UK Plasma for Medicines – Patient FAQs (supplied by NHS England)

1. What is the UK Plasma for Medicines Programme

The UK Plasma for Medicines Programme is an initiative led by NHS England to provide fractionation services to produce plasma derived medicinal products (PDMPs) from plasma donated in the UK. The programme will make use of valuable UK resources, with all products to be provided for use within the UK. The Devolved Administrations for Northern Ireland, Scotland and Wales also have the option to participate.

As part of the programme, NHS England has led a procurement process to select a supplier to provide the fractionation services. The procurement was completed in July 2023 and Octapharma was appointed as sole fractionator.

2. Who are Octapharma?

Established in 1983, Octapharma are a pharmaceutical company based in Switzerland. They are one of the world's largest plasma fractionators and have been supplying the NHS with plasma-derived products for more than 30 years.

3. When will plasma derived medicinal products manufactured from UK plasma be available for patients?

The contract was awarded in August 2023, and the project is now in the mobilisation phase.

In August 2024, the MHRA completed the regulatory process, granting approval for the UK Plasma Master File and Marketing Authorisations for low (5%) and high (20%) strength albumin and 10% intravenous immunoglobulin (IVIg) products manufactured using UK plasma.

The next stages that need to be completed before treatments can be delivered to patients, include plasma release and shipment, fractionation, packaging, import and distribution.

If these stages all meet their expected timeframes, patients could begin to receive medicines derived from UK plasma in the first few months of 2025.

4. What products will be supplied using UK plasma?

The products to be manufactured will be low (5%) and high (20%) strength albumin, and 10% intravenous immunoglobulin (IVIg).

NHS England has already started working with clinicians, pharmacists, transfusion and nursing staff to plan for implementing products and aligning patient treatments. Further details of when specific products will be available will be provided as the next stages are reached.

5. What will be the differences between existing products and those made from UK plasma?

The granting of a product license means that medicinal products derived from UK plasma have had the same rigorous regulatory oversight as imported plasma products. For this reason, albumin and immunoglobulin products manufactured using UK plasma will, in functional terms, exhibit the same efficacy as existing products manufactured from global plasma.

While the brand names of the products will be new in the UK, they are manufactured in the same way as existing products.

6. Will I be offered products manufactured from UK plasma?

To ensure viability of UK plasma-derived products, clinicians will prioritise prescribing of these products to new patients and short-term treatments. For patients on existing long-term therapy, clinicians will be encouraged to have discussions with selected patients to facilitate switching. Switching necessitated by insufficient supply has previously been successfully implemented and patients should be reassured that any changes will be undertaken safely.

7. Are there any plans to expand the current plasma donation centres?

NHSBT is currently working to identify locations in England for future plasma or combined plasma / platelet / whole blood donor centres. This is a huge piece of work, the first part of which requires NHSBT to analyse population / demographic data, along with intelligence about donors and donor behaviour.

NHSBT hope that by the end of 2024 or early in 2025 they can identify locations and will then pursue their ambition of expanding the number of plasma donor centre across England.

In the meantime, they will continue to educate the public about plasma and its life-saving benefits, along with how they can donate plasma, or if not near a Plasma Donation Centre, how they can help by donating blood.

8. How can family members and friends can donate right now?

There is a growing need for the unique medicines made from plasma. NHSBT works in collaboration with patient groups to promote UK plasma, recruit more donors and educate other stakeholders on why self-sufficiency of UK plasma is essential.

People can donate plasma more often than they can donate blood, because the recovery time is shorter. For more information about Plasma donation or how to donate <u>www.nhsbt.nhs.uk/what-we-do/blood-services/plasma-donation/</u>.

People can also help by donating blood if a Plasma Donation Centre is not near them, because NHSBT will remove the plasma from the blood donation to freeze and use to make medicines.