Local Health Economy Formulary Policy

What is the Local Health Economy Formulary?

The Local Health Economy (LHE) Formulary is a continually updated database of medicines that designates the local preferences for prescribing based on medicines included in the British National Formulary (BNF) and the Drug Tariff. It is available on the Medicines Management Team website www.centralandeasterncheshiremmt.nhs.uk.

All prescribers are asked to take the Local Health Economy (LHE) Formulary into account when exercising their clinical judgement.

The LHE Formulary is intended to cover:

- prescriptions written in primary care
- prescriptions or recommendations by hospital doctors in respect of outpatients or patients leaving hospital after an admission.

The LHE Formulary is for use in Vale Royal, South Cheshire and Eastern Cheshire. It should be taken into account by prescribers in the following hospitals and prescribers who prescribe for residents in the geographical areas covered by the CCGs:

Acute and Mental Health Trusts
- East Cheshire NHS Trust
- Mid Cheshire Hospitals NHS Foundation Trust
- Cheshire and Wirral Partnership Trust

Clinical Commissioning Groups (CCG)
- NHS Eastern Cheshire CCG
- NHS South Cheshire CCG
- NHS Vale Royal CCG

The LHE Formulary is hosted by Prescribing Services Ltd on the Eclipse system that imports prescribing data from primary care. Medicines are described at the presentation level (i.e. each entry is specific to the medicine, brand, dose and formulation) and formulary status is designated by a coloured dot as follows.

- Green = Recommended
- Green/Yellow = On formulary
- Yellow = A second or third line option within a drug group
• Pink (Specialist Recommendation) = Medicines that can safely be initiated in primary care on the recommendation of a specialist

• Pink (Specialist Initiation) = Medicines that require specialist initiation and/or stabilisation before prescribing is transferred to primary care

• Pink (Shared Care) = Medicines that require a more formal shared-care approach including regular secondary care review and monitoring

• Purple = Consultant / Specialist only prescribing

• Red = Discouraged

• Grey = Discouraged; not considered suitable for prescribing

• Blue = No formulary decision made / formulary position not yet considered (not to be prescribed until a formulary status has been agreed)

Additional notes on the scope of the Local Health Economy Formulary

• The LHE Formulary covers all chapters of the British National Formulary (BNF), and is designed to be used in conjunction with the BNF. Prescribers should refer to the BNF and individual medicines’ summary of product characteristics for prescribing information (see www.emc.medicines.org.uk), and take note of any relevant safety alerts;

• The LHE Formulary does not include an exhaustive list of unlicensed preparations and “specials”, although commonly prescribed preparations are included;

• The LHE formulary does not include all cancer medicines in the BNF; Clinical Commissioning Groups (CCGs) do not commission cancer services and decisions are not made at a local level.

• The LHE Formulary should be taken into account by prescribers when exercising their clinical judgement. However, it does not override the individual responsibility of prescribers to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any medicines they are considering.

The Local Health Economy Formulary is principally concerned with NHS prescribing. However, it is recognised that private providers may make recommendations / requests of general practice to prescribe. The principles that should be considered on receipt of such recommendations to prescribe privately are described in brief below, and in more detail in the Prescribing Commissioning Policy for patients referred privately requesting NHS Prescriptions (available at www.centralandeasterncheshireMMT.nhs.uk).
• Medicines that are routinely prescribed in primary care and are green (recommended), green/yellow (on formulary), yellow (second line) or pink (recommended) are suitable for prescribing on the recommendation of a private provider.

• Medicines that are not considered suitable for general practice prescribing and where an NHS consultant would normally retain responsibility for prescribing should not be prescribed in general practice on the recommendation of a private provider. These medicines have a purple (consultant/specialist only prescribing) status on the formulary. Ideally, patients should be made aware before a private referral that they may incur costs relating to treatment including prescriptions (the most common scenario is where patients seek private fertility treatment as all of the medicines are considered to be “consultant only” medicines).

• Where a medicine is designated as either suitable for shared care or for specialist initiation and/or stabilisation, the private specialist is expected to follow the same guidance as an NHS specialist. GPs should not be asked to take over prescribing until the patient is stable and the specialist has discharged any monitoring/dosage titration required, even if his means the patient incurs costs for part of their course of treatment. If a patient is unwilling or unable to pay for privately initiated treatment, the patient should be referred to an NHS specialist to initiate and stabilise treatment, or to take part in shared care, as required.

• Where a medicine is recommended by a private provider but is not normally considered suitable for prescribing within the LHE Formulary (i.e “grey listed”) the items should not generally be prescribed on the recommendation of a private provider, but should be substituted for a suitable formulary item (for example if a private provider recommends a brand name that is “grey listed” the primary care clinician may offer the patient the generic medicine or a formulary listed medicine with the same indication).

Note that patients and referring clinicians should be made aware of the LHE Formulary and that requests to prescribe medicines that are not included in the LHE Formulary may be declined. It is recommended that GPs include the following text in referral letters to both NHS and private providers:

**NHS Eastern Cheshire Clinical Commissioning Group [or NHS South Cheshire Clinical Commissioning Group or NHS Vale Royal Clinical Commissioning Group]**

has agreed to prescribe in line with the Local Health Economy Formulary. If a medicine is required that is not on the Local Health Economy Formulary please indicate the reason for this choice on the discharge notice or clinic letter. If no reason is stated it will be assumed that an alternative medicine from the Formulary can be substituted. The Local Health Economy Formulary is available at www.centralandeasterncheshiremmt.nhs.uk

**NICE Technology Appraisal guidance and the Local Health Economy Formulary**

Medicines recommended by NICE Technology Appraisal Guidance (TAG) are regarded as
included in the Local Health Economy within 3 months of the date of the publication of the TAG unless the medicine will only be prescribed for hospital inpatients. Some medicines will be fast-tracked and must be available within 30 days of NICE TAG. Commissioners have a statutory responsibility to make funding available for a drug or treatment recommended by NICE TAG within the timeframe recommended in that guidance.

When a TAG recommends use of a medicine that is not already in the LHE Formulary, the medicine will appear in the formulary within 3 months. Updated iterations will be published in electronic format several times a year and made available on the CCG websites.

Note that NICE TAGs are indication specific, and that some medicines require the development of a new care pathway during the transitional period between publication of the NICE TAG and inclusion in the formulary. While the formulary is able to give brief details of pathways, prescribers should be prepared to cross reference between the formulary and clinical guidelines and pathways.

**Specialist Only Prescribing**

A number of medicines in the LHE Formulary are marked with a purple dot and the description “Specialist only”. These medicines require specialist knowledge, intensive monitoring, specific dose adjustments or further evaluation in use, and primary care prescribing is not recommended. These treatments should be initiated by specialists only and prescribing retained within secondary/specialist care for the duration of treatment. If, however, a primary care prescriber has particular specialist knowledge or experience of prescribing a particular drug for a particular patient it would not always be appropriate for them to expect to transfer that prescribing responsibility back to secondary care.

Primary care prescribers may wish to prescribe “specialist only” medicines in exceptional circumstances to patients to ensure continuity of supply while arrangements are made to obtain usual supplies from secondary care.

The specialist only designation relates to the clinical responsibility for prescribing and does not imply that CCGs commission services including those medicines in particular pathways. Most high cost drugs will be designated as specialist only, and prescribers should familiarise themselves with the process for securing funding for these medicines before prescribing.

**Shared Care / Specialist initiation / Specialist Recommendation Medicines**

A number of medicines in the LHE Formulary are marked with a pink dot and the description “Shared Care”, “Specialist Initiation” or “Specialist Recommendation”. These words should be interpreted as an attempt to reduce the risk of harm and taken into account by prescribers when exercising their clinical judgement. These medicines may require careful dosage titration, be used for particular indications requiring specialist knowledge to assess response, or require significant near patient testing and an enduring oversight by specialist clinicians.

**Pink (Specialist Recommendation) =** Specialist recommends that the GP prescribes a medicine and the GP issues the first supply or Specialist recommends a treatment, issues the
first supply and GP continues treatment beyond the initial supply. The GP monitors, makes dose changes and manages the medicine. It is reasonable for a GP to write the first prescription after a telephone conversation or on receipt of a clinical letter from a relevant specialist clinician.

**Pink (Specialist Initiation)** = Specialist initiates and if required monitors, makes dose changes and manages the medicine until the patient is in a stable condition and any necessary dosage titration is complete. GP may issue repeat prescriptions for the medicine following specialist initiation and/or stabilisation.

The initial supply of medicine should be prescribed by a relevant specialist, and if monitoring of effectiveness and toxicity is required during a period of dosage titration and/or condition stabilisation this will be the specialist’s responsibility until treatment is stable, at which point the patient’s GP can be asked whether s/he will take over prescribing. The ‘Specialist Initiation’ annotations say nothing about who is or is not a relevant specialist in respect of a medicine. It will be reasonable for some of these medicines to be initiated by prescribers from more than one speciality.

**Pink (Shared Care Agreement)** = Specialist initiates treatment and transfers prescribing to the GP only following the specific advice in the shared care agreement for that specific medicine. If a shared care agreement is not in place then responsibility for prescribing remains within secondary care (see Appendix A for the shared care agreement template). Shared care agreements that have been agreed are available on the MMT website.

Different GPs might reasonably take different decisions regarding whether or when to prescribe, depending on their knowledge and experience, but decisions should be made for clinical rather than financial reasons. Legal responsibility for prescribing lies with the prescriber who signs the prescription.

**Transfer of Prescribing Responsibility**

When clinical and/or prescribing responsibility for a patient is transferred from secondary to primary care, the primary care prescriber should have the appropriate competence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a primary care prescriber would not normally be familiar with, must involve the ‘sharing of information with the primary care prescriber and their mutual agreement to the transfer of care.’

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP subject to his/her clinical confidence. These are not rigid guidelines. In all cases, secondary and primary care prescribers should discuss the appropriate management of individual patients personally. On occasions both parties may agree to work outside of this guidance, and this agreement should be clearly documented in the patient’s medical records.

**Other prescribing of medicines not included in the LHE Formulary**

The LHE Formulary includes a broad range of medicines but occasionally a prescriber may conclude that a non-formulary medicine is needed for a patient. Prescribers in both primary and secondary care should be able to justify the choice of a non-formulary medicine if called upon to do so. Hospital doctors should communicate the reason for the non-formulary choice to the patient’s GP and ideally seek the GP’s agreement before asking them to prescribe the non-
formulary item. Patients may be assessed by specialists other than local acute trusts whose formulary may vary from the local formulary. In these situations, it is acceptable to follow the recommendation of that specialist as long as it is in line with their local formulary e.g. GMMMG. Initiation or recommendation of non-formulary medicines may be challenged. CCGs may challenge practices with high levels of non-formulary prescribing; GPs, primary care prescribing advisers and CCG Governing body members or managers may challenge hospital doctors who prescribe or recommend non-formulary medicines.

Formulary Compliance

The CCGs have set a standard for formulary compliance for general practice members. The standard is that 95% or above of all prescribed items should be included on the formulary i.e. less than 5% of items should be specialist only (purple), discouraged (red) or discouraged; not considered suitable for prescribing (grey) listed. Primary care prescribers can check formulary status on the MMT website and preferred alternatives within the Eclipse formulary system, and via Optimise Rx (or similar point of care prescribing software). Practices will receive regular reports from the Medicines Management Team including formulary compliance.

Processes for Updating the LHE Formulary

The LHE formulary requires continual maintenance to take account of medicines that are introduced or discontinued or produced in new formulations or brands, as well as changes to NICE guidance and local care pathways.

The LHE formulary is administered and maintained by the Medicines Management Team. Clinicians may request items be added to the LHE formulary by a variety of routes.

If the requestor is a secondary care prescriber

Requests for new medicines that originate in secondary care should be communicated with members of the New Medicines Subgroup (NMSG) to avoid duplication of work between acute trusts. The NMSG will keep a log of all new medicines requested in the local area from both primary and secondary care. A New Pharmaceutical Product Request Form (Appendix B) should be completed, (if one has not already been completed) by the requesting clinician, supported by pharmacy team members. New product requests should be accompanied by a clinical pathway, if appropriate showing the place in therapy of the proposed addition to the formulary. This should then be forwarded for consideration to the New Medicines Subgroup (NMSG) of the Area Prescribing Group for them to develop a recommendation for the Area Prescribing Group (APG)\(^\text{1}\). It should also be considered at the Hospital Medicines Management Groups and final approval for inclusion onto the joint formulary occurs at APG if the medicine is likely to be prescribed in primary care. In certain circumstances (e.g. high financial or reputational risk to the CCG) the new product request will need to be approved by the CCG executive team / governing body prior to approval at APG.

If the requestor is a primary care prescriber

Requests for new medicines that originate in primary care should be communicated with

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members of the New Medicines Subgroup, and if appropriate a New Pharmaceutical Product Request Form will be completed for consideration at the relevant Medicines Management Groups and Area Prescribing Group. (Appendix B).

Medicines identified as newly prescribed

The software that holds the LHE Formulary provides a facility to identify new presentations that have been prescribed without having been previously considered by the Medicines Management Groups or Area Prescribing Group. These products are identified by a blue dot within the system.

On a monthly basis, a member of the medicines management team will review products with a “No formulary decision made / formulary position not yet considered” status and collate proposed changes on to a list for consideration at the NMSG to offer a recommendation to the Medicines Management Groups and / or Area Prescribing Group. The following principles will apply:

- Medicines with a positive NICE TAG issued more than 3 months ago will be included in the formulary for use in line with the NICE criteria only.
- Medicines with a positive NICE TAG with fast-track status issued more than 30 days ago will be included in the formulary for use in line with the NICE criteria only.
- Medicines that have been included in the formulary previously (Recommended, On Formulary or Second Line/Specialist initiation) that become available as generics in category M will automatically have the generic presentations added to the formulary.
- Branded medicines that are available in category M as lower cost generic medicines will generally be designated as “Grey – unsuitable for prescribing” to optimize the cost effectiveness of prescribing.
- Medicines that are new additions to BNF categories that already have formulary status will be accorded similar status to other medicines in the same category unless they have particular advantages over established agents. Medicines in a category with an existing extensive range of formulary choices that are more costly than existing agents will be categorised as either Red or Grey (discouraged/not suitable for prescribing).

All changes proposed on the monthly review list will be considered at the CCG Executive Prescribing Committee (EPC) initially, and the proposals either accepted or referred onwards to the relevant Medicines Management Group and / or the Area Prescribing Group for ratification. Medicines may be referred for completion of a New Pharmaceutical Product Request form if the medicine is entirely novel or represents a significant change in prescribing practice.

1 The Area Prescribing Group includes the Head of Prescribing and Medicines Optimisation and the Deputy Heads of Prescribing and Medicines Optimisation, the GP Prescribing Leads (NHS Eastern Cheshire CCG, NHS South Cheshire CCG and NHS Vale Royal CCG), the Directors of Pharmacy and Chair of the Medicines Management Committees from both East Cheshire NHS Trust and MidCheshire NHS Foundation Trust and a representative from Cheshire and Wirral Partnership Trust—see terms of reference on MMT website.

2 The Executive Prescribing Committee includes the Head of Prescribing and Medicines Optimisation and the Deputy Heads of Prescribing and Medicines Optimisation and the GP Prescribing Leads for NHS Eastern Cheshire CCG, NHS South Cheshire CCG and NHS Vale Royal CCG.
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Updating Formulary Status

- From time to time, BNF sections may be reviewed and updated, with whole sections considered by the Medicines Management Groups.

- Formulary status may be reviewed following receipt of drug safety information (for example where a Drug Safety Update recommends restricting medicines to a second line choice or use by specialists).

- Formulary status may be reviewed following the development of clinical pathways and guidance that include other medicines. Where the pathways have been agreed at Medicines Management Groups, the changes to formulary status will not require further ratification.

- Formulary status may be reviewed following the development of Quality, Innovation, Productivity and Prevention (QIPP) initiatives, including those that involve rebates from pharmaceutical industry (in line with the CCG rebate policy).

For further information

Please contact your Trust Chief Pharmacist or the Head of Prescribing and Medicines Optimisation in the first instance, via the Team Secretary:

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This policy was approved at the Area Prescribing Group on 13 March 2018. For review April 2020.

Appendix A (Template Shared Care Agreement)

http://www.centralandeasterncheshiremmt.nhs.uk/uploads/6864
Appendix B (Template New Pharmaceutical Product Request forms)

http://www.centralandeastcheshiremmt.nhs.uk/uploads/6861

Section A Joint New Pharmaceutical Prod.

http://www.centralandeastcheshiremmt.nhs.uk/uploads/6861

Section B Joint New Pharmaceutical Prod.

Section C - Consultation Response

http://www.centralandeastcheshiremmt.nhs.uk/uploads/6865

New Pharmaceutical Product Request Proc