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| **A. Applicant details** |
| 1. Name: Click here to enter text  | 2. Applying Trust / Organisation / GP Practice / Working Group?Click here to enter text  |
| 3. e-mail address:Click here to enter text  | 4. Directorate/Division (Secondary care only): Click here to enter text  |
| 5. Position:Click here to enter text  | 6. GP Practice (Primary care only): Click here to enter text  |
| 7. Secondary Care Only: Please confirm that clinicians across the relevant service groups have been involved in this proposal to ensure consistent practice across the Trust.

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| [ ]  | Musgrove Park Hospital | Clinician Name: Click here to enter text  | Position: Click here to enter text  |
| [ ]  | Yeovil Hospital | Clinician Name: Click here to enter text  | Position: Click here to enter text  |
| [ ]  | Community Services | Clinician Name: Click here to enter text  | Position: Click here to enter text  |
| [ ]  | Mental Health Services | Clinician Name: Click here to enter text  | Position: Click here to enter text  |

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| **B. Drug details** |
| 1. Approved name:

Click here to enter text | 2. Brand name:Click here to enter text  |
| 3. Manufacturer:Click here to enter text  | 4. Formulation(s) & strength requested: Click here to enter text  |
| 5. Licensed indications & dosage: Click here to enter text  |
| 6. Patent expiry (*Please indicate if the new drug or any alternative(s) have a patent expiry within the next 18 months)*: Click here to enter text  |
| 7. Is this an application to: (please tick)1. Add a new drug to the formulary? [ ]
2. Add a new indication for an existing formulary drug? [ ]
3. Add a new formulation for an existing formulary drug? [ ]
4. Change the traffic light status of an existing formulary drug? *(see traffic light status’ below)* [ ]
5. To support an Individual Funding Request (IFR) application [ ]
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| **C. Intended use** |
| Proposed Traffic Light Status.(please tick) | **Red** – Appropriate for specialist prescribing only | [ ]  |
| **Amber1 –** Appropriate for Primary Care prescribing without formal shared care protocol, may be initiated by GP on trust advice | [ ]  |
| **Amber2** Appropriate for Primary Care prescribing when trust initiated, without formal shared care protocol | [ ]  |
| **Amber3 (shared-care) –** Appropriate for Primary Care prescribing when trust initiated, with formal contractual shared care protocol. Shared-care protocols must be set out in the Somerset ICB template and attached as an appendix to this application.Shared Care Agreement attached | [ ] [ ]  |
| **Green** – medicines suitable for routine prescribing in primary and secondary care as per licensed indications, in accordance with nationally recognised formularies e.g. BNF, BNFc, Palliative Care Handbook.  | [ ]  |
| Define use of drug: | 1. Intended patient cohort for prescription of this treatment. Adult [ ] Paediatric[ ] Both[ ]

Click here to enter text  |
| 1. Licensing: (please tick)
2. Is this product licensed for this indication? Yes [ ] No [ ]
3. Is it a licensed medicine being used off-label? Yes [ ] No [ ]
4. Is it an unlicensed medicine? Yes [ ]  No [ ]

*If 2b or 2c is Yes*Prescribers must complete [an](#appendix) Unlicensed or Off-Label declaration form and obtain patient consent.*If 2c is Yes*Why is an unlicensed Medicine being considered? * Pharmaceutically Equivalent Licensed product temporarily unobtainable Yes [ ] No [ ]
* Equivalent UK licensed product unavailable / unsuitable Yes [ ] No [ ]
* Other [ ] (give details) Click here to enter text
 |
| 1. Dosage & duration of treatment.

Click here to enter text  |
| 1. What are the monitoring requirements? Specify relevant clinical investigations.

Click here to enter text  |
| 1. Where appropriate, define the stopping criteria.

Click here to enter text  |
| Number of people affected: | 1. What is the population affected (prevalence) of the condition to be treated e.g. number per 100,000?

Click here to enter text  |
| 1. Anticipated number of patients likely to receive this treatment per year?

 Click here to enter text  |
| Finances***DO NOT*** *rely on prices provided by drug reps or BNF. Costings should be calculated in liaison with respective ICB Medicines Management or Trust Pharmacy Teams.* | 1. Expected annual cost: Click here to enter text

Funding category (please tick as appropriate): * In PbR tariff (requires Trust directorate financial agreement see section H) [ ]
* PbR excluded – NHSE funded [ ]  **or** ICB funded [ ]
* Primary Care [ ]
 |
| 1. Administration, consumables, administrative and/or monitoring costs of new medicine.

Click here to enter text  |
| Comparison with existing formulary therapies. | 1. What is the current practice? Include available formulary choices and indicate any replacements.

Click here to enter text  |
| 1. How does this treatment differ from existing formulary choices?

Click here to enter text  |
| 1. Cost of current practice / medicines / treatment.

Click here to enter text  |
| Finance Validation***To be completed by ICB Medicines Management / Trust Pharmacy staff*** | 1. Finance section validated by: ICB Medicines Management [ ] / Trust Pharmacy [ ]

Validator name: Click here to enter text Date of validation: Click here to enter date. |
| Anticipated health outcomes of using this drug. | 1. Please detail the anticipated health outcomes e.g. symptom control, prevention, cure.

Click here to enter text  |
| Implications of not using this treatment. | 1. What are the alternatives to treatment?

Click here to enter text  |
| Impact on pathway. | 1. Please detail whether the introduction of this treatment would result in any changes on the patient pathway.

Click here to enter text  |
| Patient choice. | 1. What are the views of the individual patients and patient groups?

Click here to enter text  |
| Equity. | 1. Has this treatment been approved for use by other organisations in the UK?

Click here to enter text  |

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| **D. Evidence for efficacy** |
| Assigned Evidence Level as per below: | Click here to enter text  |
| *(Taken from* [*SIGN 50:*](https://www.sign.ac.uk/assets/sign_grading_system_1999_2012.pdf) *A Guideline Developer’s Handbook guidance)*

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| 1++ | High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias |
| 1+ | Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias |
| 1- | Meta-analyses, systematic reviews, or RCTs with a high risk of bias |
| 2++ | High quality systematic reviews of case control or cohort or studies.High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal. |
| 2+ | Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal |
| 2- | Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal |
| 3 | Non-analytic studies, e.g. case reports, case series |
| 4 | Expert opinion |

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| National policy and guidance. | 1. National Institute for Health and Care Excellence (NICE) including NICE Evidence Summary: new medicines

Guidance: Click here to enter text Date: Click here to enter a date. |
| 1. Scottish Medicines Consortium (SMC)

Guidance: Click here to enter text Date: Click here to enter a date. |
| 1. All Wales Medicines Strategy Group (AWMSG)

Guidance: Click here to enter text Date: Click here to enter a date. |
| Other regional/national/ local policy and guidance. | Click here to enter text  |
| Professional peer- support guidance e.g. Royal Colleges. | Click here to enter text  |
| 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 3 pieces of evidence, please supply as an appendix.* |
| **1.** Summary of clinical evidence (Type of evidence, overview, strengths & limitations). | Click here to enter text  |
| Response to treatment. | Click here to enter text  |
| Primary outcome. | Click here to enter text  |
| Secondary outcomes. | Click here to enter text  |
| Data from extension studies (if available). | Click here to enter text  |
| **2.** Summary of clinical evidence (Type of evidence, overview, strengths & limitations). | Click here to enter text  |
| Response to treatment. | Click here to enter text  |
| Primary outcome. | Click here to enter text  |
| Secondary outcomes. | Click here to enter text  |
| Data from extension studies (if available). | Click here to enter text  |
| **3.** Summary of clinical evidence (Type of evidence, overview, strengths & limitations). | Click here to enter text  |
| Response to treatment. | Click here to enter text  |
| Primary outcome. | Click here to enter text  |
| Secondary outcomes. | Click here to enter text  |
| Data from extension studies (if available). | Click here to enter text  |

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| **E. Safety** |
| 1. Adverse Drug Reactions.

*(List all serious/significant, very common* (≥ 1/10) *or common* (≥ 1/100 to < 1/10) *events.)* | Click here to enter text  |
| 1. Should therapy be used with caution in any patient cohort?
 | Click here to enter text  |
| 1. Is this a black triangle drug?
 | Yes [ ]  No [ ]  |
| 1. Is this therapy known to be addictive or habit forming?
 | Click here to enter text  |
| 1. Staff training issues which might arise due to therapy.
 | Click here to enter text  |
| 1. Special storage requirements.
 | Click here to enter text  |
| 1. List significant issues possible with transfer of therapy across the prescribing interface.
 | Click here to enter text  |
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| **F. Declaration of conflicts of interest - must be completed by applicant** |
| Please list:1. Any gifts or hospitality received from the manufacturer of the product concerned (exceeding value of £20) in the last year.
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.

If NIL – Please state: Click here to enter text *NB – You are not required to declare the actual monetary value of the above. Use separate sheet if necessary.* |
| Signature of applicant:  | Date: Click here to enter date. |

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| **G. ACUTE TRUST DIRECTORATE SUPPORT – Supportive of application and aware of potential budgetary impact to directorate within Trusts** |
| **Service Group Finance Manager**  | Print Name: Click here to enter text  | Signature: | Date: Click here to enter date. |
| **Service Director**  | Print Name: Click here to enter text  | Signature: | Date: Click here to enter date. |

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| **H. D&TC and /or MPB sign- off – Post Committee discussion, approval for addition to formulary** |
| **D&TC Chair**  | Print Name: Click here to enter text  | Signature: | Date: Click here to enter date. |
| **MPB Chair**  | Print Name: Click here to enter text  | Signature: | Date: Click here to enter date. |