NICE National Institute for Health and Care Excellence

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 formularies[1]?

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, patients[2] 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 treatments[3] 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 hospital[4]. There is no provision to take affordability into account when adding NICE-approved medicines to local formularies.

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[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 medicine[3] 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 formularies[1] for use in line with the guidance. If there is more than one NICE-approved medicine for the same indication, local NHS organisations may indicate that a particular medicine is preferred locally if one of the medicines is cheaper than the other(s), or there is a clear local clinical consensus, or to achieve optimal stock control. However, clinicians and their patients must remain able choose any NICE-recommended treatment if, after an informed discussion, they consider it appropriate to do so.

3. **Can providers or commissioners specify criteria regarding use of a NICE-approved medicine[3] 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 formulary[1] 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.

   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 reasons[2], and must not result in an unreasonable restriction in access to the medicine, whether this is intentional or unintentional.

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