NHS
West Suffolk
Clinical Commissioning Group

NHS
Ipswich and East Suffolk
Clinical Commissioning Group

On-going access to treatment following third party funding including clinical trials and excess treatment costs

Commissioning Policy

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1. Purpose of this document:

As a result of research and development, certain costs are incurred, both during a clinical trial and after its completion. This document aims to be transparent and allow for clarity and so reduce any areas of dispute in future revolving around responsibility for these costs. This policy also provides guidance on the Clinical Commissioning Group's role on continued funding when third party funding of non-commissioned treatment comes to an end.

This updated version of the document incorporates amendments made following a consultation on 9th June 2015, with CCG, Public Health Suffolk, West Suffolk Hospital and Ipswich Hospital Trust representatives.

2. Introduction

In 1997 the Department of Health published guidance on how excess costs are supported (HSG(97)32 – Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS). The later document released by the Department of Health in 2012 (Attributing the costs of health and social care Research and Development) maintained the same principles. The documents recommend that NHS commissioners should fund excess treatment costs of non-commercial clinical trials, following agreements between the Department of Health and non-commercial research and development organisations. Under these arrangements an NHS commissioner is likely to have already funded part of excess treatment costs associated with these clinical trials. However the Clinical Commissioning Group has no legal obligation to fund excess treatment costs and will therefore exercise discretion with regard its financial support to clinical trials.

The documents state that excess treatment costs in the trial period associated with commercial trials should be fully funded by the commercial company.

This document aims to set out West Suffolk CCG and Ipswich & East Suffolk CCG's policy on who is responsible for R&D related costs, both during trials and incurred costs of continuing treatment after cessation of third party funding. This policy also provides guidance on the Clinical Commissioning Group's role

on continued funding when third party funding of non-commissioned treatment comes to an end.

3. Funding policy

3.1 Industry sponsored/commercial trials* funding position:

- All costs above those of standard NHS treatment to be fully met by the company concerned
- CCG will not pick up funding at trial end unless there is written agreement prior to commencement of treatment/trial, between the trial sponsors and the CCG or DoH centrally
- The patient must be fully informed prior to trial commencement that continued funding is in no way guaranteed at trial end. This is the responsibility of their clinician, organisation conducting the trial and pharmaceutical/medical devices company
- If the treatment becomes licensed, then the existing commissioning policies for that treatment will apply. The usual 90 day period for implementing NICE Technology Appraisal will apply.
- An Individual Funding Request (IFR) request may be submitted for continuing treatment if this is believed to be appropriate and the case exceptional. Cases will be considered on an individual basis and funding is never guaranteed through this route.

***** A study/trial that is conducted by a commercial/industry sponsor whose primary aim is public benefit rather than commercial benefit may be considered as non-commercial.

3.2 Non-commercially funded trials:

3.2.1. Definition of trial costs

Some key terms are highlighted below:

- **Research Costs** – the costs of the R&D itself that end when the research ends. They relate to activities that are being undertaken to answer the research questions. These are usually met by grant funders through the award of a research grant. However, there are some specific research activities where, in England, the costs will be met by the Department of Health. These are outlined in Annexes A and B.

- **NHS Treatment Costs** – the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped. Costs are met through the normal commissioning process. Annex B outlines the arrangements in England.

- **NHS Support Costs** - the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided. Costs are met from the R&D budget by the Health Departments of the United Kingdom. Annex B outlines the arrangements in England.

- **Excess treatment Costs** - The difference between NHS treatment costs and standard NHS treatment

Annex A can be found at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/351185/AcoRD_Annex_A_-_List_of_Common_research_Activities_March_2013_for_publication.pdf

Annex B can be found at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/351186/AcoRD_-_FAQs_updated_August_2014_-_for_publication.pdf

3.2.2. Non-commercial trials funding position

The CCG will consider funding of excess treatment costs if:

- Clinical trial was wholly funded by non-commercial bodies
- AND the trial was included on the National Institute of Health Research (NIHR) research portfolio

- AND clinical benefit is demonstrated from the reported trial outcomes and the clinician's assessment of the patient's improvement
- AND the CCG is able to afford the treatment given its other commitments
- Agreeing to fund this treatment for one patient does not constitute a policy decision and every case must be considered on individual merit. Currently the IFR process is the only mechanism to consider such requests, however each trial will be considered on its own merits. This does not oblige the CCG to fund this treatment who were not part of the clinical trial

If there is an excess treatment saving, rather than cost, this factor will be taken into account by the CCG.

As with commercial trials, patients in non-commercial trials should be fully informed prior to trial commencement that funding is not guaranteed after the trial ends. Due to the volume of information given at the start of the trial, and the inevitable focus on the trial period at this time, this statement should be reiterated at follow-up appointments during the course of the trial. This would aid the management of the patient's expectations as the trial draws to an end.

The CCG will fulfil its obligations and meet any central directions regarding 'in-trial' funding arrangements for non-commercial trials.

4. NICE Technology Appraisal outcomes

If a NICE Technology Appraisal (TA) is developed as a result of any of this research, the CCG will provide funding from the time the TA becomes applicable (usually 90 days after publication) if the patient meets the criteria for the TA. Funding for continuing treatment that does not meet TA criteria will not be routinely funded.

In practice, 90 days is required for organisational aspects of implementing the NICE TA. If the patient is responding well to the treatment, the commercial trial sponsor usually continues to fund the drug after the trial period until the TA is applicable. It is important that clinicians emphasise to patients receiving treatment in a trial that patients responding favourably to the trial drug still

need to fulfil the NICE criteria to obtain the drug after the 90 days implementation period. To ensure those not meeting the criteria due to a good response to the treatment during the trial period are not disadvantaged, the CCG should also consider the patient's pre-trial 'baseline' presentation when considering post-trial funding of excess treatment costs (e.g. as an exceptionality factor). Trial entry criteria may capture different data to the NICE criteria, so the clinician may need to obtain baseline data from reviewing pre-trial clinical notes.

5. **Third party funding for non-commissioned treatment:**

On occasion, patients may receive funding for non-commissioned treatments on compassionate/charitable grounds or via other means e.g. private (e.g. health insurance)/self-funding and might demonstrate benefit from treatment.

The CCG will NOT automatically continue the funding after this period as this will create inequalities as these opportunities are not equally available to all patients. As such a good response to the treatment is not sufficient grounds for continuation of funding.

A request for continued funding must be made through the normal channels, and each request will be considered on its own individual merits.

The patient must be made aware that continued funding is in no way guaranteed, and this should be clearly documented before third party funding commences.

Any patients/clinical scenarios considered exceptional, clinicians should use the established process of submitting Individual Funding Requests as appropriate.

6. Bibliography

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3. Department of Health: AcoRD Annex A: List of common research activities attributed to the Research Costs, NHS Treatment Costs and NHS Support Costs, March 2013
4. Department of Health: AcoRD Annex B: Frequently Asked Questions, August 2014
5. Department of Health: Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for a subvention, April 2009
6. NHS commissioning board, Commissioning Policy: On-going access to treatment following industry sponsored clinical trials or funding April 2013 Ref: NHSCB/CP/13
7. East Midlands Specialised Commissioning Group, Commissioning Policy (EMSCG P019V1), Ongoing access to treatment following completion of NHS commissioner-funded trials, August 2013
8. NHS Sandwell and West Birmingham CCG, On-going access to treatment following the completion of non-commercially funded clinical trials covered by department of health guidance HSG(97)32, SWBCCG Pol 14, March 2013
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