NHS

Greater Manchester
Commissioning Support Unit

Out of tariff high cost drug / technology business case template

GMCSU | Enabling Excellence

Out of tariff high cost drug / technology business case template

Please read all the criteria before completing any of the template

For further information on Greater Manchester CCG's commissioning arrangements for out of tariff high cost drugs please contact your hospital Chief Pharmacist or Greater Manchester CSU (GMCSU) medicines management team using the contact details below.

Developments that are primarily about new drugs/technologies or new uses for treatments will be considered by GMCSU on behalf of Greater Manchester CCG's in line with GMMMG's High cost drugs service development guideline.

This business case template is only to be used for drugs associated with medical treatments that are commissioned by CCGs and not those by NHS England.

Submission of a case is no guarantee of funding, and conversely, absence of a business case will not make requests for funding any more or less likely to be accepted as exceptional cases. If drugs are not funded, exceptional cases will be judged in line with GMCSU's Effective Use of Resources Policy.

- **For details of drug costs and associated costs, the pharmacy department should be contacted.**
- **ALL costs must be included** – including **diagnostics, PbR charges for hospital spells, out-patient 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 activity and cost data must be completed.**
- **Incomplete business cases will not be accepted and will be returned.**

Completed business case template(s) should be returned to: GMCSU Strategic medicines management team gmcsu.medsman@nhs.net Tel: 0161 212 5680

Out of Tariff High Cost Drug/Technology Business Case Template

All sections must be completed in order for the business case to be considered effectively

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:	
WHAT ARE COMMISSIONERS BEING ASKED TO CONSIDER FUNDING?		
The name of the drug/technology is:		
Click on box to select as appropriate A request to prescribe/use: ☐ A request to develop shared care guidelines: ☐ Other: ☐		
Indication or condition that this treatment will address - ***only one indication per business case proforma.***		
Please indicate other business cases being submitted for this indication, where appropriate.		
Who will initiate treatment, i.e. GP, Hospital, Other? *(where other please clarify)*		

Anticipated duration of treatment.	
Who is responsible for long term prescribing/use i.e. GP, hospital, other (where other please clarify)?	
Describe the major outcome achieved by the treatment.	
Have therapeutics committees considered this locally and rejected or supported its use for this indication; note that hospitals may treat patients within their own resources where considered clinically necessary even if the treatment is not funded specifically by CCGs?	
Has this treatment been the subject of a Drug and Therapeutics Committee Chairman's action or exceptional case request / individual funding request to a Greater Manchester CCG? If yes, please specify.	.
Criteria proposed for initiating therapy.	
Criteria proposed for stopping therapy.	
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 no, why not?	Yes ☐ *Click on box to select as appropriate* No ☐

• If shared care required, attach copy when a SCG has been approved or is available as a draft.		
Is a home care provider to be considered/used for delivery of this treatment?	Yes ☐ *Click on box to select as appropriate* No ☐	
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, specify (a) potential provider, (b) cost charged by home care provider where they differ from costs shown below.	a.	
	b.	
Costs of drug/technology - *Note: in setting priorities, Greater Manchester CSU wish to consider net cost per patient per year, to assist in comparisons between treatments wherever appropriate.*		
Drugs - average dose and drugs cost, include average cost for one dose to be recharged to commissioners. Other technologies – average cost per patient per year		
Will the introduction of this treatment change threshold for treatment? If yes in what way?		
Will the introduction of this treatment increase total cost on treatments for this condition? If yes state additional cost per patient		
Other costs associated with the business case		
Other costs to commissioners, e.g. hospital visits, including HRG costs, associated tariff or indicative tariff over and above drug/technology costs for the submitted business case.		
Cost of tests related to use of submitted drug/technology that will be charged to commissioners, i.e. not in tariff price or		

indicative tariff.		
Other costs to commissioners, e.g. hospital visits, including HRG/ PbR tariff or indicative tariff over and above drug/technology costs for the historical treatment the submitted drug/technology will replace (if appropriate)		
Cost of tests related to use of the current or alternative treatment the submitted drug/technology replaces that will be charged to commissioners, i.e. not in tariff price or indicative tariff (if appropriate).		
Cost for average length of treatment of the submitted drug/technology or annual cost (please specify)	Hospital	
	GP	
Cost for average length of treatment or annual cost (please specify) for the historical treatment the submitted drug/technology will replace	Hospital	
	GP	
Marginal cost (i.e. difference in cost of submitted drug/technology compared to historical treatment) for hospital and for GP budgets).	Hospital	
	GP	
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 treatment, 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)	This year	
	Next financial year	
	In subsequent years	

How does this development help progress towards local and national priorities and targets? Please give details – NOTE: planned NICE TAGs are already noted by commissioners, but applicants are asked to provide information on NICE clinical guidelines and other best-practice guidance that they are aware are being developed.	
SECTION TWO – WHAT BENEFITS WOULD THIS DELIVER?	
Effectiveness	
Describe the impact on individual patients of the condition that this particular business case addresses, e.g. symptoms, impact on independent living, impact on life expectancy.	
What treatment would be given if this business case was not funded?	
Would you describe the severity of the illness to be treated as mild, moderate, serious or life threatening?	
What is the NNT in relation to this outcome compared to the treatment that would be given if this business case was not funded?	
What is the primary harm caused by this drug/technology? If more than one frequently occurring serious adverse effect please state these also. Please state NNH if known. Please complete NNT and NNH compared to current standard treatments, wherever available, to expedite consideration of business cases.	
Please provide information, where available, regarding cost per QALY or cost per life year gained. If this information is not available please provide the costs of any elements of care that may be avoided by this treatment and which may be used in such calculations.	

Strength of evidence: In line with NICE, evidence should be rated according to the SORT system (Strength of Recommendation Taxonomy) Evidence should be graded 1, 2 or 3 where 1 is the highest level. Patient Orientated Outcomes (POOs) will generally be of a higher level than Disease Orientated Outcomes (DOOs)	
Level 1: good quality patient- oriented evidence • Systematic reviews (SRs) or meta-analyses (MAs) of randomised controlled trials (RCTs) with consistent findings related to POOs • High quality** individual RCTs which examine POOs • All or none studies***	
**To be categorised as high quality, an RCT must meet the following criteria: allocation concealment, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (greater than 80 percent). ***All or none studies are defined as being when the treatment causes a dramatic change in outcomes, such as antibiotics for meningitis or surgery for appendicitis, which precludes study in a controlled trial.	
Level 2: limited quality patient-oriented evidence • SRs or MAs of lower-quality studies related to POOs or of RCTs with inconsistent findings which examine POOs • Lower-quality clinical trials which examine POOs • Cohort studies which examine POOs • Case-control studies which examine POOs	
Level 3: other evidence • Any DOO study • Case series • Opinion • Consensus guidelines • Modelling from bench research	
Is the trial population similar to the local population?	
Were there any significant differences in treatment regimes between comparator treatments and local therapy?	

Were existing local or UK treatments for this indication used as the comparator?	
Were there any other potentially significant differences between trial comparator and local facilities for treatment?	
How do the benefits offered by this treatment differ from other treatments offered for management of this condition at present?	
Which treatment that offers less benefit can be stopped to release resources to provide this drug/technology?	
How acceptable is this proposal likely to be to the public/patient?	
Population burden of disease:	
How common is the condition that this particular business case addresses through use of high cost drugs/technologies? **(Cases per 100,000 population.)**	
Total number of Greater Manchester patients that you expect may fit criteria for treatment with this high cost drug.	
What is the total number of Greater Manchester patients submitted in all business cases for this **INDICATION?**	
Number of new patients per annum, **per 100,000 population**, anticipated to present who may fit criteria proposed for treatment – from national data sources or from local knowledge of the Greater Manchester population. If local estimate differs from national data, please advise reason for difference.	

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 be changed as a direct result of introducing this drug/technology 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?	
Does this development encourage self-care?	
Does this development facilitate a potential reduction in health services costs, e.g. reducing risk of hospital admission or increase use of self-care?	Yes ☐ *Click on box to select as appropriate:* No ☐
▪ If yes, when might this reduction expect to be realised?	

References

Completed business case to be sent to GMCSU medicines management team at gmcsu.medsman@nhs.net