ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

NEW AND NON-FORMULARY DRUGS

1. INTRODUCTION

1.1. When new drugs are introduced, there is usually only limited clinical experience and data on efficacy and adverse effects. New drugs also tend to be considerably more expensive than existing alternatives. All licensed drugs have been considered by the licensing authority to be safe and to be more effective than placebo for the licensed indication(s). However comparison with other drugs and relative cost-effectiveness are not considered during the licensing process.

1.2. The Formulary and Prescribing Guidelines list medicines that have been approved for use within the Trust. These can usually be prescribed without restriction unless specifically indicated otherwise within the Formulary (for example consultant-only use).

1.3. Newly-introduced drugs that are not listed in the Formulary may not be prescribed unless they have been approved by the Medicines Management Group (MMG). Before approving the use of a new product, the Committee has a responsibility to consider whether the drug is:

- More effective and/or safer than existing drugs
- Equally as effective and safe as existing drugs, but less expensive
- Equally as effective and safe as existing drugs. but more expensive

1.4. The introduction of many new drugs into clinical practice is associated with additional cost. It is therefore important that the MMG can make an assessment of the likely cost implications of approving a new drug for inclusion within the Formulary and Prescribing Guidelines in terms of both drug acquisition costs and any associated non-drug costs (i.e., staff resources, training, biochemical tests etc). If GPs are expected to provide on-going treatment, the Committee will also need to consider the likely impact on primary care prescribing costs.

1.5. For drugs with a cost implication of over £5,000 per year to the Trust, a final decision regarding inclusion in the formulary will be made by the Clinical Governance and Quality Sub- Committee, based on the recommendation of the MMG.

1.6. The Medicines Management Group will consider what advantages the drug demonstrates in comparison with alternatives as demonstrated in peer-reviewed clinical trials. Criteria considers may include:

- reduction in mortality / morbidity or improved quality of life
- improved safety or tolerability (i.e. proven lower incidence of major adverse effects)

- improvement in surrogate markers (e.g. biochemical parameters)
- more convenient administration
- savings in drug or non-drug costs

2. REQUESTING A NEW DRUG TO BE ADDED TO THE FORMULARY

2.1. Clinicians wishing to use a new medicine that is not listed in the Trust Formulary are required to complete a 'New Drug Request Form' (see Annex 1), which should be countersigned by the appropriate Clinical Director.

2.2. Requests for new drugs to be made available for prescribing within the Trust will be considered by the Medicines Management Group at the next available meeting, as long as there is sufficient information available for an informed discussion to take place. Evidence supporting the effectiveness of the drug, rationale for its use, anticipated place in therapy, and likely cost implications should also be provided. Where necessary, an evidence-based product evaluation will be sought from the local Medicines Information Service. Where this is necessary it may take longer for the request to be considered.

2.3. The requesting consultant must be prepared to attend the Medicines Management Group at which the request will be considered.

2.4. Research projects must have the approval of the Trust's Research Governance Group.

2.5. If it is considered necessary to obtain a new drug as a matter of clinical urgency, this can be authorised by the MMG Chair. However, approval for continued use must still be sought by submitting a completed request form.

2.6. In circumstances where a consultant wishes to try a drug for an individual patient before requesting inclusion in the Formulary and Prescribing Guidelines, or where a patient is admitted who is already stabilised on a drug which is not included in the Formulary and Prescribing Guidelines a 'Non-Formulary Request Form' should be authorised by the MMG Chair (see Annex 2). Where a patient is stabilised on non-formulary therapy already treatment may continue whilst the paperwork is being processed.

2.7. In the absence of the MMG Chair, and for submissions by the MMG Chair, 'New Drug Request' or Non-Formulary Request' forms should be sent to the Chief Pharmacist who will identify another senior clinician such as the MMG Vice Chair, Medical Director or Deputy Medical Director to authorise them.

2.8. Where a new drug has general relevance to the Trust, a new drug submission may be added to the MMG agenda by the Chief Pharmacist or MMG Chair, without a specific consultant request being received.

Annex 1

Essex Partnership University
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NEW DRUG REQUEST FORM

(To be completed by Consultants only)

Approved name of drug:	
Brand name:	
Requested by:	
Clinical Directorate / Specialty:	

	YES	NO
1. Is this a new drug? (i.e. one not listed in the Formulary and Prescribing Guidelines)		
2. Is it a new clinical indication for a drug already listed in the Formulary and Prescribing Guidelines?		
3. Is it a new formulation of a drug already listed in the Formulary and Prescribing Guidelines?		
4. Is it an unlicensed use of a drug?		
5. Could this drug replace a drug that is already listed in the Formulary and Prescribing Guidelines? If YES, which drug it could replace? If NO, what is the proposed place in therapy?		
6. Estimate YOUR annual usage for this drug (no of patients):		
7. Are you aware that other clinicians may also wish to prescribe this drug? If yes, please give names:		
8. Has this request been discussed within your directorate?		
9. Are there any non-drug resource implications associated with the product (e.g. training, staffing, biochemical tests)? If YES please specify:		
10. Should prescribing be restricted to specialists?		
If NO, is it appropriate for GPs to take on clinical responsibility for the patient and for prescribing on-going treatment		
If GPs will be requested to prescribe the drug, are there significant cost implications for primary care?		

Main advantages in terms of indication(s), benefits and cost compared to existing treatments:
Manufacturer:
Formulations available:
Indications:
Dosage:
Cost:
Pharmacology:
Pharmacokinetics:
Efficacy:
Adverse effects:
Interactions:

Contraindications / Precautions:
Existing alternative treatments:
Advantages over existing treatments:
Disadvantages compared to existing treatments:
Consequences of not using drug:
Other comments:

Please enclose published evidence (e.g. clinical trials) to support your request.

Declaration

	YES	NO
Have you received any funding or other benefits from, or have any interest in, the manufacturer of the drug requested?		

If YES, please provide details

Consultant Name:	Signature:
Telephone No:	E-mail:
Date:	
Clinical Director Name:	Signature:

Annex 2

Essex Partnership University
NHS Foundation Trust

NON FORMULARY DRUG REQUEST FORM

Name and formulation of drug:	

Patient's name:		Date of Birth:	
Consultant:		Ward:	

TREATMENT WITH NON-FORMULARY DRUGS SHOULD BE REVIEWED AT REGULAR INTERVALS AND DISCONTINUED IF NO ADDITIONAL CLINICAL BENEFIT IS OBSERVED

Current Medication

Drug name and formulation	Dose

Current diagnosis and reason for prescribing non-formulary drug

Expected outcome and review period

Additional information including relevant references

Medication previously prescribed for this indication

Drug name	Total daily dose	Reason for stopping

Consultant Name:	**Signature:**	**Date:**
MMG Chair's Name:	**Signature (if approved):**	**Date:**

This form to be completed and sent to the MMG Chair prior to commencing treatment. If approved a signed copy to be returned to the ward to be filed in the patient's healthcare record and sent to the relevant pharmacy team

Feedback on Response

CONTINUATION Y / N