**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 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 availableformulary 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 ofusing this drug. | 12. Please detail the anticipated health outcomes: Choose an item. |
| Implication of not using thisTreatment. | 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.netPlease 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   |
| Great Western Hospitals NHS Foundation Trust | gwh.formulary@nhs.net  |
| Royal United Hospitals Bath NHS Foundation Trust | ruh-tr.formulary@nhs.net  |
| Salisbury NHS Foundation Trust | peterdavies1@nhs.net  |