Policy for Clinical and Prescribing Responsibility between Care Settings, including defining traffic light status.

Contents

1. INTRODUCTION

This policy supports the safe and effective prescribing of medicines and medicines- related devices (both referred to as drugs in this document). It provides a framework for all prescribers, both medical and non-medical, around transfer of care involving prescribing of medicines. It does not provide clinical guidance on medication choice.

This policy defines the process for clarifying the clinical and prescribing responsibilities within Mid and South Essex Integrated Care System (MSEICS).
It includes:

- Mid and South Essex ICS formulary
- Prescribing policies and guidelines
- Clinical responsibility for prescribing
- Responsibilities to patients
- The 'Traffic Light' classification of drugs
- Primary care funding arrangements

This policy is applicable to primary care clinicians and clinicians in NHS Trusts or other provider organisations where MSE Integrated Care Board (ICB) is the coordinating commissioner. It covers the introduction of new drugs, new uses for existing drugs, continuing and shared care prescribing arrangements, and the transfer of prescribing responsibility from one setting to another.

2. FORMULARY, POLICIES AND PRESCRIBING GUIDELINES

The **Formulary** is designed to promote safe, effective and cost-efficient use of medicines. It is maintained and regularly updated by the Mid and South Essex Medicines Optimisation Committee (MSE MOC), which reviews evidence and makes decisions about which drugs should be included based on factors such as clinical efficacy, safety and cost effectiveness. The formulary is an essential tool for ensuring that patients receive appropriate, effective and equitable treatments while also managing healthcare costs.

The Formulary is a list of drugs which have been approved for use within the MSE ICS, each drug is assigned a Traffic Light status (TLS). This TLS applies to all licensed indications for the formulary entry unless specified otherwise. If a specific list of indications is provided and a licensed/unlicensed indication is not on the list or the indication is specifically excluded, it is non-formulary for those indications The TLS applies only to the specified indications and patient cohort as stated. A drug may have multiple TLS based on the specific indications or patient group being treated. Where a NICE Technology Appraisal (TA) is applicable to a drug, its use must follow the criteria set out in the TA, which may restrict its licensed indication.

A request to add a new drug to the formulary may be made by a provider or ICB prescribing group or any individual prescriber and must be accompanied by a pathway defining its place in therapy. The formulary and TLS are reviewed regularly, and drugs may be re-classified in the light of new evidence or increased experience of use.

The aim is for the formulary to cover around 90% of prescribing; however, it is recognised that there are occasions when it is clinically necessary for a non-formulary medicine to be prescribed. Non-formulary medicines should be prescribed only when formulary choices are not suitable or

have been exhausted. Non-formulary prescribing should not be used to bypass usual NHS commissioned pathways.

Prescribers are reminded they are committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite NHS resources in line with principle 6 of the NHS Constitution for England.

Where a drug is not listed, or where the drug is listed but indication or group of patients is not listed or is excluded the drug is non-formulary; this means that the clinical and cost-effectiveness and/or place in a prescribing pathway for a specified indication/cohort of patients has not been considered locally.

Clinical and prescribing responsibility for non-formulary medicines is at the clinical discretion of the prescriber. Requests to prescribe should demonstrate why formulary choices are not suitable and the rationale for use. Clinical need, suitability for prescribing within primary care, and the prescriber's clinical competence to prescribe should all be considered by the prescriber when deciding whether to prescribe. Transfer of prescribing to primary care should only happen with the agreement of the primary care prescriber.

Prescribing **policies (**position statements) define the clinical circumstances in which formulary drugs may be prescribed and those circumstances when prescribing is not supported. See also **Medicines and Medicines Related Devices Commissioning Policy.**

Prescribing **guidelines** allow professional discretion and choice of prescribing using best practice drug pathways.

3. RESPONSIBILITY TO PATIENT

Decisions about who should take responsibility for care or treatment after initial diagnosis or assessment should be based on the patient's best interests, rather than on convenience or the cost of the medicine and associated monitoring or follow-up. Sharing of care assumes good communication between the specialist, primary care clinician and patient. It is important that patients are consulted about treatment and agree on-going care arrangements.

Patients should be involved in the decision about their treatment and agree to any shared/continuing care arrangements. Patients should 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.

4. CLINICAL RESPONSIBILITY

Clinical responsibility for prescribing should sit with professionals in the best position and appropriately skilled to deliver care which meets the patient's needs.

Legal responsibility for prescribing lies with the prescriber who signs the prescription, and it is the responsibility of the individual prescriber to prescribe within their own level of competence. This includes the correct completion of the prescription and full or shared clinical responsibility for the treatment of the patient.

There must be clarity on the responsibilities of all professionals involved in transfer of prescribing across primary, secondary and tertiary care, and including community, specialised services, and secure residential settings.

When decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the prescriber e.g. GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which the prescriber would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual prescribers. If the prescriber considers him- or herself unable to take on this responsibility, then this should be discussed between the relevant parties so that additional information or support can be made available, or alternative arrangements made.

Where a primary care clinician is uncertain about their competence to take responsibility for a patient's continued care, they should ask for further information or advice from the clinician who is sharing care responsibilities or from another experienced colleague. If still not satisfied, the primary care clinician should explain this to the other clinician and to the patient and make appropriate arrangements for their continued care (Good practice in prescribing and managing medicines and devices - shared care, GMC).

Primary care clinicians are encouraged to accept shared care in line with this policy. Declining to participate in shared care arrangements should be exceptional, cannot be resolved through adequate and appropriate training of prescribers within the GP practice and is in the best interests of the patient, provided the shared care protocol in question is of high quality and in line with MSE MOC shared care principles.

According to Good Medical Practice, clinicians must recognise and work within the limits of their competence and must keep their knowledge and skills up to date. If a clinician is unsure about a prescribing and managing medicines, they should seek advice from experience colleagues. Further advice on this is contained within the General Medical Council's (GMC) core guidance; Good Medical Practice or relevant practice guidance for non-medical prescribers.

4.1 Specialists from NHS tertiary or specialist centres

It is normally expected that the care and treatment of patients referred to tertiary care will remain the responsibility of the tertiary centre while they continue to require specialist care or as indicated within NHS England service specifications. If NHS England Commissioned Services are providing an advisory service for the assessment and development of a treatment plan only before transferring back to the referrer, the original referrer is responsible for making prescribing decisions in relation to the referral.

4.2 Out of area requests

Different ICBs have different formularies and TLS classifications which their prescribers are expected to follow, and which may lead to MSE non-formulary or conflicting TLS requests. If the primary care clinician feels that the drug is not suitable for primary care prescribing, this should be promptly communicated to the specialist with reasons for declining. However, requests may be accepted if primary care clinicians believe it is in the patient's best interest. The decision to prescribe, including for non-formulary items and where differing TLS, remains at the clinical discretion of the prescriber.

4.3 Unlicensed, off-label or specials medicines

For clarity:

- **Unlicensed medicines do not** have a marketing authorisation (license) and are not covered by any UK standard of quality, safety or effectiveness.
- **Off-label** means using a *licensed* medicine outside of the terms of the licence. This includes prescribing for a different indication or by a different route of administration from the licence e.g. crushing or dispersing tablets or opening up capsules.
- **Specials** are unlicensed medicines that are manufactured specifically to meet the special clinical needs of an individual patient. They are often liquids and are not usually listed in the BNF.

For unlicensed and/or off-label medicines the prescriber (either specialist or primary care clinician) and patient and/or patient representative should be aware of the unlicensed/off-label nature of the drug.

However, to note, there are many situations where an unlicensed/off-label medicine may be used for routine practice and continuation by GP may be entirely appropriate. For example, if there is a widespread acceptance of use of the medication for a particular indication or group of patients by a recognised national body.

Unlicensed and/or off-label use for an indication where there is no established evidence base should not be transferred to primary care under any circumstances. See Good Practice for Prescribing Unlicensed and Off-label Medicines.

4.4 Paediatric Medicines

Where there is a substantial body of evidence to support the use of unlicensed, off-label or specials medicines in paediatrics, the GP may be asked to prescribe. However, the GP, patient and/or patient representative should be fully informed of the unlicensed/off-label nature of the drug. The GP should refer to the Children's BNF as a guide for prescribing unlicensed or off-label medicines. The GP must be in full agreement of continuation of prescribing before prescribing is transferred.

Prescribers may wish to access the GMC guidance on prescribing off-label or unlicensed medications: http://www.gmcuk.org/guidance/ethical_guidance/14327.asp

4.5 Private specialist requests

Refer to Mid and South Essex ICB 080 Defining the Boundaries between NHS and Private Healthcare Policy - Mid and South Essex Integrated Care System This outlines the management of patients whose treatment is initiated by a private provider.

5. TRAFFIC LIGHT CLASSIFICATION

The traffic light system classification TLS (Black, Red, Amber, Yellow and Green) offers guidance on prescribing responsibilities and commissioning intention for selected products. It supports implementation of the guidance provided in the NHS England guidance Responsibility for prescribing between primary and secondary/tertiary care

The classification provides a framework for defining where clinical and therefore prescribing responsibility should lie through categorisation of individual drugs and/or indications. The criteria used for defining status is based on the **specialist nature of the drug and/or indication**, the **complexity of the assessment and monitoring** arrangements required for the care of the patient, **clinical responsibility and competency** associated with the prescribing of a medicine and is not based on the cost of a medication. The TLS of a drug does not determine whether or not it will be included in a local enhanced service. That is the decision of the Primary Care Commissioning Committee (PCCC).

It is important to note that the TLS assigned to a drug is advisory. Where necessary, specialists and primary care prescribers should discuss the appropriate management of individual patients personally taking into account monitoring requirements, drug interactions, frequency of routine patient visits to the specialist and the specialist nature of the condition being treated. Clinical judgement should be used to arrive at the most reasonable outcome and consider where prescribing is best managed. On occasions both parties may agree to work outside of this guidance.

MSE ICB has classified drugs using the following colour framework:

BLACK: Not commissioned. No NHS prescribing in any care setting.

RED: Restricted use – Prescribing to remain with the hospital or specialist service due to the requirement for specialist knowledge, long-term monitoring requirements, or restrictions which mean medicine supplies only available to/via hospitals. Not recommended for prescribing in primary care. Includes acute and mental health trusts and other specialist commissioning services.

AMBER: Initiated and stabilised by a specialist and prescribing can be continued in primary care in line with a Shared Care Agreement.

YELLOW: Continuation of prescribing in primary care following initiation or recommendation by a specialist. The term ‘specialist’ is not linked with a particular care setting and may be found in primary, secondary or community care. GPs may consider themselves to be specialists in certain areas of care, and as such choose to initiate a yellow drug.

GREEN: Initiation/prescribing within any care setting.

Definitions of traffic light statuses are shown below and the process to support TLS decision making is shown in Appendix 1.

5.1 BLACK TRAFFIC LIGHT STATUS

BLACK: Not commissioned and not recommended for prescribing in any care setting.

Black TLS drugs are those that have been formally assessed for prescribing within the Mid and South Essex area and considered to be low priority for funding/prescribing in any care setting e.g. primary care, community, or secondary care.

Drugs are given Black TLS when the decision has been made by MSE MOC **not to add** to the formulary for all or specified indications due to limited or no evidence of clinical and cost-effectiveness, or where the evidence available indicates that the drug is clinically ineffective or is not cost effective or there are safety concerns.

Drugs may be considered not appropriate for prescribing in primary, secondary or community care due to one or more of these reasons:

- Lack of data on clinical effectiveness compared with standard therapy.
- Lack of data on safety compared with standard therapy.
- Known increase in risk of adverse events compared with standard therapy.
- Lack of data on cost-effectiveness compared with standard therapy.
- Less cost-effective than current standard therapy.
- NICE guidance which does not recommend the use of the drug. Note any technology appraisals terminated by NICE will automatically be designated as Black TLS.
- Not a priority for funding.

Following formal consideration and approval by the MSE MOC, drugs which are considered to be clinically effective, safe and cost-effective are added to the formulary and assigned a TLS.

5.2 RED TRAFFIC LIGHT STATUS

RED: Restricted use – Prescribing to remain with the hospital or specialist service due to the requirement for specialist knowledge, long-term monitoring requirements, or restrictions which mean medicine supplies are only available to hospitals. Not recommended for prescribing in primary care. Includes acute and mental health trusts and other specialist commissioning services.

Red TLS drugs are considered suitable for specialist (consultant or accredited specialist) prescribing only, for the stated condition. Prescribing responsibility remains with specialists because of clinical issues or because funding responsibility lies with NHS England, and/or in line with Integrated Care Board policies.

A Red TLS may be assigned to drugs due to one or more of these reasons (note that this list is not exhaustive):

- Drugs 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.
- The condition is not commonly treated in primary care.
- Not appropriate for a primary care clinician to take full clinical responsibility for the patient (e.g. monitoring takes place within secondary care).
- The individual primary care clinician is unable to monitor therapy sufficiently to oversee treatment or adjust the dose where necessary to ensure safety. This includes the requirement of specialist monitoring of toxicity (because the side-effect profile necessitates rigorous supervision by the hospital consultant or, the full range of possible side-effects, particularly long-term effects, needs to be established).
- The drug or condition requires specialist knowledge to ensure safe prescribing and monitoring. The safe management of patients in primary care cannot be supported through provision of comprehensive written information.
- Drug, dressing or appliance is only available through a hospital.
- The drugs is only approved for use at the NHS discounted price which is only available through a hospital or specialist provider.
- Drugs by manufacturer's recommendation as being specialist only.

5.3 AMBER (Shared Care) TRAFFIC LIGHT STATUS

AMBER (shared care): Recommended for prescribing following specialist initiation and stabilisation in line with a Shared Care Agreement.

Specialists are responsible for any baseline monitoring and prescribing should remain with the specialist until such time that the dose has been titrated and stabilised, side effects monitored appropriately, and beneficial response demonstrated. Following on from this, responsibility for clinical prescribing can be transferred to primary care clinicians in conjunction with a Shared Care Agreement or equivalent or (where appropriate) with patient specific information provided by the hospital specialist.

Locally adopted or agreed shared care protocols, supporting the Shared Care Agreement, are available (shared care), however where an agreed protocol is not in place, individual shared care agreements between primary and secondary care can be exchanged. These drugs 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 the primary medical services core contract.

For drugs allocated to Amber TLS:

- Hospital consultants and primary care clinicians come to a written agreement that they will share clinical responsibility for a patient who is being seen by both of them.
- Responsibilities for prescribing in these circumstances are included in the SCP for each individual drug and taking into consideration condition(s) where appropriate. It is recommended that in most circumstances monitoring and prescribing of the drug is undertaken by the same clinician.
- The primary care clinician's role in the care of the patient should be justifiable in terms of improvement in patient care. Primary care clinicians should have sufficient competence

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 protocols.
- Adequate support, education and information from the specialist service must be available to primary care clinicians who "share care" of patients with a consultant.

Various considerations will lead to the decision that a drug is suitable as Amber TLS, including (but not limited to):
- Who is responsible for adjusting the dose and/or making the decision to discontinue it?
- Is there additional drug monitoring associated with prescribing?
  - Is the frequency of the additional drug monitoring considered above core primary care essential services, e.g. more frequently than six-monthly?
  - Is it safe and practical to undertake this additional monitoring in primary care?
- What will the patient gain by the care being shared?
- Is the drug included in a Local Enhanced Scheme agreed by PCCC?

5.3.1 Development of shared care protocols

The ICB will use nationally developed shared care protocols (SCP) where they are available. MSE MOC will approve all locally developed or national adopted or adapted shared care protocols before they are used and will ensure that they are regularly reviewed and updated. Until an SCP is in place, prescribing and monitoring responsibility remains with the prescriber who initiated the medicine.

Individual prescribers may accept sharing of care using an out-of-area shared care protocol at their discretion, the SCP is in line with MSEMOC shared care principles.

The SCP developed should reflect all of the preceding principles. The aim of the SCP is to define the role and responsibilities of the clinicians who are agreeing to share clinical and prescribing responsibility for a particular patient with a particular disease or condition. For further information on shared care within Mid and South Essex, please see the following link.

5.4 YELLOW TRAFFIC LIGHT STATUS

YELLOW (continuing care): Continuation of prescribing in primary care following initiation or recommendation by a specialist e.g. following advice and guidance.

The term 'specialist' is not linked with a particular care setting and may be found in primary, secondary or community care. Prescribers, e.g. GPs may consider themselves to be specialists in certain areas of care, and as such choose to initiate a 'yellow' drug.

Prescribers must recognise and work within the limits of their competence and must maintain and develop knowledge and skills relevant to their role and practice, including prescribing and managing medicines. If a primary care clinician is uncertain about their competence to take responsibility for continuing care, we would encourage them to seek further information or advice from the clinician who initiated or recommended the medication, or from another experienced colleague.

A formal shared care agreement is not required for drugs with a Yellow TLS however, the primary care clinician must be supplied with sufficient information about the medication such as advice on monitoring, dose adjustments, side-effect profile to ensure safe and effective prescribing in

primary care. This can be communicated in the form of a SCP if appropriate or another form of written communication such as a clinic letter or entry into the clinical system.

The formulary entry may make recommendations for the length of time prescribing remains with the specialist before the primary care clinician should accept prescribing responsibility.

5.5 GREEN TRAFFIC LIGHT STATUS

GREEN: Recommended for prescribing and treatment and considered to be suitable for initiation in any care setting, i.e. primary, secondary or community care and continuation in primary care

Prescribers must recognise and work within the limits of their competence and must maintain and develop knowledge and skills relevant to their role and practice, including prescribing and managing medicines. Green status does not mean that a treatment must be initiated by a prescriber if they consider it is not within the limits of their competence and they do not have the current clinical knowledge and skills. This may be particularly relevant for recently licensed/approved medicines/new indication(s) for existing medicine. Advice can be sought from an appropriate experienced colleague, or advice and guidance can be sought from an appropriate specialist to support a prescribing decision.

Associated Documents

1. Ethical Framework
2. Formulary application for the use of a new medicine or existing medicine for a new indication
3. Mid and South Essex Integrated Care System Medicines Standards 2022-2027
4. Medicines Optimisation Service Specification for Mid and South Essex Foundation Trust

Version	4
Developed by	MSEMOC working group
Acknowledgements	NHS Suffolk and Northeast Essex Area Prescribing Committee
Approved by	Mid and South Essex Medicine Optimisation Committee (MSEMOC)
Date approved	September 2024
Review date	September 2029

Appendix 1: Flowchart to support defining TLS of a drug