

# Application for Inclusion of a Medicinal Product in the Joint Formulary for the South Staffordshire Health Economy

## Guidance

1. Formulary applications for medicines that are excluded from Payment by Results (PbR) AND do not have NICE approval OR require additional funding in order to be introduced must be supported by a full business case.
2. Applications completed largely by industry representatives will not be considered.

## Section 1: Information on the Medicinal Product

Date Submitted
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Approved/ generic name	
Brand Name	
BNF Chapter Reference	
Pharmaceutical form and strength	
Indication(s)	
Is the medicinal product licensed for this indication?	
Dosage	
If product is unlicensed or to be used "off label", references to support dosage	
Reason for request	
Reason for request continued	

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Section 2: Clinical Evidence to Support the Application

2a: Evidence of Efficacy

Please report clinical outcomes in preference to surrogate markers; absolute and relative risk/hazard ratios; and NNTs as a minimum, where available.

Vs placebo	
Vs current "best available therapy"	
Vs other comparators	
References <b>Please provide copies of peer reviewed papers</b>	

2b Evidence of Safety

Please report incidence of adverse effects in both active and comparator arms of trials, absolute and relative risk increases and NNHs, where available.

Principal adverse effects	
Serious adverse effects	
Please indicate approximate number of subjects who have been exposed to the product during clinical	

trials.	
Were any significant patient groups excluded from clinical trials?	
Please detail any monitoring requirements	
Please detail any safety issues in relation to prescribing/preparation/use/administration/disposal.  Where appropriate, compare its safety in relation to current treatment options.	
References <b>Please provide copies of peer reviewed papers</b>	

Section 3: Position within therapy

Where within the current drug treatment pathway/algorithm do you intend to use this product?	
Please indicate if there is a sub-group of patients in whom this product has demonstrated particular benefit.	
If you wish to make any other comments in support of the application, please do so here:	

Section 4: Position within the Formulary

**Position in Formulary:**

**GREEN:** .....These medicines are freely prescribable within primary and secondary care.

**AMBER:** ..... These medicines are considered as second choice or they are restricted in some other way eg. May need to be prescribed with an Effective Shared Care Arrangement. The restriction is stated next to the medicine. They may be prescribed within primary and secondary care.

**RED:** ..... These drugs are for specialist use only. They should not be prescribed in primary care.

**Inclusion in the Formulary does not guarantee that specific funding arrangements are in place.**

Proposed position in Formulary (see above for guidance)	
Which products are currently in the Formulary for a similar indication?	
Will this product replace a product currently in the Formulary? If not, why not?	
What are the alleged advantages over existing Formulary products?	
How substantial is that benefit for the patient?	
If the product is subject to a NICE appraisal or guideline, please indicate, expected) date of publication.	
Is the medicine included in PbR?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this medicine likely to be prescribed in an outpatient setting?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If Yes is the outpatient appointment PbR excluded	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

Section 5: Potential expenditure across the Health Community

5a: Cost per patient

Please provide information for both Acute and Primary Care settings		
	Hospital	Primary Care

Cost of product per patient per 28 days' treatment (or other if appropriate, please specify)		
Where appropriate, cost of product which this will replace - per patient per 28 days' treatment (or other if appropriate, please specify)		
Please detail any indirect cost savings		
Please detail any indirect increased costs		

**5b: Estimate of Number of patients to be treated**

Please provide information for both Acute and Primary Care settings		
	Hospital	
	Hospital	Primary Care Please give figures per PCT population (606k)
In the first year		
In the second year		
Over the next 3-5 years (will there be a trend?)		

**Section 6: Sponsor of Application**

Requested by:	
Signature:	
Directorate	
Date of request	
Please declare here any relationships with the manufacturer or marketer of the product  Eg drug company funded research and/or staff; sponsorship etc, see below **.	

Please indicate any assistance received from pharmaceutical companies in completing this application	
<p>By signing below,          Directorate Pharmacists and Clinical Directors are indicating support for this application in terms of clinical benefit to patients.          Directorate Managers are indicating support for this application in terms of any financial implications and capacity planning</p>	
<b>Directorate Manager</b>	
<b>Signature:</b>	
<b>Clinical Director</b>	
<b>Signature:</b>	

Please return this form electronically to: Lesley Arnold, Medicines Support Officer, Merlin House, Etchell Road, Bitterscote, Tamworth B78 3HF [lesley.arnold2@northstaffs.nhs.uk](mailto:lesley.arnold2@northstaffs.nhs.uk) in addition to providing a paper copy with appropriate signatures. On receipt of both copies, your application will be taken to the Formulary Working Group for consideration.

\*\* You must fully disclose: clinical trial work; other paid or sponsored research or audit (clinical or non clinical); meeting(s) sponsored in part or whole; meeting attendances paid or sponsored in part or whole; Advisory panel or consulting work or other employment; paid lecturing; gifts, meals, hotel accommodation or other hospitality; any other potential conflict of interest (including shares held). Articles of low intrinsic value, i.e. less than £50, such as diaries or calendars, need not be declared. Modest hospitality, such as meals, does not need to be declared provided that the individual cost per year is less than £50. However, if more than one gift or meal is made from the same or a related source within a 12 month period totalling more than £50, they should be declared. Declaration of funding source should include financial interests over the three years to date, and should include prospectively agreed research income for the next year. Declarations do not distinguish between personal payment and payment to a Trust fund or research account and should include financial association of immediate family members. Code relationships as follows:

- A >£50 and < £5,000
- B £5,000 - £20,000
- C > £20,000