

Biologic and biosimilar treatment for skin conditions

What are biologics?

The word **biologics** means any product made from living things such as plants or animals. This includes lots of different types of products, such as vaccines or blood products.

Biologics used as skin treatments are medicines used for long term (chronic) skin conditions. These biologics are made from protein and are grown from animal, human, or micro-organic material in a laboratory.

In skin conditions some parts of the body's immune system can cause skin conditions by overreacting or working without need. Biologics work by stopping, or switching off, a small part of the immune system. Biologics do this by acting like substances naturally made in the body by the immune system. Sometimes biologics are referred to as **targeted immunosuppressants**.

What are biosimilars?

Biosimilars can be thought of as copies of Biologics. Making biologics is complex, and it is difficult to make exact copies. Research so far has shown that biosimilars work as well as biologics. Biosimilars have been used in Europe since 2006.

What skin conditions are treated with biologics or biosimilars?

The skin conditions treated by biologics and biosimilars include:

- Psoriasis
- Eczema
- Hidradenitis Suppurativa
- Urticaria

Can any other skin condition be treated with a biologic or biosimilar?

When a biologic or biosimilar is made, the drug company that makes it will name the skin conditions that these products can be used for, and how to use them. This is called the **drug license**.

Sometimes dermatologists (skin doctors) use biologics or biosimilars for skin conditions that the drug company did not make them for. This is called **off license use**. The dermatologist will have looked at the best evidence about treatments for this skin condition, before deciding to use them. Sometimes, for some people, the best treatment will be a biologic or biosimilar.

The dermatologist has to ask for funding to use biologics or biosimilars off license. This is called an Individual Funding Request (or IFR) and it is the Clinical Commissioning group (CCG) who decide if it will be funded.

Who can have biologics or biosimilars?

Usually, people with severe psoriasis or urticaria, or people with moderate to severe Hidradenitis Suppurativa or eczema, can have biologic or biosimilar treatment.

The National Institute for Health and Care Excellence (NICE) gives information to the NHS about when biologics or biosimilars should be used. This information can be looked at by anyone on the NICE website (see the end of the leaflet for the NICE website address).

NICE advises that, before an NHS doctor or dermatologist uses a biologic or biosimilar:

- Other treatments (usually tablets) need to have been tried first
- The skin condition needs to have had a big effect on someone's 'quality of life'
- It needs to be severe (or moderate to severe in Hidradenitis Suppurativa and eczema)

Dermatologists measure how severe skin conditions are by using a written tool. For example, psoriasis is measured by the PASI score; eczema by the EASI score; urticaria by the UAS7 score; and Hidradenitis Suppurativa by the Hurley or HS-PGA score. Photographs are often also used with Hidradenitis Suppurativa. The effect of a skin condition on someone's quality of life is measured with the DLQI tool: this is a questionnaire that patients fill in.

How are biologics and biosimilars prescribed and dispensed?

Your dermatologist or dermatology Clinical Nurse Specialist (CNS) will decide with you if a biologic or biosimilar is the right treatment for you. They will look at your skin condition using an assessment tool, to make sure that a biologic or biosimilar is the right thing for you according to NICE advice. They may need you to have screening tests to check the biologic or biosimilar is safe for you, such as blood tests and a chest X-ray.

The dermatologist will prescribe the biologic or biosimilar (if they know NICE will advise you should have them; if your screening tests are OK; and if you agree you want to have them).

The dermatologist or CNS will also complete a registration form. This is a form with your name, contact details, diagnosis, weight, and allergies. For the biologic called Infliximab, a registration form is not used.

The biologic or biosimilar prescription and registration form is sent through to the Brighton and Sussex University Hospital pharmacy team who forward it to a homecare company. On your biologic consent form you will be asked to consent for the passing of your details to the healthcare companies prior to us sharing them. The homecare company then log the prescription with their pharmacy and arrange a delivery of the drug to you. They will contact you using the details on the registration form to arrange a convenient day and time.

Examples of homecare companies are **Health Care at Home**, **HealthNet Homecare** and **Lloyds Pharmacy Homecare**.

Biologics and biosimilars need to be stored in a fridge: this is a normal domestic fridge that you keep your food in. Do not store the injections next to raw meat or fish. Avoid the injection boxes becoming frozen or wet. It is important that your fridge is in good working order as biologics/ biosimilars are expensive and should not be wasted because of a faulty fridge. If you have a problem with your fridge please contact your pharmacist, dermatologist or dermatology nurse to see if your injection can still be used.

The homecare company will also arrange a nurse from their company to show you how to inject yourself if you need to learn how to do this. They will also give you some advice about using biologics. For the biologic called Ustekinumab the nurse will arrange with you to come to your home to give the injection every time.

How are biologics or biosimilars given?

Most biologics or biosimilars are given as a small injection just under the skin. For most biologics or biosimilars you are taught how to give this injection yourself. A nurse comes to your home to show you how to self inject.

A nurse will come to your home and give you the injection if you are prescribed a biologic called Ustekinumab. Another biologic, called Infliximab, is given by a drip (infusion) in the hospital, usually every 6-8 weeks.

The biologic or biosimilar injections that you inject yourself with can come in a pre-filled syringe or in an easy to use pen-like device. How often you inject yourself depends on the biologic or biosimilar prescribed. Some can be as often as twice a week and some only once every twelve weeks.

How are biologics or biosimilars paid for?

Biologics and biosimilars are high cost drugs. The Clinical Commissioning Group (CCG) for your local area will pay for biologics or biosimilars if NICE advise that you should be prescribed them, or if an IFR (Individual Funding Request) is agreed. You do not have to pay any NHS prescription charges.

An IFR is used for rare and exceptional cases when the dermatologist thinks you should be prescribed a biologic or biosimilar and there is no NICE advice on it. The CCG can decide not to fund the biologic or biosimilar even if an IFR has been completed.

Are there any side effects with biologics and biosimilars?

There can be several possible side effects with biologics or biosimilars. Your dermatologist or dermatology CNS should advise you what they are. Your homecare nurse will also give you information on side effects. There is information on side effects in the patient information sheet that is dispensed with every biologic or biosimilar injection box.

The most serious side effect is an increased risk for severe infection and other infections. Your dermatologist or dermatology CNS will advise you on how to care for yourself to reduce the chance of getting a very severe infection (see leaflet: **Looking after yourself while on biologics or biosimilars**).

Biologics and biosimilars will carry a chance of an allergic reaction. This can be mild, such as redness and swelling around the injection site, to very severe, such as anaphylaxis (difficulty breathing, quickly feeling very unwell, and collapse). Anaphylaxis is not common.

More common side effects can include feeling tired, headaches, and chest infections. It is thought there could be some links with

cancer, but it is rare and most biologics/biosimilars do not list cancer as a known side effect.

Each biologic or biosimilar will have certain known side effects. It is important to let your Dermatologist or CNS know about any changes in your health so they can advise you.

How long are biologics or biosimilars prescribed for?

Biologics and biosimilars are prescribed for as long as they are needed. There are three main reasons why a Dermatologist or CNS may decide to not continue to prescribe them:

- If they do not work well. Sometimes they do not work well when first prescribed. Sometimes they work well to start with and then stop working at a later date. The assessment tools are used to see if the biologic or biosimilar is working. A different biologic or biosimilar can be prescribed for psoriasis sometimes, if the skin condition stays or becomes severe.
- If you develop side effects. The prescription is stopped if there is a severe health risk from the side effects, or if they affect the quality of your life more than the skin condition being treated.
- If you develop what is called a 'contraindication'. This means a condition in which it is not safe to prescribe the biologic or biosimilar. Examples of these are cancer, motor neurone disease or severe heart failure. These conditions are not a contraindication for all biologics or biosimilars. It is important that you tell your dermatologist or CNS about any changes in health because of this.

Where can I find more information about biologics and biosimilars?

Please ask your dermatologist or dermatology CNS if you have any questions.

The CNS can be contacted on **01273 665035** (answer phone available) or email bsuh.dermatology.treatment.queries@nhs.net. Using email is often the best way to get in contact with the CNS. Replies to phone calls or emails can take a few days.

Please ring the dermatology secretaries on **01273 665019** if your question is urgent or you do not get a reply from the nurse.

Other sources of information and support on biologics or biosimilars for skin conditions can be through the following web sites or phone numbers:

Psoriasis: www.psoriasis-association.org.uk
telephone: **01604 251620**

Psoriasis and Psoriatic arthritis: www.papaa.org
telephone: **01923 672837**

Eczema: www.eczema.org telephone: **020 7281 3553**

Hidradenitis Suppurativa: www.hstrust.org
telephone: **0300 123 0870**

Information on various treatments: www.bad.org.uk

Information on technology appraisals and NICE guidance:
www.nice.org.uk/guidance/published?type=apg,csg,cg,mpg,ph,sg,sc

This leaflet is intended for patients receiving care in Brighton & Hove or Haywards Heath

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Author: Alison Lowe

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