**BSW Formulary Application Form**

**Do NOT complete this document for a drug that is commissioned as part of a prescribed specialised service by NHS England and/or approved as a NICE Technology Appraisal. A separate form is required- see APC website:** [**www.prescribing.bswccg.nhs.uk/bsw-drug-application-forms**](http://www.prescribing.bswccg.nhs.uk/bsw-drug-application-forms)

# Guidance notes:

* This form should be used to propose inclusion of a drug (or product such as medical device, dressing, continence/stoma product, chemical reagent, feed) on the [BSW formulary](http://bswformulary.nhs.uk/default.asp) and can be completed by a consultant or GP (with pharmacy support if necessary).
* If you wish to change the traffic-light status of a drug already on formulary a [separate form](https://bswtogether.org.uk/medicines/area-prescribing-committee/drug-application-forms/) is required.
* Applications should be received in plenty of time – please contact the [APC formulary team](mailto:bswicb.formulary@nhs.net) or Trust contacts (see end of document) for further information.

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| **A. Applicant details** | |
| 1. Name: | 2. Applying Trust / Working Group? |
| 3. E-mail address: | 4. Directorate/Division |
| 5. Position: | 6. GP Practice (Primary care only): |

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| **B. Drug details** | |
| 1. 1. Approved name: | 2. Brand name: |
| 3. Manufacturer: | 4. Formulation(s) & strength requested: |
| 5. Licensed indications & Dosage: | |
| 6. Is this an application to:  Choose an item. | |

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| **C. Intended Use** | |
| 1. Define use of drug | 1. Intended patient cohort for prescription of this treatment: |
| 2. Is this just an adult cohort or is it likely to impact the paediatric population? |
| 3. Licensing: Is this product licensed for this indication? Choose an item. Is it a licensed medicine being used off-label? Choose an item. Is it an unlicensed medicine? Choose an item. |
| 4. Dose and duration of treatment: |
| 5. What are the monitoring requirements? Specify relevant clinical investigations. |
| 6. Where appropriate, define the stopping criteria: |
| Number of people affected: | 7. What is the population affected (prevalence) of the condition to be treated e.g. number per 100,000? |
| 8. Anticipated number of patient likely to receive this treatment in BSW ICB:  Primary care:  Secondary care: |
| 9. Any other relevant information regarding patient numbers: |
| Standard care/currently available  formulary alternatives. | 10. What is the current practice? Include available formulary choices and indicate any replacements. |
| Comparison with existing  formulary therapies. | 11. Please detail how this treatment differs from existing formulary choices. |
| Anticipated health outcomes of  using this drug. | 12. Please detail the anticipated health outcomes:  Choose an item. |
| Implication of not using this  Treatment. | 13. What are the alternatives to treatment? |
| Impact on pathway. | 14. Please detail whether the introduction of this treatment would result in any changes on the patient pathway: |
| Patient choice. | 15. What are the views of the individual patients and patient groups? |
| Equity. | 16. Have other health economies approved the use of this treatment for this indication?  Choose an item. |
| Proposed Traffic Light Status:  Definitions can be found [here](https://www.bswformulary.nhs.uk/about.asp) | Choose an item. |
| Prescribing restrictions. | Any prescriber  Consultant only (secondary care only) / GPwSI  Speciality Consultant teams only (please specify)  Consultant initiation; GP under shared care protocol  Other (please specify) |

| **D. Evidence for efficacy** | | | |
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| 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: | | Date: |
| 2. [Scottish Medicines Consortium (SMC)](https://www.scottishmedicines.org.uk/) | | |
| Guidance: | | Date: |
| 3. [All Wales Medicines Strategy Group (AWMSG)](https://awmsg.nhs.wales/) | | |
| Guidance: | | Date: |
| Other regional/national/ local policy and guidance. |  | | |
| Professional peer- support guidance e.g. Royal College. |  | | |
| If none of the above are available or inadequate please summarise additional clinical evidence supporting this application, indicating the types of evidence available e.g. clinical trials, meta-analyses, and also noting any planned trials or extension studies.  If you wish to submit more than 2 pieces of evidence, please supply as an appendix. | | | |
| 1. Summary of clinical evidence.  Types of evidence, overview, strengths and limitations. | |  | |
| Response to treatment | |  | |
| Primary outcome | |  | |
| Secondary outcomes | |  | |
| Data from extension studies (if available) | |  | |
| 2. Summary of clinical evidence.  Types of evidence, overview, strengths and limitations. | |  | |
| Response to treatment | |  | |
| Primary outcome | |  | |
| Secondary outcomes | |  | |
| Data from extension studies (if available) | |  | |

| **E. Safety** | |
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| 1. Adverse Drug Reactions.  *(List all serious/significant, very common* (≥ 1/10) *or common* (≥ 1/100 to < 1/10) *events.)* |  |
| 2. Should therapy be used with caution in any patient cohort? |  |
| 3. Is this a black triangle drug? | Choose an item. |
| 4. Is this therapy known to be addictive or habit forming? | Choose an item. |
| 5. Staff training issues which might arise due to therapy. |  |
| 6. Special storage requirements. |  |
| 7. List significant issues possible with transfer of therapy across the prescribing interface. |  |

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| **F. Financial implications** | | | | |
| Is there any pre-existing cost- effectiveness information for this medication/indication?  *If so, please provide full details including source.* |  | | | |
|  | **New Medicine** | | **Comparator Medicine** | |
| Unit Cost |  | |  | |
| Treatment dose & course length e.g. 2 tablets TDS 7/7. |  | |  | |  |
| Cost per course or per annum (whichever most appropriate). |  | |  | |  |
| Expected number of patients per year. |  | |  | |  |
| Total expected annual cost for the medicine. |  | |  | |  |
| Administration, consumables, administrative and/or monitoring costs of new medicine. |  | | | |  |
| Off-set costs of new medicine. |  | | | |  |
| Funding category:  Choose an item. | | | | |  |
| **G. Declaration of conflicts of interest -** must be completed by applicant. **If NIL – please state** | | | | |
| I have no declarations of interest to declare:  I do have declarations of interest to declare: Please fill in the form that is found [here](https://bswtogether.org.uk/medicines/area-prescribing-committee/drug-application-forms/) and return to [bswicb.formulary@nhs.net](mailto:bswicb.formulary@nhs.net)  Please note the [ABPI disclosure data base](https://www.abpi.org.uk/reputation/disclosure-uk) will be searched | | | | |
| Signature of applicant (electronic signature received from a valid NHS email account is acceptable): | | | Date: | |

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| **H. DIRECTORATE SUPPORT** – Supportive of application and aware of potential budgetary impact to directorate within Trusts | |
| **General Manager** | |
| Signature of applicant: | Date: |
| **Clinical Director** | |
| Signature of applicant: | Date: |

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| **I. How urgent is this request?** Please advise below |
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**BSW Formulary Contacts**

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| **Organisation or Acute Trust** | **Email** |
| BaNES, Swindon and Wiltshire ICB | [bswicb.formulary@nhs.net](mailto:bswicb.formulary@nhs.net%20) |
| Great Western Hospitals NHS Foundation Trust | [gwh.formulary@nhs.net](mailto:gwh.formulary@nhs.net) |
| Royal United Hospitals Bath NHS Foundation Trust | [ruh-tr.formulary@nhs.net](mailto:ruh-tr.formulary@nhs.net) |
| Salisbury NHS Foundation Trust | [peterdavies1@nhs.net](mailto:peterdavies1@nhs.net) |