### BNSSG Joint Formulary Group - New Drug Request Form

This form is in two parts –**blue sections** are to be completed by the requesting clinician. The **green sections** are to be completed by a Trust/Sirona/ICB Pharmacist or Public Health colleague following submission. Requesting clinicians, please ensure every blue section of this form is filled out. Support is available from your Pharmacy team if required, either via the local pharmacy department, or ICB Medicines Optimisation team.

Please ensure relevant colleagues including those at all other trusts or community services within the BNSSG system are consulted prior to submitting the application. Failure to do this will result in a delay to the request.

Application forms to be signed by Trust/Sirona Divisional Clinical Director and/or ICB Clinical Lead supporting consideration of application PLUS the Trust/Sirona Divisional Manager.

Completed forms for new formulary items must be received at least 6 weeks prior to the next Joint Formulary Group. Exact deadlines are available on the [Joint Formulary Website](https://remedy.bnssg.icb.nhs.uk/formulary-adult/formulary-process-and-paperwork/meeting-dates/).

Requesting clinicians, or a representative, will be required to attend the meeting to present their case.

Do NOT complete this document for a drug that is commissioned as part of a specialised service by NHS England and/or approved as a NICE Technology Appraisal. Seek advice from pharmacy if unsure.

Applications completed by representatives of the pharmaceutical industry are not accepted.

Applications from Secondary Care and Community Services: Please send completed application to local pharmacy department:

UHBW – PharmacyMI@uhbw.nhs.uk

NBT – formulary@nbt.nhs.uk

AWP – awp.FormularyPharmacy@nhs.net

Sirona – sirona.medicines.management@nhs.net

Applications from Primary Care: Please send completed applications to BNSSG Formulary Pharmacists: bnssg.formulary@nhs.net

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| **New Drug Request Application**  |
| **Drug details** |
| **Approved name:**Click here to enter text. | **Brand name (where applicable):**Click here to enter text. |
| **Manufacturer:**Click here to enter text. | **Formulation(s) requested:**Click here to enter text. |
| **Application for:** |
| Adults [ ]   | Paediatrics [ ]  |
|  |  |
| **Applicant(s) Details** |
| **Applicant(s) name(s):**Click here to enter text. | **Applicant Location (Trust or Organisation name)**Click here to enter text. |
| **E-mail address(es):**Click here to enter text. | **Specialty (where applicable)**Click here to enter text. |
| **Position(s):**Click here to enter text. | **Additional applicant(s) at other BNSSG organisations***Ensure inclusion of an applicant for each relevant organisation***Name:** Click here to enter text.**Email-address:** Click here to enter text.**Position:** Click here to enter text. |
| **Any other parties who wish to be notified:**Click here to enter text. |
| **Divisional Clinical Director / ICB Clinical Lead supporting application** |
| *Name*: Click here to enter text.*Position*: Click here to enter text. | *Location (Trust or Organisation name)* Click here to enter text. |
| **Divisional Manager supporting application** |
| *Name*: Click here to enter text.*Position:* Click here to enter text. | *Location (Trust or Organisation name)* Click here to enter text. |
| **Additional Divisional Clinical Director / Manager at other BNSSG organisations (or ICB Clinical Lead for applications relevant to Primary Care)** |
| *Name*: Click here to enter text.*Position:* Click here to enter text.*Organisation:* Click here to enter text. | *Name:* Click here to enter text.*Position:* Click here to enter text.*Organisation*: Click here to enter text. |
| **Declaration of Interest** *– must be completed by applicant. Electronic signature is suitable.* |
| *If Nil – Please state:*  Click here to enter text.***Please list:***1. *Any gifts or hospitality received from the manufacturer of the product concerned (exceeding value of £20) in the last year. Actual monetary value not required.*
2. *Presentations, advisory panels, consultancy work (including retainers), or written materials for which payment has been received from the product manufacturer.*
3. *Shares held in the company (where known).*
4. *Sponsorship of research, members of staff, equipment or other materials in your department, practice or clinical specialty funded by the product manufacturer.*
5. *Any other forms of benefit or relationships which could be classed as a potential conflict of interest*
 |
| *Signature of applicant*: Click here to enter text. | *Date*: Click here to enter text. |
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| **Intended Use** |
| **Define use of drug:** | *Indication of drug*: Click here to enter text.*Licensed for this indication?* Yes [ ]  No [ ]  |
| *Dosage*: Click here to enter text.*Licensed dose for this indication?* Yes [ ]  No [ ]  |
| **Background** | *Nature of disease, current service provision, etc:*Click here to enter text. |
| **Treatment pathway for this cohort and where this treatment would fit** | *Why would this treatment be started? Who would start it, and at which point in patient journey? Please use table below if appropriate.*Click here to enter text. |
| *1st Line* | Click here to enter text. |
| *2nd Line* | Click here to enter text. |
| *3rd Line* | Click here to enter text. |
| **Monitoring requirements:** | *Baseline Tests*Click here to enter text. |
| *Subsequent Tests*Click here to enter text. |
| Test | Frequency | Taken By | Interpreted by |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Outcome measures** | *Will treatment be curative/ symptom control? How will treatment be deemed successful?* Click here to enter text. |
| **Patient Safety/Risks of Treatment**  | *Significant side effects or dangers in use and how these will be mitigated*Click here to enter text. |
| **Stopping Criteria** | *Or duration of treatment*Click here to enter text. |
| **What current formulary option would this replace?** | *If any*Click here to enter text. |
| **Patient choice** | *Has there been an official statement from a patient advocacy group/charity?*Click here to enter text. |
| **Equity** / **Health inequalities** | *Have other health economies (other ICBs or comparable trusts) approved the use of this treatment for this indication? Will this treatment reduce / have an impact on health inequalities?*Click here to enter text. |
| **Local Health Priorities** | *What are the priorities within your service?*Click here to enter text. |
| **Environmental Impact / Sustainability** | *E.g. are there CFCs or significant burden of manufacture?*Click here to enter text. |
| **Who will initiate and continue prescribing i.e. what traffic light status would be appropriate?** | *Please note if requesting amber 1 or 3 months, a shared care protocol will be written after application***Red** [ ]  (i.e. prescribing will remain within secondary care or with specialist team) **Amber** Shared Care:3 months with shared care protocol [ ]  (prescribing will remain with specialist team for 3 months to stabilise).1 month with shared care protocol [ ]  (prescribing will remain with specialist team for 1 month to stabilise).Specialist Initiated [ ]  (initiated and stabilised by specialist, no shared care protocol required due to little or no monitoring, in particular after initiation phase)Specialist Recommended [ ]  (recommended by a specialist but GP may initiate following advice, no shared care protocol required due to less complex monitoring or dose change requirements).**Green** [ ]  (any primary or secondary care prescriber may start). **Blue** [ ]  (second / third line to a green option or only for prescribing in specific circumstances / indications or additional training required before prescribing). *Please state what the green option or specific indication or additional training would be:* Click here to enter text. |
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| **Review of National Evidence** |
| **National policy and guidance** | 1. [National Institute for Health and Care Excellence (NICE)](https://www.nice.org.uk/) including NICE Evidence Summary: new medicines  |
| *Guidance*: Click here to enter text. | *Date:* Click here to enter text. |
| Click here to enter text. |
| 2. [Scottish Medicines Consortium (SMC)](https://www.scottishmedicines.org.uk/) |
| *Guidance*: Click here to enter text. | *Date:* Click here to enter text. |
| Click here to enter text. |
| 3. [All Wales Medicines Strategy Group (AWMSG)](https://awmsg.nhs.wales/) |
| *Guidance*: Click here to enter text. | *Date:* Click here to enter text. |
|  | Click here to enter text. |
| **Other guidance** | *Provide all relevant regional, national, local policy and guidance including professional peer reviewed guidance* Click here to enter text. |
| **Is this drug on other formularies for this indication?** | Click here to enter text. |
| **Current/future research** | *Please detail any known current or planned clinical trials, extension studies etc*Click here to enter text. |
| **References** | Click here to enter text. |
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| **Evidence for Efficacy** |
| **For completion by applicant** *Please provide a summary of the relevant clinical evidence and cost-effectiveness supporting this application. If the application is supported by national guidance, applicant to provide links to relevant guidance e.g. NICE, Royal College, etc.*  |
| Click here to enter text. |
| Please list the references below that support the application |
| Reference – List first author and Title | Main points |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
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| **Financial Implications** |
| **What is the anticipated number of patients in BNSSG likely to receive this treatment per year?***Applicant to liaise with your colleagues in other BNSSG organisations to obtain system wide estimates**If full cohort not seen in year 1, please give an indication of anticipated patient numbers in years 1-5 depending on when patient numbers will reach a steady state.*  |
|  | **Anticipated Annual Patient Numbers** |
| *Year 1* | *Year 2* | *Year 3* | *Year 4* | *Year 5* |
| **Organisation** | *Adults* | *Paeds* | *Adults* | *Paeds* | *Adults* | *Paeds* | *Adults* | *Paeds* | *Adults* | *Paeds* |
| *NBT* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| *UHBW* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| *Sirona* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| *AWP* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| *Primary Care* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Total** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| **Costs of proposed new drug** |
| *Price of Drug (original pack)* | *Cost per 28 days treatment or total treatment course (give lowest and highest dose costs if necessary)* | *Cost per years treatment or total treatment course**(give range if necessary)* | *Year 1 total cost for cohort**(give range if necessary)* |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Drug costs to be offset if any**  |
| *Other formulary drugs* | *Price of Drug (original pack)* | *Cost per 28 days treatment or total treatment course (at average dose)* | *Cost per years treatment or total treatment course at average dose* | *Cost per years treatment of cohort*  |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Any other costs to be offset (e.g. surgery, bed days or outpatient appointments etc)** |
| Click here to enter text. |
| **Financial Considerations** |
| *Included in aligned payment / fixed element? “In block”*Yes[ ]  No [ ]  (can be found on the NHS tariff workbook).*Please specify any financial considerations / concerns if application approved* Click here to enter text. |
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| **For completion by Trust / Sirona / ICB Pharmacist or Public Health Colleague***Please provide a full critical appraisal of the evidence provided and include any additional relevant clinical evidence or guidance.* |
| **Person undertaking critical appraisal** | Click here to enter text. | **Date:**Click here to enter text. |
| **Email address:**Click here to enter text. | **Position:**Click here to enter text. | **Location (Trust or Organisation):**Click here to enter text. |
| **Efficacy and Clinical Effectiveness** |
| Click here to enter text. |
| **Safety** |
| Click here to enter text. |
| **Cost Effectiveness** |
| *Include summary of formulary drug cost comparisons, including any administration costs or consumables*Click here to enter text. |
| **Risk Management Issues** |
| *E.g. training considerations, storage requirements etc.*Click here to enter text. |
| **References** |
| Click here to enter text. |
|  |
| **Conclusion: For completion by Trust / Sirona / ICB Pharmacist or Public Health Colleague** |
| *Please summarise the application using the Joint Formulary Group decision-making criteria below****1. Patient safety –*** Click here to enter text.***2. Clinical effectiveness –*** Click here to enter text.***3. Strength of evidence –*** Click here to enter text.***4. Cost effectiveness or resource impact –*** Click here to enter text.***5. Place in therapy relative to available treatments –*** Click here to enter text.***6. National guidance and priorities –*** Click here to enter text. ***7. Local health priorities –*** Click here to enter text.***8. Equity of access / Health inequalities –*** Click here to enter text.***9. Environmental impact / Sustainability –*** Click here to enter text.***Other considerations:***Click here to enter text. |
| **Recommendation**please state your recommendation for use of this drug in the BNSSG Joint Formulary |
| Click here to enter text. |