 | 117,564 |
| Grams/Episode | 23 | 32 | 19 | 27 | 39 | 44 | 27 | 29 | 28 |
| Grams per 1,000 Population | 1 | 12 | 4 | 1 | 1 | 10 | 1 | 1 | 5 |
| Kidney transplantation pre-transplant | Patients | 44 | 19 | 7 | 5 | <5 | <5 |  |  | 79 |
| Average Age | 48 | 50 | 45 | 57 | 45 | 39 |  |  | 49 |
| Average Weight | 75 | 81 | 88 | 85 | 84 | 55 |  |  | 78 |
| Grams | 2,965 | 1,010 | 563 | 245 | 392 | 255 |  |  | 5,430 |
| Grams/Episode | 39 | 11 | 16 | 41 | 28 | 28 |  |  | 23 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| Microscopic polyangiitis | Patients |  | <5 | <5 |  | <5 |  | <5 |  | 7 |
| Average Age |  | 50 | 30 |  | 35 |  | 41 |  | 40 |
| Average Weight |  | 123 | 70 |  | 60 |  | 83 |  | 91 |
| Grams |  | 456 | 146 |  | 316 |  | 530 |  | 1,448 |
| Grams/Episode |  | 46 | 24 |  | 21 |  | 44 |  | 34 |
| Grams per 1,000 Population |  | 0 | 0 |  | 0 |  | 2 |  | 0 |
| Multiple sclerosis - severe relapse with no response to high dose methylprednisolone | Patients | 7 | <5 | 9 |  |  |  |  |  | 20 |
| Average Age | 49 | 52 | 49 |  |  |  |  |  | 50 |
| Average Weight | 76 | 70 | 79 |  |  |  |  |  | 76 |
| Grams | 1,618 | 777 | 1,491 |  |  |  |  |  | 3,886 |
| Grams/Episode | 28 | 32 | 39 |  |  |  |  |  | 33 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  |  |  |  | 0 |
| Multiple sclerosis in pregnancy and the immediate post-partum period | Patients | <5 |  | <5 |  |  |  |  |  | <5 |
| Average Age | 34 |  | 27 |  |  |  |  |  | 29 |
| Average Weight | 63 |  | 77 |  |  |  |  |  | 72 |
| Grams | 125 |  | 118 |  |  |  |  |  | 243 |
| Grams/Episode | 25 |  | 39 |  |  |  |  |  | 30 |
| Grams per 1,000 | 0 |  | 0 |  |  |  |  |  | 0 |
| Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed | Patients | 19 | <5 | <5 |  |  |  |  | <5 | 25 |
| Average Age | 40 | 42 | 59 |  |  |  |  | 45 | 43 |
| Average Weight | 84 | 90 | 87 |  |  |  |  | 60 | 84 |
| Grams | 7,076 | 767 | 835 |  |  |  |  | 200 | 8,878 |
| Grams/Episode | 33 | 28 | 38 |  |  |  |  | 20 | 33 |
| Grams per 1,000 Population | 1 | 0 | 0 |  |  |  |  | 0 | 0 |
| Opsoclonus myoclonus ataxia | Patients | 13 | 7 | <5 | <5 | <5 |  |  |  | 28 |
| Average Age | 14 | 25 | 2 | 50 | 2 |  |  |  | 16 |
| Average Weight | 30 | 34 | 15 | 71 | 12 |  |  |  | 30 |
| Grams | 2,005 | 1,032 | 487 | 1,355 | 227 |  |  |  | 5,105 |
| Grams/Episode | 20 | 19 | 13 | 65 | 8 |  |  |  | 21 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 |  |  |  | 0 |
| Pemphigus foliaceus | Patients | <5 | <5 | <5 |  |  |  |  |  | 6 |
| Average Age | 65 | 55 | 55 |  |  |  |  |  | 56 |
| Average Weight | 62 | 92 | 85 |  |  |  |  |  | 84 |
| Grams | 320 | 1,575 | 1,195 |  |  |  |  |  | 3,090 |
| Grams/Episode | 40 | 87 | 33 |  |  |  |  |  | 50 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  |  |  |  | 0 |
| Pemphigus vulgaris | Patients | 12 | <5 | 7 |  | <5 |  |  | <5 | 24 |
| Average Age | 59 | 35 | 59 |  | 55 |  |  | 41 | 56 |
| Average Weight | 88 | 70 | 88 |  | 111 |  |  | 70 | 88 |
| Grams | 7,773 | 1,558 | 3,490 |  | 1,824 |  |  | 278 | 14,923 |
| Grams/Episode | 61 | 71 | 45 |  | 47 |  |  | 35 | 54 |
| Grams per 1,000 Population | 1 | 0 | 1 |  | 1 |  |  | 1 | 1 |
| Post-tranfusion purpura | Patients |  |  |  |  | <5 |  |  |  | <5 |
| Average Age |  |  |  |  | 84 |  |  |  | 84 |
| Average Weight |  |  |  |  | 58 |  |  |  | 58 |
| Grams |  |  |  |  | 60 |  |  |  | 60 |
| Grams/Episode |  |  |  |  | 60 |  |  |  | 60 |
| Grams per 1,000 Population |  |  |  |  | 0 |  |  |  | 0 |
| PR3 or MPO ANCA-positive idiopathic rapidly progressive glomerulonephritis | Patients | <5 | <5 | 6 |  |  |  |  |  | 11 |
| Average Age | 64 | 47 | 72 |  |  |  |  |  | 68 |
| Average Weight | 89 | 200 | 81 |  |  |  |  |  | 91 |
| Grams | 340 | 198 | 2,549 |  |  |  |  |  | 3,087 |
| Grams/Episode | 34 | 99 | 45 |  |  |  |  |  | 45 |
| Grams per 1,000 Population | 0 | 0 | 1 |  |  |  |  |  | 0 |
| Secondary hypogammaglobulinaemia (excluding haematological malignancies) | Patients | 287 | 180 | 230 | 15 | 47 | 16 |  | 10 | 781 |
| Average Age | 56 | 53 | 57 | 51 | 42 | 61 | 59 | 63 | 55 |
| Average Weight | 72 | 64 | 74 | 56 | 63 | 80 | 100 | 63 | 70 |
| Grams | 68,256 | 34,926 | 60,414 | 3,298 | 7,205 | 4,646 | 33 | 2,055 | 180,831 |
| Grams/Episode | 27 | 21 | 23 | 20 | 16 | 27 | 33 | 18 | 23 |
| Grams per 1,000 Population | 9 | 6 | 12 | 2 | 3 | 9 | 0 | 5 | 7 |
| Solid organ - heart | Patients | 10 | <5 | <5 |  | <5 |  |  |  | 14 |
| Average Age | 48 | 13 | 54 |  | 51 |  |  |  | 44 |
| Average Weight | 81 | 42 | 68 |  | 65 |  |  |  | 73 |
| Grams | 1,494 | 221 | 445 |  | 120 |  |  |  | 2,279 |
| Grams/Episode | 20 | 44 | 23 |  | 120 |  |  |  | 23 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 |  |  |  | 0 |
| Solid organ - heart/lung | Patients | 5 | <5 | <5 |  | <5 |  |  |  | 10 |
| Average Age | 52 | 19 | 43 |  | 33 |  |  |  | 36 |
| Average Weight | 70 | 42 | 59 |  | 84 |  |  |  | 62 |
| Grams | 1,185 | 176 | 54 |  | 140 |  |  |  | 1,555 |
| Grams/Episode | 31 | 10 | 27 |  | 70 |  |  |  | 26 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 |  |  |  | 0 |
| Solid organ - liver | Patients | <5 |  | <5 | <5 |  |  |  |  | 6 |
| Average Age | 26 |  | 24 | 60 |  |  |  |  | 30 |
| Average Weight | 40 |  | 76 | 74 |  |  |  |  | 55 |
| Grams | 207 |  | 221 | 825 |  |  |  |  | 1,253 |
| Grams/Episode | 35 |  | 6 | 25 |  |  |  |  | 16 |
| Grams per 1,000 Population | 0 |  | 0 | 0 |  |  |  |  | 0 |
| Solid organ - lung | Patients | 22 | 66 | 6 | <5 | <5 | <5 |  |  | 104 |
| Average Age | 44 | 51 | 38 | 51 | 50 | 48 |  |  | 49 |
| Average Weight | 58 | 67 | 57 | 58 | 56 | 71 |  |  | 64 |
| Grams | 3,123 | 9,055 | 531 | 855 | 346 | 735 |  |  | 14,645 |
| Grams/Episode | 27 | 22 | 12 | 20 | 38 | 27 |  |  | 23 |
| Grams per 1,000 Population | 0 | 1 | 0 | 0 | 0 | 1 |  |  | 1 |
| Solid organ - other | Patients |  | <5 |  |  |  |  |  |  | <5 |
| Average Age |  | 37 |  |  |  |  |  |  | 37 |
| Average Weight |  | 59 |  |  |  |  |  |  | 59 |
| Grams |  | 862 |  |  |  |  |  |  | 862 |
| Grams/Episode |  | 57 |  |  |  |  |  |  | 57 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| Specific antibody deficiency | Patients | 117 | 44 | 49 | 20 | 67 | <5 |  | 7 | 301 |
| Average Age | 52 | 55 | 51 | 55 | 46 | 51 | 11 | 40 | 51 |
| Average Weight | 71 | 69 | 71 | 71 | 73 | 84 | 27 | 72 | 71 |
| Grams | 32,161 | 11,133 | 13,684 | 5,421 | 15,805 | 214 | 120 | 2,213 | 80,751 |
| Grams/Episode | 18 | 23 | 23 | 19 | 17 | 15 | 10 | 19 | 19 |
| Grams per 1,000 Population | 4 | 2 | 3 | 3 | 6 | 0 | 0 | 5 | 3 |
| Staphylococcal TSS | Patients | 13 | 11 | 5 | <5 | 5 | <5 |  |  | 39 |
| Average Age | 40 | 50 | 41 | 26 | 39 | 8 |  |  | 39 |
| Average Weight | 79 | 76 | 64 | 65 | 72 | 43 |  |  | 71 |
| Grams | 1,976 | 1,330 | 539 | 497 | 550 | 209 |  |  | 5,101 |
| Grams/Episode | 94 | 89 | 67 | 41 | 55 | 52 |  |  | 73 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| Streptococcal TSS | Patients | 42 | 51 | 19 | 10 | 11 | <5 | <5 | <5 | 141 |
| Average Age | 46 | 42 | 42 | 38 | 50 | 54 | 45 | 50 | 44 |
| Average Weight | 80 | 73 | 74 | 63 | 72 | 105 | 76 | 100 | 75 |
| Grams | 6,346 | 6,114 | 2,327 | 881 | 1,548 | 200 | 359 | 604 | 18,377 |
| Grams/Episode | 75 | 68 | 80 | 42 | 77 | 200 | 51 | 151 | 72 |
| Grams per 1,000 Population | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 1 | 1 |
| Toxic epidermal necrolysis/Stevens–Johnson syndrome | Patients | 25 | 22 |  | 6 | <5 | <5 | <5 | <5 | 64 |
| Average Age | 51 | 37 |  | 54 | 59 | 37 | 50 | 34 | 45 |
| Average Weight | 67 | 68 |  | 75 | 84 | 66 | 65 | 85 | 69 |
| Grams | 3,483 | 3,219 |  | 846 | 290 | 378 | 502 | 341 | 9,059 |
| Grams/Episode | 54 | 59 |  | 45 | 73 | 95 | 84 | 43 | 56 |
| Grams per 1,000 Population | 0 | 1 |  | 0 | 0 | 1 | 2 | 1 | 0 |
| Wegener granulomatosis | Patients |  | <5 | <5 | <5 |  |  |  |  | <5 |
| Average Age |  | 73 | 61 | 30 |  |  |  |  | 49 |
| Average Weight |  | 65 | 100 | 78 |  |  |  |  | 80 |
| Grams |  | 25 | 180 | 353 |  |  |  |  | 558 |
| Grams/Episode |  | 25 | 45 | 27 |  |  |  |  | 31 |
| Grams per 1,000 Population |  | 0 | 0 | 0 |  |  |  |  | 0 |
| **Chapter 6 Total** | Patients | 885 | 812 | 584 | 137 | 203 | 64 | 17 | 35 | 2,722 |
| Average Age | 50 | 49 | 52 | 46 | 44 | 49 | 43 | 44 | 49 |
| Average Weight | 70 | 69 | 72 | 64 | 70 | 72 | 72 | 66 | 70 |
| Grams | 214,152 | 179,289 | 148,022 | 31,958 | 43,184 | 17,276 | 2,345 | 9,411 | 645,636 |
| Grams/Episode | 30 | 29 | 25 | 28 | 22 | 33 | 37 | 29 | 28 |
| Grams per 1,000 Population | 27 | 29 | 30 | 19 | 17 | 33 | 10 | 23 | 26 |
| **Chapter 7** |  |  |  |  |  |  |  |  |  |  |
|
| Acute leukaemia in children | Patients |  | 9 | 7 |  | <5 |  |  |  | 17 |
| Average Age |  | 9 | 8 |  | 6 |  |  |  | 9 |
| Average Weight |  | 32 | 38 |  | 22 |  |  |  | 33 |
| Grams |  | 947 | 112 |  | 58 |  |  |  | 1,117 |
| Grams/Episode |  | 39 | 11 |  | 10 |  |  |  | 28 |
| Grams per 1,000 Population |  | 0 | 0 |  | 0 |  |  |  | 0 |
| Autoimmune neutropenia | Patients | <5 | 5 | <5 |  | <5 |  | <5 | v | 14 |
| Average Age | 52 | 57 | 48 |  | 45 |  | 48 | 59 | 52 |
| Average Weight | 53 | 72 | 73 |  | 67 |  | 119 | 41 | 73 |
| Grams | 665 | 514 | 475 |  | 130 |  | 1,209 | 90 | 3,083 |
| Grams/Episode | 39 | 51 | 30 |  | 22 |  | 71 | 45 | 45 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 |  | 5 | 0 | 0 |
| Autoimmune uveitis | Patients | <5 | <5 |  |  |  |  |  |  | <5 |
| Average Age | 49 | 59 |  |  |  |  |  |  | 57 |
| Average Weight | 95 | 74 |  |  |  |  |  |  | 79 |
| Grams | 235 | 1,012 |  |  |  |  |  |  | 1,247 |
| Grams/Episode | 34 | 63 |  |  |  |  |  |  | 54 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Catastrophic antiphospholipid syndrome | Patients | 8 | <5 | <5 |  | <5 |  |  |  | 16 |
| Average Age | 37 | 38 | 67 |  | 45 |  |  |  | 45 |
| Average Weight | 75 | 113 | 74 |  | 86 |  |  |  | 83 |
| Grams | 1,617 | 579 | 675 |  | 280 |  |  |  | 3,151 |
| Grams/Episode | 44 | 53 | 34 |  | 56 |  |  |  | 43 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 |  |  |  | 0 |
| Cerebellar degeneration | Patients | <5 | 7 | 6 | <5 | <5 | <5 |  | <5 | 21 |
| Average Age | 70 | 60 | 64 | 55 | 65 | 64 |  | 48 | 62 |
| Average Weight | 63 | 81 | 65 | 75 | 70 | 83 |  | 74 | 73 |
| Grams | 310 | 1,135 | 1,310 | 60 | 1,365 | 540 |  | 148 | 4,868 |
| Grams/Episode | 28 | 26 | 21 | 30 | 65 | 30 |  | 30 | 30 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 1 | 1 |  | 0 | 0 |
| Coagulation factor inhibitors | Patients | <5 | <5 | 5 | <5 | <5 |  |  |  | 16 |
| Average Age | 71 | 75 | 55 | 68 | 55 |  |  |  | 63 |
| Average Weight | 54 | 65 | 102 | 67 | 50 |  |  |  | 75 |
| Grams | 1,319 | 120 | 3,610 | 1,075 | 100 |  |  |  | 6,224 |
| Grams/Episode | 47 | 60 | 74 | 31 | 50 |  |  |  | 54 |
| Grams per 1,000 Population | 0 | 0 | 1 | 1 | 0 |  |  |  | 0 |
| Devic disease (neuromyelitis optica) | Patients | 24 | <5 | 5 | 5 | <5 | <5 | <5 |  | 40 |
| Average Age | 50 | 30 | 50 | 57 | 57 | 6 | 45 |  | 49 |
| Average Weight | 70 | 59 | 66 | 68 | 87 | 18 | 75 |  | 69 |
| Grams | 7,807 | 790 | 1,385 | 475 | 1,800 | 125 | 215 |  | 12,597 |
| Grams/Episode | 35 | 38 | 20 | 25 | 69 | 16 | 54 |  | 34 |
| Grams per 1,000 Population | 1 | 0 | 0 | 0 | 1 | 0 | 1 |  | 1 |
| Diabetic amyotrophy | Patients | <5 | 6 | 6 |  |  |  |  |  | 15 |
| Average Age | 63 | 71 | 63 |  |  |  |  |  | 65 |
| Average Weight | 78 | 76 | 75 |  |  |  |  |  | 76 |
| Grams | 1,191 | 1,496 | 1,160 |  |  |  |  |  | 3,847 |
| Grams/Episode | 26 | 42 | 31 |  |  |  |  |  | 33 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  |  |  |  | 0 |
| Epidermolysis bullosa acquisita | Patients |  | <5 |  |  | <5 |  |  | <5 | 5 |
| Average Age |  | 72 |  |  | 69 |  |  | 47 | 64 |
| Average Weight |  | 79 |  |  | 126 |  |  | 81 | 99 |
| Grams |  | 474 |  |  | 3,190 |  |  | 1,800 | 5,464 |
| Grams/Episode |  | 95 |  |  | 69 |  |  | 58 | 67 |
| Grams per 1,000 Population |  | 0 |  |  | 1 |  |  | 4 | 0 |
| Epilepsy (rare childhood cases) | Patients | 5 | 5 | <5 |  | <5 | <5 |  |  | 17 |
| Average Age | 15 | 13 | 16 |  | 8 | 7 |  |  | 13 |
| Average Weight | 45 | 51 | 47 |  | 27 | 30 |  |  | 45 |
| Grams | 843 | 1,882 | 941 |  | 400 | 60 |  |  | 4,126 |
| Grams/Episode | 30 | 38 | 24 |  | 33 | 30 |  |  | 31 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 | 0 |  |  | 0 |
| Graves ophthalmopathy | Patients |  |  | <5 |  | <5 |  |  |  | <5 |
| Average Age |  |  | 52 |  | 55 |  |  |  | 53 |
| Average Weight |  |  | 76 |  | 47 |  |  |  | 70 |
| Grams |  |  | 1,360 |  | 95 |  |  |  | 1,455 |
| Grams/Episode |  |  | 40 |  | 32 |  |  |  | 39 |
| Grams per 1,000 Population |  |  | 0 |  | 0 |  |  |  | 0 |
| Haemolytic disease of the newborn | Patients | 25 | 23 | <5 | 10 | 9 | <5 | <5 | 8 | 80 |
| Average Age | 0 | 0 | 22 | 0 | 7 | 0 | 0 | 0 | 1 |
| Average Weight | 3 | 3 | 49 | 3 | 25 | 4 | 2 | 3 | 7 |
| Grams | 83 | 79 | 81 | 32 | 1,400 | 6 | 3 | 45 | 1,727 |
| Grams/Episode | 3 | 3 | 20 | 3 | 58 | 3 | 3 | 3 | 16 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| Haemolytic transfusion reaction | Patients | <5 |  |  | <5 |  |  |  |  | <5 |
| Average Age | 45 |  |  | 0 |  |  |  |  | 23 |
| Average Weight | 60 |  |  | 3 |  |  |  |  | 32 |
| Grams | 180 |  |  | 3 |  |  |  |  | 183 |
| Grams/Episode | 60 |  |  | 3 |  |  |  |  | 46 |
| Grams per 1,000 Population | 0 |  |  | 0 |  |  |  |  | 0 |
| Hashimoto encephalopathy | Patients | 8 | <5 | <5 |  | 5 |  |  |  | 18 |
| Average Age | 42 | 44 | 78 |  | 47 |  |  |  | 46 |
| Average Weight | 77 | 79 | 78 |  | 65 |  |  |  | 74 |
| Grams | 2,940 | 1,050 | 446 |  | 1,993 |  |  |  | 6,428 |
| Grams/Episode | 30 | 35 | 25 |  | 34 |  |  |  | 31 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 1 |  |  |  | 0 |
| Limbic encephalitis | Patients | 11 | 12 | 16 | <5 | 7 | <5 | <5 | <5 | 53 |
| Average Age | 48 | 48 | 47 | 72 | 40 | 17 | 73 | 58 | 49 |
| Average Weight | 68 | 86 | 76 | 77 | 62 | 68 | 56 | 56 | 74 |
| Grams | 2,240 | 2,179 | 2,416 | 495 | 779 | 135 | 110 | 252 | 8,605 |
| Grams/Episode | 30 | 36 | 32 | 26 | 25 | 135 | 37 | 18 | 31 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Limbic encephalitis, nonparaneoplastic | Patients | 87 | 63 | 102 | 7 | 12 | <5 | <5 | <5 | 279 |
| Average Age | 49 | 51 | 44 | 39 | 59 | 43 | 43 | 28 | 47 |
| Average Weight | 72 | 70 | 75 | 68 | 70 | 70 | 54 | 67 | 72 |
| Grams | 19,542 | 12,006 | 27,635 | 967 | 3,863 | 952 | 220 | 1,261 | 66,445 |
| Grams/Episode | 30 | 34 | 29 | 26 | 38 | 29 | 22 | 50 | 31 |
| Grams per 1,000 Population | 3 | 2 | 6 | 1 | 2 | 2 | 1 | 3 | 3 |
| Myocarditis in children | Patients | <5 | 18 | <5 | <5 | <5 |  | <5 |  | 29 |
| Average Age | 3 | 2 | 1 | 5 | 1 |  | 0 |  | 2 |
| Average Weight | 11 | 11 | 7 | 18 | 8 |  | 2 |  | 11 |
| Grams | 69 | 444 | 24 | 62 | 30 |  | 6 |  | 635 |
| Grams/Episode | 14 | 14 | 12 | 21 | 15 |  | 6 |  | 14 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  | 0 |  | 0 |
| PANDAS/tic disorders | Patients | 13 | <5 | 5 | <5 | <5 |  |  |  | 23 |
| Average Age | 9 | 14 | 10 | 18 | 13 |  |  |  | 11 |
| Average Weight | 33 | 48 | 50 | 60 | 60 |  |  |  | 41 |
| Grams | 2,158 | 2,196 | 1,283 | 125 | 132 |  |  |  | 5,893 |
| Grams/Episode | 41 | 31 | 31 | 25 | 33 |  |  |  | 34 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  |  |  | 0 |
| Potassium channel antibody-associated encephalopathy | Patients | 15 | <5 | <5 | <5 | <5 | <5 |  |  | 27 |
| Average Age | 47 | 57 | 55 | 60 | 59 | 51 |  |  | 52 |
| Average Weight | 75 | 74 | 73 | 53 | 72 | 87 |  |  | 75 |
| Grams | 6,098 | 608 | 1,104 | 608 | 1,470 | 1,425 |  |  | 11,312 |
| Grams/Episode | 38 | 32 | 53 | 36 | 36 | 27 |  |  | 36 |
| Grams per 1,000 Population | 1 | 0 | 0 | 0 | 1 | 3 |  |  | 0 |
| Pure red cell aplasia | Patients | 12 | 13 | 12 |  | <5 | <5 |  |  | 39 |
| Average Age | 56 | 34 | 51 |  | 88 | 48 |  |  | 48 |
| Average Weight | 74 | 51 | 76 |  | 82 | 88 |  |  | 69 |
| Grams | 3,060 | 825 | 3,292 |  | 80 | 1,560 |  |  | 8,816 |
| Grams/Episode | 36 | 36 | 38 |  | 80 | 40 |  |  | 38 |
| Grams per 1,000 Population | 0 | 0 | 1 |  | 0 | 3 |  |  | 0 |
| Pyoderma gangrenosum | Patients | 6 | 12 | <5 |  | <5 | <5 |  |  | 23 |
| Average Age | 67 | 59 | 60 | 53 | 47 | 28 |  |  | 59 |
| Average Weight | 79 | 97 | 68 | 69 | 70 | 100 |  |  | 88 |
| Grams | 2,500 | 5,978 | 200 | 690 | 670 |  |  |  | 10,038 |
| Grams/Episode | 69 | 52 | 40 | 57 | 42 | 0 |  |  | 54 |
| Grams per 1,000 Population | 0 | 1 | 0 | 0 | 0 |  |  |  | 0 |
| Rasmussen Syndrome | Patients | 13 | <5 | <5 | <5 |  |  |  | <5 | 22 |
| Average Age | 34 | 44 | 39 | 34 |  |  |  | 36 | 37 |
| Average Weight | 72 | 72 | 68 | 137 |  |  |  | 57 | 72 |
| Grams | 3,847 | 1,370 | 1,146 | 660 |  |  |  | 789 | 7,812 |
| Grams/Episode | 43 | 31 | 29 | 47 |  |  |  | 25 | 36 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 |  |  |  | 2 | 0 |
| Scleromyxedema | Patients | 5 | <5 | <5 | <5 | <5 |  |  |  | 15 |
| Average Age | 66 | 64 | 68 | 72 | 36 |  |  |  | 62 |
| Average Weight | 75 | 75 | 80 | 57 | 84 |  |  |  | 73 |
| Grams | 2,731 | 3,445 | 960 | 2,190 | 280 |  |  |  | 9,606 |
| Grams/Episode | 45 | 37 | 69 | 35 | 40 |  |  |  | 41 |
| Grams per 1,000 Population | 0 | 1 | 0 | 1 | 0 |  |  |  | 0 |
| Sjögren’s syndrome | Patients | 13 | <5 | 5 | <5 |  |  |  | <5 | 25 |
| Average Age | 57 | 81 | 46 | 55 |  |  |  | 52 | 56 |
| Average Weight | 72 | 67 | 72 | 72 |  |  |  | 75 | 72 |
| Grams | 4,510 | 527 | 1,460 | 1,511 |  |  |  | 2,920 | 10,928 |
| Grams/Episode | 33 | 20 | 18 | 47 |  |  |  | 57 | 34 |
| Grams per 1,000 Population | 1 | 0 | 0 | 1 |  |  |  | 7 | 0 |
| Subacute sensory neuropathy | Patients | <5 | 7 | 7 | <5 | <5 |  |  |  | 21 |
| Average Age | 63 | 64 | 55 | 64 | 65 |  | 49 |  | 61 |
| Average Weight | 55 | 78 | 86 | 72 | 62 |  | 80 |  | 75 |
| Grams | 955 | 872 | 2,260 | 428 | 250 |  | 320 |  | 5,085 |
| Grams/Episode | 26 | 42 | 32 | 27 | 36 |  | 80 |  | 33 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  | 1 |  | 0 |
| Susac syndrome | Patients | 9 |  | 5 |  |  |  |  |  | 13 |
| Average Age | 49 |  | 47 |  |  |  |  |  | 48 |
| Average Weight | 87 |  | 86 |  |  |  |  |  | 86 |
| Grams | 7,746 |  | 2,776 |  |  |  |  |  | 10,522 |
| Grams/Episode | 61 |  | 39 |  |  |  |  |  | 53 |
| Grams per 1,000 Population | 1 |  | 1 |  |  |  |  |  | 0 |
| Systemic capillary leak syndrome | Patients | 7 | <5 | 5 |  |  |  | <5 | <5 | 16 |
| Average Age | 39 | 56 | 33 |  |  |  | 0 | 66 | 40 |
| Average Weight | 68 | 82 | 72 |  |  |  | 1 | 80 | 69 |
| Grams | 1,599 | 2,200 | 3,352 |  |  |  | 3 | 1,760 | 8,914 |
| Grams/Episode | 39 | 71 | 42 |  |  |  | 3 | 88 | 52 |
| Grams per 1,000 Population | 0 | 0 | 1 |  |  |  | 0 | 4 | 0 |
| **Chapter 7 Total** | Patients | 275 | 202 | 200 | 44 | 61 | 15 | 9 | 21 | 824 |
| Average Age | 42 | 42 | 45 | 42 | 44 | 38 | 36 | 34 | 42 |
| Average Weight | 64 | 60 | 73 | 53 | 62 | 68 | 58 | 47 | 64 |
| Grams | 74,241 | 42,725 | 59,462 | 9,379 | 18,364 | 4,802 | 2,086 | 9,064 | 220,122 |
| Grams/Episode | 36 | 37 | 31 | 33 | 44 | 31 | 51 | 47 | 35 |
| Grams per 1,000 Population | 10 | 7 | 12 | 5 | 7 | 9 | 8 | 22 | 9 |
| **Chapter 8** |  |  |  |  |  |  |  |  |  |  |
|
| Aplastic anaemia/pancytopenia | Patients |  | <5 |  |  |  |  |  |  | <5 |
| Average Age |  | 79 |  |  |  |  |  |  | 79 |
| Average Weight |  | 78 |  |  |  |  |  |  | 78 |
| Grams |  | 78 |  |  |  |  |  |  | 78 |
| Grams/Episode |  | 78 |  |  |  |  |  |  | 78 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| Sepsis | Patients |  | <5 |  |  |  |  |  |  | <5 |
| Average Age |  | 41 |  |  |  |  |  |  | 41 |
| Average Weight |  | 82 |  |  |  |  |  |  | 82 |
| Grams |  | 663 |  |  |  |  |  |  | 663 |
| Grams/Episode |  | 133 |  |  |  |  |  |  | 133 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| **Chapter 8 Total** | Patients |  | 5 |  |  |  |  |  |  | 5 |
| Average Age |  | 49 |  |  |  |  |  |  | 49 |
| Average Weight |  | 82 |  |  |  |  |  |  | 82 |
| Grams |  | 741 |  |  |  |  |  |  | 741 |
| Grams/Episode |  | 124 |  |  |  |  |  |  | 124 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| chorea | Patients |  |  |  |  |  |  | <5 |  | <5 |
| Average Age |  |  |  |  |  |  | 10 |  | 10 |
| Average Weight |  |  |  |  |  |  | 32 |  | 32 |
| Grams |  |  |  |  |  |  | 60 |  | 60 |
| Grams/Episode |  |  |  |  |  |  | 60 |  | 60 |
| Grams per 1,000 Population |  |  |  |  |  |  | 0 |  | 0 |
| contact with a measles patient | Patients |  |  |  | <5 |  |  |  |  | <5 |
| Average Age |  |  |  | 81 |  |  |  |  | 81 |
| Average Weight |  |  |  | 92 |  |  |  |  | 92 |
| Grams |  |  |  | 36 |  |  |  |  | 36 |
| Grams/Episode |  |  |  | 36 |  |  |  |  | 36 |
| Grams per 1,000 Population |  |  |  | 0 |  |  |  |  | 0 |
| **Total** | Patients | 6,627 | 4,134 | 4,428 | 1,043 | 1,115 | 339 | 83 | 308 | 17,958 |
| Average Age | 57 | 56 | 60 | 58 | 52 | 57 | 49 | 54 | 57 |
| Average Weight | 74 | 73 | 77 | 74 | 74 | 77 | 73 | 73 | 75 |
| Grams | 1,981,690 | 1,185,409 | 1,449,386 | 287,699 | 353,171 | 106,422 | 24,152 | 99,583 | 5,487,511 |
| Grams/Episode | 31 | 32 | 28 | 30 | 32 | 30 | 44 | 30 | 30 |
| Grams per 1,000 Population | 254 | 190 | 297 | 168 | 138 | 205 | 98 | 245 | 225 |

Note: The national patient count only includes one count for each patient. This may result in the sum of the state and territory totals being greater than the national total.

# Appendix E – Grams Ig Issued by State and Territory

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** |
| **2006-07** | Imported Ig | 103,270 | 88,398 | 79,393 | 18,375 | 20,577 | 11,065 |  | 7170 |
| Domestic Ig | 493,172 | 407,244 | 337,301 | 92,958 | 155,821 | 50,583 | 6,732 | 26,470 |
| **2007-08** | Imported Ig | 105,633 | 111,010 | 85,055 | 18,416 | 38,445 | 11,740 |  | 16,875 |
|  | Domestic Ig | 599,126 | 423,170 | 400,144 | 108,596 | 148,986 | 52,755 | 6,825 | 27,393 |
| **2008-09** | Imported Ig | 249,905 | 131,228 | 171,367 | 27,604 | 42,895 | 19,965 |  | 14,200 |
|  | Domestic Ig | 562,320 | 417,574 | 383,865 | 128,511 | 143,628 | 53,745 | 10,503 | 22,841 |
| **2009-10** | Imported Ig | 252,416 | 101,930 | 200,264 | 31,244 | 16,248 | 17,110 |  | 11,550 |
|  | Domestic Ig | 668,526 | 507,038 | 439,089 | 143,285 | 162,963 | 61,686 | 8,610 | 33,225 |
| **2010-11** | Imported Ig | 136,728 | 93,835 | 107,798 | 27,383 | 30,108 | 8,843 | 80 | 11,900 |
|  | Domestic Ig | 887,016 | 577,260 | 631,545 | 139,296 | 167,745 | 76,197 | 9,099 | 45,540 |
| **2011-12** | Imported Ig | 265,995 | 144,284 | 183,435 | 35,775 | 59,900 | 12,138 | 30 | 14,708 |
|  | Domestic Ig | 874,995 | 570,969 | 674,277 | 145,134 | 150,294 | 73,491 | 13,440 | 52,446 |
| **2012-13** | Imported Ig | 467,371 | 321,085 | 361,654 | 72,613 | 92,914 | 16,436 | 9,551 | 26,648 |
|  | Domestic Ig | 804,375 | 484,680 | 589,662 | 123,810 | 132,108 | 64,305 | 6,744 | 48,480 |
| **2013-14** | Imported Ig | 469,174 | 312,713 | 291,460 | 87,901 | 70,709 | 24,069 | 10,429 | 30,626 |
|  | Domestic Ig | 934,478 | 584,561 | 771,037 | 138,876 | 168,295 | 67,776 | 6,036 | 53,723 |
| **2014-15** | Imported Ig | 593,045 | 416,868 | 458,189 | 107,343 | 111,570 | 41,608 | 12,861 | 32,199 |
|  | Domestic Ig | 930,412 | 579,560 | 735,658 | 135,795 | 155,977 | 57,987 | 4,863 | 59,210 |
| **2015-16** | Imported Ig | 724,960 | 451,770 | 584,275 | 103,165 | 159,631 | 48,003 | 18,489 | 41,264 |
|  | Domestic Ig | 1,004,528 | 643,340 | 771,182 | 167,599 | 152,900 | 53,207 | 5,589 | 52,601 |
| **2016-17** | Imported Ig | 914,742 | 480,381 | 639,087 | 114,989 | 174,908 | 49,712 | 18,205 | 45,305 |
|  | Domestic Ig | 1,057,386 | 732,525 | 821,999 | 182,943 | 192,437 | 55,969 | 7,215 | 54,710 |

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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Year | Quarter | NSW | VIC | QLD | SA | WA | TAS | NT | ACT | AUST |
| 2009-10 | Q1 | 2,434 | 1,367 | 1,644 | 400 | 380 | 183 | 23 | 112 | 6,508 |
| Q2 | 2,496 | 1,378 | 1,667 | 440 | 356 | 177 | 20 | 109 | 6,619 |
| Q3 | 2,554 | 1,386 | 1,682 | 395 | 353 | 183 | 15 | 102 | 6,640 |
| Q4 | 2,602 | 1,451 | 1,752 | 413 | 371 | 189 | 22 | 120 | 6,889 |
| 2010-11 | Q1 | 2,692 | 1,492 | 1,839 | 420 | 376 | 197 | 22 | 143 | 7,148 |
| Q2 | 2,781 | 1,533 | 1,886 | 394 | 394 | 205 | 21 | 132 | 7,315 |
| Q3 | 2,752 | 1,532 | 1,884 | 396 | 376 | 211 | 15 | 130 | 7,262 |
| Q4 | 2,791 | 1,622 | 1,946 | 417 | 385 | 197 | 23 | 142 | 7,496 |
| 2011-12 | Q1 | 2,921 | 1,658 | 2,047 | 419 | 407 | 199 | 27 | 142 | 7,794 |
| Q2 | 2,971 | 1,628 | 2,115 | 428 | 413 | 206 | 22 | 137 | 7,898 |
| Q3 | 2,949 | 1,590 | 2,150 | 430 | 401 | 203 | 23 | 150 | 7,860 |
| Q4 | 2,961 | 1,632 | 2,215 | 458 | 405 | 202 | 29 | 154 | 8,019 |
| 2012-13 | Q1 | 3,107 | 1,751 | 2,391 | 449 | 449 | 205 | 32 | 168 | 8,494 |
| Q2 | 3,139 | 1,809 | 2,360 | 462 | 436 | 196 | 26 | 171 | 8,557 |
| Q3 | 3,211 | 1,753 | 2,298 | 454 | 410 | 183 | 33 | 164 | 8,465 |
| Q4 | 3,309 | 1,821 | 2,378 | 463 | 425 | 187 | 36 | 170 | 8,737 |
| 2013-14 | Q1 | 3,406 | 1,890 | 2,472 | 506 | 435 | 204 | 36 | 181 | 9,081 |
| Q2 | 3,428 | 1,971 | 2,510 | 481 | 472 | 209 | 36 | 172 | 9,237 |
| Q3 | 3,440 | 1,952 | 2,583 | 502 | 454 | 213 | 30 | 188 | 9,317 |
| Q4 | 3,550 | 2,042 | 2,660 | 493 | 513 | 215 | 34 | 188 | 9,653 |
| 2014-15 | Q1 | 3,713 | 2,150 | 2,763 | 545 | 518 | 238 | 41 | 189 | 10,099 |
| Q2 | 3,725 | 2,169 | 2,719 | 506 | 521 | 228 | 32 | 202 | 10,057 |
| Q3 | 3,733 | 2,161 | 2,772 | 530 | 510 | 215 | 25 | 191 | 10,096 |
| Q4 | 3,846 | 2,249 | 2,868 | 555 | 514 | 223 | 31 | 202 | 10,440 |
| 2015-16 | Q1 | 4,101 | 2,354 | 3,026 | 587 | 554 | 234 | 46 | 202 | 11,033 |
| Q2 | 4,103 | 2,346 | 3,067 | 591 | 583 | 225 | 38 | 198 | 11,081 |
| Q3 | 4,161 | 2,358 | 3,073 | 595 | 583 | 226 | 41 | 197 | 11,164 |
| Q4 | 4,263 | 2,400 | 3,132 | 601 | 602 | 227 | 50 | 207 | 11,424 |
| 2016-17 | Q1 | 4,442 | 2,474 | 3,202 | 641 | 650 | 226 | 39 | 211 | 11,827 |
| Q2 | 4,499 | 2,516 | 3,279 | 651 | 682 | 217 | 40 | 161 | 12,022 |
| Q3 | 4,622 | 2,583 | 3,296 | 645 | 663 | 214 | 46 | 221 | 12,253 |
| Q4 | 4,772 | 2,673 | 3,403 | 644 | 680 | 228 | 54 | 219 | 12,621 |

# Appendix G – System Source for Tables and Figures

[Table 1 Growth in Ig grams issued since 2007-08 IDMS](#_Toc18840693)

[Table 2 Percentage change in grams issued over time by state and territory IDMS](#_Toc18840694)

[Table 3 Annual numbers of patients, treatment episodes and grams STARS and BloodSTAR](#_Toc18840695)

[Table 4 Basic numbers STARS and BloodSTAR](#_Toc18840696)

[Table 5 Patient numbers and average weight by age range STARS and BloodSTAR](#_Toc18840697)

[Table 6 Issues of domestic Ig compared with imported Ig IDMS](#_Toc18840698)

[Table 7 Issues of domestic Ig compared with imported Ig and public versus private IDMS](#_Toc18840699)

[Table 8 Ig issues (g) by criteria chapter STARS and BloodSTAR](#_Toc18840700)

[Table 9 Ig issues by criteria chapter (percentage) STARS and BloodSTAR](#_Toc18840701)

[Table 10 Ig grams issued for top 10 medical conditions over time STARS and BloodSTAR](#_Toc18840702)

[Table 11 Difference in grams issued for kidney transplantation (percentage) STARS and BloodSTAR](#_Toc18840703)

[Table 12 Patient numbers and age for the top 20 specific conditions by private and public facilities STARS and BloodSTAR](#_Toc18840704)

[Table 13 Ig grams issued by clinical speciality STARS and BloodSTAR](#_Toc18840705)

[Table 14 Grams of Ig issued by state and territory IDMS](#_Toc18840706)

[Table 15 Grams of Ig issued per 1,000 population by state and territory for top 10 specific conditions STARS and BloodSTAR](#_Toc18840707)

[Table 16 Ig grams per kg weight per episode STARS and BloodSTAR](#_Toc18840708)

[Table 17 Patient numbers for products issued by state and territory in 2016-17 STARS and BloodSTAR](#_Toc18840709)

[Table 18 Grams of product issued by state and territory in 2016-17 STARS and BloodSTAR](#_Toc18840710)

[Table 19 Treatment episode numbers for products issued by state and territory in 2016-17 STARS and BloodSTAR](#_Toc18840711)

[Table 20 Patient numbers for products issued by medical condition in 2016-17 STARS and BloodSTAR](#_Toc18840712)

[Table 21 Grams of product issued by medical condition in 2016-17 STARS and BloodSTAR](#_Toc18840713)

[Table 22 Treatment episodes for product issued by medical condition in 2016-17 STARS and BloodSTAR](#_Toc18840714)

[Table 23 NHIg issued from 2012-13 to 2016-17 IDMS](#_Toc18840715)

[Table 24 Grams of NHIg issued by state and territory IDMS](#_Toc18840716)

[Table 25 Grams per 1,000 population of NHIg issued by state and territory IDMS](#_Toc18840717)

[Figure 1 Ten year trends in issues of Ig IDMS](#_Toc18840910)

[Figure 2 Ten year trends in expenditure on Ig IDMS](#_Toc18840911)

[Figure 3 Patients per 1,000 population 2015-16 and 2016-17 STARS and BloodSTAR](#_Toc18840912)

[Figure 4 Grams of Ig per 1,000 population by state and territory over time IDMS](#_Toc18840913)

[Figure 5 Patient age compared to average Australian age STARS and BloodSTAR](#_Toc18840914)

[Figure 6 Patient weights relative to Australian average STARS and BloodSTAR](#_Toc18840915)

[Figure 7 Ig expenditure as a proportion of the national blood budget IDMS](#_Toc18840916)

[Figure 8 Ig grams issued by medical condition STARS and BloodSTAR](#_Toc18840917)

[Figure 9 Proportion of Ig used for top 10 medical conditions STARS and BloodSTAR](#_Toc18840918)

[Figure 10 Ig issues by clinical speciality STARS and BloodSTAR](#_Toc18840919)

[Figure 11 Percentage Ig issues by clinical speciality for top 10 medical conditions STARS and BloodSTAR](#_Toc18840920)

[Figure 12 Grams per episode by specific condition STARS and BloodSTAR](#_Toc18840921)

[Figure 13 Grams per kg weight by specific condition STARS and BloodSTAR](#_Toc18840922)

[Figure 14 NHIg grams issued and grams issued per 1,000 population IDMS](#_Toc18840923)

Appendix D – Dataset of Ig supply by state/territory ………………………………………………………………………………………………………………………………STARS and BloodSTAR

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

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

1. Robert, Patrick. [*Global Use Of Plasma-Derived Medicinal Products*](http://www.ipfa.nl/UserFiles/File/WS%202015/IPFA%20Cape%20Town%202015/Proceedings%20Publicly%20Published/1_4_Robert_amended.pdf), 2015 [↑](#footnote-ref-2)
2. ABS 3101.0 [↑](#footnote-ref-3)
3. World Health Organization, <https://www.who.int/features/factfiles/ageing/en/> [↑](#footnote-ref-4)
4. ABS 4841.0 (latest statistics available) [↑](#footnote-ref-5)
5. ABS 4841.0 (average of male and female) [↑](#footnote-ref-6)
6. ABS 4364.0.55.001 [↑](#footnote-ref-7)
7. Other here covers NHIg sent to the New Zealand Blood Service. [↑](#footnote-ref-8)