

Procedure for Prescribing Non-Formulary Medicines

Purpose of this procedure:

The aim of this procedure is to outline the process in NHS Lothian for handling requests for approval for prescription of non-formulary medicines.

The key **objectives** of this procedure are:

- to ensure a consistent approach across Lothian
- to ensure individual patient need is met

The Procedure:

1.0 Scope of Procedure

This procedure applies to all healthcare professionals involved in the prescribing and supply of non formulary medicines, in NHS Lothian.

When this procedure refers to medicines it also includes any products that are licensed as a medical device but are used in the place of a licensed medicine. For example eye drops.

A further definition is a medicinal product for human use (2001/83/EC):

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

2.0 Introduction and Background

Formulary medicines will meet the needs of the vast majority of patients but individual patients may have a need for a medicine which is non-formulary.

There needs to be a mechanism for prescribing a medicine to an individual patient when clinical circumstances prevail, and the medicine has not been approved by the Formulary Committee (FC).

There may be a delay in obtaining the medicine if it is not routinely stocked in the pharmacy store.

It is important that NHS Lothian has a simple and clear process to facilitate the prescribing of non-formulary medicines where there is a clear patient need.

This procedure covers all non-formulary medicines except those that are not recommended by the SMC. Separate policies are in place for medicines not recommended for use in NHS Scotland.

3.0 Definitions

The NHS Lothian Formulary classification is as follows:

Formulary Medicines

The medicines considered to be formulary are those:

- (a) **Included** in the Lothian Joint Formulary; first or second choice or in the prescribing notes
- (b) **Additional List**: are approved for use in specialist units or when formulary drugs are ineffective, not tolerated or are contraindicated.

As per the standard template for recording decisions developed by the ADTC Collaborative, Formulary Committee will classify medicines using the standard wording as below:

Routinely available in line with national guidance;

Routinely available in line with local or regional guidance;

Routinely available from a specialist centre in another health board;

Unlicensed medicines are classified by a traffic light system as set out in the ADTC NHS Lothian '[Policy and procedures for the Use of unlicensed medicines](#)' - see full document via this link.

RED: Specialist Use only

AMBER: General Use with restrictions

GREEN: Unrestricted General Use

BLACK: Not approved for use (*non-formulary medicine*)

Non-Formulary Medicines

The medicines considered to be non-formulary are those:

- (a) **Not included**: recommended by the SMC but not included in Lothian as suitable alternatives exist or an applications has not been made to the Formulary Committee. (Prescribing of these medicines can be approved through non-formulary medicines route.)
- (b) **Not recommended**: not recommended by the SMC (as not cost effective), therefore, nor by the ADTC/Formulary Committee for use in Lothian. (Prescribing of these medicines may be approved through the PTR route, where appropriate.) **This is not included in this procedure.**

As per the standard template for recording decisions developed by the ADTC Collaborative, Formulary Committee will classify medicines using the standard wording as below:

Not routinely available as not recommended for use in NHSScotland;

Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines;

Not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts - decision expected by [date].

4.0 Procedure for Approval for a Prescription of a Non-Formulary Medicine

When a request for a non-formulary medicine for an individual patient is made by a Clinical Team, they should discuss its clinical appropriateness and any alternative approved choices and agree on the best treatment. In all circumstances except SMC not recommended medicines a non-formulary medicine request form should be completed (Appendix 1) detailing reasons for choice and in particular why approved alternatives are not suitable.

For licensed medicines which are SMC not recommended /not yet assessed by the SMC follow the [PACS1/PACS2 procedure](#).

Requests for use should be made for each individual patient.

If the consultant would like to introduce a non-formulary medicine in to routine clinical practice, they should complete the appropriate formulary form.

See www.ljf.scot.nhs.uk/FormularyCommittee/FormularyApplicationForms/Pages/default.aspx

These should be returned to the Formulary Pharmacist for consideration by the Formulary Committee. Send to prescribing@nhslothian.scot.nhs.uk

4.1 Consultant's Responsibilities

The consultant in charge of the patient's treatment plan is the key individual who can initiate and prescribe non-formulary medicines.

The consultant should discuss the need for a non-formulary medicine with the relevant clinical pharmacist to ensure that there are no alternative medicines available for use and gain information on associated costs of treatment.

The Consultant must discuss with the Clinical Director any significant resource implications prior to implementing the treatment plan in order to identify a budget. This element should be expedited as soon as possible to avoid any detriment to patient care. Once agreement obtained the appropriate form must be completed.

4.2 Clinical Pharmacist's Responsibilities

The clinical pharmacist should provide professional advice regarding the non-formulary medicine and identify any alternative medicines which are approved that may be appropriate for treating the patient. If the non-formulary medicine is seen to be the only alternative, the clinical pharmacist will direct clinicians to the appropriate forms and procedure for their completion.

They will also ensure the applying clinician is aware of any necessary steps which the team need to undertake to implement use of the non-formulary medicine. This may include (but is not limited to): protocol development, completion of ULM paperwork, setting up of JAC stock files, aseptic worksheets, liaison with the MDT to scope service impact and staff education.

If authorisation is given to prescribe the non-formulary medicine, the Non-formulary Medicine Request Form (Appendix 1) signed by the appropriate clinical director (or deputy) should be received from the consultant prior to arrangements for supply or dispensing of the medicine being made

The clinical pharmacist will work with the relevant Pharmacy department to arrange the supply of the medicine.

The pharmacy department may not routinely stock a non-formulary medicine and therefore, this may result in a delay in supply of the non-formulary medicine.

In the event of professional disagreement between the consultant and the clinical pharmacist as to the appropriateness or otherwise of the prescription of a non-formulary medicine the discussion may be referred to the relevant Clinical Director, Site Lead Pharmacist, Associate Director of Pharmacy, or Chair of Drug and Therapeutics Committee for arbitration.

If in the professional judgement of the prescriber and the clinical pharmacist there is an emergency situation and CD approval is not available in an appropriate timescale, then no further consultation is required and the medicine should be obtained without delay with retrospective completion of the relevant forms.

Forms should be returned to the Medicines Management teams as soon as completed, they should not be stockpiled and returned in batches.

4.3 Clinical Director's Responsibilities

Clinical Director's approval must be sought for all treatment with a non-formulary medicine.

For adult cancer medicines the cancer medicines management committee (MMC) has devolved responsibility to make decisions for non-formulary requests. Clinicians should submit completed forms via email to: CancerMedicines.Mgmt@nhslothian.scot.nhs.uk.

4.4 Budget Holder's Responsibilities

The Budget Holder will need to consult with the relevant Director of Operations if the prescription cannot be managed within the overall directorate budget allocation or the appropriate Health and Social Care Partnership manager.

5.0 Monitoring

The Medicines Management teams will collate the completed forms and provide summaries to Drugs and Therapeutics Committees and Medicines Utilisation Review Group (MURG) as requested.

The Drug and Therapeutics Committees are required to review the summary reports in order to identify trends and to take appropriate action. This may involve identifying the need for a submission suggesting changes to the Lothian Joint Formulary.

The MURG will collate information on non-formulary prescribing and report it as appropriate to Area Drugs and Therapeutics Committee. The report should consider any prescribing patterns and the appropriateness of the prescribing.

6.0 Conclusion

- A medicine should not normally be prescribed unless it is an NHS Lothian approved medicine.
- Prescribers are encouraged to submit the appropriate formulary request forms to the Lothian Formulary Committee for any proposal to change the classification of a medicine.

To ensure that prescribing of non-formulary medicines is appropriate, NHS Lothian needs to ensure that systems exist to:

- Remind prescribers of the NHS Lothian classification of the medicine which is being prescribed.
- Collect information on reasons for prescribing non-formulary medicines.
- Peer review non-formulary medicines prescribing.

Associated materials/references:

Appendix 1	Non-Formulary Medicine Request Form
Appendix 2	Medicines Management Applications Forms Flowchart