

FORM B – Request for a Medicine Which Lacks Substantive Funding

This form should be submitted to the appropriate Associate Medical Director after consultation with the team lead (where appropriate) and pharmacy department. This should be done as far as possible in advance of anticipated treatment. Please note incomplete or illegible forms will be returned to the requesting clinician for clarification, which may result in delays for patients. Forms can be submitted by (1) e-mail (N.B. use only secure e-mail from nhs.net to nhs.net address) (2) Secure FAX, or (3) post to AMD.

Note – this form should not be used for requests for licensed medicines which are not approved for use by SMC– requests for SMC ‘no’ medicines must be made as Individual Patient Treatment Requests (See NHSL Protocol for Individual Patient Treatment Requests for guidance)

Patient details (addressograph) (do not send patient details via unsecure e-mail)	Diagnosis / indication
	Requesting consultant and pager contact details (please print)

Medicine name _____	
Formulation _____	Dose _____
Expected duration / no. of cycles _____	
Is it a licensed drug ? * see over Yes <input type="checkbox"/> No <input type="checkbox"/>	Is it a licensed indication? Yes <input type="checkbox"/> No <input type="checkbox"/>
Does this treatment conform to guidance issued by: SMC <input type="checkbox"/> NICE <input type="checkbox"/> Other <input style="width: 50px;" type="text"/> <i>please specify</i>	
This form is only for medicines that have been accepted by SMC	
Please insert SMC no. if known <input style="width: 80px;" type="text"/>	

Clinical evidence/rationale for use in this patient, including expected outcome (please submit any clinical papers referenced with this form)
Effectiveness banding A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E <input type="checkbox"/> F <input type="checkbox"/> G <input type="checkbox"/>

Expected toxicity/side-effect profile	Details of additional therapies required (include treatment of side-effects)

Availability and estimate of expected cost (please contact pharmacy for assistance)
If expanded access programme will medicine supply continue free of charge post licence for this patient:
Yes <input type="checkbox"/> No <input type="checkbox"/>

- | | |
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| A. Imminently life threatening condition where no other therapeutic treatment current available and patient not eligible for a clinical trial.
B. Imminently life threatening condition where alternative therapeutic treatment exists but with reduced efficacy.
C. Drugs with ability to significantly improve mortality outcomes (evidence based or perceived benefit where data not yet available), no other therapeutic treatments currently exist and patient not eligible for trial.
D. Drugs with ability to significantly improve mortality outcomes (evidence based or perceived benefit where data not yet available), where alternative therapeutic treatment exists but with reduced efficacy. | E. Drugs with ability to significantly improve morbidity outcomes (evidence based or perceived benefit where data not yet available), no other therapeutic treatments currently exist and patient not eligible for trial.
F. Drugs with ability to significantly improve morbidity outcomes (evidence based or perceived benefit where data not yet available), where alternative therapeutic treatment exists but with reduced efficacy.
G. Equivalent to other therapeutic options. |
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<p>Previous treatment for this indication many regimes? _____ (Please list previous treatments (if applicable))</p>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	How
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Reason other drug not selected?

What would be used if this drug not available or authorised?

Current patient performance status?

Planned review (please state when and how response will be measured)

Where is the treatment to be delivered?

Consultant signature _____ **Date** _____

Pharmacy comment (e.g. service impact, drug storage, drug availability etc)

Signed (Clinical Pharmacist) _____ **Date** _____

Print name _____

***N.B. Unlicensed medicines:** Section 9 of the Medicines Act (1968) permits the use of unlicensed medicines by doctors, on a named patient basis. A doctor prescribing an unlicensed medicine does so entirely on his/her own responsibility carrying the total burden of the patient’s welfare and may be called to justify his/her actions in the event of an adverse reaction. Although all possible steps are taken to ensure the quality and safety of unlicensed products it cannot be guaranteed. Medical staff must complete NHSL Physician Request Form for Unlicensed Medicines and obtain informed patient consent prior to commencing any approved treatment.

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<p>Associate Medical Director approval for use: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If YES, any conditions, including limits on duration / number of cycles?</p> <p>If NO, reason?</p> <p>Signed (Medical Director) _____ Date _____</p>

N.B. If this request is time limited, a follow-up form will automatically be sent out from pharmacy and re-authorisation must be sought before further cycles can be arranged. Patient outcome information will be gathered on completion of therapy on the same follow-up form.

<p>The original form will be retained by the Associate Medical Director with copies to:</p> <p>1. Requesting physician 2. Pharmacy for information and collection of statistics</p>
