



**University
Hospitals Sussex**
NHS Foundation Trust

Biologics and biosimilar treatment for skin conditions

Department of Dermatology

Patient information

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.

Parts of the body's immune system can cause skin conditions in some people sometimes 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?

The skin conditions treated by biologics and biosimilars may 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 Integrated Care Boards (ICBs) 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 article 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.

You may need to have screening tests to check the biologic or biosimilar is safe for you, such as blood tests and a chest X-ray. You may need a blood test to screen for Tuberculosis (TB). This is called a T-spot and it needs to be taken in a hospital and not at a community clinic or GP surgery. Your doctor or nurse can advise you when it can be taken.

T- spots (blood tests for TB) can be taken at the following phlebotomy (blood) clinics to ensure they are sent to the laboratory on time:

Laboratories

Princess Royal Hospital

(Monday, Tuesday, Wednesday)

9:00 am to 11:30 am

Royal Sussex County Hospital

(Monday, Tuesday, Wednesday, Thursday)

9:00 am to 3:00 pm

St Richards Hospital

(Monday, Tuesday, Wednesday, Thursday)

9:00 am to 3:00 pm

Worthing Hospital

(Monday, Tuesday, Wednesday, Thursday)

9:00 am to 11:30 am

Details for phlebotomy services/booking blood tests are available on Services at Worthing, St Richard's and Southlands Hospital

<https://www.uhsussex.nhs.uk/services/blood-tests/services-at-worthing-st-richards-and-southlands-hospital/>

or call **01903 285149**.

Services at Royal Sussex County, Princess Royal and Alex Children's Hospital <https://www.uhsussex.nhs.uk/services/blood-tests/services-at-royal-sussex-county-princess-royal-and-alex-childrens-hospital/> or call **01444 441881 (extension 68199)**.

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 clinical nurse specialist (CNS) will also complete a registration form which is sent to a homecare company. This is a form with your name, contact details, diagnosis, weight, and if you have a carer then also their contact details. You will be asked to consent to your details being shared with the homecare company. Homecare companies include HealthNet and Sciencus.

The biologic or biosimilar prescription and registration form is sent through to the Hospital pharmacy team who forward it to a homecare company. The homecare company then log the prescription with their own 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.

How should I store my biologics and biosimilars?

Biologics and biosimilars need to be stored in a fridge: this is a normal domestic fridge that you keep your food in. Avoid the injection boxes becoming frozen or wet. Do not store them next to raw meat or fish.

How are biologics or biosimilars given?

Most biologics or biosimilars are given as a small injection just under the skin. A nurse from your homecare company will contact you to arrange a time to visit you at home. They will teach you or your carer how to inject and give you some advice on biologic treatment. The biologic or biosimilar injections 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.

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

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.

Common side effects can include feeling tired, headaches, and chest infections. Injecting can feel a little sore although some people may find it painful, and others feel no pain at all. It is best to advise your dermatology nurses or homecare nurse if you are finding injections painful, as they may be able to give you advice on how to reduce or stop any pain on injection.

A possible serious side effect is an increased risk for very severe infection. Your dermatologist or clinical nurse specialist 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 uncommon or rare. You should ring **999** if you are having difficulty breathing or suspect anaphylaxis.

It is thought there could be some links with cancer or allowing cancer to spread, but it is rare so most biologics or biosimilars do not list cancer as a known side effect.

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 later. The assessment tools are used to see if the biologic or biosimilar is working. A different biologic

or biosimilar can sometimes be prescribed 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.

The hospital may stop your prescription if you do not attend appointments (phone or face to face appointments) or have monitoring blood tests as required. Appointments and blood tests are usually 3 to 4 months after starting treatment and then at least every 6 months. Your dermatologists or clinical nurse specialist will advise you.

It is not considered safe to prescribe biologics or biosimilars without regular monitoring and sometimes the hospital pharmacy will prevent your prescription being dispensed if you do not attend appointments or have blood tests.

Where can I find more information about biologics and biosimilars?

Please ask your dermatologist or clinical nurse specialist if you have any questions.

For patients attending Southlands Hospital, Worthing Hospital or St Richards Hospital the dermatology nurses can be contacted on:

01903 205111 extension 83212

email queries to uhsussex.dermatologysec@nhs.net

Please ring **01903 205111 extension 83607** if your question is urgent or you do not get a reply from the nurse.

For patients attending The Princess Royal Hospital, The Brighton General Hospital, or the Royal Alexandra Children's Hospital, the dermatology clinicians can be contacted on:

01273 665035 (answer phone available)

Please ring the dermatology secretaries on **01273 665019**

if your question is urgent or you do not get a reply.

Replies to phone calls or emails can take a few days.

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

The Psoriasis Association

Telephone **01604 251620**

<https://www.psoriasis-association.org.uk/>

The Psoriasis and Psoriatic Arthritis Alliance

Telephone **01923 672837**

<https://www.papaa.org>

National Eczema Society

Telephone **020 7281 3553**

<https://www.eczema.org/>

The Hidradenitis Suppurativa Trust

Telephone **0300 123 0870**

<https://www.hstrust.org/>

Information on various treatments

Information:

British Association of Dermatologists

<https://www.bad.org.uk/pils/immunisation-recommendations-for-children-and-adult-patients-treated-with-immune-suppressing-medicines/>

Information:

Information on technology appraisals and NICE guidance

<https://www.nice.org.uk/>

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