NHS

Immunoglobulin Database

Annual Report 2017/18

mdsas
medical data solutions and services

Compiled by
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.

This report will provide a snapshot of the data from the database for the calendar year 2017-18. Also included is an update from NHS England and the Commercial Medicines Unit (CMU).

During this year the database has been heavily involved in helping to manage product shortage situations, providing information, and working closely with NHS England, CMU and Trusts. The CMU continues to utilise the database to support the supply and procurement of immunoglobulins.

The annual increase in immunoglobulin sales continues at approximately 13%. In-line with previous expectations it is expected that national costs for immunoglobulin products will be around £220 million per annum next year.

The database continues to grow, since its initiation the database has captured information on almost 82,000 patients and 95,000 separate treatment episodes. Trusts have entered over 1.1 million treatment entries, accounting for over 41 million grams of immunoglobulin recorded on the database - this equates in value (at an average price of per gram of £34) to almost £1.4 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 the coming year future developments are being evaluated to potentially introduce prior approval for prescribing of immunoglobulin for certain conditions. This development will be discussed at the annual Immunoglobulin Database Meeting in December.

Developments have been made to the database reports for clinical service dashboards, including supporting more direct reporting to Methods who manage the evaluation of dashboards for NHS England.

The highly successful patient home diary application Haemtrack has been adapted for use with immunoglobulin patients on home therapy. The system links patients in community with hospital clinicians, allowing them to review patient's therapy diary entries in real-time. During the year the system was successfully piloted, and it will be rolled out more widely next year

Annual Meeting

The annual database meeting is to be held at The Royal College of Physicians, 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

**Text from 2016/17 report

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

Darryn Boardman

Contract Picture

All Immunoglobulin (Ig) 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 a robust supply chain and deliver best value for money, whilst adhering to EU and UK legislative tendering procedures. There are separate agreements for Wales and Scotland which are managed directly in those countries.

The current framework commenced on 1st July 2017 for an initial period of twelve months. The contract was extended for a further twelve month period from 1st July 2018 until 30th June 2019. The framework provides compliant access to nineteen Immunoglobulin products and almost seven million grams of Ig from seven contracted suppliers.

Increasing Ig Usage

There has been a continued growth in sales on both previous and current Ig frameworks. Sales in the twelve months prior to the current framework were 5,696,718g. Sales in the first year of the current framework were 6,173,316g, which represents a growth of 8% year on year.

In the year prior to the current framework being put in place, Ig spend was £170m per annum. The forecast spend for the first twelve months of the framework was £192m, which represented an increase of £22m (13%).

Actual spend on the Immunoglobulin framework in the first twelve months was £207 million, with £164m spent on IVIg and £43m on SCIg. This value represents an increase of £37m (22%) compared with the twelve months prior to launching the current framework and an increase of £15m (8%) above forecast.

Market Disruptions

The Ig market was significantly disrupted in early 2018 when Shire took a global decision to withdraw Kiovig from the UK. Kiovig held a 6% share in IVIg and the decision to pull out of the market left a shortfall of 285,000g. Through negotiation with CSL, the CMU managed to secure an additional 300,000g per annum of Privigen to offset the deficit.

Shire also discontinued Subcuvia globally, substituting the Subcuvia volumes with additional Cuvitru. Current Subcuvia patients would be supported without switching until 2019.

At the extension of the framework three suppliers requested price variations on their products to secure volumes for the contract period. Biotest increased Intratect by 9.7%, Grifols increased Flebogamma by 7.4% and Gamunex by 10%, and Octapharma increased Octagam and Gammanorm by 3.8%. If annual volumes remained constant then these increases represented a £3.9m cost pressure to the NHS.

A number of changes to the market mean the NHS faces another 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.

Immunoglobulin Stakeholders

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 ensures that stable supply and best value are at the forefront of its delivery. 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 services. CMU will continue to work proactively with their contacts in Trusts across the diverse range of treatment areas.

Forecasting Demand

CMU will continue to work with Trusts to review 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 darryn.boardman@nhs.net or 01138 070456.

5 Data Update

Mark Foster

The Eighth National Database Annual Report

This Data Update chapter in the eighth edition of the National Database Annual Report utilises 38 data sets to provide readers with an overview of immunoglobulin use in England for 2017/18. All data recorded on the database by the 5th November 2018 is included in this report.

Increasing Data Capture

The total volume of immunoglobulin recorded in England for 2017/18 was 5.8 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 95% 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 (38%), haematology (7%). Conditions falling under 'other' specialties as defined in the clinical guidelines make up the remaining 11%.

Usage in Top Conditions

Primary immunodeficiencies remain the number one condition for number of patients treated (3,836) and volume of immunoglobulin recorded (1,472,250 grams). Secondary antibody deficiencies is the second highest condition for number of patients treated (2,395), third is Idiopathic Thrombocytopenic Purpura (1,545). Chronic Inflammatory Demyelinating Polyneuropathy is the second highest volume using condition (1,202,243 grams), third is MMN (614,838 grams). Secondary antibody deficiencies saw a 19% increase in the number of patients treated and a 28% increase in the recorded volume of immunoglobulin. This is the third year of significant increases for this condition.

Figure 1.1.1 Monthly patient registrations 2017/18

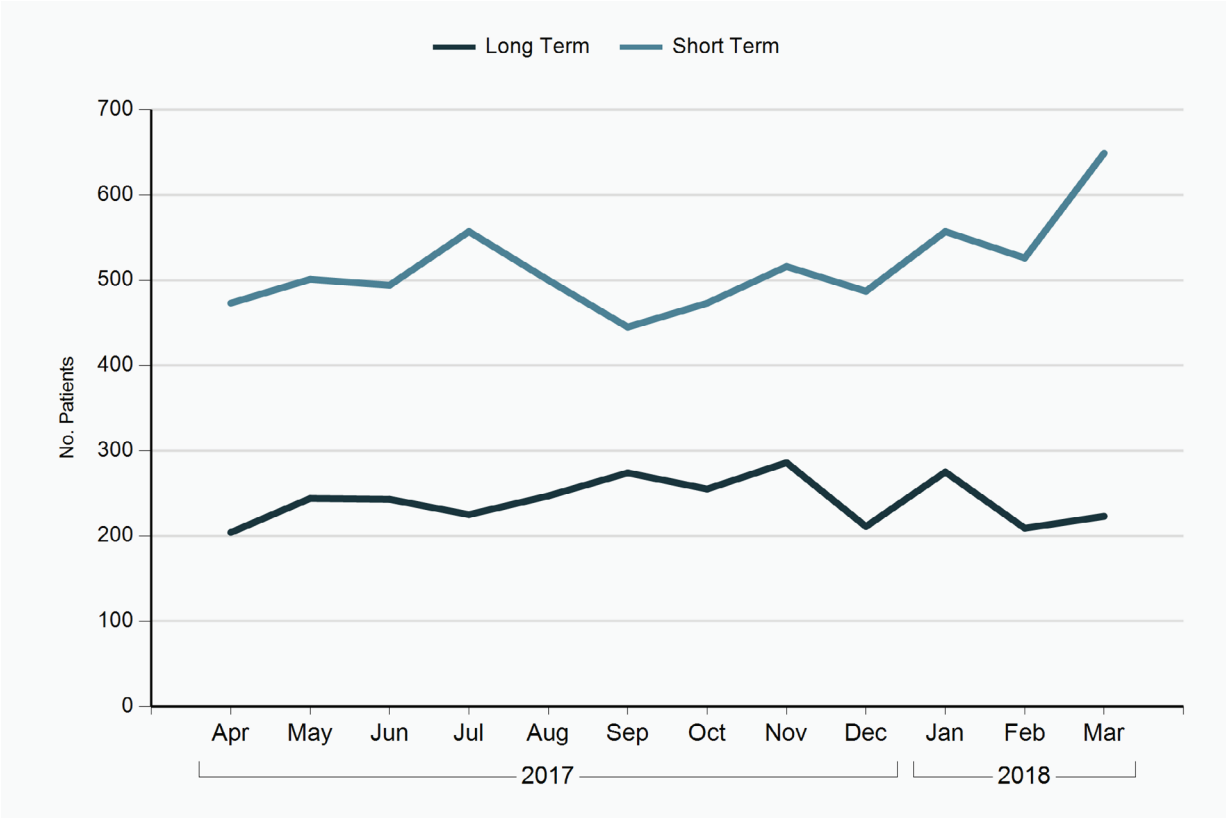

Figure 1.1.2 Yearly patient registrations 2013/14 - 2017/18

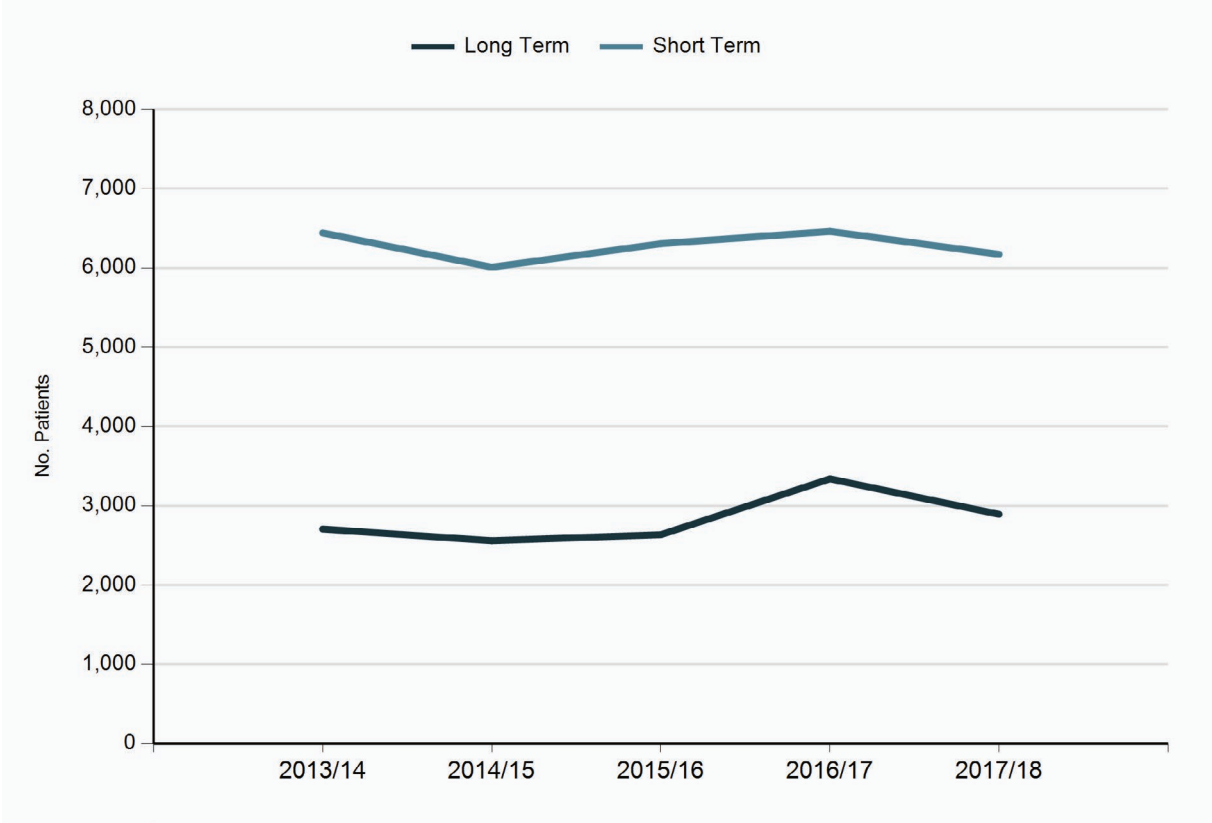

Figure 1.2 Yearly patient registrations by speciality 2017/18

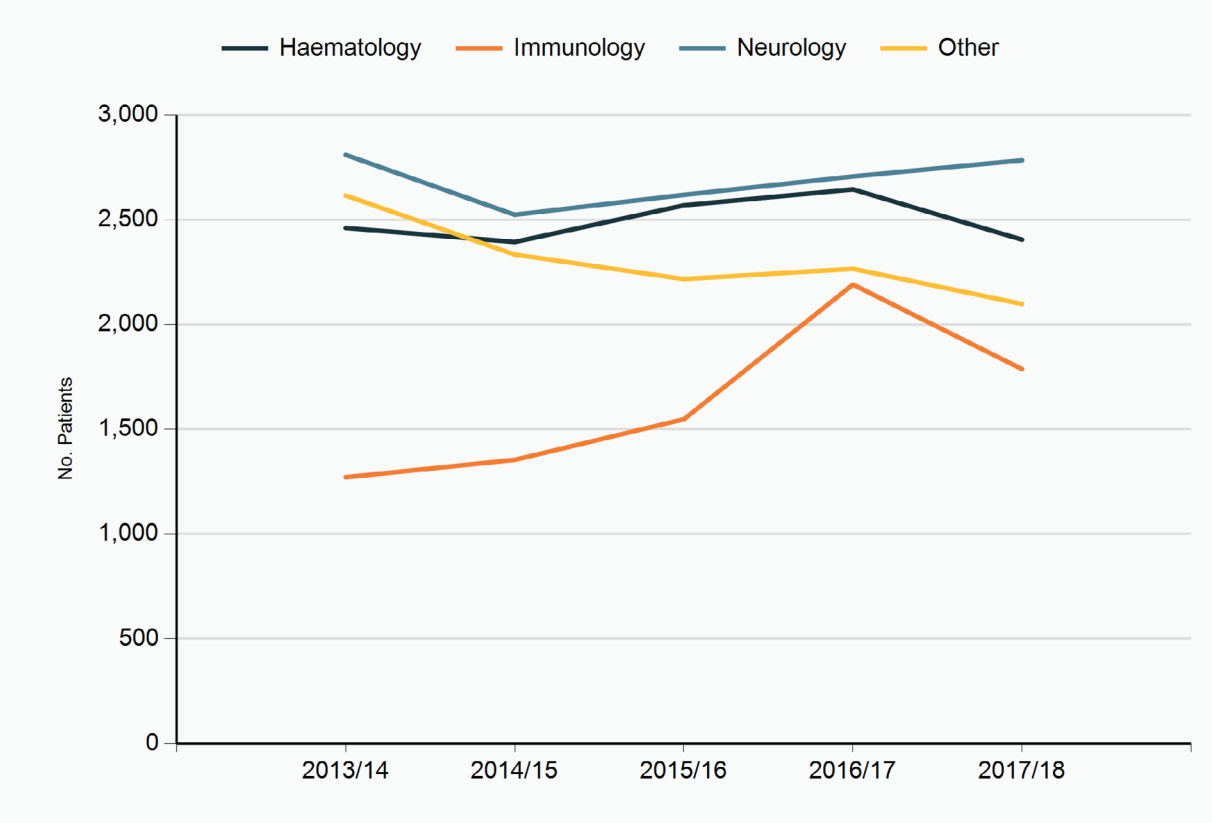

Figure 1.3 Patient registrations by region 2017/18

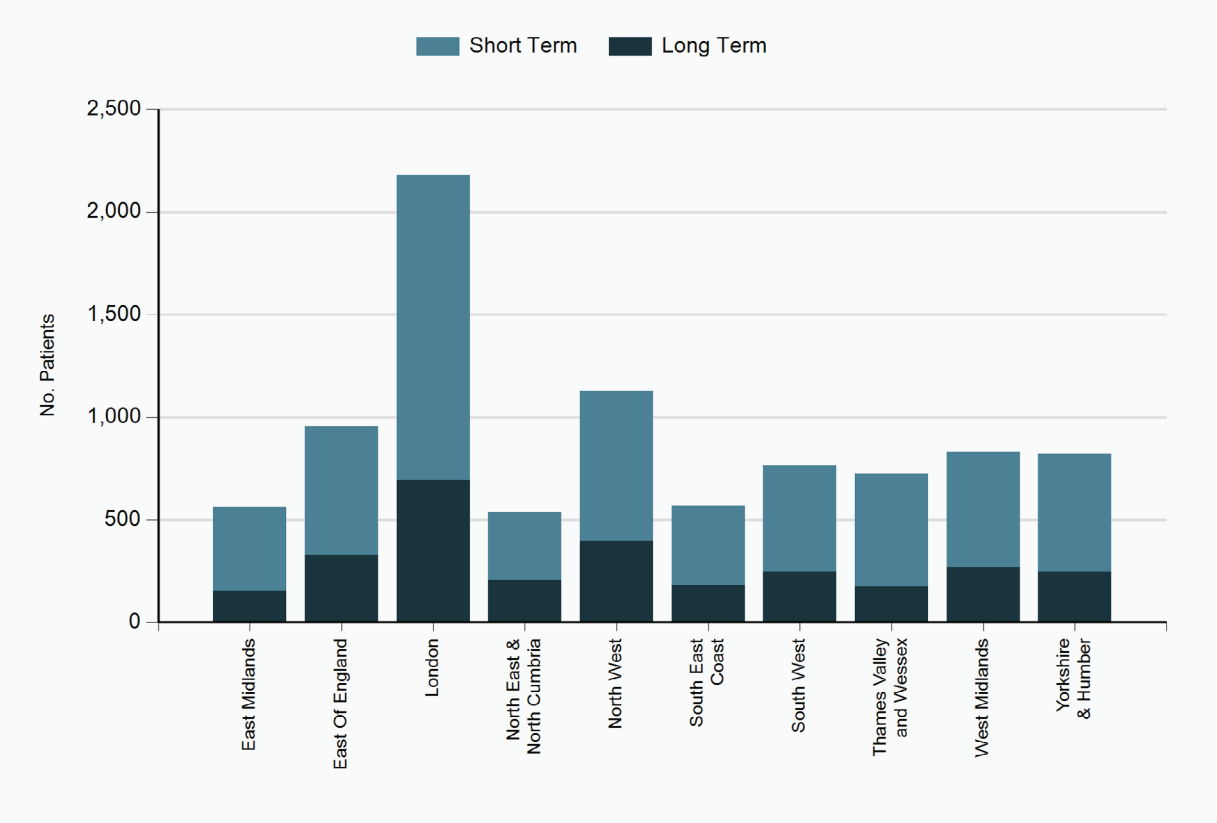

Figure 2.1.1 Monthly number of patients treated 2017/18

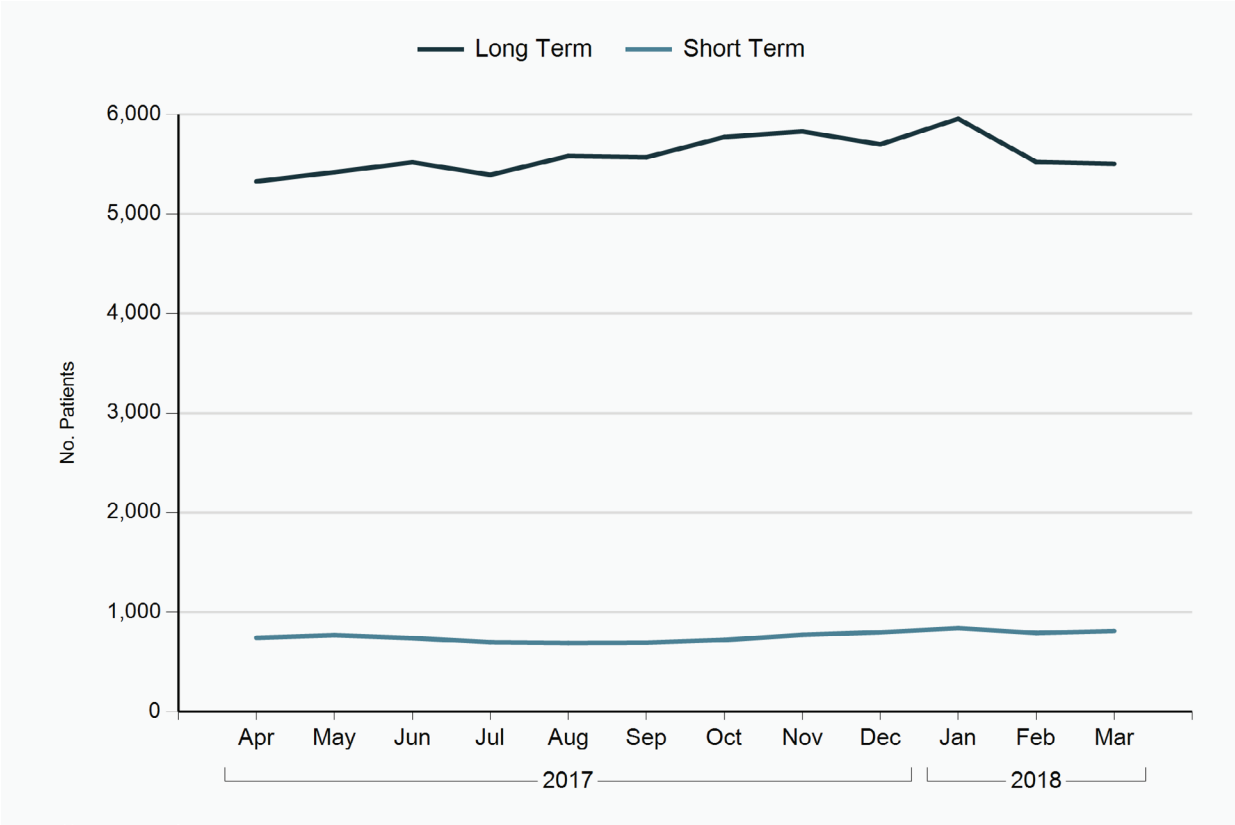

Figure 2.1.2 Yearly number of patients treated 2013/14 - 2017/18

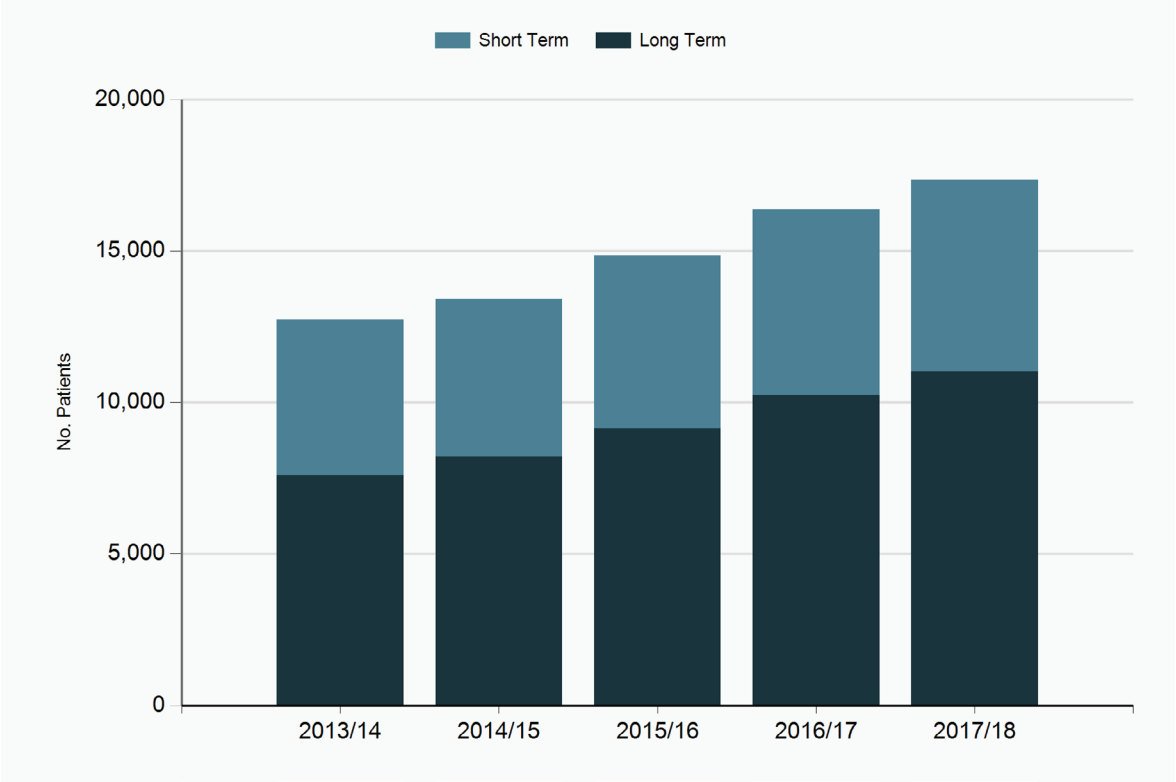

Figure 2.2.1 Monthly number of patients treated by speciality 2017/18

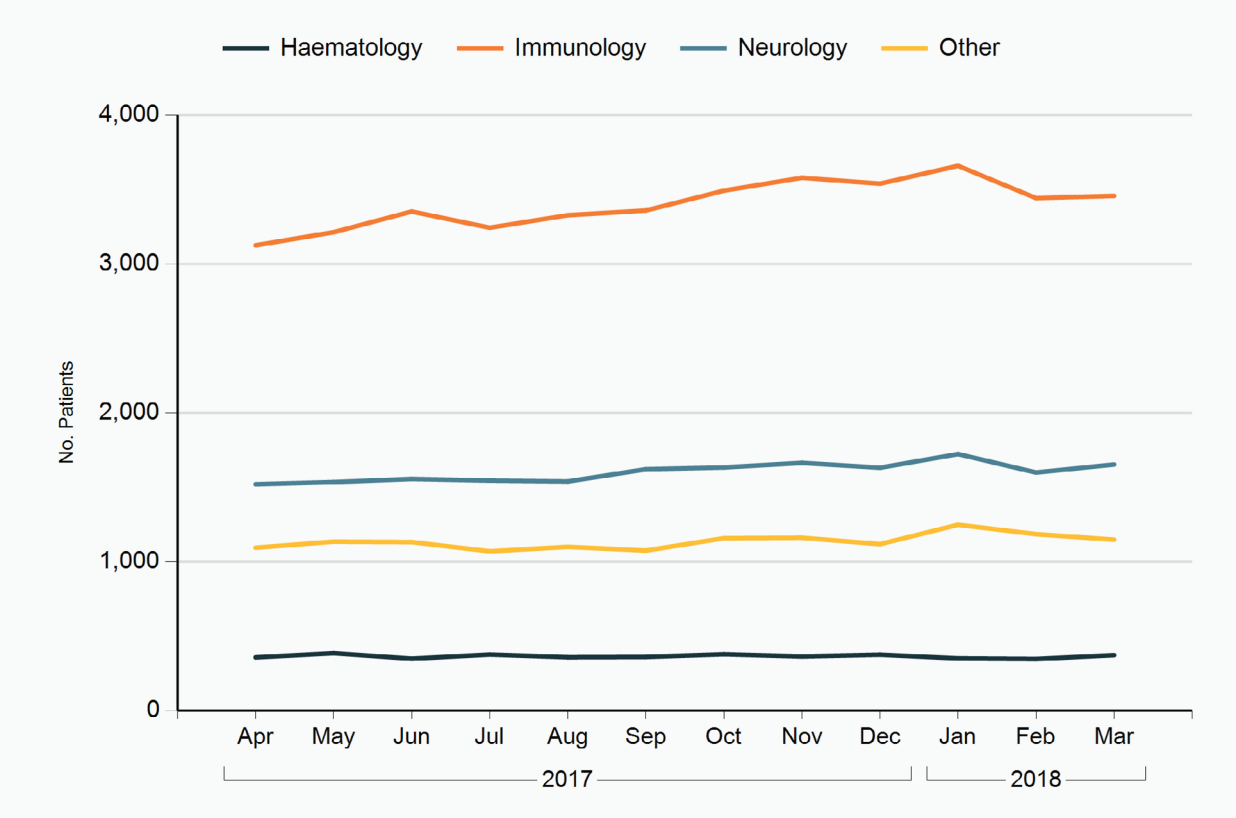

Figure 2.2.2 Yearly number of patients treated by speciality 2013/14 - 2017/18

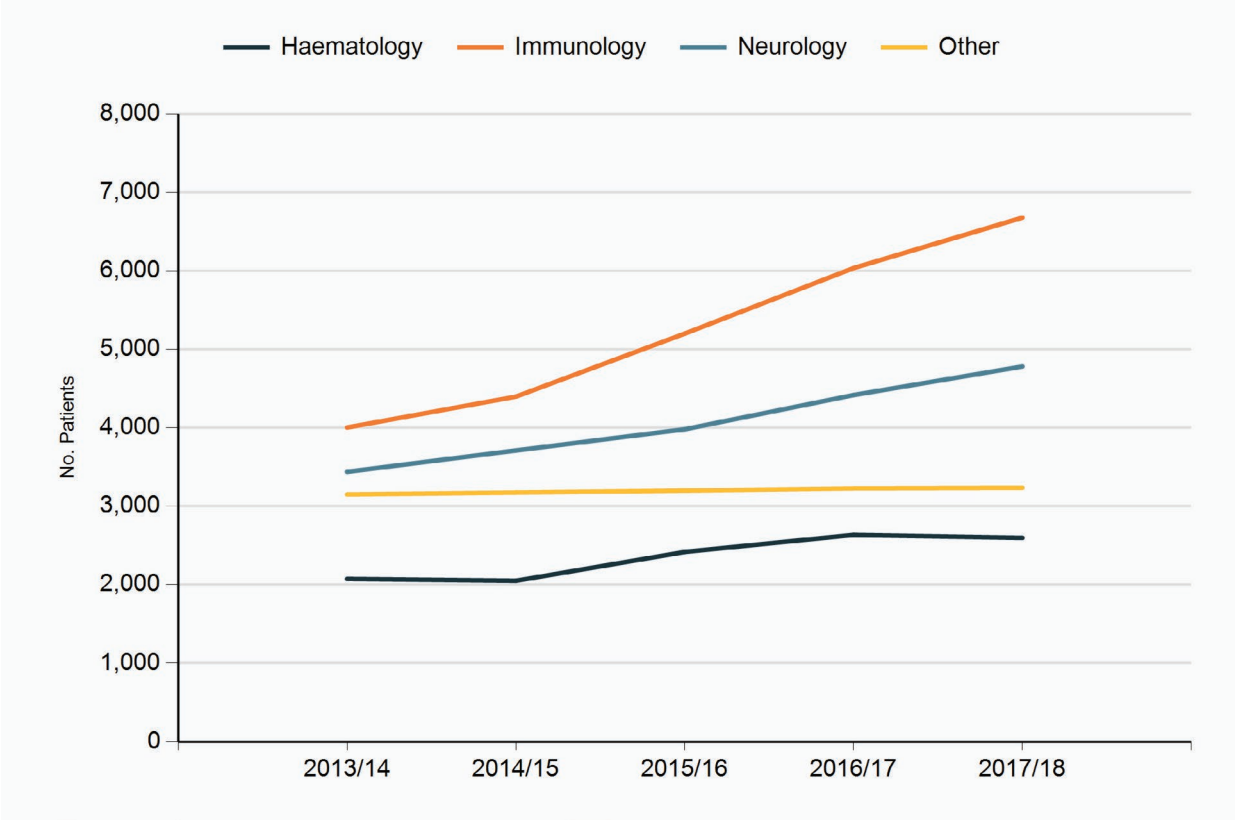

Figure 2.3.1 Number of patients treated by region 2017/18

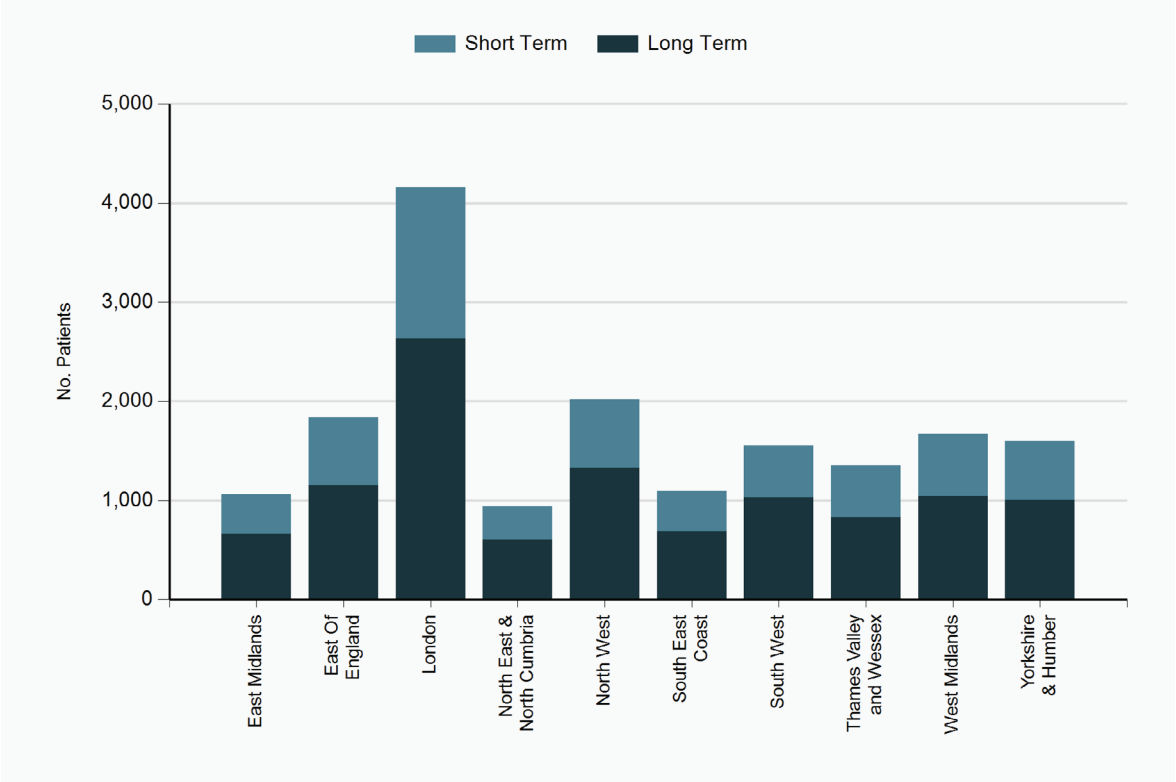

Figure 2.3.2 Yearly patients treated by region 2013/14 - 2017/18

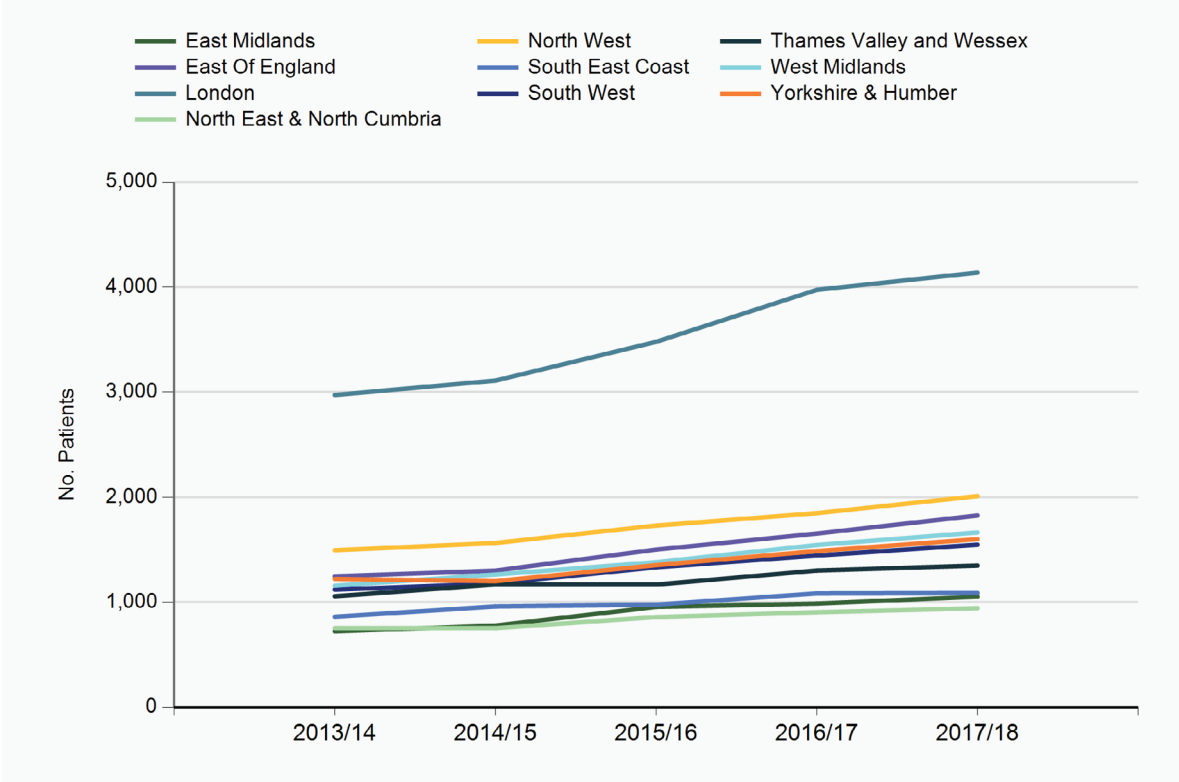

Figure 2.4 Yearly patients treated by treatment place 2013/14 - 2017/18

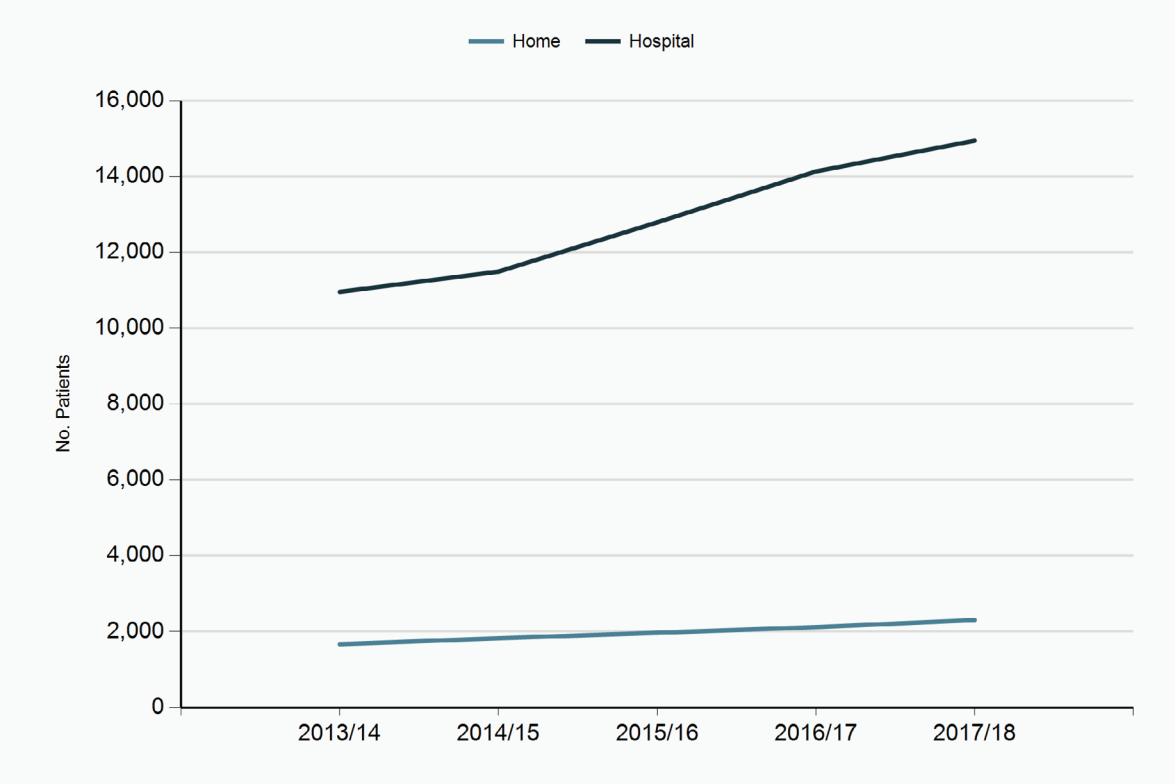

Figure 2.5 Number of patients treated for top 20 diagnoses 2017/18

Diagnosis	2017/18	Change
Primary Immunodeficiencies	3,836	+7%
Secondary Antibody Deficiencies	2,395	+19%
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	1,545	+7%
Immune Thrombocytopenic Purpura - Acute	1,494	-6%
Guillain–Barré Syndrome	1,097	+14%
Other Conditions	1,045	+6%
Chronic Lymphocytic Leukaemia	849	-3%
Myasthenia Gravis	753	+10%
Multifocal Motor Neuropathy	659	+2%
Inflammatory Myopathies	382	+7%
Kawasaki Disease	355	-9%
Staphylococcal Toxic Shock Syndrome	266	+43%
Specific Antibody Deficiency	256	+9%
Autoimmune Encephalitis	249	+30%
Multiple Myeloma	238	-2%
Transplantation (Solid Organ)	222	-3%
Autoimmune Haemolytic Anaemia	215	-
Haemolytic Disease of The Fetus and New born	172	-18%
Immune Thrombocytopenic Purpura - Persistent	163	-29%
Low Serum IgG Levels following HSCT for Malignancy	160	-8%

Figure 2.6 Number of patients treated in top 20 Trusts 2017/18

NHS Trust	2017/18	Change
Royal Free NHS Trust	533	+6%
Barts Health NHS Trust	483	+5%
Leeds Teaching Hospitals NHS Trust	436	+5%
King's College Hospital NHS Foundation Trust	417	+7%
Cambridge University Hospitals NHS Foundation Trust	411	+9%
Sheffield Teaching Hospitals NHS Foundation Trust	405	+21%
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	404	-8%
Oxford Radcliffe Hospitals NHS Trust	385	+2%
Imperial College Healthcare NHS Trust	377	+9%
University College London Hospitals NHS Foundation Trust	375	-9%
Salford Royal NHS Foundation Trust	350	+7%
Nottingham University Hospitals NHS Trust	349	+6%
Guy's And St Thomas' NHS Foundation Trust	307	+6%
Heart of England NHS Foundation Trust	304	+1%
Southampton University Hospitals NHS Trust	298	+16%
Great Ormond Street Hospital for Children NHS Trust	278	+36%
University Hospital Birmingham NHS Foundation Trust	253	+21%
University Hospitals of Leicester NHS Trust	251	+5%
North Bristol NHS Trust	247	+26%
Central Manchester and Manchester Children's NHS Trust	243	+7%

Figure 2.7 Number of grey patients treated and grey outcomes recorded 2013/14 - 2017/18

Year	2013/14	2014/15	2015/16	2016/17	2017/18
Grey Requests	918	778	762	790	716
Grey Requests with Outcome Data	273	241	268	347	626
Percentage	30%	31%	35%	43%	87%

Figure 2.8 Number of long term patients treated and Follow-Ups recorded 2013/14 - 2017/18

Year	2013/14	2014/15	2015/16	2016/17	2017/18
Long Term Patients	7,577	8,177	8,950	9,976	10,988
Long Term Patients with Follow-Up	3,298	4,037	5,145	6,234	8,472
Percentage	43%	50%	57%	62%	77%

Figure 3.1.1 Recorded monthly immunoglobulin use by regime 2017/18

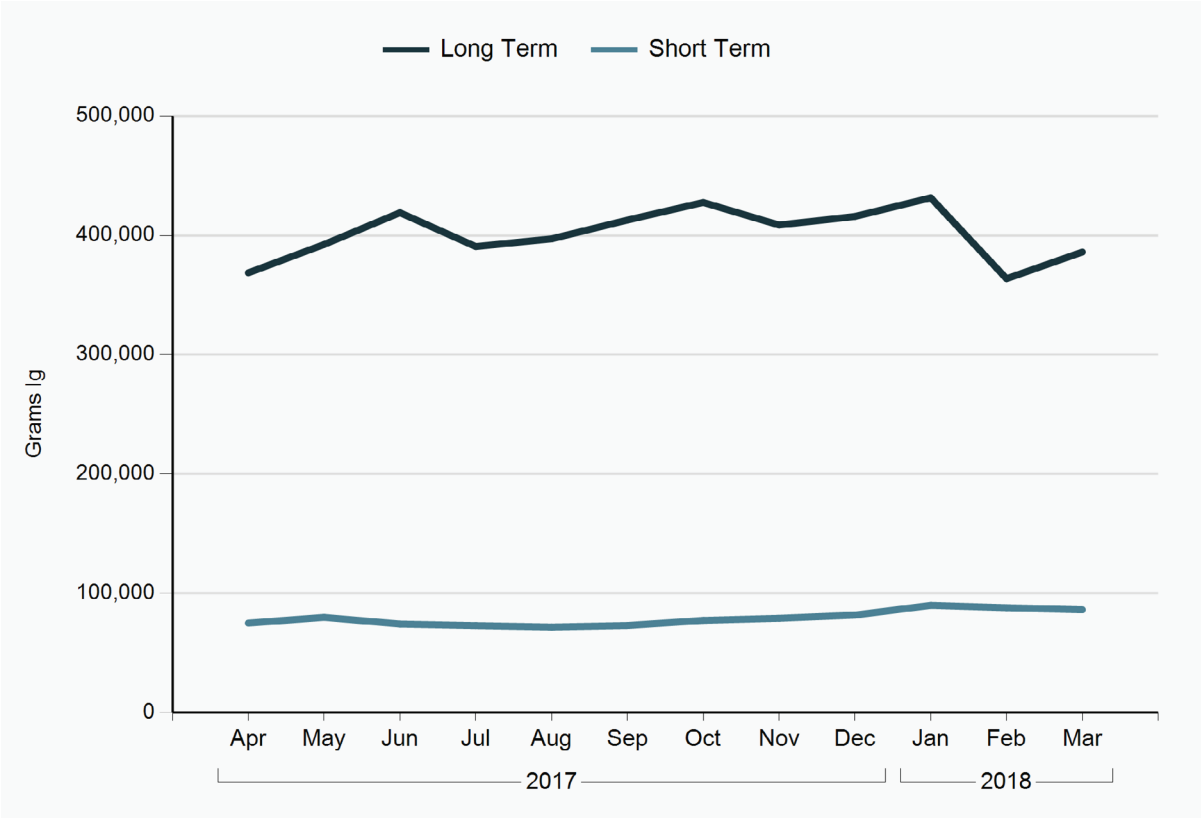

Figure 3.1.2 Recorded yearly immunoglobulin use by regime 2013/14 - 2017/18

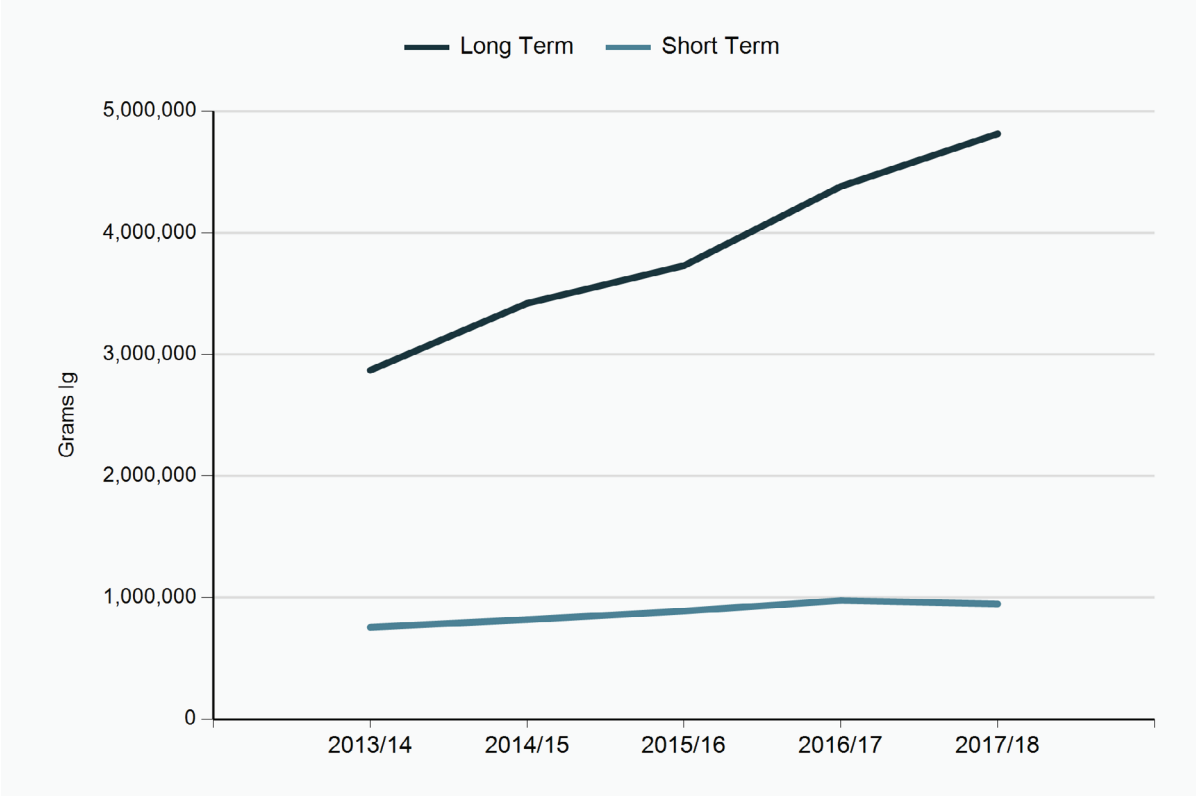

Figure 3.2.1 Recorded monthly immunoglobulin use by speciality 2017/18

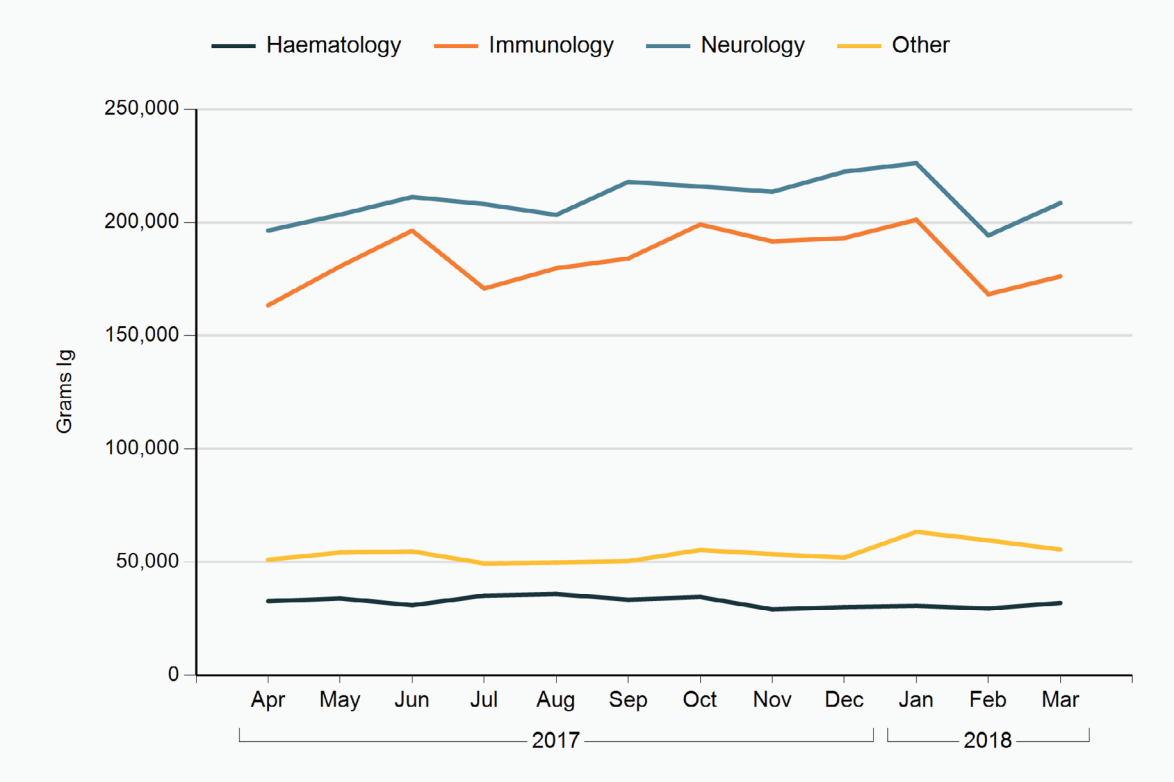

Figure 3.2.2 Recorded yearly immunoglobulin use by speciality 2013/14 - 2017/18

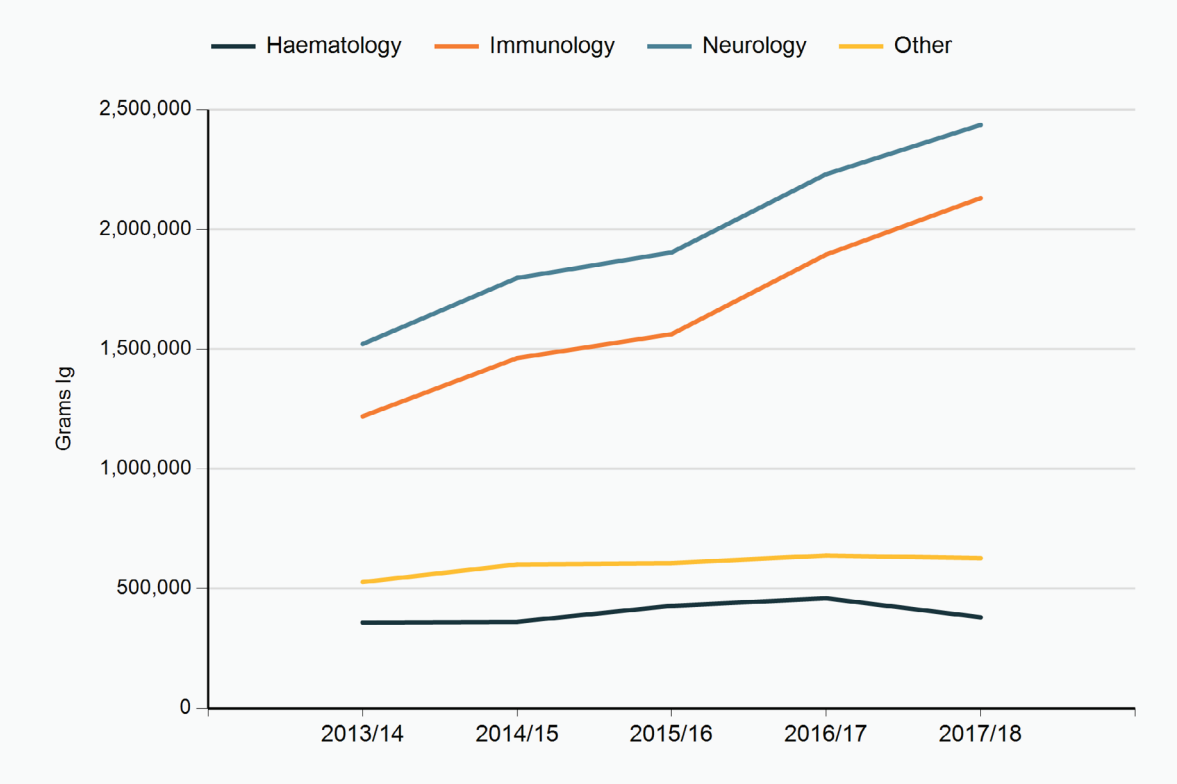

Figure 3.3.1 Recorded monthly immunoglobulin use by Indication 2017/18

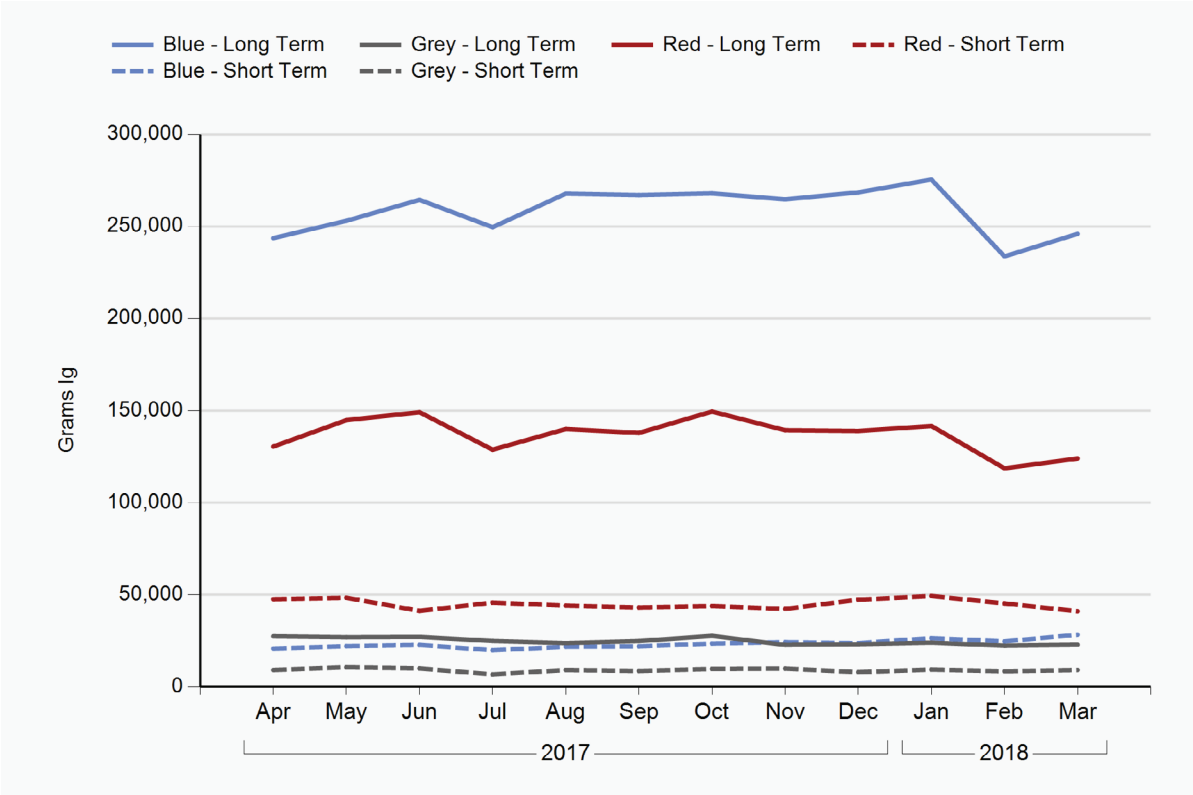

Figure 3.3.2 Recorded yearly immunoglobulin use by Indication 2013/14 - 2017/18

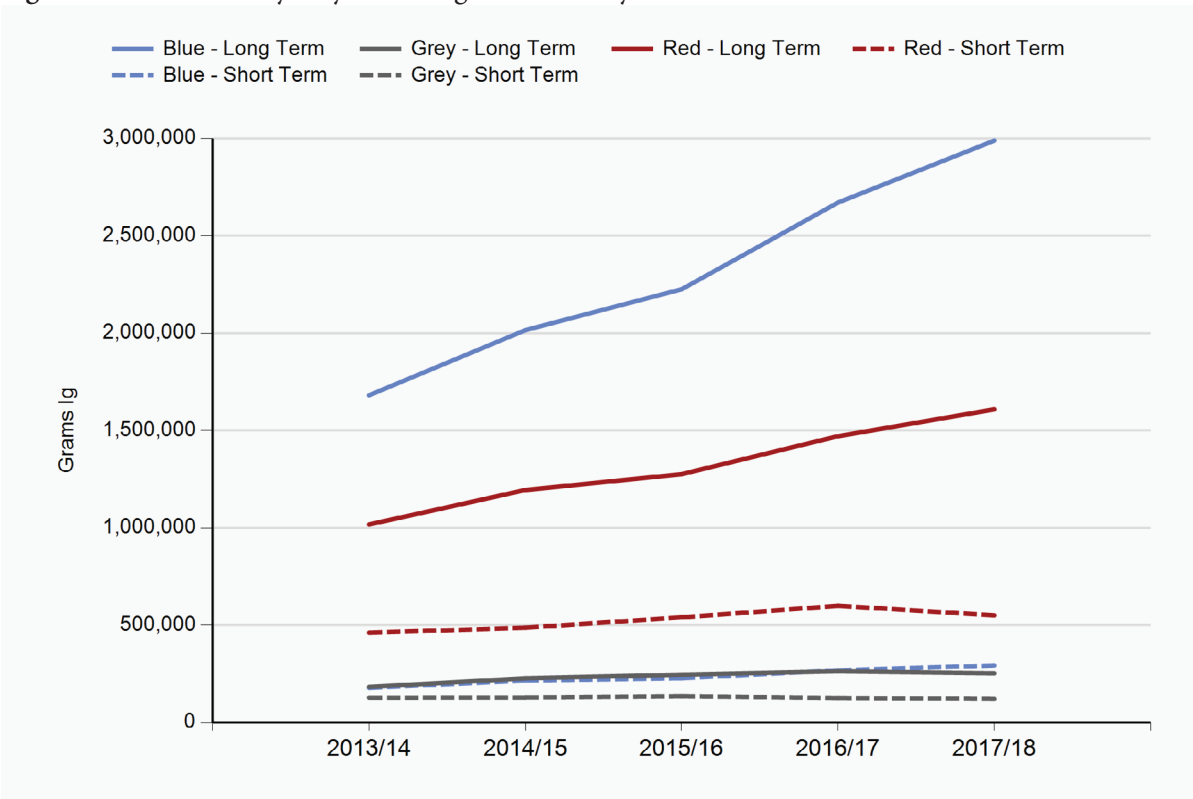

Figure 3.4.1 Recorded immunoglobulin use by region 2017/18

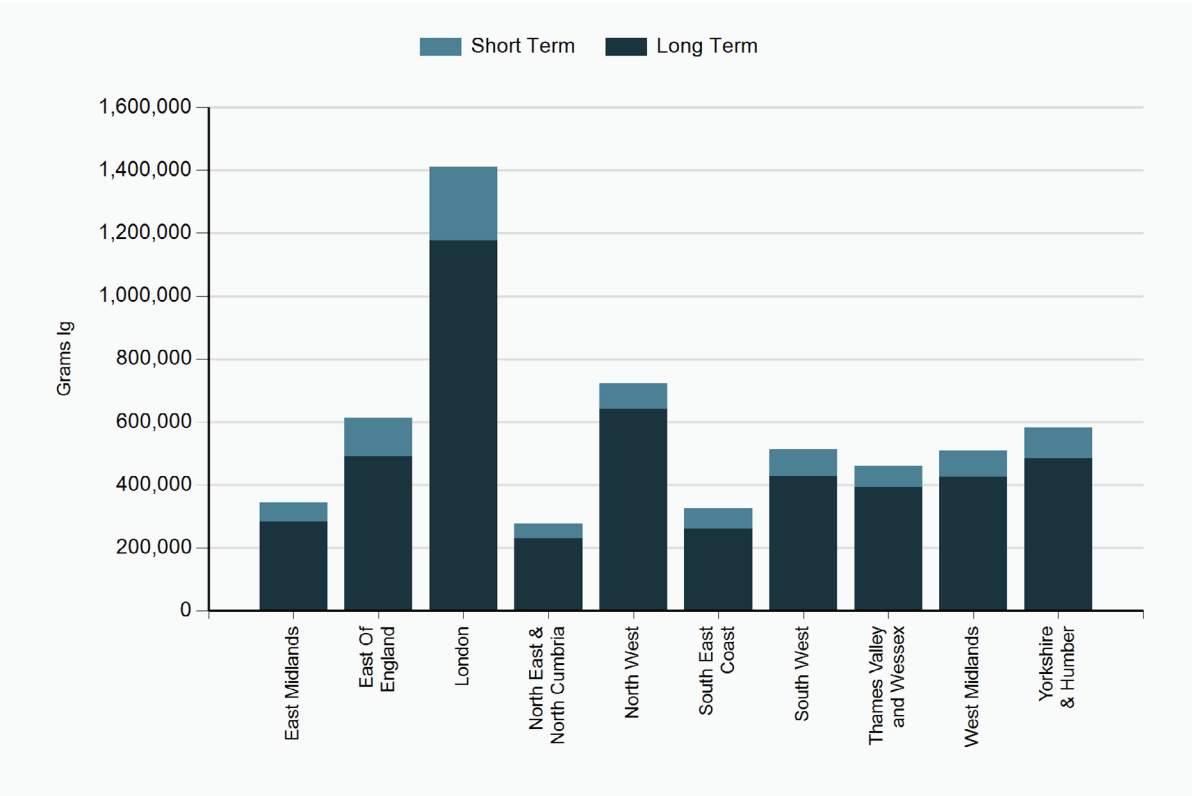

Figure 3.4.2 Recorded yearly immunoglobulin use by region 2013/14 - 2017/18

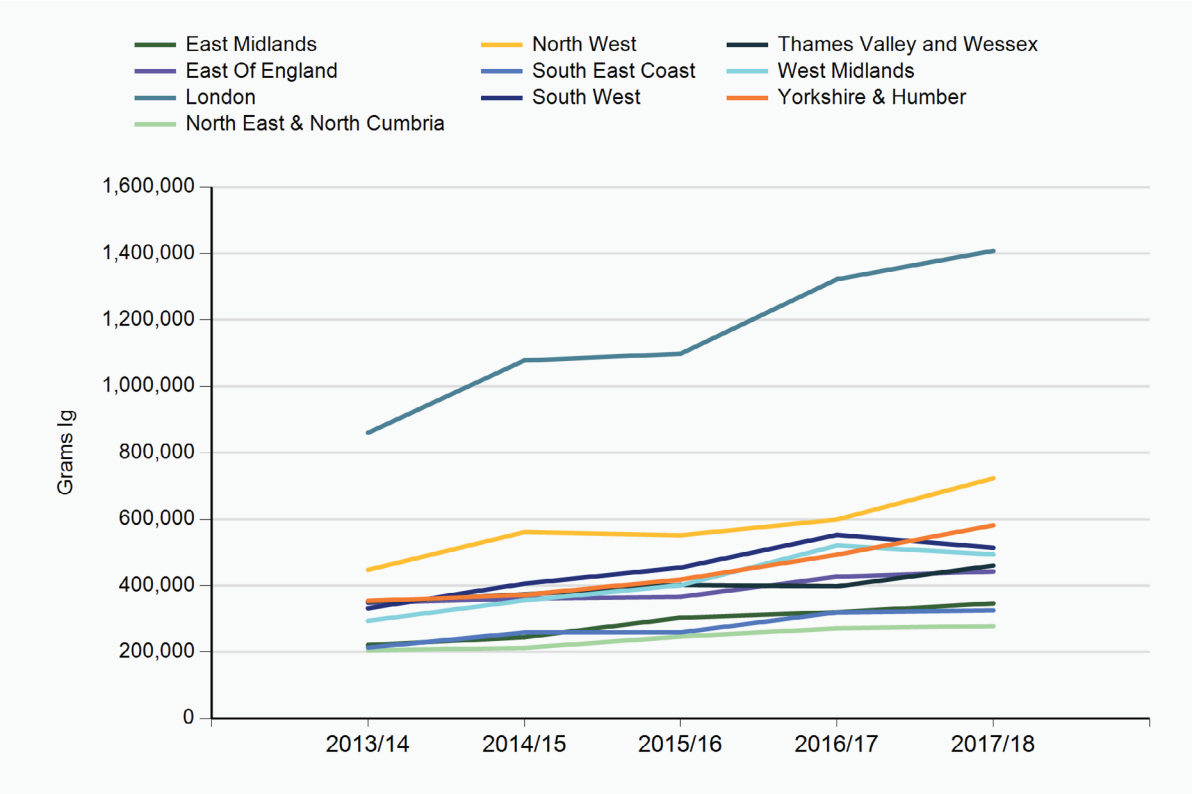

Figure 3.5.1 Volume of immunoglobulin used for the top 10 diagnoses 2017/18

Diagnosis	2017/18	Change
Primary Immunodeficiencies	1,472,250	+8%
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	1,202,243	+11%
Multifocal Motor Neuropathy	614,838	+12%
Secondary Antibody Deficiencies	596,232	+28%
Other Conditions	275,780	-1%
Myasthenia Gravis	226,413	+12%
Chronic Lymphocytic Leukaemia	220,628	-
Immune Thrombocytopenic Purpura - Acute	217,059	-22%
Inflammatory Myopathies	162,793	+5%
Guillain–Barré Syndrome	183,833	+9%

Figure 3.5.2 Recorded yearly immunoglobulin use for the top 10 diagnoses 2013/14 - 2017/18

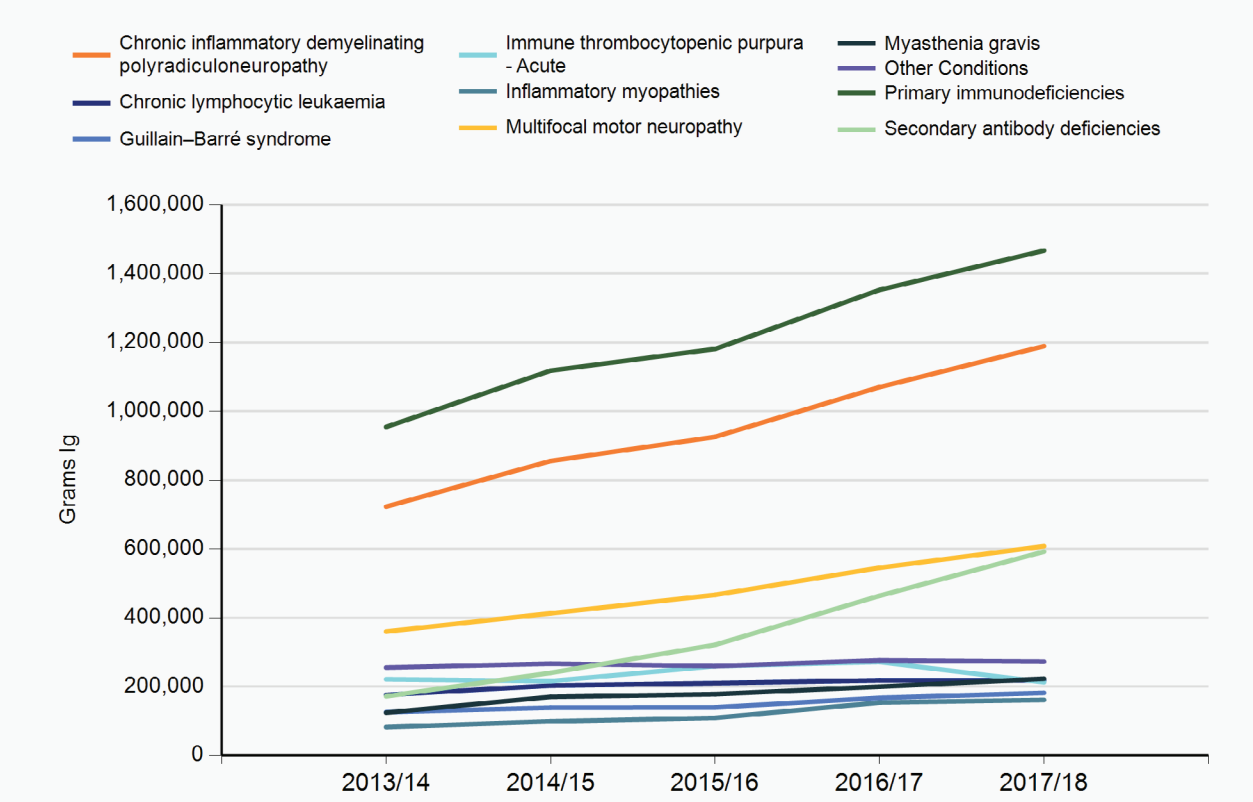

Figure 3.6 Volume of immunoglobulin used in top 20 Trusts 2017/18

NHS Trust	2017/18	Change
University College London Hospitals NHS Foundation Trust	285,019	-
Salford Royal NHS Foundation Trust	265,347	+47%
Royal Free NHS Trust	238,605	+7%
Sheffield Teaching Hospitals NHS Foundation Trust	229,874	+51%
Cambridge University Hospitals NHS Foundation Trust	197,454	+7%
Oxford Radcliffe Hospitals NHS Trust	183,761	+26%
Barts Health NHS Trust	177,473	+20%
King's College Hospital NHS Foundation Trust	155,472	+5%
Leeds Teaching Hospitals NHS Trust	144,478	+8%
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	130,416	-2%
Heart of England NHS Foundation Trust	129,549	-21%
Nottingham University Hospitals NHS Trust	118,683	+11%
University Hospitals of Leicester NHS Trust	114,656	+9%
University Hospital Birmingham NHS Foundation Trust	107,352	+13%
Imperial College Healthcare NHS Trust	97,835	+1%
Walton Centre for Neurology and Neurosurgery NHS Trust	94,375	+7%
Lancashire Teaching Hospitals NHS Foundation Trust	90,686	+5%
North Bristol NHS Trust	84,903	-24%
Royal Cornwall Hospitals NHS Trust	83,589	-24%
Plymouth Hospitals NHS Trust	78,829	-

Figure 3.7.1 Recorded monthly use of intravenous and subcutaneous immunoglobulin 2017/18

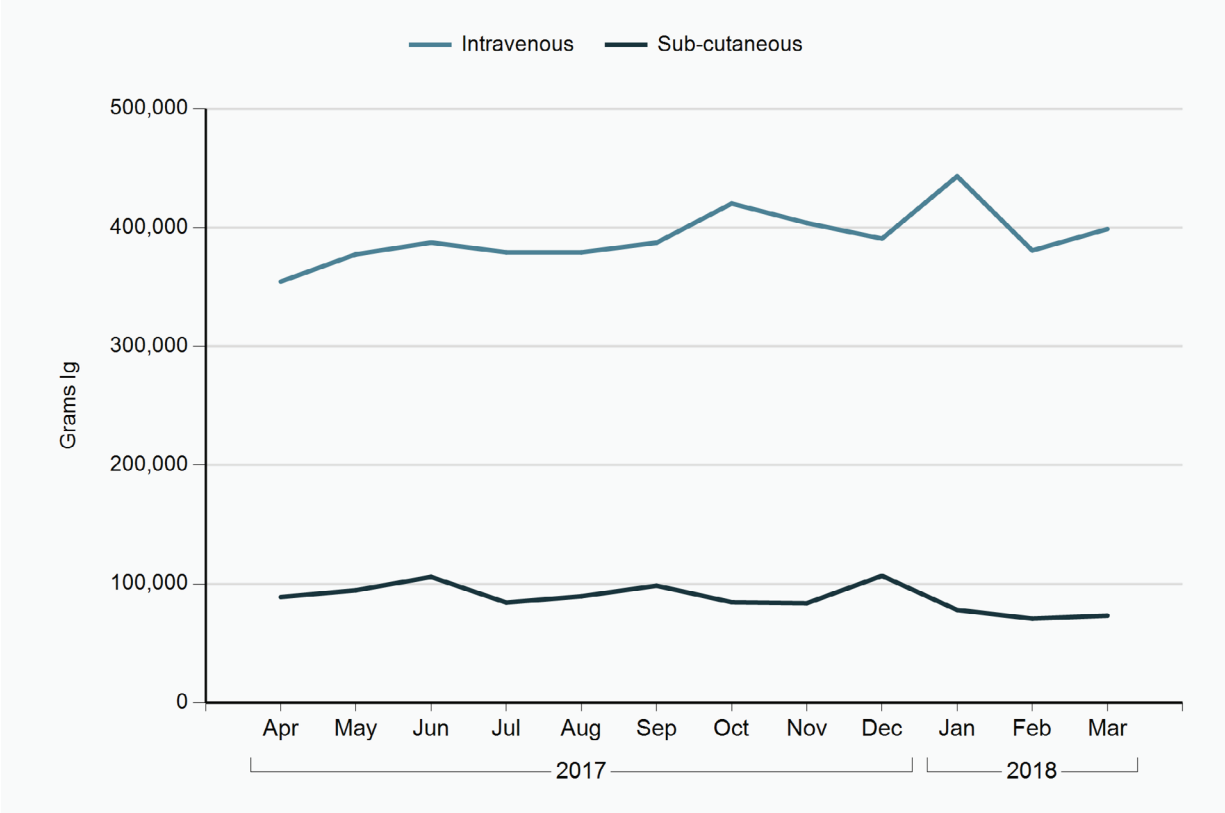

Figure 3.7.2 Recorded yearly use of intravenous and subcutaneous immunoglobulin 2013/14 - 2017/18

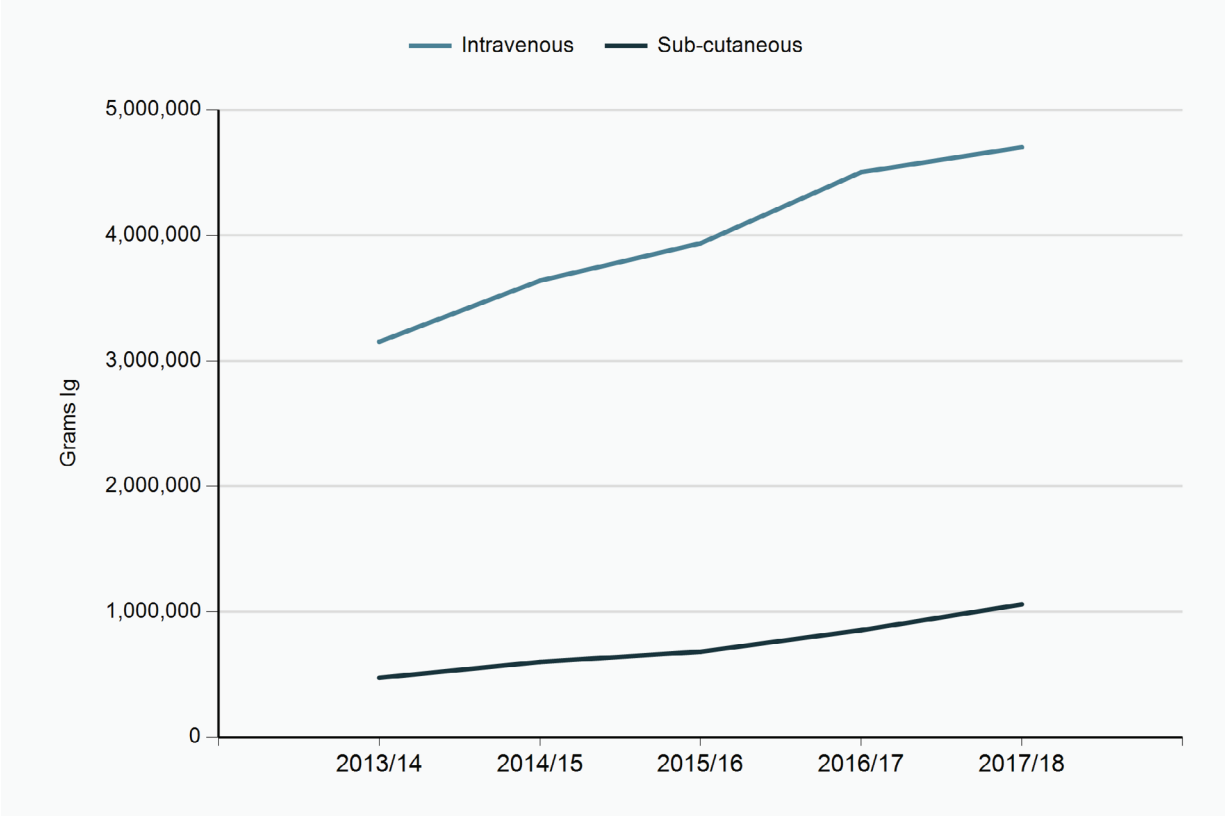

Figure 3.8.1 Recorded monthly use of intravenous immunoglobulin products 2017/18

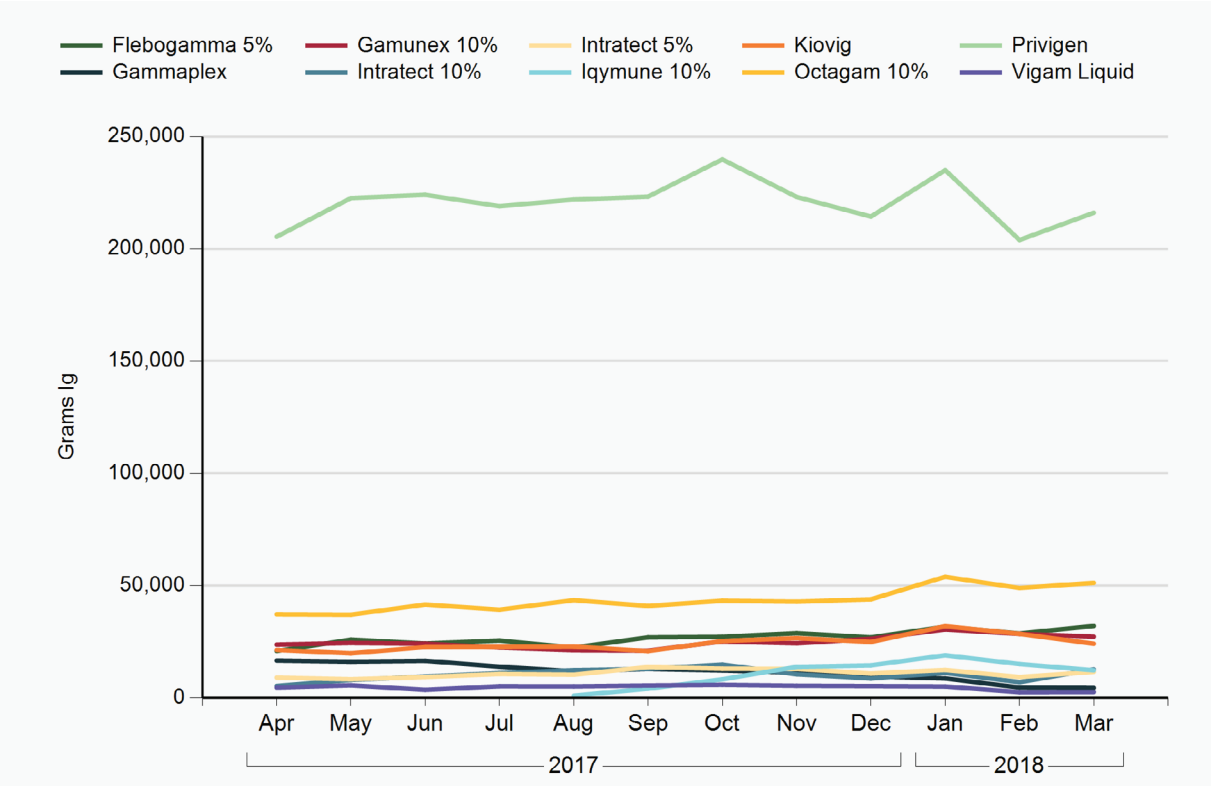

Figure 3.8.2 Recorded yearly use of intravenous immunoglobulin products 2013/14 - 2017/18

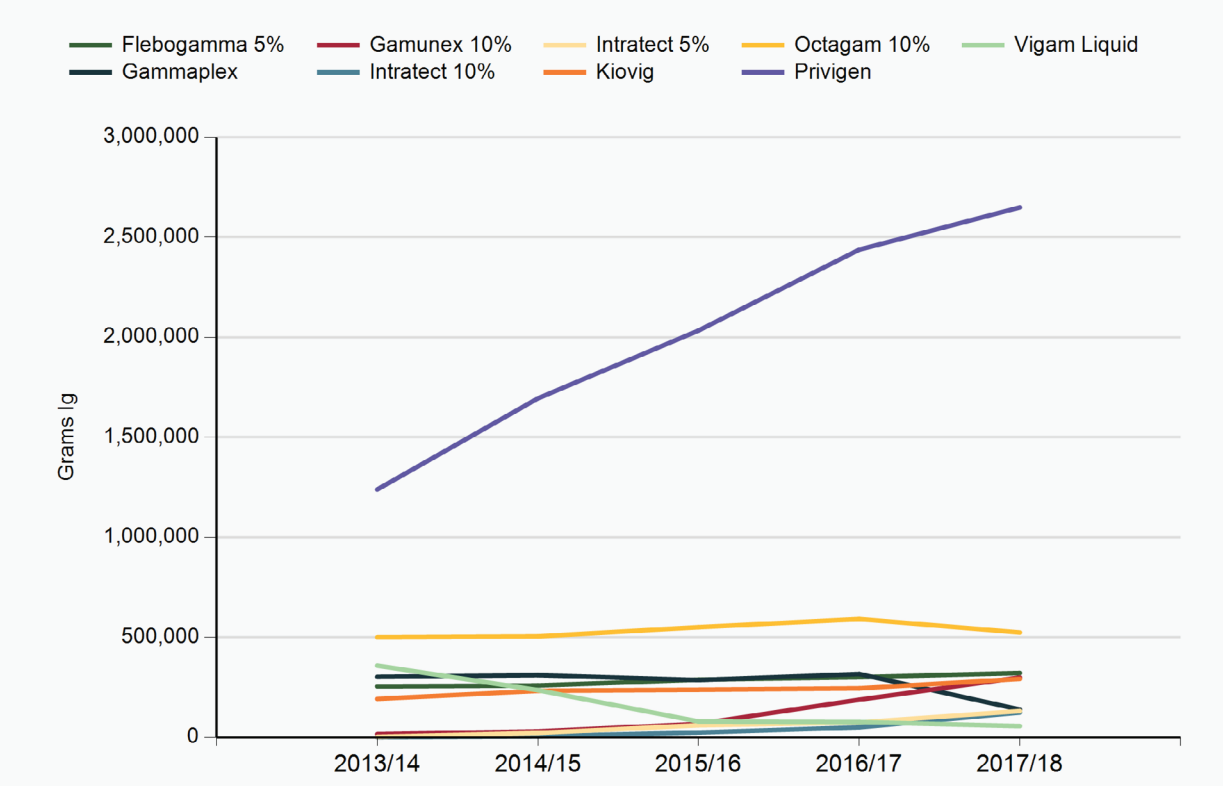

Figure 3.9.1 Recorded monthly use of subcutaneous immunoglobulin products 2017/18

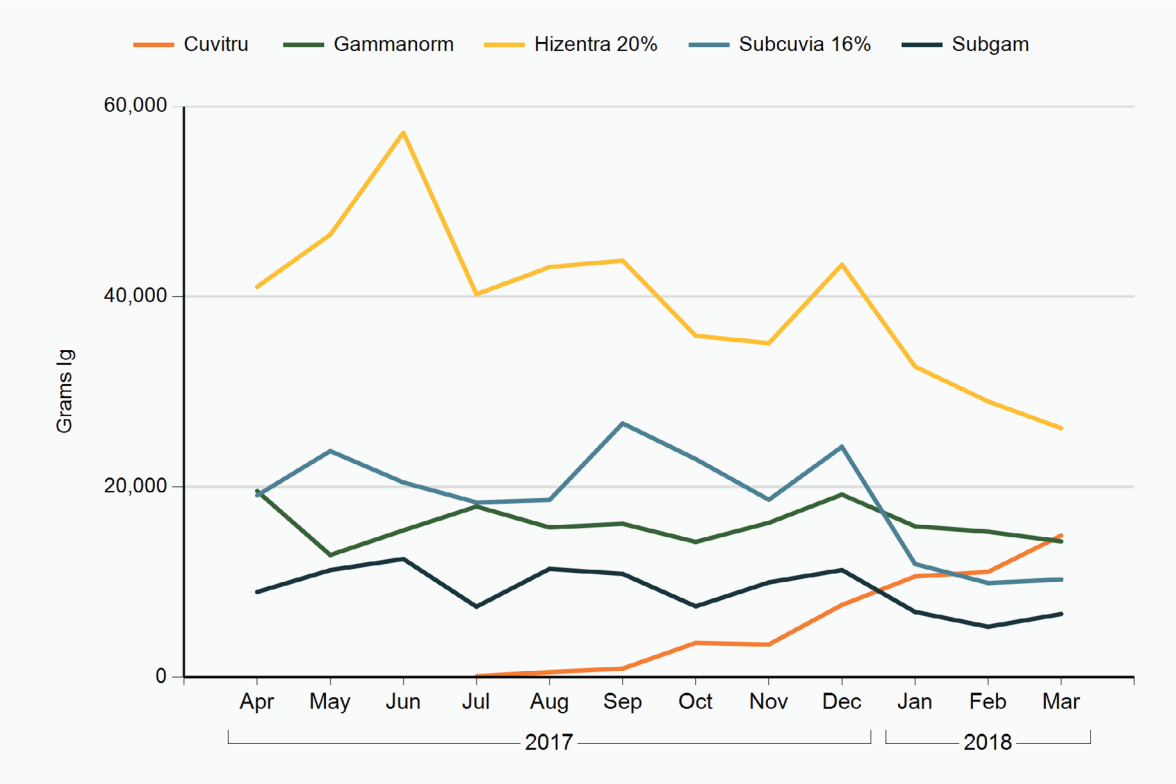

Figure 3.9.2 Recorded yearly use of subcutaneous immunoglobulin products 2017/18

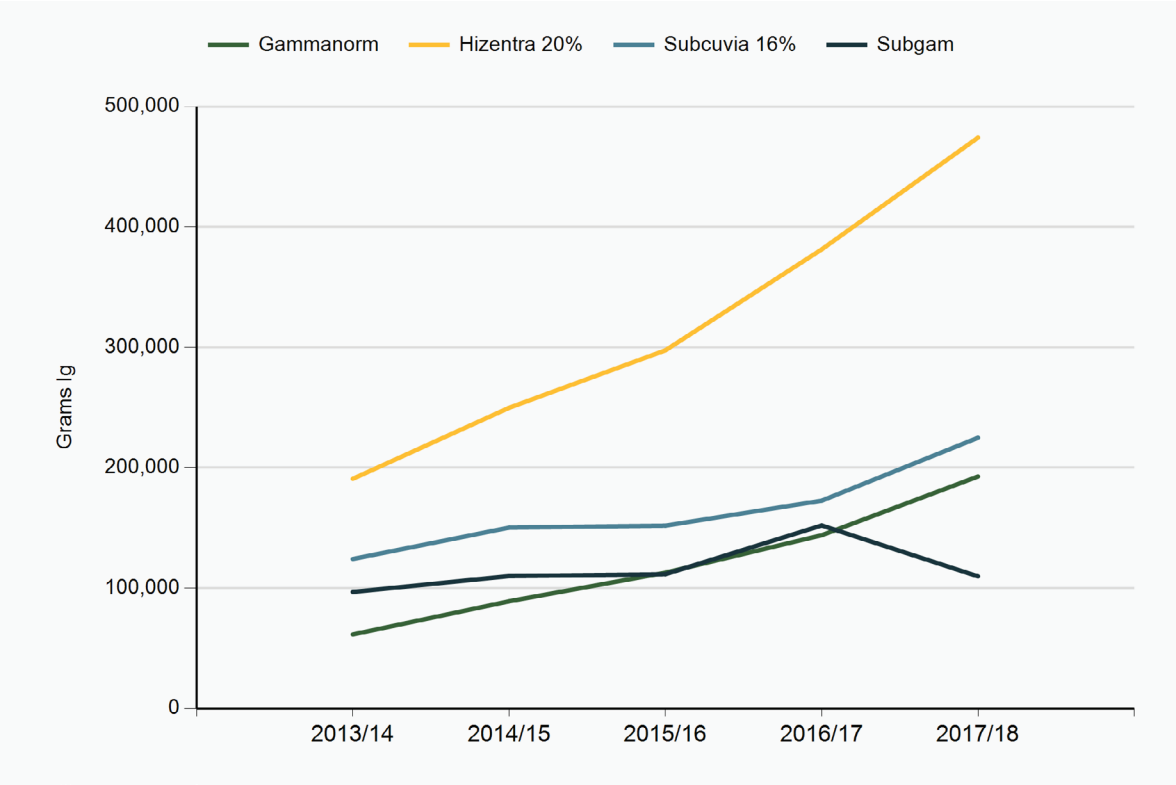

Figure 3.10.1 Recorded monthly use of immunoglobulin products by manufacturer 2017/18

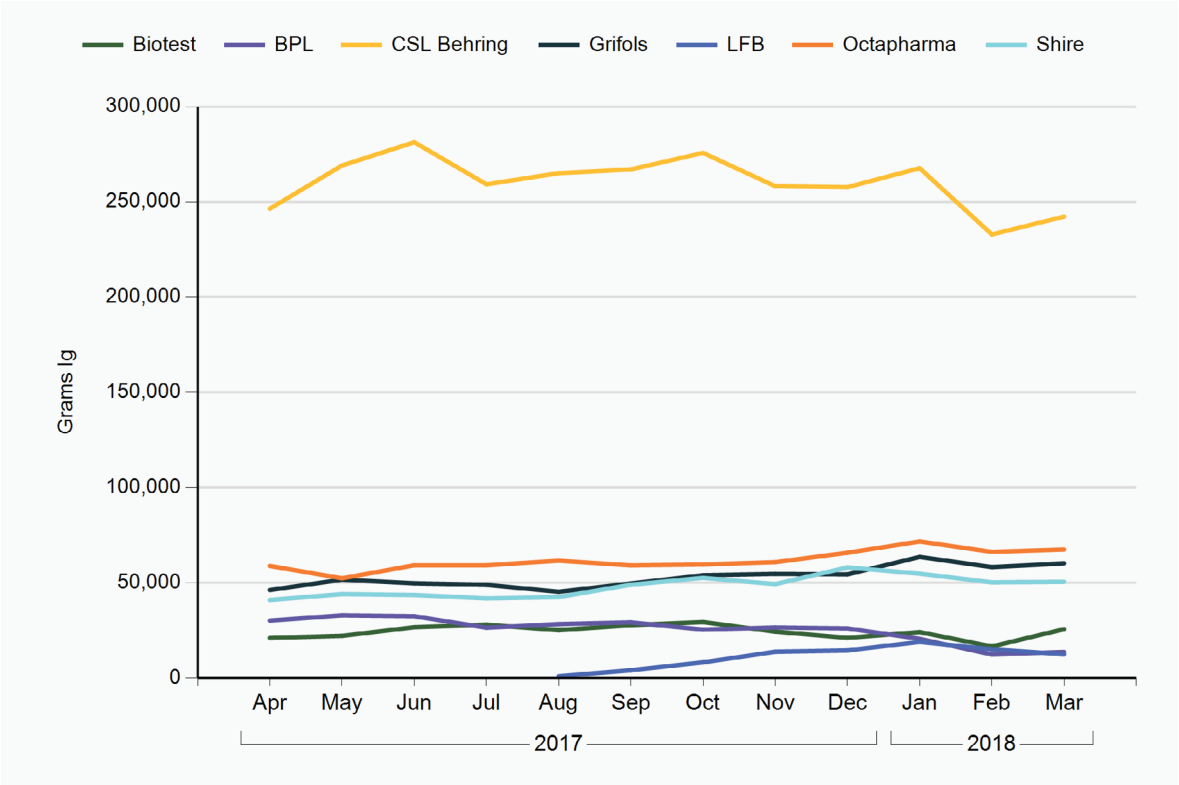

Figure 3.10.2 Recorded yearly use of immunoglobulin products by manufacturer 2013/14 - 2017/18

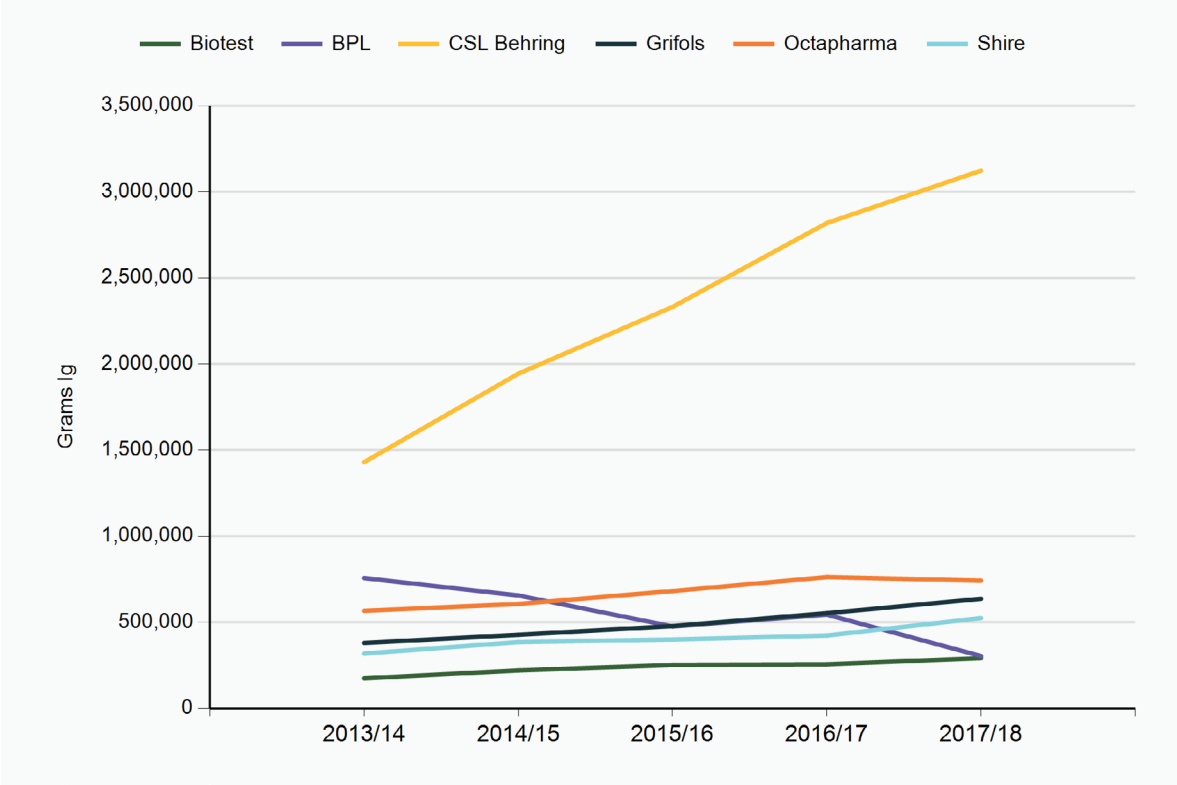

Figure 3.11.1 Average use of immunoglobulin per patient by speciality 2013/14 - 2017/18

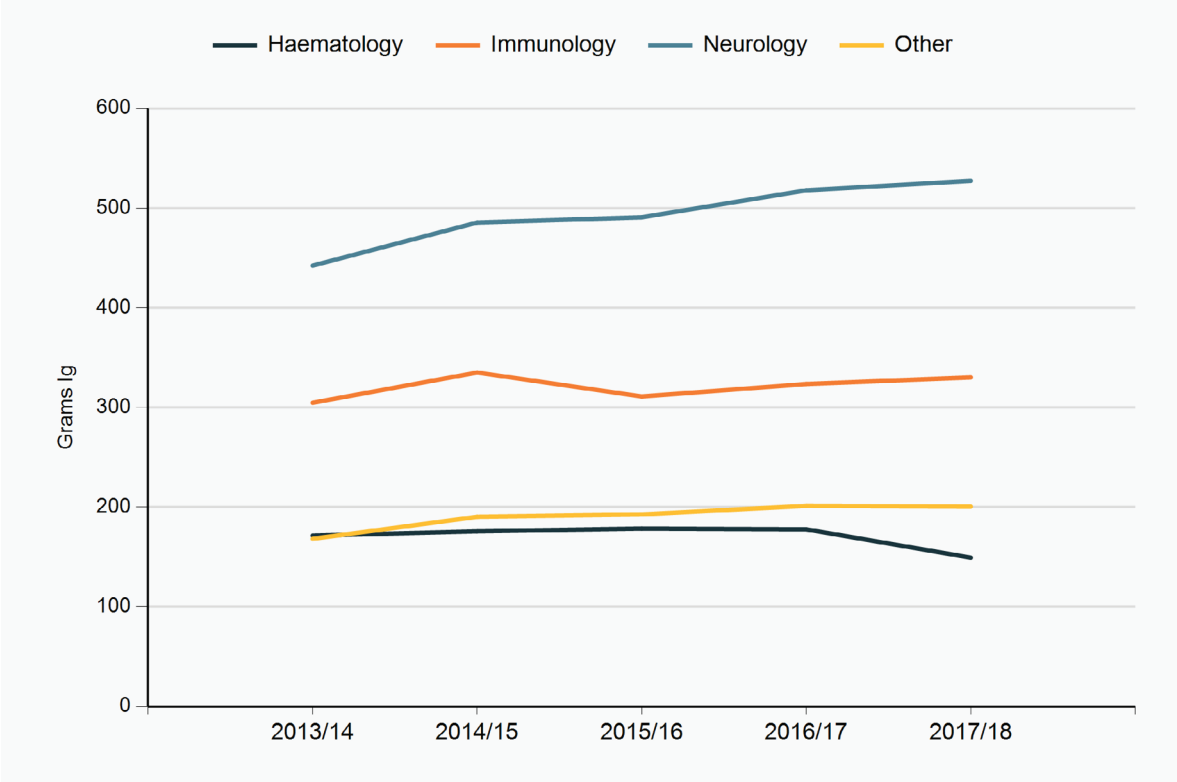

Figure 3.11.2 Average use of immunoglobulin per patient by indication & regime 2013/14 - 2017/18

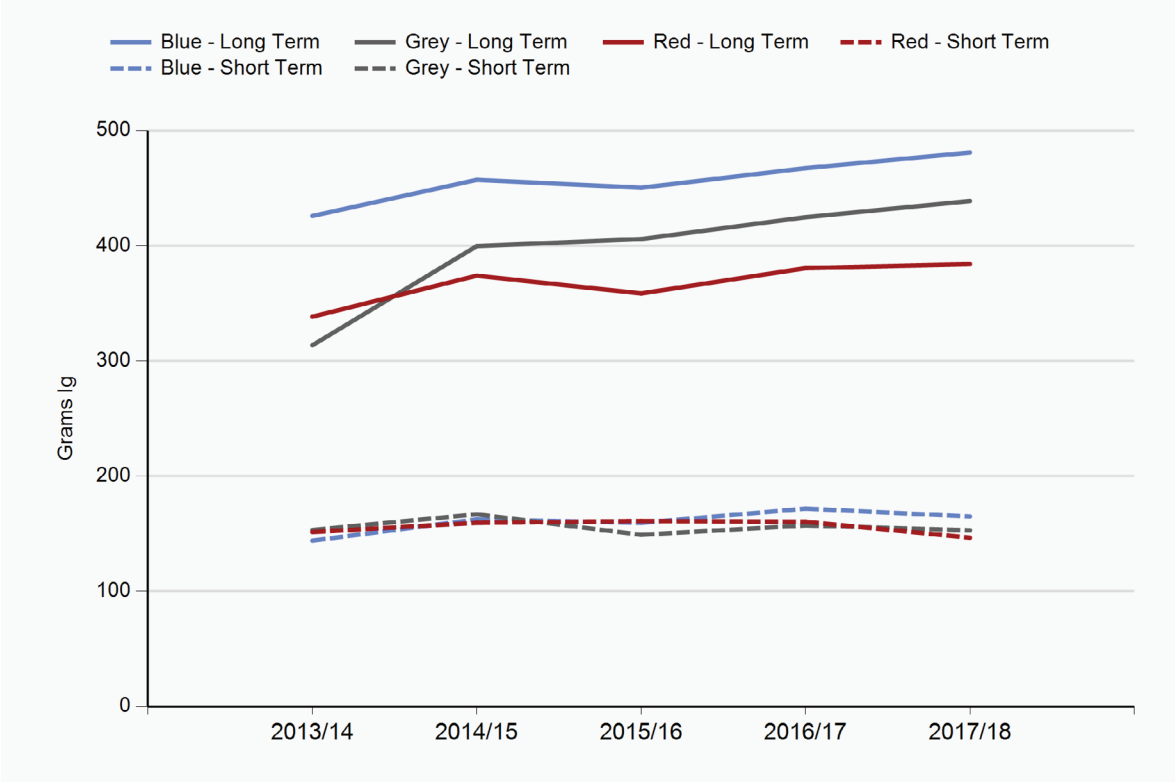

Figure 3.11.3 Average use of immunoglobulin per patient by region 2013/14 - 2017/18

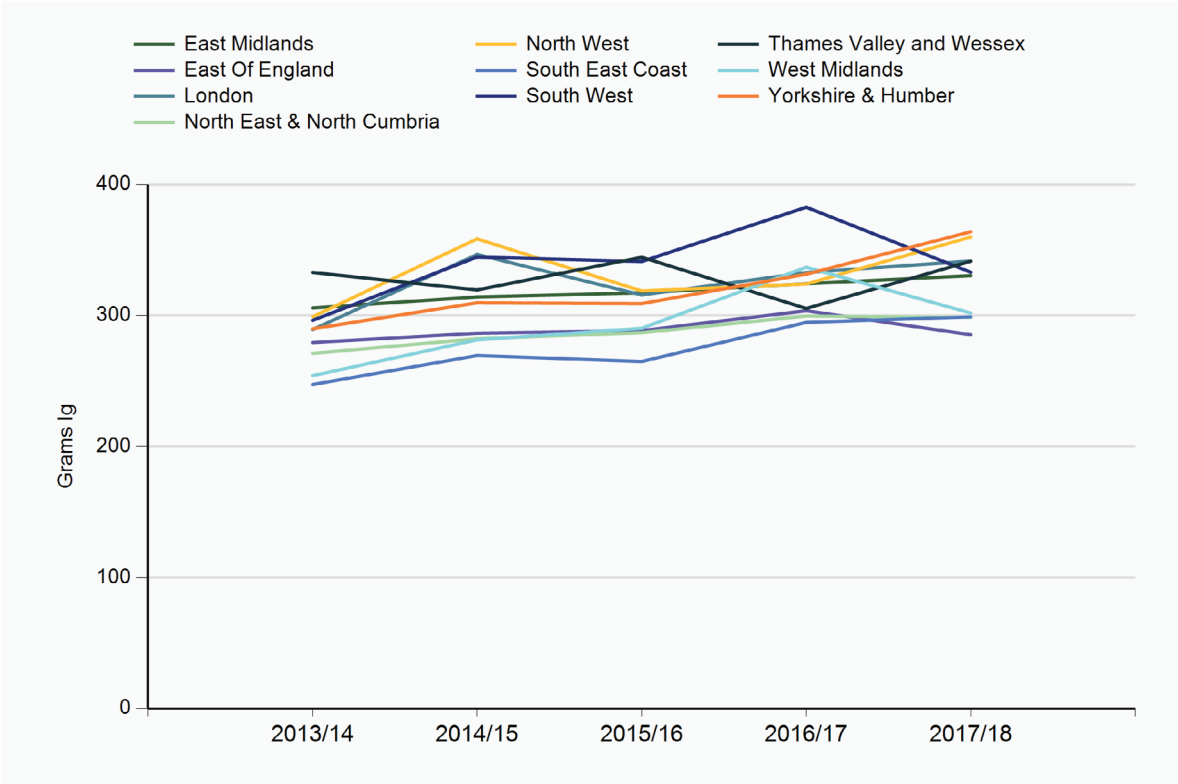

Figure 3.11.4 Average use of immunoglobulin per patient for top conditions 2013/14 - 2017/18