

Application for INCLUSION of a New Medicine or Significant Change of indication in Use of Medicine in the Royal Free London’s Formulary

* *Decisions on applications for inclusion of a new medicine or significant change in indication in use of a medicine in the Royal Free London NHS Foundation Trust’s Formulary by the Drugs and Therapeutics Committee are driven by an evidence based approach.*
* *Please complete ALL relevant sections legibly and comprehensively. Any missing or illegible information will delay the application.*
* *If the medicine affects or is intended to be used across a number of specialities then application forms should be completed for all areas.*
* *Return application form, supporting evidence and guidelines to* [*rf-tr.rfldtcpharmacyadmin@nhs.net*](mailto:rf-tr.rfldtcpharmacyadmin@nhs.net) *Pharmacy Department, Royal Free London NHS Foundation Trust.*

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| **Name of medicine applied for:** | **being** |  | | **Manufacturer:** |
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| 1. **Applicant’s details:** | | | | |
| **1.1 Consultant name (block capitals):** | | | | |
| **1.2 Email address:** | | | | |
| **1.3 Department:** | | | **1.4 Division:** | |
| **Consultant name and signature** | | | **Clinical Service Lead Approval (name and signature)** | |
| **Divisional Clinical Director Approval (name and signature)** | | | **Director of Operations Approval (name and**  **signature)** | |
| **Divisional Business Analyst (name and signature) and Rationale for sign off** | | |  | |

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| 1. **Funding and commissioning:** | | | |
| **Question** | **Description** | **Options** | **Outcome for this Medicine** |
| Is drug / product a TEDD | Tariff excluded drug/device? | Yes / No |  |
| Funding | * Pass through (previous Cost & Volume) – All costs are passthrough to relevant commissioner (no cost or benefit to Trust) * Block – Fixed income * In Tariff (payment received for patient treatments with drugs not on TEDD list) | Passthrough (Cost &  Volume) / Block |  |
| Responsible commissioner |  | NHSE / ICB  / Trust |  |
| Total budgetary impact (per annum) to the Trust. | Please state the total incremental (Net) costs which will be spent by the Division per | £ Divisional costs |  |

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|  | annum. If this is no impact to the Divisional  budgets, please state reason i.e., FOC / Private patients. |  |  |
| Indirect financial impact to the Trust (non-drug costs) | For example – reduces LOS, reduces outpatient appointments |  |  |
| Total budgetary impact to the wider health economy | Although there might be an impact to the Royal Free budget i.e., an additional cost pressure, drug proposal might be an overall saving to the wider health economy. Please state financial impact if known. | £ Impact to wider health economy. |  |

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| 1. **EPMA/EPR:** |
| Change required on EPR? Yes  No  Has a EPMA development request been logged? Yes  No |

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| 1. **Sustainability:** | | | |
| Drug | Any environment impact (e.g., CFC MDI, excess consumables, packaging, transporting) | Potential alternatives or  ways to reduce impact (Any manufacturer information available?) | Type of impact  (Positive, negative, no impact) |
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| **5. Injectable Drugs Risk Assessment and Reduction Summary:** Include any risks associated with administration and describe any risk reduction measures taken to reduce the risk. Score will determine where product should be prepared. NPSA RAG Rating Score 1-2= low risk: suitable to prepare on ward/clinical area/outpatient setting, 3-5=moderate risk: full review required to determine preparation area, 6+=high risk: preparation must be in pharmacy and refer to Technical/QA pharmacy team for full risk review and advice. | | | | | | | | | | | | | | | |
| **Drug** | **Therapeutic risk** | **Use of concentrate** | **Complex calculation** | **Complex preparation** | **Reconstitute vial** | **Part/multiple container** | **Use of infusion pump/drive** | **Non-standard infusion set** | **Unlicensed route** | | **Unfamiliar process** | **Total Risk Factors** | **Overall NPSA RAG Risk Rating (select drop down)** | **Risk Reduction Measure(s)** | **Preparation area (see above for scoring)** |
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| **Name of pharmacist approval and date:** | | | | | | | | | | **Name of clinical practitioner approval and date:** | | | | | |

Please see appendix 1, NPSA Risk Assessment Tool for Injectable Medicines, for risk reduction measures.

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| **6. If applicable for injectable drugs, where will this drug be prepared and administered?** State any additional precautions & risk assessment required to prepare & administer in this location. |
| Additional Precautions & Risk Assessment Undertaken: |

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| **7. Checklist:** |
|  Application Form [A]  Supporting Evidence  Guidelines for Use  Shared Care Protocol  Homecare |

**The applicant must ensure that the above stages are complete before submission to the DTC.**

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| **Application form for the use of a new medicine (or indication) in North Central London** | | |
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| **1. APPLICANT’S DETAILS** | | |
| Applicant name: | Email address: | |
| Role: | Trust/Organisation: | |
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| **2. DECLARATIONS OF INTEREST** | | |
| Please tick any personal or non-personal interest that you may have associated with the drug or manufacturer of the medicine **within the last two years**:  **A.**  **Personal Interests (any form of payment to an individual by a pharmaceutical company):** £   * **Consultancies:** any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind. * **Fee-paid work:** any work commissioned by the pharmaceutical industry for which the individual is paid in cash or kind. * **Shareholdings:** any shareholding in or other beneficial interest in the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the individual has no influence on financial management. * **Expenses/hospitality provided by a pharmaceutical company**   **B.**  **Non-Personal Interests (involves payment that benefits a department for which an individual is responsible):** £   * **Fellowships:** the holding of a fellowship endowed by the pharmaceutical industry or any other relevant industry. * **Support by the pharmaceutical industry or any other relevant industry:** any payment, other support or sponsorship by the pharmaceutical or other industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department. * **Grants from a company:** for example, for the running of a unit or department for which an individual is responsible * **Grants or fellowships to sponsor a post or staff member in the unit for which the individual is responsible:** this does not include financial assistance given to individual students * **Commissioning of research or other work or advice from staff who work in a unit for which the individual is responsible**   **C.  Nil declarations of interest** | | |
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| **3. MEDICINE DETAILS** | | |
| Name (generic and brand), strength & form: | | |
| Dose & frequency: | | Anticipated duration of treatment: |
| Intended indication(s) for use: | | |
| Is this product licensed for the proposed indication? Choose an item. | | |
| Starting criteria for the medicine: | | |
| Continuation criteria for the medicine (provide desired treatment outcomes, and how/when will these be assessed): | | |

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| **4. CONTEXT AND RATIONALE FOR APPLICATION** |
| What is the current treatment pathway for this condition? Include any supporting local/national/international guidance. |
| Where in the pathway does this application sit: |
| Describe the unmet need that this application addresses: |
| How would these patients be treated if the application was not approved (i.e. what is the real-world comparator for this application)? |
| Please describe below how the application addresses the unmet need.  Key efficacy benefit(s), compared to existing treatment options:    Key safety benefit(s), compare to existing treatment options:    Key patient convenience benefit(s), compared to existing treatment options: |

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| **5. EVIDENCE TO SUPPORT APPLICATION** | |
| **Reference(s)** | **Applicability to the application** |
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| Summarise any experience of using this medicine for the proposed indication (e.g. from local Trust approval for individual patients): | |

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| **6. PROVISION OF CARE** |
| Is the medicine intended for GPs to initiate?Choose an item.  Within hospitals, will prescribing be restricted to specific specialities? If yes, please describe. |
| Is the medicine intended for GPs to continue?Choose an item.  Is there a regular, ongoing need for monitoring and/or assessment of effectiveness/toxicity? If yes, please describe.    Is there a need for a shared care protocol or a GP fact sheet (ie. >2 patients per 100,000 population and regular ongoing monitoring required)?Choose an item.  After what time period would GPs be expected to take on prescribing responsibility? |
| How do potential risks of this medicine compare to current standard treatment? Consider risk of errors relating to the complexity of prescribing or administration, staff/user training requirements or patient monitoring. |
| If the medicine is for limited/restricted use, please specify how the medicine use would be controlled? |
| Compared with current standard of care, describe any impact this application will have on NHS activity. Consider activity for administration, monitoring and prescribing/dispensing.   |  |  | | --- | --- | |  | Impact on activity vs. standard-of-care (per patient) | | Outpatient appointments (e.g. monitoring): |  | | Day case appointments (e.g. administration): |  | | Inpatient bed days: |  | | Other: |  | | Primary care or community interventions: |  | |

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| **7. FINANCIAL IMPLICATIONS** Choose an item. | | | |
| Who is the commissioner for this service? | | | |
| Is the medicine classified as a high cost drug? Choose an item. | | | |
| If yes, funding from Choose an item.  If no, funding from Choose an item.  If this application is for a free of charge scheme, follow local guidance:  <https://www.ncl-mon.nhs.uk/wp-content/uploads/2020/11/JFC_Free-of-charge_Schemes.pdf> | | | |
| Specify a unit cost excluding VAT for a course (or a year) per patient:  Specify source of financial information: | | | |
| Specify the number of patients **initiated** **on treatment**:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Current | Year 1 | Year 2 | Year 3 | Maximum number eligible | | Trust |  |  |  |  |  | | NCL |  |  |  |  |  |   Specify the **cumulative number of patients** **on treatment**:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Current | Year 1 | Year 2 | Year 3 | Maximum number eligible | | Trust |  |  |  |  |  | | NCL |  |  |  |  |  | | | | |
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| **8. CONSULTATION WITH COLLEAGUES AT OTHER TRUSTS IN NORTH CENTRAL LONDON** | | | |
| Is this medication included on formulary at any other NCL Trust for the proposed indication? Choose an item.  If so, which? | | | |
| Please indicate below whether this application has been discussed with colleagues across NCL and whether they support your application:  Barnet, Enfield and Haringey Mental Health NHS Trust:Choose an item.  Camden & Islington (Mental Health) NHS Foundation Trust:Choose an item.  Great Ormond Street Hospital for Children NHS Foundation Trust:Choose an item.  Moorfields Eye Hospital NHS Foundation Trust:Choose an item.  North Middlesex University Hospital NHS Trust:Choose an item.  Royal Free London NHS Foundation Trust:Choose an item.  Royal National Orthopaedic Hospital NHS Trust:Choose an item.  University College London Hospitals NHS Foundation Trust:Choose an item.  Whittington Hospital NHS Trust:Choose an item.  Primary care:Choose an item.  Please summarise the opinions of colleagues: | | | |
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| **9. DECLARATION** | | | |
| This submission form has been completed by a clinician(s) and not by a pharmaceutical industry representative: | | | |
| Post | Name | Signature | Date |
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| **10. APPLICATION SUPPORTED BY** | | | |
| Post | Name | Signature | Date |
| Divisional Director |  |  |  |
| Clinical Director |  |  |  |
| Pharmacist lead |  |  |  |

**Please email any queries, completed forms and supporting documents to** [**rf-tr.rfldtcpharmacyadmin@nhs.net**](mailto:rf-tr.rfldtcpharmacyadmin@nhs.net)

**INCOMPLETE FORMS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO THE REQUESTING CONSULTANT**

**Appendix 1**