bhnft logo  

**Barnsley Area Prescribing Committee (APC)**

**New Drug Application and Assessment Procedure**

This procedure covers requests for new products.

1. A new product is defined as any preparation that is not on the Barnsley primary and secondary care joint formulary (available at: [www.barnsleyformulary.nhs.uk/](http://www.barnsleyformulary.nhs.uk/) ) Sustained release preparations of existing products are considered as new products.
2. Requests are made by applicants on the appropriate New Product Request Form available on the CCG website (<http://www.barnsleyccg.nhs.uk/members-professionals/area-prescribing-committee.htm> ) or from the APC secretary ([nicola.brazier@nhs.net](mailto:nicola.brazier@nhs.net) ).

This must be countersigned by the Clinical Management Team (CMT) Clinical Head of Service or Medical Director Barnsley CCG and Head of Medicines Optimisation.

1. New Product Request Forms must be completed by the applicant and requested on clinical grounds. If it is apparent that an applicant has had little or no involvement in the application, it will be rejected.
2. New product requests are assessed at appropriate committees. (Primary Care: Quality and Cost Effective Prescribing Group, SWYPFT: Drug and Therapeutics Committee, BHNFT: Medicines Management Group)

1. New product requests are then considered by the APC who will approve, reject or defer the application for further supporting information. Applicants are welcome to attend such meetings of the APC to support their application.
2. If approval is given, the product may be prescribed by the applicant and members of their team and, if required, other consultants from the CMT. Consultants from other CMTs must make separate applications, unless full formulary status is given. Joint applications from different CMTs may be made if appropriate.
3. An indication of the likely traffic light status of the drug will be required.
4. Appeals against decisions are taken in person, or in writing, through the Chairman of APC.
5. If the applicant remains dissatisfied with the decision of the APC an outside assessor will be invited by the APC to give their views.
6. If agreement is not reached at this stage, the applicant may appeal formally to the appropriate Trust board against a decision of the APC.
7. Only drugs purchased and supplied by the pharmacy department BHNFT may be used within BHNFT (with the exception of patients own drugs).

Date of approval: February 2022 Review date: February 2024

**Flow of New Formulary Drug Application Process**

**Applicant e.g. consultant or GP obtains a “New Product Application and Assessment form”**

Available to download at the following link: <http://www.barnsleyccg.nhs.uk/members-professionals/area-prescribing-committee.htm>

or available via the APC secretary ([nicola.brazier@nhs.net](mailto:nicola.brazier@nhs.net))

Applicant returns completed electronic form and APC declaration of interest form to the APC secretary ([nicola.brazier@nhs.net](mailto:nicola.brazier@nhs.net))

APC secretary:

* sends a copy of the form to relevant pharmacists (Primary and Secondary Care)
* confirms receipt to applicant
* Gives the new product application a reference number and adds to the New Product Application log

Nominated pharmacist undertakes an Independent Assessment/Review and forwards completed assessment to APC Secretary. Reviews will be completed within 3 months of receipt of the new product application.

APC Chair or representative informs the applicant of the APC decision by letter/email.

**New drug is introduced or requested**

**Does the drug have a positive NICE technology appraisal?**

No

Yes

Electronic formulary and traffic light list updated with the APC decision following on from the meeting.

Considered at the APC to determine use locally and agree both a traffic light classification and the need for any supporting guidelines.

**BARNSLEY AREA PRESCRIBING COMMITTEE**

**NEW PRODUCT APPLICATION**

Requests should be made by a Consultant, GP or other independent prescriber. Please ensure all sections are completed to avoid any delay in consideration by APC.

Drug Name, Strength and Form: ……………………………………………………………

Manufacturer: …………………………………………………………………………………

Name of clinician requesting drug …………………………………………………..

CMT / Speciality………………………………………………………………………………

Contact Email Address: …………………………… Telephone Number: .…..…………

(please indicate preferred route of contact)

|  |  |  |  |
| --- | --- | --- | --- |
| **Received by:** | **Name:** | **Signature:** | **Date:** |
| Applicant |  |  |  |
| Clinical Head of CMT (BHNFT) ***or*** Medical Director (SWYFT) ***or***  Medical Director Barnsley CCG |  |  |  |
| Chief Pharmacist (BHNFT/SWYFT) |  |  |  |
| Medicines Information Pharmacist (BHNFT) |  |  |  |
| Head of Medicines Optimisation, Barnsley CCG |  |  |  |

An Area Prescribing Committee Declaration of Interest form must be completed and submitted to the Area Prescribing Committee secretary ([nicola.brazier@nhs.net](mailto:nicola.brazier@nhs.net)) before new product applications can be considered by the Committee. Any commercial sponsorship associated with this application (associated with either the drug or manufacturer) must be stated on the Declaration of Interest form. Commercial sponsorship is defined as including

NHS funding from an external source, including funding of all or part of the costs of a member of staff, NHS research, staff, training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), buildings of premises.

Date signed declaration of interest form submitted: …………………………………………………….

…………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………

Has this drug been considered for formulary or Traffic Light status within any other local NHS organisation of which you are aware?

……………………………………………………………………………………………………..

|  |  |  |
| --- | --- | --- |
| 1 | What is the drug? Is it a truly new medicine or a ‘me-too’ product/line extension? | |
| 2 | What is the proposed indication for this drug? | |
| What are the licensed indications? | |
| Are there restrictions on who should initiate treatment or administer the drug?  Restricted to secondary care prescribing only (Red)  If so specify if use should be further restricted to use by speciality/team/consultant:  …………………………………………………………………………………………………………….  To be initiated and titrated to a stable dose by a specialist with follow up prescribing and  monitoring by primary care under a shared care agreement (Amber)  To be recommended or initiated by a specialist\* with follow up prescribing and monitoring by  primary care clinicians (Amber G)  No restriction on prescribing (suitable for initiation in primary care) (Green) | |
|  | What is its Traffic Light and Formulary status across South Yorkshire? | |
| Rotherham: | |
| Doncaster: | |
| Sheffield: | |
| 4 | How effective is this drug? | |
| What grade of evidence can claims be substantiated with?  (circle as appropriate)  Ia Evidence obtained from meta-analysis of RCTs\*  Ib Evidence obtained from at least one RCT  IIa Evidence obtained from at least one well designed controlled study without randomisation  IIb Evidence obtained from at least one other type of well-designed quasi-experimental study  III Evidence obtained from well-designed non-experimental descriptive studies, e.g. case series, cross sectional studies  IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities  \* One good quality large RCT may be better quality evidence than, e.g. a meta-analysis of small, or observational, studies | |
| How does it compare with existing drugs, or non-drug therapies? | |
|  | Is it included within any NICE guidance? | |
| 5 | How safe is the drug? | |
| Are there any published comparative safety data? | |
| Has it been widely used in other countries? | |
| Are there any clinically important drug interactions? | |
| Are there any monitoring requirements?  Who would be responsible for monitoring? | |
| 6 | Who should not receive it? | |
| Are there particular groups of patients in which this drug is contra-indicated or where it should be used with caution? | |
| 7 | What is its place in therapy? | |
| Will this replace a product currently included on the formulary? (if yes include details of the product you are proposing it should replace) | |
| What are the advantages of this drug over current therapy? (consider formulary medicines or others in the same therapeutic class or used for the same indication as requested) | |
| What other formulary options are there? | |
| Where should it be positioned? | |
| Are there some patients who may particularly benefit? | |
| What are the considerations from the patient’s perspective? | |
| 8 | Does this drug provide good value for money? | |
| Is there any good quality evidence that it is more cost-effective than other available interventions? | |
| Are the benefits from this drug worth the costs involved? | |
| Cost of new drug:  Hospital ……………………………  Primary Care ……………………..  Estimate number of hospital patients requiring drug in one month? …………...  What impact would this drug have on the prescribing budget?  In Secondary Care? *(to be completed ONLY by nominated pharmacist working within*  *secondary care)*  In Primary Care? *(to be completed ONLY by CCG Head of Medicines Optimisation or nominated deputy)*  Are there any service implications? (e.g. access, impact on other sectors etc) | |
| 9 | What is the balance of responsibility?  Your proposed Traffic light status for this drug: red / amber shared care /amber-G / green | |
| 10 | | Form Completed by…………………………………………………………………………..  Designation……………………………………………………………………………………  Date……………………………………………………………………………………………. |

Please list some key published references to support your application. These should be the most recent and relevant available. If there is a good systematic review you need not include the original papers. References are requested from reputable sources that are unbiased with good methodology. Reviews from expert groups will also be considered.