Gloucestershire Hospitals
NHS Foundation Trust

Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) Biologics Policy v2.0 (October 2023)

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 cost 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 aim of this policy is to ensure that GHNHSFT is utilising the most cost-effective and best value biologic. This includes the adoption of biosimilars at pace and 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 aspects 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 is 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 likely to be identical.[2] Batch to batch variations and manufacturing changes are overseen by the regulatory authorities, 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.

Produced by Farah Longerstaey
Approved by the Drug & Therapeutics Committee, 10/10/2023
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Choosing the best value biologic

Increasingly more and more biosimilars are becoming available. In April 2023 the European Medicines Agency and the Heads of Medicines Agencies (HMA) issued a joint statement on interchangeability; 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 biologics 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 removal and other product specific considerations
- If compounding is needed consider 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:

Where a biosimilar has been approved for use and is more cost-effective than the originator the biosimilar should be the product of choice. The decision to use the biosimilar will be made in accordance with national guidance such as NICE TAGs, NHS England advice and after discussion with the relevant clinical groups.

- **New patients:** When initiating patients on biologics prescribers should advise patients that they may receive different brands over the course of their treatment. Where a biosimilar medication is approved for use, it is Trust policy that this preparation must be used in preference to originators for all new patients started on that therapy. Details of biosimilars approved for use can be found on the biologics pathways or can be confirmed with the Biologics Pharmacist.

- **Switch Programmes:** For existing patients the use of the biosimilar will be discussed with the relevant specialties, either directly or via the Biologics Steering Group and an implementation plan and suitable time frames will be agreed.

- **Biosimilar to biosimilar switch:** Where more than one biosimilar is available the most cost-effective biosimilar should be considered; any such switches will be discussed with the specialty and an implementation plan agreed. 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.

- **Substitution,** the practice of dispensing one medicine instead of another equivalent medicine at the pharmacy level without consulting the prescriber, is not permitted for any biological medicine (including biosimilars).[4,5]

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 developed**

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 originator:

The Biologics Policy Variance Notification form has been removed from use. If a prescriber chooses to prescribe an originator where a biosimilar has been approved for use by the Biologics Steering Group then the decision to continue the patient on the originator will be reviewed and agreed by the Drug &Therapeutics Committee. This is to ensure patient equity where biosimilars are available and prevent financial loss to GHNHSFT.

Prescribing and Dispensing:

All biologics must be prescribed by **brand name**. Substitution of a biologics is not permitted without the prescriber's prior knowledge. At the point of dispensing all biologics should be booked out to the medical consultant and **not** the ward or unit.

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	Added this table. 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 the course of their treatment. The decision to continue a patient on originator therapy (if prescribed after April 2023) will need to be discussed with the prescriber and if needed approved by the Drug & Therapeutics Lead.
Next update due October 2025				