PAN MERSEY APC

NHS
Pan Mersey
Area Prescribing Committee

Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary

Objectives

It is important for patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Secondary or Tertiary Care and Primary Care prescribers.

These guidelines reinforce the basic premise that:

"When clinical and / or prescribing responsibility for a patient is transferred from Secondary (or Tertiary) 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, Tertiary, 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.

This document supports the approach taken in the GMC Good practice in prescribing and managing medicines and devices (2013) guide: http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

Criteria for the inclusion of medicines on these lists, 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 can be found in the Pan Mersey Area Prescribing Committee Policy Document.

Definitions and Criteria for Inclusion

Red

Definition

Drugs which should be prescribed only by a specialist clinician.

Primary Care prescribing of these medicines is **NOT** recommended unless there is a specific reason and a specific protocol and service set up to support this.

Primary Care prescribers may prescribe RED medicines in exceptional circumstances to ensure continuity of supply while arrangements are made to obtain usual supplies from Secondary Care, but should be mindful of the responsibilities they accept in doing this.

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 READ code 8B2D (hospital prescription), or add to patients medication list as a hospital drug.

NB: Inclusion of medicines on the RED list does not mean that the medicine is approved for use, or it will be commissioned (this is a local decision). The list merely states where the clinical responsibility for prescribing should lie if it were approved for use.

Criteria for Inclusion Red Medicines

RED status will be allocated if **any one** of the following applies:

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 (DH), National Institute of Clinical Excellence (NICE) or BNF.

R5 Where a medicine has been classified as Shared Care but a Shared Care Agreement has not been approved by the Pan Mersey Area Prescribing Committee. 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.

Amber

Definition

These medicines are considered suitable for primary care prescribing following varied levels of specialist input as described below:

- **Amber Recommended** requires specialist assessment and recommendation to GP to prescribe in Primary Care
- **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.

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.

Prescribing support information will be available as required.

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 this document. This policy must be referred to in all cases of Shared Care.

All drugs to be included in this category must meet Shared Care criteria 1 to 3

SC1 Requires specialist assessment to enable patient selection and also initiation, stabilisation and review of treatment and the patient's condition.

SC2 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.

SC3 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).

Implicit in any shared care agreement is the understanding that participation is at the discretion of the Primary Care prescriber subject to their clinical confidence.

Black

Definition

Medicines not recommended for use because of lack of evidence of clinical effectiveness, cost prioritisation or concerns over safety.

Black medicines must meet at least one of the following criteria

B1 Lack of data on clinical effectiveness compared with standard therapy

B2 Lack of data on safety compared with standard therapy

B3 Known excess of significant adverse events compared with standard therapy

B4 Lack of data on cost-effectiveness compared with standard therapy

B5 Less cost-effective than current standard therapy

B6 Not accepted as cost effective compared to other service development opportunities

B7 No significant advantage over currently supported therapy

Grey

Definition

These medicines 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.

Green

Definition

Medicines for which GPs 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.

http://www.panmerseyapc.nhs.uk/index.html

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 Care with no special restrictions, specialist knowledge or experience.