Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) Biologics Policy v2.1

Introduction

Biological products are used to treat a range of conditions from cancer through to chronic inflammatory conditions such as rheumatoid arthritis and inflammatory bowel disease.[1] They are currently the largest cost and growth areas in the NHS medicines budget.[2] Many biological medicines are coming off patent and "biosimilars" are becoming available.[1] The adoption of biosimilars will help provide much needed savings to the NHS which may be utilised to further benefit patient care. As more and more biosimilars become available there is increased pressure to realise the potential savings by switching patients to the best-value biologic at pace. The aims of this policy are to ensure that GHNHSFT is utilising the most cost-effective biologics and to outline the governance processes to ensure patient safety and equity in their use. This is an overarching policy that applies to the prescribing of all biologics at GHNHSFT and is of relevance to medical, nursing, pharmacy and other key staff involved in any aspect of providing biosimilar medicines to patients.

Useful Definitions

Biologic (sometimes referred to as a biological medicine or biologicals) - refers to any medication that is produced using recombinant DNA technology or derived from a living source, such as bacteria or viruses, blood, tissues or living cells in culture. Compared to small drug molecules, biologic molecules are typically very large proteins with a complex structure.[2,3] Due to the complex nature of these molecules no two batches of the product are identical.[2] Batch to batch variation and manufacturing changes are overseen by the regulatory authorities; the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

The original biologic is known as the originator or biologic reference medicine.

The Biosimilar is a biological medicine highly similar to the reference medication and may only be marketed after the patent and period of exclusivity of the originator has expired. A biosimilar medicine must have 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.

The Best-Value Biologic is defined as the biologic drug that is the best-value for patients, in some circumstances this may be the originator product.

Choosing the Best-Value Biologic

In April 2023 the European Medicines Agency and the Heads of Medicines Agencies (HMA) issued a joint statement on interchangeability of biosimilar medicines:

Biosimilar medicines authorised in the EU can now be interchanged with their reference medicine or an equivalent biosimilar product.[4,5]

Where there is a choice of biologic, the following criteria will be considered when deciding which biologic is the best-value for the patient, for GHNHSFT and for the commissioner:

- Acquisition cost, including VAT when relevant
- Homecare Provision: local and regional contracts
- Supply Chain Resilience/Security
- Product licenses
- Patient Factors: Device and product range available including doses/strengths; provision of patient support / training available to patients; waste considerations
- If compounding is needed, consideration of complexity and any additional outsourcing costs
- Product stability
- Therapeutic drug monitoring and antibody testing requirements and costs
- Any other product specific factors

Trust Policy Statement:

- **Prescribing:** All biologics must be prescribed by brand name.
- **New patients:** New patients should be prescribed the best-value biologic. Details of biosimilars approved for use can be found on the biologics pathways or can be confirmed with the Biologics Pharmacist. When initiating patients on a biologic medicine, the prescriber must inform them that, over the course of their treatment, it is likely that the brand of medicine will change (as may the Homecare provider, where applicable).
- **Switch Programmes:** Where a better-value biosimilar becomes available (assessed using the above considerations) a switch programme of existing patients will be undertaken in consultation with the relevant specialties, either directly or via the Biologics Steering Group. Patients will be informed in advance. Switches will not be made on the basis of frequent price changes. A biosimilar-to-biosimilar switch may also be recommended as part of a strategy to manage adverse effects.
- **Pharmacovigilance and Governance:** All suspected adverse reactions to biologic medicines must be reported via the Yellow Card Scheme. Adverse reaction reports should clearly state the brand name and the batch number of the suspected medicine. If the biologic has black triangle status, then all suspected reactions to that drug must be reported.
- **Switching back to originators:** Where an originator-to-biosimilar switch has been undertaken, any requests for individual patients to revert back to the originator should be made to the Biologics Pharmacist in the first instance, along with full clinical details and relevant treatment timelines. Switching to an alternative biosimilar (where available) would be considered prior to returning to the originator. The Drug &Therapeutics Committee may be asked to support the decision making process.
- **Substitution:** Automatic substitution between biosimilars by Pharmacy is not permitted. Where a supply problem occurs with the prescribed biologic, switching to the next best-value biosimilar will be discussed with the prescriber and the patient will be informed.

This policy should be used in conjunction with the following treatment pathways:

- IBD Biologic Pathway
- Biologics Severe RA Pathway
- Psoriatic arthritis Biologic Pathway
- Psoriasis Biologics Pathway
- Biologics pathway for Adult Axial Spondyloarthritis and non-radiographic Axial Spondyloarthritis Pathway
- **Other relevant clinical pathways that are subsequently added**

References:

1. Commissioning framework for biological medicines (including biosimilar medicines). NHS England 2017. biosimilar-medicines-commissioning-framework.pdf (england.nhs.uk) [Last accessed 29/09/2023]
2. 'Biosimilar Medicines' NHS England (2023) *NHS England » Biosimilar medicines*. [Last accessed 29/09/2023]
3. Standards for biological medicines - understanding them and how they make a difference - GOV.UK (www.gov.uk) [Last accessed 29/09/2023]
4. 'What is a biosimilar medicine' NHS England (2023) NHS England » What is a biosimilar medicine? [Last accessed 29/09/2023]
5. European Pharmaceutical Review. EMA approves biosimilar interchangeability in EU. EMA approves biosimilar interchangeability in EU (europeanpharmaceuticalreview.com) [Last accessed 29/09/2023]

Document Change Control				
Date of Version	Version Number	Lead for revisions	Type of Revision	Description of Revision
May 2021	1.0	Farah Longerstaey – Biologics Pharmacist	Major	New Policy
September 2023	2.0	Farah Longerstaey – Biologics Pharmacist	Moderate	Changes to layout. EMA approval of Interchangeability. Criteria when choosing best value biologic. Removal of use of biologics policy variation notification form. Prescribers should advise patients that the brand of their biologic may change over time and that they should not expect to remain on the same brand throughout their treatment. Added this table.
March 2025	2.1	Marcus Jones – Formulary Pharmacist Leela Terry – Biologics Pharmacist	Moderate	Trust Policy Statement reworded for clarity.