ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

THE MANAGED ENTRY OF NEW MEDICINES, DRESSINGS AND APPLIANCES AND USE OF NON-FORMULARY PRODUCTS

1. INTRODUCTION

This document is intended for use by registered practitioners who initiate treatment with medicines for patients under the care of EPUT Community Health Services. The Trust acknowledges that patients transferred to its care may be on established treatment with medicines that are not listed on the local Formulary, and that it may be in the patient's best interests to continue on that medicine.

The managed entry of new medicines and dressings/appliances within primary care (by GPs) and secondary care (acute hospitals) is usually controlled by an Area Prescribing Group or Drugs and Therapeutics/Medicines Management Group within those organisations, and is beyond the scope of these guidelines.

The Trust may be given opportunity to participate in local "Horizon Scanning" exercises to anticipate uptake of new medicines and dressings/appliances expected on to the market. It is essential that prescribers participate constructively with the Community Health Services Pharmacy Lead and Chief Pharmacist within these processes, to ensure funding is adequately considered for new medicines and dressings/appliances anticipated.

1.1. When new medicines and dressings/appliances are introduced, there is usually limited clinical experience and data on efficacy and adverse effects. New medicines, dressings and appliances also may be more expensive than existing alternatives. All licensed medicines 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 medicines and relative cost-effectiveness are not considered during the licensing process.

1.2. Local 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 medicines 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 Group has a responsibility to consider whether the medicine is:

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

1.4. The introduction of many new medicines, dressings or appliances 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 medicine for inclusion within the Formulary and Prescribing Guidelines in terms of both medicine acquisition costs and any associated non-medicine costs (i.e., staff resources, training, biochemical tests etc). If GPs are expected to provide on-going treatment, the Group will also need to consider the likely impact on primary care prescribing costs.

1.5. For medicines 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 Group, based on the recommendation of the MMG.

1.6. The Medicines Management Group will consider what advantages the medicine 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 medicine or non-medicine costs

2. REQUESTING A NEW MEDICINE

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

2.2. Requests for new medicines, dressings and appliances to be made available for prescribing/using 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 medicine, 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 prescriber 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 medicine 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 prescriber wishes to try a medicine for an individual patient before requesting inclusion in the Formulary and Prescribing Guidelines a Non-Formulary Request Form should be used (see Annex 2).

2.7. Where a new medicine has general relevance to the Trust, a new medicine 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
NHS Foundation Trust

NEW MEDICINE / DRESSING / APPLIANCE REQUEST FORM

Approved name of medicine, dressing or /appliance:	
Brand name:	
Requested by:	
Clinical Directorate / Specialty:	

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

Main advantages in terms of indication(s), benefits and cost compared to existing treatments:
Manufacturer:
Formulations/sizes available:
Indications/ type of wound:
Dosage:
Cost:
Pharmacology/Rationale for use:
Pharmacokinetics:
Efficacy:
Adverse effects:
Interactions:
Contraindications / Precautions:

Existing alternative treatments:
Advantages over existing treatments:
Disadvantages compared to existing treatments:
Consequences of not using product:
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 product requested?		
If YES, please provide details		

Name of Prescriber:	Signature:
Telephone No:	E-mail:
Date:	
Name of Clinical Service Manager :	Signature:

Annex 2

Essex Partnership University NHS Foundation Trust

NON FORMULARY MEDICINE / DRESSING / APPLIANCE REQUEST FORM

Name and formulation of product:	

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

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

Current Products used

Drug name and formulation/dressing/appliance	Dose/size/area of anatomy

Current diagnosis and reason for prescribing non-formulary product

Product previously prescribed for this indication

Product name	Total daily dose/ size	Reason for stopping

Prescriber's Name:	**Signature:**	**Date:**
Pharmacist Name:	**Signature:**	**Date:**

This form to be completed and sent to pharmacy / CHS Lead Pharmacist prior to commencing treatment. A copy will be returned to the ward to be filed in the patient's healthcare record. Discussion may need to take place with the Clinical Commissioning Group before a decision can be made.