**[Name of group/APC] new drug referral**

**Qualifying Criteria Application Form**

**Please complete this section first before proceeding further with the application. Only medications which meet the criteria below should be referred to [Group acronym] for a [Region]** **wide review. Applications will only be accepted from [Group acronym] member organisations.**

**Application criteria**

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| **For a medicine application to be considered through the [Group acronym] process, BOTH the following criteria must first be met:** | **BOTH MUST APPLY**  **delete as appropriate** |
| Commissioning responsibility will lie with CCGs rather than the NCB; **AND** | Choose an item. |
| The medicine is not subject to NICE guidance for the proposed indication due to be issued within 6 months of the application. | Choose an item. |

**IN ADDITION**, at least one of the following criteria should be met:

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| **Additional criteria:** | **✓** |
| The medicine is or will be a PbR tariff excluded product. | Choose an item. |
| The annual cost per patient, inclusive of associated service costs, will exceed £5,000. | Choose an item. |
| Use of the medicine could create a significant cost pressure in the primary care prescribing budget. | Choose an item. |
| Use of the medicine could release significant cost savings in the prescribing budget. | Choose an item. |
| The product is a genuinely novel treatment, i.e. first in class or a significant new indication for an existing medicine | Choose an item. |
| There are existing variations in use of the medicine across **[Region]**, which are undesirable on clinical, therapeutic or equitable access grounds. | Choose an item. |
| There is a need for local interpretation or clarification of existing NICE guidance | Choose an item. |
| In the case of a medicine which has previously been considered by **[Group acronym]**, substantial new clinical evidence should be available and be detailed in the application. | Choose an item. |

**N.B.** The following categories of product **will not** usually be considered through the **[Group acronym]**

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| **Product categories NOT usually considered by [Group acronym]:** | 🗶 |
| Combination products of medicines already available for the same general indication. | Choose an item. |
| A product which is an isomer or metabolite of an existing medicine for the same general indication. | Choose an item. |
| A medicine which is a “me too” product, branded generic, or a new delivery system or formulation of an existing medicine for the same general indication. | Choose an item. |

**[Group acronym]** member organisation may request that prescribable items which do not fulfil these criterial be reviewed via the **[Group acronym]** processes. All such requests will be considered by **[Group acronym]** and added to its work plan if agreed by the group.

For new drug requests which do not meet the above criteria please discuss with your local medicines management team.

**New Medicine Application**

**N.B.** Please complete ALL relevant sections legibly and comprehensively. Text boxes will expand to fit as information is added. Please note that any missing or illegible information will require the form to be returned to you for amendment and so may delay the application.

**Please submit completed forms to [Blank]@nhs.net**

**Section 1: Medicine Details**

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| **Name of medicine** (generic & brand name)**:**  Click here to enter text. |
| **Strength(s) and Form(s):**  Click here to enter text. |
| **Licensed indication(s):**  Click here to enter text. |
| **Proposed indication(s) for use** (if different from or in addition to the above): |

**Section 2: Evidence to Support Proposed Use**

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| **2.1 Evidence of effectiveness in the proposed indication:** |
| **What evidence is there of effectiveness for this medicine in its intended use?** Please supply information on the principal trials supporting the indication(s) described above and the overall results regarding outcomes (e.g. absolute or relative risk reduction or NNT) and efficacy? Please state what the principal outcome measures are and provide copies of **up to 3 (maximum)** relevant references.  Click here to enter text. |
| **2.2 Summary of evidence on comparative efficacy** |
| **What are the advantages of this medicine compared to other treatments?** Consider medicines already recommended in your local formulary or others in the same therapeutic  Click here to enter text. |
| **2.3 Summary of evidence on comparative safety** |
| **How does this medicine compare to existing alternatives in terms of its safety and any associated monitoring requirements?** In summarising monitoring requirements, please indicate whether they are during initial stages of treatment until the patient is stable, or are required for the full duration of therapy.  Click here to enter text. |
| **2.4** **Summary of evidence on cost effectiveness and patient outcomes** |
| **Is this medicine more cost-effective than alternatives, or does it result in improved quality of life for patients?** Please provide information on the cost effectiveness of this medicine in terms of absolute risk reduction and cost per QALY and/or quality of life benefits.  Click here to enter text. |

**Section 3: Place in Therapy and Impact on Alternatives**

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| **3.1 How will using this medicine change the use of other medicines or treatments?** |
| Please indicate whether this medicine would be used in addition to or instead of others, and where in the treatment pathway it is planned to use it, e.g. 1st/2nd /3rd line/ reserved for particular patient groups. If it will replace an existing medicine, please state which one. **N.B**. Please give reasons for your proposed place in therapy.  Click here to enter text. |
| **3.2 How will using this medicine affect how services are delivered to patients?** |
| For example, will it require fewer or more hospital visits, enable care to be delivered closer to home, etc?  Click here to enter text. |
| **3.3 Are there other any non-medicine costs or savings related to using this medicine?** |
| For example, will it require additional clinics to be set up, avoid a surgical procedure, or result in reduced length of stay in hospital?  Click here to enter text. |

**Section 4 Financial Implications**

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| **4.1 What is the cost per patient of the medicine each year?** |
| If a full course of treatment last less than one year, please indicate this and give the cost of the course**.**  Click here to enter text. |
| **4.2 If this medicine replaces an alternative medicine or treatment, what is the current annual cost per patient of this alternative?** |
| Please include the name of the alternative medicine or treatment and the cost of one full course or one year’s therapy per patient.  Click here to enter text. |
| **4.3 How many patients would receive this medicine each year?** |
| If possible, please indicate what proportion of patients with the condition to be treated would be prescribed this medicine OR indicate whether your estimate relates only to patients to be treated by your own organisation or the total across all of **[Region]**.  Click here to enter text. |
| **4.4 Where would prescribing take place?** Delete as appropriate. |
| Hospital/specialist services only  Initiated in hospital/specialist service and continued in primary care  Initiated and continued in primary care |
| **4.5 If prescribing in primary care is envisaged, do you think shared care guidance would be required?** Please give the reason for your answer.  Click here to enter text. |

**Section 5: Declaration of Potential Conflicts of Interest**

**5.1 Personal interests over the last 12 months**

This involves payments\* (or other support) from any one company to an individual clinician or their spouse/partner/cohabittee or close relative. The main examples are consultancies, fee-paid work, travel grants or pharmaceutical company shares. (The amount of money involved does not have to be declared).

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| **Company** | **Nature or purpose of support from the company** | **Period of support**  **From To** | |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Name of Clinician:** Click here to enter text.  **Date:** Click here to enter text. | | | |

**5.2 Organisational interests over the last 12 months**

This implies support\* from any one company for your unit or place of work. It may be financial or in kind, e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

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| --- | --- | --- | --- |
| **Company** | **Nature or purpose of support from the company** | **Period of support**  **From To** | |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Name of Clinician:**Click here to enter text.  **Date:** Click here to enter text. | | | |

\* for practical purposes, payments and/or support to a value in excess of £100 annually should be declared. (Threshold of £100 chosen locally to exclude amounts for trivial items such as pens, post-its, books, etc)

**Section 6: Background Information**

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| **6.1 Application Completed by:** |
| **GP/Consultant** - Name, specialty, full postal address and email address:  Click here to enter text. |
| **Clinical Pharmacist** - Name, full postal address and email address:  Click here to enter text. |

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| **6.2 Organisational support for submission given by:** |
| **Clinical Director –** Name, date:  Click here to enter text. |
| **Chief Pharmacist –** Name, date  Click here to enter text. |

**N.B.** Individuals submitting request are responsible for ensuring their own organisation supports the application before submitting it for consideration.