Agenda Item
4.2.1

Joint Commissioning Committee

Management of Immunoglobulins in NHS Wales Report

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	N/A
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Pwrpas yr Adroddiad / Report Purpose	For Approval

Engagement (internal/external) undertaken to date (including receipt/consideration at Committee/Group)		
Committee / Group / Individuals	**Date**	**Outcome**
Health Board Medical Directors	05/12/2025	Approved
All Wales Immunology Strategy Group	09/12/2025	Noted
Chief Pharmacists Peer Group	19/12/2025	Noted
Directors of Finance	19/12/2025	Noted
Chief Pharmacists Peer Group	24/06/2026	Noted
NWJCC CCLG	11/08/2026	Endorsed
SLT	09/09/2026	Endorsed

1. SITUATION/BACKGROUND

Currently, the commissioning responsibilities for immunoglobulins in NHS Wales is split between NWJCC and the individual Health Boards.

NWJCC commission the Specialised Immunology services specifically for patients with inborn errors of immunity (IEI)/Primary immunodeficiency disease (PID) of all ages from Cardiff & Vale University Hospital (C&VUHB) and University of Birmingham, Liverpool & Broadgreen, Alder Hey Children's Hospital and Manchester University Hospital (for patients from North Wales).

Recently, NWJCC have funded on an individual basis some cases (71 out of 346 patients; 20% total) of secondary/unknown causes of immunodeficiency via C&VUHB. These are patients with complex conditions and administration needs who have been referred to the C&VUHB PID/IEI service for their expertise.

The Health Boards (HBs) commission and provide immunoglobulin treatment for other indications – secondary immunodeficiencies and immunomodulatory conditions (36 indications out of the 39 listed in the NHS England Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2025) excluding immunoglobulins used in the treatment and prevention of infectious diseases). The latter are commissioned by the Health Boards on the advice of the Regional Public Health Protection Teams and Public Health Wales.

The Welsh Blood Service (WBS) procure immunoglobulins centrally through a multi-year contract on behalf of all the Health Boards in Wales and distribute to either Blood Banks or Pharmacies in the Health Boards who then issue immunoglobulins via prescription or transfusion request form. Administration is recorded either on the All-Wales Inpatient Medication Administration Chart (AWMAR) (otherwise known as the All-Wales Inpatient Prescription Chart) or Blood transfusion Chart (BTC). The WBS via the all-Wales Immunology Strategy Group (a-WISG) issue guidance to the service on which immunoglobulin products are available on contract, the Immunoglobulin Product Selection Guide, which is updated regularly. This was introduced to manage shortages of immunoglobulins in the 2010's and successfully minimised patient switching.

1.1 NWJCC Commissioning

NWJCC was asked to look at the Stewardship of Immunoglobulins by the Welsh Government and this coincided with the issue of the letter: Plasma-Derived Medicinal Products funding (19th August 2025) from the NHS Wales Chief Executive.

NWJCC produced a report – Report Commissioning for Value – Adopting Best Practice in Specialised Immunology and Immunoglobulin Therapy in Wales which analysed the spend on immunoglobulins in NHS Wales over the last 5 years using contract data and benchmarked against data from NHS England and concluded that 'there are clear benefits for Wales in adopting the NHS England Ig Clinical

Commissioning Policy and processes' including joining the new procurement framework with NHS England, Scotland & Northern Ireland in December 2027,the adoption of the NHS England Clinical Commissioning Policy indications for Ig treatments, the MDSAS immunoglobulin referral system to register patients and outcomes and the development of a Welsh equivalent of the Sub-Regional immunoglobulin Regional Advisory Panel (SRiAP) which oversees the appropriate clinical use of immunoglobulins. They estimate that, if these measures were introduced, NHS Wales could realise up to £5 million in savings per annum. However, further analysis suggests that these savings are more likely to be cost avoidance as any savings will be offset by the increasing number of indications requiring the use of immunoglobulins

Currently NWJCC commissions the Specialist Immunology Service based in South Wales for patients requiring immunoglobulin replacement for PID/IEI including funding the cost of the immunoglobulins. However, the Specialist Immunology Service also treats patients with complex secondary immune deficiency (SID) (20% of total) predominantly from neighbouring Health Boards creating an inequity of care. For North Wales, NWJCC commissions care for PID/IEI patients from a variety of centres based in Birmingham, Liverpool and Manchester. In addition, NWJCC pay for immunoglobulin for patients treated at the Walton Centre based in Liverpool, while BCUHB commission adult neurology services from the Walton Centre.

As NWJCC do not commission adult neurology, adult haematology or other specialised services providing immunoglobulin treatment in NHS Wales that data is not available for analysis.

The report proposed that NWJCC would commission and fund all immunoglobulin use in NHS Wales regardless of indication, develop a SRiAP peer review process to quality assure appropriate use and introduce a referral registry system to provide clinically appropriate, equitable care for all patients, allow for future planning and potentially realise significant financial savings. This proposal was accepted by the Health Board Medical Directors and Directors of Finance.

1.2 Health Board Commissioning

Health Boards (HBs) commission and provide immunoglobulins for indications other than PID/IEI although some Health Boards provide these patients with ongoing immunoglobulin treatments due to a variety of historical reasons including access to treatment closer to home. Immunoglobulins for secondary immune-deficiency (SID) and immunomodulatory treatment for autoimmune diseases (the majority being neurological patients) are commissioned and provided by HBs with provider HBs cross-charging commissioner HBs. The HBs do not appear to audit the specialities' use systematically or provide commissioner HBs with pro-active data on the indication or outcomes of their patients. Validation of the charges are carried out manually by Commissioner HBs by assessing yearly assessment letters for their patients held on Welsh Clinical Portal.

BCUHB has a comprehensive database of patients receiving immunoglobulins through the completion of a paper Immunoglobulin Request Form on initiation of treatment. They note that continuation/review forms are difficult to come by despite reminders to the clinical teams.

1.3 Procurement of Immunoglobulins

Welsh Blood Service negotiates and holds a multi-year contract on behalf of the Welsh Health Boards. Currently this includes 14 immunoglobulin products for intravenous, subcutaneous and facilitated subcutaneous use from 5 companies. WBS have held a central contract for immunoglobulins for longer than NHS England.

In contrast the NHS England 2025 contract includes 10 products from 3 main companies (with 3 reserve companies). The contract includes Gamten 10% IVig which is manufactured from plasma donated within the United Kingdom. The NHS England contract resulted in 10-20% patients requiring a product switch which created work for staff and patients. This additional work was reimbursed in part. Less than 20 patients (out of 6,000 switched) remained on their original product after SRiAP approval. The new contract is estimated to have saved £47million; currently NHS England is undertaking a 'lessons learnt' review including patient feedback to inform the future strategy plans and reduce disruption from changes. Clinical staff and patients disliked the disruption caused by product switches and the restriction of clinical choice. In the recent Immunoglobulin Database Annual Report 2024/25, immunoglobulin use has returned to 2019/20 levels mainly driven by an increase in neurology use and a 20% increase in secondary antibody deficiencies as a consequent of the introduction and increasing use of bispecific antibodies in multiple myeloma and Chimeric antigen receptor T cells (CAR-T) treatment depleting B-cells leading to profound immunodepletion. NHS Wales is also using these therapies and is likely to see the same increases in immunoglobulin use.

In August 2025, the Welsh Government approved WBS contracting with Octapharma Ag to supply plasma donated in Wales for the manufacture of immunoglobulins (PDMPs) and requested that any savings from reviews of the use of PDMPs are redirected to supports the costs of this from 2026-2027. (Ref: Letter NHS Wales CEO to Health Boards. Plasma-Derived Medicinal Products – funding 19 08 2025).

1.4 Stewardship of Immunoglobulins

1.4.1 All-Wales Immunoglobulin Stewardship Group

The all-Wales Immunoglobulin Stewardship Group (a-WISG) comprises of clinicians from the relevant specialities, scientists from the Welsh Blood Service, patient representatives and members representing Health Boards (clinicians, blood banks and/or pharmacy) who met on a regular basis to discuss new products, contracts and clinical issues on a regular basis. Having attended only one meeting to present the scope of the immunoglobulin project, I am unable to gauge the normal range of issues that the group considers. I am awaiting a copy

of the Terms of Reference to determine where the group reports to and the extent of their responsibilities.

1.4.2 Issue of Immunoglobulins

Immunoglobulins are Plasma-Derived Medicinal Products (PDMPs) and require a robust traceability trail ('Between donor and recipient') as part of the approval for the use of UK plasma to industrially manufacture PDMPs following the variant Creutzfeldt-Jakob disease (vCDJ) outbreak in 1999. (MHRA Critical risk assessment report: use of UK plasma for the manufacture of immunoglobulins and vCJD risk April 2021).

Blood Banks issue all immunoglobulins in ABUHB, CAVUHB, SBUHB, one hospital in HDdUHB and one in CTMUHB while Pharmacy issues immunoglobins in BCUHB and the remaining hospitals in HDdUHB (3 sites) and CTMUHB (2 sites). The split in supply in CTMUHB arose when the Princess of Wales Hospital in Bridgend moved from SBUHB to CTMUHB. The reasons for 3 sites in HDdUHB moving supply to pharmacy with 1 remaining in Blood Bank remains unclear.

HB	ABUHB	BCUHB	CAVUHB	CTMUHB	HDdUHB	SBUHB	Powys Teaching HB	Velindre NHS Trust
Blood Bank	✓		✓	✓ 1 site	✓ 1 site	✓	Via provider	Not used
Pharmacy		✓		✓ 2 sites	✓ 3 sites			

1.4.3 Issue via Blood Bank

In hospitals where Blood Banks supply, immunoglobulins are ordered using Blood Request Forms and each supply (including batch numbers and expiries) is recorded on their stock management system. The clinic/ward also completes the traceability tags sent with the units and returned to the Blood Bank, who then update their computer system to reflect the traceability. The electronic record is available at all times, and the returned tags are kept for 30 years as a backup record. This is the same procedure for all products and components issued by blood transfusion in line with MHRA BSQR. Blood Banks allocate individual numbers to each immunoglobulin vial when they are received into the department.

It is unclear how this practice will aid traceability when the pharmaceutical company only requires their batch number/expiry if a recall or 'look back' exercise is required.

Some Blood Banks require the indication to be written on the Request Form. In some Blood Banks the request is queried prior to issue but this is usually to clarify the preparation required or changes from previous requests. In one Blood Bank (Prince Philip Hospital), requests are queried by the Consultant Haematologist, when necessary, based on the NHS England Clinical Commissioning Policy.

The Blood Banks can print off a report giving details of patients who have received immunoglobulins (and, where requested, the indication) for their Health Board but not on a national basis.

1.4.4 Issue by Pharmacy

Pharmacy departments issue immunoglobulins on receipt of a prescription written on the All-Wales Medicines Administration Record (aka 'Inpatient prescription chart') after clinical screening by a pharmacist, before dispensing and recording the batch number and expiry of the vials issued either electronically or on paper. No post-transfusion confirmation is required. Clinical screening may include the NHS England Clinical Commissioning Policy for unusual indications but is not mandated**.**

One Health Board (BCUHB) require an Immunoglobulin Request Form to be completed either prior to issue or after administration depending on the evidence for use as per the NHS England Clinical Commissioning Policy. This form contains details of the indication, dose, duration of treatment and outcome measures. Continuation/review forms are also used but completion can be difficult to achieve. A summary of the request forms is kept electronically.

Unusual indications are directed to Commissioner Health Board IPFR panels for approval prior to treatment starting.

National data on the issue of immunoglobulins from pharmacies (via Careflow) can be obtained which lists the patients' details (but not the indication). DHCW have been asked if the recorded batch number and expiry can be reported but a reply has not yet been received. However, if the pharmacies are inputting batch numbers and expiries into Careflow on receipt, then the system can be searched to provide an audit trail.

1.4.5 Immunoglobulin administration

Intravenous immunoglobulins are administered either to in-patients on wards or to outpatients as day cases. Where Blood Banks issue immunoglobulins, prescribing and administration is generally facilitated via the All-Wales Blood Transfusion Chart and, where pharmacy supplies, via the All-Wales Medicines Administration Record. The batch numbers and expiries of the vials administered are recorded on the chart. Although the Careflow ePMA system does have a set to enable the prescribing, administration and recording of batch numbers of intravenous immunoglobulins, it has not yet been implemented. In other hospitals, ePMA has not yet been deployed in the outpatient clinics or Day Units where the majority of regular maintenance immunoglobulin administration occurs.

Reference sources (in the clinic or ward) for the administration of immunoglobulins include the product information leaflets contained in the immunoglobulin package or via the online electronic medicines' compendium. The Medusa eIV guide includes detailed information on administration (including

charts detailing the escalating infusion rates) and is widely available via hospital intranets.

1.4.6 Homecare Treatment for immunoglobulins

Homecare treatment with immunoglobulins offers three main advantages, firstly, to patients who can be treated in their own homes, reducing the travel and time taken to receive treatment, secondly, to free up space in busy infusion units and thirdly, it is exempt from VAT.

In Wales, homecare is mainly used for PID/IEI patients through the service based in CAVUHB. Patients are trained in the unit by the Specialist Clinical Nurse before their immunoglobulins are delivered by a third-party homecare provider. The administration for the homecare deliveries is managed by the Specialist Clinical Nurse who has been advised by the National Homecare Manager – Pharmacy. Some subcutaneous immunoglobulin products are used in the infusion day units to reduce the duration of infusions and increase capacity.

Some neurology homecare takes place, again managed by the Specialist Clinical Nurse, who sources the immunoglobulins and administration associated equipment through the hospital which is then collected every 3 months by the patients. This method of providing homecare does not realise VAT exemption savings (20%).

1.5 Audit of immunoglobulin use

There does not appear to be any regular audit of immunoglobulin patients on a population level by Health Boards or Clinical Specialities currently. However, it should be borne in mind that, except for the PID/IEI service based in CAVUHB, no Health Board based services have been asked to provide audit data historically. Discussions during this project have shown that services are focused on providing good, individualised care to patients, but they do not have the formal data to demonstrate this to Commissioners. Therefore, clinical services should be supported to develop systems to demonstrate their clinically appropriate use, stewardship of immunoglobulins and patient outcomes going forward.

WBS submitted a business case to NWJCC in 2015 for a data analyst to develop and administer a patient registration system to manage immunoglobulin supplies which was not approved. With the advances in technology, a clinician completed electronic initiation/continuation system could be introduced to reduce data entry needs. Remodelling this post could be used to manage the Wales immunoglobulin Advisory Panel (WiAP) panel in addition to producing data analysis reports and supporting clinicians using immunoglobulins.

1.6 Patient Registration Systems

Two registry systems were found: BCUHB's Immunoglobulin Request Form register and CAVUHB's PID/IEI Unit's for Homecare patients.

Information on the use of immunoglobulins across a Health Board's population could be extracted from the issue system used and then indications and other information retrieved from Welsh Clinical Portal manually. This is a time-consuming process.

Estimates of patient numbers are as follows:

- CAVUHB PID/IEI 346 patients (71 are referred secondary ID)
- Morriston Neurology 40-50 patients
- BCUHB 213 patients
- HDUHB 79 patients (over a 6-month period all indications)
- HDUHB Commissioning Cross-Charges from SBUHB: 28 patients (over 4 months).

This does not include information from other Health Boards (or specialities in CAVUHB/SBUHB) and so the total number of patients across NHS Wales is unknown.

Colleagues from NHS England have confirmed that immunoglobulins for Welsh cross-border patients are approved via the local SRiAP in line with NHS England patients. This results in inequity for patients being treated inside and outside of Wales due to different processes within Wales and England.

As Health Boards commission services from NHS England providers which may include immunoglobulins, details of these patients may be held by each Health Board's Commissioning Team. Powys Teaching HB request backing data (NHS number and provider) to support invoices from NHS England providers. NWJCC do pay for immunoglobulins for NHS Wales patients treated in certain centres (e.g. The Walton Centre) however there is not a single centralised list of Welsh patients receiving immunoglobulin treatment via NHS England services.

We are in the process of asking for patient numbers from the NHS England MDSAS Immunoglobulin Database; information governance discussions are ongoing.

2 SPECIFIC MATTERS FOR CONSIDERATION

2.1 Commissioning

A single commissioner for immunoglobulins will focus attention on the use and stewardship of immunoglobulins and allow the introduction of mechanisms to audit and promote immunoglobulin stewardship. It will also ensure parity between all the clinical services using immunoglobulin.

It must be clear in the commissioning policy that JCC will be commissioning the immunoglobulins but <u>not</u> the services providing them. A mechanism for each Health Board to invoice JCC must be available unless WBS invoices JCC at the point of issue to the HBs. WBS are currently able to provide NWJCC with data on the supply to individual Health Boards which, in conjunction with Blueteq data, will give financial oversight for immunoglobulin use. A reconciliation/validation

process between the Blueteq forms submitted and HBs issue data will have to be undertaken.

It should be noted that where HBs (BCUHB) are already monitoring the use of immunoglobulins against the NHS England Clinical Commissioning Policy criteria, cost-savings are less likely.

In negotiating with the HBs, as some prescribing and cost-charging is occurring from NHS England providers (some already paid by NWJCC), HBs should transfer their current spend on immunoglobulins (based on data from pharmacy/Blood Banks/commissioning) to NWJCC rather than on a pro-rata population basis.

NHS England providers already use Blueteq to submit funding requests to NWJCC for other high-cost medicines.

Cost-savings arising from Immunoglobulin Stewardship may be required to address the increasing use of immunoglobulins as seen in the other UK nations, support the operation of the WiAP and support the continued donation of plasma for the manufacturer of PDMP's.

2.2 Guidance NHS E/BloodStar

Initially, the NHS England Clinical Commissioning Policy for Immunoglobulins should be endorsed for All Wales use. However, in time, members of WiAP will review the guidance and adjust it to meet the needs of the Welsh population. Other national guidelines (for example, BloodSTAR in Australia) may also be adopted/adapted where their criteria and accessibility are preferable.

2.3 Procurement

Although WBS set up Wales-wide, multi-year, fixed-price contracts before NHS England; ahead of the next NHS England contract renewal (2027-2030) WBS should conduct an options appraisal to quantify the risks and benefits of joining the NHS England contract and explore whether a looser equal party relationship similar to the NHS Scotland model is feasible and offers benefits for NHS Wales.

2.4 Standardise documentation

Documentation for the ordering, supply and administration should be standardised across NHS Wales, regardless of the source of immunoglobulin supply to reduce confusion for staff. These processes may now be electronic.

2.5 Patient registration and audit system

NHS England use MDSAS as their Immunoglobulin Database. It has been recently upgraded to increase the ease of use for clinicians. In addition to inputting patient registration, indication and eligibility MDSAS records the batch number and expiry for each vial infused. MDSAS is unpopular with clinicians as it closely ties registration to stock allocation which has led to shortages in some circumstances. Disquiet has been expressed about the rigidity of eligibility and review criteria which highlights the importance of involving clinicians in the development of the

criteria from the beginning. A major disadvantage of MDSAS is the lack of automatic approval where patients meet the eligibility criteria for treatment stated in the NHS England Clinical Commissioning Policy for Immunoglobulins Appendix A. This means that each application has to be read and approved by the SRiAP panel. The average response time is 40.2% within the day and 26.6% within the week of application.

The Australian National Blood Authority manage their immunoglobulin use via BloodSTAR. We are currently arranging a demonstration. The system contains more precise eligibility and review criteria which are evidence based and easily accessible online.

Blueteq is currently being introduced in NHS Wales for the assurance and monitoring of high-cost drug use. It has already been commissioned and has passed information governance requirements and integration with other clinical systems in all Health Boards and NWJCC. The specialities which use immunoglobulins will be using Blueteq for other high-cost drugs that they prescribe so training will already be provided. Blueteq has an automatic approval function when patients meet the eligibility criteria. The ability to record the dose, batch numbers and expiries and date of administration will be introduced within the next 4 months, which will provide an easily accessible, nationwide robust 'donor to recipient' audit trail. Some draft forms for immunoglobulins have been developed to test the concept and will need input from the clinical teams. Haematology based in UHW want to explore their use of immunoglobulins and could pilot the use of Blueteq forms to run the audit.

2.6 Peer review of prescribing

SRiAPs in NHS England are instrumental in ensuring equitable stewardship of immunoglobulins. NHS Wales is a similar size to the population covered by the SRiAPs and a single WiAP (Welsh Immunoglobulin Advisory Panel) is proposed. This will comprise of respected clinical specialists with the experience, knowledge and understanding to advise colleagues on the appropriate use of immunoglobulins. A single, independent panel will function in a similar fashion to the All Wales MDT for severe asthma which discusses patients prior to starting biological monoclonal antibody treatment and uses the Blueteq database to provide a registry of patients for outcome and research data.

2.7 Patient factors/feedback

A-WISG already has patient representatives as members. Immunodeficiency UK and other patient support groups are active in Wales. Patient representatives from haematology and neurology support groups can also be sought.

As any proposed changes in the management of immunoglobulins in NHS Wales for patients receiving long-term immunoglobulin treatment will cause anxiety and concern, the changes should be communicated clearly in advance to patients, including the reasons for changes, and patients given an opportunity to discuss the implications for their individual care. Where patients would not meet the

criteria for treatment, the same approach as NICE should be taken (i.e. 'This recommendation is not intended to affect treatment with immunoglobulins that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change, until they and their NHS healthcare professional consider it appropriate to stop.')

3 KEY RISKS / MATTERS FOR ESCALATION

3.1 Lack of an All-Wales Data set for clinical audit and Immunoglobulin Stewardship

Currently, NHS Wales does not have a patient registration system recording the use of immunoglobulins, so is unable to determine the appropriateness of use of immunoglobulins or audit use against a set of agreed standards.

3.2 Inequity of access to immunoglobulins (in particular, home administration)

Patients are more likely to be offered homecare treatment if they have PID/IEI than secondary immunodeficiency or immunomodulating treatment. This is an important factor for enabling patients living in rural or remote areas to receive treatment. There appears to be less patients with PID/IEI in North Wales but the lack of a patient registration system (which includes patients treated in NHS England and cross-charged) means that this cannot be investigated further.

3.3 Inconsistencies in the supply of immunoglobulins

Immunoglobulins are issued by either Blood Bank or Pharmacy in different hospitals. While this can be accommodated, it may cause confusion for staff who rotate through different hospital sites during training.

Clinicians, Blood Banks and Pharmacies need to adopt consistent clinical treatment guidelines so that access to treatment is equal across all Health Boards. The indication for treatment must be recorded on request forms and screened for compliance with the guidelines before issue or challenged where non-compliant.

Both Blood Banks and Pharmacy need to demonstrate an equivalent robust, easily available traceability record ('Between donor and recipient'). In NHS England, the recording of batch numbers and expiries of the immunoglobulin vials administered in the patient's MDSAS record is used to provide this audit trail.

Homecare treatment (as detailed in 3.2 above) also leads to inconsistencies in supply.

3.4 Service resistance to change

Resistance to changes comes, in the main, from workload pressures in both the clinical and supply services and because the commissioning of services using immunoglobulin has been split between Health Boards and JCC which has meant that the audit and assurance of immunoglobulin use has not been requested to date (besides the JCC service audit of the PID/IEI).

In addition, clinicians, looking at their colleagues' experiences in NHS England, are concerned that any changes may reduce their ability to individualise patient care including product choice, require switches for non-clinical reasons and delay starting urgent treatment. Therefore, clinicians in all specialities using immunoglobulins, should be actively engaged in the change process to minimise adverse impacts and design a bespoke, collaborative system for Wales.

Good aspects of the current immunoglobulin stewardship approach need to be recognised:

- the WBS central, multi-year contract for immunoglobulin and guidance to manage shortages while minimising the switching of products where possible
- A-WISG which provides peer guidance to the clinical services and includes representatives from the clinical specialities using immunoglobulins from across Wales and patient representation
- and the dedicated and highly experienced staff who provide research-based, patient-focused services both in the clinics and the supply chains.

In conclusion, these staff need to be supported so they can demonstrate their good Immunoglobulin Stewardship to commissioners and develop consistent assured services across Wales.

4 ASSESSMENT

Objectives / Strategy	
Dolen i Amcan (au) Strategol CBC / Link to JCC Strategic Objectives(s)	Maximise Value
	If more than one applies please list below: Ensure quality Improve equity and population health
Dolen i Ddeddf Llesiant Cenedlaethau'r Dyfodol – Nodau Llesiant / Link to Wellbeing of Future Generations Act – Wellbeing Goals *150623-guide-to-the-fg-act-en.pdf (futuregenerations.wales)*	A Healthier Wales
Dolen i Hwyluswyr Ansawdd *(Canllawiau Statudol Dyletswydd Ansawdd (llyw.cymru)) /*	Data to Knowledge
	If more than one applies please list below: Learning, Improvement and Research Whole-systems perspective

Link to Enablers of Quality *(Duty of Quality Statutory Guidance (gov.wales))*	
Dolen i Feysydd Ansawdd *(Canllawiau Statudol Dyletswydd Ansawdd (llyw.cymru))* / **Link to Domains of Quality** *(Duty of Quality Statutory Guidance (gov.wales))*	Effective
Effaith Amgylcheddol/ Cynaliadwyedd (5R) / Environmental /Sustainability Impact (5Rs)	No - Not Applicable

Impact Assessment	
Ansawdd *Ydych chi wedi ymgymryd â Sgrinio Asesiad o'r Effaith ar Ansawdd?* / **Quality** *Have you undertaken a Quality Impact Assessment Screening?*	Yes: ✓
	Outcome: The impact of the proposed recommendation is assessed as overall positive with an initially high level of activity required during implementation falling to a low-moderate level.
Cydraddoldeb *Ydych chi wedi ymgymryd â Sgrinio Asesiad o'r Effaith ar Gydraddoldeb?* / **Equality** *Have you undertaken an Equality Impact Assessment Screening?*	Yes: ✓
	Outcome: The proposed recommendations are expected to have a positive or neutral impact on the protected characteristic groups. No actions need to be taken to mitigate the impact of the proposed recommendations.
Cyfreithiol / Legal	The supply of an intravenous medicinal product (specifically a PDMP) by Blood Banks. The WG Chief Pharmacist and the Clinical Directors of Pharmacy are considering this issue.
Enw da / Reputational	There is no direct impact on the reputation of the Joint Committee as a result of the activity outlined in this report.
Effaith Adnoddau	Yes

(Pobl /Ariannol) / **Resource Impact** *(People / Financial)*	• WiAP Administrator/Data Analyst: Band 4-7 dependant on the detailed Job Description. • Sessional payments for clinicians for involvement in the WiAP. • Blueteq licence and maintenance is • already paid by NWJCC. The estimated cost-savings through improved stewardship of immunoglobulins can be redirected to funding the clinician and data-analysis/administration of WiAP.

5. RECOMMENDATIONS

It is proposed that the NWJCC:

- Commission immunoglobulins for all indications on an all-Wales basis.
- Formally endorse the NHS England Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2025).
- Continue to procure immunoglobulins via the WBS multi-year contracts and advise on product selection using the all-WISG Immunoglobulin Product Selection Guide.
- Work with the WBS to conduct an options appraisal into the risks and benefits of joining the NHS England contract at the next renewal (2027-2030).
- Continue to minimise product switches due to the burden on services and patients.
- Introduce an NHS Wales wide standard patient registration, follow-up and audit system.
- Set up a Wales immunoglobulin Advisory Panel (WiAP) as a sub-group of the all-Wales Immunoglobulin Strategy Group (a-WISG).
- Immunoglobulin supply: maintain the status quo with the same All Wales documentation used by both pharmacy and blood banks.
- Ensure that Blood Bank and Pharmacies to demonstrate compliance with traceability requirements from donor to recipient and that these records are easily available for audit and 'look back' purposes.
- Work to improve the availability and equity of access of home treatment for immunoglobulin patients across all indications.
- Work with Health Boards to use existing mechanisms for the urgent (including 'out-of-hours') approval of high-cost drugs for immunoglobulin approval.

6. NEXT STEPS

Subject to prior Joint Committee approval:

- **NWJCC to formally agree commissioning of all immunoglobulins** through agreement by members of the NHS Wales Joint Commissioning Committee which includes the CEOs of all Health Boards and NHS Trusts in Wales.
- **Formally endorse the NHS England Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2025).**
- **Introduce an NHS Wales wide standard patient registration, follow-up and audit system.** Initially using Blueteq (already commissioned, contains an auto-approval mechanism and will be used by the Clinical services for other High-Cost medicines).
- **Engage separately with each clinical service using immunoglobulins**: PID/IEI, haematology and neurology to develop Blueteq forms for indications. Pilot the haematology forms as part of a multi-centre pilot audit.
- Set up a **Wales immunoglobulin Advisory Panel (WiAP)** as a sub-group of the all-Wales Immunoglobulin Strategy Group (a-WISG). Consider funding administrative support and membership to include clinical representation from specialities regularly using immunoglobulins, JCC, WBS & HB representatives with a remit to include:
    - peer review of registration & follow up aggregated data (including data for Welsh patients treated in NHS England), analyse and advise on changes in practice to optimise use.
    - advice on applications which do not meet automatic approval criteria
    - patient representative and service feedback.
    - advise on changes to the NHS England Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England based on Welsh clinical practice and population factors.
- **Chief Pharmacists' peer review group to explore the impact of supplying all immunoglobulins from pharmacies.** Blood Bank and Pharmacies to demonstrate compliance with traceability requirements from donor to recipient and that these records are easily available for audit and 'look back' purposes.
- **Homecare:** review the services currently providing homecare for sustainability and assess the potential for other specialities to provide homecare.
- **Health Boards** to demonstrate that their existing mechanisms for the urgent (including 'out-of-hours') approval of high-cost drugs includes immunoglobulin approval.

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