NHS
Cheshire and Merseyside

Cheshire and Merseyside Area Prescribing Group Biosimilar Formulary Policy

February 2025

Summary

By default, all biosimilar brands of biologic drugs will be included in the Cheshire and Merseyside formulary alongside the originator brand where they are equivalent or lower cost to the originator brand without needing specific APG approval. The exception to this will be where a biosimilar is not dose equivalent or is more expensive compared to the originator, where it will be assessed by the relevant subgroup and recommendations presented to APG. If biosimilar indications differ to the originator biologic product this will be highlighted in the formulary entry.

A general message will be added to biosimilar entries in the formulary stating:

"Where biosimilar versions are included in the formulary, the least costly brand should be used where possible. Biologic drugs must be prescribed by brand name."

Biosimilar versions of biologic drugs are normally less costly than originator brands. Adding them to the formulary by default will expedite their uptake and reduce the APG's workload by eliminating the need for individual approvals. The ICB New QIPP Opportunities group and high-cost drugs working group will be informed as appropriate when all biosimilars are added to formulary. The first biosimilar of a drug will be taken to APG for noting.

Background

Biosimilar medicines are functionally (clinically) the same but not identical to the originator biologic product.

Biologic medicines are derived from a biological source. There is some variability between the different batches of the same biologic medicine. This is controlled and monitored during manufacturing to ensure that the characteristics of the medicine remain within defined and approved limits. When the patent of an original biologic medicine expires, other manufacturers can produce and market a version of it. This is known as a biosimilar medicine. Biosimilar medicines are similar to, but not the same as, the original biologic in molecular structure. However, they are developed in a way which allows the manufacturer to demonstrate that safety and efficacy is the same as that for the reference product.[1]

It is accepted in practice that biosimilars are therapeutically equivalent (pharmacodynamic and pharmacokinetic properties) and there are no clinically meaningful differences to the reference product. Consequently, they can be used interchangeably.

NHS England have issued guidance on the safe, effective and consistent use of biosimilar medicines.[2] This guidance recommends that biosimilars should be used because:

- They offer the same clinical effectiveness and safety as the reference products, but usually at substantially lower cost.
- Their approval is based on comprehensive comparability studies with the reference product, which is a well-established approach used to ensure any variability from manufacture does not affect the quality, safety and efficacy of biological medicines.

- They are interchangeable with the original biological reference product and with other biosimilar medicines when approved, which is reflected in government guidance on the licensing of biosimilar products* and supported by the joint EMA-HMA statement** on interchangeability.
- NICE has decided that normally all relevant published guidance that includes the originator molecule will apply to biosimilar medicinal products at the time it is made available for use in the NHS.[3]
- By increasing the cost effectiveness of medicines, biosimilar medicines enable increased patient access to treatment, and release funding for innovative treatments and improvements in pathways of care.
- As patents expire on originator biological medicines, increasing numbers of biosimilar medicines will become available in different therapeutic areas, and so the increased market competition between biological medicines has the potential to deliver significant savings to the NHS.

*UK Government Guidance on interchangeability[4]

"Once authorised, a biosimilar product is considered to be interchangeable with their Reference Medicinal Product (RMP), which means a prescriber can choose the biosimilar medicine over the RMP (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 RMP.

As a result of interchangeability, switching patients from one product to another (RMP 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[2]."

**EMA-HMA statement[5]

"Biosimilars approved in the EU are interchangeable.

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect.

HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product. Interchange should only take place after careful consideration of the approved conditions of use (i.e., consulting the most recent product information).

Decisions on how to implement interchangeability either through switching (under the control of the prescriber) and/or substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber, such as automatic substitution at the pharmacy level), are not within the remit of EMA and are managed by individual member states."

Suggested principles for biologic prescribing[2]

- Follow a shared decision-making approach.
- Make evidence-based decisions; choice of product should be based on value. Firstly considering clinical and patient specific considerations; secondly considering the cost of treatments to achieve desired defined patient outcomes.
- Prescribe by brand name.
- Prescribe for approved indications as in the Summary of Product Characteristics (SmPC), where commissioning policy has been established by the relevant governance process.
- Prescribe in line with information in the British National Formulary.

- Inform the patient of the biological medicine they are being prescribed and counsel them that the brand may be subject to change to a biosimilar product in the future.
- Review biological medicines prescriptions regularly, following SmPC guidance.

Initiating patients on a biologic medicine

- New patients prescribed a biologic medicine will be provided with the best value product available at that time.
- Patient counselling and any supplementary leaflet supplied should be specific to the biologic medicine (e.g. adalimumab, ranibizumab, rituximab) and not to a specific brand.
- Patients should be consented to receive the biologic medicine and informed as part of this process that the brand may change during their course of treatment.
- Biosimilar Medicines PIL should be provided to the patient when they are counselled

Switching patients between biosimilar medicine brands (secondary care)

- New biosimilar brands will be noted at Medicines Value Group (or similar) before being supplied for the first time.
- The Medicines Value team (or similar) will consult clinical teams in relation to new relevant biosimilars and will support implementation; this will involve updates to prescriptions and clinical governance documents, and when relevant, liaison with the pharmacy homecare team.
- Individual patient consent is not required for a brand change, but it is considered good practice to inform patients that the brand is changing.
- Biosimilar medicines may also be referred to as bioequivalent medicines and the terms are considered interchangeable. Patients may find the term bioequivalent more reassuring because it affirms that the clinical impact to them should be minimal.

Switching patients between biosimilar medicine brands (primary care)

- Specific information supporting switching to a biosimilar in primary care will normally be produced as part of the implementation guidance.

Exceptions

- Some patients may have exceptional clinical circumstances which require a specific treatment or brand. These exceptions should be noted during the implementation phase and followed up periodically.
- Some patient groups, where the least costly biosimilar brand may not be suitable due to device, excipient content, licensing or aseptic preparation considerations.

Biologic medicine guidelines

- New guidelines and updates to existing guidelines which refer to biologic medicines should use the name of the medicine not the brand with a clear statement that they should be prescribed by brand.

Legislation, regulations, standards and references

1. Specialist Pharmacy Service (2023) – The first stop for professional medicines advice - Understanding biological and biosimilar medicines. Accessed 28.05.2024
2. NHS England Guidance on Biosimilar Use. Available at: NHS England » What is a biosimilar medicine? Accessed 22.01.2024
3. NICE Biosimilar technologies: NICE position statement. Available at: Biosimilar technologies: NICE position statement | Technology appraisal guidance | NICE guidance | Our programmes | What we do | About | NICE Accessed 28.05.2024

4. MHRA Guidance on the licensing of biosimilar products (07 Nov 2022). Available at: Guidance on the licensing of biosimilar products - GOV.UK (www.gov.uk) Accessed 22.01.2024
5. EMA-HMA Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU (21 April 2023). Available at: statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines - EMA review following PROM endorsement (europa.eu) Accessed 22.01.2023

Acknowledgement: the inclusion of material from Liverpool University Hospitals NHSFT, Warrington & Halton Hospitals NHSFT and Wirral University Teaching Hospital NHSFT is acknowledged