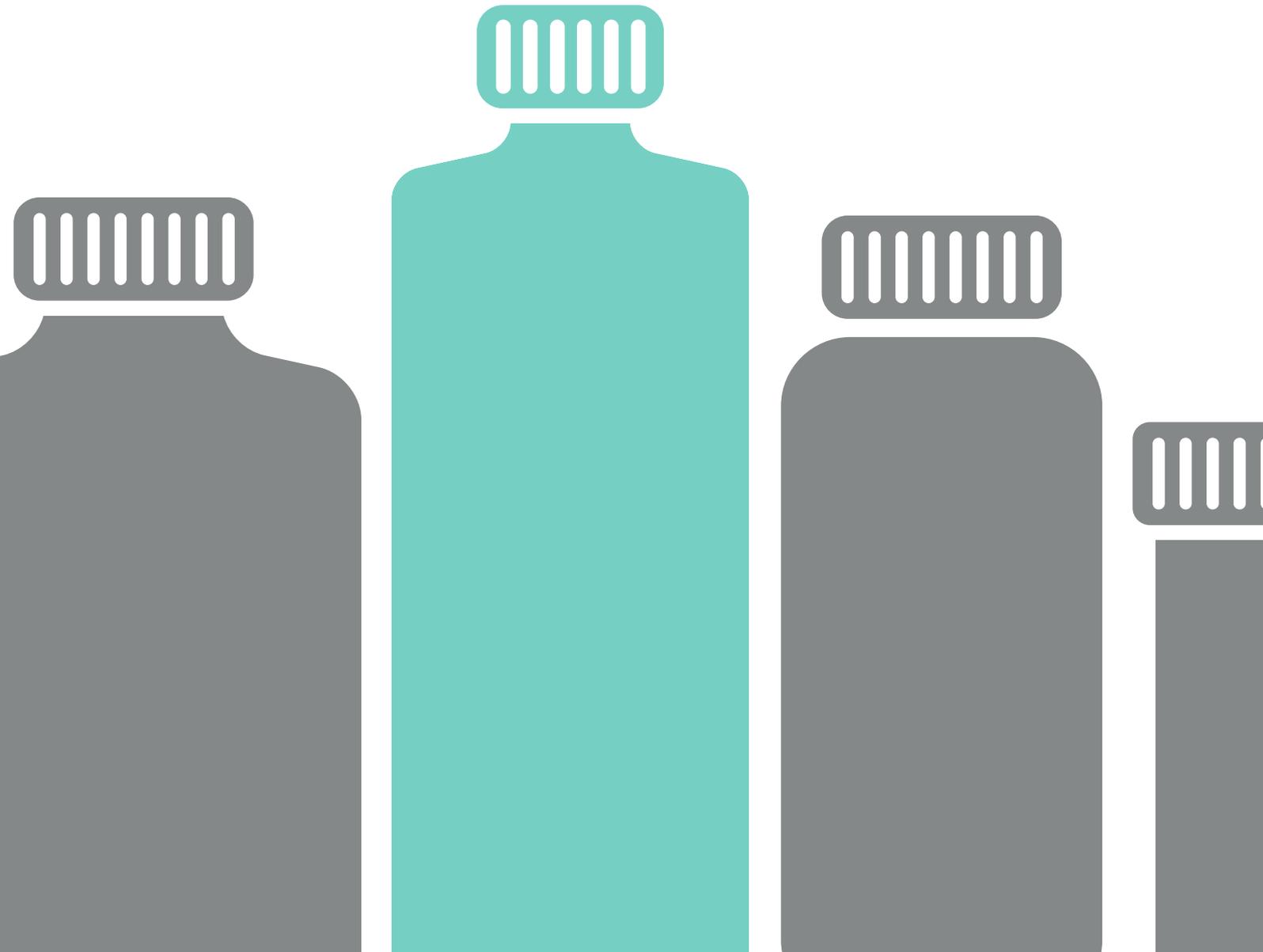


Medicines Management

High cost drugs service development guideline

Greater Manchester Medicines
Management Group (GMMMG) Guidance



DOCUMENT CONTROL

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Copies of this document can be obtained from:

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Revision History

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Approvals

This document must be approved by the following before distribution:

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Andrew Martin	Senior strategic pharmacist GMCSU	29.07.2013	0.1
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High cost drugs service development guideline

Executive Summary

- A service development is any aspect of healthcare that Greater Manchester CCG's have not agreed to fund and which will require additional and predictable recurrent funding.
- The term refers to all decisions which have the consequence of committing Greater Manchester CCG's to new expenditure for a cohort of patients.
- Any request for a service development that includes a high cost drug treatment will be considered by GMCSU on behalf of Greater Manchester CCGs.
- Any resulting commissioning policy will require approval by GMMMGM prior to adoption by Greater Manchester CCG's.
- This policy outlines the process and the criteria that will be used by Greater Manchester CSU and GMMMGM to determine whether it will fund an in-year service development.
- Throughout this document the term GMCSU can be used to represent Greater Manchester CCGs.

1. Background

- An in-year service development is any aspect of healthcare, other than one which is the subject of a successful Individual Funding Request (IFR), which a CCG agrees to fund outside of the annual commissioning round.
- When considering funding a service development outside the normal commissioning process, it is vital that other areas of competing health needs are taken into account.
- Unplanned investment decisions should only be made where they have been approved in accordance with the terms of this policy.
- It is common for clinicians to submit an IFR for a patient who is the first individual of a group of patients wanting a particular treatment. Any IFR citing circumstances which could equally apply to a group represents a request for a service development.
- Accordingly the IFR route is usually an inappropriate one for those seeking funding for such treatments as they constitute service developments.
- These funding requests are highly likely to be returned to the provider Trust, with a request being made for the clinicians to follow the normal processes to submit a request for a service development.

2. The concept of a cohort of patients

- The policy recognises that there needs to be a distinction between cases where the clinical circumstances are genuinely exceptional and those where they are equally representative of a small group of other patients.
- Where the presenting clinical circumstances are representative of a small group of other patients, the policy of the GMCSU is that, if funding is to be provided, this ought to be by way of a commissioning policy which will then apply equally to all other patients who have the same presenting clinical circumstances.
- The GMCSU Effective Use of Resources Policy has set the limit for cases that can be funded by way of an IFR as five or more patients plus a financial commitment that is likely to result in expenditure of more than £100,000 per year.
- If the likely number of patients is above five the GMCSU will treat this as a service development.

3. Policy

- This policy applies to any patient in circumstances where a Greater Manchester CCG is the responsible commissioner for their NHS care.
- GMCSU will not consider treatments that are classed as highly specialist and are commissioned by NHS England.
- A service development is an application to the GMCSU to consider a particular treatment to be routinely funded by a CCG for a defined group of patients.
- A service development will usually require additional and predictable recurrent funding to be provided by the CCG for that healthcare intervention.
- GMCSU recognises that they will receive applications from provider Trusts and/or clinical teams to commission services which are not in the Annual Commissioning Plan. Such applications will be referred to as proposed service developments.
- No decision will be made to commission NHS services as part of any proposed service development until it has been assessed, prioritised and a policy decision has been taken.
- A consequence of this approach is that the CCG's default interim policy will be to not fund a proposed service development.
- Any application for a service development must be set out in a detailed business plan which describes the proposed policy change, the evidence base to support the

policy and sets out the costs of both making the policy change and of not making the policy change.

- GMCSU will provide a business case template for provider Trusts to complete when requesting a service development. The information that will be required will include compelling evidence of both the clinical and cost effectiveness, estimated number of patients to be treated and proposed cost to Greater Manchester CCGs and opportunities for disinvestment in lower priority treatments.

An in-year service development will not be approved unless GMCSU / GMMMG can reach a clear conclusion that the following tests are satisfied:

- i. The proposed service development is both clinically and cost effective.
- ii. The proposed service development is affordable in the current financial year.
- iii. The proposed service development would have been highly likely to have been supported by Greater Manchester CCGs in the last annual commissioning round, in priority to those service developments which could not be afforded at that time and thereafter.

Having considered the above and any other relevant factors, the recommendation to GMMMG can be to either:

- i. Give approval to the proposed service development; or
- ii. Commission further analysis of, or other work on, the proposed service development as the GMCSU may consider appropriate; or
- iii. Conclude that the proposed service development does not have sufficient merit to justify supporting it and formulate a policy to reflect this; or
- iv. Conclude that there is merit in funding the requested treatment, but consider that the GMCSU should delay funding because the development does not have sufficient priority. The proposal in this instance will be considered as part of the next annual commissioning round.

Until prioritised and funded the default position will operate unless otherwise stated.

4. The process

The consideration for a service development can be initiated following:

1. The submission of five or more IFR's for the same treatment and indication.
2. The submission of an IFR citing circumstances which could equally apply to a cohort of patients.

3. The submission of a business case application from a provider Trusts and/or clinical teams to commission services which are not routinely commissioned.
 - The provider will be required to complete a business case request application. The template will be provided by the lead CCG or GMCSU.
 - Any request for a service development that includes a drug treatment will be considered by GMCSU on behalf of Greater Manchester CCGs.
 - An independent evidence based review will be carried out by the Regional Drug and Therapeutics Centre.
 - In the interim the provider cannot expect any CCG to fund any further IFR's, solely on the basis that they have submitted a business case or that a commissioning policy is being developed.
 - Clinical urgency will be dealt with outside of this consideration. The process is expected to take 8-10 weeks from submission.
 - Following evaluation of the business case the review will be submitted to the GMMMG Interface Prescribing and New Therapies Subgroup (IPNTS) for consideration so that a commissioning recommendation can be made.
 - A recommendation to fund or otherwise will then be submitted by IPNTS to GMMMG for approval.
 - If a commissioning policy is approved by GMMMG, this will become Greater Manchester's recommended policy.
 - To be implemented, individual CCGs must adopt the policy. GMCSU will submit a recommendation to the Greater Manchester CCG Accountable Officers to adopt this Greater Manchester wide.
 - If a business case or commissioning policy requires a prior approval process to be initiated or a contract variation then this needs to be considered by the Total Provider Management (TPM) team.
 - If a business case results in a change of service or pathway then the GMCSU Service Redesign team should be consulted. Input will depend on which CCGs have commissioned that service from the CSU. For CCGs that do not commission Service Redesign, a process for ensuring review by those CCGs should be established.

References

Acknowledgments