NHS

Immunoglobulin Database

Annual Report 2016/17

mdsas
medical data solutions and services

Compiled by
Rob Hollingsworth, Mark Foster MDSAS

1 Database Overview

Rob Hollingsworth

Introduction

As is the case each year, I would firstly like to thank all Trusts and their staff that continue to support and provide data to the National Immunoglobulin Database. The considerable work undertaken to manage the collection and entry of data is recognised and very much appreciated.

I would also like to thank the database steering group members (including the new members that have joined this year) for their input into the successful running of the database.

This report will provide a snapshot of the data from the database for the calendar year 2016-17. Also included is an update from NHS England and the Commercial Medicines Unit (CMU).

Each year the database continues to develop and this year updates have been produced to enable the reporting of newly introduced CQUIN measures. During the year we have worked between NHS England and Trusts to improve both the measures themselves and the database reports used to produce the required data.

The annual increase in immunoglobulin sales continues at approximately 10%. In-line with previous expectations it is expected that national costs for immunoglobulin products will be around £190-200 million per annum next year.

The database continues to grow, since its initiation the database has captured information on almost 72,000 patients and 85,000 separate treatment episodes. Trusts have entered over 930,000 treatment entries, accounting for over 31 million grams of immunoglobulin recorded on the database - this equates in value at an average price per gram of £34 per gram to just over £1 billion.

Database Developments

The database continues to be used extensively by NHS England to support commissioning and therapy initiatives for immunoglobulins. Continued initiatives have related to investigating Immune Thrombocytopenic Purpura (ITP) dosing in accordance to guidelines and the validation of Trust financial re-imbursement for immunoglobulin use. In conjunction with excellent work from Trusts this work has resulted in a reduction in usage for ITP patients more in-line with national guidance.

The Commercial Medicines Unit (CMU) continues to utilise the database to support the supply and procurement of immunoglobulins, including

The CQUIN measures introduced by NHS England and monitored through the database have resulted in significant improvements in the completeness of data entered onto the database. A specific example of this relates to the recording of patient weight onto the database. This has moved from 60% complete to 90% complete as of December 2017.

Annual Meeting

The annual database meeting is again being held in December at Etc. Venues in Pimlico, London. The event is again a great success with all available places for the meeting taken. A big thank you must go to all our speakers, and to all attendees and sponsors who, with their feedback and support, help make the meeting so successful.

Annual Report

This report provides an analysis of immunoglobulin usage across England. Communications from key stakeholders are also included. Feedback on the annual report is very welcome from all stakeholders. If there is something additional that you would like to see in the report then please send your suggestions to support@mdsas.com.

2 Commissioning Update

Rob Coster

Immunoglobulin (Ig) is a high-cost drug entirely funded by NHS England. In terms of cost, Ig is in the top 10 drugs for expenditure, with NHS England spending ~£150m in 16/17 and this is increasing by about 10% per annum. The tender framework in July 2017 also created a further impact on the total cost of Ig provision to the NHS of approximately 12%-18% depending on the success of switching usage to cheaper products.

NHS England is in the second year of the Immunoglobulin Improving Value project, ensuring the appropriate and cost-effective use of Ig. The project is focusing on the following:

- Improved recording of outcome data on MDSAS data base.
- Review of present DH Clinical Guidelines for Immunoglobulin Use.
- Review of the effectiveness of Immunoglobulin Review Panels
- Appropriate dosing of intravenous immunoglobulin in various treatments
- Encouraging the uptake of home care for long term immunoglobulin users.

Improved recording on MDSAS database

This year saw the implementation of the medicines optimisation CQUIN to improve data recording on MDSAS. We have seen a significant improvement in the amount of data recorded on the data base, including timely entry of usage, weight, recording of reviews and outcomes. The CQUIN will continue into 17/18 and NHS England expects this to become business as normal in the future.

Review of present DH Clinical Guidelines for Immunoglobulin Use

Overall the commissioning of immunoglobulin (Ig) is not consistent with the policy approach of NHS England. In discussion with stakeholders, while agreeing the need to have a consistent approach for commissioning for Ig, they do not wish to see individual policies developed for each indication or group of indications, as users are used to having all indications in one place for easy reference. NHS England is in the process of producing a single commissioning document for Ig.

Present Red / Blue and Black indications

NHS England plan to move away from commissioning by 'colour coding' to an evidence-based policy approach with either routinely or not routinely commissioned position.

Clinical Reference Groups, Royal Colleges and specialist societies have been asked to undertake a 'rapid clinical review' of current clinical guidelines underpinning each indication to assess whether the previous evidence needs updating to identify changing evidence and possible recommendation for decommissioning or black indications for which the evidence had shifted.

As a principle, unless clinical practice identifies changes to blue, red or black indications, these will be translated directly into routinely commissioned (red / blue) or not routinely (black) commissioned positions.

Four Policy Working Groups (Immunology, Neurology, Haematology and others) have been established to confirm that eligibility criterion for all indications and dosing are correct; identifying where clinical practice means that red or blue indications are no longer valid; identifying changes to any black indications and confirming any new grey indications.

Grey Indications

For grey indications including new indications, the focus is on assessment of the evidence of clinical effectiveness to ensure an equitable approach in the consideration of Ig compared to other treatments. This is a comprehensive approach and would cover 27 indications and likely to take a considerable period of time and resource.

The grey indications in the short term will continue to be commissioned with approval via Immunoglobulin Assessment Panels (IAP) and/or IFR process. As part of project, work is being undertaken to improve IAP scrutiny of Ig usage within Trusts.

Review of the effectiveness of Immunoglobulin Review Panels

There is considerable variation in the effectiveness of IAPs across England based on usage data, feedback and a survey of all trusts accessing the immunoglobulin database in September 2016.

Generally individual hospitals have their own panels, but it is clear the effectiveness varies. NHS England will be encouraging providers to move to a hub and spoke model, with a trust collaborative immunoglobulin panel providing approval and guidance to requestors from surrounding region. This model has the advantage of sharing best practice and experience across a region. It is anticipated that developing regional immunoglobulin panels will help spread best practice as well as providing an opportunity to review, audit and improve the advice given by each panel. This would reduce variations in prescribing and ensure clinical commissioning policy is being implemented appropriately across the country.

Appropriate dosing of immunoglobulin in various treatments

Appropriate dosing of intravenous immunoglobulin, primarily for immune thrombocytopenic purpura (ITP) where dosing evidence is available, has seen a significant decrease in usage of Ig in this condition. With more than 60% of patients now receiving the recommended 1g/kg in most areas of the country. Although further work is required to improve this to a minimum of 75% of patients, resulting in savings of several million pounds/annum.

Encouraging the uptake of home care for long term immunoglobulin users

A longer term project for the immunoglobulin project is to develop plans to increase home therapy amongst long term Ig users. Whilst most immunology departments appear to have established homecare services, NHS England would like to see this expanded to include Neurology, Haematology and other long term Ig users.

Immunoglobulin Events

The project group along with MDSAS ran a series of successful immunoglobulin events across England to maintain the momentum of the work to date. The events, made available to each Commissioning Hub offered an opportunity to learn more about the project, CQUINs and future plans. The audience for these events included pharmacists, commissioners and clinicians/IAP members from local trusts involved in immunoglobulin use.

By working with providers, commissioners, must deliver improved outcomes, improve use of resources and be fair and consistent throughout the country, and ensure that all patients have equal access to services regardless of their condition or location. The NHS England Immunoglobulin Improving Value project is an important part of this work.

3 NHS Purchasing

Alison Greenwood

Contract Picture

All immunoglobulin purchased in England and Northern Ireland is covered by a national framework agreement tendered and managed by the Commercial Medicines Unit (CMU), part of the Specialised Commissioning team at NHS England. The aim of the framework is to maintain security of supply and deliver value for money, whilst following EU tender procedures. There are separate agreements for Wales and Scotland managed in those countries.

The current spend on the Immunoglobulin framework, awarded on 1st July 2017, is forecast to be £192 million per annum (an increase of 12% on the previous year). This covers fourteen different products and just over six million grams of product through the eight contracted suppliers of product. The current framework has seen a significant switching in products being used by the NHS and CMU in an ongoing process, working with trusts to capture accurate forecasted product usage. This will help to ensure suppliers have the most up-to-date information to manage demand in line with their indicated volumes.

There has been a continued growth in IG sales over the previous and current contract of up to 20% and, although there had been a steady reduction in price per gram equating to 6.8% between 2011 and 2016, the current framework will see the average price increase of 12% per gram. CMU will continue to work with trusts, suppliers and the commissioners to achieve value for money for the NHS and aid supply of product to patients.

The new framework commenced on 1st July 2017. A number of changes to the market mean the NHS faces a challenging year for blood products; changes to available product volumes, the discontinuation and introduction of new IG products during this framework, the impact of Brexit and its future implications for product supply into the UK market, growing global markets for blood products and the proposed changes to the statutory scheme to control the prices of branded health services medicines all need to be managed by the stakeholder group for the framework to be as effective as possible.

The stakeholders are critical for the successful management of any issues that may arise during the contract period. The ongoing support and collaboration of this group to ensure that patient supply and value for money are at the forefront of its delivery are essential. Pharmacists, commissioners, clinicians, the IG Database, relevant CRGs, patient groups and nursing staff are invaluable in relation to ensuring requirements are met and effective communications are disseminated to frontline procurement services. CMU will continue to work towards strengthening their contacts within trusts across the diverse range of treatment areas as a priority.

The usage data from the IG Database will continue to be used to inform and steer the strategy for product switching and to identify any issues as early as possible. CMU will continue to work with trusts to monitor and manage the forecast demand and will work with the stakeholder group to advise trusts as necessary.

Contacting CMU

For further information on the framework agreement, contracting process or if you wish to be formally engaged as part of the stakeholder group, please contact CMU at alison.greenwood3@nhs.net or Tel. 01928 755221.

4 Data Update

Mark Foster

The Seventh National Database Annual Report

This Data Update chapter in the seventh edition of the National Database Annual Report utilises 38 data sets to provide readers with an overview of immunoglobulin use in England for 2016/17. Data recorded on the database by the end of October 2017 is included in reporting

Increasing Data Capture

The total volume of immunoglobulin recorded in England for 2016/17 was 5.25 million grams, once again this is the highest volume recorded by the database since its launch. Comparing volumes recorded with Commercial Medicines Unit (CMU) sales figures, it is estimated that the database captures around 96% of the volume purchased by CMU.

Usage in Specialisms

As highlighted in previous reports, neurological conditions use the most immunoglobulin (44%) by volume, then immunology (32%), haematology (9%). Conditions falling under 'other' specialties as defined in the clinical guidelines make up the remaining 15%.

Usage in Top Conditions

Primary immunodeficiencies remain the number one condition for number of patients treated (3,532) and volume of immunoglobulin recorded (1,329,255 grams). Secondary antibody deficiencies is the second highest condition for number of patients treated (1,925), third is Idiopathic Thrombocytopenic Purpura (1,563). Chronic Inflammatory Demyelinating Polyneuropathy is the second highest volume using condition (1,039,990 grams), third is MMN (521,706 grams). Secondary antibody deficiencies saw a 36% increase in the number of patients treated and a 44% increase in the recorded volume of immunoglobulin. This is the second year of significant increases for this condition.

CQUINs

Trigger 4 of the Medicines Optimisation programme saw the creation of 4 immunoglobulin related CQUIN measures. The aim of these measures is to improve data quality associated with outcomes, annual reviews, recording of patients' weight and improved data entry time for the recording of infusions. Initial analysis of CQUIN performance from the database is positive. A full breakdown of CQUIN peformance for 2017/18 will be provided in next years annual report.

Figure 1.1.1 Monthly patient registrations 2016/17

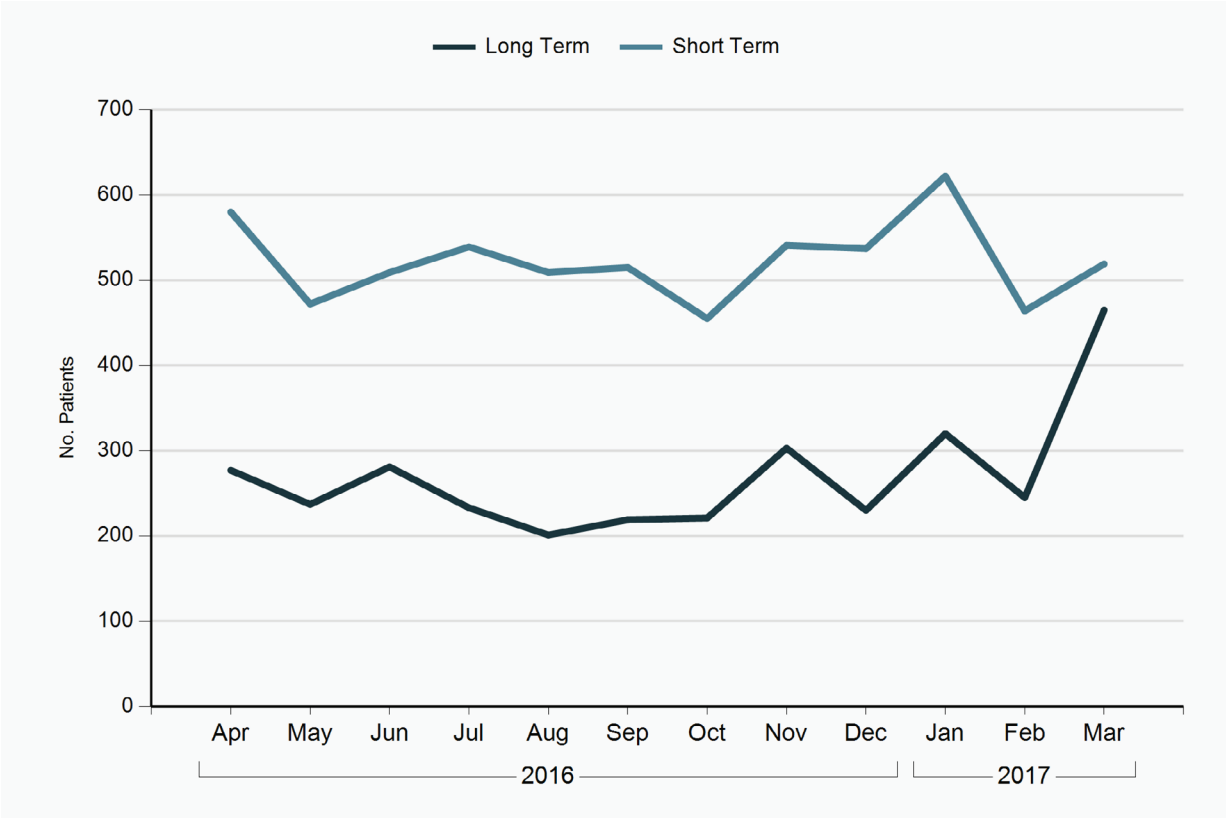

Figure 1.1.2 Yearly patient registrations 2012/13 - 2016/17

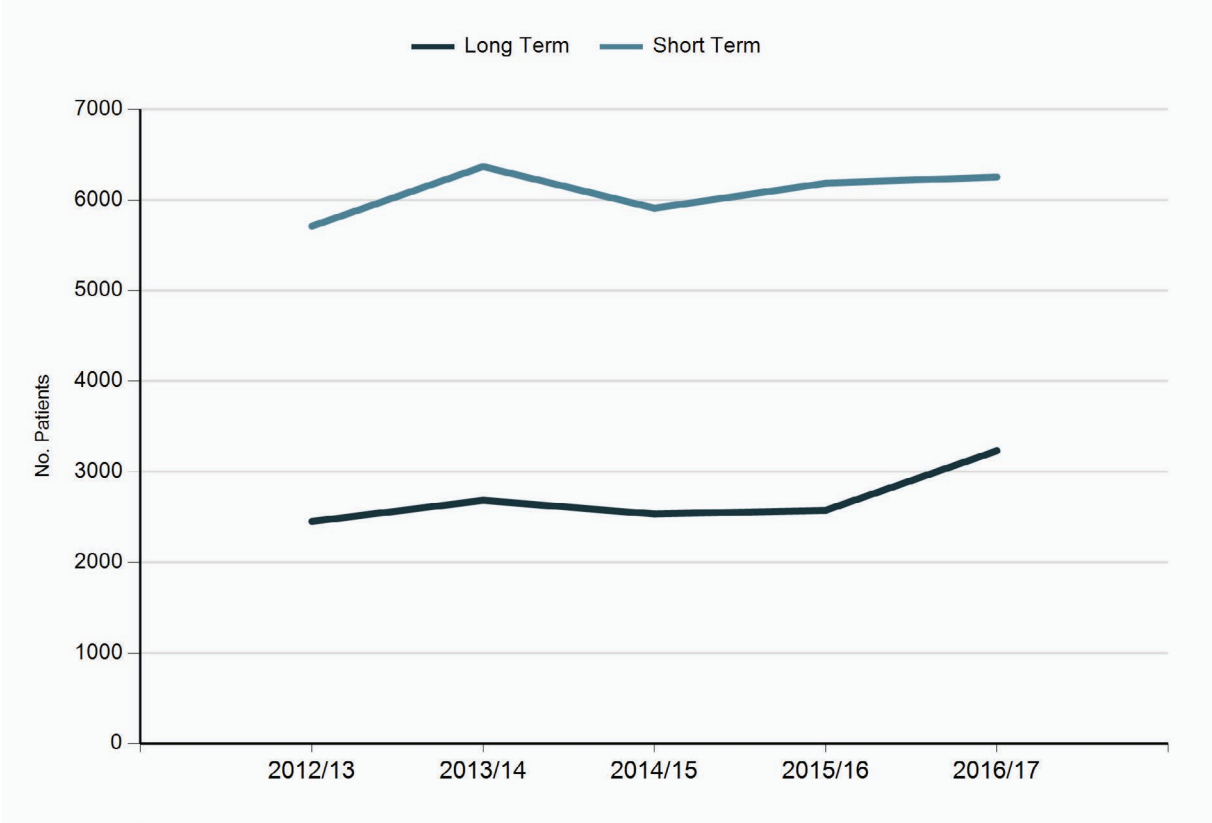

Figure 1.2 Yearly patient registrations by speciality 2016/17

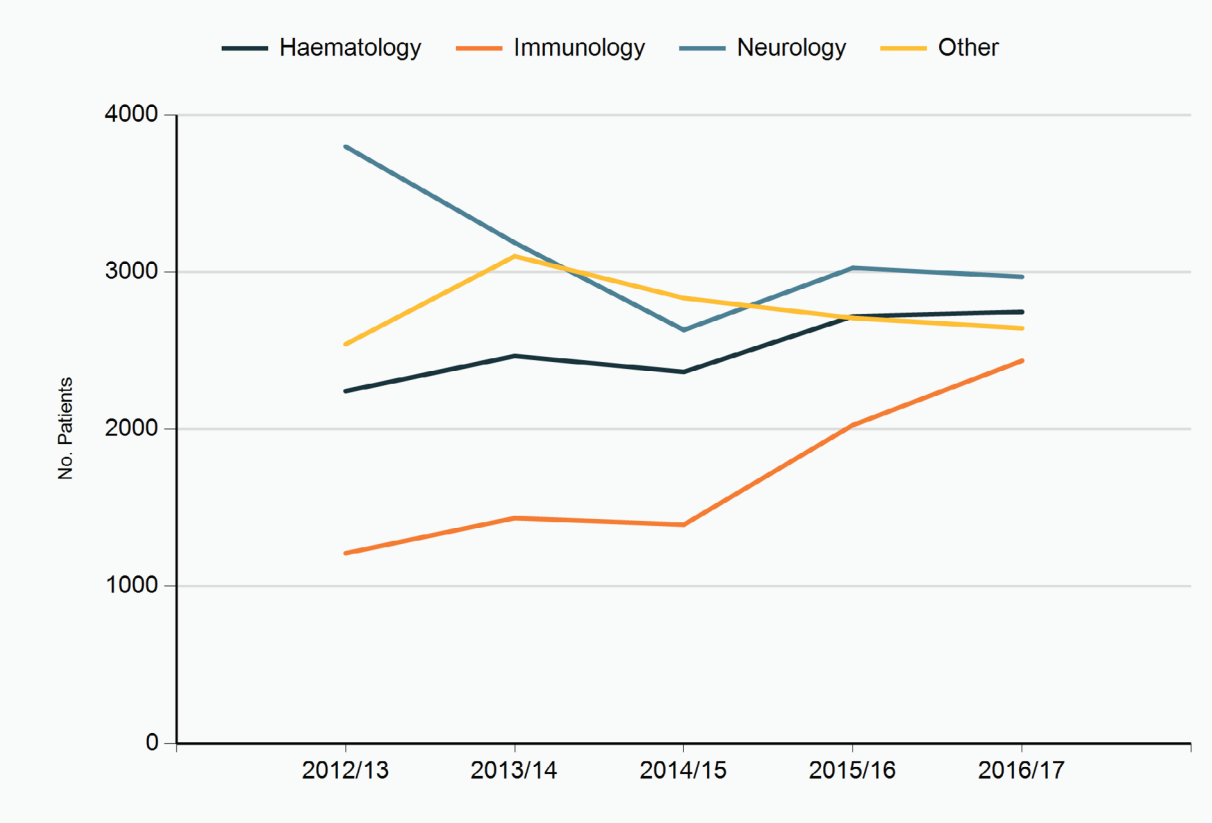

Figure 1.3 Patient registrations by region 2016/17

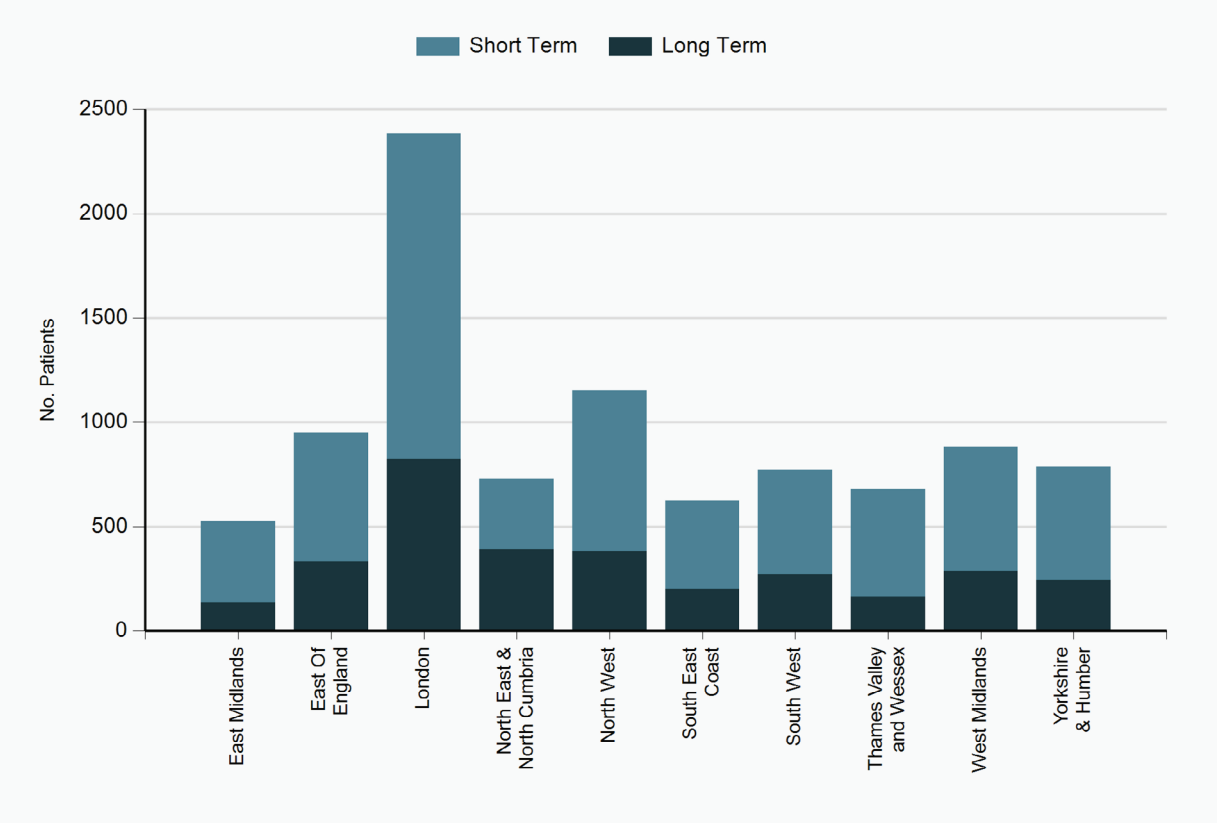

Figure 2.1.1 Monthly number of patients treated 2016/17

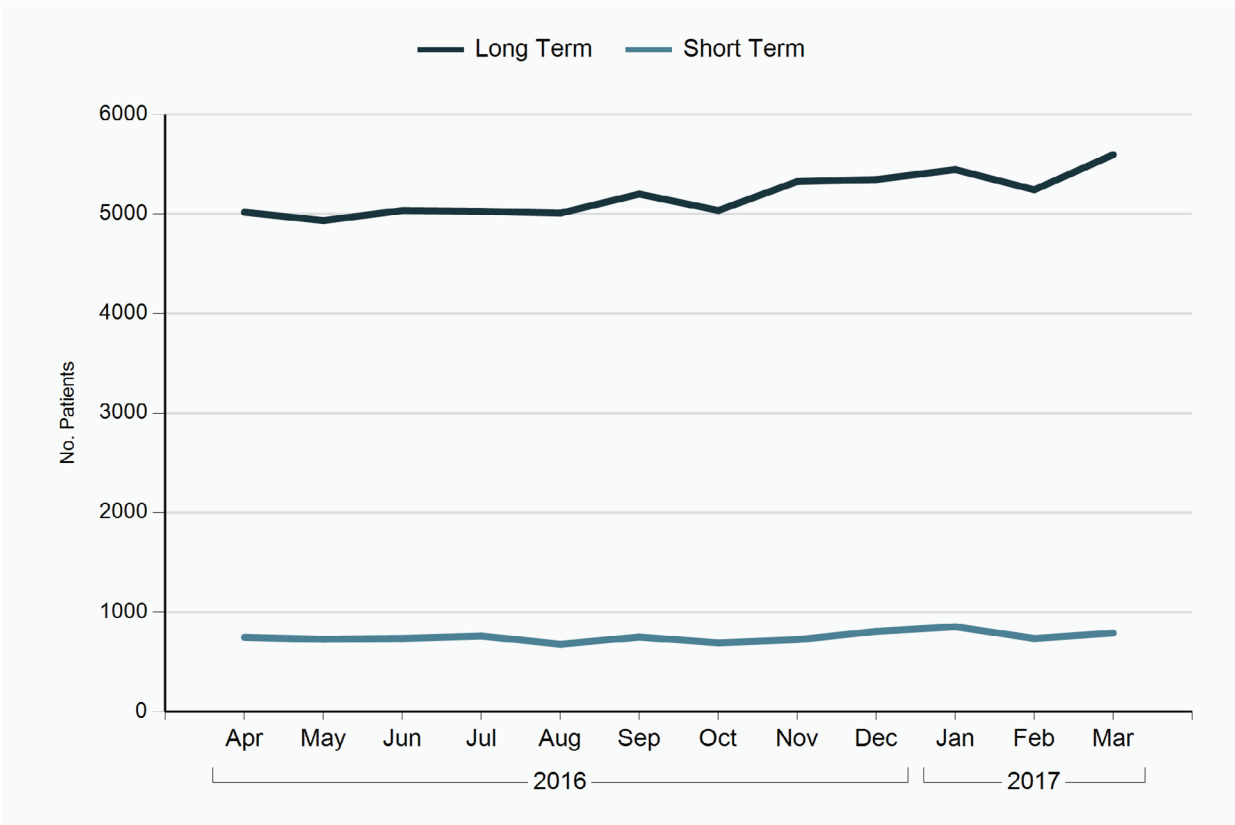

Figure 2.1.2 Yearly number of patients treated 2012/13 - 2016/17

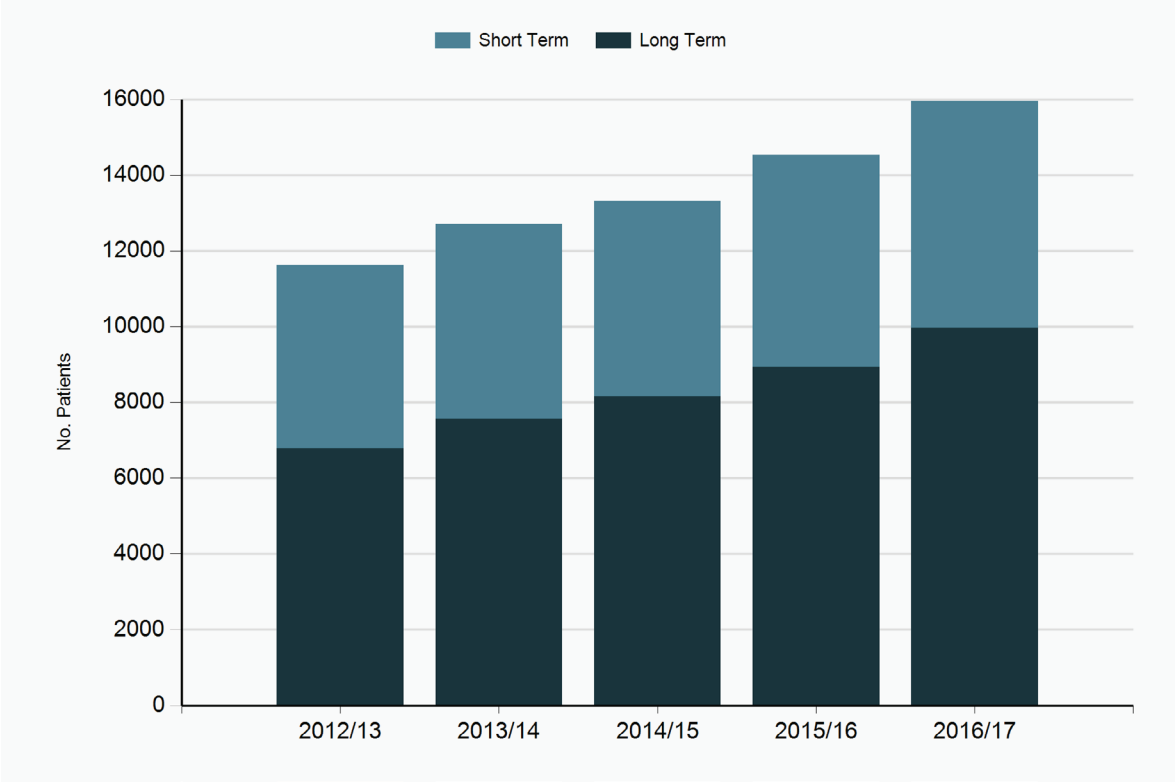

Figure 2.2.1 Monthly number of patients treated by speciality 2016/17

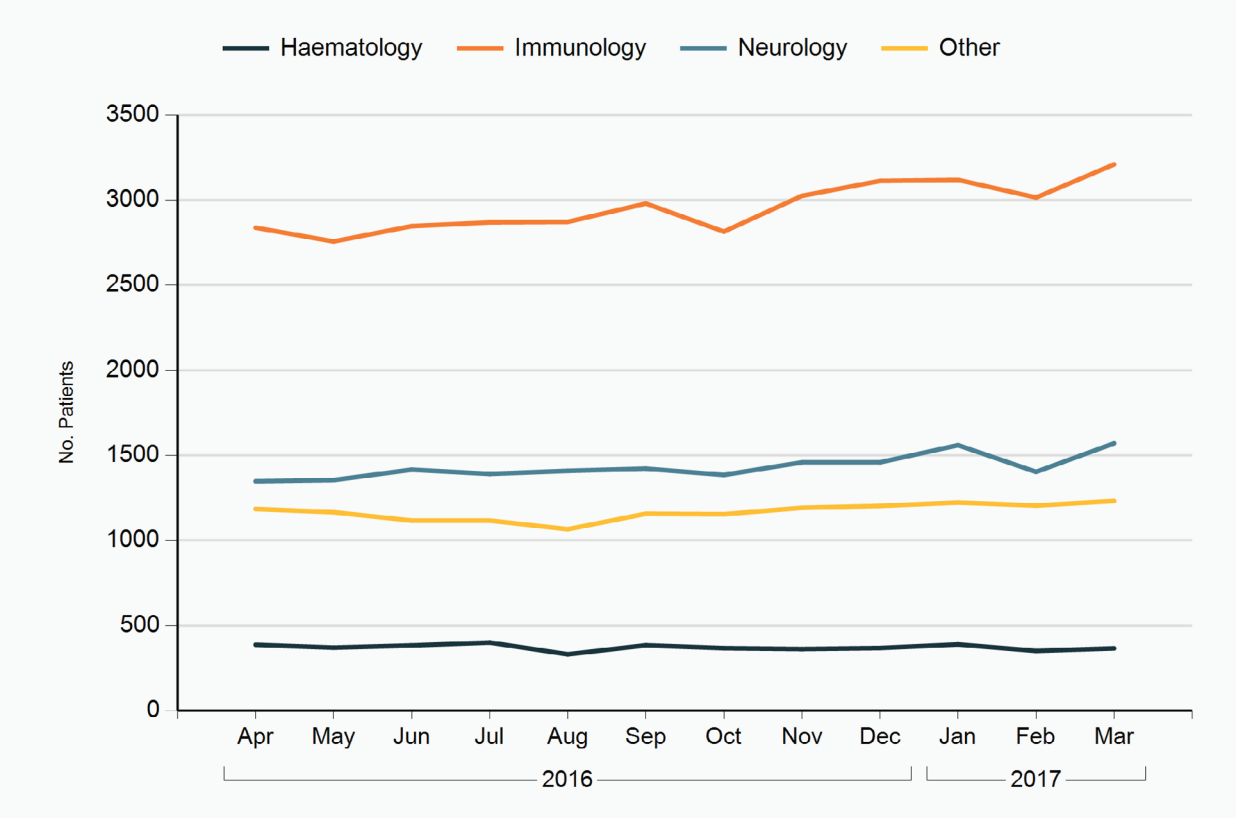

Figure 2.2.2 Yearly number of patients treated by speciality 2012/13 - 2016/17

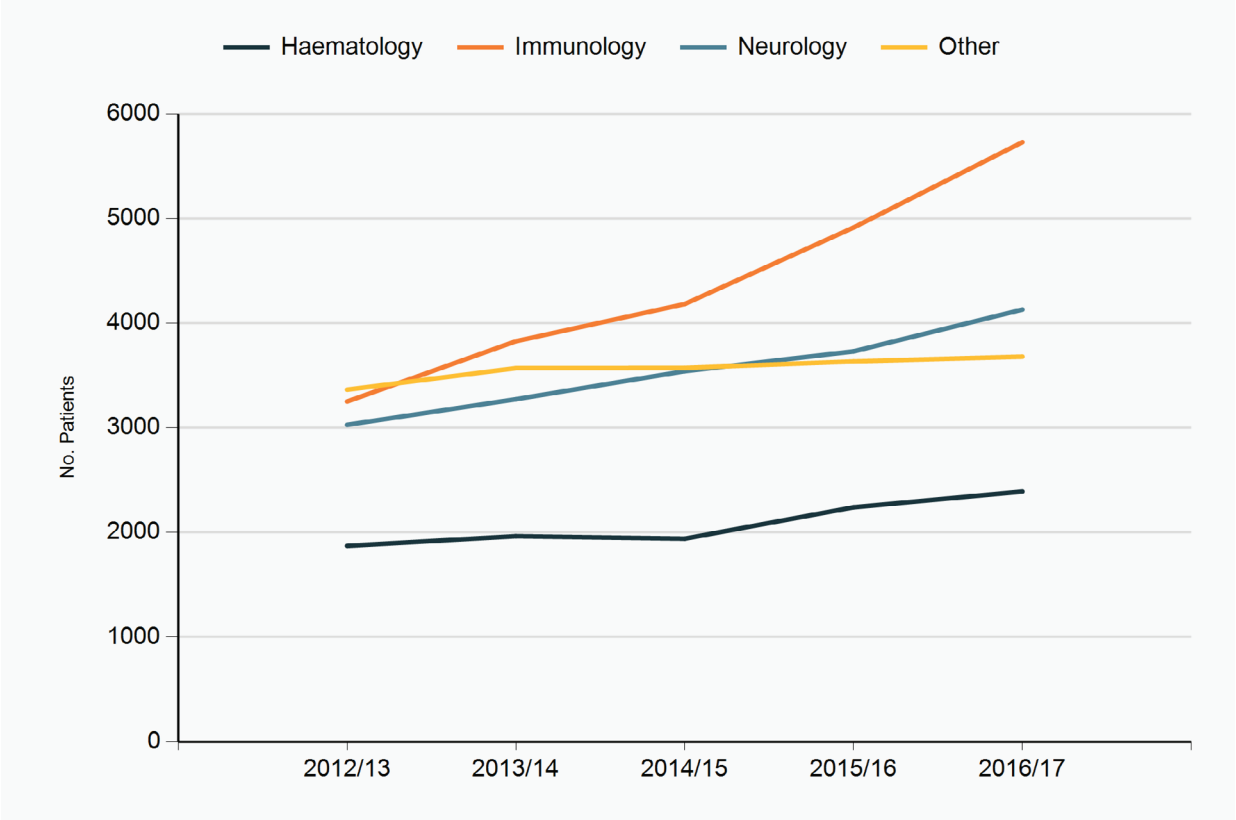

Figure 2.3.1 Number of patients treated by region 2016/17

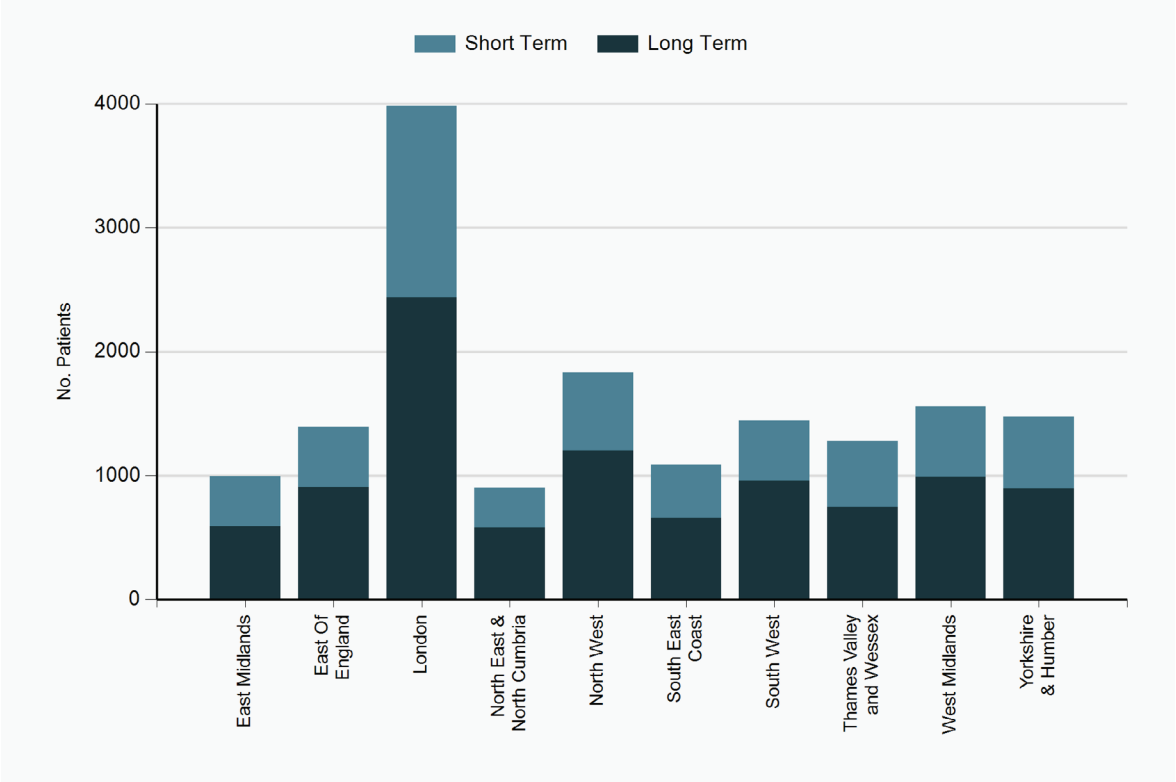

Figure 2.3.2 Yearly patients treated by region 2012/13 - 2016/17

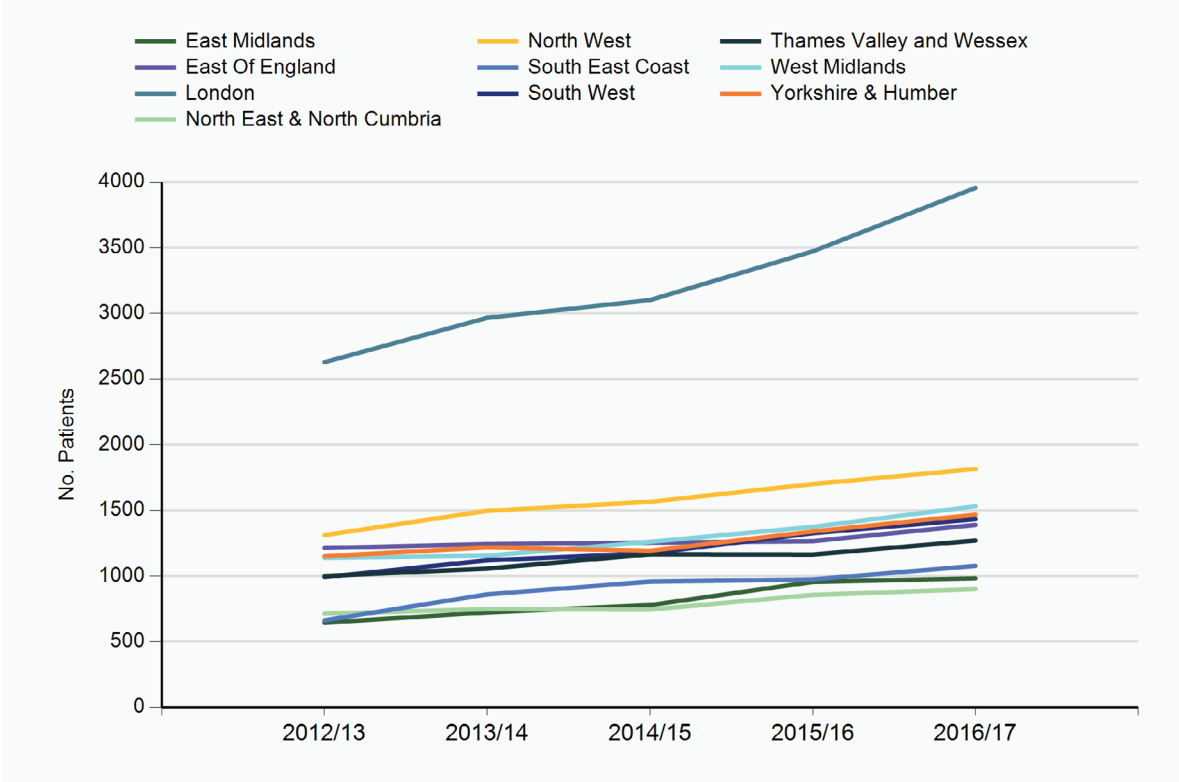

Figure 2.4 Yearly patients treated by treatment place 2012/13 - 2016/17

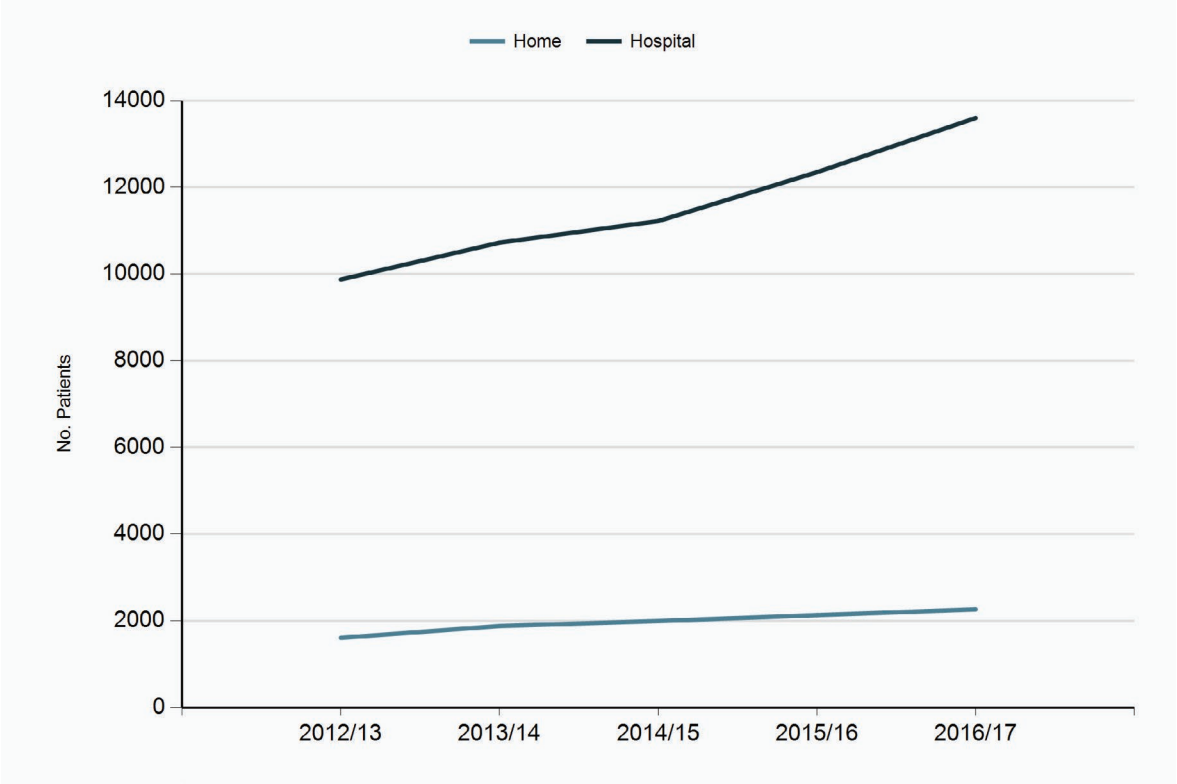

Figure 2.5 Number of patients treated for top 20 diagnoses 2016/17

Diagnosis	2016/17	2015/16 Change
Primary immunodeficiencies	3532	+7%
Secondary antibody deficiencies	1925	+36%
Immune thrombocytopenic purpura - Acute	1563	+4%
Chronic inflammatory demyelinating polyradiculoneuropathy	1412	+9%
Other Conditions	982	+4%
Guillain–Barré syndrome	943	+11%
Chronic lymphocytic leukaemia	873	-4%
Myasthenia gravis	666	+9%
Multifocal motor neuropathy	621	+10%
Kawasaki disease	388	+27%
Inflammatory myopathies	346	+33%
Multiple Myeloma	242	-11%
Specific antibody deficiency	231	+30%
Transplantation (Solid Organ)	229	+8%
Immune thrombocytopenic purpura - Persistent	226	-4%
Autoimmune haemolytic anaemia	212	+56%
Haemolytic disease of the fetus and newborn	202	+22%
Autoimmune encephalitis	183	+24%
Staphylococcal toxic shock syndrome	181	-7%
Low serum IgG levels following HSCT for malignancy	175	-3%

Figure 2.6 Number of patients treated in top 20 trusts 2016/17

NHS Trust	2016/17	Change
Royal Free NHS Trust	504	+3%
Barts And The London NHS Trust	459	-1%
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	441	+15%
Leeds Teaching Hospitals NHS Trust	416	+13%
University College London Hospitals NHS Foundation Trust	414	+25%
King's College Hospital NHS Foundation Trust	383	New user
Oxford Radcliffe Hospitals NHS Trust	376	+13%
Imperial College Healthcare NHS Trust	345	+1%
Sheffield Teaching Hospitals NHS Foundation Trust	333	-
Salford Royal NHS Foundation Trust	328	+1%
Nottingham University Hospitals NHS Trust	326	+12%
Heart Of England NHS Foundation Trust	300	+7%
Guy's And St Thomas' NHS Foundation Trust	287	+3%
Southampton University Hospitals NHS Trust	255	+2%
University Hospitals Of Leicester NHS Trust	240	-11%
Central Manchester & Manchester Children's University Hospitals NHS Trust	227	+22%
Plymouth Hospitals NHS Trust	227	+14%
University Hospital Birmingham NHS Foundation Trust	210	+12%
Great Ormond Street Hospital for Children NHS Trust	204	-14%
Maidstone and Tunbridge Wells NHS Trust	199	+5%

Figure 2.7 Number of grey patients treated and grey outcomes recorded 2012/13 - 2016/17

Year	2012/13	2013/14	2014/15	2015/16	2016/17
Grey Requests	854	918	778	762	790
Grey Requests with Outcome Data	N/A	273	241	268	347
Percentage	N/A	30%	31%	35%	43%

Figure 2.8 Number of long term patients treated and Follow-Ups recorded

Year	2012/13	2013/14	2014/15	2015/16	2016/17
Long Term Patients	6800	7577	8177	8950	9976
Long Term Patients with Follow-Up	2253	3298	4037	5145	6234
Percentage	33%	43%	50%	57%	62%

Figure 3.1.1 Recorded monthly immunoglobulin use by regime 2016/17

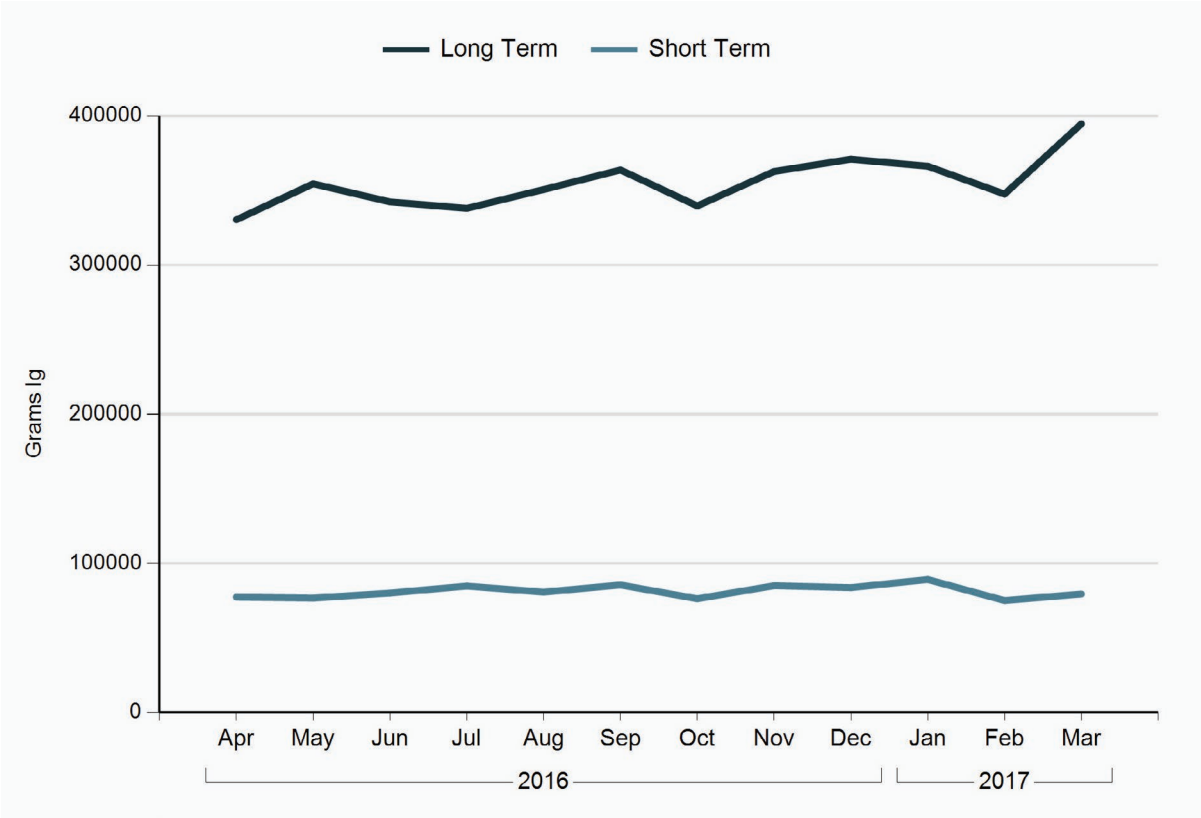

Figure 3.1.2 Recorded yearly immunoglobulin use by regime 2012/13 - 2016/17

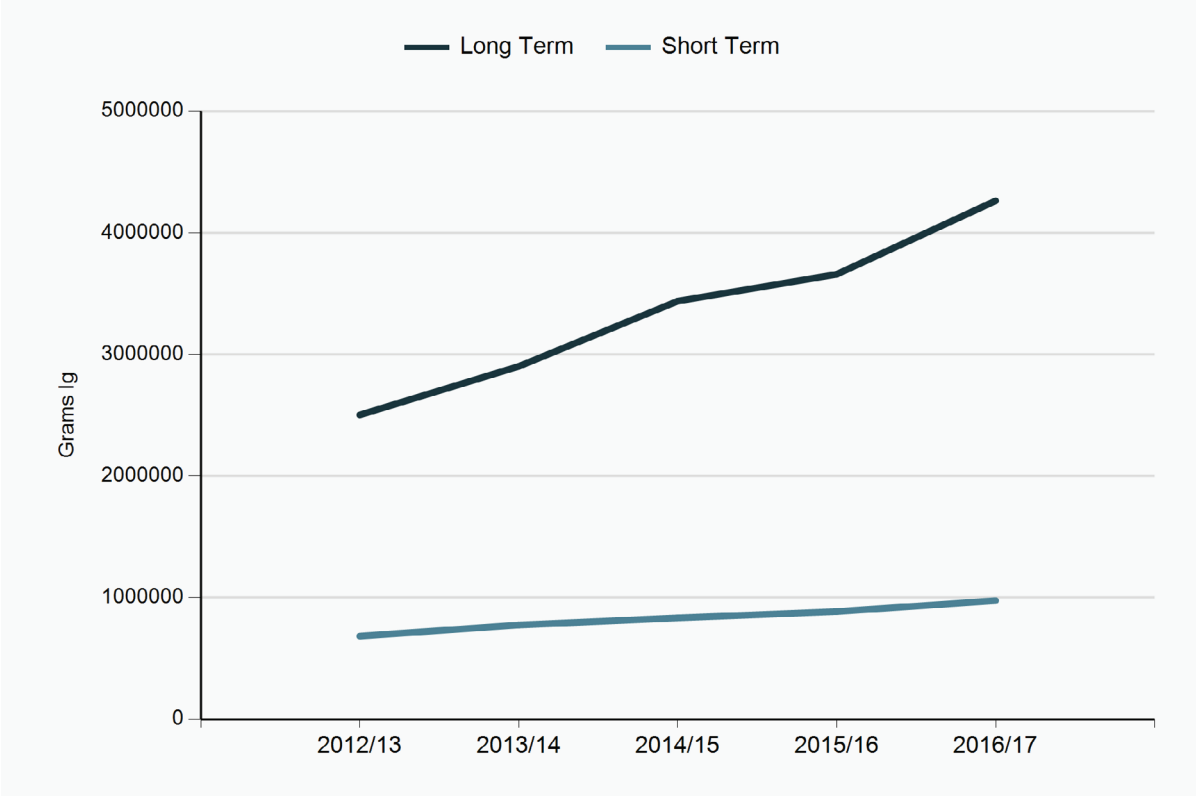

Figure 3.2.1 Recorded monthly immunoglobulin use by speciality 2016/17

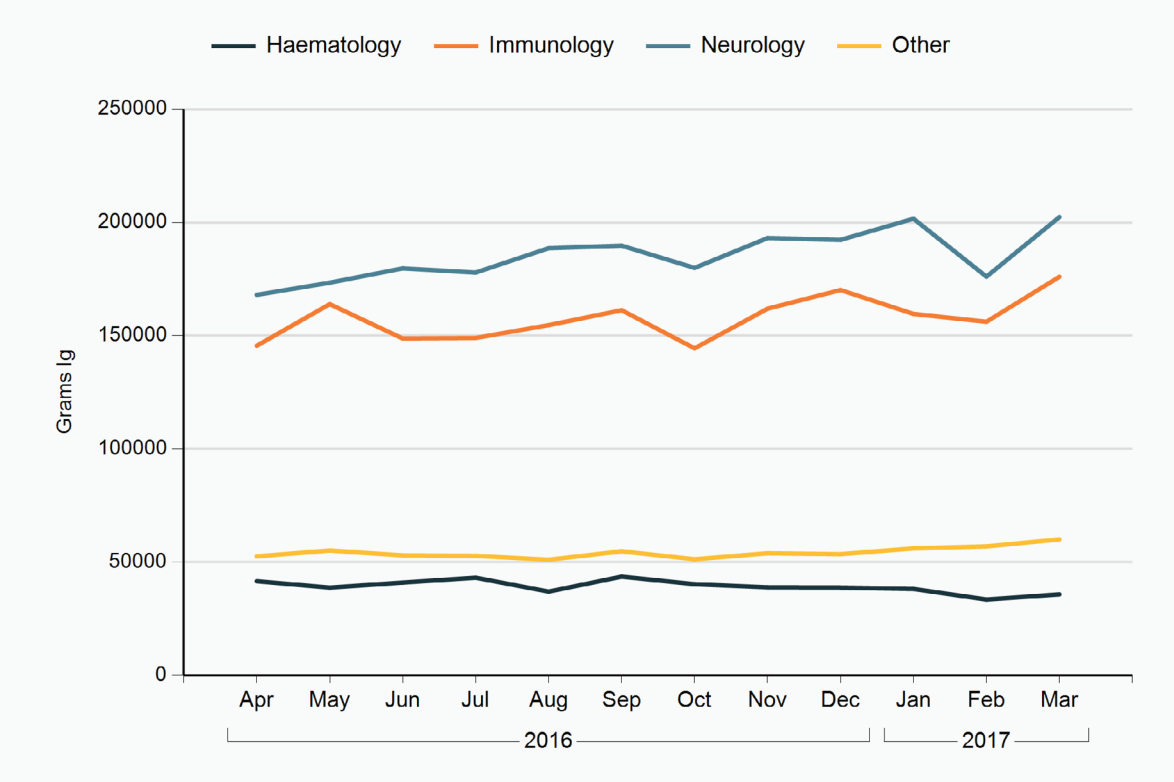

Figure 3.2.2 Recorded yearly immunoglobulin use by speciality 2012/13 - 2016/17

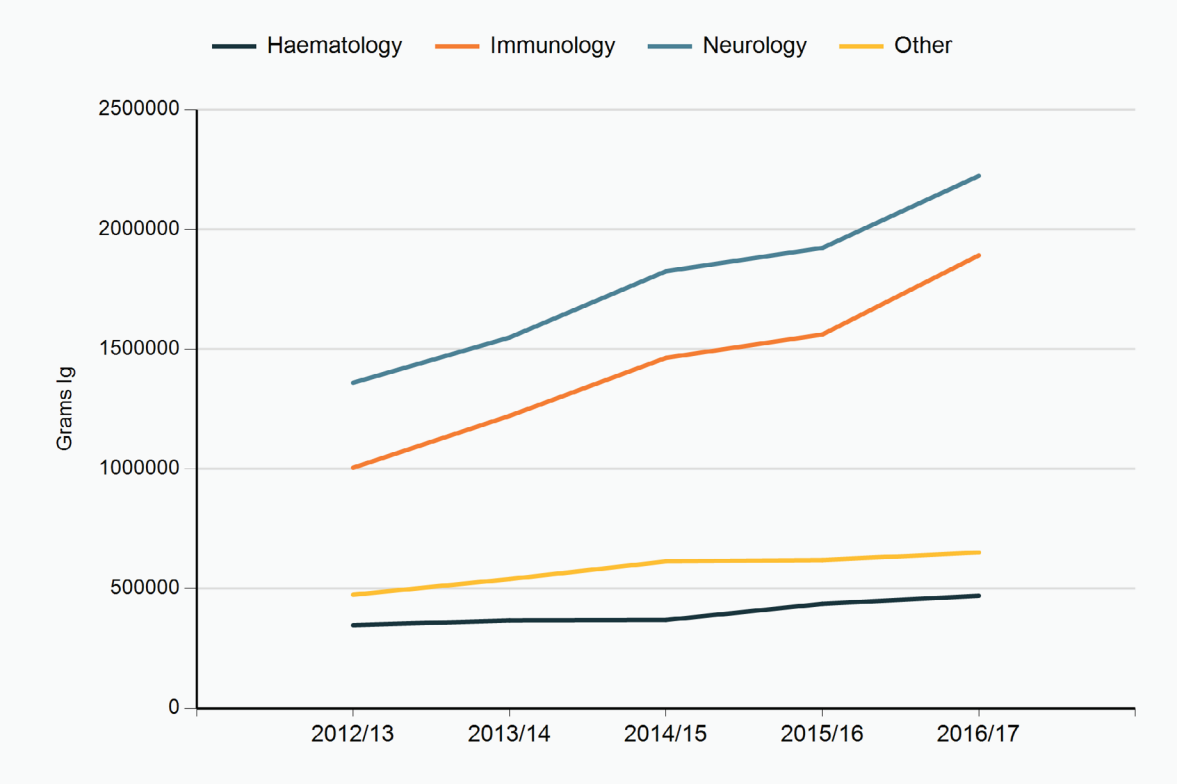

Figure 3.3.1 Recorded monthly immunoglobulin use by Indication 2016/17

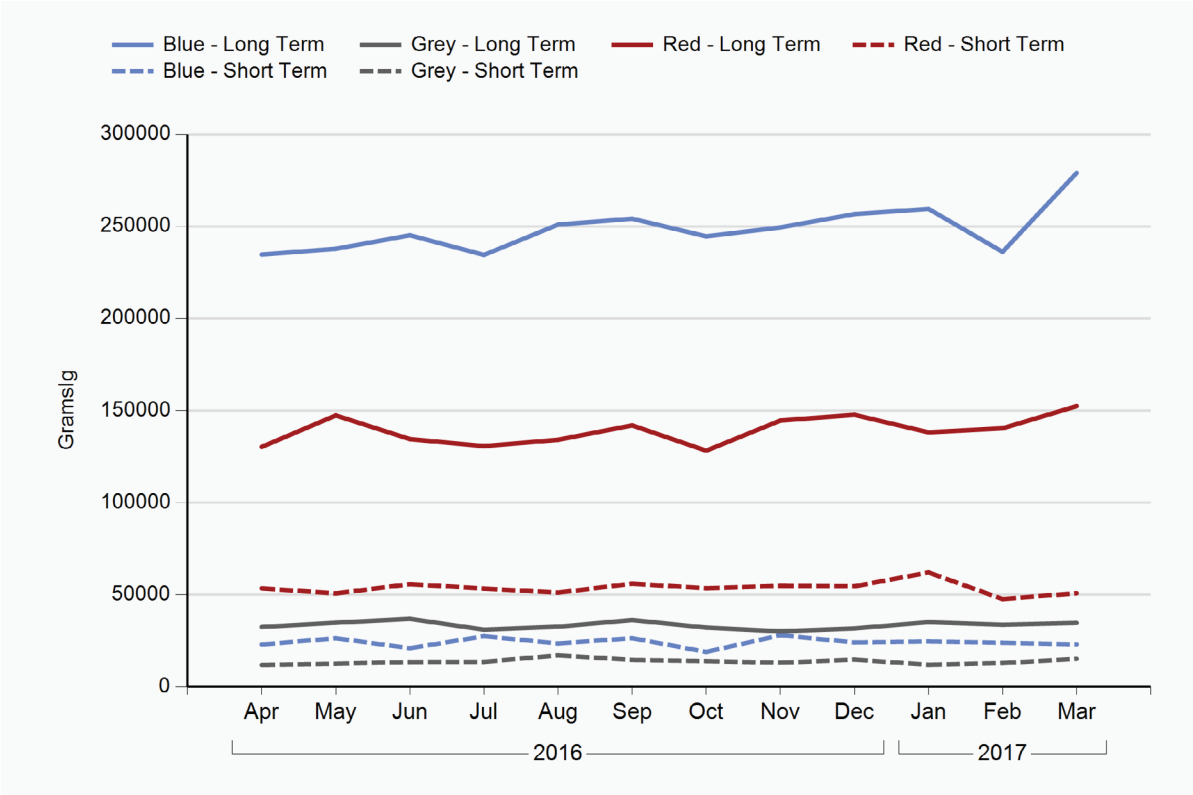

Figure 3.3.2 Recorded yearly immunoglobulin use by Indication 2012/13 - 2016/17

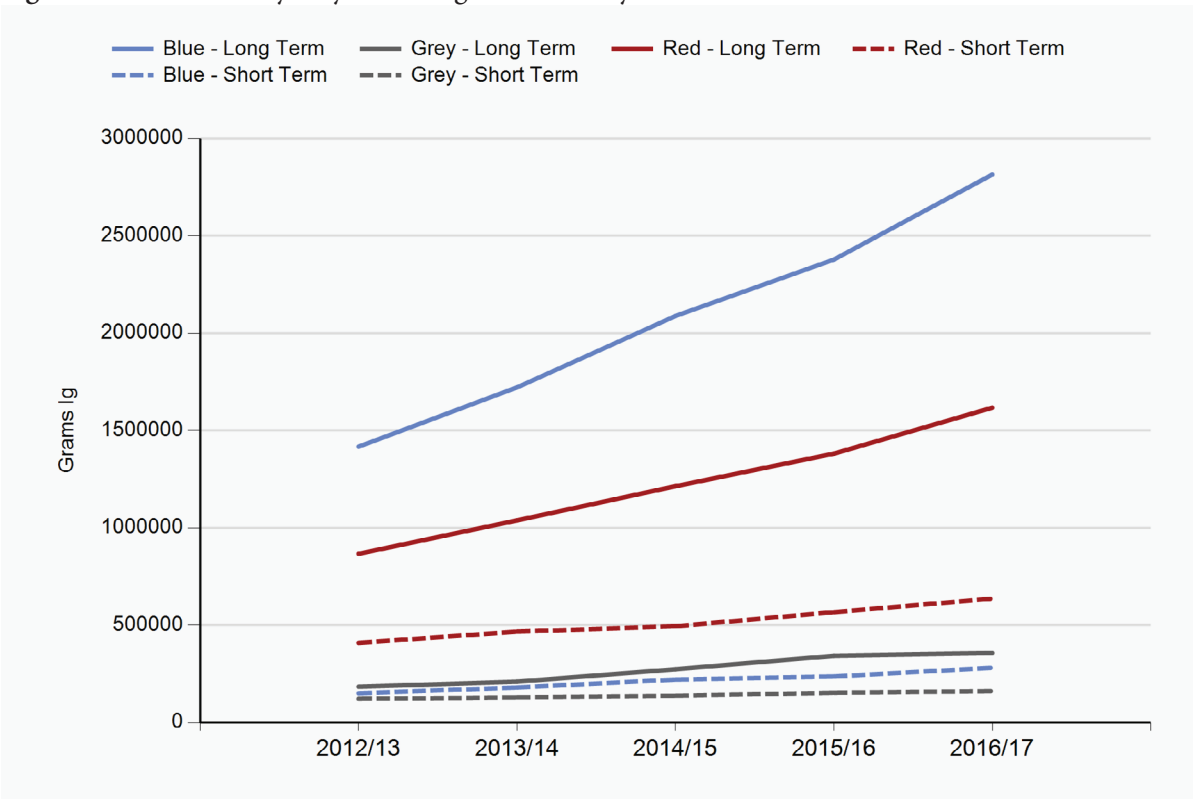

Figure 3.4.1 Recorded immunoglobulin use by region 2016/17

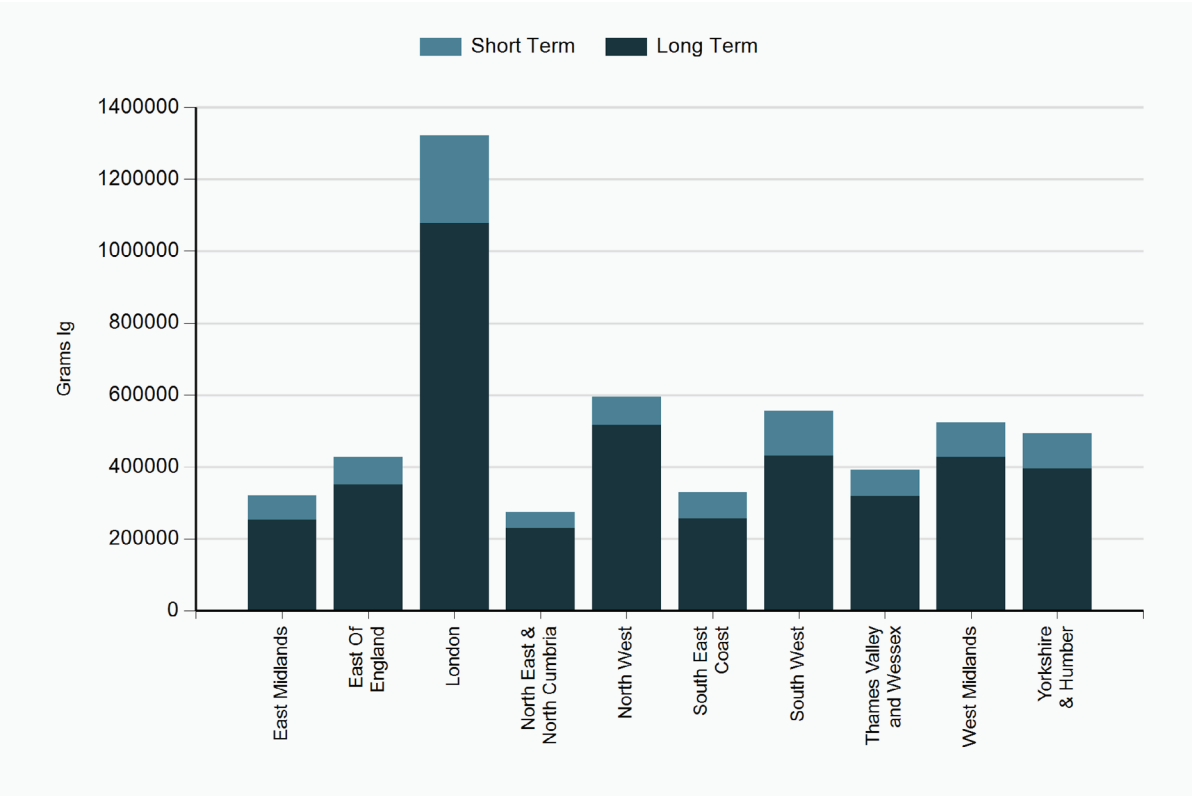

Figure 3.4.2 Recorded yearly immunoglobulin use by region 2012/13 - 2016/17

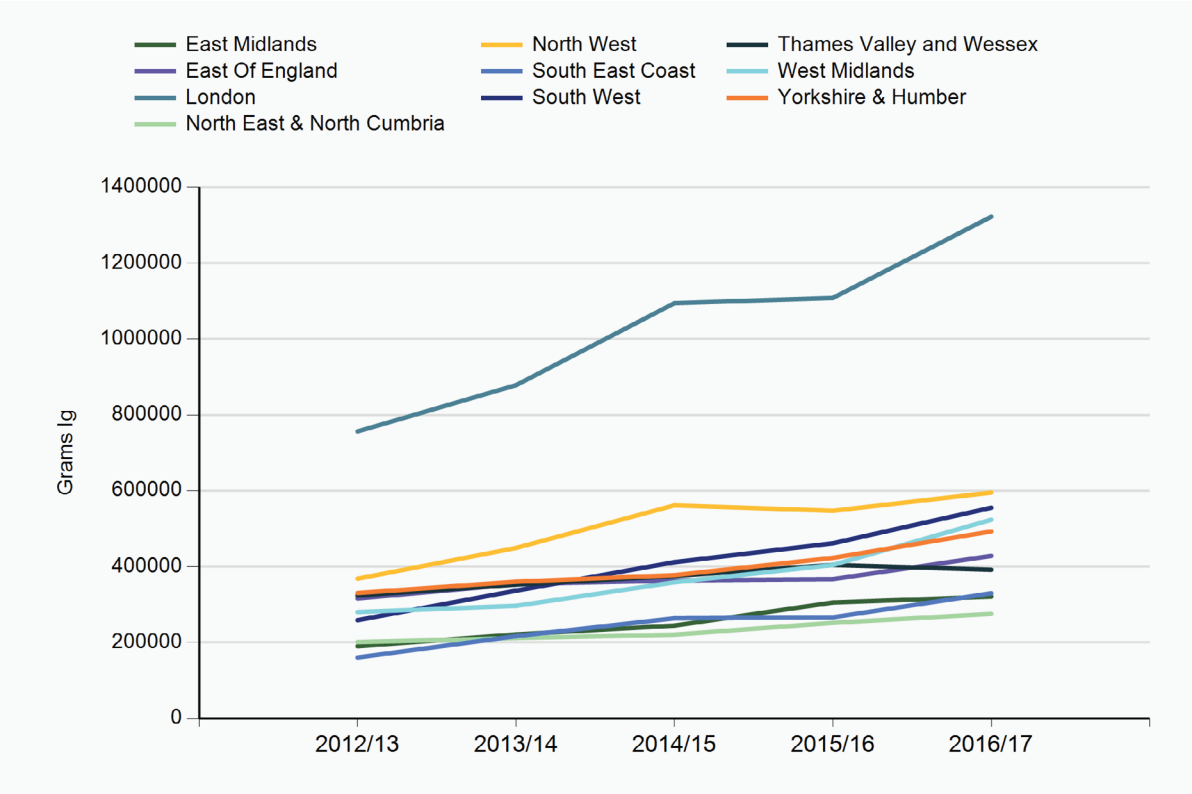

Figure 3.5.1 Volume of immunoglobulin used for the top 10 diagnoses 2016/17

Diagnosis	Usage (Grams)	2015/16 Difference
Primary immunodeficiencies	1,329,255	+15%
Chronic inflammatory demyelinating polyradiculoneuropathy	1,039,990	+14%
Multifocal motor neuropathy	521,706	+15%
Secondary antibody deficiencies	432,436	+44%
Immune thrombocytopenic purpura - acute	277,998	+5%
Other conditions	275,230	+6%
Chronic lymphocytic leukaemia	219,446	+4%
Myasthenia gravis	195,282	+11%
Guillain–Barré syndrome	164,801	+19%
Inflammatory myopathies	152,199	+40%

Figure 3.5.2 Recorded yearly immunoglobulin use for the top 10 diagnoses 2012/13 - 2016/17

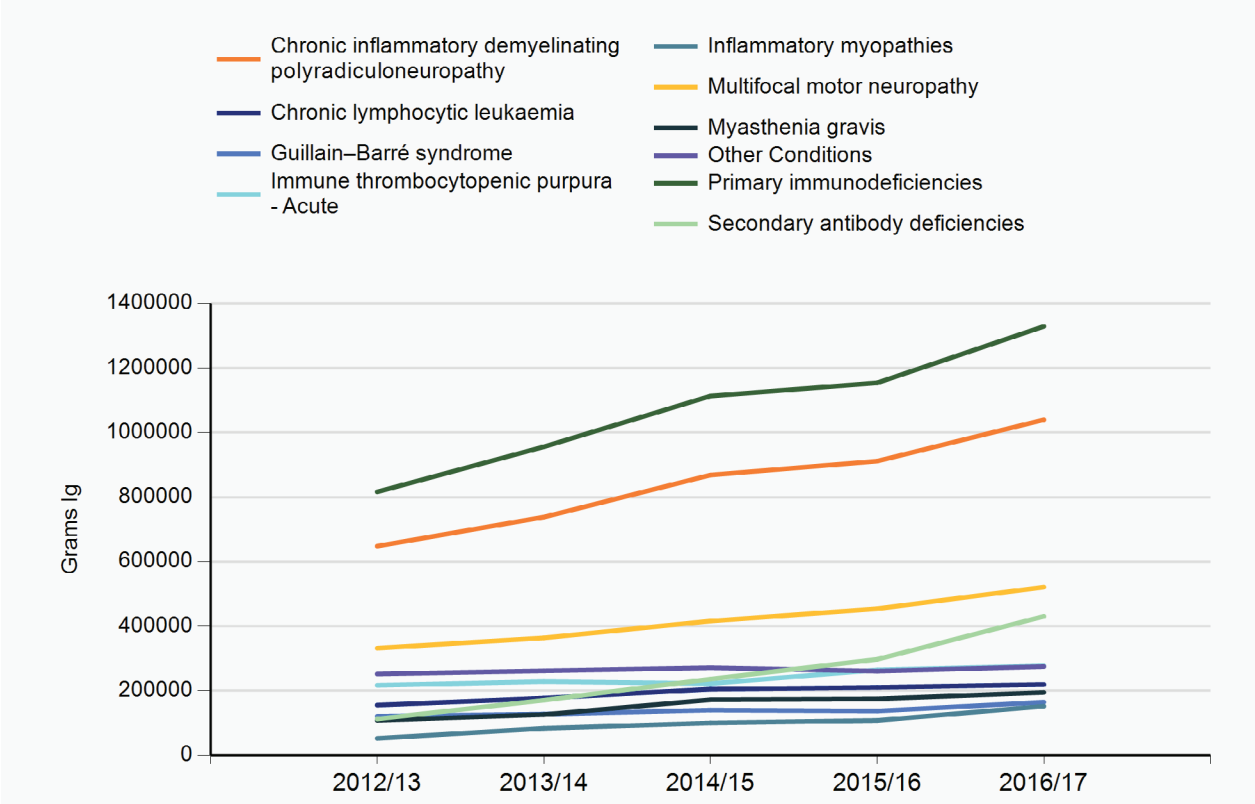

Figure 3.6 Volume of immunoglobulin used in top 20 trusts 2016/17

NHS Trust	Usage (Grams)	2015/16 Difference
University College London Hospitals NHS Foundation Trust	278,028	+19%
Royal Free NHS Trust	223,796	+15%
Salford Royal NHS Foundation Trust	179,917	+6%
Heart Of England NHS Foundation Trust	163,363	+52%
Sheffield Teaching Hospitals NHS Foundation Trust	150,311	+10%
Barts And The London NHS Trust	147,736	-21%
King's College Hospital NHS Foundation Trust	147,533	New user
Oxford Radcliffe Hospitals NHS Trust	142,794	-18%
Leeds Teaching Hospitals NHS Trust	133,453	+7%
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	133,029	+15%
Royal Cornwall Hospitals NHS Trust	110,205	+13%
Nottingham University Hospitals NHS Trust	107,038	+14%
North Bristol NHS Trust	105,268	+56%
University Hospitals Of Leicester NHS Trust	105,075	-7%
Imperial College Healthcare NHS Trust	96,744	+12%
University Hospital Birmingham NHS Foundation Trust	94,955	+27%
Lancashire Teaching Hospitals NHS Foundation Trust	86,361	+2%
Walton Centre for Neurology and Neurosurgery NHS Trust	86,200	-4%
Guy's And St Thomas' NHS Foundation Trust	83,514	+3%
Plymouth Hospitals NHS Trust	79,108	+6%

Figure 3.7.1 Recorded monthly use of intravenous and subcutaneous immunoglobulin 2016/17

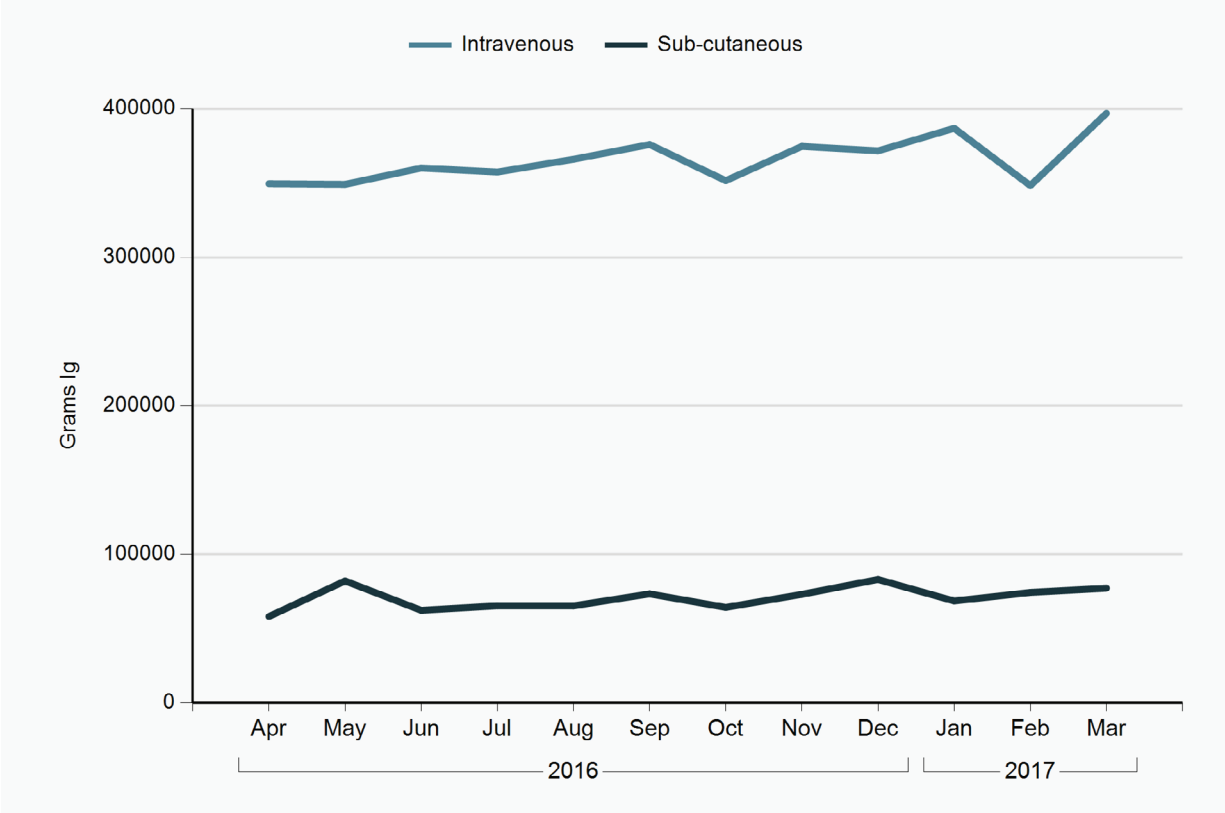

Figure 3.7.2 Recorded yearly use of intravenous and subcutaneous immunoglobulin 2012/13 - 2016/17

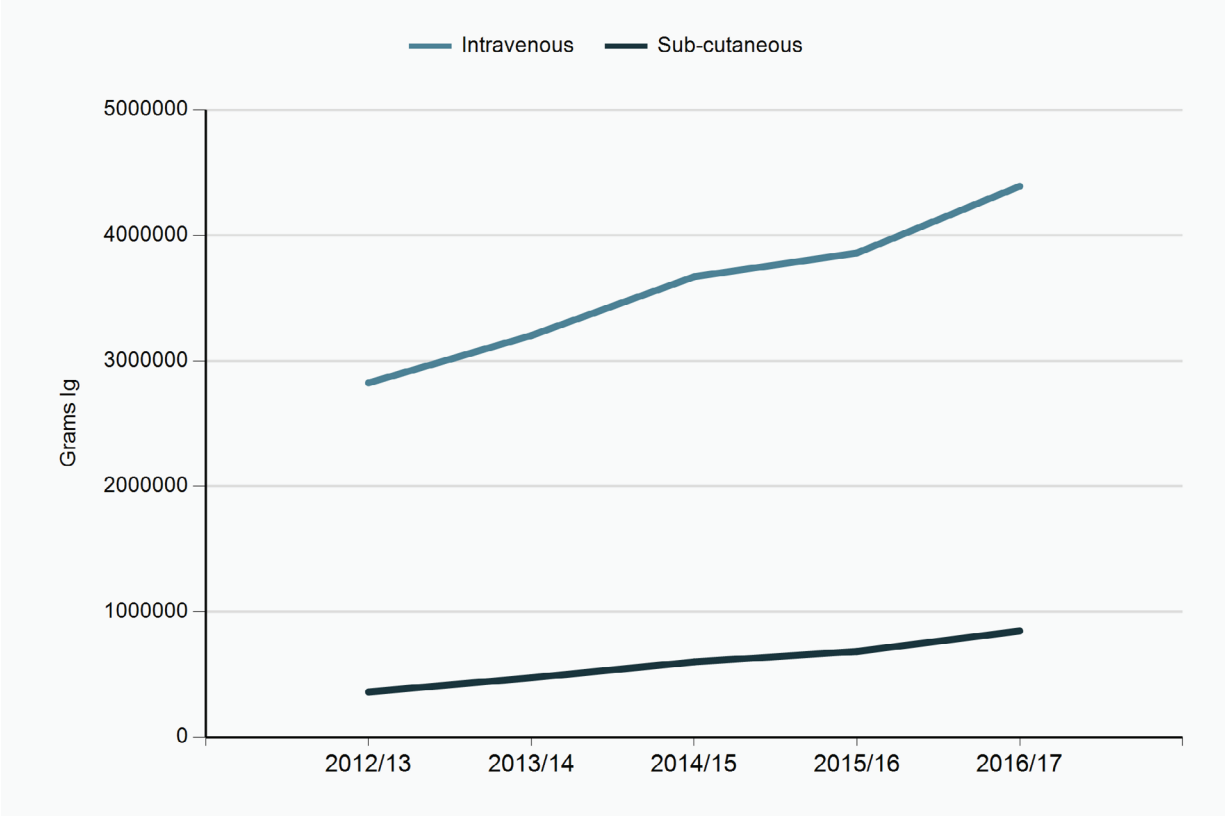

Figure 3.8.1 Recorded monthly use of intravenous immunoglobulin products 2016/17

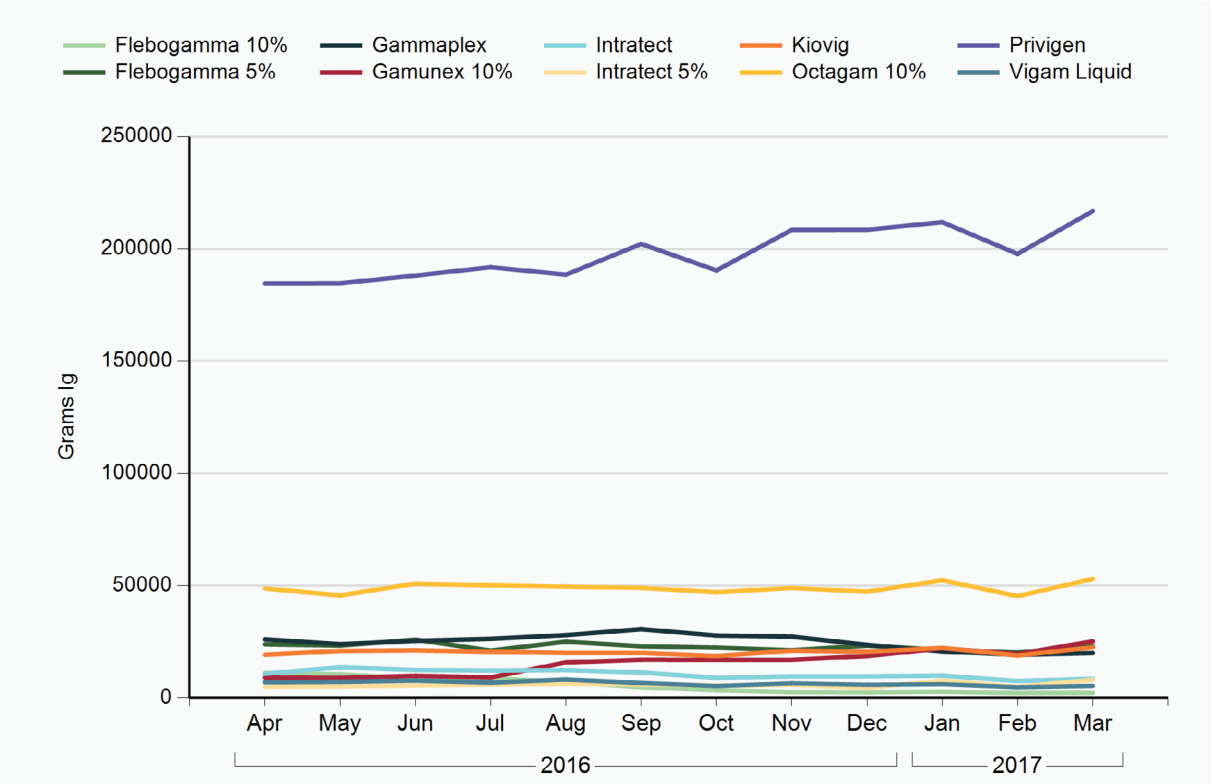

Figure 3.8.2 Recorded yearly use of intravenous immunoglobulin products 2012/13 - 2016/17

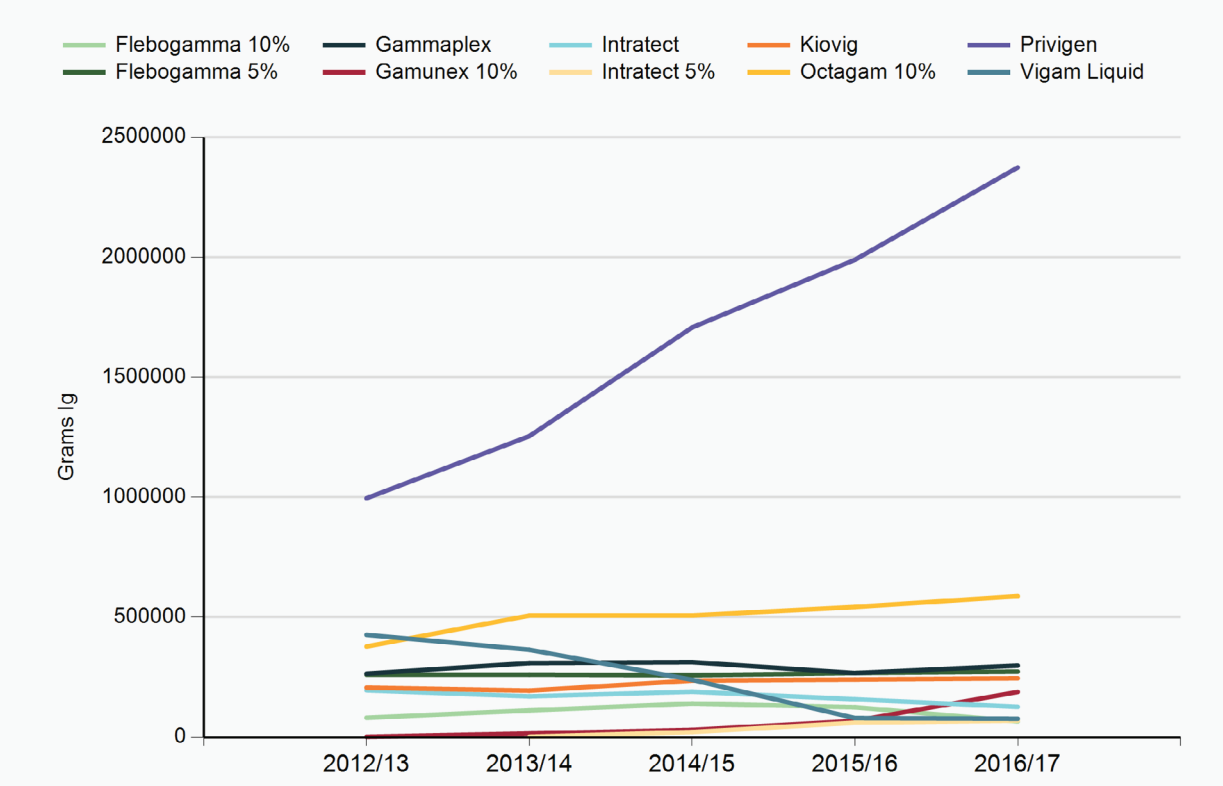

Figure 3.9.1 Recorded monthly use of subcutaneous immunoglobulin products 2016/17

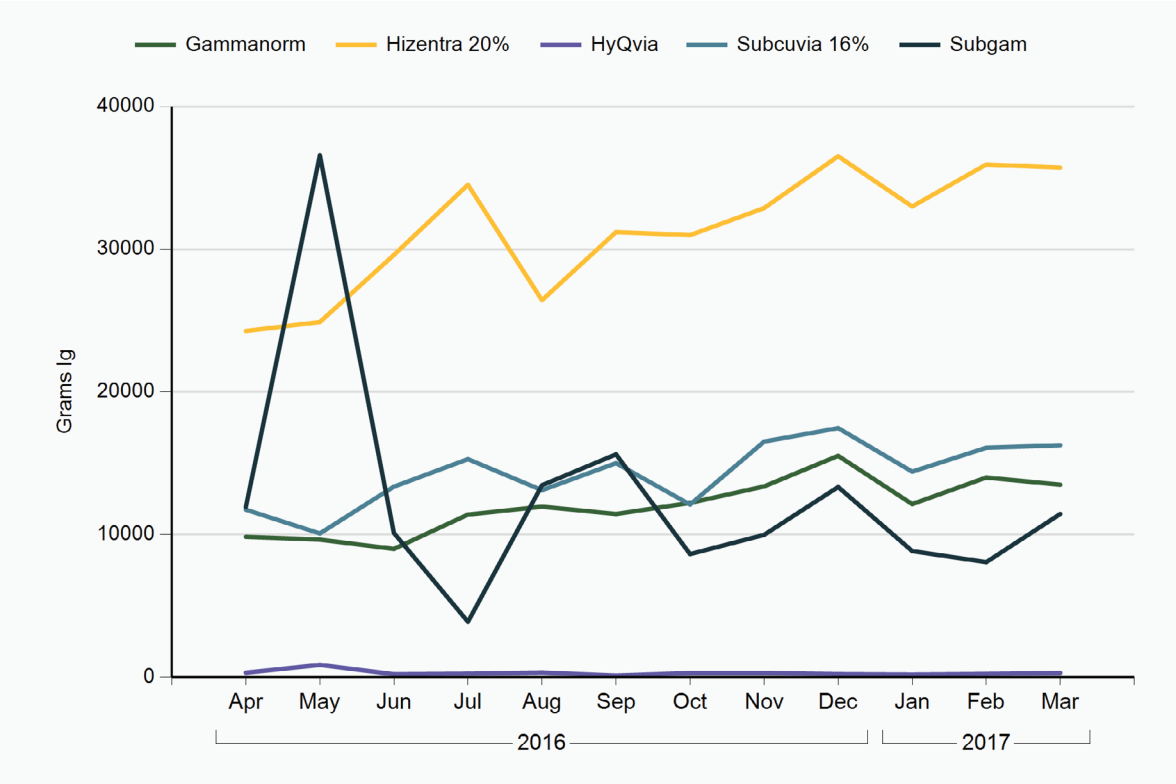

Figure 3.9.2 Recorded yearly use of subcutaneous immunoglobulin products 2016/17

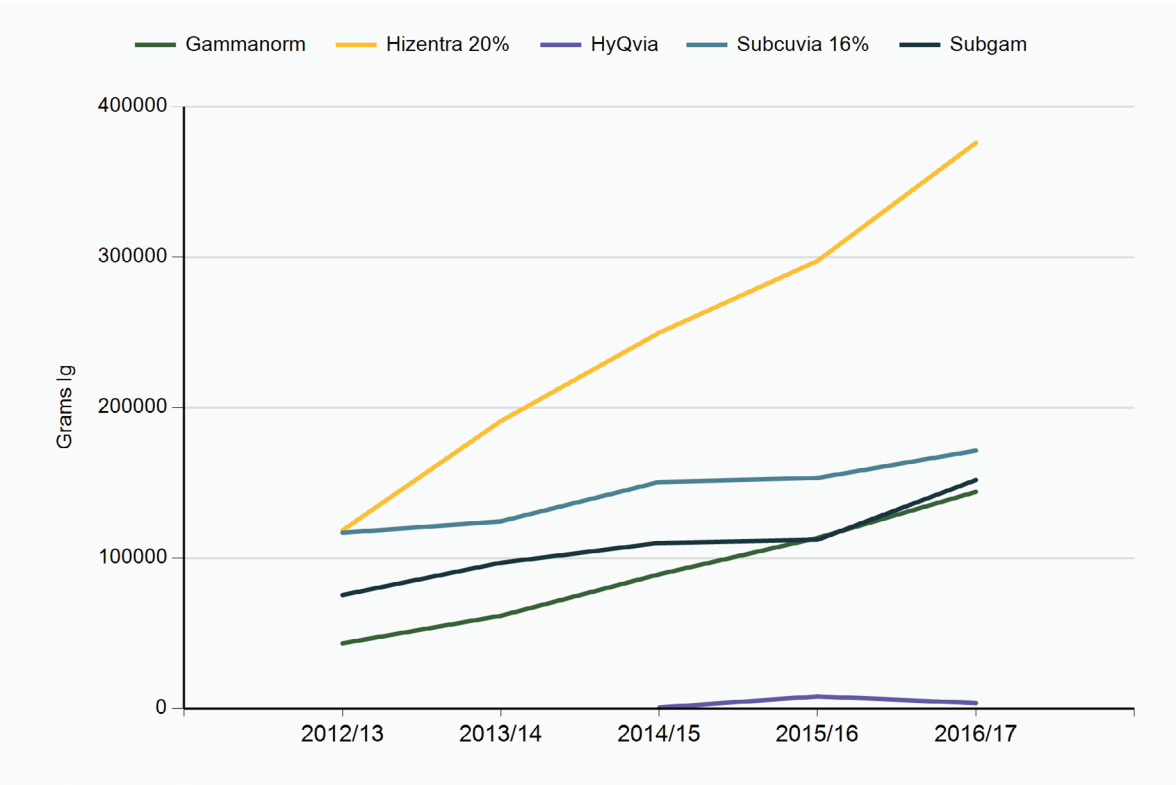

Figure 3.10.1 Recorded monthly use of immunoglobulin products by manufacturer 2016/17

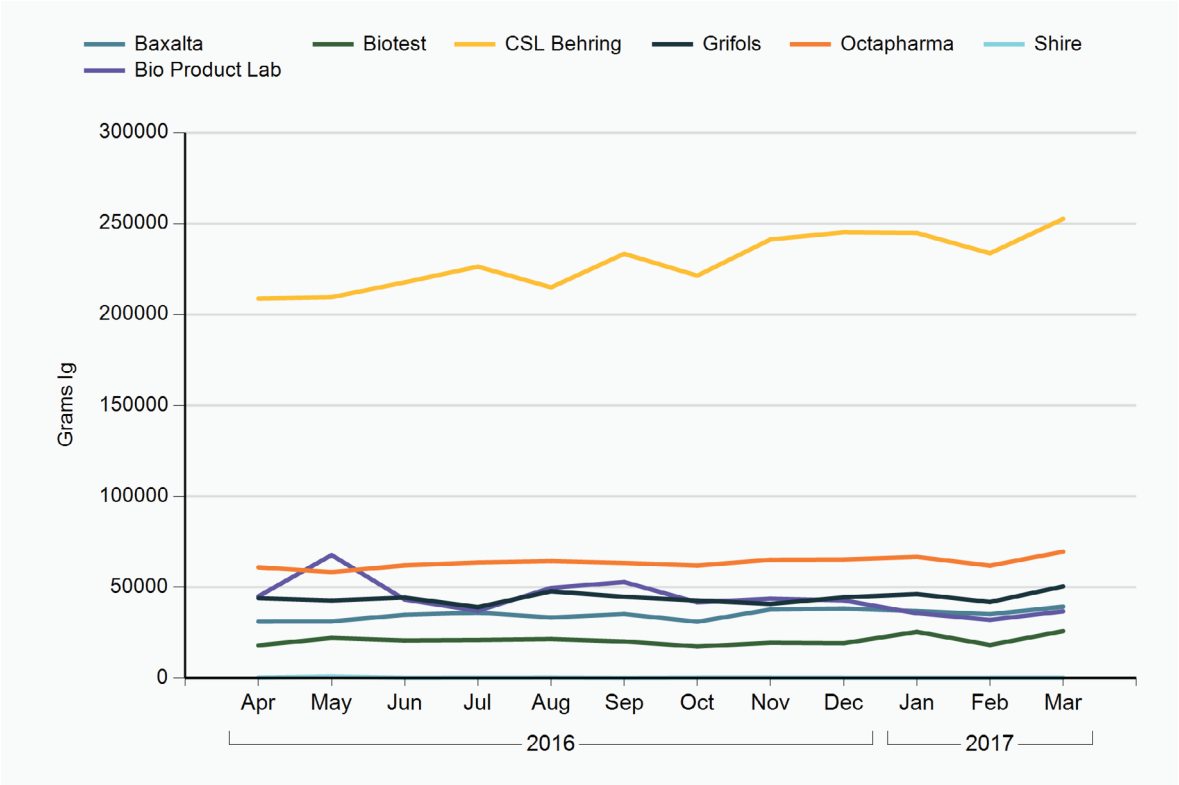

Figure 3.10.2 Recorded yearly use of immunoglobulin products by manufacturer 2012/13 - 2016/17

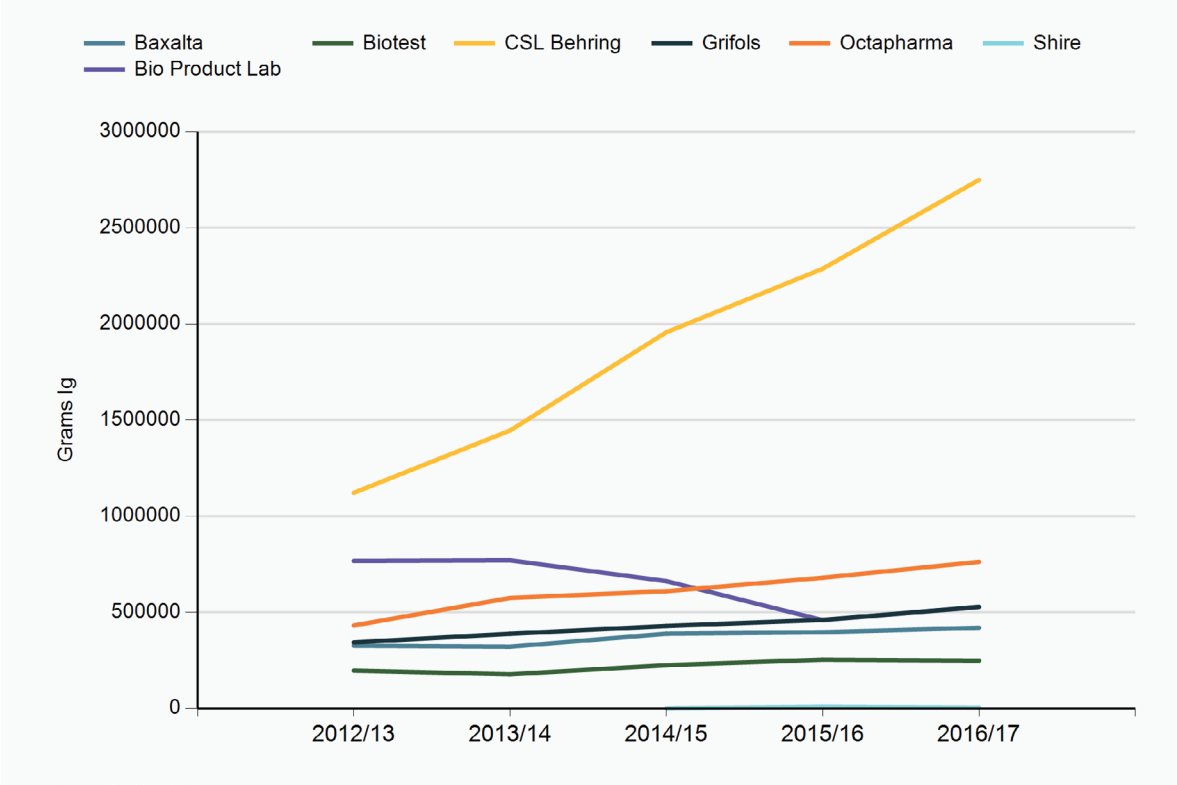

Figure 3.11.1 Average use of immunoglobulin per patient by speciality 2012/13 - 2016/17

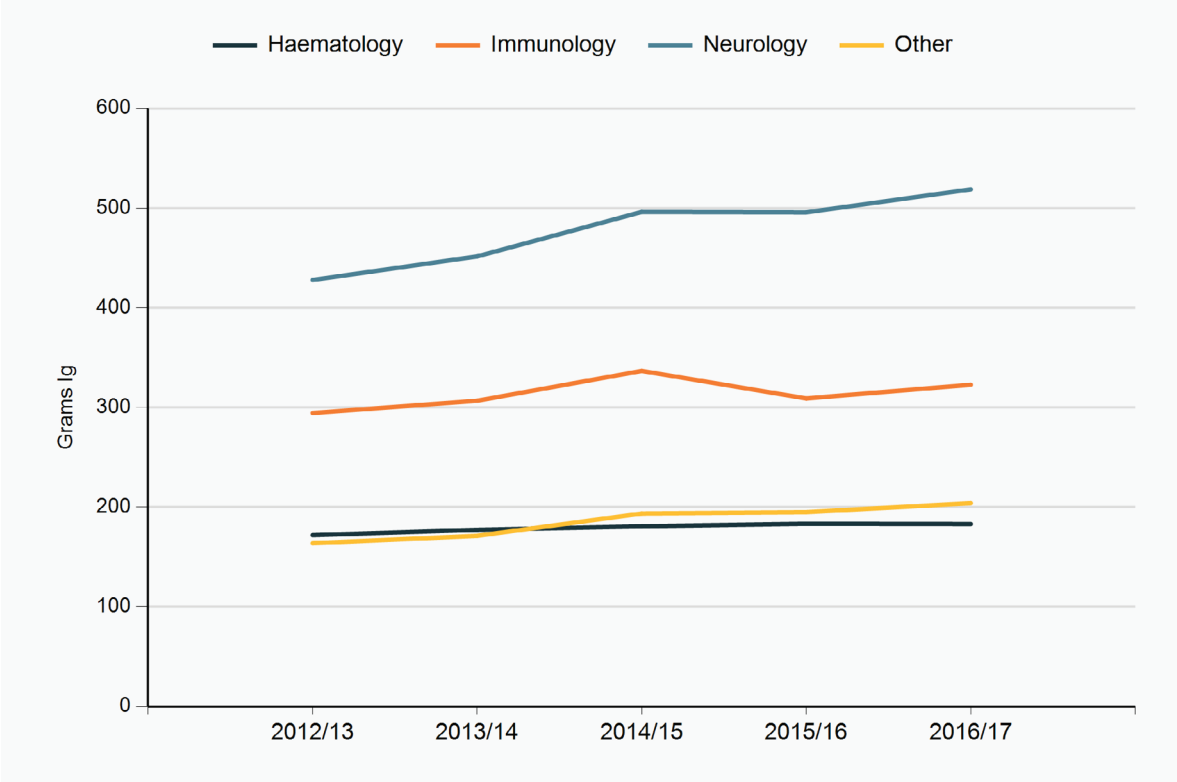

Figure 3.11.2 Average use of immunoglobulin per patient by indication & regime 2012/13 - 2016/17

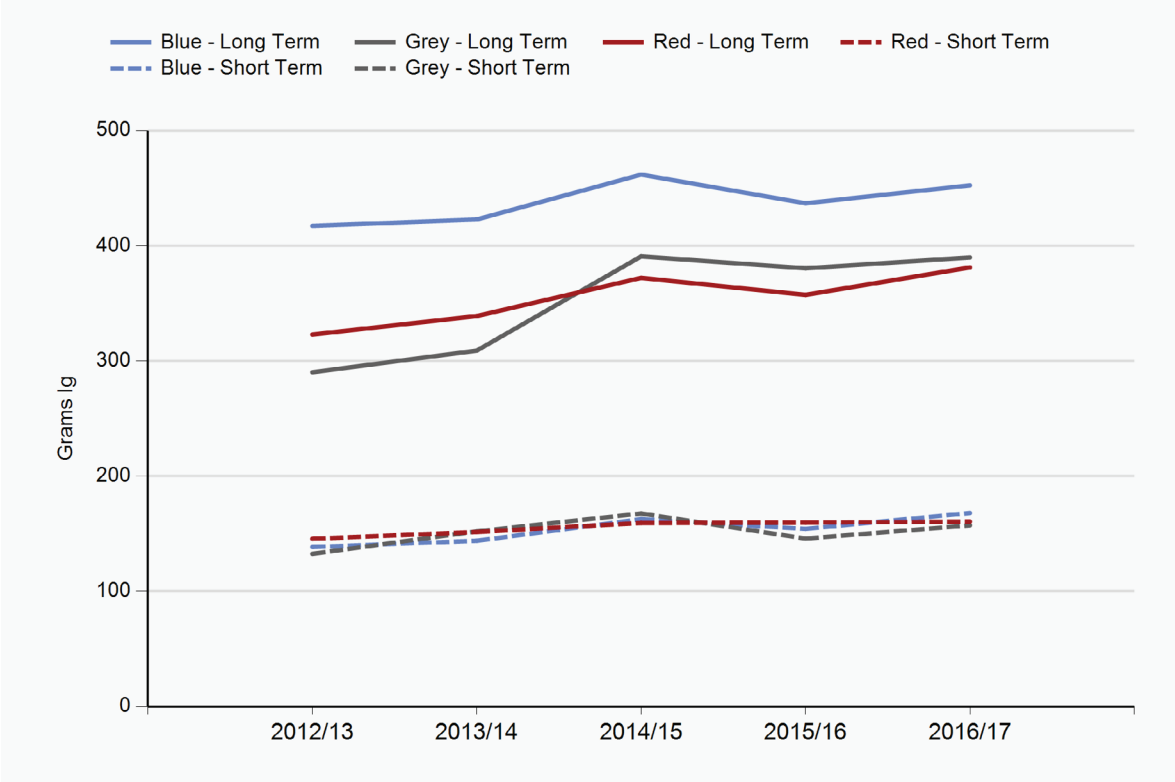

Figure 3.11.3 Average use of immunoglobulin per patient by region 2012/13 - 2016/17

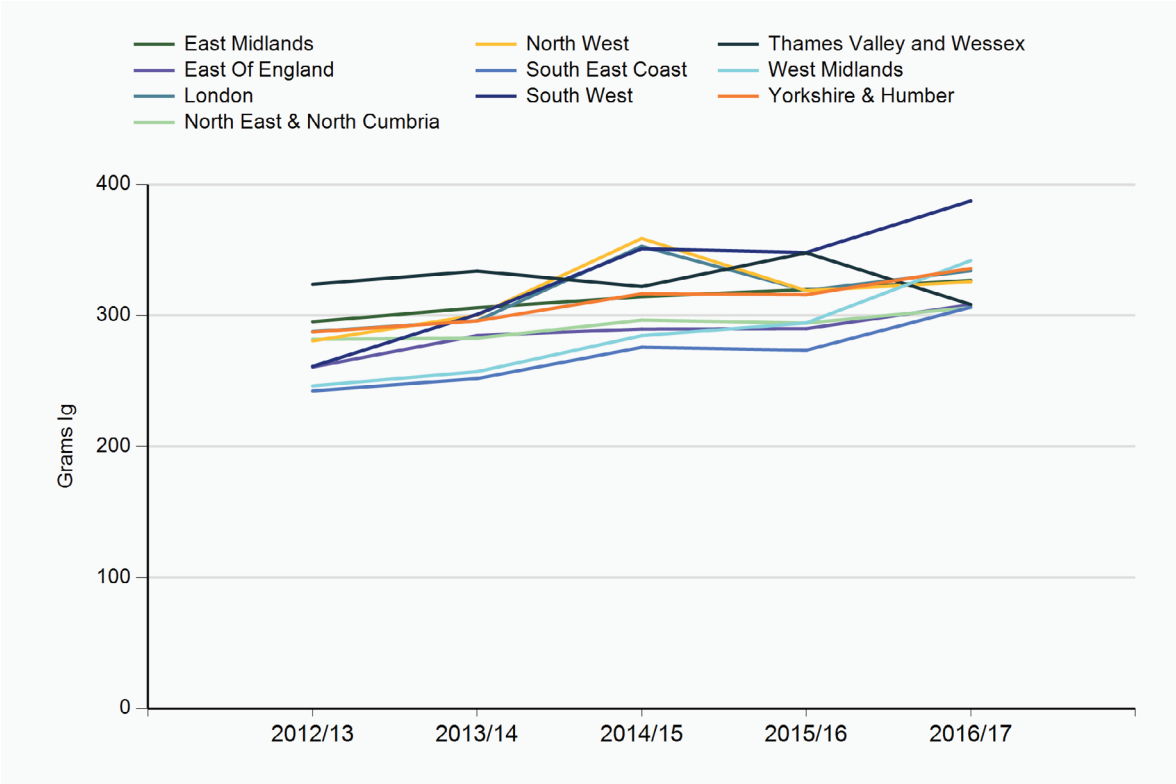

Figure 3.11.4 Average use of immunoglobulin per patient for top conditions 2012/13 - 2016/17