

Consultation Guide

Commissioning Policies: Funding of Treatment outside of Clinical Commissioning Policy or Mandated NICE Guidance

- A. In-year service development**
- B. Individual Funding Requests**
- C. Funding for experimental and unproven treatments**
- D. Continuing funding after clinical trials**



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Publications Gateway Reference: 05965

Document Purpose	Policy
Document Name	<p>Consultation Guide</p> <p>Commissioning Policies: Funding of Treatment outside of Clinical Commissioning Policy or Mandated NICE Guidance</p> <p>A. In-year service development B. Individual Funding Requests C. Funding for experimental and unproven treatments D. Continuing funding after clinical trials</p>
Author	Gareth Arthur
Publication Date	13 October 2016
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, Foundation Trust CEs , Medical Directors, Local Authority CEs, NHS Trust Board Chairs, NHS Trust CEs, Patients/Public/Voluntary Sector organisations/Industry and commercial partners/Royal Colleges
Additional Circulation List	CCG Clinical Leaders, CCG Accountable Officers, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, Local Authority CEs, NHS Trust Board Chairs, All NHS
Description	This consultation seeks your views on NHS England's updated policies for making commissioning decisions outside the normal processes. All feedback received via the online consultation will be collated and summarised. NHS England will publish a report outlining the key themes of the consultation findings and feedback on its website.
Cross Reference	N/A
Superseded Docs (if applicable)	N/A
Action Required	N/A
Timing / Deadlines (if applicable)	The consultation period runs from 13 October 2016 to 15 January 2017
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Document Status

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**Consultation Guide on Commissioning Policies:
Funding of Treatment outside of Clinical Commissioning Policy or Mandated
NICE Guidance**

Consultation Guide

Version number: 2

First published: October 2016

Prepared by: Specialised Commissioning, NHS England

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

1 Introduction

- 1 This document sets out four distinct NHS England policies on funding treatments which are not currently routinely commissioned or subject to a mandated guidance from NICE¹, including for funding urgent cases and in exceptional circumstances. It also sets out how we propose to further simplify NHS England's set of generic clinical commissioning policies.

2 Why we are consulting

- 2 NHS England is committed to providing the most effective, fair and sustainable use of finite resources that meet the needs of the diverse population and are sustainable in the longer term.
- 3 NHS England seeks to remain open, engaged and transparent in discharging its responsibilities for the direct commissioning of specific health services. In conducting a full public consultation, NHS England is seeking to ensure that the principles and process for making decisions on investing in specialised services are well informed, evidence-led and in line with the expectations of patients and the public. In doing so, NHS England seeks to comply with the best practice consultation principles issued by the Cabinet Office in 2012.²
- 4 NHS England is committed to promoting equality and reducing health inequalities throughout the health service. Consultation provides the opportunity to gain information about any potential impact on health inequalities which might arise as a result of new or changed processes for making decisions about health services that are directly commissioned by NHS England. This information will feed into an Equality and Health Inequalities Analysis on this programme of work.

¹ NICE Technology Appraisals or Highly Specialised Technology Appraisals

² www.gov.uk/government/uploads/system/uploads/attachment_data/file/60937/Consultation-Principles.pdf

3 Scope of this Consultation

3.1 Generic Commissioning Policies

- 1 From April 2013, NHS England became responsible for commissioning specialised services. Commissioning these services nationally brought the opportunity to achieve greater consistency and quality of care through national policies and national service specifications
- 2 When first established, NHS England published a set of a set of eleven so-called 'generic commissioning policies' to guide its decision-making for all directly commissioned services. They were called 'generic' as they applied to all NHS England's clinical commissioning responsibility, rather than being service-specific.
- 3 Over the past year, NHS England has reviewed the set of policies to test whether they are sufficiently clear and effective in supporting decision making. This review has included engagement with stakeholders and learned lessons from experience of using the policies in practice. This consultation reflects work to reduce duplication and put them on a firmer footing.
- 4 The feedback and review indicated that many of the policies are no longer needed, as they are covered by existing Department of Health policy or NHS England policy.
- 5 Four areas still require distinct policies, and they are the focus of this consultation. The four policies are: in-year service developments, individual funding requests (IFRs), funding for experimental and unproven treatments, and continuing funding after clinical trials.
- 6 We welcome views from stakeholders, the public and patients on this revised set of four distinct policies.

3.2 Funding of Treatment outside of Clinical Commissioning Policy or Mandated NICE Guidance

- 7 This document sets out four distinct NHS England policies on funding treatments which are not currently routinely commissioned or subject to a mandated guidance from NICE.
- 8 The treatments may not be commissioned because an individual falls outside the category of patients covered by an existing clinical commissioning policy, a NICE technology appraisal or NICE highly specialised technology appraisal, or because a clinical commissioning policy does not exist for the relevant treatment.

- 9 The four policies are:
- A. In-year service developments
 - B. Individual funding requests (IFR)
 - C. Funding for experimental treatments
 - D. Continuing of funding following clinical trials.
- 10 The policies in this consultation apply to specialised acute, mental health and learning disabilities services and treatments that are directly commissioned by NHS England. The policy on individual funding requests (IFRs) also apply to the public health services, health and justice services and health services for the armed forces. Primary care services are out of scope for this consultation, as are services that are commissioned by Clinical Commissioning Groups
- 11 Throughout this document a 'treatment' refers to any healthcare intervention provided or proposed to be provided by an NHS clinician.

4 Proposed changes to the policies

4.1 Overview

- 12 The four policies in this consultation are:
- A. In-year service development policy** – decisions on introducing a new clinical commissioning policy for a treatment or changes to an existing clinical commissioning policy that takes place in-year. The policy applies only to specialised services.
 - B. Individual funding requests policy** – applications by NHS clinicians, on behalf of an individual patient, for funding for a treatment that is not routinely commissioned by NHS England or subject to a mandated guidance from NICE. Funding for all services that are directly commissioned by NHS England may be considered through this process.
 - C. Funding experimental and unproven treatments policy** – funding experimental or unproven treatments outside a clinical trial and on continuing funding following such a trial of a treatment which is not part of a formal clinical research framework.
 - D. Continuing funding after clinical trials policy** – continuing funding after a clinical trial, whether NHS England funded, commercially-funded or non-commercially funded.
- 13 These policies have each been reviewed, in light of feedback from partners and stakeholders, in order to provide greater clarity about each policy and how

each of the policies relates to the others, particularly regarding the different routes for funding and the criteria that are used to assess each of those routes.

Consultation questions:

Q: On a scale of 1 (not clear) to 5 (very clear) how clear are the revised set of policies overall in setting out how NHS England makes funding decisions?

Q: What are the potential gaps in the set of generic policies? Are there any foreseeable cases that would not be addressed by this suite of policies?

Q: Do the changes being proposed create any risks, issues or potential adverse impacts for patients/stakeholders generally or for any particular groups?

4.2 A. In-year Service Development Policy

- 14 For specialised services, NHS England makes decisions on which treatments are routinely commissioned or not routinely commissioned through an annual commissioning prioritisation round. To help ensure these decisions are made effectively, transparently and lawfully, NHS England uses a prioritisation framework. NHS England consulted separately on the features of the prioritisation framework in 2015 and has subsequently consulted in on the new decision making methodology. The methodology was used for the first time in May 2016.
- 15 NHS England may also decide to introduce new treatments, in-year. These changes to services are known as 'in-year service developments'.
- 16 It is usually only cost neutral or cost saving service developments that will be introduced in this way, because ordinarily their clinical effectiveness and value for money would need to be considered alongside those for other new treatments. There are some treatments that become available at short notice where there is a strong impact on clinical outcomes supported by the highest quality clinical research that need additional resources to introduce. The in-year service development policy allows these proposals to be considered.
- 17 The policy has been revised to provide greater clarity on a number of aspects:
 - **The circumstances in which NHS England might fund an in-year service development.** The new policy sets the expectation that in-year service developments would normally only be accepted when the proposal is cost- neutral or cost-saving over five years, unless they were of such high priority that it would be unreasonable to delay consideration until the annual commissioning prioritisation.

- **How decisions are made on prioritisation of those new treatments.** The policy has been updated to reflect the new prioritisation framework, adopted by NHS England in May 2016 and used to underpin the new decision-making methodology for the annual commissioning round.
- **The process to be followed.** The new policy describes the role of the Clinical Priorities Advisory Group (CPAG) in making recommendations to NHS England, along with the expectations of the information to be submitted to CPAG.
- **How to determine whether a new treatment should be considered as an in-year service development rather than an individual funding request.** In particular, the policy removes the previous threshold of 20 patients, instead allowing more discretion.

Consultation questions

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the in-year service development policy on circumstances in which it should apply?

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the policy on the process to be followed, including the role of the Clinical Priorities Advisory Group and the required information?

Q: How could the in-year service development policy be improved, in terms of the clarity and the process to be followed?

Q: How could the in-year service development policy be improved to provide greater certainty in dealing with clinically critically urgent cases in a fair and open way?

4.2 B. Individual Funding Requests Policy

14 The policy on individual funding requests (IFRs) sets out how clinicians may, on behalf of patients, make requests to NHS England for funding for treatments in exceptional cases.

15 The new policy has been updated in response to the engagement to provide greater detail and clarity on both the underlying policy and on the process to be followed in determining exceptionality.

16 The key changes to the policies are:

- **The circumstances in which NHS clinicians might apply for an IFR.** The new policy is intended to provide greater clarity on how exceptionality

is considered. In particular, the policy has been updated to make it clear that IFRs applies to patients whose clinical circumstances fall outside of the criteria in an established clinical policy for whom there is no clinical policy in place.

- **The process that will be followed to make decisions on IFRs.** The new policy includes greater detail on the information to be submitted to the IFR Panel, how requests are screened for exceptionality and how appeals on the decisions can be made.
- **How decisions will be made for IFRs.** As previously, the policy sets out that decisions on funding requests are made by NHS England's IFR Panel. The new policy sets out the issues that the IFR Panel will consider in making the decisions about whether to support the IFR.
- **Approach for making decisions in urgent circumstances.** The policy explains that the IFR Panel now meets fortnightly, thus ensuring timely decisions and avoiding the need for urgent meetings of the Panel.

Consultation questions

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the circumstances in which it should be applied and the basis for taking decisions?

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the process to be followed in determining whether NHS England will support an IFR?

Q: What are your concerns, if any, with the revised policy for including on determining exceptionality and rarity?

Q: What are your concerns with the process to be followed for IFRs including in urgent circumstances?

4.3 C. Funding for Experimental Treatment and Unproven Treatment Policy

- 17 The policy on funding for experimental treatments or unproven treatments sets out the circumstances in which NHS England will give consideration to supporting an existing treatment in an experimental context.
- 18 The policy on funding for experimental or unproven treatments has not changed significantly. The main changes are intended to provide greater clarity on the circumstances for seeking funding for experimental treatments and on the distinction between this funding route and the policy on continuing treatment costs following a formal clinical trial.

4.4 D. Continuing Funding after Clinical Trials Policy

- 18 The policy on continuing treatment costs sets out the circumstances in which NHS England will continue to fund treatment after clinical trials. In general, NHS England would expect the funding of any additional costs to be agreed before the clinical trial.
- 19 The continuing treatment costs policy has not changed significantly. However, it has been streamlined to bring a number of previously separate policies into one:
- On-going treatment following a NHS England Funded Trial
 - On-going Treatment Following Non-Commercially Funded Clinical Trials
 - On-going Access to Treatment Following Industry Sponsored Clinical Trials or Funding
- 20 The policy also now describes NHS England's responsibilities in relation to research and provides greater clarity about the responsibility for agreeing the period of funding following a clinical trial.

Consultation questions

Q: On a scale of 1 (not clear) to 5 (very clear) how far does the policy on continuing funding after clinical trial provide clarity on the circumstances in which funding can be sought?

Q: Do you think there are any areas of the continuing funding after clinical trial policy that require further clarity?

5. Details of the consultation

21 The consultation is open to everyone and will run for three months from the date of issue. The closing date for the consultation is 15 January 2017.

22 Where possible, please respond to the consultation via the online consultation portal at <https://www.engage.england.nhs.uk/consultation/af642939/>

23 NHS England will also accept written submissions by email or post:

Email: england.scengagement@nhs.net

Post: Helen Jones, Specialised Commissioning - Area 3A
Skipton House, 80 London Road, London SE1 6LH

24 All feedback received via the online consultation will be collated and summarised and a report of the consultation findings will be considered by NHS England.

25 Before responding to the consultation you must declare any financial or other interests in any specialised services. For example, if you are responding on behalf of a voluntary organisation and your organisation received any funding within the last two years (including sponsorship or grants) from companies that manufacture drugs or treatments used in the treatment of specialised services, you must declare it.

26 We also ask respondents to indicate the type of organisation they are responding on behalf of, or if they are responding as an individual. This information will help us to understand how the views of stakeholder groups may differ.

27 NHS England will publish a report outlining the key themes of the consultation findings and feedback on its website.

28 Please note, consultation responses must be considered public documents. Therefore, if responses include confidential information that should not be made public, please ensure that the information is clearly marked "confidential".

6. Summary of Consultation Questions

6.2 Overview

Q: On a scale of 1 (not clear) to 5 (very clear) how clear are the revised set of policies overall in setting out how NHS England makes funding decisions?

Q: What are the potential gaps in the set of generic policies? Are there any foreseeable cases that would not be addressed by this suite of policies?

Q: Do the changes being proposed create any risks, issues or potential adverse impacts for patients/stakeholders generally or for any particular groups?

6.3 In-year Service Developments Policy

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the in-year service development policy on circumstances in which it should apply?

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the policy on the process to be followed, including the role of the Clinical Priorities Advisory Group and the required information?

Q: How could the in-year service development policy be improved, in terms of the clarity and the process to be followed?

Q: How could the in-year service development policy be improved to provide greater certainty in dealing with clinically critically urgent cases in a fair and open way?

6.4 Individual Funding Requests Policy

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the circumstances in which it should be applied and the basis for taking decisions?

Q: On a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the process to be followed in determining whether NHS England will support an IFR?

Q: What are your concerns, if any, with the revised policy for including on determining exceptionality and rarity?

Q: What are your concerns with the process to be followed for IFRs including in urgent circumstances?

6.5 Funding for Experimental and Unproven Treatments Policy

Q: On a scale of 1 (not clear) to 5 (very clear) how far does the policy on experimental and unproven treatments provide clarity on the circumstances in which funding can be sought?

Q: How could the policy on experimental and unproven treatments be improved? And how could we provide greater clarity and certainty?

6.6 Continuing Funding after Clinical Trials Policy

Q: On a scale of 1 (not clear) to 5 (very clear) how far does the policy on continuing funding after clinical trial provide clarity on the circumstances in which funding can be sought?

Q: Do you think there are any areas of the continuing funding after clinical trial policy that require further clarity?