Non-Formulary Prescribing Policy

Background

The Mid Essex area wide formulary has been established in the Mid Essex area since 2005. The management of medicines relating to the formulary is robust and forms the basis of good prescribing practice.

Following completion of a "Form A – New Drug Formulary Application" (see Appendix A) a new medicine or new indication for an existing medicine is reviewed and sent to the bimonthly Mid Essex Area Prescribing Committee (MEAPC) meetings for decision.

An evidence based approach aims to provide clinicians with a suitable range of effective and cost-effective treatment options.

Medicines may be added to the formulary for general use, with restrictions or for prescribing in certain conditions or by a restricted group of clinicians and this information is clearly stated. It is often considered good practice for many new medicines to include a treatment pathway to identify the medicines place in therapy. This assists all clinicians in treatment planning and also aids audit.

Policy statement

Prescribing from the formulary is consistent with good clinical practice. It is recognised that there may be occasions when the need to prescribe a non-formulary medicine will however occur. Guidelines or protocols containing non-formulary medicines will not be approved for inclusion to the formulary. New medicines (or indications for existing medicines) under consideration by the MEAPC are not included in the formulary until the committee have approved them.

Where a non-formulary medicine is considered to be the only treatment option then a "Form B – Individual Patient Non-Formulary Request" (see Appendix B) must be completed. This recognises that there are occasions when a specific patient will need rare variations from normal therapeutic choices which a clinician feels duty bound to offer. The completed form B should be sent to

a. the Chief Pharmacist at MEHT if treatment is to be initiated or remain within secondary care

b. the Chief pharmacist of the CCG if treatment is to be initiated or remain within primary care for assessment with lead clinicians.

All sections must be completed in full to enable a complete and fair evaluation to be made. It is expected that a form B will be completed for one patient only. The form B process is not for multiple patient use to bypass the usual formulary processes. If more than one patient is to be considered then a form A may be more appropriate.

Decisions

The aim is to support the clinician where possible however requests will only be approved where there is a clear clinical case that formulary prescribing is not possible or appropriate and where agreed treatment pathways have been written.

Appeals

Should the non-formulary prescribing request be declined then the clinician may appeal to the MEAPC who will review the request at the next planned meeting unless the decision is considered to be more urgent based on the information provided on the form B.

Communication

The decision will be communicated to the clinician completing the form B and copied to the chair of the MEAPC. The decision will be communicated to the MEAPC at the next planned meeting. Where appropriate the decision will be communicated to other clinicians/colleagues.

A record of the form B and the decision will be kept by the secretary of the MEAPC.

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Consulted with	n/a
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Previous version	**Key changes**
Non Formulary Prescribing Policy (no version)	Document Management added. Forms A and B updated and included in Appendices

Appendix A

FORM A - Application Form for a New Drug to be Included in the Formulary

Mid Essex Locality

This entire form must be completed by the requestor – please consult the Broomfield Pharmacy Medicines Information department for any issues or queries.

Applicant Information	
Name of Consultant/GP making request	
Contact details	
Speciality (secondary care only)	
Directorate (secondary care only)	
Practice (CCG only)	
Drug Information	

Approved drug name	
Brand name	
Manufacturer	
Formulation(s) requested	
Strength	
Indication for intended use	
Is the product licensed for intended use?	**Y** **N**
Further Information	
Is an existing formulation of this product already formulary?	**Y** **N**

Is this NICE approved or part of the NICE working programme?	**Y N**
Will the product replace an existing formulary drug? Please list current alternatives being used in the Trust to treat this indication (including approximate costs)	**Y N**
Will the product complement existing formulary drugs? Please list current alternatives being used in the Trust to treat this indication (including approximate costs)	**Y N**
*** Does a pathway/guidance document already exist for this indication?**	**Y N**
*** If yes, has this been updated?** **Please attach indicating where this product will fit, if approved.** **If no, what is the current route taken for these patients?**	**Y N**

Please identify the appropriate formulary addition category from the list below: **Hospital only** **Primary care only** **Specialist shared care** **Specialist initiation** **First line** **Second line** **Other: please give details**	**Please note that all requests will need to be reviewed at MMC *prior* to inclusion in the formulary, unless they are hospital only.**
*** The ideal scenario involves a review at MMC before submissions to APC to ensure both primary and secondary care have been considered, if applicable.** **It is not, however, essential to have a pathway/guidance updated or developed before approval at APC, although this will need to occur before inclusion into the formulary.**	
Supporting Information	
Please choose one of the following that most closely supports your application:	
It is the only licensed drug treatment available for this indication	
It is more effective than existing drug treatments for this indication	
When total treatment costs are considered it is less expensive	
It is safer than existing drug treatments for this indication	
It is more cost effective than existing drug treatments for this indication	
It could treat patients who do not tolerate existing treatments	
It could treat patients who do not respond to existing treatments	
It could treat patients when existing treatments are contraindicated	
It is more acceptable to some patients than existing drug treatments	

It will provide patients with more choice	
It is an option when the usual non-drug options are not appropriate	
Other (please specify below:	
Evidence	
Is the product "black triangle"?	**Y N**
What are the significant adverse effects listed in the SPC or trials?	
Summarise the safety and tolerability of this product compared with comparator drugs or placebo	
Summarise the efficacy of this product compared with comparator drugs or placebo	

Please give a short summary of key trials supporting the use of this drug for this indication or any published evidence in support of this request.

Financial Information	
Approximate cost per treatment cycle	
Is the treatment continuous or for a defined course/period? i.e. what are the stopping criteria	
Number of existing patients/on a waiting list ready for treatment post-approval i.e. will there be a one-off surge of patients eligible for treatment?	
Estimated annual usage (number of patients – cumulative if treatment is continuous)	Year 1: Year 2: Year 3: Year 4: Year 5:
Are there other cost implications or savings associated with the use of this drug for this indication? For example other health resources e.g. monitoring, hospital stays, etc.	
Signature of applicant	
Date of application	

Please send completed form to Medicines Information, Pharmacy Department, Broomfield Hospital

Date application received	
Reasons/conditions/other information	
Signed	
Date	

Appendix B

FORM B - REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE FOR AN INDIVIDUAL PATIENT

This form should be completed by a prescriber who wishes a patient to receive a non-formulary medicine in any of the following circumstances:

Unlicensed

- unlicensed medicines *(category 1)*

Licensed

- "off-label" medicines *(category 2)*
- prior to Mid Essex Area Prescribing committee decision/advice *(category 3)*

2	**Clinical team/speciality:**	
3	**Requesting clinician:**	
4	**Patient details (name, hospital number/NHS number, DOB):**	
5	**Requested medicine:**	
6	**Indication the medicine is to be used for:**	
7	**Dose:** (including strength, form and frequency)	
8	**Anticipated duration of treatment:**	
9	**Treatment cost:**	**Annual Cost:**
10	**Exception category** (*please tick*)	☐ Unlicensed for any indication (Category 1) **NB: Read Policy for unlicensed medicine** **I have read and understood policy. Signed: ……..** ☐ Off-label i.e. licensed for other indications (Category 2) ☐ Licensed and prior to MEAPC decision/ advice (Category 3) **Licensed but non-formulary (Category 3)**

11	**Reason for Request:** **Continuation of medicine initiated in primary care** ☐ **Go to section 21** (If previous authorisation not granted: supply may be refused) **Continuation of previous hospital supply** ☐ **Go to section 21** (If previous authorisation not granted: supply may be refused) **Continuation of medicine approved in other health Trust** ☐ **New treatment decision** ☐
12	**Will treatment continue:** **Only in hospital** ☐ **Hospital and then primary care** ☐ **Only in Primary care** ☐ **If to be continued in primary care:** **Individual Patient Treatment Plan written*** ☐ ***Seek advice from Pharmacist.**
13	**Previous treatments that the patient has received:**

14	**Explain why available licensed and formulary medicines are not appropriate in this case:**

15 **Summary of peer reviewed evidence for use in this indication in terms of safety, clinical and cost effectiveness if available.** (attach relevant references)**:**

NB: If for category 1 or 2 then safety evidence is necessary to enable a risk/benefit assessment.

Category 3 –evidence is optional

Evidence Quality *Please tick*

	I	RCTs
	II	Case control or cohort studies
	III	Non-analytic studies e.g. case reports, case series
	IV	Expert opinion

16 **Treatment outcomes and timescales:**

Please note that treatment will only be authorised if agreed outcomes and timescales are clear. If approved, circumstances in which treatment may cease should be explained to the patient or carer by the prescriber. Please indicate clearly circumstances in which treatment will be stopped.

17	**Service implications (if any) (for example increased monitoring/clinic time/staffing):**
18	**Exceptionality** Eg. Explain how the patient is expected to gain significantly greater benefit from this drug than the normal treatment group considered by MEAPC
19	**Monitoring requirements for treatment:** If required of primary care, an individual patient treatment plan is needed (seek advice from pharmacy)
20	**Details of all discussions relevant to this case (if any):** Eg. Advised by national experts, second opinions, colleagues etc.
21	**Timeliness:** **Please indicate timeframe, if relevant, in which decision is needed.** **This must be realistic and clinically relevant.**

22	**Declaration:** **I declare I have completed a conflict of interest form and that I have explained this process to the patient or carer and that approval is not guaranteed.** **Signed:** **BLOCK CAPITALS:** **Signature:** **Clinician in support of application:** **E-mail address:** **Bleep number:** **Telephone number:**

AUTHORISATION:

To be completed by the Chief Pharmacist/Principal pharmacist & lead clinician

We have reviewed the request and the evidence for safety, clinical and cost effectiveness.

Request Approved ☐

Request referred to MEAPC ☐

Request referred to IPTR panel ☐

Request rejected ☐

Name: Signature: Date:

Name: Signature: Date:

Rationale behind decision: