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| Intervention | **152: Biological and Bioequivalent/Biosimilar Medicines** |
| For the treatment of | Multiple acute and chronic conditions |
| Commissioning Position | These interventions are commissioned if:   * Their use is consistent with their status, scope and order of preference, as defined within the Humber and North Yorkshire Area Prescribing Committee (HNY APC) Formulary AND * Their use is consistent with applicable NICE TA recommendations and/or MHRA drug safety updates.   Provider organisations should normally achieve the following standards, which will be reviewed through contract monitoring:   * Adoption of best value biological products, including biosimilars, in 90% of new patients within one quarter of new addition to/extension of scope (clinical indication) in the HNY APC. * Adoption of best value biological products, including biosimilars, in 80% of applicable existing patients within one year of addition to/extension of scope (clinical indication) in the HNY APC (except if standard treatment course is < 6 months). |
| Summary of Rationale | Clinicians should always use the best value treatment choice, for example, biosimilars and generic medicines, where clinically appropriate. If there are multiple treatment options for the same indication, and patients and their clinicians consider them all to be suitable treatments, the least costly should be used.  Where HNY APC has defined a place in therapy/published a local pathway for a medicine, clinicians should follow the pathway when prescribing (or making a recommendation on prescribing) for NHS patients.  Definition of a bioequivalent/biosimilar medicine  A bioequivalent/biosimilar medicine is a biological medicine which has been shown not to have any clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy.  Where NICE has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar of that originator. ​  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 a ‘reference medicinal product’ (RMP)).  Once authorised, a biosimilar product is considered to be interchangeable with their RMP, which means a prescriber can choose the biosimilar medicine over the RMP (or vice versa) and expect to achieve the same therapeutic effect. Likewise, a biosimilar product is considered to be interchangeable with another biosimilar to the same RMP.  HNY APC considers the clinical effectiveness of medicines and decides on the commissioning status of medicines (and prescribable products/devices) for use by clinicians in all sectors when treating people for whom HNY ICB has commissioning responsibility. If a medicine is approved for use by HNY APC it will be added to the HNY APC Formulary, as a minimum, with a ‘traffic light status’ to define who can prescribe the medicine and for what conditions, but sometimes also indicating a place in therapy (first line/second line etc.) or with a full treatment pathway.  HNY ICB acknowledges that medicines recommended in NICE Technology Appraisals for use at NHS cost must be available as a treatment option. |
| References | [NHS England » Biosimilar medicines](https://www.england.nhs.uk/medicines-2/biosimilar-medicines/)  [Guidance on the licensing of biosimilar products - GOV.UK](https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products#interchangeability)  [NHS England: Biosimilar medicines commissioning framework](https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf)  [Biosimilar technologies: NICE position statement | Technology appraisal guidance (NICE)](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/biosimilar-technologies-nice-position-statement) |
| Effective from | February 2025 |
| Policy Review Date | February 2028 |