County Durham and Darlington Area Prescribing Committee

APPLICATION FOR NEW PRODUCT TO BE APPROVED FOR USE IN NHS COUNTY DURHAM AND DARLINGTON

This form is to be used for applications for new drugs, new formulations and extensions to previously agreed uses for drugs and other relevant pharmaceutical products including medicated dressings, prescribable nutritional products, borderline substances and pharmaceutical medical devices.

Requests must be made by a consultant, general practitioner, or other appropriate senior professional, e.g. PCT Pharmaceutical Advisor, dentist, optician, senior dietician.

Applications must consist of evidence-based data outlining the efficacy, therapeutic advantage, safety or cost relative to the products already used. Ideally, supporting data should be from randomised controlled studies from peer reviewed journals.

Guidelines for completion:

- Please complete **all** details – incomplete forms will be returned.
- **The form should be submitted electronically by e-mail by completing this document and sending to:**
  - **For CDDFT Beverley.Walton2@nhs.net**
  - **For TEWV christopher.williams@nhs.net**
  - **For Primary Care rdtc.rxsupp@nuth.nhs.uk**
- The application MUST be supported by the relevant Clinical Director (secondary care) and or GP Prescribing Lead (primary care)[1].
- An application for a drug that has been rejected within the last 12 months will normally be refused, unless it is for a different indication, is based on new evidence/ new national guidance or in circumstances deemed exceptional by the Committee.
- The manufacturer/ supplier (drug company) may provide information supporting the application, but the application **must** come from an appropriate applicant (see above).
- Where possible electronic versions of any references and other supporting documents (preferably Word or PDF format) should be e mailed at the same time.
- Secondary care consultants must discuss their request with, and obtain support from, other consultants working in their speciality prior to submitting a request. When this is done please give details in the appropriate section of this form.

To ensure that requests are processed as quickly as possible applicants are asked to see that completed request forms are returned at least two weeks before APC formulary sub-group meetings.

Requests received after these dates will be deferred to the next meeting.

[1] If it is not possible for this support to be obtained before submission, support should be obtained as soon as possible, and must be obtained before the request is considered by the APC.

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1. Applicant details

Name	Click here to enter text.
Position/ role	Click here to enter text.
Department/ unit	Click here to enter text.
NHS organisation	Click here to enter text.
Address	Click here to enter text.
E-mail	Click here to enter text.
Telephone	Click here to enter text.
Clinical director	Click here to enter text.

2. Drug details

Generic/ non-proprietary name	Click here to enter text.
Brand/ proprietary name	Click here to enter text.
Dosage form and strength	Click here to enter text.
Is this drug licensed in the UK?	Yes ☐ No ☐
Is the drug licensed for this indication?	Yes ☐ No ☐
PHARMACY USE ONLY: Would this product require assessment against NPSA 20?	Yes ☐ No ☐

3. Indications for use

Licensed indication (See product SPC)	Click here to enter text.
Indication for which product is requested	Click here to enter text.

4. Reason for request

Reason for request Please tick **all** boxes that apply	Therapeutic advantage over existing treatment Cheaper than alternative treatment Improved compliance No alternative New formulation Other (please specify below) Click here to enter additional text.	☐ ☐ ☐ ☐ ☐ ☐

Advantage(s) over existing drugs/ treatments for same indication: Click here to enter text.
Details of evidence for these advantages in terms of **efficacy, safety, convenience** or **cost effectiveness**: Note that detailed clinical trials and papers do not need to be referenced if the product has been through and received a positive NICE Technology Apprisal or NETAG Recommendation for your requested indication(s). Copies of key papers, product appraisals and guidelines referred to should be submitted with the application. Please continue on a separate sheet if necessary. Click here to enter text.

5. Anticipated place in therapy

Please give a clear guideline including algorithms or flowcharts as necessary, indicating **exactly** which group(s) of patients should **and should not** be eligible to receive this drug, including details of whether the drug is first line and the suggested criteria for selecting or not selecting the drug. Please continue on a separate sheet if necessary.
Click here to enter text.

6. Potential problems/ disadvantages

Details of disadvantages and any perceived problems with product (please include details of significant clinical problems e.g. adverse reactions, training issues, and potential problems regarding funding if product is expensive).
Click here to enter text.

7. Existing drugs

Please list any existing product(s) for the same indication(s):	Click here to enter text.
Would the product requested be:	1. An addition to what is already existing **(YES / NO)**
	2. A replacement for what is already existing **(YES / NO)**
If a replacement, which product(s) can be deleted	

8. Existing pathway & new pathway

Please list how the existing drugs are administered i.e. prescription only, injection, IV infusion:	Click here to enter text.
Please list the setting of administration for existing drugs i.e OP clinic, regular day admission, patient's home	
Would any activity be altered by the administration of the new drug (increased or decreased)	
What setting will the new drug be administered in?	

9. Prescribing and monitoring

Dosage regimen proposed for this application:	
Dose and frequency:	Likely duration of treatment:
Click here to enter text.	Click here to enter text.
Monitoring requirements (including criteria for stopping treatment) and implications for continued care:	
Click here to enter text.	
Prescriber restrictions (e.g. consultant only):	
Click here to enter text.	

10. Plans for product introduction

Please outline steps that will be taken to ensure the safe introduction of this drug into clinical practice? Please outline in this section whether there is any potential for pathway redesign through the introduction of this product. Please include details of training, awareness sessions, information to patients etc.
Click here to enter text.

11. Financial details

Number of patients likely to be treated **per year**.	Click here to enter text.
Average daily dose	Click here to enter text.
Likely duration of treatment	Click here to enter text.
Proportion of treatment likely to be supplied by secondary care	Click here to enter text.
Estimated cost in next 12 months for County	Click here to enter text.

Durham & Darlington in subsequent years	Click here to enter text.
Is this product PbR excluded	YES / NO
Details of how estimated costs have been calculated/ obtained Click here to enter text.	
Details of compensatory saving resulting from use of new product (inc. cost savings from not using the original drug) Please include details of possible savings in areas other than drugs expenditure. Click here to enter text.	
Details of any changes in secondary care activity (including clinics and length of stay) resulting from use of new product	
What is the likely impact of this product on primary care prescribing? Click here to enter text.	
Accountant Name	Click here to enter text.
Accoutant Designation	Click here to enter text.
Financial approval	YES / NO
Reason, if not approved	
Accountant Signature *Please print name and e-mail address for electronic submissions. The authenticity of the e-mailed document will be verified when the application is processed.*	Click here to enter text.
Date	Click here to enter a date.

12. Other supporting information

Applicants must discuss their request with their clinical director/ clinical colleagues. Please give details of their support below with any other information you may wish to include (emails, letters, minutes of meetings etc.). Click here to enter text.

13. Declaration of interest

Please provide details of any support or sponsorship to an individual and/or the department/organisation(for staff include clinical trials, other research etc.) submitting this request received or likely to be received from the manufacturer of this product within the last/ next 12 months. If none, please state 'none'. Click here to enter text.

14. Applicant signature

Applicant's signature Please print name and e-mail address for electronic submissions. The authenticity of the e-mailed document will be verified when the application is processed.	Click here to enter text.
Date	Click here to enter a date.

15. REQUIRED FIELD Additional comments by Clinical Director and GP Prescribing Lead (primary care) or Trust-wide Speciality Lead (secondary care)

Comments relating to clinical and/or financial aspects of this product's possible use. If use of this product is likely to add to costs, please give details of any arrangements that have been made to fund its use.	
Click here to enter text.	
Please tick the box that applies:	
I support the request from a clinical perspective ☐	
I support the request from a financial perspective on the understanding that: Please tick **one** box.	
The product will not increase costs ☐ Additional costs will be met from the current budget ☐ Additional costs will be met from additional income ☐	
Name	Click here to enter text.
Designation	Click here to enter text.
Signature *Please print name and e-mail address for electronic submissions. The authenticity of the e-mailed document will be verified when the application is processed.*	Click here to enter text.
Date	Click here to enter a date.

16. Additional comments by Specialists/ Clinical Leads from other Departments/ Trusts where appropriate

Views and comments relating to this product's possible clinical use	
Click here to enter text.	
Likely annual usage and expenditure within your department/ organisation if appropriate	
Click here to enter text.	
Other comments	
Click here to enter text.	
Name	Click here to enter text.

Designation	Click here to enter text.
Signature Please print name and e-mail address for electronic submissions. The authenticity of the e-mailed document will be verified when the application is processed.	Click here to enter text.
Date	Click here to enter a date.