Biosimilar prescribing policy

V1.1

February 2018

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1. Introduction

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. Six of the top 10 medicines prescribed in hospitals by spend are biological products and are used to treat a range of conditions from cancer through to chronic inflammatory conditions such as rheumatoid arthritis and inflammatory bowel disease.

Many biological medicines are coming off patent and "biosimilars" are becoming available. Common biosimilars already in use in the NHS include infliximab (2015), rituximab (2016) and etanercept (2017).These medicines are highly similar to other biological medicines already licensed for use but are typically much cheaper than the originator products. This competition provides the NHS with an opportunity to save hundreds of millions of pounds, and may increase access to these important medicines. There is the potential to realise savings of at least £200-300m per year by 2020/21 if the NHS embraces the use of best value biological medicines in a proactive, systematic, and safe way. NHS aim is 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.

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.

2. Purpose of this Policy/Procedure

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.

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. Pharmacy, after consultation and agreement with the relevant specialities, and taking account of any commissioning stance (NHS England or NHS Kernow CCG) 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.

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

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.

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

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

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').

To be licensed by the European Commission on the advice of the European Medicines Agency, a biosimilar medicine must be shown not to have any clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy. 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.

5. Ownership and Responsibilities

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

6. Standards and Practice

- 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.

- 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.

- 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.

- 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.

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

- 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

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

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

8. Monitoring compliance and effectiveness

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 Group.
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 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 & Human Rights Policy' or the Equality and Diversity website.

10.2. Equality Impact Assessment

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

Appendix 1. Governance Information

Document Title	Biosimilar prescribing policy		
Date Issued/Approved:	2 February 2018		
Date Valid From:	February 2018		
Date Valid To:	February 2021		
Directorate / Department responsible (author/owner):	Mike Wilcock, Sarah Griffiths, Andy Pothecary. Pharmacy Department		
Contact details:	01872 253548		
Brief summary of contents	Policy on the Trust's approach to use of relevant biosimilar medicines.		
Suggested Keywords:	Biosimilar		
Target Audience	RCHT	CFT	KCCG
	✓		
Executive Director responsible for Policy:	Medical Director		
Date revised:			
This document replaces (exact title of previous version):	New Document		
Approval route (names of committees)/consultation:	Medication Practice Committee		
Divisional Manager confirming approval processes			

Name and Post Title of additional signatories	Not Required			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Pharmacy			
Links to key external standards				
Related Documents:	NHS South West Clinical Senate Council: Biosimilars Recommendations			
Training Need Identified?	No			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*

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

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed (hereafter referred to as *policy*) (Provide brief description): Biosimilar prescribing policy	
Directorate and service area: Pharmacy	Is this a new or existing Policy? New
Name of individual completing assessment: M Wilcock	Telephone: 01872 253548
1. Policy Aim* Who is the strategy / policy / proposal / service function aimed at?	To provide guidance on the Trust's approach to use of biosimilar medicines
2. Policy Objectives*	To ensure the safe implementation of biosimilars
3. Policy – intended Outcomes*	Patient safety, efficiency
4. *How will you measure the 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) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b) If yes, have these *groups been consulted? C). Please list any groups who have been consulted about this procedure.	No

7. The Impact
Please complete the following table.

Are there concerns that the policy **could** have differential impact on:

Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		**No**	Policy for all patients
Sex (male, female, trans-gender / gender reassignment)		**no**	Policy for all patients

Race / Ethnic communities /groups		**No**	Policy for all patients
Disability - Learning disability, physical disability, sensory impairment and mental health problems		**No**	Policy for all patients
Religion / other beliefs		**No**	Policy for all patients
Marriage and civil partnership		**No**	Policy for all patients
Pregnancy and maternity		**No**	Policy for all patients
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**No**	Policy for all patients

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**	**No** ✓

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director	Date of completion and submission

Names and signatures of members carrying out the Screening Assessment	1. Mike Wilcock 2.	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____

Date _____