Shropshire and Telford Local Health Economy

Biosimilar Implementation Commissioning Policy

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1. Background & Scope

Aim of this policy:

This document provides generic guidance and outlines the adoption of biosimilars within the Shropshire and Telford Local Health Economy. The policy is seen as an overarching policy, which can link into specific Standard Operating Procedures (SOPs) for individual biosimilar medicines if required.

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

The policy has been developed in line with recommendations from the Cancer Vanguard – Biosimilar adoption programme

The use of biosimilar medicines is set to increase as patents of originator biologics expire. The adoption of biosimilars will help to provide much needed savings to the NHS, which may be utilised to further benefit patient care. Their introduction however should not be driven purely by financial considerations. The purpose of this policy is to aid the early adoption process in order for the benefits to be realised. The use of biosimilars should not alter the care provided to patients, and the patient should see no change in their treatment experience.

Adoption process for biosimilars should include:

- Considerations prior to adoption
- Approach to homecare if required
- Existing versus New Patients
- Governance requirements and local approval
- Informing and involving patients
- Prescribing requirements
- IT readiness
- Pharmacovigilance and monitoring
- Clinical outcomes monitoring
- Tracking of any savings

The policy is overarching and should be used in conjunction with individual SOPs developed for the introduction and use of specific biosimilars within the health economy.

2. Definitions:

Biological medicine – a 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, which 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.

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

To note: Biosimilar medicines are not considered as generic to the originator biological medicines the they "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.

3. Duties & Responsibilities

Commissioner

- To horizon scan and quantify the opportunity through conversations with the provider
- Support the proposed biosimilar introduction, in the agreed patient groups and endorse the Drugs and Therapeutics Committee (DTC) or Area Prescribing Committee (APC) submission as appropriate
- Be involved in the co-ordination and implementation of the biosimilar

Trust Lead Consultant (and clinical team)

- Support the proposed biosimilar introduction, in the agreed patient groups and endorse the DTC submission on behalf of the clinical unit
- Be involved in and develop a process for patient consultation in the lead up to biosimilar medicine adoption (see also specialist nurses and pharmacists)

Trust Pharmacy Department

- Be involved in the coordination and management of an effective implementation programme
- Where available specialist pharmacists to be able to provide information on biosimilars to Healthcare professionals (HCPs) and patients
- Provide the required detail for the management of trust prescribing systems and aseptics unit work sheets (if required)
- Reporting on the uptake of the biosimilar medicine following any biosimilar introduction and reporting financial savings from its adoption
- Procurement of the selected biosimilar
- If the biosimilar is to be delivered via a Homecare delivery service, coordination and requirements of a biosimilar introduction will need to be considered

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

- Carry out initial consultation with patients in the lead up to the adoption of a biosimilar medicine
- 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

- Licensed indications of the biosimilar compared with the originator
- Anticipated launch date and supply chain details
- Patient groups to be included:
    - Adult and paediatric setting?
    - Will the biosimilar be intended for all indications or only specific indications?

- Patent Restrictions for specific clinical indications
- Process to be adopted:
  - Is it to be introduced by the Trust for existing patients?
  - Is it to be introduced by the Trust for new patients?
  - Or is it both of the above?
- The biosimilar presentations compared with the originator
- The biosimilar stability once prepared and storage conditions compared with the originator
- The biosimilar administration requirements compared with the originator e.g. route, frequency and length of administration?
- Are the required clinical outcomes data available prior to review by the Trusts DTC?
- Are a number of biosimilar medicines for the same originator biological medicine anticipated to be launched around the same time by different manufacturers? If so a decision will need to be made on which will be adopted, and when, with an aim to avoid further changes in the short-term as this may introduce risk and damage patient confidence (see also section 4.10 pharmacy purchasing).
- NHS contracting and procurement arrangements as determined by NHSEI and the Commercial Medicines Unit (CMU)
- Whether a national reference price (NRP) has been set
- Possible resource implications of the adoption process. These may include:
  - patient counselling requirements
  - Multi-disciplinary team (MDT) education and training requirements
  - possible administration route change e.g. subcutaneous (SC) to intravenous (IV)
  - possible change in length of administration time
  - is the biological originator medicine given in the Homecare setting and will this have to be reviewed? (e.g. for initial dosing or patient self-administration training)
  - prescription changes, additional administration and patient database requirements for biosimilar medicines
  - Aseptic compounding

4.2 Internal governance requirements

DTC submission as per local requirements. The submission should include points highlighted in 4.1.

4.3 Commissioner position

Prior to undertaking the change from originator biological medicine to a new biosimilar medicine, the position of the commissioner should be sought regarding the requirements of initiatives such as QIPPs (Quality, Innovation, Productivity and Prevention) and any required timeframe.

In line with the commissioning framework for biological medicines[i], there is an expectation that 90% of new patient patients being on the best value biological medicine within 3 months of the product being available to the trust and 80% of existing patients within 12 months, or sooner if possible

4.4 Financial arrangements

Gainshare arrangements will apply from the time the biosimilar becomes available to the provider, for a period of 12 months from that date.

Where a National Reference Price (NRP) is in place, the provider shall charge the commissioner at the NRP, with any difference between the NRP and the actual cost of drug to the supplier being deemed as the gainshare allocated to the Trust.

Depending on the model adopted; after the time period set for the NRP or 12 months from the date the biosimilar became available to the supplier, the suppliers shall charge the commissioner at the actual cost of the biosimilar medicine as a 'pass through' price.

The NRP will be applied to the drugs data from the 1st day of the month after the biosimilar became available to the provider (it will not be applied retrospectively).

Where a NRP is not in place the commissioner agrees a 50/50 gainshare from the time the biosimilar becomes available to the provider, for a period of 12 months from that date or until such time an NRP is introduced. The baseline cost should be the average cost to the supplier over the previous 12 months. The cost charged to the commissioner will be the difference between this baseline cost and the new biosimilar price divided by 2.

These costs will be included in the Local Price Schedule in the contract.

Where legacy costs are identified these should be agreed with the commissioner.

Where a patient cannot or will not switch to a biosimilar or where a patient needs to switch back to the originator product the commissioner must be notified and a reason provided

Where a biological medicine requires compounding using the aseptic services from the provider then the commissioner will pay for the cost of the medicine inclusive of any prior agreed compounding costs.

The provider will ensure that discounts or patient access schemes are applied and passed on to the commissioner.

Homecare costs are not included within this proposal and are covered in the Homecare Commissioning Policy for Medicines.

4.5 Informing and involving patients

- The decision by the local health economy is that there is no requirement to inform new patients once the biosimilar has been approved and adopted. For new patients this is not a change but a recommended treatment by a clinician.
- It is required at point of initial adoption to inform and educate currently-treated patients. How this is carried out will be dependent on the biological medicine in question e.g. how often it is prescribed, the setting in which it is given (in-patient, out-patient, or Homecare) and how the clinics are set up.
- Possible methods for informing and involving patients may include:
    - focus groups prior to adoption
    - one to one patient consultation by trained clinician, nurse or pharmacist in lead up to the adoption (feasibility will be dependent on how the clinic is coordinated at the trust)
    - the utilisation of a patient information leaflet with Q&A section and contact details of relevant HCP if patients wish to discuss further
    - patient letter to be sent out to patients explaining:
        - the planned change
        - how the decision has been undertaken
        - that clinical efficacy and safety have not been affected
        - that significant financial benefits will be achieved for the NHS and/or the Trust.

4.6 Prescribing requirements & interchangeability

Biosimilar medicines must be prescribed by brand name and "International Non-proprietary Name (INN)" i.e. "Remsima ® (Infliximab)" (see section 4.7). This is in line with good practice and international recommendations over the use of biosimilar medicines.

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.

It is recommended a biosimilar should be continued for a minimum of 2 years before further switching occurs. This will maintain the confidence of patients in the use of biosimilar medicines and manage the burden on healthcare professionals and organisations involved in switching schemes.

Where supply and availability problems are encountered or the contracting arrangements within the NHS change significantly the adoption of an alternative biosimilar may need to be considered during this time period.

4.7 IT readiness

If the originator biological medicine and biosimilar are both to continue to be used at the trust (e.g. in change over period or for different indications) the pharmacy systems clearly need to differentiate between the two. The data provided to the commissioner must include the INN and the brand. Systems will include dispensing, prescribing and in some cases aseptic unit systems.

4.8 Pharmacovigilance and monitoring

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. Databases must be maintained to provide information to the MHRA over the use and switching of patients receiving biosimilar medicines.

4.9 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 occurs at a national level.

4.10 Monitoring patient satisfaction

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

4.11 Pharmacy Purchasing requirements

Close liaison with the Commercial Medicines Unit (CMU) and NHS network procurement teams should take place, in order to keep up to date with new biosimilar medicines. This should include:

- anticipated launch dates
- planned tenders and timelines
- product specifications
- pricing information

4.12 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.

This may include a 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
- metrics and indicators in line with any commissioning requirements e.g. Medicines Optimisation and QIPPs

4.13 Evaluation of Service impact on the Trust 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 switched patients. Any resource impact should then be further discussed with commissioners.

5. **Review and maintenance of policy**

   This commissioning policy will be reviewed annually before the end of the financial year or earlier in response to new local/national guidance.

6. **Bibliography**

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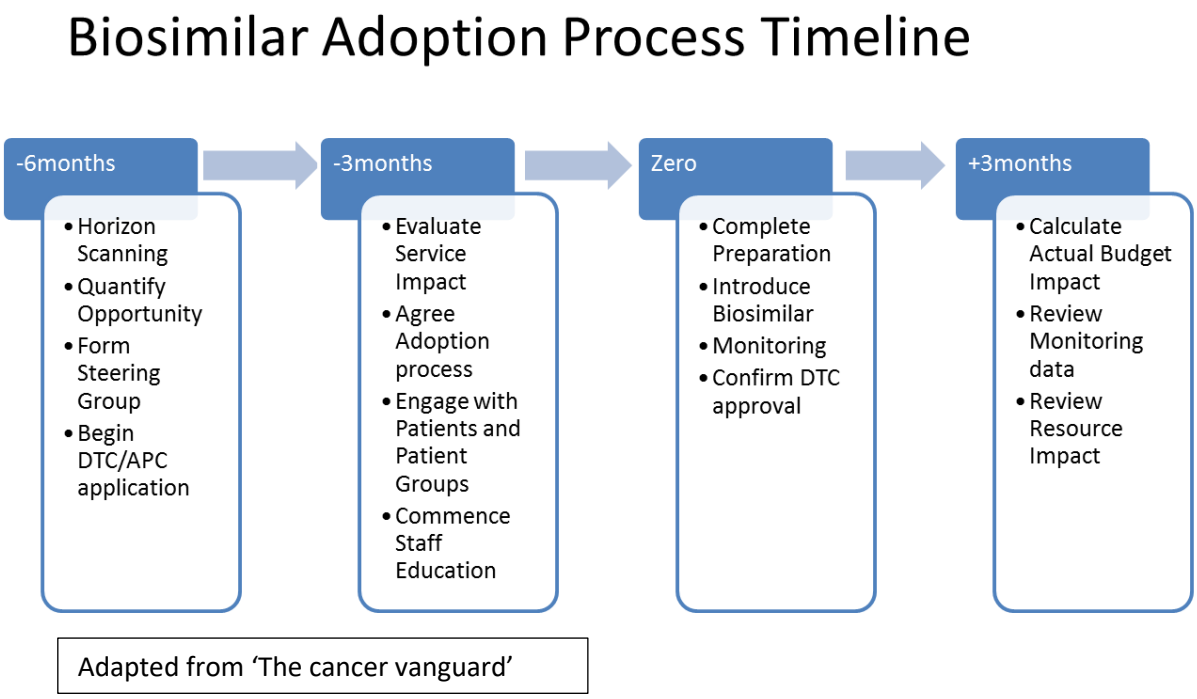
Appendix 1. Biosimilar Adoption Process Timeline



[i] Commissioning framework for biological medicines. NHSEI 12 September 2017