

DRUG & THERAPEUTICS COMMITTEES plus DORSET MEDICINES ADVISORY GROUP

New Drug Assessment / Traffic Light Allocation Form

This form has been developed in conjunction with NHS Dorset Clinical Commissioning Group, Dorset County Hospital NHS Foundation Trust, Dorset Healthcare University NHS Foundation Trust, Poole Hospital NHS Foundation Trust and Royal Bournemouth and Christchurch Hospitals 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.](#))

Guidance notes:

- This form should be used to propose a medicine for inclusion on the Pan-Dorset formulary or re-classify the traffic light status of a medication on the formulary.
- It should be completed by consultants making an application via their local Drug & Therapeutics Committee (D&TC): if considered appropriate by the local D&TC, applications will be forwarded by the D&TC to DMAG to consider the implications of inclusion across the Dorset healthcare community.
- Or it should be completed by a clinical working group making an application following discussion.
- Medicines should only be considered "approved" once recommended for inclusion by DMAG and following final approval by the Clinical Commissioning Committee.
- Applications should be received in plenty of time – please contact the working group, or Trust contacts in Appendix 2 for more information

A. Applicant details	
1. Name: Click here to enter text.	2. Applying Trust / Working Group? Click here to enter text.
3. e-mail address: Click here to enter text.	4. Directorate/Division Click here to enter text.
5. Position: Click here to enter text.	6. GP Practice (Primary care only): Click here to enter text.

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.	

Form Approved: Dorset Medicines Advisory Group March 2018
 Updated September 2018 by Formulary Working Group
 Review: March 2019 or before in light of changes to contact persons

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<p>6. Patent expiry (<i>Please indicate if the new drug or any alternative(s) have a patent expiry within the next 18 months</i>): Click here to enter text.</p>
<p>7. Is this an application to:</p> <p>a) Add a new drug to the formulary? <input type="checkbox"/></p> <p>b) Add a new indication for an existing formulary drug? <input type="checkbox"/></p> <p>c) Add a new formulation for an existing formulary drug? <input type="checkbox"/></p> <p>d) Change the traffic light status of an existing formulary drug? <input type="checkbox"/></p>

C. Intended use	
Define use of drug:	<p>1. Intended patient cohort for prescription of this treatment. Click here to enter text.</p>
	<p>2. Is this just an adult cohort, or is this likely to impact on the paediatric population? Click here to enter text.</p>
	<p>3. Licensing:</p> <p>a) Is this product licensed for this indication? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>b) Is it a licensed medicine being used off-label? Yes <input type="checkbox"/> (please complete appendix 1) No <input type="checkbox"/></p> <p>c) Is it an unlicensed medicine? Yes <input type="checkbox"/> (please complete appendix 1) No <input type="checkbox"/></p>
	<p>4. Dosage & duration of treatment. Click here to enter text.</p>
	<p>5. What are the monitoring requirements? Specify relevant clinical investigations. Click here to enter text.</p>
	<p>6. Where appropriate, define the stopping criteria. Click here to enter text.</p>
Number of people affected:	<p>7. What is the population affected (prevalence) of the condition to be treated e.g. number per 100,000? Click here to enter text.</p>
	<p>8. Anticipated number of patients likely to receive this treatment in i.e. primary and secondary care. Click here to enter text.</p>
	<p>9. Anticipated number of patients likely to receive this treatment in your local Trust? Click here to enter text.</p>

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Standard care/ currently available formulary alternatives.	10. What is the current practice? Include available formulary choices and indicate any replacements. Click here to enter text.	
Comparison with existing formulary therapies.	11. Please detail how this treatment differs from existing formulary choices Click here to enter text.	
Anticipated health outcomes of using this drug.	12. Please detail the anticipated health outcomes e.g. symptom control, prevention, cure. Click here to enter text.	
Implications of not using this treatment.	13. What are the alternatives to treatment? Click here to enter text.	
Impact on pathway.	14. Please detail whether the introduction of this treatment would result in any changes on the patient pathway. Click here to enter text.	
Patient choice.	15. What are the views of the individual patients and patient groups? Click here to enter text.	
Equity.	16. Has this treatment been approved for use by other Trusts in Dorset? Click here to enter text.	
	17. Have other health economies approved the use of this treatment for this indication? Click here to enter text.	
Proposed Traffic Status. (please tick)	Red – medicines to be prescribed by specialists in a hospital setting	
Please note any additional restrictions <i>e.g. by Dr. A.N. Other's team for indication X, at a particular hospital.</i>	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.)	

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	<p>Amber – medicines to be prescribed in primary care only after specialist initiation or on specialist recommendation. A supporting guideline may be requested.</p>	
	<p>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.</p>	
Prescribing restrictions.	<p>Any prescriber <input type="checkbox"/></p> <p>Consultant only (secondary care only) / GPwSI <input type="checkbox"/></p> <p>Specialty Consultant teams only (Please specify teams) <input type="checkbox"/> Click here to enter text.</p> <p>Consultant initiation; GP under shared care protocol <input type="checkbox"/></p> <p>Other (please state): Click here to enter text.</p>	

D. Evidence for efficacy		
National policy and guidance.	<p>1. National Institute for Health and Care Excellence (NICE) including NICE Evidence Summary: new medicines Guidance: _____ Date: Click here to enter a date. Click here to enter text.</p>	
	<p>2. Scottish Medicines Consortium (SMC) Guidance: _____ Date: Click here to enter a date. Click here to enter text.</p>	
	<p>3. All Wales Medicines Strategy Group (AWMSG) Guidance: _____ Date: Click here to enter a date. Click here to enter text.</p>	
RMOC guidance.	<p>Click here to enter text.</p>	
Other regional/national/local policy and guidance.	<p>Click here to enter text.</p>	

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Professional peer-support guidance e.g. Royal Colleges.	Click here to enter text.
<p>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.</p> <p>If you wish to submit more than 3 pieces of evidence, please supply as an appendix.</p>	
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.

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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.

E. Safety	
<p>1. Adverse Drug Reactions.</p> <p><i>(List all serious/significant, very common (≥ 1/10) or common (≥ 1/100 to < 1/10) events.)</i></p>	

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2. Should therapy be used with caution in any patient cohort?	
3. Is this a black triangle drug?	
4. Is this therapy known to be addictive or habit forming?	
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.	

F. Financial implications		
Is there any pre-existing cost-effectiveness information for this medication/indication? <i>If so, please provide full details including source.</i>		
	New Medicine	Comparator Medicine
Unit Cost		

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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.		
Administration, consumables, administrative and/or monitoring costs of new medicine.		
Off-set costs of new medicine.		
<p>Funding category (please tick as appropriate):</p> <ul style="list-style-type: none"> • In PbR tariff (requires directorate financial agreement) <input type="checkbox"/> • PbR excluded i.e. not NICE and/or SCG approved (requires CCG funding) <input type="checkbox"/> • Primary Care <input type="checkbox"/> 		
G. Declaration of conflicts of interest - must be completed by applicant		

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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:

NB – You are not required to declare the actual monetary value of the above.
Use separate sheet if necessary.

Signature of applicant: [Click here to enter text.](#)

Date: [Click here to enter a date.](#)

H. DIRECTORATE SUPPORT – Supportive of application and aware of potential budgetary impact to directorate within Trusts

General Manager

Signature of applicant: [Click here to enter text.](#)

Date: [Click here to enter a date.](#)

Clinical Director

Signature of applicant: [Click here to enter text.](#)

Date: [Click here to enter a date.](#)

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Medicines Evaluation Checklist

To be completed at Drug and Therapeutics Committees or Dorset Medicines Advisory Working Group and signed by meeting's Chair.

This document 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.

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?	
Yes/No/Somewhat	
<i>e.g. well-designed systematic reviews/meta-analyses, RCTs with low risk of bias, consistent results, studies using relevant comparators</i>	
Assigned Evidence Level as per below:	
<i>(Taken from SIGN 50: A Guideline Developer's Handbook guidance)</i>	
1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias	

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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? <i>e.g. lack of evidence relevant to our target population, or in elderly/children/patients with concomitant medical conditions</i>	
Yes/No	
Comments:	
5. Are there any safety concerns? <i>e.g. adverse effects, interactions, contraindications/cautions for use</i>	
Yes/No/Maybe	
Comments:	

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<p>6. What is the balance of benefits vs risks? <i>How does it compare to current therapies?</i></p>	<p>Positive/Negative/Unsure</p>
<p>Comments:</p>	
<p>7. Will there be significant impact on costs? <i>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)?</i></p>	<p>Yes/No/Maybe</p>
<p>Comments:</p>	
<p>8. Is there a positive recommendation from another organization or is it a recommended treatment in published guidelines? <i>e.g. NICE, SMC, AWMSG, Royal College Physicians. How strong is the recommendation, and what evidence is it based on?</i></p>	<p>Yes/No</p>
<p>Comments:</p>	
<p>Recommendation:</p>	

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Strength of Recommendation: Strong/Unsure

Suggested traffic light status:

Is shared care/written guideline required?

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 patient/s according to the procedure set out in my Trust's unlicensed medicines policy.

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:

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Appendix 2

Trust	Main contacts	Email	Tel.	Address
Royal Bournemouth & Christchurch Hospitals NHS FT	Medicines Information	medsinfo@rbch.nhs.uk	01202 704 098	Royal Bournemouth Hospital Pharmacy Dept., BH7 7DW Post Point C20
	Laura Granger (Pharmacist)	laura.granger@rbch.nhs.uk		
Poole Hospital NHS FT	Debbie Waite (Administrator)	Deborah.Waite@poole.nhs.uk	01202 442 684	Poole Hospital Pharmacy Dept., BH15 2JB
	Tracy Lyons (Pharmacist)	Tracy.lyons@poole.nhs.uk	01202 263 373	
Dorset County Hospital NHS FT	Martin Shepherd (Pharmacist)	Martin.Shepherd@dchft.nhs.uk	01305 253 422	Dorset County Hospital Dorchester, DT1 2JY
	Sue Baggott (Business Development Manager)	Sue.Baggott@dchft.nhs.uk	01305 255 295	
Dorset Healthcare University NHS Foundation Trust	Mental Health: Richard Bradshaw	r.bradshaw@nhs.net	01202 492 429	St Anne's Hospital Pharmacy Dept., BH13 7LN
	Community Services: Adam Hocking	adam.hocking@nhs.net	01305 361 417 or 075000743 95	Medicines Management Forston Clinic Herrison Road Dorchester DT2 9TB