**This form has been developed in conjunction with NHS Dorset, Dorset County Hospital NHS Foundation Trust, Dorset Healthcare University NHS Foundation Trust, University Hospitals Dorset NHS Foundation Trust.**

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 (*refer to the ‘Manual for prescribed specialised services’ NHS Commissioning Board, available on* [NHSE website](https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services-201718/).)

# Completion notes:

* [**Formulary Proposal**](#_Formulary_proposal). This form should be used to propose a medicine for inclusion on the Dorset formulary or to re-classify the traffic light status of a medication - [**This form is included after the Medicines Evaluation Checklist**](#_Formulary_proposal)
* It should be completed and submitted by clinicians to their local Drug & Therapeutics Committee for red items (Hospital only). For amber (Specialist Initiation/Input), or green items (initiation in all sectors it should be submitted to the relevant clinical working group. If approved, applications and the completed and signed Medicines Evaluation Checklist will be forwarded to DMAG for consideration of use across the Dorset healthcare community.
* It should not be completed by representatives of the pharmaceutical industry.
* It should not be completed by a clinician who has a direct financial interest with the drug being proposed
* Medicines should only be considered “approved” following a positive DMAG recommendation and final approval of the DMAG minutes where the matter was discussed.
* Further guidance is available in Appendix 3

**Guidance notes – Presentation and Discussion – Medicines Evaluation Checklist**

* The Medicines Evaluation Checklist should be **used to guide the discussion about the application at the meeting and completed during the meeting and signed by the meeting’s Chair, before submitting to DMAG.**
* This checklist is intended as an aid to support the process of evaluating medicines before recommendation to DMAG. The objective is to ensure that all relevant evidence has been considered, to guide discussion and to provide a written record as well as ensuring that there is a consistent approach to the evaluation of evidence and drug-decision making across Dorset.

## **Medicines Evaluation Checklist – for completion during the meeting**

|  |
| --- |
| 1. Drug: Indication: Requestor: Date:  |
| Is the drug licensed for its proposed indication? | Yes [ ] No [ ]  |
| Comments:  |
| 2. Does it offer any particular advantages/disadvantages over current therapy options? | Yes [ ]  No [ ]  Maybe [ ]  |
| Comments:  |
| 3. Is there good quality evidence to support efficacy for the proposed indication?*e.g. well-designed systematic reviews/meta-analyses, RCTs with low risk of bias, consistent results, studies using relevant comparators* | Yes [ ]  No [ ]  Somewhat [ ]  |
| Assigned Evidence Level as per below *(originally taken from* SIGN 50*: A Guideline Developer’s Handbook guidance)** 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 [ ]
 |
| 4. Are there any significant gaps in evidence or need for further research?*e.g. lack of evidence relevant to our target population, or in elderly/children/patients with concomitant medical conditions* | Yes [ ] No [ ]  |
| Comments:  |
| 5. Are there any safety concerns?*e.g. adverse effects, interactions, contraindications/cautions for use* | Yes [ ]  No [ ]  Maybe [ ]  |
| Comments:  |
| 6. Are there any sustainability concerns/benefits associated with this product? | Yes [ ]  No [ ]  Maybe [ ]  |
| Comments:  |
| 7. What is the balance of benefits vs risks?*How does it compare to current therapies?* | Positive [ ]  Negative [ ]  Unsure [ ]  |
| Comments:  |
| 8. Will there be significant impact on costs?*If yes or maybe, which sector/organisation will be affected, and will the impact be positive (i.e. cost saving) or negative (i.e. cost burden)?* | Yes [ ]  No [ ]  Maybe [ ]  |
| Comments:  |
| 9. Is there a positive recommendation from another organization or is it a recommended treatment in published guidelines?*e.g. NICE, SMC, AWMSG, Royal College Physicians. How strong is the recommendation, and what evidence is it based on?* | Yes [ ] No [ ]  |
| Comments:  |
| 10. Additional comments from the Group for consideration:  |
| **Recommendations**Strength of Recommendation: Strong [ ]  Unsure [ ] Suggested traffic light status: Red [ ]  Amber [ ]  Amber with SCG [ ]  Green [ ] Is shared care/written guideline required? Yes [ ] No [ ]  |
| **Medicines Evaluation Checklist Sign off** |
| Name:  | Designation:  |
| Signature:  | Date:  |

**\*\*Please note the person signing this section should not be the same as the proposer\*\***

## **Formulary proposal**

| **A. Drug details** |
| --- |
| 1. Approved name:
 | 2. Brand name: |
| 3. Manufacturer: | 4. Formulation(s) & strength requested: |
| 5. Licensed indications & Dosage |
| 6. If the product is a liquid for paediatrics does it come in a recognised standard concentration according to national guidance? |
| 7. If the product is being considered for use in paediatrics are the excipients suitable? |
| 8. Patent expiry (*Please indicate if the new drug or any competitor(s) have a patent expiry within the next 18 months)*:  |
| 9. Is this an application to: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? [ ]
 |

| **B. Intended use** |
| --- |
| Define use of drug: | 1. 1. Intended patient cohort for prescription of this treatment?
 |
|  | 1. 2. Is this just an adult cohort, or is this likely to impact on the paediatric population?
 |
|  | 1. 3. Licensing:
2. Is this product licensed for this indication? Yes [ ] No [ ]
3. Is it a licensed medicine being used off-label? Yes [ ] (please complete appendix 1) No [ ]
4. Is it an unlicensed medicine? Yes [ ] (please complete appendix 1) No [ ]
 |
|  | 1. 4. Dosage & duration of treatment.
 |
|  | 1. 5. What are the monitoring requirements? Specify relevant clinical investigations.
 |
|  | 1. 6. Define the criteria for stopping this medication (symptoms or physiological parameters) and guidance for stopping i.e. can it be stopped immediately or must therapy be tapered down?
 |
| Number of people affected: | 1. 7. What is the population affected (prevalence) of the condition to be treated e.g. number per 100,000?
 |
|  | 1. 8. Anticipated number of patients likely to receive this treatment across Dorset?
 |
| Standard care/ currently available formulary alternatives. | 9. What is the current practice? Include available formulary choices and indicate any replacements.  |
| Comparison with existing formulary therapies. | 10. Please detail how this treatment differs from existing formulary choices   |
| Drug class | 11.Are there other drugs in this class and what is the compelling need for an additional option? |
| Anticipated health outcomes of using this drug. | 12. Please detail the anticipated health outcomes e.g. symptom control, prevention, cure. |
| Implications 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.  |
| Commissioning.  | 15. Does this treatment fall within existing commissioned activity of the health provider concerned? |
| Patient choice. | 16. What are the views of individual patients and patient groups?  |
|  | 17. Have other health economies, regionally or nationally, approved the use of this treatment for this indication? |
| Proposed Traffic Status.(please tick)Please note any additional restrictions *e.g. by Dr. A.N. Other’s team for indication X, at a particular hospital.* | **Red** – medicines to be prescribed by specialists in a hospital setting* On formulary (state which section) [ ]
* Formulary application planned (state when and by whom) [ ]
* No intent to add to formulary elsewhere [ ]

Please detail formulary status of this drug at other secondary care providers within Dorset & if not approved by other providers, state who has been consulted regarding use of this drug at other Trust sites. |[ ]
|  | **Amber (shared-care) –** medicines that should be initiated by a hospital specialist and only prescribed by in primary care under approved shared-care guidance, once the patient has been stabilised.Prior agreement must be settled between the specialist and primary care prescriber before care is transferred.(Shared-care agreements must be set out in the Dorset Medicines Advisory Group Shared Care template.) |[ ]
|  | **Amber –** medicines to be prescribed in primary care only after specialist initiation or on specialist recommendation. A supporting guideline may be requested. |[ ]
|  | **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. Primary care prescribers take full responsibility for prescribing. |[ ]
| Prescribing restrictions. | Any prescriber [ ] Consultant only (secondary care only) / GPwSI [ ] Specialty Consultant teams only (Please specify teams) [ ]  Consultant initiation; GP under shared care protocol [ ] Other (please state): [ ]   |

| **C. Evidence for efficacy** |
| --- |
| National policy and guidance. | 1. National Institute for Health and Care Excellence (NICE)  |
| Guidance:  | Date:  |
| 2. Scottish Medicines Consortium (SMC) <https://www.scottishmedicines.org.uk/> |
| Guidance:  | Date:  |
| 3. All Wales Medicines Strategy Group (AWMSG) <http://www.awmsg.org/> |
| Guidance: | Date:  |
| NICE Evidence Summary |  |
| RMOC guidance. |  |
| Other regional/national/ international guidance. |  |
| Professional peer- support guidance e.g. Royal Colleges. |  |
| 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 additional studies as an appendix.Evidence should be focused on patient-oriented outcomes in preference to surrogate markers of disease |
| 1. Summary of clinical evidence (Type of evidence, overview, strengths & limitations). | * Trial format e.g. RCT, meta-analysis, cohort study
* Objective and conclusions
* Results: Include measures such as ARR, NNT, HR and include confidence inter
* Strengths and limitations
* Risk of bias e.g. industry sponsorship
* PubMed or other link to published study
* Pre-appraised reviews or letters
 |
| Results: * Primary outcome.
* Secondary outcomes.
 |  |
| 2. Summary of clinical evidence (Type of evidence, overview, strengths & limitations). |  |
| Results: * Primary outcome.
* Secondary outcomes.
 |  |
| 3. Summary of clinical evidence (Type of evidence, overview, strengths & limitations). |  |
| Results* Primary outcome.
* Secondary outcomes.
 |  |

|  |
| --- |
| **D. Safety** |
| 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? |  |
| 4. For injectable formulations | Is this classified as Moderate or High risk as per the NPSA risk assessment? Yes or No (please circle as appropriate) |
| If classified as Moderate or High risk, define ‘risk management’ strategies to be employed. |
|  |
| 5. Is this therapy known to be addictive or habit forming? |  |
| 6. Staff training issues which might arise due to therapy? |  |
| 7. Special storage requirements. |  |
| 8. List significant issues possible with transfer of therapy across the prescribing interface. |  |
| 9. Sustainability. | Is information available regarding the product’s carbon-footprint or environmental toxicology?Is any part of the product reusable? |

|  |
| --- |
| **E. Financial implications** |
| Is there any pre-existing cost- effectiveness information for this medication/indication?*If so, please provide full details including source.* |  |
|  | **Proposed Medicine** | **Comparator Medicine** |
| Unit Cost |  |  |
| Treatment dose & course length e.g. 2 tablets TDS 7/7. |  |  |  |
| Cost per course or per annum (whichever is most appropriate). |  |  |  |
| Expected number of patients per year. |  |  |  |
| Total expected annual cost for the medicine.e.g. cost per pt x no of pts |  |  |  |
| Administration, consumables, administrative and/or monitoring costs of new medicine. |  |  |
| Off-set costs of new medicine. |  |  |
| Funding category (please tick as appropriate):* In PbR tariff (requires directorate financial agreement) [ ]
* PbR excluded but not NICE TA approved (drugs with a positive NICE TA approval do not require a formulary proposal form to be completed) and CCG required to fund. Not commissioned by NHS England Specialised Commissioning approved (requires CCG funding) [ ]
* Primary Care [ ]
 |  |

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

**\*\*Please Note**

**This formulary proposal should not be completed by a clinician who has a direct financial interest with the drug being proposed**

|  |
| --- |
| **G. 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?
6. None of the above apply

 NB – You are not required to declare the actual monetary value of the above. Use separate sheet if necessary. |
| Signature of applicant:  | Date:  |
| **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:  |

# Appendix 1 - Use of unlicensed or ‘off-label’ medicines

**Consultant declaration on intention to prescribe an unlicensed Medicine or use a licensed medicine for an unlicensed indication.**

I acknowledge that I am aware that the following product is unlicensed [ ] OR

I acknowledge that I am aware that the following product is unlicensed for this indication (off-label use) [ ] :

I agree to prescribe for my patients according to the procedure set out in my Trust’s unlicensed medicines policy. [ ]

 Pharmacy risk assessment confirms this as a HIGH/LOW risk unlicensed medicine.

|  |
| --- |
| High risk items may be defined as such. |
| Imports | * Unlicensed in country of origin
* Source country outside EU/USA/Canada/Australia/NZ
* Insufficient labelling or staff/patient information present.
 |
| Specials | * If made by a supplier without a specials licence
* No certificate of analysis/conformity available
 |
| Storage | * Requires refrigeration/frozen storage
 |
| MHRA/Manufacturer restrictions to use | * Yes
 |
| Product preparation | * Requires manipulation, calculations, reconstitution or multiple vials
* Ingredients/excipients pose a safety risk to patients or staff if not

 used/disposed of correctly |

Informed consent will be obtained and the reasons for prescribing this medicine will be documented in the medical notes where required/appropriate [ ] .

Signed:

(Prescribing Consultant)

Date:

# Appendix 2

|  |  |  |  |
| --- | --- | --- | --- |
| **Trust** | **Main contacts** | **Email** | **Tel.** |
| **University Hospitals Dorset** | D&TC email (for submissions) | DTCommittee@uhd.nhs.uk | 0300 019 4096 |
| Laura Granger (Pharmacist RBH) | Laura.Granger@UHD.nhs.uk | 0300 019 4098 |
| Tracy Lyons (Pharmacist PH) | Tracy.Lyons@UHD.nhs.uk | 0300 019 3373 |
| **Dorset County Hospital NHS FT** | Fergal Nolan (Pharmacy Operational Services Manager) | Fergal.Nolan@dchft.nhs.uk | 01305 255587 |
| Christine Dodd (Deputy Chief Pharmacist) | Christine.Dodd@dchft.nhs.uk  | 01305 255172 |
| **Dorset Healthcare University NHS Foundation Trust** | **Mental Health:** Richard Bradshaw | R.Bradshaw@nhs.net | 01202 492 429 |
| **Community Services:** Adam Hocking | Adam.Hocking@nhs.net | 01305 361 417 or07500 074 395 |
| **NHS Dorset**  | Michelle Trevett | Medicine.Question@nhsdorset.nhs.uk  | 01305 213548 |

**Appendix 3**

It has been requested to develop a set of principles to guide prescribers and pharmacists when they consider whether to start a drug formulary proposal

Some points to consider:

* Has this product been included in the horizon scanning process?
* Is it a “me-too”?
* Combination products are generally considered less suitable for prescribing and will not normally be successful
* NHS Dorset does not support the use of branded generics
* Has the product been nationally evaluated or is it planned?
* Does it provide an economic advantage over existing products?
* Is this for a patient cohort (80% of formulary adherence is the aim, there may be a reason (for an individual patient) to prescribe a product not on the formulary)
* Does the drug provide an advantage within a pathway of patient management?

If any of the criteria below apply, products are unlikely to be approved:

* Products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation would not generally be considered
* Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
* Products which are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding