Patient Information Leaflet

Immunoglobulin Replacement Therapy

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

In some cases, companies are ceasing to make a particular immunoglobulin (IG) product and have introduced an alternative product, so it is no longer available. Also some companies have decided not to continue to provide an IG product for the time being. In both of these instances, patients will have to switch to another product. In other cases it will be because there is a clinically equivalent product available at a lower cost.

Why is this happening now?

NHS England has recently negotiated a new agreement for the supply of IG products. During this process, it has worked with IG suppliers, patient groups and other stakeholders across the country in order to secure the amount of IG needed by the NHS in England, and at the best prices possible. Unfortunately, as well as some products being discontinued, the price of all IG products has risen since the last contract was negotiated. This means it is even more important that doctors and their patients work together to identify the IG which is clinically effective for their condition, at the lowest price. The medicines budget for NHS England is not unlimited and so to ensure all patients who have a clinical need for IG can be treated, clinicians and patients are working together to switch to a clinically equivalent product available at a lower cost.

Our commitment to you

NHS England fully understands the anxiety that long-term patients may experience at the thought of changing their IG product and recognises the need to maintain the supply of high quality IG products. The NHS recognises that supply issues have happened previously and it will continue to work closely with suppliers and hospitals to plan so that enough IG replacement therapy is available to long-term patients, such as those with an antibody deficiency (primary or secondary) or autoimmune neuropathy.

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 the optimum product and there may be some circumstances where a patient and their clinical team decide that it is not appropriate to switch. For example, if it has been difficult to find a product that suited a patient in the past, or if a patient has a significant reaction to a product when they attempt to switch. 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 during your routine clinic visit. Your wishes will be taken into account in making this decision and you will be given the time you need to consider the switch proposed. You should be given advice on who you can contact if you have any further questions. However if your product is one of those that has been discontinued you will be required to switch products to ensure your treatment can continue.

What will switching IG products involve for me?

As the changes take effect, your consultant, in discussion with you, will make decisions about which product is most suitable for you based on your clinical need. Your treatment centre should bring you into the clinic for your first infusion when you are switching to a new IG product. This is purely a precaution since a minority 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 supervised at your treatment centre 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 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.

How do I know my IG product is safe?

Every IG product purchased by the NHS 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. This includes meeting requirements for the prevention of blood-borne viruses. People who donate the blood from which plasma is taken and IG replacement therapy produced, are screened and tested for infections. Anyone who is carrying an infection will not be able to donate their blood. At every point of the production process of immunoglobulins, there are checks to make certain that there is nothing in it which could cause an infection.

Are all replacement IG products effective?

All IG products have to obtain a licence, after they have proved that they have the right amount of IG in them and are effective. The licence states what the IG product can be used for.

How will NHS England make sure that there is always enough IG?

Continuity of supply is hugely important and the NHS understands the concern that you, as a patient, may have about this. The NHS team that develops the contractual agreements works closely with hospitals to find out how much IG will be needed and with suppliers to ensure that they can supply enough to cover this need. 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 and NHS England is working to ensure that consultants can prescribe from a reasonable choice of products.

How long is the transition phase going to take?

Hospitals with a large group of patients may have over 100 patients who will need to be switched. NHS England does not under-estimate the challenge of safely switching existing patients who will need to be supervised and supported during this process and recognises the issues involved. It is likely that the process of switching may take six months and this will depend on the capacity of each centre.

What benefits to the NHS does switching IGs have?

When patients are being switched because an IG product is no longer available, there is no specific financial benefit to the NHS other than ensuring patients needing IG continue to receive IG therapy. However NHS England also needs to be able to show that it gets the best quality and value from the treatments provided to patients. Where there are alternative products available which are as effective as current treatments but available at a lower cost, it is important that the more cost-effective treatment is used. The cost of not making the switches to lower price clinically effective IG products is expected to be in excess of £20 million per year.

Produced by the Specialised Immunology and Allergy Clinical Reference Group in conjunction with UKPIPS Limited – October 2017