* *This form is to be used to request addition of products that are not currently on the Formularies.*
* *Please see Appendix 1 for general guidance on how to complete and submit for discussion and approval.*

**Full Formulary Application Form**

**Bedfordshire, Luton and Milton Keynes Area Prescribing Committee (BLMK APC) – Formulary Subgroup**

**[Enter date]**

**Agenda item X.X**

**Title**

|  |
| --- |
| **What is the item?** |
| **What is the APC being asked to discuss?** |
| **Who is bringing this to the APC?** |
| **What are the options available?** |
| **Option 1:** |
| **Option 2:** |
| **Option 3:** |

|  |
| --- |
| **Reason for application:**  **Guidance notes: What is the driver for this application? E.g. Is this in response to new guidance? Is it a new product to market? What is in place at the moment (if anything) that needs to change? Will this replace other products or be added as another option?** |
|  |
| **Service user impact:**  **Guidance notes: What is the prevalence of the disease being treated? How will this change address the need for treatment for service users in BLMK? Who will the service users be? Is this applicable to patients across Bedford, Luton AND Milton Keynes? Are there other options available to treat the disease? What are the expected patient numbers?** |
|  |
| **About the medicine(s)/device(s):**  **Guidance notes: Include here as much information as possible about the product. If there are any special considerations such as special storage requirements, short shelf life, complex reconstitution or known risks associated with the medicine please include it here.** |
| **Name**: |
| **Strength/formulation/route**: |
| **Dosage and duration of therapy**: |
| **Pack size**: |
| **Cost of pack (include source of information)**: |
| **Licensed or unlicensed product?** |
| **Dosage**: |
| **Intended indication for use**: |
| **Licensed or unlicensed indication**: |
| **Monitoring requirements**: |
| **Special considerations**: |
| **Additional option or replacement of another product (state product):** |
| **Place in therapy (e.g. 1st line / 2nd line/restricted to certain groups?):** |
| **Evidence to support use of medicine for intended indication:**  **Guidance notes: Include in this section clinical evidence to support efficacy and/or safety. This could be NICE guidelines, statements from professional bodies, or evidence from clinical trials where applicable. Include reasons for benefit over other products available where applicable** |
|  |
| **References:** |
|  |
| **Cost Impact & patient numbers:**  **Guidance notes: How many patients are anticipated to be prescribed the medicine(s) across BLMK? How much will this cost? Will the change result in any cost savings elsewhere that will off-set the costs? Is this the most cost-effective option available? Include source of cost and whether VAT is included. Please also consider non-drug costs e.g. appointments, blood tests and consumables** |
|  |
| **Stakeholder comments**  **Guidance notes: Include here any support/comments from stakeholders. Please attempt to obtain comment from those that will initiate, monitor and continue the therapy across the relevant settings e.g. secondary care / primary care / clinics** |
|  |
| **Short summary:**  **Guidance notes: Please provide a brief summary of key points in relation to the request** |
|  |
| **Proposed traffic light position on Formulary & nature of prescribing:**  **Guidance notes: See Formulary for available designations. Who will be prescribing and monitoring the medicine?** |
|  |

**Bedfordshire, Luton and Milton Keynes (BLMK) Area Prescribing Committee (APC)**

**Assessment against Ethical and Commissioning Principles**

|  |  |
| --- | --- |
| **Treatment assessed (Month and Year):** | |
| **APC Recommendation**  TBC post meeting | |
| 1. **Clinical Effectiveness**   *e.g. according to national guidelines…* | |
| 1. **Cost Effectiveness**   *e.g. most appropriate and cost- effective products have been recommended* | |
| 1. **Needs of the community**   *e.g. prevalence and incidence of disease being treated?* | |
| 1. **Equity & Equality Impact Assessment** (see also embedded additional information including factsheet below to aid completion of this section)   Consider whether this decision of the APC will have an impact for patients or staff in regard to Equality, Inclusion and Human Rights legislation.  Such impacts (negative) could include:   * Restriction of a drug which could benefit those with certain conditions1,2   Where the implementation of the decision of the BLMK APC may impact on one or more equality group differently to others, a full equality impact assessment may need to be completed as advised by the BLMK Equality and Diversity Lead.  **Protected Characteristics (under the Equality Act 2010):**  Age; Disability; Gender reassignment; Marriage & Civil Partnership (in employment only); Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual orientation; carers; other identified groups.    1 NB Equality and Diversity is only one part of an assessment of the new drug/indication.  2 It should be noted that where the BLMK APC is following national guidance, these have been developed with consultation and are required to have been subject to Equality Analysis and Due Regard. | |
| Please state whether the decision will have an impact: | |
| Yes  No | *If* ***YES,*** *the proposal is likely to impact patients or staff. Please set out those impacts and any mitigations that have been identified in the section below. Examples include a process where the needs of exceptional cases can be met.*  ***NO****, please state that the decision has been reviewed with regard to Equality, Inclusion and Human Rights and no issues have been identified in the section below.* |
| Provide rationale for impact assessment:  *Should a significant impact be identified a full EQIA should be completed* | |
| 1. **Need for healthcare (incorporates patient choice and exceptional need**)   *e.g. are there alternative therapies available or is this a completely new treatment option?* | |
| 1. **Policy drivers:**   *e.g. relevant local or national guidance* | |
| 1. **Disinvestment:**  * *How will this medicine help to address local health priorities?* * *By using this medicine, what disinvestment in other medicines, interventions and services may be possible?* * *How much would this save?* * *Affordability considerations?* * *Will this medicine help to address local health priorities?* | |
| 1. **Environmental impact of decision (if applicable)** | |

**If high financial impact, signature of person with financial authority for the organisation is required:**

|  |  |
| --- | --- |
| Name of financial authority: | Click or tap here to enter text. |
| Job title: | Click or tap here to enter text. |
| Signature: | Click or tap here to enter text. |
| Date: | Click or tap here to enter text. |
| Contact information: | Click or tap here to enter text. |

**Declaration of Interest:**

I confirm that I have no conflicts of interest in relation to this application

I have a conflict of interest to declare and enclose further information (see link)

**See link to** [**DOI form and information**](https://medicines.blmkccg.nhs.uk/guideline/declaration-of-interests-form-template/)

|  |  |
| --- | --- |
| Name: | Click or tap here to enter text. |
| Job title: | Click or tap here to enter text. |
| Signature: | Click or tap here to enter text. |

**Applicant Information:**

|  |  |
| --- | --- |
| Name: | Click or tap here to enter text. |
| Job title: | Click or tap here to enter text. |
| Signature: | Click or tap here to enter text. |
| Date: | Click or tap here to enter text. |
| Contact information: | Click or tap here to enter text. |

**Appendix 1: General guidance for completing the form:**

* Please complete the form in full. Any blank sections will be sent back for completion by the applicant.
* It is expected that applications will have considered patients across the entire ICB to ensure equity of access for all patients within Bedfordshire, Luton and Milton Keynes to result in a harmonised approach within the system. Where an application covers only a selection of patients please state the reason for this.
* Primary and Secondary Care will inform each other immediately, via Chief Pharmacists / Formulary Pharmacists, where drug/device use has an effect on effect on patient pathways and/or if an application is relevant to their organisation.
* The application must reflect consensus from your directorate / Commissioning Support Unit / specialty / area.
* Each submission with high cost impact must be countersigned by a professional with accountability for clinical and budget management in your organisation. These are:

|  |  |
| --- | --- |
| Clinical Management | Budget Management |
| MKUH NHS FT – Clinical Director of the relevant CSU | Finance Business Partner or Manager of the relevant CSU / Trust |
| BLMK ICB – Associate Director Medicines Optimisation |
| CNWL-MK / CCS / ELFT – Medical Director or Chief Pharmacist |
| Bedfordshire Hospitals – Clinical Director of the relevant CSU |

* Submit completed forms to the place based lead pharmacist.

Place based lead Pharmacist contact details:

* Reena Pankhania - [Reena.pankhania@ldh.nhs.uk](mailto:Reena.pankhania@ldh.nhs.uk) Bedfordshire Hospitals NHS FT
* Janet Corbett - Janet.Corbett@mkuh.nhs.uk –Milton Keynes UH NHS FT
* Taiya Large – [taiya.large1@nhs.net](mailto:taiya.large1@nhs.net) – BLMK ICB
* Anne Graeff – [Anne.graeff@nhs.net](mailto:Anne.graeff@nhs.net) – BLMK ICB
* Reginald Akaruese - [r.akaruese@nhs.net](mailto:r.akaruese@nhs.net) – CNWL
* Saema Arain [saema.arain3@nhs.net](mailto:saema.arain3@nhs.net) - ELFT
* Yolanda Abunga – [yabunga@nhs.net](mailto:yabunga@nhs.net%20) – CCS

**Submission to the BLMK Formulary Subgroup**

* The BLMK Formulary Group meetings are scheduled for five dates over the year. Please see the [BLMK Website](https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/categories/formulary/) for dates.
* Applications should normally be submitted 6 to 8 weeks before the meeting, whenever possible.
* Meetings are usually held in: February, April, June, September and November - exact dates within the month vary.
* The place-based Formulary Pharmacist / APC professional secretary will notify you of the date of the meeting when the application will be considered, subject to the receipt of all necessary information including that relating to sources of funding.
* You will be invited to attend to put forward the case for inclusion and answer any questions the group may have. If you are unable to attend, you may send a representative on your behalf or request to defer to a later meeting date.
* Submissions will be considered, at the discretion of the Chair of the BLMK Formulary Group, in the absence of the applicant if appropriate information is available at the time when the agenda and papers are prepared.
* Applicants will not be present when the BLMK Formulary Group/APC discusses its recommendation or decision.
* We suggest that you contact your organisation’s pharmacy/medicines management service before you complete this form, so that they may provide you with support and advice on the process.

**Please email** [blmkicb.medsopt@nhs.net](mailto:blmkicb.medsopt@nhs.net) **for further information regarding any of the above.**