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Immunoglobulin replacement therapy

Information for patients from the NHS and the UK Primary Immunodeficiency Network

5 November 2021

Why am I being asked to switch from my current immunoglobulin (IG) to another product?

Due to the COVID-19 pandemic, fewer people have been able to donate blood, resulting in less availability of IG products as these are extracted from donated blood. Internationally, demand for IG is increasing, further impacting on available supply of IG.

As a result, the supply of IG in the United Kingdom was reduced by an estimated 14% in 2021, with the impact persisting into the beginning of 2022. For the IG products where there is a decreased supply, patients may have to switch to another product.

The Department of Health and Social Care (DHSC), NHS England and NHS Improvement will continue to work closely with suppliers and hospitals to forward plan so that the impact of a reduction in IG supply is minimised wherever possible.

How will it be decided which patients are switched?

NHS England's Clinical Reference Group for Immunology and Allergy, which consists of consultant immunologists, specialist immunology organisations and patient representatives, has produced guidance for clinicians outlining the principles of safe switching.

Is switching compulsory for all patients?

No, some patients will already be on a product which is not experiencing changes in supply. However, if your product is one of those which is impacted by a decreased supply, then you may be required to switch products to ensure your treatment can continue.

The ultimate decision about which treatment is most appropriate for you will be taken by your clinical team, who should discuss the options available to you. Your wishes will be taken into

account in making this decision. You should be given advice on who you can contact if you have any further questions.

What will switching IG products involve for me?

Your consultant, in discussion with you, will help reach a decision about which product is most suitable for you based on your clinical need. Your treatment centre may bring you into the clinic for your first infusion when you are switching to a new IG product or will provide you with support in advance of the change. This is purely a precautionary measure since a small number of patients may experience mild to moderate side effects. As soon as you and your clinical team are happy that the new product is right for you, you will be able to return to your normal pattern of infusions.

What side effects may be experienced when switching?

The most common side effects when switching IG product include headaches, chills and tiredness. You will be provided with support from your clinical team to ensure that you can tolerate the product. Prior to your first infusion you will be provided with advice, guidance and any training required for your new product. Your clinical team are there to support you, so please ask if you require any further information on switching IG products.

How do I know my IG product is safe?

Every IG product purchased is required to be rigorously tested and prepared to ensure that they are safe in accordance with rules set by the regulatory bodies. The organisations which regulate therapies such as IG in the UK, Europe and America have very stringent quality requirements, which all products have to comply with.

Are all replacement IG products effective?

All IG products have to obtain a licence and will have gone through regulatory approval after they have proved that they have the right amount of IG in them and are effective.

How will the government and NHS make sure that there is always enough IG?

By having a range of IG products available, no single product should be dominant over any other in the treatment of patients who require long-term replacement IG therapy. Doctors should be able to prescribe from a choice of products.

What products are impacted?

If you are receiving one of the following products, you may need to be switched. This is not the case for everyone, so please speak to your clinical team.

In the UK, supply remains challenging and in some regions shortages may still occur. Individual patients may still be impacted. The below tables provide updated information on the products likely to be affected by this shortage:

Strength	Product	Level of supply shortage*
10% IVIg	Gamunex (10%)	Severe
10% IVIg	Privigen	Severe
5% IVIg	FlebogammaDIF (5%)	Moderate
SCIg	Hizentra	Severe
SCIg	Hizentra PFS	Minimal

^{*}Minimal <10% cf normal stock levels; moderate 10-30%; severe over 30%

Alternative products that you may be switched on to:

Strength	Product
10% IVIg	Intratect (10%)
10% IVIg	Iqymune
10% IVIg	Kiovig
10% IVIg	Panzyga
fSCIg	HyQvia
SCIg	Cutaquig
SCIg	Cuvitru
SCIg	Gammanorm

Other products where stock levels should require **no** switching:

Strength	Product
10% IVIg	Octagam 10%
10% IVIg	Gammaplex (10%)
5% IVIg	Octagam 5%
5% IVIg	Gammaplex (5%)
5% IVIg	Gammagard
5% IVIg	Intratect (5%)
SCIg	Subgam

Further information

This guidance has been supported by the UK Primary Immunodeficiency Network (UKPIN).

For further information please contact your NHS hospital trust.