Prescribing of high cost biosimilar biological medicines

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DOCUMENT CONTROL

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Revision History

The latest and master version of this document is held on the Medicines Optimisation SharePoint:

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
01 May 2016	S Jacobs	Initial review of 'Rheumatology prescribing of biosimilars' statement	1.1
06 May 2016	S Jacobs	Changes following comments from Greater Manchester Shared Service Strategic medicines Optimisation team	1.2
16 May 2016	S Jacobs	Changes following discussion with Ben Parker, representing the biologics pathway group	1.3
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Approvals

This document must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
GMMMG	GMMMG Members		2.0

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Various	Strategic medicines optimisation team, GM Shared Service	02 May 2016	1.1
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Guidance for the prescribing of high cost biosimilar biological medicines

1. Background

- Biological medicines (biologics) are currently the largest cost and cost growth area in the NHS drug budget.
- Biologics are made or derived from a biological source and are complex molecules, with inherent variability in structure.
- A biosimilar medicine (biosimilar) is a biologic which is highly similar (essentially the same substance) to the biologic originator product already licensed for use.
- For a biosimilar to gain marketing authorisation the manufacturer needs to show that the product does not have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy.
- The continuing development of biologics, including biosimilars, creates increased choice for patients and clinicians, increased commercial competition and enhanced value propositions for individual medicines.
- Biosimilars have the potential to offer the NHS considerable cost savings and widen the access to innovative medicines.
- The principles below will apply to each biosimilar that becomes available to the UK market.

2. Initiating treatment with a biologic

- The choice of biologic used should be guided by clinical judgement, national or local guidance and the overall value proposition offered by the individual medicines. The rationale for choice should be documented.
- If more than one treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose).
- When the biologic treatment has been selected, the least expensive product, either biosimilar or originator should be prescribed.
- If the least expensive product is not prescribed, the reasons why must be documented and made available to commissioners if required.
- Where NICE has already recommended the originator biological medicine, the same guidance will apply to the biosimilar.
- In line with MHRA guidelines: Gov.uk/drug-safety-update/biosimilar-products biologics, including biosimilars must be prescribed by brand name to support on-going pharmacovigilance of the individual products.
- Pharmacovigilance is essential for any new biological medicine including biosimilars and additional monitoring is indicated through the black triangle. Patients prescribed a biologic should be enrolled on to relevant registries which gather data on the safety and effectiveness of the medicine in clinical practice.

3. Changing from originator to a biosimilar

- There is accumulating evidence that patients who are in a stable clinical response or remission may be changed over to the biosimilar at the same dose and dose interval. This should only be done after discussion and agreement with individual patients with an explanation for the reason for changing.

- Changing a patient on a biologic originator medicine to a biosimilar should be done at the point of prescribing.

- There should be no automatic substitution of a biologic with a biosimilar at the point of dispensing.

4. GMMMG pathways that incorporate this biosimilar biological medicines guidance

- GMMMG: Harmonised Biologics Pathway for treating Rheumatoid Arthritis
- GMMMG Harmonised Biologics Pathway for Axial Spondyloarthropathy (Ankylosing Spondylitis - AS) and Peripheral Spondyloarthropathy (Psoriatic Arthritis - PsA)
- GMMMG Harmonised Biologics Pathway for Inflammatory Bowel Disease

These can be found on the pathways section of the GMMMG website: GMMMG: Pathways

5. Gain share arrangements for cost savings in biologic prescribing

- Local gain share arrangements for high cost PbR excluded drugs should be agreed by lead commissioners and their providers, but apply to all Greater Manchester patients.

- A gain share agreement should specify the agreed payment split between commissioner and provider related to net savings of PbR excluded drugs through clearly specified mechanisms (such as biosimilar use, reduced wastage, care closer to home, dose reduction etc.)

- Information on current local NHS procurement arrangements and preferred products available should be transparent and readily available to prescribers and commissioners.

- Drugs should be charged at procurement price and gain share costs must be incorporated into a separate line from the drug costs within the high cost drugs PbR excluded data.

Further Resources

NHS England: What is a biosimilar medicine? September 2015
European Medicines Agency (EMA). Questions and Answers: Biosimilar medicines.
NICE position statement on evaluating biosimilar medicines. January 2015.
NICE advice [KTT15]. Biosimilar medicines. February 2016. NICE advice KTT15 Biosimilars.
Drug Safety Update: Biosimilar products. February 2008.
Drug Safety Update: Reporting suspected adverse drug reactions to vaccines and biological medicines. November 2012.
NICE TA329. Tools and resources. Health technology adoption programme. February 2015.