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

**ANNUAL REPORT 2021-22**

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

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ISSN 1839-1079 (online version)

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

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# Introduction

Immunoglobulin (Ig) products, derived from pooled human plasma, are a precious and high-cost resource. Strengthening Ig governance is a priority for the National Blood Authority (NBA), and several 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 are referred to as Ig unless specifically stated. Normal human Ig is reported separately. Immunoglobulin 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 2021-22, also considering trends in supply over the last 10 years.

In Australia it is estimated that over 99 per cent 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, purchasing blood and blood products on behalf of all Australian governments, developing and implementing national strategies to encourage better governance, promoting appropriate use of blood and blood products, and providing expert advice to support government policy development. Further background is at **Appendix A.**

The 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 criteria 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 Immunoglobulin in Australia* (the Criteria) was developed in collaboration with expert specialist clinicians and identify the medical conditions and circumstances for which the use of Ig is clinically appropriate and where there are no safe, effective and cost-effective alternative treatments. First published in 2007 (Version 1), with the second edition (Version 2) in 2012 and the third revision implemented in October 2018 (Version 3), the Criteria identifies the conditions and circumstances for which the use of Ig is funded under national blood arrangements. In the third edition, eligibility criteria were updated to align with new evidence and best clinical practice, along with other improvements to aid prescribers. Version 3 also reflects earlier updated access arrangements for SCIg and NHIg.

Version 3 of the Criteria clearly articulates and standardises the qualifying and continuing Ig access requirements. In 2021-22 139 specific conditions or 56 medical conditions were classified into 4 categories:

1. conditions for which Ig has an established therapeutic role
2. conditions that have an emerging therapeutic role
3. conditions where Ig has application in exceptional circumstances only
4. conditions for which Ig should not be supplied under the 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, persons in prescriber role can request patient authorisation for access to government-funded Ig. Under the governance arrangements, persons in dispenser roles 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, standardises prescribing practices, and increases efficiency and transparency while strengthening decision-making and improving data capture. BloodSTAR implementation commenced in July 2016 and was completed in October 2018.

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. Subcutaneous Ig 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.

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

Immunoglobulin products should be prescribed and dispensed in accordance with the relevant 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*.

Demand for Ig is met through domestic and imported Ig products. Domestic Ig is manufactured by CSL Behring (Australia) Pty Ltd (CSL Behring) using plasma collected from voluntary, non-remunerated Australian donations. Both domestic and imported Ig are distributed by the Australian Red Cross Lifeblood (Lifeblood).

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 10 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 10 medical conditions account for about 88 per cent of all Ig supplied in 2021-22, and for this reason specific analysis focuses on these groups.

**Issues of Immunoglobulin**

Immunoglobulin comprises approximately 56 per cent of total blood expenditure each year. Demand for Ig was growing at an annual rate of more than 10 per cent up to and including 2017-18. This growth in demand moderated and did not exceed 7.4 per cent in each of last 4 years. This is the lowest annual rate of increase since 2004-05 when Australia first secured an adequate national sufficiency of Ig supply through the importation of Ig by the NBA. Growth since 2016-17 is shown below.

Table : Ig growth for the last 5 years

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **2017-18** | **2018-19** | **2019-20** | **2020-21** | **2021-22** |
| 10.6% | 7.2% | 6.7% | 7.4% | 6.9% |

In 2021-22, a total of approximately 8 million grams of Ig was issued nationally at a cost of $810.4 million (including the cost of plasma for fractionation). Of this amount, about 58 per cent of Ig was produced in Australia and 42 per cent was imported.

The NBA maintains arrangements with a diverse set of suppliers to secure a range of Ig products. Immunoglobulin products imported from overseas complement the supply of domestic plasma-derived products supplied by CSL Behring under the National Fractionation Agreement for Australia (NaFAA) and ensure that the overall clinical demand for blood products in Australia is met.

There are 4 contracts in place for the supply of imported Ig under the national blood arrangements. These contracts commenced progressively from 1 January 2021 and will continue for up to five years, with extension options available. The suppliers are CSL Behring, Grifols Australia Pty Ltd (Grifols), Takeda Pharmaceutical Company (Takeda) and Octapharma Pty Ltd (Octapharma).

# Report Snapshot

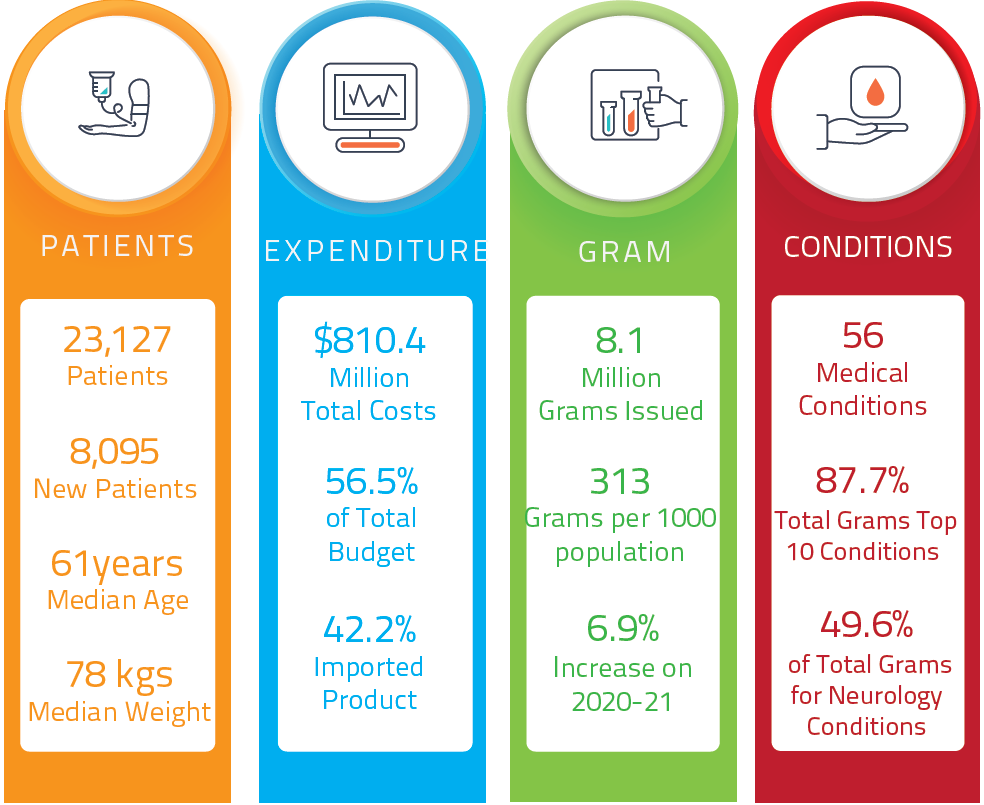


Figure 1: Snapshot

A graph of a number of bars

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Figure 2: Per cent Issued grams by medical condition

# Methodology

Prior to 2016-17, authorisation and dispense data were collected by Lifeblood, and in 2016 states and territories commenced transition to using BloodSTAR as per Table 2. Lifeblood entered information on current patients and authorisations into BloodSTAR using information from Supply Tracking Analysis Recording System (STARS). These data are known as l*egacy* data. When comparing data across time there are limitations to some data that may not be directly comparable due to changes in Criteria versions, or whether the data has come from BloodSTAR or STARS. More information about these differences can be found in the data quality section below.

Table : Go live dates for BloodSTAR

|  |  |
| --- | --- |
| State and Territory | 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 | 22 October 2018 |

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

The Criteria groups together several specific conditions into one medical condition. For example, Primary Immunodeficiency Diseases (PID) is a medical condition in the Criteria,with this group incorporating several specific conditions. In some cases, the analysis 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 most 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 E**.

Note that the grams per 1,000 population measure shown in earlier reports, has been a poor indicator for benchmarking. Raw population figures do not consider the underlying population age structure, hospital usage patterns, and cross-border referrals; nor do total issues consider varying product wastage rates across time, and states and territories. A study done in South Australia (SA) in 2010 (Australian Health Review article - "Red alert - a new perspective on patterns of blood use in the South Australian public sector") shows this. It 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. These factors are:

* The reconciliation of data held in STARS, BloodSTAR/BloodNet and Integrated Data Management System (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 being dispensed to a patient.
* Patient and authorisation data for some records are incomplete. For example, data from STARS and BloodSTAR may not include weight. Legacy data entered in BloodSTAR did not include weight.
* The Australian Bureau of Statistics (ABS) Australian Demographic Statistics (cat. No 3101.0) was used from 2011-12.
* Care should be taken when interpreting the data relating to the smaller states and territories since one or 2 patients can overly influence the use as 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.
* States and territories are based on the state or territory of the facility which dispensed the product, not the treating facility state or territory.
* The STARS data have age and weight data recorded at treatment dates (first reported in 2009‑10). This data changes over time. Weight data is complete in 2018-19 based on the transition to BloodSTAR. Age data are based on the patient’s age on 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 Dispense Events.
* 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
* product dispensed in more than one state or territory
* dispense events recorded at both a private facility and at a public facility
* received IVIg and SCIg, or
* received both domestic and imported product.
* In some cases, grams issued or dispensed may not total as the aggregate may be round to the nearest integer.
* Earlier versions of the Criteriaclassified medical conditions into 4 Chapters based on the level of evidence supporting the use of Ig. In BloodSTAR these are known as Categories and are used in reporting from 2020-21.
* 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.
* Dispensed data can be entered into BloodSTAR at any time if there is a valid and active authorisation. This means that a Dispense Event may be recorded in one month and the actual Dispense Event was in another month which means data for 2020-21 could be recorded in 2021-22.
* To maintain the anonymity of individual patients and health providers, data showing less than 5 may be suppressed or aggregated if there is a potential to re-identify or exceptions are agreed between national and state/territory data custodians.

This report uses data from three primary sources, as follows:

1. Data collected by the NBA on the units of Ig issued to Australian Health Providers (AHPs) and purchases from suppliers. These data are held in the NBA’s IDMS.
2. Data collected by Lifeblood under contractual arrangements with the NBA on behalf of all Australian governments. These data are collected either when an order is placed for Ig or is collected following the treatment where product is issued as imprest stock. The data are collected into Lifeblood’s STARS database, and
3. Data collected by the NBA on the units dispensed by AHPs to be administered to the patient. The data are collected into the NBAs BloodNet and BloodSTAR systems.

**Table 3** shows the reconciliation between the 3 systems used for this report. A variance of 2.2 per cent represents less than one week of issues. This difference relates to timing of data entry or product held as imprest stock.

Table : Grams recorded in the different systems held by the NBA

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Total Issued Grams** | **BloodSTAR Dispensed Grams** | **Difference Grams** | **Difference %** |
|  |
| NSW | 2,802,986 | 2,701,090 | 101,897 | 3.6% |  |
| VIC | 1,780,164 | 1,745,372 | 34,792 | 2.0% |  |
| QLD | 1,976,360 | 1,963,638 | 12,722 | 0.6% |  |
| SA | 436,091 | 428,408 | 7,683 | 1.8% |  |
| WA | 660,819 | 642,279 | 18,540 | 2.8% |  |
| TAS | 176,058 | 175,223 | 835 | 0.5% |  |
| NT | 36,996 | 36,373 | 623 | 1.7% |  |
| ACT | 181,540 | 178,419 | 3,121 | 1.7% |  |
| **Total** | **8,051,013** | **7,870,800** | **180,213** | **2.2%** |  |

*\*Note: Includes NHIg*

# Trends

## Demand Trends

In 2021-22, a total of 8,051,013 grams of Ig was issued, representing an increase of 520,702 grams (6.9 per cent) over 2020-21. Prior to 2018-19, the increase in Ig use averaged 11 per cent, with the greatest proportion of that increase comprising imported products (Figure 3).

While a proportion of this increase may be attributable to population increases, there has also been a steady increase in the use of Ig per 1,000 population since the introduction of the Criteria in 2008.

A graph with orange bars and black line

Description automatically generated**Figure 3: Ten-year trend in issues of Ig**

A breakdown of the change per year in grams issued by state and territory is provided in **Table 4**.

Over the past 10 years, Western Australia (WA) has been growing at the fastest rate over the past ten years at an average of 12 per cent.

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| 2011-12 | 11% | 7% | 16% | 9% | 6% | 1% | 47% | 17% | **11%** |
| 2012-13 | 11% | 13% | 11% | 9% | 7% | -6% | 21% | 12% | **11%** |
| 2013-14 | 10% | 11% | 12% | 15% | 6% | 14% | 1% | 12% | **11%** |
| 2014-15 | 9% | 11% | 12% | 7% | 12% | 8% | 8% | 8% | **10%** |
| 2015-16 | 14% | 10% | 14% | 11% | 17% | 2% | 36% | 3% | **12%** |
| 2016-17 | 14% | 11% | 8% | 10% | 18% | 4% | 6% | 7% | **11%** |
| 2017-18 | 11% | 12% | 10% | 5% | 9% | 21% | 23% | 13% | **11%** |
| 2018-19 | 9% | 8% | 4% | 7% | 5% | 8% | 0% | 19% | **7%** |
| 2019-20 | 4% | 7% | 7% | 7% | 16% | 9% | -11% | 18% | **7%** |
| 2020-21 | 8% | 5% | 6% | 6% | 16% | 12% | 0% | 12% | 7% |
| 2021-22 | 5% | 9% | 3% | 16% | 18% | 5% | 33% | 2% | 7% |
| **Average last 10 years** | **10%** | **10%** | **9%** | **9%** | **12%** | **8%** | **12%** | **11%** | **9%** |

## Financial Trends

Total expenditure on Ig (excluding plasma for fractionation) in 2021-22 was $505.4 million, an increase of $66.7 million (about 15 per cent) over 2020-21 (**Figure 4**). The increased expenditure predominately represents increases in demand and increasing 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.

A graph showing different colored bars

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Figure : Ten-year trend in expenditure on Ig

In Australia, the total cost of domestic Ig supply comprises the cost of the plasma collected by Lifeblood, plus the cost of purchase of the finished Ig product from the supplier (CSL Behring). Imported Ig product is purchased at a total product cost only.

The cost of Ig as a proportion of the national blood budget is shown at **Figure 5**. Immunoglobulin is the largest budget item, representing 35 per cent of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, Ig accounts for 56 per cent of the total blood budget, at a total expenditure of $810.4 million (excluding specific hyperimmune plasma for fractionation).

A pie chart with text

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

Of the Ig supplied under national blood arrangements in Australia in 2021-22, 58 per cent was manufactured domestically and 42 per cent was imported from overseas (**Table 5**). This represents a 3.4 per cent decrease in product importation from 2020-21. Domestic supply is driven by the amount of plasma for fractionation collected in Australia, and this decreased by 5.4 per cent in 2021-22 over 2020‑21. Intragam 10% (IVIg) and Evogam (SCIg) were Ig products manufactured domestically in 2021‑22.

The imported products available were Privigen (IVIg), Flebogamma (IVIg), Gamunex (IVIg), Cuvitru (SCIg), Octagam (IVIg) and Hizentra (SCIg). When a patient is allocated to receive one of the imported products the clinician may choose a product different to that allocated by BloodSTAR if there is a valid clinical reason. Supply of Privigen constituted about 54 per cent of the supply of imported Ig.

**Table 6** shows the split between Ig issues for domestic and imported products, by public and private AHPs for 2021-22.

Table : Issues of domestic Ig compared with imported Ig

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **NSW** | | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| **Domestic Ig** | Intragam 10 | g | | 1,647,565 | 988,613 | 1,127,980 | 251,528 | 373,833 | 87,380 | 13,258 | 78,130 | **4,568,285** |
| Evogam | g | | 26,282 | 15,672 | 20,687 | 12,040 | 3,995 | 1,038 | 506 | 1,856 | **82,075** |
| **Total Domestic** | **g** | | **1,673,847** | **1,004,285** | **1,148,667** | **263,568** | **377,828** | **88,418** | **13,763** | **79,986** | **4,650,360** |
| **Imported Ig** | Cuvitru | g | | 13,750 | 11,701 | 8,746 | 3,771 | 16,789 | 708 | 56 | 546 | **56,067** |
| Flebogamma | g | | 146,709 | 92,683 | 111,338 | 12,901 | 45,173 | 2,988 | 1,540 | 8,180 | **421,511** |
| Gamunex | g | | 33,230 | 23,685 | 30,940 | 13,075 | 10,105 | 335 | 30 | 255 | **111,655** |
| Hizentra | g | | 217,311 | 141,975 | 142,429 | 31,781 | 45,990 | 20,579 | 2,112 | 18,563 | **620,740** |
| Octagam | g | | 120,005 | 88,595 | 54,140 | 32,205 | 38,720 | 490 | 60 | 6,320 | **340,535** |
| Privigen | g | | 598,135 | 417,240 | 480,100 | 78,790 | 126,215 | 62,540 | 19,435 | 67,690 | **1,850,145** |
| **Total Imported** | **g** | | **1,129,140** | **775,879** | **827,693** | **172,523** | **282,992** | **87,640** | **23,233** | **101,554** | **3,400,653** |
| **Ig Cost excluding the cost of plasma for fractionation** | | $(m) | | $174.8 | $112.3 | $123.9 | $27.1 | $41.6 | $11.3 | $2.5 | $11.9 | $505.4 |
| **Proportion of domestic to imported Ig** | | g% | | 57% | 60% | 56% | 58% | 60% | 57% | 50% | 37% | **44%** |

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

Note: Excludes Norfolk Island

Table : Issues of domestic Ig compared with imported Ig and public versus private Australian Health Providers

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **NSW** | | | **VIC** | | **QLD** | | **SA** | | **WA** | | **TAS** | | **NT** | | **ACT** | | **National** | |
| **Domestic Ig** | Public | g | | 1,177,167 | 615,797 | | 461,175 | | 226,635 | | 264,030 | | 48,523 | | 13,763 | | 78,041 | | 2,885,131 | |
| Private | g | | 496,679 | 388,488 | | 687,492 | | 36,933 | | 113,797 | | 39,895 | | - | | 1,945 | | 1,765,229 | |
| **Total Domestic** | g | | **1,673,847** | **1,004,285** | | **1,148,667** | | **263,568** | | **377,828** | | **88,418** | | **13,763** | | **79,986** | | **4,650,360** | |
| **Imported Ig** | Public | g | | 898,419 | 516,484 | | 411,665 | | 153,228 | | 220,646 | | 64,456 | | 23,233 | | 98,424 | | 2,386,554 | |
| Private | g | | 230,721 | 259,395 | | 416,029 | | 19,295 | | 62,346 | | 23,184 | | - | | 3,130 | | 1,014,100 | |
| **Total Imported** | g | | **1,129,140** | **775,879** | | **827,693** | | **172,523** | | **282,992** | | **87,640** | | **23,233** | | **101,554** | | **3,400,653** | |
| **Total Ig** | Public | g | | 2,075,586 | 1,132,281 | | 872,839 | | 379,863 | | 484,676 | | 112,979 | | 36,996 | | 176,465 | | 5,271,685 | |
| Private | g | | 727,400 | 647,883 | | 1,103,521 | | 56,228 | | 176,143 | | 63,079 | | - | | 5,075 | | 2,779,329 | |
| **Total Ig** | g | | **2,802,986** | **1,780,164** | | **1,976,360** | | **436,091** | | **660,819** | | **176,058** | | **36,996** | | **181,540** | | **8,051,013** | |
| **Ig as portion of National** | Public | g% | | 39% | 21% | | 17% | | 7% | | 9% | | 2% | | 1% | | 3% | | 100% | |
| Private | g% | | 26% | 23% | | 40% | | 2% | | 6% | | 2% | | 0% | | 0% | | 100% | |
| **Total Ig** | g% | | **35%** | **22%** | | **25%** | | **5%** | | **8%** | | **2%** | | **0%** | | **2%** | | **100%** | |
|  | **% of Population** |  | | **31%** | **25%** | | **20%** | | **7%** | | **11%** | | **2%** | | **1%** | | **2%** | | **100%** | |
| **Grams Per 1,000 Population** | Public |  | | 256.4 | 172.6 | | 165.8 | | 210.3 | | 175.5 | | 198.3 | | 148.4 | | 389.3 | | 204.6 | |
| Private |  | | 89.9 | 98.8 | | 209.6 | | 31.1 | | 63.8 | | 110.7 | | - | | 11.2 | | 107.9 | |
| **Total Ig** |  | | **346.2** | **271.4** | | **375.4** | | **241.4** | | **239.2** | | **309.0** | | **148.4** | | **400.5** | | **312.5** | |

Note: Excludes Norfolk Island

# Patient demographics

## Patient Numbers

A total of 23,187 patients were dispensed Ig under the national blood arrangements during 2021-22 and 8,095 were new patients. This represents about a 9 per cent increase in the number of patients since 2020‑21 compared to about a 3 per cent increase in 2020-21 over 2019-20. A summary of new and total patient numbers is provided in **Figure 6**.

Chart, bar chart

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Figure : New and total patients for the last 10 years

The number of patients per 1,000 population dispensed Ig varies between state and territory. Complete data for specific conditions by state and territory can be found at **Appendix D**.

**Table 7** shows a breakdown of the proportion of patients in each state and territory with a comparison to the proportion of the population in each state and territory.

Table : Patient numbers by state and territory

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## age and weight

The distribution of estimated age is shown in **Figure 7** where it is compared with the age distribution of the Australian population as at September 2021.[[1]](#footnote-1) A peak can be seen in the patient population treated with Ig, with most Ig recipients 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.[[2]](#footnote-2)

Immunoglobulin 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.

Chart, bar chart

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Figure : Patient age relative to Australian average

Note: The above figure calculations relate to only 2021-22 patients.

**Figure 7** compares the age of Ig recipients in Australia in 2021-22 and the Australian population using stats from the ABS 3101.

The amount of Ig prescribed for a patient may vary depending on the indication as well as a patient’s weight and is set out in the Criteria. When prescribing Ig, persons in the prescriber role 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 (IBW) for some patients. A calculator is available in BloodSTAR to facilitate this where appropriate.

With an increasingly obese population, we may expect increases in demand if total (rather than ideal) body weight dosing is continued. Reviews conducted of the literature relating to lean body mass dosing should be considered for future research*.*

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

**Table 8** shows the number of distinct patients and the average weight by age ranges for patients with dispenses in 2021-22.

Table : Patient numbers and average weight by age range

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Age Range** | **Patient Counts** | **Average Weight (kg)** | **Treatment Episodes** | **Grams Dispensed** |
| 0-4 | 709 | 14 | 2,623 | 24,780 |
| 5-9 | 430 | 27 | 3,014 | 38,698 |
| 10-14 | 374 | 47 | 3,215 | 74,058 |
| 15-17 | 222 | 61 | 2,525 | 65,735 |
| 18-19 | 151 | 66 | 1,560 | 40,487 |
| 20-29 | 911 | 74 | 9,911 | 279,696 |
| 30-39 | 1,361 | 79 | 15,181 | 461,129 |
| 40-49 | 1,791 | 82 | 22,322 | 735,164 |
| 50-59 | 2,983 | 83 | 36,224 | 1,177,810 |
| 60-69 | 5,253 | 82 | 63,109 | 1,967,105 |
| 70-79 | 5,916 | 79 | 68,569 | 2,100,535 |
| 80-89 | 2,720 | 75 | 29,196 | 834,428 |
| 90 or more | 306 | 69 | 2,816 | 71,176 |
| **Total** | **23,127** | **78** | **260,265** | **7,870,800** |

# Ig Dispenses

## Ig Dispenses by criteria category

TheCriteriaclassifies medical conditions into 4 categories based on the level of evidence supporting the use of Ig, as follows:

* conditions for which Ig has an established therapeutic role
* conditions for which Ig has an emerging therapeutic role
* conditions for which Ig has application in exceptional circumstances only
* conditions for which Ig use is not supported.

Immunoglobulin was predominately dispensed for medical conditions within *Conditions for which Ig has an established therapeutic role.* Refer to **Appendix D** for further information.

Table : Ig grams dispensed by criteria category

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Category** | **2017-18** | **2018-19** | **2019-20** | **2020-21** | **2021-22** |
| Has an established therapeutic role | 5,081,838 | 5,406,598 | 5,760,834 | 6,143,262 | 6,465,105 |
| Has an emerging therapeutic role | 721,766 | 792,821 | 908,889 | 1,046,454 | 1,142,519 |
| Has application in exceptional circumstances only | 271,817 | 246,231 | 181,777 | 220,762 | 261,544 |
| Use is not supported | 288 | 453 | 1,890 | 1,888 | 1,633 |
| Other | 25 |  |  |  |  |
| **Total** | **6,075,733** | **6,446,102** | **6,853,389** | **7,412,365** | **7,870,800** |

While Ig may be dispensed without an approved authorisation in life threatening situations (including prior to a confirmed diagnosis or in situations where the diagnosis is unclear at the time of treatment), under the National Policy, an authorisation for access must be submitted retrospectively. The *Conditions for which Ig use is not supported* and *Other* dispenses generally reflect situations where a retrospective authorisation request identified Ig was used in an emergency to treat a condition that is not supported, or not otherwise mentioned in the Criteria. Data to support compliance with all aspects of qualifying criteria for each specific condition were not always collected in STARS.

## Ig Dispenses by Speciality

Medical Conditions are classified under a medical speciality. The key specialities are Neurology, Haemotology and Immunology. Other is the total for Nephrology, Transplant Medicine, and Dermatology specialities.

All Prescribers are responsible for registering for access to BloodSTAR at each hospital/health facility where they practice and/or are employed. Medical specialists must have their particular speciality field of practice registered with the Australian Health Practitioner Regulation Agency (AHPRA) for the specialty field to be recognised for the purposes of meeting eligibility requirements as specified in the Criteria.

Since 2017-18, there has been a 31 per cent increase in Ig issues for neurological conditions, as compared with a 29 per cent increase for haematological conditions and a 31 per cent increase for immunological conditions.

The variation across states and territories in number of new and total patients, and the amount of Ig dispensed per clinical speciality is illustrated in **Tables 10 to 12** for 2021-22.

Chart, bar chart

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Figure : Grams of Ig dispensed by speciality

The data also illustrate the variation between states and territories in the relative amount of Ig used per patient for the same speciality. For example, about 37 per cent of WA’s Ig patients are haematology patients, using 21 per cent of the state’s total Ig issue in 2021-22. 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.

Table : Ig grams dispensed by speciality and state and territory for 2021-22

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Specialities** | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| Dermatology\* | 13,498 | 20,760 | 12,678 | 6,315 | 8,070 | 1,820 | - | 1,585 | 64,725 |
| Haematology | 679,706 | 471,480 | 655,484 | 167,676 | 131,541 | 69,436 | 8,316 | 26,549 | 2,210,189 |
| Immunology | 576,480 | 323,686 | 327,067 | 71,764 | 123,901 | 21,898 | 3,957 | 44,675 | 1,493,426 |
| Neurology | 1,410,524 | 801,753 | 951,010 | 174,133 | 370,825 | 70,374 | 21,785 | 104,755 | 3,905,158 |
| Transplant Medicine\* | 20,883 | 127,693 | 17,400 | 8,520 | 7,943 | 11,695 | 2,315 | 855 | 197,303 |
| **Total** | **2,701,090** | **1,745,372** | **1,963,638** | **428,408** | **642,279** | **175,223** | **36,373** | **178,419** | **7,870,800** |

*\*Included as Other in Figure 8*

Table : Patients dispensed Ig by speciality and state and territory for 2021-22

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Specialities** | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| Dermatology\* | 18 | 32 | 22 | 5 | 12 | <5 | - | <5 | <99 |
| Haematology | 3,057 | 2,056 | 2,406 | 735 | 660 | 242 | 41 | 131 | 9,216 |
| Immunology | 2,070 | 1,141 | 1,092 | 261 | 447 | 78 | 24 | 150 | 5,178 |
| Neurology | 3,066 | 1,729 | 1,997 | 390 | 647 | 154 | 59 | 231 | 8,123 |
| Transplant Medicine\* | 150 | 317 | 60 | 40 | 41 | 20 | 14 | 7 | 644 |
| **Total** | **8,311** | **5,245** | **5,551** | **1,427** | **1,795** | **495** | **138** | **520** | **23,127** |

*\*Included as Other in Figure 8*

Table : New patients dispensed Ig by speciality and state and territory for 2021-22

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Specialities** | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| Dermatology\* | 8 | 9 | 5 | <5 | <5 | - | - | - | <32 |
| Haematology | 1,275 | 851 | 689 | 336 | 302 | 59 | 20 | 49 | 3,569 |
| Immunology | 537 | 387 | 294 | 75 | 130 | 15 | 9 | 35 | 1,473 |
| Neurology | 1,016 | 638 | 546 | 170 | 241 | 51 | 32 | 71 | 2,739 |
| Transplant Medicine\* | 100 | 136 | 32 | 20 | 24 | 8 | 10 | <5 | 331 |
| **Total** | **2,918** | **2,010** | **1,557** | **599** | **<702** | **133** | **71** | **<160** | **8,095** |

*\*Included as Other in Figure 8*

## Ig Dispenses by Medical Condition

The top 10 medical conditions account for about 88 per cent of all Ig supplied, with the top 3 medical conditions accounting for 55 per cent. Acquired hypogammaglobulinaemia — haematological malignancy and post haemopoietic stem cell transplantation (HSCT) is the medical condition for which the greatest percentage of Ig was dispensed in 2021-22 (23 per cent), closely followed by chronic inflammatory demyelinating polyneuropathy (CIDP) (22 per cent). Primary immunodeficiency diseases (PID) with antibody deficiency accounted for around 10 per cent of total Ig use.

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Figure : Grams of Ig dispensed by top 10 medical conditions

The top 10 medical conditions by state and territory for 2021-22 is presented in **Table 13**.

Table : Grams dispensed by states and territories and medical condition for 2021-22

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Specialities** | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| Acquired hypogammaglobulinaemia | 542,856 | 378,955 | 554,834 | 125,999 | 106,649 | 63,184 | 5,371 | 23,184 | 1,801,031 |
| CIDP | 684,257 | 340,553 | 433,281 | 54,458 | 145,647 | 37,494 | 7,460 | 40,524 | 1,743,672 |
| Primary immunodeficiency diseases | 344,254 | 153,105 | 153,468 | 43,337 | 50,576 | 10,866 | 2,530 | 26,689 | 784,823 |
| Myasthenia gravis | 198,970 | 163,203 | 176,342 | 17,628 | 80,688 | 8,178 | 2,055 | 14,218 | 661,279 |
| Inflammatory myopathies | 122,387 | 95,798 | 101,475 | 35,418 | 56,330 | 3,748 | 3,548 | 9,938 | 428,639 |
| Multifocal motor neuropathy | 141,659 | 80,740 | 83,613 | 37,208 | 43,150 | 7,868 | 4,320 | 20,307 | 418,863 |
| Secondary hypogammaglobulinaemia | 138,132 | 70,792 | 113,637 | 7,541 | 21,620 | 9,389 | 446 | 8,022 | 369,579 |
| Immune thrombocytopenic purpura | 99,868 | 68,775 | 77,610 | 30,275 | 16,638 | 5,503 | 2,145 | 1,673 | 302,485 |
| Solid organ transplantation | 20,883 | 127,693 | 17,400 | 8,520 | 7,943 | 11,695 | 2,315 | 855 | 197,303 |
| AMAE | 85,449 | 28,060 | 48,735 | 5,725 | 12,885 | 3,245 | 900 | 6,510 | 191,509 |
| **Total** | **2,378,712** | **1,507,672** | **1,760,394** | **366,108** | **542,124** | **161,168** | **31,089** | **151,917** | **6,899,182** |

# Ig Dispenses - IVIg and SCIg

In March 2013, the Jurisdictional Blood Committee (JBC) approved the introduction of SCIg under the national blood arrangements. In 2021-22 the SCIg products supplied by the NBA are:

* Evogam 16% 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (domestic)
* Hizentra 5% 1g/5ml, 2g/10ml, 4g/20ml and 10g/50ml supplied by CSL Behring (imported), and
* Cuvitru 1g/5ml, 2g/10ml, 4g/20ml and 8g/40ml supplied by Takeda Pharmaceuticals (Australia) Pty Ltd (imported).

In addition to the clinical and diagnostic criteria for access to Ig 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. Subcutaneous Ig 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.

In 2021-22, the medical conditions that SCIg can be used to treat are:

* primary immunodeficiency diseases (PID)
* 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), and
* chronic inflammatory demyelinating polyneuropathy (CIDP).

These products are authorised and distributed by Lifeblood in the same manner as IVIg. **Tables 14-15** show the patient numbers, grams dispensed, by medical condition and by IVIg and SCIg products in 2021-22. **Tables 16-17** show the patient numbers, grams dispensed, by medical condition and by state and territory in 2021-22.

Table : Patients dispensed by SCIg/NHIg/IVIg medical conditions and product for 2021-22

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | | **NHIg** | **SCIg** | | |  |
| **Medical Condition** | **Flebogamma 5%** | **Flebogamma 10%** | **Gamunex 10%** | | **Intragam 10** | **Octagam 10%** | **Privigen 10%** | **Normal Immunoglobulin** | **Cuvitru** | **Evogam** | **Hizentra** | **Total** |
| Acquired-hypogammaglobulinaemia | 41 | 33 | 115 | 5,433 | | 11 | 899 | - | 143 | 52 | 550 | **7,004** |
| Chronic inflammatory demyelinating polyneuropathy | 96 | 92 | 32 | 1,612 | | 119 | 1,050 | - | 29 | <5 | 152 | **2,992** |
| Primary immunodeficiency diseases | 29 | 6 | <5 | 1,438 | | 23 | 58 | <5 | 86 | 232 | 568 | **2,265** |
| Secondary hypogammaglobulinaemia | 24 | 26 | 67 | 917 | | 52 | 192 | - | 50 | 36 | 193 | **1,468** |
| Specific antibody deficiency | 6 | <5 | <5 | 273 | | 30 | 26 | - | 25 | 33 | 100 | **460** |

Table : Grams dispensed by SCIg/NHIg/IVIg medical conditions and product for 2021-22

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **IVIg** | | | | | | **NHIg** | **SCIg** | | |  |
| **Medical Condition** | **Flebogamma 5%** | **Flebogamma 10%** | **Gamunex 10%** | **Intragam 10** | **Octagam 10%** | **Privigen 10%** | **Normal Immunoglobulin** | **Cuvitru** | **Evogam** | **Hizentra** | **Total** |
| Acquired-hypogammaglobulinaemia | 11,361 | 4,075 | 29,770 | 1,279,688 | 1,215 | 260,060 | - | 20,090 | 11,598 | 183,175 | **1,801,031** |
| Chronic inflammatory demyelinating polyneuropathy | 48,230 | 35,570 | 18,940 | 826,125 | 52,270 | 634,145 | - | 7,065 | 186 | 121,142 | **1,743,672** |
| Primary immunodeficiency diseases | 10,987 | 645 | 480 | 482,508 | 4,680 | 19,455 | 482 | 12,985 | 51,518 | 201,085 | **784,823** |
| Secondary hypogammaglobulinaemia | 5,989 | 3,325 | 7,690 | 222,570 | 8,670 | 48,595 | - | 6,979 | 7,200 | 58,561 | **369,579** |
| Specific antibody deficiency | 1,710 | 585 | 690 | 82,078 | 4,755 | 7,890 | - | 2,721 | 8,095 | 32,118 | **140,642** |

Table : Patients dispensed by SCIg medical conditions, and state and territory for 2021-22

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Products** | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| Acquired-hypogammaglobulinaemia | 210 | 190 | 135 | 81 | 100 | 26 | <5 | 13 | **739** |
| Chronic inflammatory demyelinating polyneuropathy | 54 | 46 | 44 | <5 | 22 | 8 | <5 | 9 | **180** |
| Primary immunodeficiency diseases | 338 | 201 | 178 | 70 | 63 | 11 | <5 | 32 | **876** |
| Secondary hypogammaglobulinaemia | 92 | 40 | 99 | 11 | 23 | 7 | <5 | <5 | **<285** |
| Specific antibody deficiency | 59 | 28 | 21 | 15 | 26 | <5 | <5 | 5 | **154** |

Table : Grams dispensed by SCIg medical conditions, and state and territory for 2021-22

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Products** | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| Acquired-hypogammaglobulinaemia | 63,356 | 54,842 | 37,492 | 20,951 | 25,926 | 9,203 | 63 | 3,029 | **214,863** |
| Chronic inflammatory demyelinating polyneuropathy | 33,065 | 33,145 | 33,018 | 918 | 15,047 | 6,064 | 1,080 | 6,056 | **128,393** |
| Primary immunodeficiency diseases | 100,750 | 59,136 | 60,760 | 16,942 | 13,548 | 3,806 | 1,080 | 9,567 | **265,588** |
| Secondary hypogammaglobulinaemia | 25,472 | 8,265 | 29,222 | 3,356 | 3,840 | 1,779 | 56 | 749 | **72,740** |
| Specific antibody deficiency | 17,186 | 7,714 | 6,597 | 3,617 | 5,548 | 260 | 179 | 1,832 | **42,934** |

# Ig Issued – NHIg

In 2013-14, due to the introduction of SCIg as discussed above, demand for NHIg reduced significantly by 19 per cent. CSL Behring produces NHIg from hyperimmune plasma specially collected by Lifeblood. The volume of product is limited by the availability of this specialised plasma, and by production scheduling arrangements in CSL Behring’s manufacturing facility.

Demand for NHIg further declined in 2014-15 by 78 per cent because of implementation of the NHIg policy outlining the national position on access and use under the national blood arrangements.

**Figure 10** shows the grams issued and the grams issued per 1,000 population by states and territories for either purpose listed above.

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

# Appendices

## Appendix A – Background

**Funding for Ig**

The Commonwealth funded 63 per cent of Ig supplied under the national blood arrangements, with the remaining 37 per cent funded by the state or territory to which the product is supplied.

**The Criteria**

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

Version 3 of the Criteria, was published in October 2018, replacing the *Criteria for the Clinical use of Intravenous Immunoglobulin in Australia* – *Second Edition* (v2) from August 2012. Eligibility criteria were updated to align with new evidence and best clinical practice, along with other improvements to aid prescribers. Version 3 also reflects earlier updated access arrangements for SCIg and NHIg.

**Supply of Product**

Immunoglobulin is made from donated human plasma. In Australia, Lifeblood is contracted to collect plasma for fractionation, which is then supplied to CSL Behring, who is responsible for the manufacture of Australian plasma derived products. To supplement the supply of Australian Immunoglobulin, the NBA contracts additional suppliers to import Ig products to ensure demand can be met adequately.

There are two main ways Ig is available in Australia:

1. Supply under national blood arrangements

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

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

In its role as authoriser of requests for Ig, Lifeblood previously maintained a database of requests, and provides data to the NBA for use as a basis for reporting on the [annual use of Ig in Australia](http://www.blood.gov.au/data-analysis-reporting), known as STARS data. BloodSTAR now holds these data for all states and territories.

1. Direct order and other supply arrangements

For several reasons, medical specialists may sometimes want to prescribe Ig for medical conditions that are not funded under the national blood arrangements as defined in the Criteria. In such cases, IVIg or SCIg may be available either through jurisdictional direct order (JDO) arrangements, or directly from suppliers on a commercial basis, at private expense.

Under JDO arrangements, AHPs can purchase imported product only (IVIg or SCIg) directly from the supplier at an equivalent price to that negotiated by the NBA.

Every state or territory health department is responsible for advising each supplier of imported IVIg and SCIg product of the AHPs in their state or territory. Processes vary, with some states or territories confirming AHP status to the supplier each time a JDO is requested, and others having longer-standing arrangements.

Application and approval arrangements for doctors seeking access to imported Ig products raised through a JDO vary between hospitals and states and territories, but usually involve seeking access through the local hospital therapeutics or Ig committee, or equivalent. Where approval is granted, the cost of the imported Ig product purchased through a JDO is usually borne directly by the AHP.

**2021-22 Activities**

The history of NBA activities prior to 2021-22 can be found in previous *National Report on the Issues and Use of Immunoglobulin (Ig) – Annual Reports.*

The NBA Ig Governance Program continued its work throughout **2021-22** to improve the governance and management of publicly funded Ig. This program aims to ensure that:

* 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,
* access to Ig products is consistent with the Criteria for access determined by governments, and
* capture of information on the need for, use of, and outcomes of treatment (including adverse events) with Ig products is improved, to better inform future changes to the Criteria.

In 2021–22 the Ig Governance Program continued to:

* Implement and promote the *National Policy: Access to Government-funded Immunoglobulin Products in Australia*, which defines the role and responsibilities of all professionals involved in the prescription, management and use of Ig,
* oversee the digital Ig management system BloodSTAR, which facilitates clinical requests for patient access to Ig products,
* monitor and improve access to Ig, including reviewing and refining the *Criteria for the Clinical Use of Immunoglobulin in Australia* (the Criteria), which defines eligibility for access to Ig based on expert clinical assessment and advice, and
* advise and support clinical staff by reporting on Ig usage and responding to enquiries relating to access to Ig.

Working towards further improvements, the Ig Governance Program also:

* assisted in the development of enhancements to BloodSTAR to further streamline access to Ig by making the system easier for clinicians to use, and
* began a review of the National SCIg Program with the aim of identifying options to overcome current barriers to program uptake and inform the future direction of the program. HealthConsult has been engaged to undertake the review, with outcomes expected in mid-2023.

As reported in the NBA’s 2020-21 Annual Report, PricewaterhouseCoopers completed an evaluation of the impact of the Ig Governance Program in May 2021, which showed that:

* since the implementation of the Ig Governance Program, the rate of growth in Ig usage had decreased from almost 11 per cent annually to 7.3 per cent. The rate of growth in 2021-22 was 6.9 per cent, consistent with this trend,
* there is a correlation between key components of the Ig Governance Program and decreasing use of Ig, most notably following the introduction of Version 3 of the Criteria (2018) and BloodSTAR,
* the reduced growth in Ig demand translates to an estimated $90 million saving in Ig product expenditure between 2018-19 and 2020-21. It is predicted that this trend will continue, with savings expected to grow to an estimated $2.2 billion over the decade to 2030-31, and
* no major changes were observed in the use of Ig for the 10 most treated medical conditions, and there had been no reduction in the doses administered. This indicates that the reduced rate of growth in Ig usage has been achieved through more targeted access to Ig, not through ceasing or limiting access to Ig for patients who need it.

In 2021-22, the Ig Governance team progressed the recommendations from the report. The NBA will continue to explore further opportunities to support the efficient, effective, ethical and most appropriate use of this precious resource and enable continued patient access to Ig therapy under national funding arrangements.

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

|  |  |
| --- | --- |
| ABS | Australian Bureau of Statistics |
| ACT | Australian Capital Territory |
| AHP | Australian Health Provider |
| AHPRA | Australian Health Practitioner Regulation Agency |
| AMAE | Autoimmune encephalitis mediated by antibodies targeting cell-surface antigens |
| ANZSBT | Australia and New Zealand Society of Blood Transfusion |
| BloodNet | The national online ordering and inventory management system |
| BloodSTAR | Blood System for Tracking Authorisations and Reviews |
| HSCT | Hematopoietic stem cell transplantation |
| IDMS | Integrated Data Management System |
| Ig | Immunoglobulin products including IVIg and SCIg |
| IVIg | Intravenous immunoglobulin |
| JBC | Jurisdictional Blood Committee |
| NaFAA | National Fractionation Agreement for Australia |
| NBA | National Blood Authority |
| NHIg | Normal human immunoglobulin |
| NIGAC | National Immunoglobulin Governance Advisory Committee |
| NSQHS | National Safety and Quality Health Service |
| NSW | New South Wales |
| NT | Northern Territory |
| PID | Primary Immunodeficiency Diseases |
| QLD | Queensland |
| SA | South Australia |
| SCIg | Subcutaneous Immunoglobulin |
| STARS | Supply Tracking Analysis Recording System |
| TAS | Tasmania |
| VIC | Victoria |
| WA | Western Australia |

Glossary of terms

| Term | Description |
| --- | --- |
| Blood products | Products manufactured from human blood |
| Lifeblood | The Australian Red Cross Lifeblood |
| 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) 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 immunoglobulin in Australia (*theCriteria*)* | 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 | Previously known as Jurisdictional Direct Orders. Arrangements implemented by the NBA with suppliers to facilitate the purchase of Ig for the treatment of conditions not satisfying the *Criteria for the clinical use of Ig in Australia* |
| 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 and held at their site |
| 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 or Dispense Event | 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 or dispense event |

## Appendix C – Version 3 Conditions By Speciality

| Specific Condition | Medical Condition | Speciality | Category |
| --- | --- | --- | --- |
| Acquired bleeding disorder, other coagulation factors (Prothrombin, factor V, factor VII, factor X, factor XI, and factor XIII) | Coagulation factor inhibitors | Haematology | Has application in exceptional circumstances only |
| Acquired haemophilia A | Coagulation factor inhibitors | Haematology | Has application in exceptional circumstances only |
| Acquired von Willebrand syndrome | Coagulation factor inhibitors | Haematology | Has application in exceptional circumstances only |
| Acute leukaemia | Acquired-hypogammaglobulinaemia — haematological malignancy or post HSCT | Haematology | Has an established therapeutic role |
| Anti-neutrophil cytoplasmic antibody (ANCA) (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis | Anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis | Immunology | Has application in exceptional circumstances only |
| Ataxic sensory neuronopathy | Sjögren’s syndrome | Neurology | Has application in exceptional circumstances only |
| Atypical rolandic epilepsy | Childhood epileptic encephalopathy | Neurology | Has application in exceptional circumstances only |
| Autoimmune haemolytic anaemia | Autoimmune haemolytic anaemia (AIHA) | Haematology | Has an emerging therapeutic role |
| Autoimmune neutropenia | Autoimmune neutropenia | Haematology | Has application in exceptional circumstances only |
| Autoimmune retinopathy | Autoimmune retinopathy (AIR) | Immunology | Has application in exceptional circumstances only |
| Autonomic neuropathy | Sjögren’s syndrome | Neurology | Has application in exceptional circumstances only |
| Bullous Pemphigoid | Bullous pemphigoid | Immunology | Has an emerging therapeutic role |
| Catastrophic anti-phospholipid syndrome | Catastrophic anti-phospholipid syndrome (CAPS) | Immunology | Has application in exceptional circumstances only |
| Chronic Immune thrombocytopenic purpura (ITP) | Immune thrombocytopenic purpura (ITP) — adult | Haematology | Has an established therapeutic role |
| Chronic inflammatory demyelinating polyneuropathy (CIDP) | Chronic inflammatory demyelinating polyneuropathy (CIDP) | Neurology | Has an established therapeutic role |
| Chronic lymphocytic leukaemia (CLL) | Acquired-hypogammaglobulinaemia — haematological malignancy or post HSCT | Haematology | Has an established therapeutic role |
| Cicatricial pemphigoid (CP) | Cicatricial pemphigoid (CP) or Mucous Membrane Pemphigoid (MMP) | Dermatology | Has an emerging therapeutic role |
| Combined immunodeficiency generally less profound than SCID (e.g. thymoma) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Combined immunodeficiency with associated or syndromal features (e.g. Wiskott Aldrich syndrome; ataxia telangiectasia) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Confirmed autoimmune congenital heart block in a fetus | Autoimmune congenital heart block | Immunology | Has application in exceptional circumstances only |
| Congenital haemophilia A with acquired factor VIII inhibitor | Coagulation factor inhibitors | Haematology | Has application in exceptional circumstances only |
| Dermatomyositis (DM) | Inflammatory myopathies: polymyositis, dermatomyositis and necrotising autoimmune myopathy | Neurology | Has an established therapeutic role |
| Diabetic amyotrophy | Diabetic amyotrophy | Neurology | Use is not supported |
| Drug-induced pemphigus foliaceus | Pemphigus foliaceus (PF) | Immunology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to AMPA receptor | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to CASPR2 | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to DPPX | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to GABA (A or B) receptor | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to glycine receptor | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to LGI1 | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to NMDA receptor | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Encephalitis associated with antibodies to VGKC | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Endemic pemphigus foliaceus | Pemphigus foliaceus (PF) | Immunology | Has an emerging therapeutic role |
| Eosinophilic granulomatosis with polyangiitis (Churg-Strauss Syndrome) | Anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis | Immunology | Has application in exceptional circumstances only |
| Epidermolysis bullosa acquisita | Epidermolysis bullosa acquisita | Immunology | Has application in exceptional circumstances only |
| Evans syndrome - with significant Immune thrombocytopenic purpura (ITP) - adult | Immune thrombocytopenic purpura (ITP) — adult | Haematology | Has an established therapeutic role |
| Evans syndrome child - with significant ITP | Immune thrombocytopenic purpura (ITP) — in children 15 years and younger | Haematology | Has an emerging therapeutic role |
| Evans Syndrome with significant AIHA | Autoimmune haemolytic anaemia (AIHA) | Haematology | Has an emerging therapeutic role |
| Existing patient - authorisation for IgG subclass deficiency | Specific antibody deficiency (SAD) | Immunology | Has an emerging therapeutic role |
| Fetal alloimmune thrombocytopenia (FAIT) | Fetal and neonatal alloimmune thrombocytopenia (FNAIT) | Haematology | Has an established therapeutic role |
| Granulomatosis with polyangiitis (Wegener Granulomatosis) | Anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis | Immunology | Has application in exceptional circumstances only |
| Graves ophthalmopathy | Graves ophthalmopathy (GO) | Immunology | Has application in exceptional circumstances only |
| Guillain–Barré Syndrome (GBS) | Guillain–Barré Syndrome (GBS) | Neurology | Has an established therapeutic role |
| Guillain–Barré Syndrome (GBS) variants | Guillain–Barré Syndrome (GBS) | Neurology | Has an established therapeutic role |
| Haemolytic disease of the fetus | Haemolytic disease of the fetus (HDF) | Haematology | Has application in exceptional circumstances only |
| Haemophagocytic lymphohistiocytosis | Haemophagocytic lymphohistiocytosis | Haematology | Has an emerging therapeutic role |
| Heart and kidney transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Heart and lung transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Heart transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Hyperhaemolysis syndrome | Hyperhaemolysis syndrome | Haematology | Has application in exceptional circumstances only |
| Hypogammaglobulinaemia following B cell depletion therapy | Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | Immunology | Has an emerging therapeutic role |
| Hypogammaglobulinaemia following Solid organ transplantation | Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | Immunology | Has an emerging therapeutic role |
| Idiopathic opsoclonus-myoclonus ataxia | Opsoclonus-myoclonus ataxia (OMA) | Neurology | Has an emerging therapeutic role |
| IgA paraproteinaemic demyelinating neuropathy | Chronic inflammatory demyelinating polyneuropathy (CIDP) | Neurology | Has an established therapeutic role |
| IgA pemphigus foliaceus | Pemphigus foliaceus (PF) | Immunology | Has an emerging therapeutic role |
| IgG paraproteinaemic demyelinating neuropathy | Chronic inflammatory demyelinating polyneuropathy (CIDP) | Neurology | Has an established therapeutic role |
| IgM paraproteinaemic demyelinating neuropathy | IgM paraproteinaemic demyelinating neuropathy | Neurology | Has an emerging therapeutic role |
| Inclusion Body Myositis (IBM) | Inclusion Body Myositis (IBM) | Neurology | Has an established therapeutic role |
| ITP - child - chronic | Immune thrombocytopenic purpura (ITP) — in children 15 years and younger | Haematology | Has an emerging therapeutic role |
| ITP - child - newly diagnosed | Immune thrombocytopenic purpura (ITP) — in children 15 years and younger | Haematology | Has an emerging therapeutic role |
| ITP - child - persistent | Immune thrombocytopenic purpura (ITP) — in children 15 years and younger | Haematology | Has an emerging therapeutic role |
| Kawasaki disease | Kawasaki disease | Immunology | Has an established therapeutic role |
| Kidney transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Lambert–Eaton myasthenic syndrome | Lambert–Eaton myasthenic syndrome (LEMS) | Neurology | Has an established therapeutic role |
| Landau Kleffner syndrome | Childhood epileptic encephalopathy | Neurology | Has application in exceptional circumstances only |
| Lennox-Gastaut syndrome | Childhood epileptic encephalopathy | Neurology | Has application in exceptional circumstances only |
| LETMs | Neuromyelitis optica spectrum disorders (NMOSD) | Neurology | Has application in exceptional circumstances only |
| Liver and kidney transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Liver transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Lung transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Lymphoproliferative syndromes (e.g. XLP1, XLP2, CD27 def) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Macrophage activation syndrome | Haemophagocytic lymphohistiocytosis | Haematology | Has an emerging therapeutic role |
| Memory B cell deficiency secondary to haemopoietic stem cell transplantation (HSCT) | Acquired-hypogammaglobulinaemia — haematological malignancy or post HSCT | Haematology | Has an established therapeutic role |
| Microscopic polyangiitis | Anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis | Immunology | Has application in exceptional circumstances only |
| Monophasic acute disseminated encephalomyelitis (ADEM) | Acute disseminated encephalomyelitis (ADEM) | Neurology | Has an emerging therapeutic role |
| Mucous Membrane Pemphigoid (MMP) | Cicatricial pemphigoid (CP) or Mucous Membrane Pemphigoid (MMP) | Dermatology | Has an emerging therapeutic role |
| Multifocal motor neuropathy with or without persistent conduction block | Multifocal motor neuropathy (MMN) | Neurology | Has an established therapeutic role |
| Multiphasic acute disseminated encephalomyelitis (ADEM) | Acute disseminated encephalomyelitis (ADEM) | Neurology | Has an emerging therapeutic role |
| Multiple myeloma (MM) | Acquired-hypogammaglobulinaemia — haematological malignancy or post HSCT | Haematology | Has an established therapeutic role |
| Myasthenia gravis (MG) | Myasthenia gravis (MG) | Neurology | Has an established therapeutic role |
| Myocarditis in children | Myocarditis in children | Immunology | Use is not supported |
| Necrotising autoimmune myopathy (NAM) | Inflammatory myopathies: polymyositis, dermatomyositis and necrotising autoimmune myopathy | Neurology | Has an established therapeutic role |
| Neonatal alloimmune thrombocytopenia (NAIT) | Fetal and neonatal alloimmune thrombocytopenia (FNAIT) | Haematology | Has an established therapeutic role |
| Neonate with haemochromatosis | Neonatal haemochromatosis (NH) | Haematology | Has an established therapeutic role |
| Newly Diagnosed Immune thrombocytopenic purpura (ITP) | Immune thrombocytopenic purpura (ITP) — adult | Haematology | Has an established therapeutic role |
| NMOSD–AQP4 ab positive | Neuromyelitis optica spectrum disorders (NMOSD) | Neurology | Has application in exceptional circumstances only |
| NMOSD–MOG ab positive | Neuromyelitis optica spectrum disorders (NMOSD) | Neurology | Has application in exceptional circumstances only |
| NMOSD–seronegative | Neuromyelitis optica spectrum disorders (NMOSD) | Neurology | Has application in exceptional circumstances only |
| Non-Hodgkin lymphoma (NHL) | Acquired-hypogammaglobulinaemia — haematological malignancy or post HSCT | Haematology | Has an established therapeutic role |
| Other Haematological malignancy | Acquired-hypogammaglobulinaemia — haematological malignancy or post HSCT | Haematology | Has an established therapeutic role |
| Other Hypogammaglobulinaemia unrelated to haematological malignancies or haemopoietic stem cell transplantation (HSCT) | Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | Immunology | Has an emerging therapeutic role |
| Other transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Paediatric acute neuropsychiatric disorders (PANS) | PANDAS/PANS | Neurology | Has application in exceptional circumstances only |
| Paediatric autoimmune neuropsychiatric disorder (PANDAS) | PANDAS/PANS | Neurology | Has application in exceptional circumstances only |
| Painful small fibre neuropathy | Sjögren’s syndrome | Neurology | Has application in exceptional circumstances only |
| Pancreas and kidney transplant | Solid organ transplantation | Transplant Medicine | Has an emerging therapeutic role |
| Paraneoplastic associated breast cancer | Opsoclonus-myoclonus ataxia (OMA) | Neurology | Has an emerging therapeutic role |
| Paraneoplastic associated neuroblastoma | Opsoclonus-myoclonus ataxia (OMA) | Neurology | Has an emerging therapeutic role |
| Paraneoplastic associated other tumour type | Opsoclonus-myoclonus ataxia (OMA) | Neurology | Has an emerging therapeutic role |
| Paraneoplastic associated small cell lung cancer | Opsoclonus-myoclonus ataxia (OMA) | Neurology | Has an emerging therapeutic role |
| Pemphigus erythematosus | Pemphigus foliaceus (PF) | Immunology | Has an emerging therapeutic role |
| Pemphigus herpetiformis | Pemphigus foliaceus (PF) | Immunology | Has an emerging therapeutic role |
| Pemphigus vulgaris | Pemphigus vulgaris (PV) | Dermatology | Has an emerging therapeutic role |
| Persistent Immune thrombocytopenic purpura (ITP) | Immune thrombocytopenic purpura (ITP) — adult | Haematology | Has an established therapeutic role |
| Polymyositis (PM) | Inflammatory myopathies: polymyositis, dermatomyositis and necrotising autoimmune myopathy | Neurology | Has an established therapeutic role |
| Polyneuropathy of critical illness | Polyneuropathy of critical illness | Immunology | Use is not supported |
| Possible Common variable immune deficiency (CVID) - below normal serum IgG but normal serum IgA level | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Pregnant woman with previous fetal loss | Neonatal haemochromatosis (NH) | Haematology | Has an established therapeutic role |
| Pure red cell aplasia – associated B19 infection | Pure red cell aplasia (PRCA) | Haematology | Has application in exceptional circumstances only |
| Pure red cell aplasia – autoimmune mediated | Pure red cell aplasia (PRCA) | Haematology | Has application in exceptional circumstances only |
| Pyoderma Gangrenosum | Pyoderma Gangrenosum (PG) | Immunology | Has application in exceptional circumstances only |
| Rasmussen encephalitis | Rasmussen encephalitis | Neurology | Has application in exceptional circumstances only |
| Recurrent acute disseminated encephalomyelitis (ADEM) | Acute disseminated encephalomyelitis (ADEM) | Neurology | Has an emerging therapeutic role |
| Relapsing remitting multiple sclerosis | Multiple sclerosis (MS – RMMS) | Neurology | Has application in exceptional circumstances only |
| Risk of autoimmune congenital heart block – previously affected sibling | Autoimmune congenital heart block | Immunology | Has application in exceptional circumstances only |
| Scleromyxedema – skin and systemic disease | Scleromyxedema | Immunology | Has application in exceptional circumstances only |
| Scleromyxedema – skin involvement only | Scleromyxedema | Immunology | Has application in exceptional circumstances only |
| Sensorimotor axonal neuropathy | Sjögren’s syndrome | Neurology | Has application in exceptional circumstances only |
| Sepsis | Sepsis | Immunology | Use is not supported |
| Sero-negative autoimmune encephalitis | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Sero-negative limbic encephalitis | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Severe combined immunodeficiency (SCID) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Severe reduction in all Ig isotypes with decreased or absent B-cells (e.g. XLA def) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Severe reduction in at least two Ig isotypes with low/normal B-cells (e.g. CVID) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Severe reduction in serum IgG and IgA with normal/elevated IgM (e.g. CD40L def) | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Specific antibody deficiency | Specific antibody deficiency (SAD) | Immunology | Has an emerging therapeutic role |
| Staphylococcal TSS | Toxic shock syndrome | Immunology | Has an emerging therapeutic role |
| Stevens–Johnson syndrome / toxic epidermal necrolysis overlap (SJS/TEN) | Toxic epidermal necrolysis / Stevens–Johnson syndrome | Immunology | Has an emerging therapeutic role |
| Stiff person syndrome | Stiff person syndrome | Neurology | Has an established therapeutic role |
| Streptococcal TSS | Toxic shock syndrome | Immunology | Has an emerging therapeutic role |
| Susac syndrome | Susac syndrome | Neurology | Has application in exceptional circumstances only |
| Suspected autoimmune encephalitis | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Suspected autoimmune limbic encephalitis | Antibody mediated autoimmune encephalitis (AMAE) | Neurology | Has an emerging therapeutic role |
| Systemic capillary leak syndrome | Systemic Capillary leak syndrome | Immunology | Has application in exceptional circumstances only |
| Thymoma-associated hypogammaglobulinaemia (Goods Syndrome) | Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency) | Immunology | Has an emerging therapeutic role |
| Toxic epidermal necrolysis (TEN) | Toxic epidermal necrolysis / Stevens–Johnson syndrome | Immunology | Has an emerging therapeutic role |
| Transient hypogammaglobulinaemia of infancy | Primary immunodeficiency diseases (PID) | Immunology | Has an established therapeutic role |
| Vaccine induced immune thrombotic thrombocytopenia (VITT) | Vaccine induced immune thrombotic thrombocytopenia (VITT) | Haematology | Has application in exceptional circumstances only |
| West syndrome | Childhood epileptic encephalopathy | Neurology | Has application in exceptional circumstances only |

## Appendix D – Dataset of Ig supply by state/territory 2021-22

| **Specific Condition** |  | **NSW** | **VIC** | **QLD** | **SA** | **WA** | **TAS** | **NT** | **ACT** | **National** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Has an established therapeutic role** | | | | | | | | | | |
| Acute leukaemia | Patients | 162 | 121 | 56 | 26 | 41 | 5 | <5 | <5 | 404 |
| Average Age | 39 | 45 | 51 | 25 | 48 | 52 | 48 | 15 | 42 |
| Average Weight | 66 | 71 | 70 | 49 | 81 | 74 | 109 | 56 | 68 |
| Grams | 18,462 | 17,888 | 11,258 | 2,453 | 5,060 | 1,263 | 480 | 318 | 57,182 |
| Grams/Episode | 20 | 21 | 22 | 11 | 20 | 19 | 40 | 14 | 20 |
| Grams per 1,0001,000 Population | 2 | 3 | 2 | 1 | 2 | 2 | 2 | 1 | 2 |
| Chronic Immune thrombocytopenic purpura (ITP) | Patients | 164 | 126 | 120 | 31 | 47 | 6 | <5 | 6 | <505 |
| Average Age | 59 | 66 | 58 | 64 | 57 | 40 | 26 | 67 | 60 |
| Average Weight | 80 | 78 | 83 | 79 | 83 | 80 | 50 | 77 | 80 |
| Grams | 31,118 | 24,190 | 27,308 | 3,670 | 7,510 | 1,058 | 100 | 605 | 95,558 |
| Grams/Episode | 47 | 50 | 35 | 46 | 62 | 44 | 50 | 50 | 44 |
| Grams per 1,000 Population | 4 | 4 | 5 | 2 | 3 | 2 | 0 | 1 | 4 |
| Chronic inflammatory demyelinating polyneuropathy (CIDP) | Patients | 1,198 | 579 | 767 | 181 | 103 | 63 | 21 | 79 | 2,927 |
| Average Age | 65 | 64 | 62 | 63 | 63 | 62 | 55 | 59 | 63 |
| Average Weight | 83 | 84 | 85 | 85 | 84 | 88 | 89 | 87 | 84 |
| Grams | 672,144 | 337,421 | 421,776 | 144,925 | 53,448 | 35,812 | 7,460 | 39,924 | 1,712,907 |
| Grams/Episode | 46 | 42 | 30 | 46 | 43 | 29 | 59 | 51 | 40 |
| Grams per 1,000 Population | 83 | 51 | 80 | 80 | 19 | 63 | 30 | 88 | 66 |
| Chronic lymphocytic leukaemia (CLL) | Patients | 573 | 372 | 436 | 121 | 127 | 57 | 6 | 30 | 1,696 |
| Average Age | 74 | 74 | 74 | 71 | 72 | 74 | 66 | 73 | 73 |
| Average Weight | 77 | 79 | 79 | 76 | 83 | 82 | 90 | 81 | 78 |
| Grams | 154,106 | 105,624 | 132,499 | 28,860 | 31,929 | 18,399 | 2,130 | 7,728 | 481,274 |
| Grams/Episode | 28 | 25 | 23 | 19 | 22 | 25 | 34 | 24 | 25 |
| Grams per 1,000 Population | 19 | 16 | 25 | 16 | 12 | 32 | 9 | 17 | 19 |
| Combined immunodeficiency generally less profound than SCID (e.g. thymoma) | Patients | 18 | 18 | 8 | 5 | <5 |  | <5 |  | <59 |
| Average Age | 52 | 32 | 38 | 68 | 14 |  | 4 |  | 42 |
| Average Weight | 65 | 50 | 59 | 74 | 42 |  | 19 |  | 58 |
| Grams | 5,318 | 3,445 | 3,207 | 1,708 | 481 |  | 100 |  | 14,260 |
| Grams/Episode | 20 | 16 | 24 | 33 | 13 |  | 8 |  | 20 |
| Grams per 1,000 Population | 1 | 1 | 1 | 1 | 0 |  | 0 |  | 1 |
| Combined immunodeficiency with associated or syndromal features (e.g. Wiskott Aldrich syndrome; ataxia telangiectasia) | Patients | 12 | 10 | 15 | 6 | <5 |  | <5 | <5 | <58 |
| Average Age | 22 | 31 | 18 | 15 | 7 |  | 16 | 31 | 20 |
| Average Weight | 53 | 62 | 43 | 36 | 25 |  | 33 | 62 | 46 |
| Grams | 3,017 | 2,400 | 2,975 | 1,173 | 350 |  | 208 | 535 | 10,657 |
| Grams/Episode | 22 | 17 | 17 | 9 | 4 |  | 10 | 15 | 15 |
| Grams per 1,000 Population | 0 | 0 | 1 | 1 | 0 |  | 1 | 1 | 0 |
| Dermatomyositis (DM) | Patients | 102 | 78 | 66 | 31 | 25 | <5 | <5 | 11 | <323 |
| Average Age | 51 | 49 | 56 | 57 | 46 | 47 | 69 | 47 | 52 |
| Average Weight | 70 | 75 | 80 | 74 | 82 | 78 | 55 | 69 | 75 |
| Grams | 38,561 | 32,555 | 28,888 | 16,110 | 11,545 | 1,135 | 350 | 4,313 | 133,456 |
| Grams/Episode | 36 | 46 | 24 | 40 | 45 | 27 | 27 | 41 | 35 |
| Grams per 1,000 Population | 5 | 5 | 5 | 9 | 4 | 2 | 1 | 10 | 5 |
| Evans syndrome - with significant Immune thrombocytopenic purpura (ITP) - adult | Patients | <5 | 5 | 5 |  | <5 | <5 |  |  | <25 |
| Average Age | 45 | 65 | 40 |  | 69 | 36 |  |  | 46 |
| Average Weight | 119 | 86 | 92 |  | 72 | 147 |  |  | 93 |
| Grams | 510 | 810 | 1,413 |  | 200 | 400 |  |  | 3,333 |
| Grams/Episode | 57 | 68 | 24 |  | 25 | 200 |  |  | 37 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 | 1 |  |  | 0 |
| Fetal alloimmune thrombocytopenia (FAIT) | Patients | <5 | <5 | <5 | <5 |  |  |  |  | <20 |
| Average Age | 32 | 34 | 37 | 28 |  |  |  |  | 34 |
| Average Weight | 73 | 93 | 65 | 64 |  |  |  |  | 86 |
| Grams | 2,395 | 5,990 | 280 | 585 |  |  |  |  | 9,250 |
| Grams/Episode | 73 | 55 | 25 | 65 |  |  |  |  | 57 |
| Grams per 1,000 Population | 0 | 1 | 0 | 0 |  |  |  |  | 0 |
| Guillain–Barré Syndrome (GBS) | Patients | 223 | 163 | 121 | 68 | 33 | 16 | <5 | 12 | <641 |
| Average Age | 56 | 55 | 55 | 57 | 60 | 68 | 61 | 68 | 56 |
| Average Weight | 79 | 82 | 82 | 81 | 77 | 81 | 64 | 83 | 81 |
| Grams | 34,360 | 25,470 | 19,800 | 10,338 | 5,030 | 3,060 | 530 | 2,093 | 100,680 |
| Grams/Episode | 34 | 42 | 22 | 33 | 36 | 20 | 38 | 72 | 32 |
| Grams per 1,000 | 4 | 4 | 4 | 6 | 2 | 5 | 2 | 5 | 4 |
| Guillain–Barré Syndrome (GBS) variants | Patients | 102 | 56 | 35 | 17 | 15 | <5 | <5 | <5 | <240 |
| Average Age | 58 | 52 | 49 | 48 | 49 | 42 | 43 | 66 | 53 |
| Average Weight | 78 | 75 | 80 | 79 | 80 | 82 | 83 | 102 | 78 |
| Grams | 14,605 | 8,593 | 5,035 | 2,265 | 2,043 | 618 | 438 | 528 | 34,123 |
| Grams/Episode | 34 | 43 | 26 | 33 | 31 | 44 | 40 | 53 | 35 |
| Grams per 1,000 Population | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 |
| IgA paraproteinaemic demyelinating neuropathy | Patients | 8 | <5 | 7 | <5 |  |  |  |  | <25 |
| Average Age | 77 | 73 | 69 | 44 |  |  |  |  | 70 |
| Average Weight | 84 | 65 | 96 | 56 |  |  |  |  | 90 |
| Grams | 2,590 | 520 | 6,815 | 225 |  |  |  |  | 10,150 |
| Grams/Episode | 38 | 40 | 38 | 28 |  |  |  |  | 38 |
| Grams per 1,000 Population | 0 | 0 | 1 | 0 |  |  |  |  | 0 |
| IgG paraproteinaemic demyelinating neuropathy | Patients | 22 | 6 | 14 | 2 | <5 | <5 |  | <5 | <57 |
| Average Age | 75 | 78 | 71 | 57 | 63 | 81 |  | 67 | 73 |
| Average Weight | 76 | 76 | 75 | 75 | 90 | 84 |  | 76 | 77 |
| Grams | 9,523 | 2,613 | 4,690 | 498 | 1,010 | 1,683 |  | 600 | 20,615 |
| Grams/Episode | 36 | 43 | 32 | 19 | 44 | 34 |  | 30 | 35 |
| Grams per 1,000 Population | 1 | 0 | 1 | 0 | 0 | 3 |  | 1 | 1 |
| Inclusion Body Myositis (IBM) | Patients | 33 | 46 | 34 | <5 | 13 | <5 |  | 6 | <142 |
| Average Age | 74 | 74 | 71 | 75 | 74 | 77 |  | 72 | 73 |
| Average Weight | 81 | 81 | 84 | 68 | 75 | 65 |  | 88 | 81 |
| Grams | 13,256 | 23,475 | 18,628 | 1,208 | 4,985 | 868 |  | 2,835 | 65,253 |
| Grams/Episode | 35 | 45 | 29 | 42 | 33 | 26 |  | 35 | 36 |
| Grams per 1,000 Population | 2 | 4 | 4 | 1 | 2 | 2 |  | 6 | 3 |
| Kawasaki disease | Patients | 190 | 161 | 92 | 43 | 39 | 8 | <5 | 7 | <545 |
| Average Age | 8 | 5 | 4 | 4 | 4 | 5 | 5 | 14 | 6 |
| Average Weight | 26 | 22 | 22 | 20 | 22 | 22 | 18 | 37 | 23 |
| Grams | 9,775 | 8,365 | 4,468 | 2,020 | 1,910 | 448 | 145 | 475 | 27,605 |
| Grams/Episode | 33 | 36 | 18 | 34 | 29 | 45 | 36 | 59 | 30 |
| Grams per 1,000 Population | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Lambert–Eaton myasthenic syndrome | Patients | 11 | 7 | 10 | <5 | <5 |  |  | <5 | <43 |
| Average Age | 66 | 70 | 59 | 80 | 63 |  |  | 77 | 63 |
| Average Weight | 67 | 85 | 73 | 66 | 91 |  |  | 64 | 75 |
| Grams | 5,225 | 3,778 | 4,328 | - | 1,205 |  |  | 710 | 15,245 |
| Grams/Episode | 40 | 48 | 20 | - | 28 |  |  | 51 | 31 |
| Grams per 1,000 Population | 1 | 1 | 1 |  | 0 |  |  | 2 | 1 |
| Lymphoproliferative syndromes (e.g. XLP1, XLP2, CD27 def) | Patients | <5 | <5 | <5 | <5 | <5 | <5 |  |  | <30 |
| Average Age | 41 | 30 | 1 | 14 | 18 | 45 |  |  | 33 |
| Average Weight | 67 | 85 | 10 | 40 | 54 | 75 |  |  | 67 |
| Grams | 1,153 | 480 | 20 | 13 | 163 | 288 |  |  | 2,116 |
| Grams/Episode | 27 | 22 | 5 | 3 | 13 | 24 |  |  | 22 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 1 |  |  | 0 |
| Memory B cell deficiency secondary to haemopoietic stem cell transplantation (HSCT) | Patients | 132 | 63 | 124 | 16 | 41 | 9 | <5 | 6 | 387 |
| Average Age | 51 | 53 | 56 | 55 | 53 | 57 | 67 | 46 | 54 |
| Average Weight | 73 | 73 | 72 | 68 | 74 | 82 | 79 | 61 | 72 |
| Grams | 26,481 | 13,002 | 31,866 | 2,867 | 8,432 | 3,083 | 320 | 1,340 | 87,390 |
| Grams/Episode | 25 | 21 | 21 | 20 | 21 | 28 | 32 | 16 | 22 |
| Grams per 1,000 Population | 3 | 2 | 6 | 2 | 3 | 5 | 1 | 3 | 3 |
| Multifocal motor neuropathy with or without persistent conduction block | Patients | 209 | 112 | 133 | 47 | 42 | 13 | <5 | 20 | 569 |
| Average Age | 58 | 58 | 59 | 60 | 61 | 64 | 51 | 56 | 59 |
| Average Weight | 79 | 83 | 81 | 80 | 85 | 83 | 75 | 88 | 81 |
| Grams | 141,659 | 80,740 | 83,613 | 43,150 | 37,208 | 7,868 | 4,320 | 20,307 | 418,863 |
| Grams/Episode | 48 | 50 | 30 | 49 | 56 | 30 | 66 | 67 | 44 |
| Grams per 1,000 Population | 17 | 12 | 16 | 24 | 13 | 14 | 17 | 45 | 16 |
| Multiple myeloma (MM) | Patients | 647 | 454 | 541 | 139 | 141 | 54 | <5 | 27 | 1,985 |
| Average Age | 72 | 69 | 71 | 69 | 70 | 69 | 63 | 72 | 71 |
| Average Weight | 77 | 80 | 79 | 81 | 83 | 82 | 95 | 74 | 79 |
| Grams | 150,885 | 109,845 | 152,045 | 31,505 | 36,871 | 17,680 | 150 | 4,934 | 503,914 |
| Grams/Episode | 27 | 24 | 23 | 15 | 20 | 23 | 38 | 23 | 23 |
| Grams per 1,000 Population | 19 | 17 | 29 | 17 | 13 | 31 | 1 | 11 | 20 |
| Myasthenia gravis (MG) | Patients | 459 | 359 | 376 | 163 | 51 | 21 | 7 | 39 | 1,445 |
| Average Age | 63 | 63 | 63 | 62 | 63 | 60 | 47 | 59 | 63 |
| Average Weight | 81 | 83 | 84 | 79 | 84 | 80 | 85 | 82 | 82 |
| Grams | 198,970 | 163,203 | 176,342 | 80,688 | 17,628 | 8,178 | 2,055 | 14,218 | 661,279 |
| Grams/Episode | 37 | 40 | 24 | 37 | 37 | 20 | 41 | 39 | 32 |
| Grams per 1,000 Population | 25 | 25 | 33 | 45 | 6 | 14 | 8 | 31 | 26 |
| Necrotising autoimmune myopathy (NAM) | Patients | 74 | 56 | 63 | 46 | 23 | <5 | 5 | <5 | <277 |
| Average Age | 66 | 64 | 67 | 59 | 65 | 45 | 50 | 53 | 64 |
| Average Weight | 78 | 77 | 82 | 84 | 78 | 106 | 76 | 59 | 80 |
| Grams | 27,891 | 28,645 | 25,298 | 25,705 | 12,873 | 1,960 | 3,135 | 275 | 125,781 |
| Grams/Episode | 36 | 50 | 22 | 42 | 45 | 35 | 48 | 16 | 36 |
| Grams per 1,000 Population | 3 | 4 | 5 | 14 | 5 | 3 | 13 | 1 | 5 |
| Neonatal alloimmune thrombocytopenia (NAIT) | Patients | 8 | 8 | <5 | 5 | <5 |  | <5 | <5 | <41 |
| Average Age | - | - | - | 31 | - |  | 36 | - | 16 |
| Average Weight | 3 | 3 | 2 | 64 | 3 |  | 117 | 3 | 39 |
| Grams | 38 | 40 | 8 | 1,758 | 15 |  | 800 | 8 | 2,665 |
| Grams/Episode | 3 | 3 | 3 | 63 | 3 |  | 100 | 3 | 37 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 |  | 3 | 0 | 0 |
| Neonate with haemochromatosis | Patients |  | <5 | <5 |  |  |  |  |  | <10 |
| Average Age |  | - | - |  |  |  |  |  | - |
| Average Weight |  | 3 | 3 |  |  |  |  |  | 3 |
| Grams |  | 10 | 13 |  |  |  |  |  | 23 |
| Grams/Episode |  | 3 | 4 |  |  |  |  |  | 3 |
| Grams per 1,000 Population |  | 0 | 0 |  |  |  |  |  | 0 |
| Newly Diagnosed Immune thrombocytopenic purpura (ITP) | Patients | 297 | 234 | 206 | 72 | 116 | 20 | 11 | 9 | 965 |
| Average Age | 60 | 60 | 62 | 62 | 64 | 60 | 52 | 61 | 61 |
| Average Weight | 77 | 76 | 82 | 80 | 85 | 88 | 86 | 78 | 80 |
| Grams | 38,960 | 26,220 | 29,038 | 9,060 | 15,395 | 2,843 | 1,563 | 1,043 | 124,120 |
| Grams/Episode | 56 | 60 | 37 | 65 | 67 | 26 | 82 | 61 | 51 |
| Grams per 1,000 Population | 5 | 4 | 6 | 5 | 6 | 5 | 6 | 2 | 5 |
| Non-Hodgkin lymphoma (NHL) | Patients | 630 | 444 | 665 | 151 | 165 | 76 | 13 | 35 | 2,135 |
| Average Age | 71 | 68 | 70 | 68 | 69 | 70 | 61 | 68 | 70 |
| Average Weight | 76 | 78 | 78 | 79 | 80 | 81 | 79 | 72 | 78 |
| Grams | 157,632 | 115,232 | 195,264 | 35,263 | 40,823 | 20,228 | 2,176 | 6,718 | 573,333 |
| Grams/Episode | 27 | 24 | 23 | 18 | 22 | 23 | 28 | 21 | 24 |
| Grams per 1,000 Population | 19 | 18 | 37 | 20 | 15 | 35 | 9 | 15 | 22 |
| Other Haematological malignancy | Patients | 180 | 74 | 118 | 31 | 13 | 10 | <5 | 6 | <437 |
| Average Age | 67 | 62 | 70 | 60 | 57 | 65 | 48 | 74 | 66 |
| Average Weight | 75 | 77 | 74 | 78 | 74 | 87 | 70 | 88 | 76 |
| Grams | 35,291 | 17,365 | 31,902 | 5,702 | 2,884 | 2,533 | 115 | 2,148 | 97,937 |
| Grams/Episode | 27 | 21 | 21 | 16 | 24 | 19 | 29 | 35 | 23 |
| Grams per 1,000 Population | 4 | 3 | 6 | 3 | 1 | 4 | 0 | 5 | 4 |
| Persistent Immune thrombocytopenic purpura (ITP) | Patients | 141 | 112 | 86 | 34 | 43 | 8 | <5 | <5 | <434 |
| Average Age | 60 | 60 | 57 | 58 | 56 | 45 | 51 | 66 | 58 |
| Average Weight | 78 | 78 | 83 | 82 | 98 | 142 | 74 | 60 | 83 |
| Grams | 29,280 | 17,555 | 19,853 | 3,908 | 7,170 | 1,203 | 483 | 25 | 79,475 |
| Grams/Episode | 51 | 56 | 34 | 60 | 66 | 25 | 48 | 25 | 47 |
| Grams per 1,000 Population | 4 | 3 | 4 | 2 | 3 | 2 | 2 | 0 | 3 |
| Polymyositis (PM) | Patients | 141 | 73 | 100 | 26 | 22 | <5 | <5 | 18 | <390 |
| Average Age | 62 | 62 | 61 | 55 | 68 | 81 | 74 | 62 | 62 |
| Average Weight | 77 | 76 | 81 | 80 | 82 | 65 | 77 | 77 | 79 |
| Grams | 55,935 | 34,598 | 47,290 | 14,515 | 11,000 | 653 | 63 | 5,350 | 169,403 |
| Grams/Episode | 35 | 46 | 26 | 44 | 43 | 26 | 63 | 39 | 35 |
| Grams per 1,000 Population | 7 | 5 | 9 | 8 | 4 | 1 | 0 | 12 | 7 |
| Possible Common variable immune deficiency (CVID) - below normal serum IgG but normal serum IgA level | Patients | 442 | 151 | 125 | 45 | 32 | 6 | <5 | 30 | 818 |
| Average Age | 60 | 47 | 57 | 42 | 58 | 48 | 24 | 50 | 55 |
| Average Weight | 77 | 70 | 76 | 66 | 74 | 86 | 51 | 81 | 75 |
| Grams | 147,578 | 47,233 | 45,839 | 12,991 | 9,027 | 2,082 | 382 | 10,460 | 275,591 |
| Grams/Episode | 29 | 21 | 24 | 17 | 19 | 16 | 21 | 22 | 25 |
| Grams per 1,000 Population | 18 | 7 | 9 | 7 | 3 | 4 | 2 | 23 | 11 |
| Pregnant woman with previous fetal loss | Patients | <5 | <5 |  |  |  |  |  |  | <10 |
| Average Age | 21 | 38 |  |  |  |  |  |  | 37 |
| Average Weight | 60 | 61 |  |  |  |  |  |  | 61 |
| Grams | 120 | 1,590 |  |  |  |  |  |  | 1,710 |
| Grams/Episode | 60 | 61 |  |  |  |  |  |  | 61 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Severe combined immunodeficiency (SCID) | Patients | 16 | 10 | 9 | <5 | <5 |  |  |  | <45 |
| Average Age | 17 | 28 | 23 | 39 | 25 |  |  |  | 23 |
| Average Weight | 39 | 54 | 58 | 106 | 77 |  |  |  | 53 |
| Grams | 3,429 | 3,112 | 3,755 | 120 | 648 |  |  |  | 11,064 |
| Grams/Episode | 22 | 21 | 16 | 30 | 21 |  |  |  | 19 |
| Grams per 1,000 Population | 0 | 0 | 1 | 0 | 0 |  |  |  | 0 |
| Severe reduction in all Ig isotypes with decreased or absent B-cells (e.g. XLA def) | Patients | 37 | 40 | 25 | 10 | 10 |  | <5 | <5 | <132 |
| Average Age | 32 | 35 | 29 | 16 | 21 |  | 18 | 45 | 29 |
| Average Weight | 74 | 68 | 66 | 45 | 50 |  | 47 | 87 | 64 |
| Grams | 15,579 | 14,388 | 7,775 | 3,022 | 2,816 |  | 672 | 749 | 45,000 |
| Grams/Episode | 33 | 23 | 22 | 10 | 18 |  | 28 | 34 | 23 |
| Grams per 1,000 Population | 2 | 2 | 1 | 2 | 1 |  | 3 | 2 | 2 |
| Severe reduction in at least two Ig isotypes with low/normal B-cells (e.g. CVID) | Patients | 466 | 215 | 232 | 93 | 80 | 21 | <5 | 43 | 1,128 |
| Average Age | 50 | 51 | 52 | 42 | 48 | 45 | 65 | 44 | 49 |
| Average Weight | 74 | 76 | 75 | 74 | 70 | 81 | 76 | 77 | 75 |
| Grams | 164,417 | 79,704 | 85,030 | 30,809 | 27,413 | 8,432 | 1,169 | 14,875 | 411,848 |
| Grams/Episode | 29 | 23 | 24 | 18 | 25 | 21 | 39 | 28 | 25 |
| Grams per 1,000 Population | 20 | 12 | 16 | 17 | 10 | 15 | 5 | 33 | 16 |
| Severe reduction in serum IgG and IgA with normal/elevated IgM (e.g. CD40L def) | Patients | 18 | 6 | 18 | <5 | 6 |  |  |  | <53 |
| Average Age | 30 | 51 | 46 | 74 | 55 |  |  |  | 44 |
| Average Weight | 45 | 79 | 61 | 77 | 70 |  |  |  | 61 |
| Grams | 3,625 | 2,343 | 4,864 | 740 | 2,351 |  |  |  | 13,922 |
| Grams/Episode | 18 | 26 | 14 | 32 | 31 |  |  |  | 19 |
| Grams per 1,000 Population | 0 | 0 | 1 | 0 | 1 |  |  |  | 1 |
| Stiff person syndrome | Patients | 58 | 12 | 22 | 10 | <5 | 5 | <5 | 8 | <125 |
| Average Age | 61 | 50 | 62 | 66 | 57 | 53 | 54 | 49 | 60 |
| Average Weight | 77 | 78 | 84 | 71 | 64 | 81 | 73 | 77 | 79 |
| Grams | 33,748 | 5,843 | 15,918 | 6,093 | 915 | 2,695 | 220 | 2,330 | 67,760 |
| Grams/Episode | 46 | 48 | 28 | 34 | 31 | 22 | 28 | 31 | 37 |
| Grams per 1,000 Population | 4 | 1 | 3 | 3 | 0 | 5 | 1 | 5 | 3 |
| Transient hypogammaglobulinaemia of infancy | Patients | <5 |  | <5 |  | <5 | <5 |  | <5 | <25 |
| Average Age | 2 |  | 1 |  | 2 | 5 |  | 1 | 2 |
| Average Weight | 13 |  | 11 |  | 12 | 14 |  | 14 | 13 |
| Grams | 139 |  | 3 |  | 90 | 64 |  | 70 | 366 |
| Grams/Episode | 4 |  | 2 |  | 4 | 4 |  | 5 | 4 |
| Grams per 1,000 Population | 0 |  | 0 |  | 0 | 0 |  | 0 | 0 |
| **Total - Has an established therapeutic role** | **Patients** | **6,627** | **4,052** | **4,536** | **1,400** | **1,206** | **409** | **104** | **406** | **18,445** |
| **Average Age** | **62** | **61** | **63** | **59** | **62** | **63** | **51** | **57** | **62** |
| **Average Weight** | **78** | **78** | **80** | **77** | **79** | **83** | **77** | **80** | **79** |
| **Grams** | **2,247,770** | **1,364,280** | **1,649,097** | **523,941** | **360,424** | **144,526** | **29,560** | **145,508** | **6,465,105** |
| **Grams/Episode** | **35** | **33** | **26** | **29** | **30** | **25** | **44** | **36** | **31** |
| **Grams per 1,000 Population** | **278** | **208** | **313** | **290** | **130** | **254** | **119** | **321** | **251** |
| **Has an emerging therapeutic role** | | | | | | | | | | |
| Autoimmune haemolytic anaemia | Patients | 42 | 34 | 38 | 6 | 9 | <5 |  |  | <139 |
| Average Age | 58 | 72 | 69 | 54 | 62 | 21 |  |  | 65 |
| Average Weight | 73 | 74 | 79 | 69 | 73 | 117 |  |  | 76 |
| Grams | 7,118 | 5,355 | 6,690 | 1,350 | 1,278 | 100 |  |  | 21,890 |
| Grams/Episode | 46 | 58 | 32 | 32 | 53 | 50 |  |  | 42 |
| Grams per 1,000 Population | 1 | 1 | 1 | 1 | 0 | 0 |  |  | 1 |
| Bullous Pemphigoid | Patients | 6 | 11 | 16 | 5 | <5 |  |  | 5 | <48 |
| Average Age | 78 | 62 | 63 | 68 | 78 |  |  | 70 | 66 |
| Average Weight | 82 | 109 | 90 | 86 | 85 |  |  | 69 | 93 |
| Grams | 3,160 | 13,570 | 14,305 | 6,135 | 3,990 |  |  | 2,445 | 43,605 |
| Grams/Episode | 49 | 62 | 39 | 61 | 45 |  |  | 79 | 50 |
| Grams per 1,000 Population | 0 | 2 | 3 | 3 | 1 |  |  | 5 | 2 |
| Cicatricial pemphigoid (CP) | Patients | <5 |  | 11 | <5 |  |  |  |  | <21 |
| Average Age | 67 |  | 68 | 82 |  |  |  |  | 71 |
| Average Weight | 76 |  | 91 | 60 |  |  |  |  | 83 |
| Grams | 3,265 |  | 6,498 | 2,288 |  |  |  |  | 12,050 |
| Grams/Episode | 76 |  | 24 | 29 |  |  |  |  | 30 |
| Grams per 1,000 Population | 0 |  | 1 | 1 |  |  |  |  | 0 |
| Drug-induced pemphigus foliaceus | Patients |  |  |  |  | <5 |  |  |  | <5 |
| Average Age |  |  |  |  | 49 |  |  |  | 49 |
| Average Weight |  |  |  |  | 125 |  |  |  | 125 |
| Grams |  |  |  |  | 200 |  |  |  | 200 |
| Grams/Episode |  |  |  |  | 29 |  |  |  | 29 |
| Grams per 1,000 Population |  |  |  |  | 0 |  |  |  | 0 |
| Encephalitis associated with antibodies to AMPA receptor | Patients | <5 |  |  | <5 |  |  |  |  | <10 |
| Average Age | 54 |  |  | 51 |  |  |  |  | 53 |
| Average Weight | 69 |  |  | 70 |  |  |  |  | 69 |
| Grams | 553 |  |  | 135 |  |  |  |  | 688 |
| Grams/Episode | 28 |  |  | 15 |  |  |  |  | 24 |
| Grams per 1,000 Population | 0 |  |  | 0 |  |  |  |  | 0 |
| Encephalitis associated with antibodies to CASPR2 | Patients | 10 | <5 | 5 | <5 | <5 | <5 |  |  | <35 |
| Average Age | 62 | 63 | 52 | 68 | 67 | 77 |  |  | 61 |
| Average Weight | 81 | 88 | 73 | 73 | 82 | 92 |  |  | 79 |
| Grams | 4,870 | 550 | 1,925 | 440 | 320 | 280 |  |  | 8,385 |
| Grams/Episode | 39 | 50 | 29 | 31 | 32 | 28 |  |  | 36 |
| Grams per 1,000 Population | 1 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| Encephalitis associated with antibodies to DPPX | Patients | <5 |  | <5 |  |  |  |  |  | <10 |
| Average Age | 56 |  | 38 |  |  |  |  |  | 41 |
| Average Weight | 71 |  | 80 |  |  |  |  |  | 78 |
| Grams | 350 |  | 670 |  |  |  |  |  | 1,020 |
| Grams/Episode | 88 |  | 37 |  |  |  |  |  | 46 |
| Grams per 1,000 Population | 0 |  | 0 |  |  |  |  |  | 0 |
| Encephalitis associated with antibodies to GABA (A or B) receptor | Patients |  |  | <5 |  |  |  |  |  | <5 |
| Average Age |  |  | 54 |  |  |  |  |  | 54 |
| Average Weight |  |  | 71 |  |  |  |  |  | 71 |
| Grams |  |  | 295 |  |  |  |  |  | 295 |
| Grams/Episode |  |  | 27 |  |  |  |  |  | 27 |
| Grams per 1,000 Population |  |  | 0 |  |  |  |  |  | 0 |
| Encephalitis associated with antibodies to glycine receptor | Patients |  |  | 5 |  |  |  |  |  | 5 |
| Average Age |  |  | 48 |  |  |  |  |  | 48 |
| Average Weight |  |  | 78 |  |  |  |  |  | 78 |
| Grams |  |  | 2,080 |  |  |  |  |  | 2,080 |
| Grams/Episode |  |  | 17 |  |  |  |  |  | 17 |
| Grams per 1,000 Population |  |  | 0 |  |  |  |  |  | 0 |
| Encephalitis associated with antibodies to LGI1 | Patients | 12 | 9 | 5 | <5 | <5 |  |  | <5 | <41 |
| Average Age | 64 | 64 | 55 | 81 | 74 |  |  | 72 | 63 |
| Average Weight | 67 | 75 | 72 | 63 | 61 |  |  | 75 | 70 |
| Grams | 3,578 | 2,573 | 1,175 | 340 | 120 |  |  | 30 | 7,815 |
| Grams/Episode | 29 | 35 | 17 | 24 | 24 |  |  | 30 | 27 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  |  | 0 | 0 |
| Encephalitis associated with antibodies to NMDA receptor | Patients | 28 | 9 | 24 | <5 | <5 | <5 | <5 | 6 | <87 |
| Average Age | 37 | 47 | 43 | 29 | 48 | 52 | 16 | 34 | 41 |
| Average Weight | 78 | 79 | 80 | 61 | 77 | 76 | 65 | 82 | 79 |
| Grams | 8,215 | 2,880 | 6,758 | 280 | 345 | 600 | 450 | 1,513 | 21,040 |
| Grams/Episode | 36 | 42 | 20 | 70 | 18 | 18 | 50 | 46 | 28 |
| Grams per 1,000 Population | 1 | 0 | 1 | 0 | 0 | 1 | 2 | 3 | 1 |
| Encephalitis associated with antibodies to VGKC | Patients | 6 | 6 | <5 | <5 | <5 |  | <5 | <5 | <37 |
| Average Age | 48 | 56 | 61 | 63 | 70 |  | 19 | 52 | 56 |
| Average Weight | 70 | 83 | 79 | 75 | 85 |  | 80 | 85 | 76 |
| Grams | 2,443 | 1,498 | 1,375 | 1,798 | 155 |  | 110 | 170 | 7,548 |
| Grams/Episode | 29 | 34 | 18 | 47 | 31 |  | 55 | 170 | 30 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 |  | 0 | 0 | 0 |
| Endemic pemphigus foliaceus | Patients |  | <5 |  |  |  |  |  | <5 | <10 |
| Average Age |  | 35 |  |  |  |  |  | 67 | 46 |
| Average Weight |  | 68 |  |  |  |  |  | 63 | 66 |
| Grams |  | 135 |  |  |  |  |  | 125 | 260 |
| Grams/Episode |  | 68 |  |  |  |  |  | 125 | 87 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  | 0 | 0 |
| Evans syndrome child - with significant ITP | Patients |  |  | <5 |  | <5 |  |  |  | <10 |
| Average Age |  |  | 14 |  | 15 |  |  |  | 15 |
| Average Weight |  |  | 62 |  | 36 |  |  |  | 38 |
| Grams |  |  | 63 |  | 460 |  |  |  | 523 |
| Grams/Episode |  |  | 31 |  | 22 |  |  |  | 23 |
| Grams per 1,000 Population |  |  | 0 |  | 0 |  |  |  | 0 |
| Evans Syndrome with significant AIHA | Patients | <5 | <5 | <5 | <5 |  | <5 |  |  | <25 |
| Average Age | 31 | 70 | 68 | 28 |  | 59 |  |  | 54 |
| Average Weight | 102 | 69 | 70 | 56 |  | 76 |  |  | 71 |
| Grams | 205 | 320 | 140 | 135 |  | 245 |  |  | 1,045 |
| Grams/Episode | 103 | 64 | 35 | 34 |  | 82 |  |  | 58 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 |  | 0 |  |  | 0 |
| Existing patient - authorisation for IgG subclass deficiency | Patients | 5 | 17 | <5 | <5 | <5 | <5 | <5 |  | <47 |
| Average Age | 70 | 69 | 64 | 76 | 69 | 83 | 3 |  | 66 |
| Average Weight | 114 | 79 | 73 | 100 | 70 | 50 | 13 |  | 81 |
| Grams | 2,493 | 5,687 | 755 | 672 | 1,048 | 260 | 83 |  | 10,997 |
| Grams/Episode | 27 | 29 | 16 | 19 | 27 | 20 | 3 |  | 24 |
| Grams per 1,000 Population | 0 | 1 | 0 | 0 | 0 | 0 | 0 |  | 0 |
| Haemophagocytic lymphohistiocytosis | Patients | 28 | 14 | 11 | <5 | <5 | <5 |  |  | <68 |
| Average Age | 48 | 45 | 54 | 78 | 41 | 35 |  |  | 50 |
| Average Weight | 66 | 68 | 73 | 80 | 55 | 100 |  |  | 69 |
| Grams | 3,848 | 1,785 | 1,810 | 145 | 433 | 200 |  |  | 8,220 |
| Grams/Episode | 57 | 64 | 29 | 48 | 43 | 100 |  |  | 48 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| Heart and kidney transplant | Patients |  | <5 | <5 |  |  | <5 |  |  | <15 |
| Average Age |  | 32 | 44 |  |  | 48 |  |  | 41 |
| Average Weight |  | 45 | 80 |  |  | 50 |  |  | 56 |
| Grams |  | 40 | 320 |  |  | 25 |  |  | 385 |
| Grams/Episode |  | 13 | 160 |  |  | 8 |  |  | 48 |
| Grams per 1,000 Population |  | 0 | 0 |  |  | 0 |  |  | 0 |
| Heart and lung transplant | Patients | <5 | <5 |  |  |  |  |  |  | <10 |
| Average Age | 41 | 53 |  |  |  |  |  |  | 48 |
| Average Weight | 60 | 71 |  |  |  |  |  |  | 66 |
| Grams | 120 | 140 |  |  |  |  |  |  | 260 |
| Grams/Episode | 24 | 20 |  |  |  |  |  |  | 22 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Heart transplant | Patients | 17 | <5 | <5 | <5 |  |  |  |  | <32 |
| Average Age | 42 | 64 | 62 | 65 |  |  |  |  | 52 |
| Average Weight | 70 | 86 | 88 | 62 |  |  |  |  | 78 |
| Grams | 1,575 | 1,000 | 2,778 | 25 |  |  |  |  | 5,378 |
| Grams/Episode | 14 | 29 | 39 | 25 |  |  |  |  | 25 |
| Grams per 1,000 Population | 0 | 0 | 1 | 0 |  |  |  |  | 0 |
| Hypogammaglobulinaemia following B cell depletion therapy | Patients | 164 | 86 | 114 | 49 | 10 | 12 | <5 | 7 | 437 |
| Average Age | 57 | 53 | 57 | 42 | 50 | 62 | 68 | 55 | 54 |
| Average Weight | 77 | 75 | 73 | 64 | 84 | 78 | 69 | 84 | 73 |
| Grams | 38,209 | 18,958 | 30,706 | 11,142 | 1,861 | 3,154 | 56 | 1,989 | 106,073 |
| Grams/Episode | 26 | 21 | 18 | 13 | 29 | 18 | 7 | 31 | 20 |
| Grams per 1,000 Population | 5 | 3 | 6 | 6 | 1 | 6 | 0 | 4 | 4 |
| Hypogammaglobulinaemia following Solid organ transplantation | Patients | 154 | 112 | 82 | 5 | 5 | 6 |  | 6 | 365 |
| Average Age | 55 | 60 | 55 | 63 | 55 | 39 |  | 56 | 56 |
| Average Weight | 68 | 70 | 74 | 73 | 77 | 78 |  | 87 | 71 |
| Grams | 29,777 | 26,860 | 17,764 | 1,057 | 1,259 | 1,410 |  | 2,065 | 80,189 |
| Grams/Episode | 23 | 21 | 16 | 16 | 19 | 15 |  | 26 | 20 |
| Grams per 1,000 Population | 4 | 4 | 3 | 1 | 0 | 2 |  | 5 | 3 |
| Idiopathic opsoclonus-myoclonus ataxia | Patients | <5 | <5 | <5 | <5 | <5 | <5 |  |  | <30 |
| Average Age | 8 | 1 | 26 | 14 | 47 | 2 |  |  | 18 |
| Average Weight | 23 | 12 | 39 | 34 | 70 | 17 |  |  | 35 |
| Grams | 598 | 338 | 325 | 910 | 2,325 | 68 |  |  | 4,563 |
| Grams/Episode | 14 | 11 | 13 | 28 | 70 | 23 |  |  | 27 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 1 | 0 |  |  | 0 |
| IgA pemphigus foliaceus | Patients |  |  | <5 |  |  |  |  |  | <5 |
| Average Age |  |  | 59 |  |  |  |  |  | 59 |
| Average Weight |  |  | 84 |  |  |  |  |  | 84 |
| Grams |  |  | 970 |  |  |  |  |  | 970 |
| Grams/Episode |  |  | 37 |  |  |  |  |  | 37 |
| Grams per 1,000 Population |  |  | 0 |  |  |  |  |  | 0 |
| IgM paraproteinaemic demyelinating neuropathy | Patients | 34 | 17 | 29 | <5 | <5 | <5 |  | <5 | <100 |
| Average Age | 77 | 76 | 72 | 82 | 62 | 76 |  | 57 | 74 |
| Average Weight | 77 | 87 | 85 | 68 | 78 | 85 |  | 65 | 82 |
| Grams | 15,653 | 6,860 | 14,128 | 2,588 | 1,183 | 1,678 |  | 330 | 42,418 |
| Grams/Episode | 37 | 42 | 26 | 51 | 28 | 27 |  | 24 | 33 |
| Grams per 1,000 Population | 2 | 1 | 3 | 1 | 0 | 3 |  | 1 | 2 |
| ITP - child - chronic | Patients | <5 | 11 | <5 | 5 | <5 |  |  |  | <31 |
| Average Age | 13 | 7 | 6 | 11 | 12 |  |  |  | 8 |
| Average Weight | 63 | 29 | 22 | 49 | 68 |  |  |  | 34 |
| Grams | 168 | 735 | 623 | 395 | 520 |  |  |  | 2,440 |
| Grams/Episode | 56 | 24 | 20 | 36 | 65 |  |  |  | 29 |
| Grams per 1,000 | 0 | 0 | 0 | 0 | 0 |  |  |  | 0 |
| ITP - child - newly diagnosed | Patients | 10 | 18 | 18 | 12 | 6 |  |  | <5 | <69 |
| Average Age | 6 | 4 | 4 | 8 | 5 |  |  | - | 5 |
| Average Weight | 33 | 18 | 25 | 45 | 27 |  |  | 9 | 29 |
| Grams | 443 | 425 | 405 | 970 | 168 |  |  | 50 | 2,460 |
| Grams/Episode | 32 | 15 | 10 | 31 | 21 |  |  | 10 | 20 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 |  |  | 0 | 0 |
| ITP - child - persistent | Patients | <5 | 7 | 6 | <5 | <5 | <5 |  |  | <33 |
| Average Age | 7 | 4 | 3 | 9 | 11 | 14 |  |  | 5 |
| Average Weight | 39 | 26 | 18 | 63 | 61 | 53 |  |  | 32 |
| Grams | 150 | 525 | 235 | 63 | 720 | 55 |  |  | 1,748 |
| Grams/Episode | 21 | 25 | 9 | 63 | 51 | 55 |  |  | 25 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| Kidney transplant | Patients | 91 | 230 | 48 | 30 | 26 | 16 | 14 | 6 | 459 |
| Average Age | 47 | 52 | 49 | 47 | 46 | 49 | 44 | 47 | 50 |
| Average Weight | 77 | 73 | 82 | 76 | 74 | 94 | 86 | 81 | 77 |
| Grams | 13,585 | 106,710 | 13,388 | 5,585 | 5,965 | 10,805 | 2,315 | 755 | 159,108 |
| Grams/Episode | 21 | 31 | 13 | 39 | 30 | 34 | 20 | 13 | 27 |
| Grams per 1,000 Population | 2 | 16 | 3 | 3 | 2 | 19 | 9 | 2 | 6 |
| Liver and kidney transplant | Patients | <5 | <5 |  |  |  |  |  |  | <10 |
| Average Age | 17 | 27 |  |  |  |  |  |  | 25 |
| Average Weight | 73 | 41 |  |  |  |  |  |  | 49 |
| Grams | 250 | 148 |  |  |  |  |  |  | 398 |
| Grams/Episode | 50 | 10 |  |  |  |  |  |  | 20 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Liver transplant | Patients | <5 | <5 | <5 |  | <5 |  |  |  | <20 |
| Average Age | 29 | 42 | 32 |  | 2 |  |  |  | 30 |
| Average Weight | 40 | 85 | 64 |  | 13 |  |  |  | 56 |
| Grams | 273 | 305 | 183 |  | 53 |  |  |  | 813 |
| Grams/Episode | 17 | 20 | 11 |  | 8 |  |  |  | 15 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 |  |  |  | 0 |
| Lung transplant | Patients | 31 | 79 | <5 | 9 | 11 | <5 |  | <5 | <145 |
| Average Age | 50 | 55 | 44 | 45 | 51 | 53 |  | 44 | 53 |
| Average Weight | 65 | 74 | 61 | 63 | 64 | 62 |  | 50 | 70 |
| Grams | 4,355 | 17,838 | 393 | 2,258 | 1,383 | 865 |  | 100 | 27,190 |
| Grams/Episode | 26 | 23 | 33 | 35 | 21 | 21 |  | 25 | 24 |
| Grams per 1,000 Population | 1 | 3 | 0 | 1 | 1 | 2 |  | 0 | 1 |
| Macrophage activation syndrome | Patients | 5 | <5 | <5 |  | <5 |  |  |  | <20 |
| Average Age | 64 | 29 | 34 |  | 66 |  |  |  | 51 |
| Average Weight | 63 | 65 | 69 |  | 85 |  |  |  | 67 |
| Grams | 600 | 130 | 260 |  | 140 |  |  |  | 1,130 |
| Grams/Episode | 33 | 65 | 19 |  | 70 |  |  |  | 31 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 0 |  |  |  | 0 |
| Monophasic acute disseminated encephalomyelitis (ADEM) | Patients | 17 | <5 | 10 | <5 | <5 | <5 |  |  | <47 |
| Average Age | 35 | 36 | 28 | 3 | 42 | 3 |  |  | 31 |
| Average Weight | 76 | 47 | 65 | 15 | 57 | 16 |  |  | 66 |
| Grams | 2,403 | 285 | 1,043 | 30 | 280 | 83 |  |  | 4,123 |
| Grams/Episode | 36 | 32 | 20 | 15 | 40 | 14 |  |  | 29 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| Mucous Membrane Pemphigoid (MMP) | Patients | 5 | 7 | <5 | <5 |  | <5 |  | <5 | <32 |
| Average Age | 64 | 66 | 77 | 71 |  | 50 |  | 82 | 69 |
| Average Weight | 81 | 94 | 78 | 67 |  | 74 |  | 64 | 79 |
| Grams | 3,000 | 7,310 | 2,490 | 2,613 |  | 1,820 |  | 1,585 | 18,818 |
| Grams/Episode | 35 | 79 | 38 | 29 |  | 140 |  | 61 | 51 |
| Grams per 1,000 Population | 0 | 1 | 0 | 1 |  | 3 |  | 3 | 1 |
| Multiphasic acute disseminated encephalomyelitis (ADEM) | Patients | 5 |  | <5 |  | <5 |  |  |  | <15 |
| Average Age | 43 |  | 46 |  | 68 |  |  |  | 47 |
| Average Weight | 55 |  | 113 |  | 73 |  |  |  | 66 |
| Grams | 840 |  | 240 |  | 145 |  |  |  | 1,225 |
| Grams/Episode | 30 |  | 40 |  | 29 |  |  |  | 31 |
| Grams per 1,000 Population | 0 |  | 0 |  | 0 |  |  |  | 0 |
| Other Hypogammaglobulinaemia unrelated to haematological malignancies or haemopoietic stem cell transplantation (HSCT) | Patients | 256 | 105 | 214 | 34 | 12 | 18 | <5 | 16 | 649 |
| Average Age | 64 | 59 | 65 | 41 | 64 | 57 | 69 | 64 | 62 |
| Average Weight | 78 | 72 | 74 | 64 | 86 | 71 | 65 | 80 | 75 |
| Grams | 67,512 | 23,890 | 63,684 | 7,935 | 3,722 | 4,394 | 390 | 3,681 | 175,207 |
| Grams/Episode | 28 | 22 | 22 | 14 | 18 | 18 | 30 | 25 | 23 |
| Grams per 1,000 Population | 8 | 4 | 12 | 4 | 1 | 8 | 2 | 8 | 7 |
| Other transplant | Patients |  | <5 |  |  |  |  |  |  | <5 |
| Average Age |  | 63 |  |  |  |  |  |  | 63 |
| Average Weight |  | 73 |  |  |  |  |  |  | 73 |
| Grams |  | 950 |  |  |  |  |  |  | 950 |
| Grams/Episode |  | 68 |  |  |  |  |  |  | 68 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| Pancreas and kidney transplant | Patients | 6 | 5 | <5 | <5 | <5 |  |  |  | <26 |
| Average Age | 37 | 56 | 40 | 41 | 34 |  |  |  | 44 |
| Average Weight | 79 | 81 | 75 | 77 | 99 |  |  |  | 81 |
| Grams | 725 | 563 | 340 | 75 | 1,120 |  |  |  | 2,823 |
| Grams/Episode | 16 | 14 | 24 | 15 | 86 |  |  |  | 25 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  |  |  | 0 |
| Paraneoplastic associated breast cancer | Patients |  |  |  | <5 |  | <5 |  |  | <10 |
| Average Age |  |  |  | 83 |  | 57 |  |  | 71 |
| Average Weight |  |  |  | 85 |  | 51 |  |  | 69 |
| Grams |  |  |  | 1,105 |  | 200 |  |  | 1,305 |
| Grams/Episode |  |  |  | 85 |  | 17 |  |  | 52 |
| Grams per 1,000 Population |  |  |  | 1 |  | 0 |  |  | 0 |
| Paraneoplastic associated neuroblastoma | Patients | <5 | <5 | 5 |  |  | <5 |  |  | <20 |
| Average Age | 5 | 1 | 2 |  |  | 2 |  |  | 3 |
| Average Weight | 23 | 11 | 14 |  |  | 16 |  |  | 16 |
| Grams | 260 | 60 | 238 |  |  | 53 |  |  | 610 |
| Grams/Episode | 17 | 10 | 7 |  |  | 18 |  |  | 10 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  | 0 |  |  | 0 |
| Paraneoplastic associated other tumour type | Patients | <5 |  |  |  |  |  |  |  | <5 |
| Average Age | 58 |  |  |  |  |  |  |  | 58 |
| Average Weight | 60 |  |  |  |  |  |  |  | 60 |
| Grams | 120 |  |  |  |  |  |  |  | 120 |
| Grams/Episode | 30 |  |  |  |  |  |  |  | 30 |
| Grams per 1,000 Population | 0 |  |  |  |  |  |  |  | 0 |
| Paraneoplastic associated small cell lung cancer | Patients | <5 |  |  |  |  |  |  |  | <5 |
| Average Age | 60 |  |  |  |  |  |  |  | 60 |
| Average Weight | 72 |  |  |  |  |  |  |  | 72 |
| Grams | 270 |  |  |  |  |  |  |  | 270 |
| Grams/Episode | 23 |  |  |  |  |  |  |  | 23 |
| Grams per 1,000 Population | 0 |  |  |  |  |  |  |  | 0 |
| Pemphigus erythematosus | Patients |  | <5 | <5 | <5 |  |  |  |  | <15 |
| Average Age |  | 53 | 51 | 90 |  |  |  |  | 55 |
| Average Weight |  | 121 | 115 | 45 |  |  |  |  | 114 |
| Grams |  | 1,645 | 1,400 | 90 |  |  |  |  | 3,135 |
| Grams/Episode |  | 63 | 200 | 30 |  |  |  |  | 87 |
| Grams per 1,000 Population |  | 0 | 0 | 0 |  |  |  |  | 0 |
| Pemphigus herpetiformis | Patients |  |  |  |  |  |  |  | <5 | <5 |
| Average Age |  |  |  |  |  |  |  | 44 | 44 |
| Average Weight |  |  |  |  |  |  |  | 70 | 70 |
| Grams |  |  |  |  |  |  |  | -140 | -140 |
| Grams/Episode |  |  |  |  |  |  |  | -140 | -140 |
| Grams per 1,000 Population |  |  |  |  |  |  |  | -0 | -0 |
| Pemphigus vulgaris | Patients | 10 | 25 | 7 | 5 | 5 |  |  |  | 52 |
| Average Age | 61 | 49 | 67 | 65 | 65 |  |  |  | 59 |
| Average Weight | 96 | 72 | 99 | 100 | 81 |  |  |  | 87 |
| Grams | 7,233 | 13,450 | 3,690 | 3,170 | 6,315 |  |  |  | 33,858 |
| Grams/Episode | 62 | 63 | 25 | 41 | 58 |  |  |  | 51 |
| Grams per 1,000 Population | 1 | 2 | 1 | 2 | 2 |  |  |  | 1 |
| Recurrent acute disseminated encephalomyelitis (ADEM) | Patients | 9 | <5 | 6 |  |  | <5 |  |  | <25 |
| Average Age | 63 | 15 | 30 |  |  | 3 |  |  | 40 |
| Average Weight | 74 | 76 | 47 |  |  | 17 |  |  | 62 |
| Grams | 2,893 | 1,210 | 1,823 |  |  | 105 |  |  | 6,030 |
| Grams/Episode | 33 | 34 | 24 |  |  | 13 |  |  | 29 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  | 0 |  |  | 0 |
| Sero-negative autoimmune encephalitis | Patients | 73 | 16 | 22 | 6 | 5 | <5 |  | <5 | <132 |
| Average Age | 47 | 52 | 59 | 36 | 60 | 16 |  | 36 | 49 |
| Average Weight | 74 | 79 | 78 | 61 | 67 | 52 |  | 96 | 75 |
| Grams | 24,198 | 5,923 | 6,305 | 1,945 | 475 | 475 |  | 993 | 40,313 |
| Grams/Episode | 37 | 43 | 23 | 41 | 23 | 15 |  | 55 | 34 |
| Grams per 1,000 Population | 3 | 1 | 1 | 1 | 0 | 1 |  | 2 | 2 |
| Sero-negative limbic encephalitis | Patients | 20 | 6 | 21 | <5 | <5 | <5 |  | <5 | <67 |
| Average Age | 54 | 49 | 45 | 53 | 72 | 45 |  | 53 | 48 |
| Average Weight | 75 | 72 | 70 | 75 | 70 | 82 |  | 98 | 74 |
| Grams | 6,859 | 1,035 | 6,945 | 825 | 140 | 910 |  | 890 | 17,604 |
| Grams/Episode | 41 | 31 | 22 | 69 | 70 | 33 |  | 37 | 31 |
| Grams per 1,000 Population | 1 | 0 | 1 | 0 | 0 | 2 |  | 2 | 1 |
| Specific antibody deficiency | Patients | 176 | 70 | 60 | 87 | 28 | <5 | <5 | 15 | 431 |
| Average Age | 56 | 54 | 60 | 45 | 57 | 66 | 20 | 44 | 53 |
| Average Weight | 69 | 74 | 74 | 63 | 68 | 85 | 79 | 79 | 69 |
| Grams | 51,856 | 20,275 | 19,934 | 24,179 | 7,357 | 935 | 96 | 5,012 | 129,645 |
| Grams/Episode | 26 | 22 | 23 | 16 | 17 | 20 | 24 | 33 | 22 |
| Grams per 1,000 Population | 6 | 3 | 4 | 13 | 3 | 2 | 0 | 11 | 5 |
| Staphylococcal TSS | Patients | 11 | 18 | 12 | 5 | <5 |  | <5 |  | <56 |
| Average Age | 63 | 29 | 37 | 56 | 19 |  | 47 |  | 39 |
| Average Weight | 74 | 68 | 78 | 88 | 69 |  | 75 |  | 74 |
| Grams | 1,320 | 1,930 | 1,790 | 640 | 350 |  | 150 |  | 6,180 |
| Grams/Episode | 102 | 71 | 75 | 91 | 88 |  | 75 |  | 80 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 |  | 1 |  | 0 |
| Stevens–Johnson syndrome / toxic epidermal necrolysis overlap (SJS/TEN) | Patients | 16 | 10 | <5 |  |  |  | <5 | 5 | <41 |
| Average Age | 56 | 38 | 8 |  |  |  | 46 | 43 | 47 |
| Average Weight | 75 | 73 | 29 |  |  |  | 70 | 70 | 71 |
| Grams | 2,030 | 1,200 | 58 |  |  |  | 165 | 678 | 4,130 |
| Grams/Episode | 51 | 57 | 14 |  |  |  | 55 | 85 | 54 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  |  | 1 | 1 | 0 |
| Streptococcal TSS | Patients | 27 | 48 | 27 | 25 | 10 |  | <5 | <5 | <147 |
| Average Age | 56 | 48 | 38 | 39 | 35 |  | 61 | 73 | 45 |
| Average Weight | 93 | 84 | 75 | 78 | 79 |  | 93 | 80 | 82 |
| Grams | 3,508 | 6,350 | 3,370 | 2,915 | 1,245 |  | 188 | 160 | 17,735 |
| Grams/Episode | 92 | 93 | 60 | 83 | 113 |  | 188 | 160 | 84 |
| Grams per 1,000 Population | 0 | 1 | 1 | 2 | 0 |  | 1 | 0 | 1 |
| Suspected autoimmune encephalitis | Patients | 110 | 63 | 50 | 19 | 28 | <5 | <5 | 10 | <290 |
| Average Age | 49 | 58 | 49 | 48 | 64 | 41 | 51 | 57 | 51 |
| Average Weight | 72 | 71 | 75 | 78 | 75 | 69 | 86 | 95 | 74 |
| Grams | 26,650 | 11,768 | 11,965 | 5,360 | 3,985 | 780 | 340 | 2,230 | 63,078 |
| Grams/Episode | 35 | 37 | 20 | 35 | 29 | 39 | 34 | 53 | 31 |
| Grams per 1,000 Population | 3 | 2 | 2 | 3 | 1 | 1 | 1 | 5 | 2 |
| Suspected autoimmune limbic encephalitis | Patients | 38 | 12 | 29 | 5 | <5 | <5 |  | <5 | <99 |
| Average Age | 54 | 63 | 51 | 58 | 69 | 70 |  | 59 | 54 |
| Average Weight | 73 | 78 | 76 | 63 | 76 | 100 |  | 88 | 75 |
| Grams | 7,735 | 1,835 | 9,243 | 1,763 | 185 | 200 |  | 685 | 21,645 |
| Grams/Episode | 32 | 44 | 22 | 38 | 26 | 200 |  | 36 | 28 |
| Grams per 1,000 Population | 1 | 0 | 2 | 1 | 0 | 0 |  | 2 | 1 |
| Thymoma-associated hypogammaglobulinaemia (Goods Syndrome) | Patients | 8 | <5 | <5 | 6 | <5 | <5 |  | <5 | <39 |
| Average Age | 60 | 69 | 64 | 71 | 63 | 68 |  | 58 | 65 |
| Average Weight | 65 | 69 | 82 | 64 | 87 | 76 |  | 66 | 71 |
| Grams | 2,635 | 1,084 | 1,484 | 1,488 | 700 | 432 |  | 288 | 8,110 |
| Grams/Episode | 26 | 20 | 36 | 23 | 18 | 8 |  | 24 | 22 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 | 1 |  | 1 | 0 |
| Toxic epidermal necrolysis (TEN) | Patients | 10 | 7 |  |  | <5 |  | <5 |  | <27 |
| Average Age | 51 | 66 |  |  | 34 |  | 34 |  | 56 |
| Average Weight | 74 | 67 |  |  | 80 |  | 77 |  | 71 |
| Grams | 1,365 | 970 |  |  | 80 |  | 155 |  | 2,570 |
| Grams/Episode | 59 | 57 |  |  | 80 |  | 155 |  | 61 |
| Grams per 1,000 Population | 0 | 0 |  |  | 0 |  | 1 |  | 0 |
| **Total - Has an emerging therapeutic role** | **Patients** | **1,428** | **1,058** | **894** | **339** | **195** | **82** | **26** | **96** | **4,074** |
| **Average Age** | **56** | **55** | **57** | **48** | **57** | **54** | **40** | **54** | **55** |
| **Average Weight** | **74** | **74** | **76** | **66** | **75** | **79** | **72** | **81** | **74** |
| **Grams** | **359,257** | **317,094** | **263,052** | **92,838** | **50,021** | **30,129** | **4,498** | **25,631** | **1,142,519** |
| **Grams/Episode** | **30** | **30** | **22** | **22** | **29** | **24** | **23** | **35** | **26** |
| **Grams per 1,000 Population** | **44** | **48** | **50** | **51** | **18** | **53** | **18** | **57** | **44** |
| **Has application in exceptional circumstances only** | | | | | | | | | | |
| Acquired bleeding disorder, other coagulation factors (Prothrombin, factor V, factor VII, factor X, factor XI, and factor XIII) | Patients | <5 | <5 |  |  |  |  |  |  | <10 |
| Average Age | 55 | 82 |  |  |  |  |  |  | 73 |
| Average Weight | 50 | 80 |  |  |  |  |  |  | 70 |
| Grams | 50 | 110 |  |  |  |  |  |  | 160 |
| Grams/Episode | 50 | 55 |  |  |  |  |  |  | 53 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Acquired haemophilia A | Patients | <5 | <5 |  |  |  |  |  |  | <10 |
| Average Age | 75 | 75 |  |  |  |  |  |  | 75 |
| Average Weight | 80 | 83 |  |  |  |  |  |  | 82 |
| Grams | 330 | 455 |  |  |  |  |  |  | 785 |
| Grams/Episode | 55 | 30 |  |  |  |  |  |  | 37 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Acquired von Willebrand syndrome | Patients | <5 | <5 | <5 | <5 | 6 |  |  | <5 | <31 |
| Average Age | 69 | 80 | 60 | 66 | 69 |  |  | 73 | 65 |
| Average Weight | 57 | 70 | 83 | 68 | 71 |  |  | 71 | 75 |
| Grams | 675 | 490 | 4,675 | 435 | 3,920 |  |  | 763 | 10,958 |
| Grams/Episode | 45 | 70 | 49 | 62 | 61 |  |  | 54 | 54 |
| Grams per 1,000 Population | 0 | 0 | 1 | 0 | 1 |  |  | 2 | 0 |
| Anti-neutrophil cytoplasmic antibody (ANCA) (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis | Patients | <5 | <5 | 5 | <5 |  |  |  |  | <20 |
| Average Age | 41 | 52 | 62 | 28 |  |  |  |  | 53 |
| Average Weight | 147 | 168 | 66 | 155 |  |  |  |  | 102 |
| Grams | 770 | 160 | 565 | 200 |  |  |  |  | 1,695 |
| Grams/Episode | 48 | 27 | 16 | 50 |  |  |  |  | 27 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 |  |  |  |  | 0 |
| Ataxic sensory neuronopathy | Patients | 7 |  | <5 | <5 |  |  |  | <5 | <22 |
| Average Age | 62 |  | 57 | 85 |  |  |  | 70 | 63 |
| Average Weight | 85 |  | 65 | 75 |  |  |  | 73 | 82 |
| Grams | 3,605 |  | 75 | 140 |  |  |  | 370 | 4,190 |
| Grams/Episode | 47 |  | 8 | 35 |  |  |  | 74 | 44 |
| Grams per 1,000 Population | 0 |  | 0 | 0 |  |  |  | 1 | 0 |
| Atypical rolandic epilepsy | Patients | <5 | 8 | <5 |  |  |  |  |  | <18 |
| Average Age | 7 | 11 | 13 |  |  |  |  |  | 12 |
| Average Weight | 21 | 46 | 38 |  |  |  |  |  | 40 |
| Grams | 210 | 1,400 | 1,578 |  |  |  |  |  | 3,188 |
| Grams/Episode | 18 | 27 | 24 |  |  |  |  |  | 25 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  |  |  |  | 0 |
| Autoimmune neutropenia | Patients | 7 |  | <5 | 5 | <5 |  |  |  | <22 |
| Average Age | 56 |  | 68 | 60 | 49 |  |  |  | 55 |
| Average Weight | 72 |  | 90 | 62 | 49 |  |  |  | 64 |
| Grams | 1,275 |  | 180 | 315 | 645 |  |  |  | 2,415 |
| Grams/Episode | 51 |  | 60 | 63 | 38 |  |  |  | 48 |
| Grams per 1,000 Population | 0 |  | 0 | 0 | 0 |  |  |  | 0 |
| Autoimmune retinopathy | Patients | <5 | 6 | <5 |  |  |  |  |  | <16 |
| Average Age | 77 | 47 | 77 |  |  |  |  |  | 54 |
| Average Weight | 103 | 89 | 100 |  |  |  |  |  | 92 |
| Grams | 660 | 3,370 | 50 |  |  |  |  |  | 4,080 |
| Grams/Episode | 60 | 96 | 50 |  |  |  |  |  | 87 |
| Grams per 1,000 Population | 0 | 1 | 0 |  |  |  |  |  | 0 |
| Autonomic neuropathy | Patients | <5 |  | <5 |  |  |  |  | <5 | <15 |
| Average Age | 57 |  | 56 |  |  |  |  | 60 | 57 |
| Average Weight | 71 |  | 87 |  |  |  |  | 90 | 77 |
| Grams | 1,370 |  | 1,190 |  |  |  |  | 285 | 2,845 |
| Grams/Episode | 24 |  | 37 |  |  |  |  | 57 | 30 |
| Grams per 1,000 Population | 0 |  | 0 |  |  |  |  | 1 | 0 |
| Catastrophic anti-phospholipid syndrome | Patients | 9 | <5 | <5 |  |  |  |  |  | <19 |
| Average Age | 54 | 40 | 49 |  |  |  |  |  | 52 |
| Average Weight | 92 | 93 | 85 |  |  |  |  |  | 89 |
| Grams | 1,835 | 185 | 680 |  |  |  |  |  | 2,700 |
| Grams/Episode | 50 | 185 | 28 |  |  |  |  |  | 44 |
| Grams per 1,000 Population | 0 | 0 | 0 |  |  |  |  |  | 0 |
| Confirmed autoimmune congenital heart block in a fetus | Patients |  | <5 |  |  |  |  |  |  | <5 |
| Average Age |  | 30 |  |  |  |  |  |  | 30 |
| Average Weight |  | 67 |  |  |  |  |  |  | 67 |
| Grams |  | 68 |  |  |  |  |  |  | 68 |
| Grams/Episode |  | 68 |  |  |  |  |  |  | 68 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| Congenital haemophilia A with acquired factor VIII inhibitor | Patients | <5 |  |  |  |  |  |  |  | <5 |
| Average Age | 78 |  |  |  |  |  |  |  | 78 |
| Average Weight | 74 |  |  |  |  |  |  |  | 74 |
| Grams | 75 |  |  |  |  |  |  |  | 75 |
| Grams/Episode | 75 |  |  |  |  |  |  |  | 75 |
| Grams per 1,000 Population | 0 |  |  |  |  |  |  |  | 0 |
| Eosinophilic granulomatosis with polyangiitis (Churg-Strauss Syndrome) | Patients |  |  |  | <5 |  |  |  |  | <5 |
| Average Age |  |  |  | 40 |  |  |  |  | 40 |
| Average Weight |  |  |  | 64 |  |  |  |  | 64 |
| Grams |  |  |  | 323 |  |  |  |  | 323 |
| Grams/Episode |  |  |  | 36 |  |  |  |  | 36 |
| Grams per 1,000 Population |  |  |  | 0 |  |  |  |  | 0 |
| Epidermolysis bullosa acquisita | Patients | <5 | <5 |  | <5 |  |  |  |  | <15 |
| Average Age | 90 | 62 |  | 76 |  |  |  |  | 69 |
| Average Weight | 75 | 108 |  | 83 |  |  |  |  | 96 |
| Grams | 80 | 480 |  | 490 |  |  |  |  | 1,050 |
| Grams/Episode | 40 | 40 |  | 70 |  |  |  |  | 50 |
| Grams per 1,000 Population | 0 | 0 |  | 0 |  |  |  |  | 0 |
| Granulomatosis with polyangiitis (Wegener Granulomatosis) | Patients |  |  | <5 | <5 |  |  |  |  | <10 |
| Average Age |  |  | 56 | 43 |  |  |  |  | 45 |
| Average Weight |  |  | 69 | 96 |  |  |  |  | 93 |
| Grams |  |  | 290 | 1,998 |  |  |  |  | 2,288 |
| Grams/Episode |  |  | 29 | 29 |  |  |  |  | 29 |
| Grams per 1,000 Population |  |  | 0 | 1 |  |  |  |  | 0 |
| Graves ophthalmopathy | Patients |  |  | <5 | 5 |  |  |  |  | <10 |
| Average Age |  |  | 49 | 56 |  |  |  |  | 56 |
| Average Weight |  |  | 90 | 83 |  |  |  |  | 84 |
| Grams |  |  | 180 | 1,260 |  |  |  |  | 1,440 |
| Grams/Episode |  |  | 45 | 37 |  |  |  |  | 38 |
| Grams per 1,000 Population |  |  | 0 | 1 |  |  |  |  | 0 |
| Haemolytic disease of the fetus | Patients | <5 | <5 |  |  | <5 |  |  | <5 | <20 |
| Average Age | 30 | 37 |  |  | 35 |  |  | 38 | 32 |
| Average Weight | 68 | 60 |  |  | 85 |  |  | 80 | 73 |
| Grams | 2,673 | 240 |  |  | 1,625 |  |  | - | 4,538 |
| Grams/Episode | 62 | 60 |  |  | 74 |  |  | - | 62 |
| Grams per 1,000 Population | 0 | 0 |  |  | 1 |  |  |  | 0 |
| Hyperhaemolysis syndrome | Patients | <5 | <5 |  |  |  |  |  | <5 | <15 |
| Average Age | 48 | 44 |  |  |  |  |  | 32 | 43 |
| Average Weight | 71 | 60 |  |  |  |  |  | 66 | 68 |
| Grams | 545 | 180 |  |  |  |  |  | 268 | 993 |
| Grams/Episode | 68 | 60 |  |  |  |  |  | 67 | 66 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  | 1 | 0 |
| Landau Kleffner syndrome | Patients | <5 | <5 |  |  |  |  |  |  | <10 |
| Average Age | 25 | 8 |  |  |  |  |  |  | 18 |
| Average Weight | 80 | 20 |  |  |  |  |  |  | 55 |
| Grams | 880 | 160 |  |  |  |  |  |  | 1,040 |
| Grams/Episode | 80 | 20 |  |  |  |  |  |  | 55 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| Lennox-Gastaut syndrome | Patients | 5 |  | 7 | <5 |  |  | <5 | <5 | <27 |
| Average Age | 8 |  | 5 | 4 |  |  | 9 | 13 | 6 |
| Average Weight | 24 |  | 19 | 18 |  |  | 24 | 41 | 22 |
| Grams | 1,025 |  | 588 | 125 |  |  | 45 | 480 | 2,263 |
| Grams/Episode | 29 |  | 7 | 16 |  |  | 45 | 34 | 16 |
| Grams per 1,000 Population | 0 |  | 0 | 0 |  |  | 0 | 1 | 0 |
| LETMs | Patients | 7 |  | <5 | <5 |  |  | <5 |  | <22 |
| Average Age | 54 |  | 43 | 13 |  |  | 44 |  | 50 |
| Average Weight | 68 |  | 101 | 55 |  |  | 50 |  | 73 |
| Grams | 1,445 |  | 590 | 130 |  |  | 100 |  | 2,265 |
| Grams/Episode | 24 |  | 35 | 43 |  |  | 33 |  | 28 |
| Grams per 1,000 Population | 0 |  | 0 | 0 |  |  | 0 |  | 0 |
| Microscopic polyangiitis | Patients |  |  | <5 | <5 |  |  |  |  | <10 |
| Average Age |  |  | 77 | 43 |  |  |  |  | 49 |
| Average Weight |  |  | 73 | 62 |  |  |  |  | 64 |
| Grams |  |  | 145 | 1,620 |  |  |  |  | 1,765 |
| Grams/Episode |  |  | 24 | 58 |  |  |  |  | 52 |
| Grams per 1,000 Population |  |  | 0 | 1 |  |  |  |  | 0 |
| NMOSD–AQP4 ab positive | Patients | 6 | <5 |  |  |  |  |  |  | <11 |
| Average Age | 61 | 62 |  |  |  |  |  |  | 61 |
| Average Weight | 67 | 76 |  |  |  |  |  |  | 68 |
| Grams | 1,760 | 258 |  |  |  |  |  |  | 2,018 |
| Grams/Episode | 38 | 43 |  |  |  |  |  |  | 39 |
| Grams per 1,000 Population | 0 | 0 |  |  |  |  |  |  | 0 |
| NMOSD–MOG ab positive | Patients | 18 | 11 | <5 | <5 | <5 |  | <5 | <5 | <54 |
| Average Age | 41 | 34 | 62 | 15 | 45 |  | 52 | 77 | 41 |
| Average Weight | 78 | 76 | 95 | 49 | 80 |  | 67 | 92 | 77 |
| Grams | 4,898 | 2,933 | 645 | 930 | 2,900 |  | 265 | 653 | 13,223 |
| Grams/Episode | 36 | 30 | 26 | 31 | 48 |  | 27 | 65 | 36 |
| Grams per 1,000 Population | 1 | 0 | 0 | 1 | 1 |  | 1 | 1 | 1 |
| NMOSD–seronegative | Patients | 18 | 7 | <5 | 6 | <5 | <5 |  |  | <46 |
| Average Age | 57 | 36 | 34 | 27 | 56 | 14 |  |  | 46 |
| Average Weight | 85 | 85 | 62 | 85 | 46 | 51 |  |  | 82 |
| Grams | 5,341 | 1,933 | 525 | 2,020 | 90 | 190 |  |  | 10,099 |
| Grams/Episode | 34 | 37 | 24 | 39 | 18 | 63 |  |  | 35 |
| Grams per 1,000 Population | 1 | 0 | 0 | 1 | 0 | 0 |  |  | 0 |
| Paediatric acute neuropsychiatric disorders (PANS) | Patients | 16 | <5 | 8 | <5 |  | <5 | <5 |  | <44 |
| Average Age | 13 | 13 | 12 | 19 |  | 10 | 13 |  | 13 |
| Average Weight | 56 | 43 | 57 | 75 |  | 45 | 57 |  | 57 |
| Grams | 10,508 | 178 | 2,963 | 1,115 |  | 90 | 113 |  | 14,965 |
| Grams/Episode | 71 | 44 | 22 | 112 |  | 11 | 56 |  | 49 |
| Grams per 1,000 Population | 1 | 0 | 1 | 1 |  | 0 | 0 |  | 1 |
| Paediatric autoimmune neuropsychiatric disorder (PANDAS) | Patients | <5 | <5 | 7 |  |  |  | <5 |  | <22 |
| Average Age | 10 | 13 | 13 |  |  |  | 13 |  | 13 |
| Average Weight | 45 | 58 | 63 |  |  |  | 58 |  | 60 |
| Grams | 865 | 1,163 | 7,220 |  |  |  | 240 |  | 9,488 |
| Grams/Episode | 38 | 45 | 45 |  |  |  | 60 |  | 45 |
| Grams per 1,000 Population | 0 | 0 | 1 |  |  |  | 1 |  | 0 |
| Painful small fibre neuropathy | Patients | <5 | <5 | <5 |  | <5 |  | <5 | <5 | <30 |
| Average Age | 64 | 48 | 60 |  | 60 |  | 76 | 68 | 60 |
| Average Weight | 68 | 65 | 51 |  | 79 |  | 80 | 76 | 69 |
| Grams | 1,285 | 1,210 | 565 |  | 1,420 |  | 880 | 1,593 | 6,953 |
| Grams/Episode | 33 | 22 | 23 |  | 39 |  | 59 | 39 | 33 |
| Grams per 1,000 Population | 0 | 0 | 0 |  | 1 |  | 4 | 4 | 0 |
| Pure red cell aplasia – associated B19 infection | Patients | 8 | <5 | 8 | <5 |  |  |  | <5 | <31 |
| Average Age | 74 | 24 | 41 | 83 |  |  |  | 37 | 45 |
| Average Weight | 86 | 30 | 64 | 97 |  |  |  | 64 | 64 |
| Grams | 1,743 | 548 | 1,980 | 135 |  |  |  | 375 | 4,780 |
| Grams/Episode | 67 | 30 | 22 | 135 |  |  |  | 75 | 34 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 |  |  |  | 1 | 0 |
| Pure red cell aplasia – autoimmune mediated | Patients | 5 | <5 | <5 | <5 | <5 | <5 |  | <5 | <35 |
| Average Age | 60 | 52 | 68 | 61 | 62 | 49 |  | 79 | 61 |
| Average Weight | 75 | 84 | 111 | 98 | 95 | 76 |  | 69 | 86 |
| Grams | 750 | 330 | 730 | 180 | 840 | 150 |  | 140 | 3,120 |
| Grams/Episode | 75 | 83 | 91 | 90 | 93 | 15 |  | 28 | 65 |
| Grams per 1,000 Population | 0 | 0 | 0 | 0 | 0 | 0 |  | 0 | 0 |
| Pyoderma Gangrenosum | Patients | 11 | 30 | 20 | <5 | <5 |  |  | <5 | <76 |
| Average Age | 57 | 62 | 62 | 45 | 50 |  |  | 21 | 60 |
| Average Weight | 83 | 86 | 90 | 65 | 115 |  |  | 71 | 87 |
| Grams | 7,578 | 28,965 | 9,000 | 1,740 | 930 |  |  | 70 | 48,283 |
| Grams/Episode | 63 | 69 | 26 | 45 | 40 |  |  | 35 | 51 |
| Grams per 1,000 Population | 1 | 4 | 2 | 1 | 0 |  |  | 0 | 2 |
| Rasmussen encephalitis | Patients | 9 | 9 | 6 | <5 | <5 | <5 |  | <5 | <44 |
| Average Age | 32 | 30 | 38 | 17 | 39 | 13 |  | 64 | 34 |
| Average Weight | 70 | 67 | 64 | 94 | 112 | 69 |  | 67 | 70 |
| Grams | 4,298 | 3,518 | 1,670 | 870 | 715 | 138 |  | 275 | 11,483 |
| Grams/Episode | 42 | 41 | 14 | 38 | 55 | 17 |  | 21 | 32 |
| Grams per 1,000 Population | 1 | 1 | 0 | 0 | 0 | 0 |  | 1 | 0 |
| Relapsing remitting multiple sclerosis | Patients | 20 | 12 | 5 |  |  |  |  | <5 | <42 |
| Average Age | 42 | 45 | 68 |  |  |  |  | 50 | 48 |
| Average Weight | 74 | 78 | 72 |  |  |  |  | 60 | 74 |
| Grams | 4,870 | 2,743 | 1,505 |  |  |  |  | 780 | 9,898 |
| Grams/Episode | 29 | 31 | 27 |  |  |  |  | 52 | 30 |
| Grams per 1,000 Population | 1 | 0 | 0 |  |  |  |  | 2 | 0 |
| Risk of autoimmune congenital heart block – previously affected sibling | Patients |  |  |  |  |  |  |  | <5 | <5 |
| Average Age |  |  |  |  |  |  |  | 37 | 37 |
| Average Weight |  |  |  |  |  |  |  | 58 | 58 |
| Grams |  |  |  |  |  |  |  | 60 | 60 |
| Grams/Episode |  |  |  |  |  |  |  | 15 | 15 |
| Grams per 1,000 Population |  |  |  |  |  |  |  | 0 | 0 |
| Scleromyxedema – skin and systemic disease | Patients | 5 | <5 |  | <5 | <5 |  |  |  | <20 |
| Average Age | 68 | 68 |  | 54 | 77 |  |  |  | 66 |
| Average Weight | 78 | 58 |  | 123 | 57 |  |  |  | 81 |
| Grams | 2,958 | 1,085 |  | 3,200 | 2,055 |  |  |  | 9,298 |
| Grams/Episode | 42 | 21 |  | 52 | 44 |  |  |  | 41 |
| Grams per 1,000 Population | 0 | 0 |  | 2 | 1 |  |  |  | 0 |
| Scleromyxedema – skin involvement only | Patients | <5 | <5 |  | <5 | <5 |  |  |  | <20 |
| Average Age | 35 | 85 |  | 62 | 35 |  |  |  | 63 |
| Average Weight | 97 | 91 |  | 70 | 97 |  |  |  | 82 |
| Grams | 1,755 | 2,225 |  | 2,765 | 780 |  |  |  | 7,525 |
| Grams/Episode | 98 | 62 |  | 48 | 98 |  |  |  | 63 |
| Grams per 1,000 Population | 0 | 0 |  | 2 | 0 |  |  |  | 0 |
| Sensorimotor axonal neuropathy | Patients | 5 | <5 |  |  | <5 |  | <5 |  | <20 |
| Average Age | 65 | 74 |  |  | 62 |  | 72 |  | 68 |
| Average Weight | 61 | 54 |  |  | 60 |  | 90 |  | 64 |
| Grams | 1,810 | 283 |  |  | 150 |  | 600 |  | 2,843 |
| Grams/Episode | 39 | 22 |  |  | 25 |  | 50 |  | 36 |
| Grams per 1,000 Population | 0 | 0 |  |  | 0 |  | 2 |  | 0 |
| Susac syndrome | Patients | 11 | <5 | 9 | <5 | <5 |  | <5 |  | <40 |
| Average Age | 39 | 50 | 51 | 58 | 35 |  | 40 |  | 47 |
| Average Weight | 97 | 69 | 90 | 65 | 76 |  | 74 |  | 87 |
| Grams | 9,408 | 1,575 | 6,638 | 2,260 | 258 |  | 73 |  | 20,210 |
| Grams/Episode | 50 | 36 | 38 | 30 | 43 |  | 73 |  | 41 |
| Grams per 1,000 Population | 1 | 0 | 1 | 1 | 0 |  | 0 |  | 1 |
| Systemic capillary leak syndrome | Patients | 7 | <5 | <5 | <5 | <5 |  |  | <5 | <32 |
| Average Age | 50 | 74 | 64 | 32 | 51 |  |  | 61 | 60 |
| Average Weight | 79 | 77 | 72 | 82 | 80 |  |  | 75 | 76 |
| Grams | 2,638 | 2,660 | 1,990 | 1,040 | 940 |  |  | 800 | 10,068 |
| Grams/Episode | 33 | 46 | 22 | 80 | 72 |  |  | 80 | 38 |
| Grams per 1,000 Population | 0 | 0 | 0 | 1 | 0 |  |  | 2 | 0 |
| Vaccine induced immune thrombotic thrombocytopenia (VITT) | Patients | 99 | 37 | 33 | 17 | 5 |  |  | <5 | <196 |
| Average Age | 62 | 67 | 62 | 66 | 73 |  |  | 27 | 63 |
| Average Weight | 83 | 80 | 83 | 80 | 83 |  |  | 87 | 82 |
| Grams | 13,785 | 4,493 | 4,950 | 1,790 | 640 |  |  | 90 | 25,748 |
| Grams/Episode | 64 | 68 | 41 | 51 | 80 |  |  | 90 | 58 |
| Grams per 1,000 Population | 2 | 1 | 1 | 1 | 0 |  |  | 0 | 1 |
| West syndrome | Patients |  |  | <5 |  | <5 |  |  |  | <10 |
| Average Age |  |  | 7 |  | 6 |  |  |  | 7 |
| Average Weight |  |  | 21 |  | 28 |  |  |  | 22 |
| Grams |  |  | 313 |  | 55 |  |  |  | 368 |
| Grams/Episode |  |  | 13 |  | 14 |  |  |  | 13 |
| Grams per 1,000 Population |  |  | 0 |  | 0 |  |  |  | 0 |
| **Total - Has application in exceptional circumstances only** | **Patients** | **296** | **158** | **150** | **63** | **35** | **<25** | **<30** | **<45** | **720** |
| **Average Age** | **47** | **52** | **44** | **46** | **56** | **25** | **58** | **57** | **48** |
| **Average Weight** | **77** | **77** | **72** | **80** | **77** | **63** | **74** | **70** | **75** |
| **Grams** | **93,749** | **63,393** | **51,478** | **25,080** | **17,963** | **568** | **2,315** | **7,000** | **261,544** |
| **Grams/Episode** | **47** | **50** | **29** | **43** | **53** | **20** | **48** | **46** | **42** |
| **Grams per 1,000 Population** | **12** | **10** | **10** | **14** | **7** | **1** | **9** | **15** | **10** |
| **Use is not supported** | | | | | | | | | | |
| Diabetic amyotrophy | Patients |  | <5 |  |  |  |  |  |  | <5 |
| Average Age |  | 82 |  |  |  |  |  |  | 82 |
| Average Weight |  | 88 |  |  |  |  |  |  | 88 |
| Grams |  | 140 |  |  |  |  |  |  | 140 |
| Grams/Episode |  | 35 |  |  |  |  |  |  | 35 |
| Grams per 1,000 Population |  | 0 |  |  |  |  |  |  | 0 |
| Myocarditis in children | Patients |  | <5 | <5 |  |  |  |  |  | <10 |
| Average Age |  | 12 | 1 |  |  |  |  |  | 5 |
| Average Weight |  | 48 | 12 |  |  |  |  |  | 24 |
| Grams |  | 95 | 13 |  |  |  |  |  | 108 |
| Grams/Episode |  | 95 | 6 |  |  |  |  |  | 36 |
| Grams per 1,000 Population |  | 0 | 0 |  |  |  |  |  | 0 |
| Polyneuropathy of critical illness | Patients |  |  |  |  |  |  |  | <5 | <5 |
| Average Age |  |  |  |  |  |  |  | 70 | 70 |
| Average Weight |  |  |  |  |  |  |  | 145 | 145 |
| Grams |  |  |  |  |  |  |  | 280 | 280 |
| Grams/Episode |  |  |  |  |  |  |  | 47 | 47 |
| Grams per 1,000 Population |  |  |  |  |  |  |  | 1 | 0 |
| Sepsis | Patients | <5 | <5 |  | <5 |  |  |  |  | <15 |
| Average Age | 36 | 40 |  | 56 |  |  |  |  | 45 |
| Average Weight | 75 | 110 |  | 69 |  |  |  |  | 81 |
| Grams | 315 | 370 |  | 420 |  |  |  |  | 1,105 |
| Grams/Episode | 79 | 123 |  | 84 |  |  |  |  | 92 |
| Grams per 1,000 Population | 0 | 0 |  | 0 |  |  |  |  | 0 |
| **Total - Use is not supported** | **Patients** | **<5** | **<5** | **<5** | **<5** |  |  |  | **<5** | **<25** |
| **Average Age** | **36** | **40** |  | **56** |  |  |  |  | **45** |
| **Average Weight** | **75** | **110** |  | **69** |  |  |  |  | **81** |
| **Grams** | **315** | **370** |  | **420** |  |  |  |  | **1,105** |
| **Grams/Episode** | **79** | **123** |  | **84** |  |  |  |  | **92** |
| **Grams per 1,000 Population** | **0** | **0** |  | **0** |  |  |  |  | **0** |
| **Total** | **Patients** | **8,311** | **5,245** | **5,551** | **1,795** | **1,427** | **495** | **138** | **520** | **23,127** |
| **Average Age** | **61** | **60** | **62** | **57** | **61** | **62** | **49** | **57** | **61** |
| **Average Weight** | **77** | **78** | **79** | **75** | **78** | **82** | **76** | **80** | **78** |
| **Grams** | **2,701,090** | **1,745,372** | **1,963,638** | **642,279** | **428,408** | **175,223** | **36,373** | **178,419** | **7,870,800** |
| **Grams/Episode** | **35** | **32** | **25** | **28** | **30** | **25** | **40** | **36** | **30** |
| **Grams per 1,000 Population** | **334** | **266** | **373** | **356** | **155** | **308** | **146** | **394** | **306** |

Note 1: All patient counts are distinct counts. Each patient is counted only once. This may result in the sum of the state and territory totals being greater than the national total.

## Appendix E – System Source for Tables and Figures

Table 1: Ig growth for the last 5 years………………………………………………………………………………………………………………………………………………………………………………………………………………………………………IDMS

[Table 1: Ig growth for the last 5 years 1](#_Toc159936439)

[Table 2: Go live dates for BloodSTAR 1](#_Toc159936440)

[Table 3: Grams recorded in the different systems held by the NBA 1](#_Toc159936441)

[Table 4: Percentage change in grams issued over time by state and territory 1](#_Toc159936442)

[Table 5: Issues of domestic Ig compared with imported Ig 1](#_Toc159936443)

[Table 6: Issues of domestic Ig compared with imported Ig and public versus private Australian Health Providers 1](#_Toc159936444)

[Table 7: Patient numbers by state and territory 1](#_Toc159936445)

[Table 8: Patient numbers and average weight by age range 1](#_Toc159936446)

[Table 9: Ig grams dispensed by criteria category 1](#_Toc159936447)

[Table 10: Ig grams dispensed by speciality and state and territory for 2021-22 1](#_Toc159936448)

[Table 11: Patients dispensed Ig by speciality and state and territory for 2021-22 1](#_Toc159936449)

[Table 12: New patients dispensed Ig by speciality and state and territory for 2021-22 1](#_Toc159936450)

[Table 13: Grams dispensed by states and territories and medical condition for 2021-22 1](#_Toc159936451)

[Table 14: Patients dispensed by SCIg/IVIg medical conditions and product for 2021-22 1](#_Toc159936452)

[Table 15: Grams dispensed by SCIg/IVIg medical conditions and product for 2021-22 1](#_Toc159936453)

[Table 16: Patients dispensed by SCIg medical conditions, and state and territory for 2021-22 1](#_Toc159936454)

[Table 17: Grams dispensed by SCIg medical conditions, and state and territory for 2021-22 1](#_Toc159936455)

[Figure 1: Snapshot](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229930) All

[Figure 2: Per cent dispensed grams by medical condition](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229931) BloodSTAR

[Figure 3: Ten-year trend in issues of Ig](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229932) IDMS

[Figure 4: Ten-year trend in expenditure on Ig](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229933) IDMS

[Figure 5: Ig expenditure as a proportion of the national blood budget](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229934) IDMS

[Figure 6: New and total patients for the last 10 years BloodSTAR](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229935)

[Figure 7: Patient age relative to Australian average BloodSTAR](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229936)

[Figure 8: Grams of Ig dispensed by speciality BloodSTAR](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229937)

[Figure 9: Grams of Ig dispensed by top 10 medical conditions BloodSTAR](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229938)

[Figure 10: NHIg grams issued and grams issued per 1,000 population IDMS](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc135229939)

Appendix A: Background [All](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc107955714)

Appendix B: Acronymns and Glossary [All](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc107955715)

Appendix C: Conditions Mapping Table [BloodSTAR](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc107955716)

Appendix D: Dataset of Ig Supply by State/Territory 2021-22 [BloodSTAR](https://bloodgovau-my.sharepoint.com/personal/sandra_cochrane_blood_gov_au/Documents/Ig%20Annual%20Reports/Ig%20Report%202019-20%20new.docx#_Toc107955717)

1. ABS 3101 [↑](#footnote-ref-1)
2. World Health Organization, [Ageing and health (who.int)](https://www.who.int/news-room/fact-sheets/detail/ageing-and-health) [↑](#footnote-ref-2)