**BEDFORDSHIRE AND LUTON CCGs - HIGH COST DRUGS COMMISSIONING FRAMEWORK**

**HIGH COST DRUGS BUSINESS CASE**

Please state title (Drug and Indication)

Name of Requesting Physician

**Completed business case templates should be returned to:** [**Jacqueline.clayton@nhs.net or Anne.Graeff@nhs.net**](mailto:Jacqueline.clayton@bedfordshireccg.nhs.uk)

**High Cost Drug Business Case Template**

The following sets out the questions that commissioners will review to help them to consider the relative priorities of new developments in high cost drugs and other developments competing for resources for the patients of Bedfordshire Clinical Commissioning Group and Luton Clinical Commissioning Group.

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| --- | --- | --- | --- | --- |
| **Title of business case:** | | | | |
| Name of Trust submitting this business case: | |  | | |
| Contact details of person completing the case and  who may be contacted (if necessary) for further  details | | Name: | |  |
| Job Title: | |  |
| Contact email or telephone phone number: | |  |
| **WHAT ARE COMMISSIONERS BEING ASKED TO CONSIDER?** | | | | |
| Name of Drug |  | | | |
| *Tick box to select as appropriate:*  Drug is Excluded from the National Tariff:  High Cost Drugs not listed as Excluded from the National Tariff (i.e. included within the Tariff)  A request to develop shared care guidelines:  Other (please state): | | | | |
| Indication or condition that this treatment will address | | |  | |
| Criteria proposed for initiating therapy. | | |  | |
| Who will initiate treatment, i.e. GP, Hospital, Other  (*where other please clarify)?* | | |  | |
| Criteria proposed for stopping therapy. | | |  | |
| Anticipated duration of treatment. | | |  | |
| Who is responsible for long term prescribing, i.e. GP, hospital,  other (where other please clarify)? | | |  | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| If treatment is initiated by specialists and it is proposed that  Prescribing is continued by GPs, specify: |  | | | |
| * Period hospital would expect to prescribe before GP takes over. |
| * Whether shared care needed yes/no.   If not, why not? | tick box *as appropriate*  Yes  No | | | |
|  | | | |
| * If shared care required, shared care guideline status, and attach copy where a shared care guideline has been approved or is available as a draft. |  | | | |
| Is a home care provider to be considered/ used for delivery of this treatment? | *tick box to select as appropriate*  Yes  No | | | |
| If a hospital anticipates this will be provided through home  delivered services, specify (a) potential provider, (b) cost charged by home care provider where they differ from costs  shown below. | a. | |  | |
| b. | |  | |
| ***Costs of drug –*** *Note: in setting priorities, Bedfordshire and Luton CCGs’ Commissioners wish to consider net cost per patient per year, to assist in comparisons between drugs wherever appropriate.* | | | | |
| Please state:   1. Annual drug cost per patient per year 2. HRG Code and Cost 3. No of hospital visits per year 4. Cost of tests related to the use of drug that will be charged to commissioners i.e**. those not in tariff price or indicative tariff** 5. Total annual cost per patient per year | | 1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   5)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Please state **additional** total cost or saving per patient per year compared to current standard treatment costs | |  | | |
| Please describe what change the business case is designed to  implement, e.g. additional drug for this indication, replacement drug for this indication. | |  | | |
| Explain how any savings within your own organisation can be released from other treatments related to this or other conditions within your specialty. | |  | | |
| If this drug, for this indication were approved for use in the health system, how many patients might be expected to fit the criteria for treatment at this hospital: | | In the last financial year (if applicable) | |  |
| In this financial year | |  |
| In subsequent financial years | |  |
| Please state incidence and prevalence for this disease. | | Incidence (number of new cases of a disease per year): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_per 100,000 population  Prevalence (overall proportion of the population who suffer from the disease):  \_\_\_\_\_\_\_\_\_\_\_\_\_per 100,000 population | | |
| How well does this development go towards identifying local and national priorities and targets? | |  | | |
| **SECTION TWO – WHAT BENEFITS WOULD THIS DELIVER?** | | | | |
| **Impact on Patients and the Community** | | | | |
| Describe the impact on individual patients of the condition that this particular business case addresses, e.g symptoms, impact on quality of life, impact on clinical outcomes. |  | | | |
| Describe the economic impact of the disease. |  | | | |
| 1. ***Responsiveness***   To what extent does this drug reflect the wishes or preferences of the public, the people at whom it is aimed or other stakeholders.   1. ***Accessibility***   Will it be easy for the people who need this drug to actually use it? |  | | | |
| What treatment would be given if this business case was not approved? |  | | | |
| Would you describe the severity of the illness to be treated as mild, moderate, serious or life threatening?  *Where appropriate, nationally recognised scoring systems should be included* |  | | | |
| Describe the major outcome achieved by the drug. |  | | | |
| What is the NNT in relation to this outcome compared to the treatment that would be given if this business case was not approved?  *Number Needed to Treat (NNT) is a measurement of the impact of a medicine or therapy by estimating the number of patients that need to be treated in order to have an impact on one person.* |  | | | |
| What is the primary harm caused by this drug? If more than one frequently occurring serious adverse effect please state these also. Please state NNH if known.  *Number Needed to Harm (NNH) is a measure of how many people need to be treated (or exposed to a risk factor) in order for one person to have a particular adverse effect.* |  | | | |
| Please complete NNT and NNH compared to current standard treatments, wherever available, to expedite consideration of business cases. | | | | |
| **Clinical Evidence- Please attach key supporting papers including key trials, DTC/New Product Subgroup Evaluation (if available)** | | | | |
| Please state level of clinical evidence:-   1. Data from meta-analysis or from at least 2 high quality RCT. 2. One high quality RCT and supporting non-randomised   (phase II) data.   1. One lower quality RCT and/or several phases II studies and or high quality observational studies. 2. Case studies/expert opinion only, single phase II study only 3. Other – please state |  | | | |
| Please provide a summary of Clinical Efficacy (and comparative efficacy) of treatment: |  | | | |
| Please provide a summary of Safety (and comparative safety) of treatment: |  | | | |
| Please provide a summary of Cost-Effectiveness of treatment: |  | | | |
| Have therapeutics committees considered this locally and rejected or supported its use for this indication? If supported, on what basis and under what conditions? Hospitals may treat patients within their own resources where considered clinically necessary. However, CCGs would want to be involved in decisions affecting the prioritisation of NHS resources. |  | | | |
| Are there any Policy Drivers which support treatment e.g. NICE Guidance/Local Policy? |  | | | |
| **SECTION THREE – WHAT WILL THE IMPACT BE ON THE HEALTH SYSTEM?** | | | | |
| How much time is required to set up the development? |  | | | |
| How long will it take to see some 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 drug, e.g. hospital visits reduced, oral vs injectable treatment? |  | | | |
| What additional facilities would have to be provided before this treatment could be implemented? |  | | | |
| What impact does this development have on equity and fairness? E.g. does it reduce inequalities in healthcare? |  | | | |
| Does this development facilitate a potential reduction in health service costs, e.g. reducing risk of hospital admission or increase use of self-care?   * If yes, when might this reduction expect to be realised? | Yes □ *tick box to select as appropriate:*  No □ | | | |
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