NHS England South West

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Dear Colleagues,

Re: Launch of UK plasma-derived immunoglobulin and changes to immunoglobulin provision

In 2025, there will be several changes to the supply of Immunoglobulin (Ig) products in England, aimed at increasing self-sufficiency and ensuring more reliable product availability. These changes will apply to all conditions that require the use of Immunoglobulins.

Launch of Gamten

A new 10% intravenous immunoglobulin (IVIg) preparation, Gamten, manufactured for the UK market using exclusively UK plasma, has been introduced into the NHS in 2025.

This product has been licensed by the UK Medicines and Healthcare products Regulatory Agency (MHRA) following regulatory scrutiny. The manufacturing process for Gamten is identical to that of Octagam 10% and all patients should be reassured that its functional efficiency will be no different to that of any other licensed preparation[1], both for antibody replacement and immunomodulation.

Gamten is the result of a partnership between NHS England, NHS Blood and Transplant, and Octapharma, through the UK plasma for medicines programme. Octapharma, established in 1983, has a proven track record as one of the world's largest plasma fractionators and have been supplying the NHS with plasma derived products for more than 30 years.

The launch of Gamten will improve resilience in the UK supply chain of Ig, as compared with the previous position of being solely reliant on Ig derived from plasma sourced from outside the UK. With on-going volatility in global Ig supplies, reducing our reliance on outsourced plasma is a welcome development for the UK.

Changes to the range of available Ig products

[1] Misbah SA. Should therapeutic immunoglobulin be considered a generic product: an evidence-based approach. J Allergy Clin Immunol Pract 2013;1:567-72

Following conclusion of a fair and transparent procurement exercise, in compliance with procurement regulations, from 1 April 2025, a new framework for the supply of immunoglobulin will begin. The Ig preparations shown in Table 1 below will **no longer be available**:

Table 1

5% IVIg	Flebogamma DIF, Gammagard, Intratect 5%
10% IVIg:	Gammaplex 10%, Iqymune, Octagam 10%, Privigen
Subcutaneous Ig (SCIg)	Hizentra, Subgam

The withdrawal of these products does not pose a risk to UK supplies since there will continue to be an adequate range of IVIg and SCIg products available for use. These will continue to be procured under a contractual framework, which guarantees ongoing supplies. The Ig preparations shown in Table 2 below **will be available**:

Table 2

5% IVIg	Octagam 5%
10% IVIg:	Gamten, Gamunex, Intratect 10%, Kiovig, Panzyga
SCIg	Cutaquig, Cuvitru, Xembify
Facilitated SCIg	HyQvia

Action required

The launch of Gamten and withdrawal of certain products will require clinicians to institute the following changes:

1) All new patients requiring either short-term or long-term IVIg should be preferentially considered for Gamten.
2) Existing patients on long-term Ig on any of the products that were not awarded to the framework, shown in Table 1 above, will need to be switched to an alternative IVIg or SCIg preparation as appropriate.
   For those patients on Privigen, Gamten should be preferentially recommended as an equivalent IVIg preparation.

The need to switch Ig preparations is a well-recognised necessity from time to time due to product withdrawals, shortages, or rarely due to adverse reactions. Previous switches have been undertaken safely, with no systemic adverse effects, as evidenced by analysis of patient experience from 30 immunology centres involving 802 product switches in 2017-18[2].

There are no functionally significant differences in any product and patients and clinicians should be reassured accordingly. It is anticipated that those patients on treatment with pre-filled Ig syringes will also be able to switch without any adverse consequences.

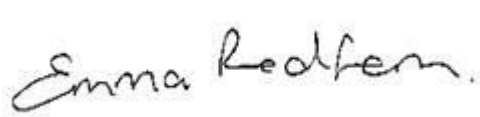
[2] Bethune C, Herriot R. Switching immunoglobulin products, what are the implications? Result of 2018 census of immunology centres. Clin Med (Lond) 2019; 19:201-204

For those rare occasions where patients may have difficulty in switching to the awarded Ig brands, sub-regional immunoglobulin assessment panels (SRIAPs) can provide advice. If a panel does not have sufficient expertise to decide on a particular clinical case, additional clinicians from relevant specialties can be invited to inform panel decisions.

The above information has been developed by the Immunoglobulin Oversight Group, with support from national clinical leaders across medical specialties including immunology and neurology.

Please cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the policy nationally.

With best wishes,



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