Royal Cornwall Hospitals
NHS Trust

Biosimilar Prescribing Policy

V3.0

June 2024

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. Biological monoclonal antibodies are widely used across the NHS to treat patients with very effective results. These are important, clinically effective medicines which can significantly impact on a patient's disease. The top 10 medicines prescribed in hospitals by spend include some biological products which are used to treat a range of conditions from cancer through to chronic inflammatory conditions such as rheumatoid arthritis and inflammatory bowel disease.

1.2. Many biological medicines have come off patent and "biosimilars" are now in use in the NHS, including infliximab, rituximab, etanercept and adalimumab. These medicines are highly similar to other biological medicines already licensed for use but are typically much cheaper than the originator products. This competition has provided the NHS with an opportunity to save hundreds of millions of pounds and may increase access to these important medicines. NHS has had an aim that at least 90% of new patients will be prescribed the best value biological medicine within 3 months of launch of a biosimilar medicine, and at least 80% of existing patients within 12 months, or sooner if possible.

1.3. Biosimilars are delivered either intravenously or via subcutaneous injection and a change from one method to another would impact on the ease of switching. It is also arguably easier to switch a patient on IV drugs delivered in a hospital setting than those patients whose subcutaneous medication is provided in the community via homecare services. Some biologics pharmaceutical companies provide support services to patients. In general, these additional services are 'bundled' in with the cost of the medicine, but ‘'unbundled' services may require additional costings to be factored in.

1.4. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

2.1. A rate limiting step in switching patients to biosimilar has been the need to advise and consent patients for such a forthcoming switch. This has typically been done by letter to the patient advising them that at their next infusion / prescription they will be receiving the biosimilar and giving them the opportunity to raise concerns.

2.2. This policy stipulates that patients are advised, either at the commencement of their treatment or during their existing treatment with a biologic medicine, that the choice of biosimilar drug may change over time. The homecare consent form contains wording that there may be a change to a different brand of the same medicine with appropriate notification. The patient will receive a letter confirming such a switch prior to it occurring. Pharmacy, after consultation and agreement with the relevant specialities, and taking account of any commissioning stance (NHS England or Cornwall and IoS ICB) will choose the best-value product based on price and other appropriate factors, noting that biosimilar medicines should be prescribed by brand and generic name.

2.3. There must be clear education and clinical engagement ahead of a new biosimilar going to market to prepare for successful whole scale switching.

2.4. Ultimately patients may have to switch between more than one biosimilar as both prices and contracts change over time. Patients must be notified of each change, but consent only needs to be sought at the point of the initial move to a biosimilar, as patients are to be informed that at some stage in the future that such a switch could occur (see also 6.4).

3. Scope

This policy applies to prescribing of biosimilars at the Royal Cornwall Hospitals NHS Trust, and is of relevance to medical, nursing, pharmacy staff and other key staff involved in any aspects of providing biosimilar medicines to patients.

4. Definitions / Glossary

4.1. Biological medicines are derived from living cells or organisms and consist of large, highly complex molecular entities.

4.2. A biosimilar medicine is a biological medicine which is highly similar to another biological medicine already licensed for use (referred to as an ‘originator medicine’ or ‘reference product’).

4.3. The Medicines and Health products Regulatory Agency (MHRA) is the UK’s medicines regulator responsible for the licensing of medicines. A detailed head-to-head comparison of the biosimilar medicine with its reference product is needed to show that there are no clinically significant differences between them, and previously proven safety and efficacy of the reference product also apply to the biosimilar. Once the MHRA authorized a product as a biosimilar, the prescriber should consider it therapeutically equivalent in these authorized indications; this is supported by real-world data. However, biosimilar medicines are not the same as generic medicines, which contain simpler chemical structures and whose active ingredients are identical in terms of molecular structure to their reference medicines.

4.4. Biosimilars do not require a separate or additional health technology appraisal (TA) as a positive NICE TA recommendation for the reference product applies to the biosimilar.

5. Ownership and Responsibilities

This policy has been written in conjunction with the relevant clinical teams and has been discussed initially at the Cornwall Area Prescribing Committee. It reflects the views of the NHS South West Clinical Senate Council: Biosimilars Recommendations and NHS England.

6. Standards and Practice

6.1. A biosimilar medicine will be deemed to be the default first choice product when a biologic medicine is considered, recognising that some patients, for reasons of tolerability, or need to use a specific device, may have to be prescribed the originator brand or an alternative biosimilar to the chosen default option.

6.2. The choice of default biosimilar will be made by pharmacy and the relevant clinical team taking account of licensing, price, and other appropriate factors such as stability, route, and duration of administration.

6.3. Where possible existing patients on a biologic would be informed of the switch in a consultation where the appropriateness of their prescription was also reviewed, with access to clinical support for follow-up questions. Alternatively, a letter / patient information leaflet could be used to communicate this change. Virtual or telephone clinics may also be used.

6.4. 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. This advice could be delivered by letter or information leaflet.

6.5. Prescribing should be done by brand and generic name for traceability of drugs and as required by the MHRA.

6.6. All biological medicines require additional monitoring for safety and any suspected adverse drug should be reported using the MHRA yellow card scheme, with the provision of the brand and the batch number.

7. Dissemination and Implementation

7.1. This policy will be disseminated to all Divisional Directors and Specialty Leads and Clinical Governance leads to ensure implementation in their areas.

7.2. Director of Pharmacy to ensure all pharmacists and pharmacy technicians are aware of the processes.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Safety incidents arising from switching patient's treatment. Patient satisfaction with switches.
Lead	Pharmacy lead involved in homecare / biosimilar use, relevant clinical team governance lead.
Tool	Datix will be used to identify clinical incidents. Patient complaints about the switch process
Frequency	The policy will be monitored every three years, or sooner as clinical incidents dictate.
Reporting arrangements	Clinical incidents on Datix / complaints will be reported to Pharmacy and the clinical team and will also be reported to the Medication Practice Committee.

Information Category	Detail of process and methodology for monitoring compliance
Acting on recommendations and Lead(s)	Actions from incident reports will be at a local level and may also result in broader actions
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned immediately. A lead member of the team(s) will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

9. Updating and Review

This document will be reviewed every 3 years by the Medicine Practice Committee (MPC).

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Biosimilar Prescribing Policy V3.0
This document replaces (exact title of previous version):	Biosimilar prescribing policy V2.0
Date Issued / Approved:	24 May 2024
Date Valid From:	June 2024
Date Valid To:	June 2027
Author / Owner:	Mike Wilcock, Head of Prescribing Support Unit, Pharmacy.
Contact details:	01872 253548
Brief summary of contents:	Description of how biologic biosimilars are to be used.
Suggested Keywords:	Prescribing, Pharmacy.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** Yes
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Medication Practice Committee
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	None
Related Documents:	NHS South West Clinical Senate Council: Biosimilars Recommendations. NHS England. What is a biosimilar medicine. February 2023.
Training Need Identified:	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
February 2017	V1.1	Initial Issue.	Mike Wilcock, Pharmacy
2021	V2.0	Minor amendments and transposed to new Trust template.	Mike Wilcock, Pharmacy
May 2024	V3.0	Full review and minor amendments.	Mike Wilcock, Head of Prescribing Support Unit, Pharmacy.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Biosimilar Prescribing Policy V3.0
Department and Service Area:	Pharmacy, Clinical Support.
Is this a new or existing document?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Mike Wilcock, Head of Prescribing Support Unit, Pharmacy.
Contact details:	01872 253548

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Healthcare professionals and its impact on patients.
2. Policy Objectives	To ensure the safe implementation of biosimilars.
3. Policy Intended Outcomes	Patient safety, efficiency.
4. How will you measure each outcome?	Incidence reports – Datix, complaints, drug spend, benchmarking with other Trusts.
5. Who is intended to benefit from the policy?	Patients under the care of RCHT.
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: Yes • External organisations: No

Information Category	Detailed Information
	• Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Medication Practice Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	

Protected Characteristic	(Yes or No)	Rationale
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Mike Wilcock, Head of Prescribing Support Unit, Pharmacy.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis