NENC Best Value Medicine

Policy Template

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**1 Introduction**

In North East North Cumbria (NENC), £668 million was spent on medicines in secondary care in 2024/25. This figure has increased 10% on average each year, significantly above the current national planning assumption of 3.3%. Contributing to this pressure is the innovation of and rising demand for new, complex and advanced therapies. The Integrated Care System (ICS) has a responsibility to ensure that NHS resources are used sustainably, effectively and equitably across the region and according to the needs of the population.

The National Institute for Heath and Care Excellence (NICE) indicates that where there is more than one treatment option for a patient then the most cost-effective option should be used.

Using the most cost-effective option as they become available means that savings can be used to fund patient care and improve access to treatments.

**2 Purpose**

To ensure that standardised best practice processes are in place across the NENC secondary care providers to ensure that all prescribing and medicines decision making considers medicines value.

To ensure that governance is in place to ensure patient safety and equity in the use of best value medicines.

To ensure that potential savings from generic or biosimilar availability can be realised at pace.

**3 Scope**

This is a system-wide policy template for local approval and adoption by secondary care providers within the NENC ICS.

**4 Definitions**

**Generic medicine**

When a drug or medicine is first developed, the Marketing Authorisation (MA) holder has a time-limited patent that means only that MA holder can make and sell that medicine during the patent period. After the patent expires, other organisations can apply to make and sell the medicines. These unbranded medicines are referred to as generic medicines.

Generic medicines contain the same drug(s) as the original brand medicine and they have been shown to have the same efficacy and safety when used at the same dose to treat the same condition. Therefore, generic medicines give patients that same treatment but at usually a much lower cost ***– they are the best value medicines to use***.

**Biologic medicine**

Biologic medicines are used to treat a large range of conditions (e.g. cancer, rheumatoid arthritis, inflammatory bowel disease, psoriasis) and are the largest cost, and cost growth areas in the NHS medicines budget.

Biologic medicines are structurally complex medicines made or derived from a biological source. Due to the nature of the biological source and the manufacturing process there is variability from one batch to the next. The variability between batches of the same medicine is controlled and monitored during manufacturing to maintain within defined and approved limits.

Like other medicines, these products are patent protected after initial manufacture. They are commonly referred to as the 'reference product' or 'the originator'.

**Biosimilar medicine**

Once the patent of the originator biologic medicine expires, other organisations can make and sell highly similar, bioequivalent molecules that have demonstrated through robust testing that they deliver no clinically meaningful differences in structure, biological activity, safety and immunogenicity.

A biosimilar contains a version of the active substance of an approved reference product.

Biosimilar medicines have been used for a number of years and there is now significant experience of switching from reference products to their biosimilar versions, as well as switching between biosimilars. Before use, best value options are assessed by procurement and pharmacy teams for quality and assurance purposes.

The Medicines and Healthcare products Regulatory Agency (MHRA) states that once authorised, a biosimilar medicine is considered ***interchangeable*** with the reference product, or with another biosimilar of the same originator, and that the same therapeutic effect can be expected1.

In April 2025, NHS England published the 'Commissioning framework for best value biological medicines' with clear targets relating to best value biological medicines:

* 100% of new patients to be initiated on the best value biologic (where clinically appropriate) within 3 months of its launch
* At least 80% of existing patients to switch within 10 months2.

In addition, when used as a comparator NICE considers biosimilar medicines to differ from the originator product only in terms of price3.

Biosimilar medicines are often significantly lower in price and so they are ***the best value medicine to use*** to provide the same treatment outcomes.

**5 Duties and Responsibilities**

**All NHS organisations**

Hold responsibility for the implementation of the best value medicines principles

Should assess the opportunities and service impacts of available or anticipated best value medicines.

Identify key stakeholders and develop implementation plans for the use of best value medicines.

Should evaluate and monitor the uptake of best value medicines through data.

Should be able to provide auditable data on continued originator use.

**6 Best Value Medicine Principles**

**Starting new patients**

All new patients should be started on the most cost-effective generic or biosimilar medicine when one is available.

Note that all biologic medicines should be prescribed by brand name (including biosimilars).

Prior to initiation patients should be informed that they are highly likely to receive different (cost-effective) brands of the same medicine over the duration of their treatment.

**Existing patients**

All existing patients on a branded medicine, biologic medicine or a biosimilar, should switch to a suitable best value medicine when one becomes available, and an implementation plan has been agreed with prescribers.

**Informing patients of switches**

The decision to use any medicine, including a biologic medicine, rests with the prescriber and the patient in line with the principles of shared decision making.

The NHS provider has discretion over which brand of medicine is prescribed and supplied but it must take into account best value medicine principles.

Patients should be made aware of which product they have or will receive(d). This may be verbally, written resources or via a homecare company. Any counselling, advice or training should be provided as required.

**Patients unable to have the best value biologic medicine**

If a patient is unable to use the approved best value medicine, consider if another cost-effective option is viable.

If a patient needs to be prescribed an originator biologic medicine approval must be sought from an appropriate panel. As a minimum the panel should include a relevant budget holder for the clinical area and a clinical independent such as a clinician from a different speciality. A minimum dataset should be held for audit and annual monitoring purposes: -

* Medicine name and formulation
* Speciality and indication
* Clinical rationale for not using best value medicine
* Best value medicines trialled

**Factors to consider when choosing the best value medicine**

* Acquisition cost; including VAT when relevant
* Homecare provision
* Supply chain resilience/ security
* Product licences
* Availability of patient support and training
* Waste and sustainability
* Product stability and storage
* Therapeutic monitoring and test requirements
* Devices and formulations available, including needle size and volume
* Excipients and latex content
* Strengths available

This list is not exhaustive.

Note that the branded or originator medicine may be the best value.

**7 Monitoring**

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| **Method** | **By** | **Frequency** |
| Assessment of missed opportunities at system level once a more cost-effective medicine becomes available | NENC Medicines Value Group | Annually |
| Monitoring of percentage of patients on originator/ branded medicines where a more cost-effective medicine is available | NENC Medicines Value Group | Every 6 months |
| Audit of originator minimum dataset | NENC Medicines Value Group | Annually |

**8 References**

1. MHRA. Guidance on the licensing of biosimilar products. Feb 2025
2. NHS England. Commissioning framework for best value biological medicines. April 2025
3. NICE. Biosimilar technologies: NICE position statement. Accessed June 2025

**9 Equality Statement**

Promoting equality and addressing health inequalities are at the heart of the NHS values. Throughout the development of the policies and processes cited in this document, we have:

• Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010 or equivalent equality legislation) and those who do not share it; and

• Given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.