Switching immunoglobulin products under the new framework in 2025

Patient Information Sheet

Alongside the introduction of a new supply of plasma-derived medicines from UK donors, from 1 April 2025 NHS England will update the range of immunoglobulin products to be offered to NHS patients.

This new framework ensures the NHS can supply effective immunoglobulin to patients and ensures the best value for money for taxpayers. In the short term, this will mean some patients being switched to a new medicine – that could be a UK product. It's important for patients to be reassured that all patients, including those switching from one product to another, will be supplied with a safe, clinically equivalent medicine. For those rare patients who may have difficulty switching, clinicians will support patients to ensure they are still able to receive the treatment they need.

Professor Stephen Powis, National Medical Director, NHS England

The information shared below outlines these changes in the NHS and is intended to support patients who rely on immunoglobulin treatment and may be required to switch to a different immunoglobulin product.

Changes to the range of immunoglobulin products available on the NHS

In 2025, a new framework for the supply of immunoglobulins will come into effect. The framework will result in changes to the availability of some existing immunoglobulin brands and the introduction of several new brands.

- Some brands of immunoglobulins which have previously been commonly prescribed will no longer be available for routine use.
- Both intravenous and subcutaneous therapy are affected by this change.

Patients who are currently being treated with a brand of immunoglobulin that is no longer available will need to switch to an alternative brand.

The timing and arrangements for product switching will depend on local arrangements and will be discussed with patients by their clinical teams.

Launch of UK plasma-derived medicines

A new 10% intravenous immunoglobulin (IVIg) preparation, Gamten, manufactured from UK-donated 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 the same rigorous safety checks as other medicines. Patients should be reassured that Gamten exhibits the same efficacy as existing products manufactured from non-UK plasma.

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The introduction of Gamten is very important to help improve resilience of UK immunoglobulin supplies, reduce dependence on imported products and reduce the very high costs of treatment in the UK for many years to come. Further information can be found on the NHS Blood and Transplant website (www.nhsbt.nhs.uk) under the 'plasma for medicines' programme.

What this means for patients

If your clinical team need to switch you to a different brand of immunoglobulin, you should continue to have your current treatment until your clinical team has made arrangements with you to organise a product switch.

For patients switching to an alternative Intravenous (IV) Immunoglobulin product

If you need to move to an alternative brand of intravenous (IV) immunoglobulin, your product switch will take place in hospital. If you routinely have your immunoglobulin treatment in hospital the new product will be administered during a routine visit. If you usually administer IV immunoglobulin at home your clinical team will arrange for you to have an appointment in the hospital so that the first dose of the new product can be given under supervision. This is purely a precaution in order to ensure that the new product is well tolerated.

Your first infusions of a new immunoglobulin may need to be given at a slower rate. You may be offered paracetamol or an antihistamine before your first infusion of a new IV immunoglobulin. This may also be offered before the second and subsequent IV infusions if you have an infusion reaction. It is important your clinical team know about any infusion reactions so your treatment options can be discussed.

There is considerable experience in switching products and the vast majority of patients will be able to make the transition without significant adverse effects. During the last major switching exercise involving 30 immunology centres and 802 product switches in 2017, no patients experienced serious adverse effects.

As soon as you and your clinical team are happy that the new product is suitable for you, you will be able to return to your normal pattern of infusions.

For patients switching to an alternative Subcutaneous Immunoglobulin product

If you need to switch to an alternative subcutaneous immunoglobulin product your clinical team will discuss with you arrangements for making the switch. Your team will take into account whether additional training will be required (for example if your delivery method is changing from a pre-filled syringe to a standard subcutaneous delivery), they will also take into account any problems that you may have had with infusions in the past. In these cases, the product switch will be arranged in the hospital under supervision and with the availability of nursing support. In some cases, it may be acceptable for a switch to a different subcutaneous product to be undertaken at home.

The vast majority of patients will be able to switch to a new subcutaneous product without any adverse effects. For a small minority who may experience local skin irritation, your local clinical team will be able to help with managing skin reactions.

Frequently asked questions

What side effects may be experienced when switching?

Common side effects when switching intravenous immunoglobulin product may include headaches, chills and tiredness. Skin irritation may occur with subcutaneous immunoglobulin. You will be supervised at your appointment to monitor any side effects you may experience and to ensure that you can tolerate the product. Please ask your clinical team for further information when switching is being discussed.

Please remember that for patients treated with intravenous immunoglobulin, you will be supervised during your first infusion of a different product to ensure that you can tolerate the product and to monitor any side effects you may have. During this infusion you will be given advice, guidance and any training required for your new product.

For patients who are well-established on subcutaneous immunoglobulin, your clinical team will, based on an individualised discussion, decide whether a product switch to an alternative subcutaneous product can be safely undertaken at home. Should a supervised switch in hospital be felt to be in a patient's best interests, this will be undertaken by your clinical team.

What if I have reacted to product switches in the past?

If you have previously had significant reactions in the past, please liaise with your clinical team. A process exists to support a small number of patients on products that are not awarded on the NHS Framework. This process requires your clinician to formally apply to their Sub Regional Immunoglobulin Assessment Panel (SRIAP) for review.

I am prescribed pre-filled immunoglobulin syringes, how will I be supported to switch?

There are no brands awarded to the new NHS Framework that currently manufacture pre-filled syringes. Patients that require switching will be brought into their treatment centre and taught how to use alternative subcutaneous immunoglobulin products.

What if I am unable to tolerate the new product?

Evidence from previous large scale immunoglobulin switches has shown us that almost all patients will be able to tolerate a new product without any adverse effects. In the very rare situation when an individual is not able to tolerate any of the routinely available products the clinical team will be able to apply to their Sub Regional Immunoglobulin Assessment Panel (SRIAP) in order to use a product not routinely available on a named patient basis.

Applications for named patient use of non-awarded "reserve" products may also be made to the SRIAP if after dedicated training with a specialist nursing team an individual is not able to manage the switch from a subcutaneous pre-filled syringe to a standard injection technique.

How do I know my immunoglobulin product is safe and effective?

All licensed immunoglobulin products are subject to the same rigorous standards of testing and regulations. There are no functional differences in terms of safety and efficacy between equivalent licensed immunoglobulin products.