Position Statement

Use of Biosimilar Medicines

Recommendation:

Where a proprietary biological medicine is indicated and biologically similar (biosimilar) medicine(s) to the reference product also exist the product with the lowest acquisition price should be used (within licensed indications).

Product choices, including changes to treatment, for individual patients should be made following assessment by the responsible clinician taking into account patient choice.

The prescribing of biosimilar preparations should be by **brand name**, followed by the concentration and recommended daily dose in units and a statement of the formulation.

For compounded medicines, the costs should be discussed and agreed with the ICB before each scheme is commenced or when cost changes occur and for all schemes at the beginning of each financial year.

Background:

Biological medicines are well established in clinical practice and offer effective and in many cases vital medicines for acute and chronic conditions including neutropenia, different types of cancers, diabetes, a wide range of inflammatory and autoimmune diseases such as arthritis, psoriasis, as well as enzyme or hormone deficiencies. Where patents expire for individual biological medicines, biosimilar medicines are being introduced to provide additional treatment options for patients and the NHS.

Where biosimilars become available, trust pharmacy teams will arrange the biosimilar supply, distribution and the provision of evidence on product choices, to allow clinicians to rapidly adopt biosimilars in a safe and evidence-based manner.

Once Biosimilars are freely available, 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.

Decision to prescribe

The role of the prescriber in treating patients with these complex medicines is of fundamental importance.

The decision to prescribe a biological medicine for an individual patient, whether a reference or biosimilar, or to change between the two, rests with the responsible prescriber in consultation with the patient, in line with the principles of shared decision making. This should be in accordance with the approved indications on the summary of product characteristic and ideally be part of a biological medicines review.

Prescribers should use all available relevant evidence to guide decisions about the care of an individual patient with the initial selection of the most appropriate molecule based on clinical considerations. Subsequently, prescribers should consider the characteristics of different products, including cost and licensed indications, as well as other factors relevant to the use of the product and likely clinical outcomes for each patient.

Substitution

Substitution, defined as the practice of dispensing one medicine instead of another equivalent medicine at the pharmacy level without consulting the prescriber, is not permitted for biological medicines, including biosimilars.

In line with MHRA guidance all biological medicines (including biosimilars) should be prescribed by brand name.

Choice

Biosimilar products are considered to be interchangeable with their reference product, which means a prescriber can choose the biosimilar of the reference product and expect to achieve the same clinical effect. This decision rests with the prescriber in consultation with the patient in line with the principles of shared decision making.

Bibliography

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2. NHS England, Medical Directorate. What is a biosimilar medicine? Version 2 Publication Gateway Reference: 03923. 30th May 2019.

3. European medicines agency. Guideline on similar biological medicinal products. CHMP/437/04 Rev 1. 23 October 2014. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/10/WC500176768.pdf

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Version Control

Version Number	Date	Amendments Made	Author
Version 1.0	June 2017	New document	AG
Version 2.0	November 2022	Commissioning arrangements	BH

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