Appendix 3 Formulary Submission Form

* **Electronic completion** – click in the box below the question and type. The box will expand to accommodate the text. Please keep comprehensive and indicate which, if any, information has been supplied by a pharmaceutical company.
* **This application should reflect a consensus agreement from your directorate/speciality.** Medicines which are to be prescribed **only** in secondary care will be considered by the trust’s Drugs and Therapeutics Committee. Medicines expected to be prescribed in primary care will be considered by the Area Prescribing Committee. These medicines are considered on a County-wide basis. Therefore, consultation should also be sought amongst relevant clinicians from other Nottinghamshire acute trusts if appropriate. Please indicate below what process you have been through to achieve this (e.g. presentation to local groups, directorate, cross-town groups).

# To be completed by Lead Clinician / GP (not for completion by medical representatives)

|  |
| --- |
| **1. Name of medicine (include route, strengths and formulations)** |
|  |
| **2. Specify organisations to which this application applies. (Delete as appropriate)** |
| Nottingham University Hospitals NHS Trust **Yes / No** Sherwood Forest Hospitals NHS Foundation Trust **Yes / No**Nottingham NHS Treatment Centre **Yes / No**Nottinghamshire Healthcare NHS Trust **Yes / No** Primary Care **Yes / No**Other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3a. Is this submission: (Delete as appropriate)** |
| 1. to add a medicine to the formulary? **Yes / No**
2. to replace an existing formulary medicine? **Yes / No**  if yes, please specify which medicine\_\_\_\_\_\_\_\_\_
3. modification of an existing formulary medicine's use (e.g. a new indication for use)? **Yes / No**
 |
| **3b. If the medication is an injectable**  |
| 1. Will it likely be administered by a district nurse? **Yes / No**

 if yes, contact NHCT pharmacy for a risk assessment1. Can it be administered as an Infusion? **Yes / No**

 Consider Medusa IV Guide availability, Drug Error Reduction Software (DERS) etc1. Is any addition equipment required? **Yes / No**

 e.g. filters, pumps, dedicated giving sets, sharps boxes |
| **4. Indication (s) covered by this submission** |
| **4a. Indication(s) covered by this submission. Is this in line with the licensed indication?** |
|  |
| **4b. Please define patient cohort this request applies to.** (Patient age, inclusion and exclusion criteria) |
|  |
| **4c. Please provide a summary of the condition(s) for which the medicine will be used.** Include any relevant morbidity, mortality and quality of life data related to the condition that may be beneficial in support of this application. |
|  |
| **4d. How will the requested product be used to treat this / these condition(s)?** Please include dosage, treatment length, place in therapy, monitoring and deprescribing requirements, etc. Please attach guidelines for the use of the medicine for this condition if relevant. In some cases, guidelines may be required before final approval. Individual trusts may have guidance on guideline production. |
|  |
| **4e. What is currently used to treat this / these condition(s)?** Please include medicine(s), doses, length of treatment, monitoring and how it will be affected if this submission is approved. |
|  |
| **4f. What are the advantages of the new medicine over the existing practice?** e.g. enhanced efficacy, route, side effect profile, compliance, reduced hospitalisation, avoidance of surgery, and reduced need for community support. |
|  |
| **4g. What are the disadvantages of the new medicine over the existing practice?** Please be as expansive as possible. e.g. It’s new, side effect profile (known or uncertain), limited familiarity among healthcare staff, higher cost, extra monitoring needs, and weak evidence for the intended use etc |
|  |
| **5. Supporting evidence** |
| **5a. Clinical Evidence**Please provide published literature (e.g., efficacy, safety) that provides a balanced view of the medicine. Comparative studies with current “gold standard treatments” and systematic reviews of all the literature, such as Cochrane reviews, are of particular interest. A list of references is insufficient, include details such as study type, number of patients and a summary of the findings. **Please provide links to the references** |
|  |
| **5b. Are there any published pharmacoeconomic evaluations to support your request?** If so, please provide details. |
|  |
| **5c. Is the use of this medicine in accordance with local or national plans (e.g. Trust / ICB business plan, NICE etc.)?** Please provide details if appropriate. |
|  |
| **6. Implementation** |
| **6. Implementation and Clinical Governance Requirements**Please provide details and include what consultation has occurred or is planned. |
|  |  | Please provide additional info / progress update in this column  |
| Is submission a consensus agreement from the directorate / speciality? | Yes/No |  |
| Guidelines: Is a new clinical or prescribing guideline or update to existing one required?  | Yes/No |  |
| What capacity impact will this have? (e.g. GP, surgery, clinic, nursing or pharmacy capacity) | Yes/No |  |
| Any training requirements? | Yes/No |  |
| Patient testing requirements? (e.g. genome) | Yes/No |  |
| Monitoring requirements?  | Yes/No |  |
| EPMA set up / amendment required? (e.g. Nervecentre, SystmOne, Chemocare) | Yes/No |  |
| Pre-printed prescription required or amendment required? | Yes/No |  |
| Risk assessment required? | Yes/No |  |
| SOP required?  | Yes/No |  |
| Input from Medicines Management or Medicines Safety required? if yes, please indicate what input is required? E.g. It is a Look Alike Sound Alike medication, prescription approval required? | Yes/No |  |
| Other actions identified? (please specify) | Yes/No |  |
| **7. Funding** |
| **7a. How many patients will likely be initiated on this medicine (by all clinicians)?** If precise numbers are unknown, indicate a range, e.g., <5, 5-10, 10-20, 20-50, 50-100, 100-500.If uptake is significantly different from that predicted, a review will be required. |
|  | **Expected patient numbers** |
| **First-year** | **Subsequent years** |
| **At NUH** | Inpatients |  |  |
| Outpatients |  |  |
| **At SFHFT** | Inpatients |  |  |
| Outpatients |  |  |
| **At Nottingham NHS Treatment Centre** | Inpatients |  |  |
| Outpatients |  |  |
| **At Nottinghamshire Healthcare Trust** | Inpatients |  |  |
| Outpatients |  |  |
| **Primary Care** |  |  |
|  |
| **7b. How is this medicine funded for this indication?**1. Reimbursed through National tariff (i.e. in tariff medicine)
2. Excluded from tariff (NHS England funded)
3. Excluded from tariff (Cancer Drugs Fund or Innovative Medicines Fund)
4. Excluded from tariff (ICB funded)
5. Other (please specify)
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|  |
| **7c. How much will this treatment cost per patient?** Please calculate per course/month/annum. Pharmacy can assist with this section if needed.For secondary care please contact pharmacy for advice on contracts and hospital prices (at NUH email nuhnt.pharmacyprocurement@nhs.net). Please consult the [BNF](https://bnf.nice.org.uk/) / [Drug Tariff](https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff) for list / primary care price. NB: medicines prescribed for in-patients incur additional VAT (not included in BNF prices). No additional VAT is paid on primary care or outpatient supplies in some circumstances. Additional guidance on free-of-charge treatments, treatment post-clinical trials may be available.  |
|  |
| **7d. What are the non-medication costs associated with this treatment?**e.g. additional clinic appointments / blood tests / scans / other service costsNB: For medications supplied free of charge through compassionate access schemes, the commissioners will only routinely fund associated activity costs if there is a formally agreed commissioning position |
|  |
| **7e. How does this cost compare to current treatments?** Please include associated costs such as administration, hospital activity etc.Pharmacy can assist with this section if needed. Some price comparison graphs are available [here](https://pharmacy.sfh-tr.nhs.uk/Formulary/MI/Price%20graphs%20index.htm). |
|  |
| **8. Environmental considerations** |
| **8. What is the environmental impact of this medicine and how does this compare to current alternatives?**e.g. Does it help optimise prescribing by reducing demand for other medicines? IV infusions require fluid bags/giving sets whereas IV boluses do not. Tablets have a lower carbon footprint than liquid and IV medicines. Does the medicine require storage in a fridge/freezer (increased energy usage)? Is the patient required to travel to receive the treatment? Would approving this application support the [NHS Green Agenda](https://www.england.nhs.uk/greenernhs/a-net-zero-nhs/)? Have you asked the pharmaceutical company for the carbon footprint info?  |
|  |
| **9. Review** |
| **9. Audit Criteria / Outcome Data**If approved, how will the impact be assessed and evaluated? Please provide audit criteria. A review should occur in six months—state reasons if a longer period is needed e.g. for efficacy assessment.You will be required to undertake the review and report back to DTC / APC.  |
|  |
| **10. What is the anticipated traffic light classification of this medicine?**  | **Please Specify**  |
| **RED –** Medicines which should normally be prescribed by specialists only. |    |
| **AMBER 1 –** Medicines that should be initiated by a specialist and prescribed by primary care prescribers only under a **shared care** protocol once the patient has been stabilised. Prior agreement must be obtained by the specialist from the primary care provider before prescribing responsibility is transferred. The shared care protocol must have been agreed upon by the relevant secondary care trust Drugs and Therapeutics Committee(s) (DTC) and approved by the Nottinghamshire APC.  |  |
| **AMBER 2 –** **Medicines suitable to be prescribed in primary care after Specialist\* recommendation or initiation.** A supporting prescribing guideline may be requested, which must have been agreed upon by the relevant secondary care trust DTC(s) and approved by the Nottinghamshire APC. *\*Specialist is defined by the APC as a clinician who has undertaken an appropriate formal qualification or recognised training programme within the described area of practice.*  |  |
| **AMBER 3** **–** **Primary care/non-specialist may initiate as per APC guidelines.** The supporting prescribing guideline must have been agreed upon by the relevant secondary care trust DTC(s) and approved by the Nottinghamshire APC. |  |
| **GREEN –** Medicines suitable for routine use and can be initiated within primary care within their licensed indication, in accordance with nationally recognised formularies, for example, the BNF, BNF for Children, or Palliative Care Formulary. Primary care prescribers take full responsibility for prescribing. |  |

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| **11. Signatures** |
| Completed forms should be signed below to confirm involvement and support / approval) Sections marked with \* must be completed.**Each person must make a declaration of interest:**Have you, a close family member, your colleagues, department or practice ever received any payment or goods, directly or in kind, from the makers of this medicine for any purpose? If yes, please give details. [This Guidance](https://www.nottsapc.nhs.uk/media/1184/apc-declaration-guidance-questions.pdf) should be used when answering this question. If no, please state ‘no’. |

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| --- |
| ***\*Submitting and Lead Clinician / GP***  |
| Name (PRINTED) |  |
| Position |  | Trust |  |
| For NUH: Care Group  |  | Directorate |  |
| Email address |  |
| Trust/ GP Practice: |  |
| Declaration of Interest\* | ***Yes / No*** | Details: |
| **Signature** |  | Date: |  |
|  |
| ***\** *Supporting* *Clinical Pharmacist***  |
| Name (PRINTED)  |  |
| Position |  | Trust: |  |
| For NUH: Care Group |  | Directorate |  |
| Email address |  |
| Trust/ GP Practice/ ICB |  |
| Declaration of Interest\* | ***Yes / No*** (see above) | Details: |
| ***Signature*** |  | Date: |  |

|  |
| --- |
| **\*Submission Approval -** confirming both clinical and financial approval in place |
|  |
| Head of Service *or*ICB GP Prescribing Lead name (PRINTED) |  |
| Position |  | Trust: |  |
| For NUH: Care Group |  | Directorate |  |
| Trust *or*ICB Name: |  |
| Email address |  |
| Declaration of Interest\* | ***Yes / No*** | Details: |
| **Signature**: |  | Date: |  |
|  |

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| --- |
| **Supporting Clinicians / GPs / Pharmacists (Optional)** |
| Name (PRINTED) |  |
| Position |  | Trust |  |
| For NUH: Care Group  |  | Directorate |  |
| Email address |  |
| Declaration of Interest\* | ***Yes / No***  | Details: |
| **Signature** |  | Date: |  |
| Name (PRINTED) |  |
| Position |  | Trust |  |
| For NUH: Care Group  |  | Directorate |  |
| Email address |  |
| Declaration of Interest\* | ***Yes / No***  | Details: |
| **Signature** |  | Date: |  |
| Name (PRINTED) |  |
| Position |  | Trust |  |
| For NUH: Care Group  |  | Directorate |  |
| Email address |  |
| Declaration of Interest\* | ***Yes / No***  | Details: |
| **Signature** |  | Date: |  |
| Name (PRINTED) |  |
| Position |  | Trust |  |
| For NUH: Care Group  |  | Directorate |  |
| Email address |  |
| Declaration of Interest\* | ***Yes / No***  | Details: |
| **Signature** |  | Date: |  |

Please request a new form for any medicine you want to request in future. Somebody else may already be submitting the same medicine, and we can send you unbiased supporting information and prices with the most up-to-date form. Blank forms and further information are available from the Formulary/ DTC Pharmacists (contact details below).

**Completed forms should be submitted as below:**

For medicines that will be used in primary care: email to nnicb-nn.nottsapc@nhs.net\*\*.

For SFH submissions: email to sfh-tr.medicines.information@nhs.net

For NUH submissions: email to nuhnt.dtcformularysubmissions@nhs.net

For NHCT submissions: email to MI@nottshc.nhs.uk

\*\* Include trust emails above if submission is from these locations. A submission can be sent to all these contacts in the same correspondence if appropriate.

**EPMA (Electronic Prescribing & Medicines Administration)**

For use at NUH:

**Medication Request Submission Form**

*This form should be used to request specific ‘dose sentences’ (pre-built prescriptions) which are to be created for use in Nervecentre EPMA.*

*Refer to examples below on how to populate the columns. This form should be completed by the submitting clinician.*

*Please note this EPMA section does not apply to parenteral SACT (Systemic Anti-Cancer Therapies) – these remain on Chemocare. Oral SACT therapies should be included here.*

*If you have any queries regarding the EPMA section of this form, please contact the team directly at: For NUH* nuhnt.epmapharmacyteam@nhs.net***.***

*Accountability for this EPMA section will be with the EPMA Pharmacy team, not the DTC.*

1. **Medication Requests - Non-Injectables**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication Name****(& Form – only if necessary)** | **Route** | **Dose Details / Dose Range****(e.g. mg, mmol)** | **Frequency** | **Minimum Interval +/- Maximum Dose in 24 Hours****(if applicable)** | **Indication****(if desired)** | **Duration****(if desired)** | **Associated Observations / Bloods Results** | **Administration Instructions / Prescriber Information** | **Additional Comments / Documents to Link** |
| e.g. Zomorph® MR 10mg Capsules | Oral | 20mg | BD | Every 12 hours – 8am & 8pm | Pain relief | 3 days (6 doses) | eGFR | If age <70 years, and eGFR >50ml/min/1.73m2 | Consider co-prescribing PRN opioid. Consider co-prescribing laxatives and anti-emetics.Add a link to the “NUH Adult Acute Pain (Including Opioid) Guidelines”  |
|  |  |  |  |  |  |  |  |  |  |

1. **Medication Requests – Injectables**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication Name** | **Route****(inc. central or peripheral, if necessary)** | **Dose Details / Dose Range****(e.g. mg, mmol)** | **Diluent****(as necessary)** | **Volume****(as a range, if necessary)** | **Duration / Rate / Maximum Concentration (as applicable)** | **Frequency** | **Indication** **(if desired)** | **Associated Observations / Bloods Results** | **Administration Instructions / Prescriber Information** | **Additional Comments / Documents to Link** |
| e.g. Piperacillin/ Tazobactam | IV Infusion | 4.5 grams | Sodium Chloride 0.9% or Glucose 5% | 50ml-150ml | 30 minutes | Every 6 hours OREvery 8 hours | Infection X | eGFR |  | Link to the Antibiotic Website. |
|  |  |  |  |  |  |  |  |  |  |  |