

INTRODUCTION

A close-up photograph of various pills and capsules scattered on a light blue surface. The pills are in various colors (white, yellow, orange, red, blue, black) and shapes (round, oval, rectangular, capsule). Some have markings like 'AV', 'PRN', and '1P.M.'.

Formulary and Prescribing Guidelines

A decorative graphic in the bottom right corner consisting of a cluster of colored dots in shades of purple, blue, and orange.

INTRODUCTION

The Trust's Medicines Management Group aids prescribers by evaluating the evidence for new and existing drugs, and making recommendations on therapies on clinical and economic grounds. Where appropriate, restrictions on the use of particular drugs may be recommended.

The Formulary and Prescribing Guidelines (F&PG) is about those drugs approved for use within Essex Partnership University NHS Foundation Trust (EPUT) by the Medicines Management Group (MMG).

The primary purpose of the formulary is to recommend preferred drug treatments for commonly-encountered clinical conditions, in order to rationalise the range of products used within the organisation. The drugs recommended in this formulary have been selected on the basis of their efficacy and side-effect profiles relative to other drugs in the same therapeutic class. If there are a number of drugs of similar efficacy and safety within the same class, the NHS price will also be taken into consideration when determining which products to include within the formulary. Prescribers should always refer to the latest edition of the [BNF](#) or [Summary of Product Characteristics](#) (SPC) for information regarding dosages, contraindications and side effects.

This document also aims to be a source of advice and guidance on best clinical practice, from both local and national perspectives. In particular, it is important that it should reflect the recommendations contained within the [NICE](#) Clinical Guidelines (CGs) and Technology Appraisals (TAs), since the Trust has a duty to ensure that local clinical practice is compliant with NICE. Information from other acknowledged psychiatric sources including the British Association of Psychopharmacology, The Maudsley Prescribing Guidelines and the Psychotropic Drug Directory are also considered.

The F&PG is designed to be a dynamic document used electronically with links available to relevant appendices, sections and annexes allowing efficient access to relevant information. Links to external sites and documents e.g. NICE CGs and TAs, have also been inserted for convenience of the reader. Whilst every attempt will be made to ensure the information contained within this document is accurate, readers are always encouraged to ensure they use the most up to date information sources to aid clinical decision making. All comments and suggestions should be forwarded to epunft.askpharmacy@nhs.net

NICE has published recommendations¹ for practitioners involved in making decisions regarding individuals who lack capacity or supporting decision-making in individuals who have capacity, to follow the 5 key principles set out in section 1 of the Mental Capacity Act 2005. As a starting point they must assume capacity unless there is evidence to suggest an assessment is required.

When giving information about a decision to the person:

- it must be accessible, relevant and tailored to their specific needs
- it should be sufficient to allow the person to make an informed choice about the specific decision in question
- it should be supported by tools such as visual materials, visual aids, communication aids and hearing aids, as appropriate

NICE has also published specific recommendations² for decision making in patients under the age of eighteen. An example of a visual aid to support decision making in young people is shown in Appendix 1.

NICE has also published general recommendations³ on shared decision making. This covers how to make shared decision making part of everyday care in all healthcare settings. It promotes ways for healthcare professionals and people using services to work together to make decisions about treatment and care. It includes recommendations on training, communicating risks, benefits and consequences, using decision aids, and how to embed shared decision making in organisational culture and practices.

NICE has published recommendations⁴ on safe prescribing and dispensing in the management of self-harm. This recommends that healthcare professionals should use consultations and medicines reviews as an opportunity to assess self-harm, asking about thoughts of self-harm, suicide, actual self-harm and access to substances that might be taken in overdose.

When prescribing medicines to someone who has previously self-harmed or who may self-harm in the future, healthcare professionals should take into account:

- the toxicity and pharmacokinetic properties of the prescribed medicines for people at risk of overdose
- their recreational drug and alcohol consumption, the risk of misuse, and possible interactions with prescribed medicines
- the person's wider access to medicines prescribed for themselves or others
- the need for effective communication where multiple prescribers are involved.

Shared decision making should be used to discuss limiting the quantity of medicines supplied to people with a history of self-harm.

The F&PG is designed to help the practitioner with such decision-making, and includes examples of such appropriate tools.

CLASSIFICATION OF DRUGS

Formulary Drugs

Drugs approved by the MMG for use within the Trust which have proven efficacy and supporting evidence.

Non-formulary drugs

Drugs that are new to the market, have unsubstantiated benefits, have significant cost implications or have serious adverse effects are included in this category. Also in this category are drugs that offer no advantages over existing similar drugs. They are not stocked in pharmacy and should not be routinely prescribed. However, they may be made available in exceptional circumstances e.g. if a patient has been maintained on the drug for some time or if a consultant wishes to try a drug for an individual patient before requesting inclusion in the formulary. Submissions for non-formulary drugs to be added to the Formulary should be made to the MMG using the paperwork contained in Appendix 1 of CLP13 SOP 03 – New and Non-formulary drugs. Non-formulary drug requests for individual patients should be made using Appendix 2 and forwarded to the chair of the MMG for consideration. Detailed information regarding non-formulary medication can be found in CLP13.

Restricted

Some drugs are required to be initiated by a consultant or under his/her direct instruction. These drugs tend to require specialist knowledge and/or monitoring.

Off-label use of licensed drugs

In psychiatry, clinicians frequently prescribe licensed drugs for indications that are not covered by the terms of their marketing authorisation (product license). In this situation, liability for any adverse consequences arising from treatment rests with the clinician and the Trust rather than with the manufacturer.

The MH & LD Formulary Listing lists unlicensed indications/off-label uses for UK licensed drugs, which are acknowledged by the Medicines Management Group as representing acceptable clinical practice. Many of these unlicensed indications (off-label use) are well-established in clinical practice, and have a sound basis in published data. Provided there is a reasonable body of medical opinion supporting the use of a drug for an unlicensed indication, the clinician and the Trust would be able to defend themselves against a claim (Bolam principle). Additional counselling will need to be provided to the patient as the indication for which the agent is being used will not be acknowledged within the patient information leaflet.

If a clinician wishes to use a licensed product off label that is not listed in the Formulary Listing, they are advised to seek the approval of the MMG using the paperwork contained in SOP 02 (Unlicensed medicines) of CLP13. Submissions should be made to the chair of

the MMG along with any supporting evidence for consideration. (Readers are referred to CLP13 for guidance relating to the request of a drug which **does not hold** a UK product licence (SOP 02) and/or new drugs which are currently non-formulary (SOP 03)).

References

1. NICE guideline NG108: Decision-making and mental capacity. Published October 2018.
2. NICE guideline NG204: Babies, children and young people's experience of healthcare. Published: 25 August 2021.
3. NICE guideline NG197: Shared decision making. Published: 17 June 2021.
4. NICE guideline NG225: Self-harm: assessment, management and preventing recurrence. Published : 7 September 2022.

Appendix 1: Visual summary setting out how to use NICE guidelines on young people's experience of healthcare.

