

Achieving and demonstrating compliance with NICE TA and HST guidance

Frequently asked questions relating to local formularies

1. Can providers or commissioners take affordability into account when developing local formularies¹?

Commissioners have a [statutory responsibility](#) to make funding available for a drug or treatment recommended by a NICE technology appraisal (TA) or highly specialised technology evaluation (HST) within the timeframe recommended in that guidance, usually within 3 months of the TA or HST being published. Under the [NHS Constitution](#), patients² have a right to receive all medicines and treatments recommended by NICE if they and their healthcare professional think that the medicine is right for them.

In practical terms, the effect of this legal obligation and the NHS constitution is that **all** NICE-approved treatments³ must be included in local formularies for use in line with the TA or HST recommendations and with no additional funding or formulary restrictions (see questions 2–3). The only exception is if the technology is not relevant to the care provided by the organisation; for example, cancer treatments would not need to be included in the formulary of a mental health trust, and treatments for dementia would not need to be included in the formulary of a specialist children's hospital⁴. There is no provision to take affordability into account when adding NICE-approved medicines to local formularies.

¹ As defined in [Developing and updating local formularies](#) (NICE MPG1, published December 2012); 'local formulary' means the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a health economy, service or organisation.

² The term 'patient' includes all people cared for by the NHS including women cared for in maternity and obstetric services and mental health service users.

³ That is, a medicine recommended in a TA or HST as an option for use

⁴ If a NICE-approved medicine has not been included in an organisation's formulary because it is not relevant to the care usually provided by that organisation, this must not be a barrier to a person under its care receiving it in line with the TA or HST guidance if they and their healthcare professional think that it is right for them.

2. Can providers or commissioners recommend that one NICE-approved medicine³ is used routinely in preference to another NICE-approved medicine, or recommend that a medicine that has not been assessed by NICE is used routinely in preference to a NICE-approved medicine?

All NICE-approved treatments must be included in local formularies¹ for use in line with the TA or HST recommendations and with no additional restrictions, as explained in question 1. If there is more than one NICE-approved medicine for the condition, providers and commissioners must not recommend that any one of them is used **routinely** in preference to the others (unless an order of preference is stated in the TAs or HSTs). Similarly, they must not recommend that a medicine that has not been assessed by NICE is used **routinely** in preference to a NICE-approved medicine.

Providers or commissioners can suggest to healthcare professionals that a particular medicine is preferred locally. Reasons for this could include cost, if a medicine is cheaper than other options, to reflect local clinical expert opinion or to achieve optimal stock control. However this local recommendation must **only** be taken into account **after** a patient² and prescriber have discussed **all** treatment options⁵ and **only** if they have **no** preference about which medicine they want to use.

3. Can providers or commissioners specify criteria regarding use of a NICE-approved medicine³ in addition to or different from those specified in the TA or HST?

Providers and commissioners must not restrict access to NICE-approved medicines by adding to or modifying the clinical eligibility criteria stated in the TA or HST. As explained in question 1, such treatments must be included in the local formulary¹ with no additional restrictions. [NICE guidance on developing and updating local formularies](#) recommends that, where appropriate, local formularies should identify the place of a NICE-approved medicine in the care pathway, in line with NICE recommendations.

⁵ If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

It may be helpful for a local formulary to indicate arrangements for use of NICE-approved medicines (for example, recommending that a particular medicine or group of medicines should be started by a particular specialist team). However, this advice must not conflict with the TA or HST guidance, must be justified for clinical or patient safety reasons², and must not result in an unreasonable restriction in access to the medicine, whether this is intentional or unintentional.

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