Policy for adoption and prescribing of Biosimilars in Acute Care settings

Title	**Policy for the adoption and prescribing of biosimilars in Acute Care settings**
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Publication Date	1st issued Feb2019 (ver1) reviewed Dec 2021 (ver2) for review Dec 2024
Target Audience	Manx Care staff involved in the use of biologic medicines
Description	Describes the process for selection, approval, adoption, prescribing and ongoing review of the use of biosimilars in acute care
Changes	Manx Care format; References added; duties and responsibilities includes medical director, chief pharmacist and Care Group managers; governance reflects Manx Care structure; added when starting patient to introduce that in future may use biosimilar product; Appendix 1 – Switch Implementation plan pro forma
Cross Reference	
Superseded Documents	**Version 1**

1. Purpose of the Policy:

The document provides guidance for the adoption and use of biosimilar drugs in all therapy areas. The policy is seen as an overarching policy which will link into specific SOPs used on wards and in departments for individual biosimilar medicines.

Summary:

What are biologics?

Medicines that are made or derived from a biological source and as such are complex with inherent variability in their structure. As biological medicines are derived from living cells or organisms there is always a small degree of variability in the manufacturing process, thus biologics may show a degree of variation from batch to batch of the product. This is also the case for biosimilars.

What are biosimilars?

Biosimilars are highly similar to the biological originator medicine (already licensed), shown by non-clinical studies (*in vivo and in vitro analysis)* and clinical studies to show no clinically meaningful differences from the originator biological medicine in relation to quality, safety and efficacy.

To note: Biosimilar medicines are **not** considered as generic to the originator biological

medicines, the two are “similar” and not identical. However in relation to licensing they have met stringent regulatory requirements based on a comprehensive scientific comparability exercise such that they do not have any clinically meaningful differences from the reference medicines in terms of quality, safety and efficacy.

2. Table of Contents

Section

Section

1. Background & scope

The policy has been developed in line with NHS England Commissioning framework for biosimilar medicines[1]; Cancer Vanguard Guidance[2]; and BOPA position statement on biosimilars[3].

The use of biosimilars has increased substantially as patents of originator biologics expire. The adoption of biosimilars provides savings to the NHS, which may be utilised to further benefit patient care. Although the introduction of biosimilars should not be driven purely by financial considerations, it is sensible to use biosimilars where it is clinically appropriate. The purpose of the policy is to aid this early adoption process in order that the benefits can be realised early. The use of biosimilars will not alter the care provided to patients, with the patient seeing no change in the treatment experience.

The policy is overarching and should be used in conjunction with individual SOPs developed for the introduction and use of specific biosimilars in acute care settings.

2. Definitions:

Biological medicine – medicine derived from living cells or organisms, consisting of large highly complex molecular entities which may be difficult to characterise.

Biosimilar medicine – a biological product that is highly similar but not identical, to the licensed originator biological medicine and shows no clinically meaningful difference in terms of quality safety and efficacy.

Generic medicine - is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

Extrapolation – the decision by the Regulator whether to extend the efficacy and safety data from an indication for which a biosimilar has been clinically tested to other conditions for which the reference product is approved.

Interchangeability – the medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient on the initiative or with the agreement of the prescriber.

3. Duties & Responsibilities

This policy applies to medical, nursing, pharmacy and other key staff involved in any aspect of providing biological or biosimilar medicines to patients.

3.1 Chief Pharmacist

a) Responsible for the cost-effective use of biosimilars and the governance framework for these medicines.
b) Responsible for ensuring accurate high cost drug data is supplied to treasury for invoicing
c) Ensure that Pharmacy staff comply with this policy.

3.2 Medical Director

a) Support the cost-effective use of biosimilars.
b) Ensure that prescribers comply with this policy.

3.3 Care Group Clinical Leads and Managers

a) Support the introduction and use of biosimilars.

3.4 Lead Consultant (and clinical team)

a) Support the proposed biosimilar introduction, in the agreed patient groups and endorse the submission on behalf of the clinical unit.
b) Carry out initial patient consultation with patients in lead up to biosimilar medicine adoption. This may also be done by specialist nurses and pharmacists.
c) Support the continued use of cost-effective biosimilars.
d) When commencing patients on biologic medicines introduce the possibility that at a future date a biosimilar medicine may be selected for their treatment if one becomes available, thereby facilitating future transitions.

3.5 Biologics Pharmacist

a) Co-ordinate and manage an effective implementation programme.
b) Co-ordinate specialist and/or unit pharmacists to be able to provide information on biosimilars to Healthcare professionals (HCP) and patients and carers.
c) Provide required details for the management of prescribing systems and aseptic work sheets (if required).
d) Report on uptake of biosimilars following their introduction and the associated financial savings realised from adoption.
e) Report ongoing use of biosimilar and originator to relevant care group leads and consultant teams.
f) Liase with the pharmacy procurement staff on the procurement of the biosimilar and originator.
g) If the biosimilar is managed via Homecare service, co-ordination with the relevant homecare provider.

3.6 Specialist nurses and specialist pharmacists (who have direct involvement with relevant patients)

a) Carry out initial consultation with patients in lead up to biosimilar medicine adoption
b) Be available to answer patient questions and provide information regarding biosimilar medicines to patients and other HCPs should it be required.

4. Introduction of a new biosimilar

4.1 Considerations to be taken prior to adoption

Introduction of a switch to a biosimilar medicine needs to be pre-planned so all stakeholders are well prepared and additional activity associated with the introduction is minimised (see Appendix 1 for pro forma).

4.2 Internal governance requirements

This policy document is ratified by the Integrated Medicines Optimisation Group (IMOG), with individual biosimilar adoption approved by the Formulary and Prescribing Guidelines group, when established.

4.3 Informing and involving patients in introduction

There will be a speciality decision on their appropriate mechanism to inform patients once the biosimilar has been approved and adopted. How this is carried out will be dependent on the

biological medicine in question e.g. how often it is prescribed, in what setting it is given (IP, OP, or Homecare), and how the clinics are set up.

For new patients initiating on biologics this is not a change but a recommended treatment choice by the clinician.

Possible methods for informing and involving patients include:

- one to one patient consultation by trained clinician, nurse or pharmacist in lead up to the adoption.
- The utilisation of a patient information leaflet with Q&A section and contact details of relevant HCP if patients wish to discuss further
- A patient letter to be sent out explaining:
    1. the planned change
    2. how the decision has been undertaken
    3. safety has not been affected and for the majority of patients there is no impact on clinical efficacy'
    4. that significant financial benefits will be achieved for Manx Care.

The method used will depend on the resources and numbers of patients in each department affected by the introduction of biosimilars

4.4 Prescribing requirements & interchangeability

Biologics (originator or biosimilar) medicines need to be prescribed by brand name for example, "International Non-proprietary Name (INN) (Brand name®)" i.e. "Filgrastim (Zarzio®)".

Prescribing by brand reduces the risk of one biosimilar brand being substituted for another without a review and due consideration by the prescribing clinician/team. This does not mean that a biosimilar medicine cannot be changed from one brand to another; however this needs to be done as part of a clinically led management process.

Biosimilars are interchangeable. Interchangeability is the practice of changing one medicine for another that is expected to achieve the same clinical effect. The decision to interchange is one that again requires review and due consideration by the prescribing clinician/team and approval via the Formulary and Prescribing Guidelines Group.

New patients commencing any biological product should be introduced to the possibility that at a future date a biosimilar product may be selected for their treatment if one becomes available, thereby enabling future treatment transitions through increasing patient awareness

Batch number must also be recorded when medicines are dispensed and administered as with all biologic medicines in case of requirement to report an ADR.

4.5 IT readiness

If the originator biological medicine and biosimilar are both to continue to be used at the hospital (e.g. in change over period or for different indications) the pharmacy and electronic prescribing and medicines administration systems clearly need to differentiate between the two (i.e. is brand name in the profile name).

4.6 Patient Registration and consultation/ shared decision making

Following the adoption of a biosimilar it will be a speciality decision on how patients need to be consulted if a biosimilar change is to take place mid treatment. All new patients will follow the standard consent process as with the reference originator medicine.

4.7 Pharmacovigilance and monitoring
All biological medicines require additional monitoring for safety and any suspected adverse drug reactions should be reported using the MHRA yellow card scheme, with the provision of the brand and the batch number. N.B. These are all black triangle drugs.

4.8 Clinical outcomes monitoring
As with all biologic medicines collection of clinical outcomes should take place, and after an agreed time period assessed to ensure quality of outcomes. This is the responsibility of the clinical team.

4.9 Monitoring patient satisfaction.
A patient experience survey in the form of a short questionnaire may be carried out pre and post implementation of biosimilar to ensure that the patient experience has not been negatively impacted following the introduction of the biosimilar medicine. The finding may also assist in supporting future biosimilar adoptions if shared with patients and MDTs.

4.10 Pharmacy Purchasing requirements
Close liaison with regional procurement leads should take place, in order to keep up to date with new biosimilar medicines:
- anticipated launch dates
- planned tenders and timelines
- product specifications
- pricing information

4.11 Tracking of savings and biosimilar adoption rate
Following implementation of a biosimilar medicine tracking of:

- the drug acquisition cost savings should be monitored and recorded on a monthly basis to calculate savings achieved from the change
- Breakdown of:
  - number of new patients on the biosimilar
  - number of patients changed to the biosimilar medicine part-way through current
  - treatment, for the approved indication
  - reasons identified for those patients that have not been changed from the originator
  - reasons identified for any patients that change from the biosimilar back to the originator

4.12 Evaluation of Service impact on the hospital of adopting a biosimilar
Data should be collected throughout the change process in order to ascertain the resource impact of adopting the biosimilar in both new and mid-treatment change patients.

References

1. NHS England Commissioning framework for biological medicines (Accessed 29.11.21) https://www.england.nhs.uk/publication/commissioning-framework-for-biological-medicines/#:~:text=The%20purpose%20of%20this%20document,biological%20medicines%2C%20including%20biosimilar%20medicines.
2. The Cancer Vanguard – Biosimilar adoption (Accessed 29.11.21) https://cancervanguard.nhs.uk/biosimilars-adoption/

3. BOPA – Biosimilar Monoclonal Antibody position statement
4. Biosimilar Medicines Policy (Apr2018) – University Hospitals Bristol NHS Foundation Trust
5. Biosimilar Prescribing Policy version 2 – Royal Cornwall Hospitals NHS Trust.

Appendix 1 – Biosimilar Implementation Plan Pro Forma

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Originator: _____

Biosimilar(s): _____

Condition(s)	Speciality	Care Group	Consultant	Clinical Nurse Specialist	Pharmacist

	Originator	Biosimilar (s)
Licensed indication		
No of Pts currently on treatment (including off island clinical trials)		
Current drug cost -Per dose -Per month per patient -Per month for patient population (estimated)		
Current delivery model		
Details of any delivery model change following implementation		
Service delivery costs		
Costs associated with additional stock storage + risk minimisation		
Shelf life		
Stability once reconstituted		
Predicted wastage		
Dose Banding		
Counselling points prior to implementation		
Preparation of patient materials and education		
Clerking pt		
Chair time +/or monitoring		

Reporting resources		
Costs associated with prescribing +/or administration		
Preparation + validation of worksheets		
Preparation for formulary application		
Development of biosimilar SOP		
Development of pt and staff education material		
Ongoing staff education		
Updating electronic prescribing and dispensing software		
Costs associated with changes to prescribing activity		
Patient satisfaction survey		

Staff Consulted	
Patient Information Strategy	
Patient Outcome monitoring	
Enablers required	
Predicted annual cost saving	
Data Collecting and reporting	

Comments:

◯ IMOG – tabled + minute outcome
◯ relevant guidelines/policies updated
◯ New HAP (Ascribe) files added
◯ Stocks of originator reduced, re-order levels amended
◯ Homecare providers informed