Northern Treatment Advisory Group

# Northern (NHS) Treatment Advisory Group

## Treatment Appraisal: Decision Summary

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| **Date** | 7th June 2022 |
| **Appraisal & Details** | **Prescribing of Biosimilar Medicines** |
| **Recommendation** | **The Northern Treatment Advisory Group (NTAG) recommends the commissioning and use in the North East & North Cumbria of biosimilar equivalents to biologics at the time of their launch, within their licensed indications. These products should be added to local formularies at that time (or soon after) to maximise the financial savings available.**<br><br>This commissioning position supports NICE guidance to "start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose)". It is also in line with the NHS England 'Commissioning framework for biological medicines (including biosimilar medicines)' which includes recommendations for commissioners to ensure that providers have in place policies to encourage clinically and cost-effective prescribing of biological medicines.<br><br>All biological medicines, including biosimilar insulin, should be prescribed by brand name so that products cannot be automatically substituted at the point of dispensing. This is particularly important with insulin to ensure that the patient has the insulin that is intended for use with a delivery device that the patient has been trained to use, and has all the necessary items (e.g. needles, pen injection devices).<br><br>The choice of whether a patient receives a biosimilar or originator biological medicine rests with the responsible clinician in consultation with the patient. 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. |
| **Background** | Biosimilars are biological medicines which are highly similar to an existing biological medicine licensed for use. They have been shown to not have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy. They are not considered generic equivalents to their originator biological medicine because the two products are similar but not identical. All biologicals may exhibit batch to batch variability which is controlled and maintained within defined approved limits.<br><br>Because of the similarities between originator and biosimilar medicines as well as growing experience with the use of biosimilar medicines, it is accepted that generic principles can be applied to biosimilar medicines with regards to addition to drug formularies.<br><br>Depending on the evidence provided for regulatory assessment of the biosimilar medicine, it will typically have the therapeutic indications established by the reference medicine.<br>NICE have produced a biosimilar position statement which states that similar |

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| | biological medicinal products (biosimilars) will usually be considered in the context of a Multiple Technology Appraisal in parallel with their reference products in the indication under consideration. Evidence summaries will use the brand names of the medicines because substitutability and interchangeability cannot be assumed. Evidence summaries do not make recommendations hence the decision regarding the choice of biosimilar or originator biologic for an individual patient rests with the responsible clinician in consultation with the patient. |
| **Clinical evidence summary** | In order for the EMA to grant regulatory approval, the variability between the biosimilar and the reference medicine will have been shown to have no effect on safety or efficacy. The aim of development is to convincingly demonstrate high similarity to the reference product. This will then allow the biosimilar to rely on, in part, the existing efficacy and safety experience with the originator product. Trial data demonstrating high similarity to the reference product will be published accompanying the release of each biosimilar product. |
| **Safety** | 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.<br><br>Care needs to be taken if switching patient from the originator to the biosimilar to ensure that the patient does not inadvertent take multiple does of the same active drug. This may be a particular issue if the patient has supply of the existing medication at home. The patient should finish the current supply of the originator before commencing the biosimilar to avoid waste and prevent dosing errors. |
| **Patient Perspective** | Biosimilars are biological medicines which are highly similar to an existing biological medicine licensed for use. They have been shown to not have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy. They are not considered generic equivalents to their originator biological medicine because the two products are similar but not identical. Many biological medicines are coming off patent and “biosimilars” are becoming available. Typically, biosimilars are much cheaper than the originator products. This provides the NHS with an opportunity to save money, whilst also increasing access to these important medicines. |
| **Cost analysis summary** | Often biosimilar agents provide the potential for a decrease in purchase price of at least a third, this represents a significant saving to the health economy. |
| **Financial impact** | Biosimilar drugs will be introduced following discussion with the relevant local clinicians and included within current local and national guidance for existing biologic drugs. |