NHS
Cheshire and Merseyside

Definitions and Criteria for Categorisation of Medicines in the Cheshire and Merseyside Formulary

Objectives

It is important for patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Specialist-led services and Primary Care prescribers.

These guidelines reinforce the basic premise that:

"When clinical and / or prescribing responsibility for a patient is transferred from Specialist-led services to Primary Care, the Primary Care prescriber should have the appropriate confidence 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, should not take place without the "sharing of information with the Primary Care prescriber and their mutual agreement to the transfer of care."

These are not rigid guidelines. Where necessary, Specialist-led services and Primary Care prescribers should discuss the appropriate management of individual patients on a case-by-case basis. On occasions, both parties may agree to work outside of this guidance.

This document supports the approach taken in the GMC guide: Good practice in prescribing and managing medicines and devices (5 April 2021)

Criteria for the categorisation of medicines on the formulary, or the moving of medicines between the groups will be primarily based on clinical issues. Issues for consideration will include:

- Evidence base
- Clinical responsibility / safety
- Patient convenience and preference
- Ensuring appropriate usage
- Ensuring efficient use (clinical and cost)
- Willingness to provide agreed shared care information
- Availability of suitable monitoring mechanisms in primary care

Further information regarding the process for review and categorisation, including devices, can be found in the Policy for the Cheshire and Merseyside Area Prescribing Group.

Definitions and Criteria for Inclusion

Red

Definition

Drugs which should be prescribed only by a specialist clinician. The specialist clinician is commonly situated in a hospital but may be within a locally commissioned specialist-led service situated in primary care.

General non-specialist prescribing of these medicines is **NOT** recommended unless there is a specific reason and a specific protocol and service set up to support this.

Non-specialist primary care prescribers may agree to prescribe RED medicines either in exceptional circumstances to ensure continuity of supply while arrangements are made to obtain usual supplies from Secondary Care, or under the locally commissioned consultant/GP specialist-led service. However, they should be mindful of the responsibilities they accept in doing this and each request must be discussed on an individual risk/benefit basis. The prescriber must ensure that the medication in question can be supplied by community pharmacies.

Primary Care prescribers must ensure that details of any RED drugs prescribed by the specialist clinician are recorded in individual patient records on computer systems. It is advisable to do so under the SNOMED code 394995008 or the READ code 8B2D (hospital prescription), and add to patients medication list as a hospital drug.

Criteria for Inclusion Red Medicines

RED medicines must satisfy any of the following criteria:

R1 Requiring specialist assessment to enable patient selection, initiation and on-going treatment.

R2 Requires long term on-going monitoring of efficacy by a specialist.

R3 Requires long term on-going monitoring of toxicity by a specialist (either because of difficulty in recognising side effects, or problematic or high cost investigations to identify toxicity).

R4 Specifically designated as “hospital only” by product licence, by Department of Health and Social Care (DHSC), National Institute for Health and Care Excellence (NICE) or British National Formulary (BNF).

R5 Where a medicine has been classified as Shared Care but a Shared Care Agreement has not been approved by the Cheshire and Merseyside Area Prescribing Group. This is a temporary situation; a shared care framework must be produced within a reasonable timescale

R6 Medicines which require preparation by the hospital pharmacy, unless an acceptable procedure for supply through a community pharmacy and/or community services pharmacy can be arranged.

R7 Where the administration requirements of a medicine makes it unsuitable for use in Primary Care.

Purple - Shared Care

Definition

Medicines are considered suitable for Primary Care prescribing and/or management, following specialist initiation of therapy, with on-going communication between the Primary Care prescriber and specialist, within the framework of a Shared Care Agreement. Medicines designated as requiring **Shared Care** require on-going input from both Specialist and Primary Care clinicians and patients should not be discharged from Specialist care.

Where prescribing and monitoring are required under Shared Care, the responsibilities rest with the clinicians as per the details within the Shared Care Agreement.

A Shared Care Agreement will always be available for Shared Care medicines and this document will include a Shared Care Agreement pro-forma which will be completed by all involved clinicians. This pro-forma will record agreement to take on defined aspects of care e.g. monitoring and/or on-going prescribing for the individual patients.

A policy detailing clinician responsibilities in Shared Care Agreements can be found in Appendix 1 of the shared care documents. This policy must be referred to in all cases of Shared Care.

Criteria for Inclusion Purple – Shared Care Medicines

All drugs to be included in this category must meet Shared Care criteria P1 to P3

P1 Requires specialist assessment to enable patient selection and also initiation, stabilisation and review of treatment and the patient's condition.

P2 Prescribing and/or management of the drug in Primary Care with specialist support and input, within the framework of the Shared Care Agreement is safe and convenient and that there is an appropriate mechanism for individual patient access in Primary Care.

P3 Requires specific long-term monitoring (blood test or other measurement) for adverse effects and / or efficacy of the drug to be completed in Primary Care, and requires on-going specialist support for the dose changes or management of adverse effects. Monitoring is required on a regular basis (typically four times a year).

Shared care agreements are intended to support both primary care and specialist trusts to deliver care within the terms of the agreement. Shared care agreements may be declined where there are reasonable concerns that the patient does not meet the criteria for shared care within the document, or primary care team does not have the resource to manage the patient. Where the concerns cannot be resolved between clinicians they can be escalated to either Place or Provider Trust for further discussion and support.

Amber

Definition

These medicines are considered suitable for primary care prescribing following varied levels of specialist input, as described below. The specialist clinician is commonly situated in a hospital but may be within a locally commissioned specialist-led service situated in primary care.

- **Amber Recommended** requires specialist assessment and recommendation to GP to prescribe in Primary Care. In accordance with the NHS Cheshire and Merseyside ICB Consensus on the Primary and Secondary Care Interface, if initiation is required within 14 days of the specialist appointment, the specialist should prescribe an initial course of at least 14 days. For courses of treatment up to 28 days, the specialist may prescribe the full course.
- **Amber Initiated** requires specialist initiation of prescribing. Prescribing to be continued by the specialist until stabilisation of the dose is achieved and the patient has been reviewed by the specialist.
- **Amber Patient Retained** requires specialist initiation of prescribing. Prescribing to be continued by specialist until stabilisation of the dose is achieved and the patient had been reviewed by the specialist. Patient remains under the care of specialist (ie not discharged) as occasional specialist input may be required.

Criteria for Inclusion Amber Medicines

Amber Recommended medicines must meet criteria A1 and A2:

A1 Requires specialist assessment to enable patient selection.

A2 Following specialist assessment, the medicine is suitable for prescribing in Primary Care.

Amber Initiated medicines must also meet criteria A3.

A3 Requires short to medium term specialist prescribing and monitoring of efficacy or toxicity until the patient's dose is stable

Amber Patient Retained medicines must meet criteria A1, A2 and A3 and must also meet criterion A4:

A4 May require occasional specialist input indefinitely and therefore the patient should not be discharged from specialist care.

Should the patient's condition become unstable with respect to the medication, the patient will be reviewed by the specialist service in an appropriate and timely manner without the need for a formal referral letter.

Where the patient's dose needs to be adjusted, this should be discussed and agreed, where appropriate, with the specialist service without the need for a formal referral back to the service.

For any complex safety issues such as the Pregnancy Prevention Programme, the specialist must not discharge the patient as occasional specialist input is required.

Prescribing support information will be produced when the Interface Prescribing subgroup and/or the ICB considers it to be required.

Green

Definition

Medicines for which Primary Care prescribers would normally take full responsibility for prescribing and monitoring. Green status does not imply that a medicine is superior to existing first-line drugs or is a recommended formulary choice. The Consensus on the Primary and Secondary Care Interface document provides clarity for prescribers across the sectors and there is no assumption that primary care automatically undertake all green prescribing.

There may be additional criteria specific to the medicine or device as part of an approved guideline or pathway, prescribers are reminded to ensure these are being used appropriately.

Criteria for Inclusion Green Medicines

Green medicines must satisfy both of the following criteria:

G1 Medicines for which Primary Care prescribers are able to take full responsibility for initiating and on-going prescribing. Local prescribing guidelines or NICE guidance may apply.

G2 Medicines are in routine use and can be prescribed within Primary and Secondary Care with no special restrictions, specialist knowledge or experience. This includes both licensed and documented unlicensed medicines.

Do Not Prescribe (DNP)

Definition

Medicines not recommended for use because of lack of evidence of clinical effectiveness, cost prioritisation or concerns over safety. Deviation from the policy may be considered on an individual basis where exceptional circumstances exist.

Criteria for Inclusion DNP Medicines

DNP medicines must meet at least one of the following criteria:

D1 Lack of data on clinical effectiveness compared with standard therapy

D2 Lack of data on safety compared with standard therapy

D3 Known excess of significant adverse events compared with standard therapy

D4 Lack of data on cost-effectiveness compared with standard therapy

D5 Less cost-effective than current standard therapy

D6 Not accepted as cost effective compared to other service development opportunities

D7 No significant advantage over currently supported therapy

D8 Discontinued less than (removed from formulary) 12-months ago.

D9 Medicines that NICE has not recommended for use and terminated technology appraisals, unless there is a local need.

Grey

Definition

These medicines have not yet been or are still being evaluated according to local processes and a decision on whether to commission their use has not yet been made. They should not be prescribed in any setting.

Non-Formulary drugs

Definition

Any drug or formulation not listed in the formulary is deemed to be non-formulary. Drugs are included in the formulary for their licensed indications – where inclusion of off-label use is considered to be included in the formulary, this is specifically stated in the formulary entry for the drug. The formulary is not an exhaustive list of hospital-only drugs.