Policy for Clinical and Prescribing Responsibility

1. INTRODUCTION

This document is intended to define the process for clarifying the clinical and prescribing responsibilities for individual drugs within Mid and South Essex Health Care Partnership (HCP).

This policy addresses:

- Joint Mid and South Essex formulary;
- Clinical responsibility for prescribing;
- Responsibilities to patients;
- The 'Traffic Lights' classification of drugs:
    - Black;
    - Red;
    - Amber;
    - Yellow;
      and
    - Green
- Principles of Shared Care guidelines.

This policy applies to primary/community care, general practitioners and hospital clinicians in the Trusts when considering the introduction of a new drug, a new use for an existing drug, the appropriateness of shared care prescribing arrangements for a particular condition or drug, or the transfer of prescribing of an individual drug from one setting to another.

2. FORMULARY

The Joint Mid and South Essex Formulary is a list of drugs approved for prescribing by the Mid and South Essex Medicines Optimisation Committee (MSEMOC).

The aim of the committee is to promote rational evidence-based, safe and cost-effective prescribing within the Mid and South-Essex HCP by all providers commissioned by Mid and South Essex CCGs.

A request to add a new drug to the formulary may be made by a Provider or CCG prescribing group or all individual prescribers in Mid and South Essex HCP. The formulary and 'Traffic Light' lists are reviewed regularly and drugs are re-classified in the light of new evidence or increased experience of use.

3. CLINICAL RESPONSIBILITY

Legal responsibility for prescribing lies with the doctor who signs the prescription. This includes the correct completion of the prescription and full or shared clinical responsibility for the treatment of the patient.

Prescribing costs may be part of discussions on clinical responsibilities between clinicians. The financial implications of the use of certain drugs form part of the contract negotiations between commissioner and provider as well as the formulary application review process.

GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list who is being treated elsewhere, but the reason for this action must be documented. GPs would be encouraged to take clinical and prescribing responsibilities for an individual drug, where the prescribing of that drug within primary care has become common practice and is supported by prescribing guidance approved by MSEMOC.

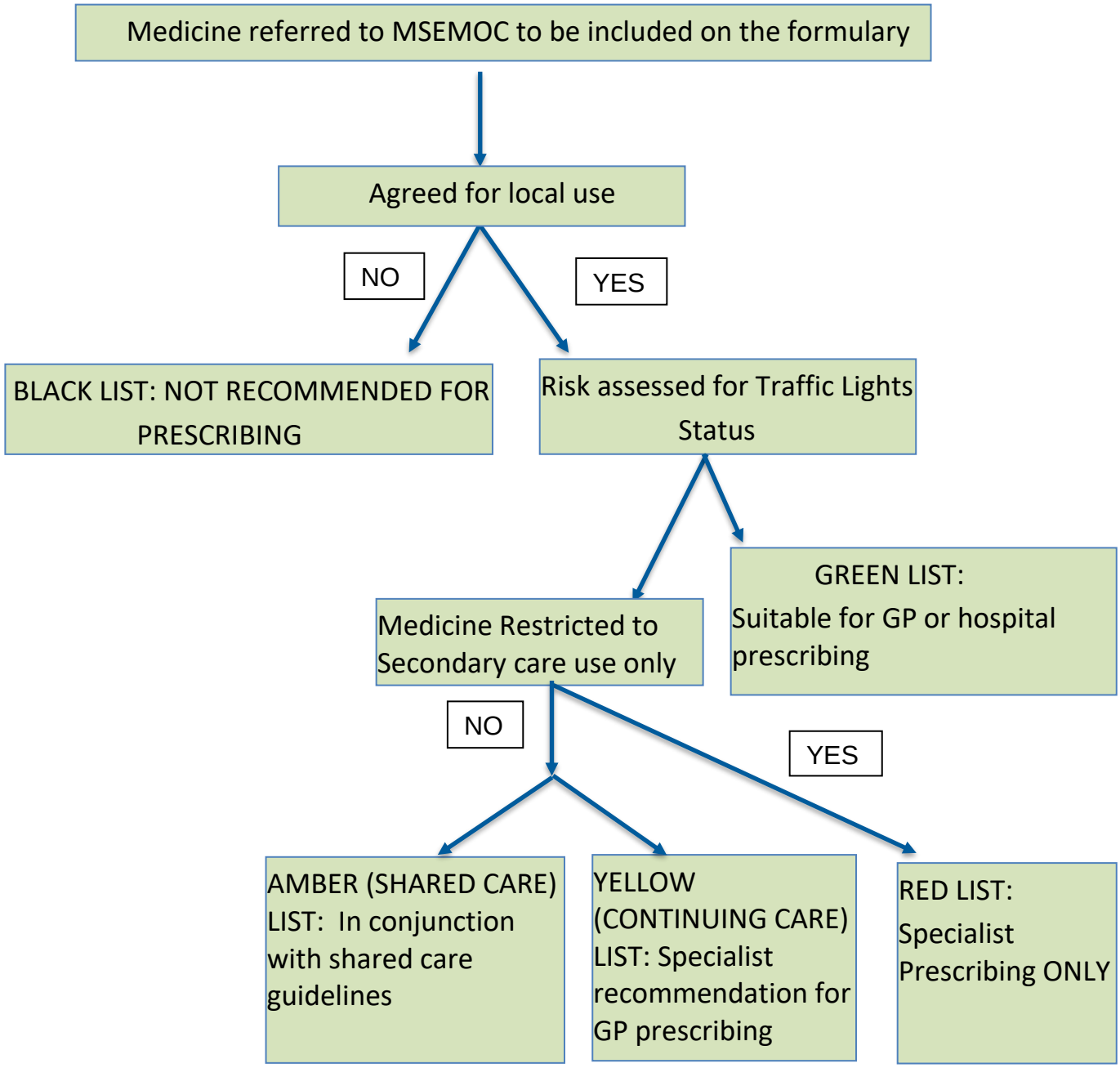
4. RESPONSIBILITIES TO PATIENTS

- Patients should be involved in the decision about their treatment but not be involved in discussions or disputes between clinicians on clinical or prescribing responsibilities. Patients may need to be kept informed about specific problems involving shared care prescribing arrangements but must not be used as intermediaries between consultants and GPs.

- The best interests and convenience of patients must be considered at all times.

- Whilst a decision is awaited as to which Traffic Light category a drug is in, or where shared care guidelines are being drawn up, the clinical responsibility and supply of the drug to the patient will be retained by the physician who initiated the treatment. The MSEMOC will consider the drug in question at their next meeting and determine the category to which it should be allocated. If a shared care guideline needs to be produced the drug will be classified as Red until such time as a shared care guideline is produced and approved.

5. TRAFFIC LIGHT CLASSIFICATION



BLACK LIST

The BLACK list is a list of drugs that have been formally assessed for prescribing within the Mid and South-Essex area and deemed not recommended. However, it should be noted that this list is not exhaustive; if a drug does not appear in the black list, it does not mean that it is recommended for prescribing within the formulary

Drugs are added to the list when, on consideration by MSEMOC, there is limited or no evidence of clinical and cost-effectiveness, or the evidence available indicates that the drug is clinically ineffective or is not cost effective or there are safety concerns.

Note any treatment appraisals terminated by NICE will automatically be designated a “BLACK” category

Conditions may be attached to drugs within this category, e.g. prescribing to be funded through Research & Development for Mid and South-Essex residents.

Drugs which are considered to be clinically effective, safe and cost-effective following formal consideration and approval by the MSEMOC are added to the formulary and assigned to one of the ‘Traffic Light’ lists:

RED LIST
Drugs on the RED list are considered suitable for specialist (consultant or accredited specialist) prescribing only, for the stated condition.

Prescribing responsibility remains with the consultant at the hospital or accredited specialist service, and must not be transferred on to the GP.

Drugs which meet the following criteria would be assigned to the RED list (Note that this list is not exhaustive):

- New drugs and new indications for older drugs where there is at present no experience of use in general practice.
- Medicines which require preparation by the hospital pharmacy, unless supply through a community pharmacist can be arranged and has prior agreement with commissioners.
- Unlicensed drugs or drugs used outside licensed indications with little clinical evidence / peer review to support the use.
- Drugs, dressings or appliances or other preparations not available or prescribable in general practice.
- Where a drug has been classified as AMBER but a fully approved shared care guideline is not yet available.
- Not appropriate for a GP to take full clinical responsibility for the patient (e.g. monitoring takes place within secondary care).
- New chemical entities marked with a black triangle i.e. under intensive monitoring. “Me-too” products marked with a black triangle, where there is experience in the use of the group of drugs to which it belongs, may be added to the GREEN list and prescribed in primary care.

Consultants may be expected to prescribe drugs from other categories in the following circumstances:

- The GP justifiably refuses to take clinical responsibility.
- A patient attends the hospital frequently for complex treatments and specialist investigations monitored by the consultant.

MSEMOC will assign drugs to either AMBER (Shared Care) or YELLOW (Continuing Care) category where ongoing specialist prescribing is not required (i.e. continued prescribing is not restricted to secondary care only) but specialist advice on regular monitoring, dose adjustments and review may be needed to ensure safe and effective use to support GP and other primary care clinicians who would not have the specialist knowledge to initiate and prescribe routinely.

AMBER (Shared Care(SC)) LIST

Drugs on the AMBER SC list are initiated by a specialist with prescribing continued by GPs and primary care in conjunction with a shared care guideline. The patient would normally be stabilised before prescribing responsibility is devolved. A shared care guideline is required detailing the prescribing clinicians' responsibility. These medicines require additional blood tests / clinical monitoring for safe prescribing which are/is considered to be over and above the level of monitoring expected for safe medication prescribing under essential services.

The difference between Amber SC and Yellow CC is that Amber SC drugs require more routine monitoring (at least every six months).

For drugs allocated to AMBER SC:

- Hospital consultants and general practitioners come to a written agreement that they will share clinical responsibility for a patient who is being seen by both of them;
- Prescribing in these circumstances is determined by the shared care prescribing arrangement agreed by MSEMOC for each individual drug and condition. It is recommended that in most circumstances monitoring and prescribing of the drug is undertaken by the same clinician. GPs are encouraged to accept shared care at local enhanced service i.e. they monitor blood results and prescribe in accordance with consultant guidance;
- The GP's role in the care of the patient should be justifiable in terms of improvement in patient care. GPs should have sufficient expertise to stop, or alter the dosage of the drug in appropriate circumstances. The degree of control which they have over this prescribing will form part of the shared care guidelines.
- Where a dispute arises in this area, advice will be sought from the CCG Medicines Management Teams who will advise the prescribers on the most appropriate way forward; and
- Adequate support, education and information from the hospital service must be available to GPs who "share care" of patients with a consultant.

Development of shared care guidelines

The MSEMOC will establish a mechanism to develop a shared care guideline for each drug allocated to this category.

- For drugs already categorised as AMBER for which no shared care guidelines are available the MSEMOC will produce guidelines for each drug, or group of drugs. For out of area secondary and tertiary referrals the originating Trust is responsible for producing and agreeing the shared care guidelines as defined below.
- Where consultants apply to the MSEMOC for a new drug to be entered onto the Formulary, or for an existing drug to be used in a new indication, advice will be sought from the MSEMOC as to which category that drug should fall. If the drug is categorised

as AMBER SC the consultant as part of the process required by the MSEMOC must produce a shared care guideline.

MSEMOC must approve all local shared care guidelines before they are used, and will ensure that they are regularly reviewed and updated. Those produced by out of area secondary and tertiary centres must be reviewed and approved by MSEMOC, if there is a requirement for use by non- associate commissioners unless an equivalent shared care guideline covering the condition and drug is already in place in Mid and South Essex. Until that point prescribing and monitoring responsibility will stay with the Trust.

The guideline developed should reflect all of the preceding principles. The aim of the guideline is to define the role and responsibilities of the GP and the Consultants who are agreeing to share clinical and prescribing responsibility for a particular patient with a particular disease or condition. A suggested format for these guidelines is detailed in Appendix 1.

When legal responsibility for overall clinical care of the patient is shared, then the manner in which it is shared will be indicated by the shared care guideline which will be in line with the principles of shared care as stated in NHSE's Responsibility for prescribing between primary and secondary/tertiary care guidance (https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/)

YELLOW

Drugs on the YELLOW list are considered suitable for prescribing in primary care once treatment has been initiated by a specialist (i.e. continuing care). A shared care guideline is not required but the GP must be supplied with sufficient information on the prescribed medication including specialist advice on regular monitoring, dose adjustments and review to ensure safe and effective use to support GP and other primary care clinicians who would not have the specialist knowledge to initiate and prescribe routinely. MSEMOC may make recommendations for the length of time prescribing remains with the specialist before the GP should accept prescribing responsibility.

GREEN

Drugs on the GREEN list are considered suitable for prescribing (including initiation) in primary care, where the GP has FULL clinical responsibility for the treatment of their patient.

Associated Documents

1. Ethical Framework
2. Formulary application for the use of a new medicine or existing medicine for a new indication
3. Traffic Light System Risk Assessment Tool

Mid and South Essex Health and Care Partnership

NHS

APPENDIX 1: SHARED CARE PRESCRIBING GUIDELINE – REQUIRED CONTENT

Background information on the condition to be treated
Including information on the disease, diagnostic criteria and investigations, general treatment and management and patient selection for drug treatment.

Drug treatment, licensed indications and management plan
Including indications and exclusion, pharmacology, products available, dosages, reconstituting, storage, administration, adverse effects, drug interactions, costs, patient information and availability of other information.

Procedures for initiating shared care prescribing
Including mechanism for reaching agreement, contractual and funding implications for Trusts, CCGs and the practices involved.

Role and responsibilities of Trust
Including the role of the consultant, prescribing responsibility and monitoring procedures, frequency of Trust attendance, emergency treatment arrangements, and exchange of information including change of treatment, special clinical and drug problems to be aware of and appropriate course of action.

Role and responsibilities of GP
Including the role of the GP, monitoring procedures, frequency of attendance at GP surgery, emergency treatment arrangements, exchange of information, prescribing responsibility, notifications of change of treatment, special clinical and drug problems to be aware of and appropriate course of action.

Role and responsibilities of patient
Including the role of the patient, understanding of the shared care agreement, completion of the consent form, contact the specialist/GP if they subsequently do not have a clear understanding of the treatment, attending for blood monitoring and follow up hospital or GP appointments, reporting any change in symptoms and adverse effects promptly to the clinician who is currently prescribing, alert GP and/or specialist of any changes of circumstance which could affect management of disease.

Proforma
Details of the specific patient, Consultant and GP for which guideline is being used. Proforma for consultant to sign will list roles and responsibilities of Trust. Proforma for GP to sign will list roles and responsibilities of GP. Each party will retain a copy of the others signed proforma. (Example: Proformas to be developed).

Support, education and information
Support available from Trust, meetings and other education or instructional courses which may be available, information available such as literature, video and audio tapes, films and other organisations and individuals who can provide information and support.

Advice help line
Arrangement for immediate advice and help from trust consultants and other appropriate staff.

Safety net
Procedure to be followed in case of problems initiating shared care.

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