Agenda Item
4.5

Joint Commissioning Committee

Immunoglobulin Optimisation

Dyddiad y Cyfarfod / Date of Meeting	25/11/2025
Statws Cyhoeddi / Publication Status	Open/ Public
	Not Applicable
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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**
NWJCC – Senior Leadership Team	19/11/2025	Noted

Acronyms / Glossary of Terms	
AWIAP	All Wales Immunoglobulin Advisory Panel
CVUHB	Cardiff and Vale University Health Board
IGT	Immunoglobulin Therapy
JC	Joint Commissioning Committee
MDSAS	Medical Data Solutions and Services
PID	Primary Immunodeficiency
SID	Secondary Immunodeficiency

1. SITUATION/BACKGROUND

There are three broad indications for immunoglobulin therapy (IGT) – primary immunodeficiency (PID) due to in-born errors of immunity; secondary immunodeficiency (SID) as a consequence of treatment received for cancer or inflammatory disorders; and a heterogenous group of diseases where immunoglobulins are used as potential immunomodulators.

1.1 Immunoglobulin Therapy

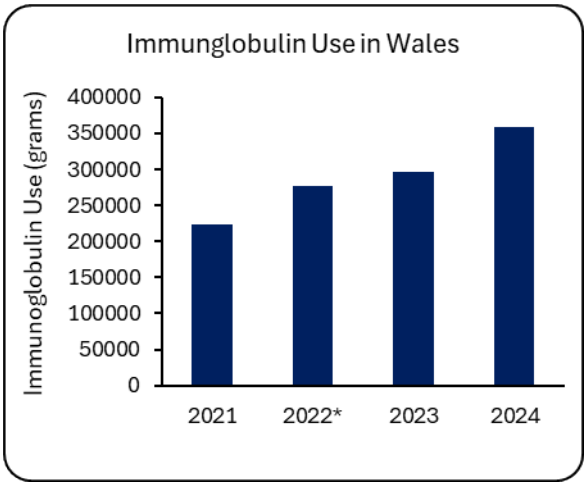
Immunoglobulins, also known as antibodies, are glycoproteins produced primarily by plasma cells, serving as key components of the adaptive immune system. Therapeutic immunoglobins are purified (through fractionation) from the pooled plasma of thousands of donors, typically containing more than 95% of unmodified immunoglobulin G (IgG) and only trace amount of IgA and IgM.

Immunoglobulin therapy began as a replacement treatment for patients with PID, where the lack of functional antibodies predisposes to recurrent infections. Today, beyond replacement therapy in PID, immunoglobulins are used in an array of conditions including autoimmune diseases, inflammatory conditions (such as Kawasaki disease and immune thrombocytopenic purpura), neurological disorders (like Guillain–Barré syndrome and chronic inflammatory demyelinating polyneuropathy), and even in select oncological applications. In a clinical context, immunoglobulins are administered intravenously or subcutaneously with the route of administration chosen to optimize dosing, convenience, and safety. Moreover, the broader immunomodulatory, anti-inflammatory, and anti-idiotypic properties of immunoglobulins have spurred their off-label use in many refractory diseases where conventional therapies fail.

1.2 Immunoglobulin prescribing in Wales

The JCC commissions specialised immunology services in Wales, as set out in our Commissioning Policy and Service Specification (SS78), and commissions PID but specifically does not commission SID. There has however been commissioning creep such that many patients with SID access IGT via Cardiff and Vale University Health Board (CVUHB), with a halo effect for JCC funded SID therapy around Cardiff. The majority of IGT for SID are prescribed via health boards, and the heterogenous group of immunomodulatory indications are delivered by health boards. This has resulted in an inequitable provision of care.

There is very little data on the indications and need in SID and other indications. Welsh Blood Service record spend on IGT per health board but does not record the number of patients or indications. Health Boards have limited data on the number of patients but not on indications as IGT is used in a number of different settings. Although the JC commissions PID for North Wales patients, there is limited data although there appears to be inequity of access to services and IGT in North Wales is proportionately significantly less that for South Wales. The volume of Ig prescribed in Wales continues to increase.



Volume of Immunoglobulin prescribed in Wales 2021-2024

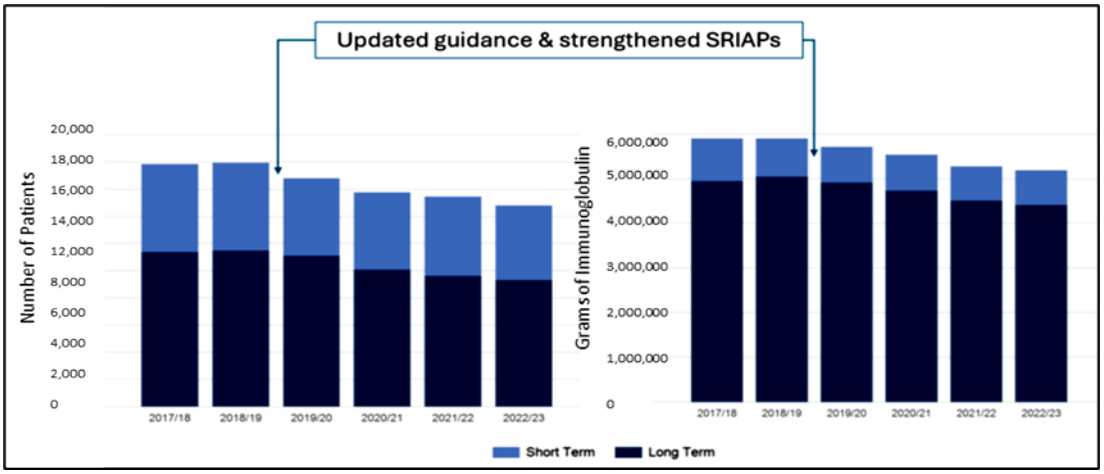
1.3 Immunoglobulin policy in the rest of the UK

Due to increasing indications and demand, the use of IG therapy is increasing and many countries have established institutional guidelines/ policies to ensure standardisation of care and good clinical stewardship

NHS England utilises a national clinical commissioning policy for all IGT indications (PID, SID and immunomodulatory) that ensures that IGT use is governed by clear clinical criteria. The process is mirrored in NHS Scotland. The policy is updated annually in line with evolving clinical evidence. The policy covers a wide variety of IG indications including immunology, neurology and haematology. The policy provides details on the role, dose and place of IGT in the treatment pathway for individual indications

A platform provided by Medical Data Solutions and Services (MDSAS) is used which has both a referral and database function. To implement, monitor and audit the policy NHS England commissions 22 Subregional Immunoglobulin Panels (SRIAPs) as part of its specialised services portfolio. The SRIAPs utilise the policy through the MDSAS platform to approve, audit IGT use, and update the policy. All IGT referrals are submitted via the MDSAS platform and are then reviewed by SRIAPs for approval. The policy differentiates between standard indications which are reviewed retrospectively, and potential indications which require prospective SRIAP approval. SRIAPs are multidisciplinary comprising immunologists, haematologists, neurologists and pharmacists. Secretariat support for SRIAPs is usually a B8a pharmacist and a B6 pharmacy technician. The pharmacist provides expert advice on appropriateness and dosage of immunoglobulins, ensuring adherence to clinical policy as well as monitoring the supply chain to ensure robustness. Of note is that most SRIAPs are responsible for a population similar in size to Wales.

In England the use of the IG policy, SRIAPs and MDSAS has resulted in standardised patient care and a significant decrease in the volume of IGs prescribed from 5.9 million to 5.2 million grams between 2018/19- 2022/2023, despite an increase in indications.



Total volume of immunoglobulin prescribing in NHSE 2017/18 – 2022/23

Crude comparisons suggest that if the NHSE/NHSS policy was extrapolated to Wales the volume prescribed would be approximately 260,000 grams per year (25% decrease in current volume). The current cost of IG is approximately £60/gram, and thus savings are potentially greater than £5M.

1.4 The need for change

Given the commissioning pathway in England, the lack of coordinated approach in Wales and the cost of IGT, there is an opportunity to optimise the pathway with clinical stewardship to ensure value and equity of delivery. The JCC medical directorate has presented the need for change in immunoglobulin prescribing in Wales, and Joint Committee gave a clear mandate to implement change.

To achieve these changes additional pharmacist capacity is required to ensure the appropriate governance and service optimisation to deliver the potential cost savings. It is anticipated that potential savings this will be between £2-5 million/year. There are potentially additional further savings to be made through changes in procurement of IGT that is outside the remit of this project.

2. SPECIFIC MATTERS FOR CONSIDERATION

There is a growing need to ensure robust, evidence-based and equitable management of immunoglobulins within Wales. The joint committee have supported the commissioning of all immunoglobulins via the NWJCC to mirror commissioning responsibilities in the rest of the UK. It is proposed to establish an All-Wales Immunoglobulin Advisory Panel (AWIAP) to scrutinise all IGT use and to offer appropriate stewardship. A WTE Band 8a pharmacist is required to scope the current IGT use in Wales and to then establish, coordinate and manage immunoglobulin requests to the All-Wales Immunoglobulin Advisory Panel (AWIAP). It is proposed to utilise the MDSAS database thus offering benchmarking and audit compared to the other devolved nations. The major financial difficulty and risk is that this plan will require investment into the JCC team, while the majority of savings will be directly in health boards. It will

therefore be essential to adequately scope and benchmark the current individual HB spend on IGT. Immunoglobulins are medicinal products, and although they may be held in blood banks, they are the responsibility of the Health Board Directors of Pharmacy. The plan will be crucially dependent on the cooperation of the Health Board Directors of Pharmacy and Finance teams.

The risk of not appointing a dedicated pharmacist into this role is that JCC will not be able to deliver and monitor immunoglobulin prescribing on an all Wales level and we would be unable to deliver cost savings as anticipated.

3. KEY RISKS / MATTERS FOR ESCALATION

The recommendation is the recruitment of a substantive WTE 8a pharmacist and the procurement of the MDSAS database (circa 20k pa). The pharmacist will focus on the immunoglobulin work portfolio as well as providing additional robustness to the medicines optimisation team and ensure operational continuity. The pharmacist will:

- Scope the current total prescribing of IGT in Wales, determining broad cost and volume in the health boards and the JCC.
- Determine potential inequity of IGT use in individual health boards.
- Support the set-up of the AWIAP.
- Review immunoglobulin requests for clinical appropriateness and ensure equitable, prioritised access.
- Scope and implement cost saving initiatives related to IGT.
- Provide cross cover for the advanced 8a pharmacist with regard to a) Blueteq form development, b) policy development and implementation and c) provide general support to the lead medicines optimisation pharmacist pertaining to all aspects of specialist commissioned medications
- Undertake Supply Chain mapping and market appraisal of immunoglobulins supply in conjunction with the Welsh Blood Service
- Reduce the number of IPFR requests

There is currently sufficient slippage in the medical directorate to support the role until the end of year, but the JC will need to go at risk to develop the infrastructure needed to deliver these significant cost savings.

4. ASSESSMENT

Objectives / Strategy	
Dolen i Amcan (au) Strategol CBC / Link to JCC Strategic Objectives(s)	Improve Equity and Population Health
	If more than one applies please list below: Maximise Value, Ensure Quality
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
	If more than one applies please list below: A More Equal Wales
Dolen i Hwyluswyr Ansawdd *(Canllawiau Statudol Dyletswydd Ansawdd (llyw.cymru)) /* **Link to Enablers of Quality** *(Duty of Quality Statutory Guidance (gov.wales))*	Whole-systems Perspective
	If more than one applies please list below:
Dolen i Feysydd Ansawdd *(Canllawiau Statudol Dyletswydd Ansawdd (llyw.cymru)) /* **Link to Domains of Quality** *(Duty of Quality Statutory Guidance (gov.wales))*	Equitable
	If more than one applies please list below: Effective and Efficient
Effaith Amgylcheddol/ Cynaliadwyedd (5R) / Environmental /Sustainability Impact (5Rs)	No - Not Applicable
	If more than one applies please list below:

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: ☐	No: ☒
	Outcome:	If no, please include rationale below: Impact Assessment will be undertaken as part of the next steps
Cydraddoldeb *Ydych chi wedi ymgymryd â Sgrinio Asesiad o'r Effaith ar Gydraddoldeb? /* **Equality** *Have you undertaken an Equality Impact Assessment Screening?*	Yes: ☐	No: ☒
	Outcome:	If no, please include rationale below: Impact Assessment will be undertaken as part of the next steps
Cyfreithiol / Legal	There are no specific legal implications related to the activity outlined in this report.	
Enw da / Reputational	Yes (Include further detail below)	
	Failure to adequately and equitability commission immunoglobulins for all residence in Wales could lead to inequity and therefore reputational damage	
Effaith Adnoddau *(Pobl /Ariannol) /* **Resource Impact** *(People / Financial)*	Yes (Include further detail below)	
	Lack of coordinated approach could lead to additional cost pressures	

5. RECOMMENDATIONS

The members of the Joint Commissioning Committee are asked to:

- **APPROVE** the financial support required to establish the immunoglobulin optimisation team.

6. NEXT STEPS

Once approved, the plan would be to appoint a B8a pharmacist to implement the plan during 2025-26.