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| **This form is used to submit requests for consideration of funding of treatments within the local health economy that are not funded through the usual channels. Although aimed primarily at high-cost drugs, this form can be used for other treatments too.**  **The level of detail is required to help provide the necessary information to the NHS Norfolk and Waveney Therapeutics Advisory Group and Commissioners to enable a decision about treatments that affect the local health economy.** Each formulary application will be considered in relation to existing and/or alternative drugs or services to meet the same or similar needs.  **Some providers already have formulary application templates. These can still be used, provided the extra information contained in this document is included also. If you wish to discuss the process, please contact your hospital Chief Pharmacist in the first instance.**  **In 2025/26, as in previous years, applications will normally only be funded if they implement a NICE Technology Appraisal Guideline or if they can be shown to produce in-year realisable savings within the wider Norfolk and Waveney health system. It should be said that submission of application is no guarantee of funding.**  **Please note:**   * All sections should be completed unless not applicable. Accompanying attachments should be submitted simultaneously. Incomplete forms will be returned to the applicant. * **ALL costs must be included** - including **diagnostics,** **PbR charges for hospital spells, OP visits, etc**. A key principle of this process is that full cost and also the NET increase in cost of the new development should be shown. * **All formulary applications MUST be submitted through the Trust commissioning department or Drug and Therapeutics Committee for peer review. If your Trust already has a proforma this can be used in place of the attached, provided all elements are included.** * **Please see appendices for current traffic light classifications and Decision-Making Framework**   **Completed applications should be returned to:** [**jennifer.carroll@nhs.net**](mailto:jennifer.carroll@nhs.net) **– Senior Technician – Interface and Formulary**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **For use by Senior I+F Technician** | **Patient numbers** | **Estimated costs** | **Suggested traffic light**  **classification** | **Pathway submitted** | **Blueteq required** | **Commissioning statement published** | **MO Programme Board ratification** | **Formulary updated** | |  |  |  |  |  |  |  |  | |

**Formulary Application Template -** **Long Form – Use for applications where there is no NICE TA or Guidance to support use**

The following sets out the questions that commissioners will review to help them to consider the relative priorities of developments in out of tariff, high-cost drugs and other developments competing for resources in the NHS in the Norfolk and Waveney area.

**All sections must be completed for the application to be considered effectively.**

|  |  |  |
| --- | --- | --- |
| **Section A - Information about you and what you are asking the local health economy to fund** | | |
| Name of Trust / organisation submitting this application: |  | |
| Contact details of person completing the form and who may be contacted (if necessary) for further details. | Name: |  |
| Job Title: |  |
| Contact email: |  |
| Name of the proposed Drug / Treatment: |  | |
| Indication for treatment (state if licensed / unlicensed) |  | |
| Have NICE published a Technology Appraisal (TA) for this drug and indication? If so, please provide details and date published |  | |
| Describe current care pathway for patients requiring this treatment and where the proposed treatment sits within it |  | |
| What treatment would be given if this application was not funded? |  | |
| How do the benefits offered by this drug / treatment differ from current treatments offered for management of this condition? |  | |
| Will the introduction of this drug / treatment change threshold for treatment? If yes, in what way? |  | |
| Estimated patient numbers |  | |

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| **Section B - Peer review of application**  The application will be considered through the local Therapeutics Advisory Group (aka the “TAG”) before a commissioning decision is made. The normal process is for all applications to undergo peer review through their Trust Drug & Therapeutics Committee or equivalent. | |
| Has the Trust Drugs & Therapeutics Committee considered this locally? If so, when and what was the outcome? |  |
| Has this treatment been the subject of a Drug and Therapeutics Committee Chair’s action or individual funding request (IFR) to any ICB? If yes, please specify (without describing individual cases that could identify a patient). |  |

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| **Section C - Effectiveness**  In requesting this treatment, and describing its place within the care pathway, you need to explain the treatment effectiveness in the proposed indication to help the commissioners for the local health economy make a decision regarding investment in this therapy. | |
| **Explain the effectiveness of this treatment:**  Effectiveness needs to be explained in terms of patient-oriented outcomes (POO) not just disease-oriented outcomes (DOO).  If unsure about the evidence available please contact your Trust Drug Information Pharmacist |  |

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| **Section D - Patient factors**  In requesting this treatment, and describing its place within the care pathway, you need to advise on the likely patient factors in the proposed indication to help the commissioners for the local health economy make a decision regarding investment in this therapy. This will include factors affecting the delivery of treatment to the patient (such as prescribing responsibility, shared care guideline, change of formulation to meet need, training requirements etc) | |
| Outline any patient-related factors relevant to this application |  |
| Is a Shared Care Agreement (SCA) required? If so, please attach copy where SCA has been approved or is available as a draft. |  |
| Is a home care provider to be considered / used for delivery of this treatment? If yes, what part of the treatment could be provided outside an acute care or day case setting, e.g. at home? |  |
| If a hospital anticipates this will be provided through home delivered services, please specify potential provider and cost |  |

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| **Section E - Safety**  In requesting this treatment, and describing its place within the care pathway, you need to advise on the safety factors in the proposed indication to help the commissioners for the local health economy make a decision regarding investment in this therapy. | |
| What are the primary harms caused by this treatment?  For information about harms refer to:   * the manufacturer’s Summary of Product Characteristics [www.medicines.org.uk](http://www.medicines.org.uk) , * the Medicines & Healthcare Products Regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk), * UKMI drug information via <https://www.sps.nhs.uk/>, and * the Food & Drugs Administration [www.fda.gov](http://www.fda.gov) |  |
| Please state “Numbers Needed to Harm” (NNHs), if known |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section F - Implementation** | | | | | | | |
| How long will it take to see results/health improvement from the development? For example, are trained staff already in post and physical space available or would additional training or new construction be needed? | | |  | | | | |
| Describe potential impact (positive or negative) on other NHS or non-NHS agencies or services | | |  | | | | |
| What gains in other parts of the system that YOU influence can change as a direct result of introducing this treatment, e.g. hospital visits reduced, oral vs injectable treatment? | | |  | | | | |
| What additional facilities would have to be provided before this treatment could be implemented? Please estimate how much time is required before implementation | | |  | | | | |
| Does this development encourage self-care? | | |  | | | | |
| **Section G - Costs**  In requesting this treatment, and describing its place within the care pathway, you need to advise on the costs of the proposed indication to help the commissioners for the local health economy make a decision regarding investment in this therapy. | | | | | | | |
| Hospital / Trust cost for average length of proposed treatment excluding VAT | | |  | | | | |
| Primary care cost for average length of proposed treatment excluding VAT | | |  | | | | |
| Other costs, e.g. hospital visits, including HRG costs, associated tariff or indicative tariff over and above treatment costs | | |  | | | | |
| Cost of tests related to use of submitted drug that will be charged to commissioners, i.e. not in tariff price or indicative tariff. | | |  | | | | |
| Other costs, e.g. hospital visits, including HRG/PbR tariff or indicative tariff over and above treatment costs for the historical treatment the submitted drug / treatment will replace (if appropriate). | | |  | | | | |
| Costs of tests related to use of the current or alternative treatment the submitted treatment replaces that will be charged to commissioners, i.e. not in tariff price or indicative tariff (if appropriate). | | |  | | | | |
| Cost for average length of treatment for the historical treatment the submitted treatment will replace | | | Hospital | Full cost (If charged as indicative tariff, value to be charged to be provided): | | | |
| GP | Full cost: | | | |
| Marginal cost (i.e. difference in cost of submitted drug / treatment compared to historical treatment) for hospital and for GP budgets). | | |  | | | | |
| Explain how any savings within your own organisation can be released from other treatments related to this or other conditions within your specialty. | | |  | | | | |
| Specify saving or costs which may occur to other organisations in the system. | | |  | | | | |
| If this drug, for this indication were funded, how many EXTRA patients might be expected to fit the criteria for treatment at this hospital (or per 100,000 population)?  **State if rates or numbers.** (Population covered may vary by specialty; higher for tertiary work) | | | In 2025/26 | |  | | |
| In subsequent years | |  | | |
| **Suggested traffic light classification – please indicate under relevant box (see Appendix 1 for further information)** | | | | | | | | |
| **RED** | **AMBER SHARED CARE AGREEMENT** | **AMBER INITIATE** | | | | **ADVICE** | **GREEN** | | |
|  |  |  | | | |  |  | | |

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| --- | --- | --- |
| **Declaration of Interests by the Applicant:** | | |
| **Have you or your department in the past five years accepted the following from an organisation that may in any way gain or lose from the acceptance or rejection of this drug:** | **Yes (*please provide brief details*)** | **No** |
| Reimbursement for attending a symposium? |  |  |
| A fee for speaking? |  |  |
| A fee for organising education? |  |  |
| Funds for research? |  |  |
| Funds for a member of staff? |  |  |
| Fees for consulting? |  |  |
| Have you in the past 5 years been employed by an organisation that may in any way gain or lose from the acceptance or rejection of this drug? |  |  |
| Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the acceptance or rejection of this drug? |  |  |
| Do you have any other competing interests? | Please specify: |  |
| Declaration: “*I have no competing interests.*” | Signature:  Date: | |

Thank you for completing this formulary application.

Please forward the completed document to [Jennifer.Carroll@nhs.net](mailto:Jennifer.Carroll@nhs.net)

**APPENDIX 1 – Current Traffic Light Classifications**

|  |  |
| --- | --- |
| **Black** | **Not commissioned. Not suitable for NHS prescribing in primary or secondary care**  This covers medication and devices that are not commissioned for use in Norfolk and Waveney. It also includes NICE TAs where the treatment has not been recommended. |
| NICE Approved | **NWICB are committed to fund positive NICE TAs. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance to be issued when available.**  This is a holding position which acknowledges NICE-approved TAs with ICB-commissioned responsibility which have not yet been allocated a traffic light classification. |
| **Blue** | **Formulary application and discussion required prior to addition to formulary.**  This includes new products on the Horizon Scanning list and those medications and devices in primary and secondary care which don’t have a NICE TA or have not yet been considered for addition to formulary. |
| **Double Red** | **Not recommended for routine use. To be used only as a last resort in exceptional circumstances. Seek advice from Medicines Optimisation Team where appropriate**  Includes situations such as transfer of care, patient moving from out of area, or where other treatment or pathway options have been exhausted. Some items may require formal approval via the IFR process. |
| Red | **Restricted Use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care**  Includes acute and mental health trusts and other specialist commissioning services. Classification does not automatically signify that a drug will be available within secondary care. |
| Amber SCA | **Shared Care Agreement** These are drugs covered by a formal shared care agreement within the current LCS. Level will be highlighted in each individual document and in the Netformulary entry. Specialist will send a request to provider when it is deemed suitable to transfer prescribing to primary care. Agreement will be assumed unless the primary care provider states otherwise. |
| Amber Initiation | **Amber Initiate - Specialist initiation. Prescribing will switch to primary care as per commissioning agreement or when clinically appropriate.**  Specialist requirements will be noted in the drug’s Netformulary entry and guidance document. Treatments listed under this classification are not included in the formal shared care LCS and there will be no additional payment for prescribing. |
| **Advice** | **Advice – Primary care initiation following specialist recommendation**  Primary care initiation following receipt of verbal or written recommendation from primary or secondary care specialist clinician with relevant expertise. |
| **Guidance documents will be developed to support prescribing of drugs within the** Amber Initiation **and the**  **Advice categories to support clinicians who may not have experience of prescribing or monitoring these drugs** | |
| **Green** | **Formulary – Can be initiated and prescribed in primary or secondary care within licensed indications**  This covers most drugs on the primary care formulary |
| **Switch** | **Not recommended for prescribing. Switch to cost-effective alternative**  This category will act as a reminder of the cost-effective switches and will be reviewed monthly |
| **OTC** | **Available to buy over the counter. Consider self-care**  Drugs in this category will be available to buy over the counter. |
| Discontinued Medicines | **Discontinued Medicines**  This category will be under constant review and updated regularly |

**APPENDIX 2 - Decision-Making Framework for Recommendations on New Medicines and Indications**

**TAG Meeting Date:**   **Agenda Item:**

**Medicine and Indication:**

**Prescriber’s Rating – To assist the TAG in clarifying its recommendation for use of a medicine or treatment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Prescriber’s Rating Definitions** | | | **Recommended for use?** |
| **1.** | **Bravo!** | The drug is a major therapeutic advance in an area where previously no treatment was available. | ***Yes*** |
| **2.** | **A real advance** | The product is an important therapeutic innovation but has certain limitations. |
| **3.** | **Offers an advantage** | The product has some value but does not fundamentally change present therapeutic practice. |
| **4.** | **Possibly Helpful** | The product offers small additional value and should not change prescribing habits except in rare circumstances. | ***Possibly*** |
| **5.** | **Judgement reserved** | The Committee postpones its judgement until better data and a more thorough evaluation of the drug are available. | ***No*** |
| **6.** | **Nothing New** | The product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available. (In most cases these are “me-too” products). |
| **7.** | **Not acceptable** | Product without evident benefit over others but with potential or real disadvantages. |
| **Prescriber’s Rating agreed by the TAG** | | **Number:** |  |

*With acknowledgement to Prescrire and NHS Suffolk D&TC*

**To assist the TAG in recommending *where* Prescribing Responsibility might rest in Norfolk and Waveney**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Criterion** | | **Red (Hospital / Specialist only)** | **Amber (Option for shared care or specialist initiation)** | **Advice (Specialist recommendation)** | **Green (Suitable for initiation in Primary Care)** |
| **Skills of the Prescriber** | Experience Of Condition | Specific | Specific | Specific | General |
|  | Diagnosis | Specific | Specific | Specific | General |
|  | Monitoring Progress Treatment | Difficult | Specific | General | General |
|  |  |  |  |  |  |
| **Therapy** | Patient Selection | Difficult | Specific | Specific | Easy |
|  | Initiation Of Treatment | Difficult | Difficult/Complex | Easy | Easy |
|  | Dose Titration | Difficult | Specific | Easy | Easy |
|  | Monitoring Of Side Effects | Complex | Easy | Easy | Easy |
|  | Method Of Administration | Complex | Standard | Standard | Standard |
|  |  |  |  |  |  |
|  | Discontinuation Of Treatment | Complex | Complex | Easy | Easy |
| **Recommended classification:** | |  |  |  |  |

**References:**

Jonsen A, Bentham In a box: Technology assessment and health care allocation. Law Med. Health Care. 1986;14:172-174

Suffolk Drugs & Therapeutics Committee – responsibility for prescribing, Hospital Trust or GP?

East of England Priorities Advisory Committee (PAC) - Documentation on requesting a PAC recommendation

|  |
| --- |
| **Treatment assessed (Month and Year):** |
| **TAG Recommendation**  TBC post meeting |
| **1) Clinical Effectiveness**  *e.g. according to national guidelines…* |
| **2) Cost Effectiveness**  *e.g. most appropriate and cost- effective products have been recommended* |
| **3) Needs of the community**  *e.g. prevalence and incidence of disease being treated?* |
| 4) **Equity & Equality Impact Assessment** (see also embedded additional information including factsheet below to aid completion of this section)  Consider whether this decision of the TAG will have an impact for patients or staff in regard to Equality, Inclusion and Human Rights legislation.  Such impacts (negative) could include:  • Restriction of a drug which could benefit those with certain conditions1,2    Where the implementation of the decision of the TAG may impact on one or more equality group differently to others, a full equality impact assessment may need to be completed.     |  | | --- | | **Protected Characteristics (under the Equality Act 2010):**  Age; Disability; Gender reassignment; Marriage & Civil Partnership (in employment only); Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual orientation; carers; other identified groups. | |
| Please state whether the decision will have an impact:  Yes ☐ *If* ***YES,*** *the proposal is likely to impact patients or staff. Please set out those impacts*  *and any mitigations that have been identified in the section below. Examples include*  *a process where the needs of exceptional cases can be met.*    No ☐ ***NO****, please state that the decision has been reviewed with regard to Equality, Inclusion and Human Rights and no issues have been identified in the section below.* |
| Provide rationale for impact assessment:  *Should a significant impact be identified a full EQIA should be completed* |
| **5) Need for healthcare (incorporates patient choice and exceptional need**)  *e.g. are there alternative therapies available or is this a completely new treatment option?* |
| **6) Policy drivers:**  *e.g. relevant local or national guidance* |
| **7) Disinvestment:**   * *How will this medicine help to address local health priorities?* * *By using this medicine, what disinvestment in other medicines, interventions and services may be possible?* * *How much would this save?* * *Affordability considerations?* * *Will this medicine help to address local health priorities?* |
| **8) Environmental impact of decision (if applicable)** |