

**North Central London**

**Joint Formulary Committee**

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| **Appeal form for reconsideration of a medicine (or indication) in North Central London** |

The North Central London (NCL) Joint Formulary Committee’s (JFC) role is to advise Commissioners and Provider Trusts on appropriate, equitable, evidence-based and cost-effective use of medicines.

Attached is an appeal form for a medicine [or indication] to be reconsidered by the NCL JFC. The Committee is driven by an evidence-based approach and this form is designed to help you highlight your grounds for appeal and rationale.

The JFC will only reconsider a decision if one of four scenarios occurs:

1. Significant new information is available requiring reconsideration of the evidence. This may include evidence of the safety or efficacy of comparator medicines.
2. The original decision was based on inaccurate or incomplete information.
3. The Committee did not follow its agreed process.
4. A perverse decision was made based on the evidence considered by the Committee.

The applicant or another clinician must submit this appeal form to the JFC Secretariat, detailing which appeal criteria applies. Additional relevant information must be presented by the appellant at this stage. The first appeal will be reviewed by the JFC Chair and secretariat, and presented to the NCL JFC. If a second appeal is received, this will be forwarded to the South East London Joint Formulary Committee for a review of the process followed. A third line appeal of the process will be escalated to the NCL Integrated Medicines Optimisation Committee (NCL IMOC).

It is essential that all relevant sections are filled in legibly and comprehensively to avoid delaying your application.

You will receive email confirmation of receipt of the appeal and have an opportunity to discuss the appeal with the JFC secretariat team. Other stakeholders within NCL may also be invited to comment on this appeal. You will be invited to attend the JFC meeting, but attendance is not mandatory (although preferred). On the day of the meeting, a Committee nominee will present your appeal and the supporting evidence-base, and you will be given the opportunity to voice any errors, misinterpretations or omissions. The Committee members may also take this opportunity to ask you any questions regarding the appeal. You will then be asked to leave and the outcome decision will be communicated to you [and other stakeholders] via email two to three weeks after the meeting.

Please return the completed form electronically to admin.ncl-mon@nhs.net along with accompanying treatment guidelines and electronic copies of the supporting references (please note abstracts will only be accepted if no full-text manuscript is available in the public domain).

Yours sincerely,

JFC Secretariat Team

On behalf of NCL JFC

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| **Appeal form for reconsideration 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. GROUNDS FOR APPEAL: select the box(es) highlighting which of the following grounds for appeal are applicable. Please include rationale for each ground for appeal that has been selected and references to support this (where applicable).** |
| [ ]  **3.1 Significant new information is available requiring reconsideration of the evidence. This may include evidence of the safety or efficacy of comparator medicines** |
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| [ ]  **3.2 The original decision was based on inaccurate or incomplete information** |
|       |
| [ ]  **3.3 The Committee did not follow its agreed process** |
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| [ ]  **3.4 A perverse decision was made based on the evidence considered by the Committee** |
|            |
| Summarise any experience of using this medicine for the proposed indication (e.g. from local Trust approval for individual patients): |

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| **Sections 4-8 reflect key information requested for formulary applications. Please append the original application and state below any details that were missing from the original application or have been updated since.** |
| **4. 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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| **5. CONTEXT AND RATIONALE FOR APPEAL** |
| What is the current treatment pathway for this condition? Include any supporting local/national/international guidance. |
| Where in the pathway does this appeal sit: |
| Describe the unmet need that this appeal addresses: |
| How would these patients be treated if the appeal was not approved (i.e. what is the real-world comparator for this application)? |
| Please describe below how the appeal 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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| **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.

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|  | 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** |
| Who is the commissioner for this service?Choose an item. |
| 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**:

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| --- | --- | --- | --- | --- | --- |
|  | Current | Year 1 | Year 2 | Year 3 | Maximum number eligible |
| Trust  |  |  |  |  |  |
| NCL |  |  |  |  |  |

Specify the **cumulative number of patients** **on treatment**:

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| --- | --- | --- | --- | --- | --- |
|  | 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. APPEAL SUPPORTED BY** |
| Post  | Name | Signature | Date |
| Divisional Director |       |       |       |
| Clinical Director |       |       |       |
| Pharmacist lead |       |       |       |

**Please email any queries, completed forms and supporting documents to** **admin.ncl-mon@nhs.net**

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