

Developing and updating local formularies

Medicines practice guideline

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[nice.org.uk/guidance/mpg1](https://www.nice.org.uk/guidance/mpg1)

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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What is this guideline about and who is it for?

This guideline covers the systems and processes for developing and updating local formularies.

Who is it for?

- People involved in handling, prescribing and commissioning medicines within the NHS.

This version of the guideline contains the recommendations and context.

In October 2015, some changes to recommendation wording were made for clarification only and did not change the meaning of the recommendations. Other changes did alter the meaning and are indicated by [amended 2015] at the end of the recommendation. For more information see [changes after publication](#).

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in [your care](#).

[Making decisions using NICE guidelines](#) explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including 'off-label' use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 *Relationships with other decision-making bodies*

- 1.1.1 When developing or reviewing the local formulary, map and understand the functions of existing medicines-related networks and decision-making groups in the local and neighbouring health economies.
- 1.1.2 Avoid duplicating work by collaborating with other local decision-making groups.
- 1.1.3 Proactively identify, discuss and implement recommendations in publications from national decision-making bodies, such as NICE, taking appropriate actions.

1.2 *Local formulary scope*

- 1.2.1 Determine the scope of the local formulary through consultation with all locally defined stakeholders. Take account of the:
 - size of patient population to be covered
 - range of healthcare treatments to be included
 - range and number of partner organisations adopting the formulary.
- 1.2.2 Ensure local arrangements take account of:
 - consistency of care pathway arrangements across the patient population
 - clinical engagement
 - resources needed to operate formulary processes.

1.3 *The local formulary decision-making group*

- 1.3.1 Agree and document terms of reference for the local formulary decision-making group. This should include:
- clarification of budgetary responsibility
 - lines of accountability and reporting arrangements
 - members' roles and responsibilities
 - declaration of interest arrangements
 - arrangements for quoracy
 - arrangements for deputies
 - pre-meeting preparation and post-meeting actions
 - the method by which final decisions will be made, recorded and disseminated
 - actions of the Chair
 - frequency of meetings.
- 1.3.2 Include a locally-defined mix of members from partner organisations and key stakeholders, such as patients and the public.
- 1.3.3 Ensure that the local formulary decision making group has the range of skills and expertise needed to undertake all necessary activities.
- 1.3.4 Hold meetings sufficiently frequently to ensure decision-making is robust and decisions are made in a reasonable and practical time frame.
- 1.3.5 Take account of the resources needed to undertake all functions of the local formulary decision-making group, as determined by the scope and geographical coverage of the local formulary. [amended 2015]
- 1.3.6 If operating a local formulary covering a small population, consider sharing resources and establishing joint processes with neighbouring local formulary decision-making groups to avoid duplicating work.

- 1.3.7 Ensure corporate governance arrangements are firmly established with clear lines of accountability for each partner organisation.
- 1.3.8 Report to relevant corporate governance bodies for each partner organisation appropriately, and as a minimum annually, and by exception when needed.

1.4 *Stakeholder engagement*

- 1.4.1 Ensure local formulary stakeholder engagement includes:
- clinical groups and networks, especially if a formulary decision needs specific knowledge and expertise or has direct implications for a clinical practice area
 - patients or patient representative groups
 - local people and communities
 - relevant manufacturers of medicines, for example, when the company can offer additional evidence and insight that can assist with decision-making
 - other relevant decision-making groups.
- 1.4.2 Ensure stakeholder engagement is proportionate to the type of decision being made and the medicine being considered.

1.5 *Processes for the adoption of medicines recommended by NICE technology appraisal guidance*

- 1.5.1 Include NICE technology appraisals as a standing agenda item in local formulary decision-making group meetings.
- 1.5.2 When a NICE technology appraisal recommends a medicine, adopt the medicine into the local formulary automatically, if clinically appropriate and relevant to the services provided by the organisation. This process should take place within 3 months. Include the medicine within the relevant care pathway(s) provided by local organisation(s), in line with NICE recommendations.
- 1.5.3 When a NICE technology appraisal does not recommend a medicine, focus discussions and actions on withdrawing and decommissioning the medicine if applicable, in line with NICE recommendations.

1.6 Processes for selecting medicines to be considered for inclusion in the local formulary

Recommendations for proactive identification of medicines not subject to a NICE technology appraisal for consideration

- 1.6.1 Ensure that there is a robust and transparent process for adopting, removing or updating medicines or indications not covered by NICE technology appraisal guidance.
- 1.6.2 Include horizon scanning as a standing agenda item in local formulary decision-making group meetings.
- 1.6.3 Prioritise medicines not subject to a NICE technology appraisal for consideration using explicit criteria. Ensure these prioritisation criteria are well known, clear and transparent. Assess:
- patient safety
 - impact on patient care
 - timelines for new medicines reaching the market
 - severity of disease and patient numbers affected
 - clinical effectiveness
 - gaps in treatment or other available treatments
 - cost effectiveness
 - resource impact, for example biosimilar medicines
 - inappropriate variation in local current practice.

Recommendations for reactive identification of medicines by health professionals for consideration

- 1.6.4 Applications to consider a medicine or new indication for inclusion in the local formulary should be submitted by a health professional, although manufacturers may support evidence gathering.

- 1.6.5 Provide information to the applicant to explain the process for considering a medicine or new indication for inclusion in the local formulary and ensure application forms are readily available. Think about inviting the applicant to a meeting to allow for constructive discussion.
- 1.6.6 Ensure the following information is included in application forms to consider a medicine or new indications:
- details of the health professional making the application, including a declaration of interests
 - local patient population
 - details of the medicine, including strength, formulation, therapeutic drug class, indication, monitoring requirements and cost
 - evidence submission with relevant supporting literature, including efficacy, safety and cost effectiveness
 - comparison with existing treatments
 - likely place in therapy
 - recommendation for the decommissioning of a current formulary medicine, if applicable
 - resource impact, for example [biosimilar medicines](#).

1.7 *Setting decision criteria*

- 1.7.1 Clearly define and consistently apply standard criteria for decision-making. Develop and/or apply a [multi-criteria decision tool](#), which should include:
- patient safety
 - clinical effectiveness
 - cost effectiveness or resource impact
 - strength of evidence
 - place in therapy relative to available treatments

- national guidance and priorities
- local health priorities
- equity of access
- stakeholder views.

1.8 *Evidence and information gathering*

- 1.8.1 When there is a NICE technology appraisal for a medicine, do not duplicate NICE's evidence assessment or challenge the technology appraisal recommendations.
- 1.8.2 When there is no NICE technology appraisal for a medicine, use NICE guidelines and advice, and other sources of high-quality information produced by national and regional horizon scanning organisations, if available. Ensure these are relevant to the medicine and indication being considered. Avoid duplicating effort locally.
- 1.8.3 If local critical appraisal and evidence synthesis is needed, ensure that evidence-gathering strategies comprehensively reflect the requirements set out in the local formulary's decision-making criteria.
- 1.8.4 If local critical appraisal and evidence synthesis is needed, ensure that individuals with specialist skills and competencies are available. This includes skills in:
- literature searching
 - critical appraisal
 - interpreting and contextualising evidence.

1.9 *Incorporating new information from regulatory authorities*

- 1.9.1 Incorporate medicines safety advice from regulatory authorities routinely into the local formulary. This could be achieved by having patient safety as a standing agenda item.

1.10 *Assessing the financial and commissioning impact when making decisions*

- 1.10.1 Routinely engage with commissioning and financial managers at an appropriate level of seniority and align local formulary decisions within the framework of clinical commissioning.
- 1.10.2 Consider addressing barriers that may delay the speed of adoption of medicines into the formulary, such as multiple applications to different decision-making groups, delayed or absent business planning, budget identification or service design. [amended 2015]

1.11 *Deliberating and reaching decisions*

- 1.11.1 Use explicit principles that are formally documented to guide deliberation in the local formulary decision-making group, such as mission statements, terms of reference, decision criteria and legal and ethical frameworks.
- 1.11.2 Support members of the local formulary decision-making group in deliberation and decision-making by providing appropriate training and constructive feedback.
- 1.11.3 Determine explicitly how local formulary decision-making groups reach final decisions.

1.12 *Documentation*

- 1.12.1 Document the deliberations and actions from local formulary decision-making group meetings, the outcomes of decisions, the rationale for each decision and all formulary policies.
- 1.12.2 Use a standard format for notes and minutes of local formulary decision-making group meetings, which ensures that the key points are summarised for all decisions. Ensure secretariat functions are sufficiently competent so that technical information is accurately recorded.

1.13 *Developing decision outputs to support local formulary decisions*

- 1.13.1 Develop decision outputs with stakeholders (including clinical groups and

networks) and other local decision-making groups in a timely manner, to prevent delays in access to treatment.

- 1.13.2 Develop decision outputs related to a NICE technology appraisal within a time frame that does not delay the adoption of the medicine into the formulary beyond the statutory requirements.

1.14 *Communicating and disseminating information about the local formulary*

- 1.14.1 Publish all relevant local formulary information online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings, decision outcomes and associated decision outputs.
- 1.14.2 Publish information that sets out which NICE technology appraisals are included in the local formulary, in line with the NHS Chief Executive's 2012 letter Innovation, Health and Wealth publication of NHS formularies.
- 1.14.3 Develop a local communication framework for the local formulary, in consultation with stakeholders, reviewed annually, to:
- disseminate targeted, concise information to other decision-making groups and key stakeholders, including patients and the public who need to know about the decision
 - routinely communicate with neighbouring local formulary decision-making groups to share practice, particularly when there are cross-boundary patient flows
 - anticipate media response to decisions.

1.15 *Reconsidering and appealing local formulary decisions*

- 1.15.1 Establish a robust and transparent process for reconsideration or appeals of decisions made by the local formulary decision-making group. Ensure relevant information is clear and easily accessible.
- 1.15.2 Clearly define the criteria for a health professional to request a reconsideration of a decision made by the local formulary decision-making group. This should include circumstances in which:

- significant new information such as a medicines safety alert has become available, which requires a reconsideration of the evidence
- the decision was based on inaccurate or incomplete information.

1.15.3 Clearly define the acceptable grounds for a health professional to appeal a decision made by the local formulary decision-making group. This should include circumstances in which the local formulary decision-making group is judged not to have followed the published process.

1.15.4 Ensure the validity of a formal appeal is assessed by an independent appeals panel. The appeals panel should inform the health professional, in writing, if the appeal does not satisfy the defined grounds. The appeals panel should direct appeals that do satisfy the defined grounds to the most appropriate decision-making group for further consideration.

1.15.5 Ensure the appeals panel has a clear statement of purpose. Members should together have the skills and expertise necessary to enable them to make the decisions being asked of them.

1.15.6 Consider collaborating with neighbouring groups to ensure that adequate training and resources for the appeals process are available. This may include providing independent cross-organisational appeals panels. [amended 2015]

1.16 *Reviewing and updating the local formulary*

1.16.1 Establish a robust and transparent process for reviewing and updating the local formulary. This includes:

- ensuring new positive NICE technology appraisal recommendations are incorporated into the formulary automatically
- ensuring that when a NICE technology appraisal does not recommend a medicine, the medicine is withdrawn from the formulary, in line with NICE recommendations
- responding to important new evidence on all medicines included in the formulary in a timely manner, including withdrawing or amending the position of a medicine in the care pathway(s)
- responding promptly to important new information on medicines safety, such as

- serious adverse effects
- reviewing and updating associated [decision outputs](#)
- ensuring requests to review and reconsider the evidence are evaluated in a timely manner
- responding promptly to the identification of technical errors
- responding promptly to the outcome of appeals
- establishing a rolling schedule of structured formulary review.

1.16.2 Collaborate effectively with relevant stakeholders, including health professionals and other local decision-making groups, when reviewing and updating the local formulary.

Terms used in this guideline

Biosimilar medicines

A biosimilar medicine is a medicine that is developed to be similar to an existing biological medicine. Biosimilar medicines have the potential to offer the NHS considerable cost savings, especially as they are often used to treat long-term conditions. NICE has published a [position statement and process](#) for developing guidance and advice for these medicines.

Decision output

A locally developed output that is aligned to local formulary decisions. Examples include implementation policies, prescribing guidelines, treatment protocols, shared care agreements, patient care pathways, patient information and recommendations to commissioners and other decision-making groups.

Local formulary

For the purposes of this guideline, a local formulary is defined as 'the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a health economy, service or organisation'.

Local formulary decision-making group

A formally constituted group that makes decisions relating to medicines to be included within a local formulary. The name of the group and its relationship with other local policy committees may vary. Examples of local formulary decision-making groups include trust formulary groups, drug and therapeutics committees, interface formulary groups and area prescribing committees.

Medicine

The term 'medicine' includes all healthcare treatments that may be considered in local formularies. Examples include wound care products, appliances and vaccines.

Multi-criteria decision tool

A tool that is used to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact on the decision of all the criteria applied and the relative importance attached to them.

Robust and transparent

Robust and transparent processes, including sharing of information and appropriate collaboration with relevant stakeholders, aim to improve the consistency of decision-making about medicines and ensure that patient safety is not compromised. This should reduce inappropriate variation in patient care when decisions are made due to inconsistent, inadequate or unsafe processes and policies.

You can also see this guideline in the NICE pathway on [local formulary development](#).

To find out what NICE has said on topics related to this guideline, see our web page on [medicines management](#).

Context

Local formularies across England vary in the number of NHS organisations covered by the formulary, the range of medicines the formulary includes, and the processes for developing and updating the formulary.

Benefits of local formularies may include:

- improving patient outcomes by optimising the use of medicines
- supporting the inclusion of patient factors in decisions about medicines
- improving local care pathways
- improving collaboration between health professionals and commissioners
- improving quality by reducing inappropriate variations in clinical care
- improving quality through access to cost-effective medicines
- supporting the supply of medicines across a local health economy
- supporting financial management and expenditure on medicines across health communities
- supporting prescribers to follow guidance published by professional regulatory bodies in relation to medicines and prescribing.

Policy

The NHS Constitution for England, produced by the Department of Health (2012, revised 2015), provides patients with the right that medicines that have been considered by NICE through the technology appraisal process and given a positive assessment should be made available, where appropriate, and therefore be included in the formulary adopted by the local healthcare providers and commissioners.

The Constitution also provides a right for patients to have decisions about medicines that have not yet been considered by, or have not received a positive recommendation for use in the NHS through, a NICE technology appraisal process to be made by the local NHS using a robust assessment of the best available evidence.

After publication of the original NHS Constitution in 2009, key documents were produced to

support rational local decision-making. Defining guiding principles for processes supporting local decision making about medicines (2009), produced by the National Prescribing Centre^[1] and Department of Health, and the accompanying Supporting rational local decision-making about medicines (and treatments) (2009), produced by the National Prescribing Centre, underpin the good practice recommendations for developing and updating local formularies.

Statutory responsibility

Directions issued by the Secretary of State for Health (2010) make it a statutory obligation for commissioners to make funding available within 3 months for medicines that have been recommended by a NICE technology appraisal, unless they are directed otherwise by the Secretary of State for Health.

Innovation health and wealth

The Department of Health's report Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS (2011, updated 2012) sets out the aspiration for the Government to support the NHS to embrace innovation to meet the current and future healthcare challenges. In particular, the NHS should ensure that local systems and processes for accessing medicines support innovation where appropriate. The report states:

'Formulary processes should proactively consider the impact of new NICE technology appraisals, and all NICE technology appraisal recommendations should – where clinically appropriate – be automatically incorporated into local formularies. This process should take place within 90 days to support compliance with the three month funding direction and the NHS constitution ensuring that these medicines are available for clinicians to prescribe, should they choose to, in a way that supports safe and clinically appropriate practice.'

NICE compliance

In this report, the Department of Health introduced a NICE compliance regime for the funding direction attached to NICE technology appraisals to ensure rapid and consistent implementation throughout the NHS. The compliance regime aims to 'reduce variation and assure patients of their access to the clinically and cost-effective technologies and medicines their doctors believe they need'. NICE has defined what constitutes compliance with a NICE-approved medicine or treatment.

In a letter from the NHS Chief Executive in 2012, Innovation, Health and Wealth publication of NHS formularies, the Department of Health stated that all NHS organisations should publish information which sets out which NICE technology appraisals are included in their local formularies

by 1 April 2013 at the very latest. The Chief Executive stated that it is 'important that the publications are online, and are clear, simple and transparent, so that patients, the public and stakeholders can easily understand them'. From 1 April 2013, this became a standard term and condition in NHS standard contracts.

^[1]The National Prescribing Centre is now the NICE Medicines and Prescribing Centre

Recommendations for research

The Guideline Committee did not make any recommendations for research.

Changes after publication

October 2015: Some changes to recommendation wording were made for clarification only and did not change the meaning of the recommendations. Other changes did alter the meaning. These are indicated by [amended 2015] at the end of the recommendation.

Recommendations that have been changed

Amended recommendation wording (change to meaning)

Recommendation at the time of publication	Recommendation in current guideline	Reason for change
Ensure resources are available to undertake all functions needed as determined by the scope and geographical coverage of the local formulary. (2.3.5)	Take account of the resources needed to undertake all functions of the local formulary decision-making group, as determined by the scope and geographical coverage of the local formulary. (1.3.5)	The strength of the recommendation has been amended to reflect the need to consider the workload and resources implications of implementing the recommendation locally.
Address barriers that may delay the speed of adoption of medicines into the formulary, such as multiple applications to different decision-making groups, delayed or absent business planning, budget identification or service design. (2.10.2)	Consider addressing barriers that may delay the speed of adoption of medicines into the formulary, such as multiple applications to different decision-making groups, delayed or absent business planning, budget identification or service design. (1.10.2)	The strength of the recommendation has been amended to reflect the need to consider the workload and resources implications of implementing the recommendation locally.

<p>Secure adequate training and resources to operate the appeals process. Consider collaborating with neighbouring groups to provide independent cross-organisational appeals panels. (2.15.6)</p>	<p>Consider collaborating with neighbouring groups to ensure adequate training and resources for the appeals process. This may include providing independent cross-organisational appeals panels. (1.15.6)</p>	<p>The strength of the recommendation has been amended to reflect the need to consider the workload and resources implications of implementing the recommendation locally.</p>
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Changes to recommendation wording for clarification only (no change to meaning)

Recommendation numbers in current guideline	Comment
<p>1.1.3, 1.2.1, 1.2.2, 1.3.3, 1.4.1, 1.5.2, 1.5.3, 1.6.1, 1.6.3, 1.6.4, 1.6.5, 1.6.6, 1.8.1, 1.8.2, 1.9.1, 1.11.1, 1.11.2, 1.12.1, 1.12.2, 1.14.2, 1.14.3, 1.15.2, 1.15.3, 1.15.4, 1.16.1, 1.16.2</p>	<p>Small wording changes have been made for clarification only. There has been no change in meaning.</p>

February 2014: From February 2014, good practice guidance became known as medicines practice guidelines. This is to bring the guideline naming in line with other NICE products. This is purely a name change – the guideline recommendations and everything else remains the same.

August 2013: Recommendation 2.6.1 was amended to provide clarity on the adoption of medicines with a positive NICE technology appraisal into the formulary. The wording 'if clinically appropriate' has been removed from the recommendation.

The Department of Health has published several documents to support the adoption of NICE technologies onto local formularies, including [The NHS Constitution](#), the 'Comply or Explain' regime (as part of [Everyone counts: Planning for patients 2013/14](#)) and [Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS](#) (2011, updated 2012). The change in wording is to avoid any misinterpretation of the recommendation.

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Accreditation

