September 2018

Best Value Biological Medicines

Frequently Asked Questions for Patients

Biological medicines

1) What is a biological medicine?

Biological medicines are made from living cells in a controlled way, rather than being built as synthetic chemicals like other medicines, such as tablets. Because they are complex medicines made from living cells, there will be some natural and slight differences between them. Biologicals were first used to treat people with serious illnesses in the UK over 20 years ago and they have improved life for millions of people worldwide.

2) What is a biosimilar?

A biosimilar medicine is a biological medicine which is highly similar to the originator ('reference') biological medicine already approved for use. You may have heard of generic medicines. For example, a supermarket own-brand ibuprofen is the generic version of Nurofen®. Generics are exact copies of the originator medicine and are relatively simple to copy and manufacture. The same idea applies to biosimilars, but it is not possible to make an exact copy of originator biological medicines due to their size and the complex way in which they are made.

3) Are biosimilars safe?

Biosimilars are thoroughly tested and analysed both in the laboratory and in clinical trials. The authorities which regulate and licence medicines in the UK and Europe are confident that biosimilar medicines are as safe and effective as the originator medicine. To be licensed by the European Medicines Agency, a biosimilar medicine must have shown it has no clinically meaningful differences from the originator biological medicine and to have met regulatory requirements in terms of quality, safety and efficacy compared to the originator medicine.

Where the National Institute for Health and Care Excellence (NICE) has recommended the originator biological medicine in its guidance, they have stated that the same guidance will normally apply to a biosimilar version of that medicine.

4) Why does the NHS wish to use biosimilar medicines?

Biosimilar medicines represent very good value for the NHS since they are often much less costly than the originator medicine. The NHS is asking clinical teams, in discussion with individual patients, to use more biosimilar medicines so that the money saved can be reinvested in new medicines and treatments. This means that

some patients will be invited to switch to a biosimilar medicine. In 2017-18, the NHS saved over £200 million by using more biosimilar medicines.

5) How can I be confident that a biosimilar medicine will work as well as the originator biological medicine for me?

Clinical studies have to be conducted with groups of people to show that the biosimilar medicine works just as well and is just as safe as the originator biological product. The decision to prescribe a biological medicine for an individual patient, whether an originator or biosimilar medicine, rests with the responsible clinician in consultation with the patient. We expect patients switching to a biosimilar to have the same response as if they had stayed on the originator biological medicine.

Adalimumab (Humira®)

Biosimilar versions of the originator biological medicine known as adalimumab (brand name Humira®) are likely to be available to NHS patients from December 2018 onwards.

Timescale:

6) When will biosimilars of adalimumab be available?

We expect the first biosimilar versions of adalimumab will be available in the NHS towards the end of 2018. More will become available over time.

It is important to note that there may be differences, for example in the pen used to inject the medicine and homecare arrangements associated with the biosimilars. Further information will be made available in due course.

Patient suitability:

7) Who is best suited to switch to a biosimilar?

Biosimilars are suitable for most patients who are currently receiving an originator biological medicine, even if they have only recently started to take that medicine. They may also be suitable for patients who have taken a different biosimilar in the past. If you have any questions about your suitability, these should be discussed with your clinical team at the hospital at your next appointment or by phone. If you are currently receiving Humira® and it is not working well for you, you should discuss this with your clinical team.

Process:

Each hospital will decide how it wishes to inform and work with patients in any switching process. NHS England has provided a template patient letter to help hospitals communicate with people.

8) How will I be informed if my hospital wants to use the new biosimilar medicines?

Generally, if a hospital wishes to use the new biosimilar medicines, your clinical team will contact you by letter. The letter should provide information about the new medicine(s) and give details of who you can contact if you have questions.

9) Do I have to switch to the biosimilar or can I stay on the originator biological product?

If you are asked to switch to a biosimilar, you should raise any questions with your clinical team. Each hospital should have alternative versions of adalimumab available for patients from December 2018 onwards. In discussion with your clinical team you can agree on the most appropriate medicine. In some cases, it may continue to be the originator biological medicine (Humira® in this case).

10) What are my rights when it comes to switching to a new medicine?

Any switching to a new medicine should involve a consultation between you and your clinical team and should take into account your needs, preferences and values as well as all the available clinical evidence. Shared decision making between clinical prescribers and patients will be vital if the best value, clinically effective medicines are to be used.

11) What is the process for patients to agree to a change to an adalimumab biosimilar?

Your clinical team will discuss your treatment with you. When you agree together the most appropriate medicine and associated homecare supplier they will document the decision. You may be asked to sign a new patient information form which documents that you have been fully informed. You will receive a copy of the form that you have signed.

12) What happens when my current prescription for Humira® runs out?

The clinical team at the hospital will be managing your prescription. If you are switching to a new treatment your clinical team will ask you to ensure that you use all supplies of Humira® first, before using the supply of the new treatment. They will also ensure that a supply of the new treatment is available before your existing supplies run out. The homecare company will be able to help you to work out the details of your prescription.

13) Would I need to go into hospital before I switch to a biosimilar of adalimumab?

There should be no need for you to go into your hospital department for a special visit. You or your health professional may wish to discuss the potential for switching to a biosimilar of adalimumab at your next scheduled clinic appointment or by phone.

14) What length of prescription will I have for the new medicine?

The length of prescription for the new medicine will be agreed between you and your clinical team, however it is likely to be for 3 or 6 months. The amount of medicines that are delivered to you is unlikely to change.

15) Will I need training to administer the new medicine and if so, who will arrange the training for me?

Your clinical team at the hospital and your homecare nursing support team will provide any training that is necessary. They will notify you if this is the case.

16) What happens if I change to a biosimilar of adalimumab but I have side effects?

We are not expecting any issues if you change to a biosimilar. If you develop a side effect, which can happen with any medicine, you should contact your clinical team at the hospital. You will then be able to talk to them about the best options for you. All suspected side effects should be reported via the Yellow Card Scheme.

17) Can I switch back to the originator biological medicine if I don't feel as well on the biosimilar?

Your clinical team at the hospital will discuss any issues with you and agree the best way forward if you are experiencing any problems. This could involve a switch back to the originator biological medicine or may involve a different product. It is important to be aware that the nature of your disease means that, each year, some people who have been stable on adalimumab will lose response to that medication and need a change of treatment, and this is to be expected.

18) Is there likely to be repeated switching between the different versions of adalimumab?

While repeated switching between biosimilar medicines is not recommended, in future, if more versions of adalimumab become available, hospitals may work with patients to switch to a different medicine if it is considered safe and effective.

<u>Homecare:</u>

19) Will I need to do anything different if I have a new homecare provider?

Your homecare provider may remain the same but if there are any changes, you will be fully informed before any changes are made.

Other:

20) Will any savings from switching patients to best value biological medicines be reinvested in the NHS?

It is not possible to 'ring-fence' savings but all NHS money is used to benefit patients. Switching to best value biological medicines has been shown to save the NHS many millions of pounds already which has been reinvested in patient care. In future, this will enable more patients to have access to these life-saving and life-enhancing treatments.

Information and support

The following patient organisations have contributed towards this patient information and support the content. Further information and support can be obtained from:

CROHN'S & COLITIS UK

Website: www.crohnsandcolitis.org.uk
Email: info@crohnsandcolitis.org.uk
Telephone: 0300 222 5700

NATIONAL ANKYLOSING SPONDYLITIS SOCIETY NASS UK

Website: https://nass.co.uk/
Email: admin@nass.co.uk
Telephone: 020 8741 1515

nras National Rheumatoid Arthritis Society

Website: www.nras.org.uk
Email: helpline@nras.org.uk
Telephone: 0800 298 7650

psoriasis association

Website: www.psoriasis-association.org.uk/
Email: mail@psoriasis-association.org.uk
Telephone: 01604 251 620