Therapeutics Advisory Group

Improving lives together
Norfolk and Waveney Integrated Care System

TAG Prescribing Guidance
Use of Biosimilars
May 2025 v3.0

Key Message

NICE advises that if NICE guidance exists for a biological medicine, the same guidance applies to the biosimilar.

NICE technology appraisal guidance often states: If more than one treatment is suitable, start treatment with the least expensive drug (considering administration costs, dose needed and product price per dose). This may vary because of differences in how the drugs are used and treatment schedules. Biosimilars will often be the least expensive option when compared to their reference medicines.

In Norfolk and Waveney, it is expected that in line with the commissioning framework for biological medicines[1]:

- where a biosimilar is available as the best value option for the patient, this should be chosen in preference to the originator (within licensed indications).
- when a biosimilar product becomes available suitable patients currently receiving the originator product should be considered following discussion for switch to biosimilar. Product choices, including changes to treatment, for individual patients should be made following assessment by the responsible clinician taking into account patient choice.

NHSE commissioning ambition is **100% of new patients** being on the best value biological medicine within **3 months following** product launch and **80% of existing patients** within **10 months**, or sooner if possible.

What are Biosimilars?[2],[3],[4]

A biosimilar medicine is a biological medicine which has been shown not to have any clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy. Where NICE has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar of that originator.

Use of biological medicines in clinical practice is well established and rapidly increasing for a broad range of acute and chronic conditions such as cancer, rheumatoid arthritis, ophthalmology and ulcerative colitis. Biosimilars of these often-high cost biological treatments provide better value options for patients and the NHS.

Why choose or switch to a Biosimilar?[5]

Increasing the use of best value biological and generic medicines, including biosimilar medicines where appropriate, is part of NHS England's Medicines Value Programme. This has been set up to improve health outcomes from medicines and ensure we are getting the best value from the NHS medicines bill. It aims to:

- Enable people to access treatment that is clinically effective, based on the latest scientific discovery, at as low a price as possible
- Support people to take their medicines as intended, with appropriate medicines reviews, so that they get the health outcomes they want.

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.

Prescribing Biosimilars[6,7,8]

The choice of whether to prescribe a biosimilar medicine or the originator biological medicine rests with the clinician in consultation with the patient. **Locally, we would expect a biosimilar to be considered as first-line option where available.**

- Treatment decisions should be made first on the basis of clinical judgement for individual patients with the initial selection of the most appropriate molecule based on clinical considerations and licensed indications and secondly on the basis of the overall value proposition offered by individual medicines.
- Biological medicines (including biosimilar medicines) must be **prescribed by brand name** and the brand name specified on the prescription should be dispensed in order to avoid inadvertent switching. Automatic substitution of brands at the point of dispensing is not appropriate for biological medicines.

If treatment decisions are not made following the above principles, the reasons why should be documented and made available to commissioners if required.

Interchangeability of biologic medications. **EU medicines regulatory network statement** and Medicines & Healthcare products Regulatory Agency (MHRA) November 2022 in their update of **Guidance on the licensing of biosimilar products** states:

Once authorised, a biosimilar product is considered to be interchangeable with their Reference Product (RP), which means a prescriber can choose the biosimilar medicine over the RP (or vice versa) and expect to achieve the same therapeutic effect. Likewise, a biosimilar product is considered to be interchangeable with another biosimilar to the same RP.
As a result of interchangeability, switching patients from one product to another (RP or biosimilar) has become clinical practice. The decision rests with the prescriber in consultation with the patient, in line with the principles of shared decision making; both need to be aware of the brand name of the product received.
All biological medicines, including biosimilars, should be prescribed by brand name.

Adverse Reactions

Biosimilar medicines are subject to a black triangle status (▼) at the time of initial authorisation. It is important to report suspected adverse reactions using the Yellow Card Scheme. For all biological medicines, adverse reaction reports should clearly state the brand name and the batch number of the suspected medicine.

In view of the subtle differences that are likely to exist between biosimilar products, even though the clinical effect of the products may be similar, and in view of the complexity of these molecules, it is very important that adverse drug reactions (ADRs) are properly assigned to the suspect product. Particular care needs to be taken when reporting ADRs associated with biosimilar products.

To ensure that any ADR that you report is assigned to the correct product, it is important that the product name rather than the substance name is used for reporting. For example, if reporting an ADR to Eprex, please report using the name Eprex rather than epoetin alpha.

Useful Resources and Further Reading

1. Commissioning framework for biological medicines – NHS England, April 2025
2. Biosimilar Medicines NHSE – Accessed May 2025
3. Understanding biological and biosimilar medicines – SPS, June 2022, last updated December 2023
4. Biosimilar products – MHRA – December 2014
5. Switching to Biosimilars – The Patients Association – accessed 26/10/2022
6. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU – Spetember 2022, updated April 2023
7. Guidance on the licensing of biosimilar products Updated February 2025
8. Guidance on prescribing – BNF – accessed 16/5/2025

Document history:

Version	Date	Author / Editor	Status	Comment
0.1	Feb 2023	Project Lead Pharmacist and TAG Lead Technician – NHS N+W	Draft	Draft presented for comment
1.0	Feb 2023	As above	Final	Updated following comments from senior team
2.0	Nov 2023	TAG Lead Technician, NWICB	Final	Review date updated ready for transfer to new KNoW website
3.0	May 2025	As above	Final	Routine update