

Medicines Governance and Local Formulary Decisions

Under the Health and Care Act 2022 (effective from 1st July 2022), the planning, arranging and managing of local health care has been transferred from Clinical Commissioning Groups to Integrated Care Boards (ICBs). ICBs now have a statutory responsibility for commissioning services for the population within available resources.^{1,2}

The NHS Constitution for England, produced by the Department of Health in 2009 and updated in 2021, provides patients with certain rights in relation to medicines and other treatments.^{3,4}

In relation to treatments that have been considered by the National Institute for Health and Care Excellence (NICE) through the technology appraisal (TA) process, the constitution states that, where appropriate, positively assessed medicines and treatments should be made available to patients and be included in the formulary adopted by the local healthcare providers and commissioners: 'Patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS if your doctor says they are clinically appropriate for them. If a medicine has been appraised by NICE and given a positive assessment, then the ICB should ensure it is available to appropriate patients within the timescales specified in the full TA guidance, usually 90 days from the full guidance being published.'^{3,4}

Not all medicines are considered by NICE and therefore the decision to use other drugs is made at a local level, and the NHS constitution specifically states that, medicines (and treatments) 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, should be considered by the local NHS using a robust assessment of the best available evidence. Patients have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence and that where a medicine has not been made available, this can be clearly explained to them by their doctor.^{3,4}

All ICBs across England, including those in the East of England (EoE), have a local formulary decision making group, often known as the Area Prescribing Committee (APC). In Norfolk and Waveney, this is the Therapeutics Advisory Group (TAG). This group provides advice to the ICB and makes decisions on whether medicines and other prescribable products e.g. medical devices, may be used for patients across their systems including in primary and secondary care. APCs will also consider their local implementation plans for NICE TAs and clinical guidance. In some areas, separate committees are in operation to consider medical devices. APCs are made up of a range of healthcare professionals and will usually consist of commissioning, hospital trust and primary care representatives (medical & pharmaceutical), from all key local stakeholders.⁴⁻⁶ The APCs will work in close collaboration with their Provider Trust Drugs and Therapeutic Committees (DTCs), which provide medicines governance and associated oversight for their organisations. APCs will also link in with any regional committees which focus on medicines use, such as the Regional Medicines Optimisation Committees (RMOCs) where established, or the East of England Priorities Advisory Committee (EoE PAC).⁴⁻⁶

The core functions of an APC include, but are not limited to:⁵

- Assessment of clinical & cost effectiveness (including affordability) of medicines and other prescribable items.

- Development & maintenance of a joint formulary, including classification of medicines under the traffic light list, if used locally.
- Implementation of NICE TAs and Clinical Guidance.
- Consideration of other relevant guidance from other advisory bodies, i.e. NHS England, Royal Colleges, RMOs and other regional committees such as EoE PAC etc.
- Development and approval of shared care guidelines.
- Development and approval of prescribing guidelines.

The Drug Tariff is produced monthly by the Pharmaceutical Directorate of the NHS Business Services Authority (NHSBSA) for the Secretary of State for Health and Social Care. The Drug Tariff provides information on what will be paid to Pharmacy and dispensing contractors for NHS Services including both reimbursement (e.g. the cost of drugs and appliances supplied against an NHS Prescription form), and remuneration (e.g. professional fees/allowances which are paid as part of the NHS pharmacy contract).^{7,8}

Inclusion of an item in the national Drug Tariff(s) does not confer a specific recommendation that the item should be used across the NHS, it is solely to facilitate payment of the items supplied on a primary care prescription form, by Pharmacy and Appliance contractors across the UK.

Similarly, the British National Formulary (BNF) contains information and advice on prescribing and the pharmacology of most of the medicines available in the UK,⁹ and inclusion of a medicine in the BNF, does not confer a specific recommendation that an item should be used across the NHS.

All ICBs across England including the EoE retain and are required under the NHS Constitution to make their own decisions in relation to any medicines, medical devices and related treatments, which have not received a positive NICE TA recommendation.³

Document history

PAC approval date	27 th March 2023	Version	1
Consultation process	PAC members		
QA process	Katie Smith, Director of Clinical Quality, PrescQIPP. 26 th May 2023.		
Adapted for local use and supported by the TAG – May 2024			

References

1. The Kings Fund. Integrated care systems: how will they work under the Health and Care Act? May 2022. <https://www.kingsfund.org.uk/audio-video/integrated-care-systems-health-and-care-act>
2. HM Government. Health and Social Care Act 2022. April 2022 <https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted>
3. Department of Health and Social Care. The NHS Constitution for England. Last updated January 2021. <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england#staff-your-responsibilities>
4. NICE. Developing and updating local formularies. Medicines practice guideline [MPG1] Last updated October 2015. <https://www.nice.org.uk/guidance/mpg1/resources/developing-and-updating-local-formularies-pdf-1779400261573>
5. NHS Clinical Commissioners & NHS Confederation. The role and functions of Medicine Optimisation teams. July 2021. <https://www.nhsconfed.org/system/files/2021-07/Role-and-functions-of-the-CCG-medicines-optimisation-team.pdf>
6. University Hospital Southampton NHS Foundation Trust. Managing medicines: Prescribing committees. Medicines Learning Portal. Last updated July 2021. <https://www.medicineslearningportal.org/2016/02/managing-medicines-prescribing.html>
7. NHS Business Services Authority. Drug Tariff. March 2023. <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>
8. Pharmaceutical Services Negotiating Committee (PSNC). Virtual Drug Tariff. Last updated March 2022. <https://psnc.org.uk/dispensing-and-supply/dispensing-process/drug-tariff-resources/virtual-drug-tariff/>
9. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. <https://www.medicinescomplete.com/>