NHS England

Commissioning Policy for Excess Treatment Costs relating to services commissioned by CCGs.

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1 Contents

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1 Policy statement

This document sets out the commissioning policy for the management of Excess Treatment Costs (ETCs) for non-commercial interventional research studies that are eligible for NIHR service support funding[1] and that are related to services commissioned by Clinical Commissioning Groups in the NHS in England.

The commissioning policy has been developed to enable operation of a new model for management of ETCs in England in which the National Institute for Health Research (NIHR) Clinical Research Network (CRN) via the 15 Local Clinical Research Networks (LCRNs) will manage reimbursement of ETCs on behalf of the CCGs in their region.

ETCs will be managed by operating the following policy:

- The study and ETCs associated with it have been costed using the Schedule of Events Cost Attribution Tool (SoECAT) to calculate an ETC per patient value.
- The ETCs associated with the study are correctly attributed according to the Attributing the costs of health and social care research and development (AcoRD) guidance[2] with verification and sign off from a CRN designated AcoRD specialist.
- For existing studies recruiting before 1st October 2018 that transitioned into the new management model there is an ETC per patient value agreed as per the transition arrangements.
- For each provider the ETCs that will be reimbursed for individual studies are calculated as ETC per patient value multiplied by the number of patients recruited.
- NHS England and NHS Improvement will allocate a provider threshold to each non primary care provider. This is a total (cumulative) ETC threshold per provider per financial year, based on provider income. Providers are required to absorb ETCs up to their threshold before additional ETCs are reimbursed. The CRN central portfolio management system will monitor the ETCs being absorbed by each provider and will trigger payments only when the threshold has been reached.
- Where ETCs in a study relate to both CCG and Specialised commissioning commissioned services a main commissioner will be allocated via a triage process undertaken by CRN and specialised commissioning representatives, ETCs for that study will be reimbursed by funding from the main

[1] Eligibility Criteria for NIHR Clinical Research Network Support. Department of Health, 2017. Found at https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Eligibility/Eligibility-Criteria-for-NIHR-Clinical-Research-Network-Support.pdf

[2] Attributing the costs of health and social care research and development (AcoRD). Department of Health, 2015. Found at https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

commissioner. This approach will be monitored and reviewed after during a six month trial period.

- Where ETCs associated with a study are above the High Cost Threshold, determined by NHS England and DHSC, the study will be scrutinised at a national level as to its value to the NHS before a decision to fund the ETCs is made.
- For primary care providers there will be a nominal value for cumulative ETCs that has to be reached before payment will be processed. ETCs will be reimbursed once the agreed value (as determined by NHS England, DHSC and partners) has been reached the, within a payment cycle (normally per quarter). ETCs will be fully reimbursed within a financial year cycle.
- The lead CCG, and other CCGs within the region where necessary, will share relevant information with CRN to enable them to undertake all activities to operate this commissioning policy.
- CRN will provide reports to the lead CCG detailing how the ETC funding allocation has been spent and any exceptional matters that have arisen during the reporting period.

2 Introduction

NHS research can result in excess treatment costs. These are costs that arise as a result of the difference between the cost of standard treatment and the cost of treatment within a research study in non-commercial research projects. The NHS is responsible for these costs which are funded through normal commissioning arrangements for commissioning patient care.
NHS England and NIHR have heard continued frustration about the complexity and variation in processes for commissioners and providers agreeing these costs which are one of a number or barrier to timely execution of research in the NHS. In order to resolve these issues in November 2017 NHS England and our partners (National Institute for Health Research, Health Research Authority), undertook a public consultation on proposals to manage excess treatment costs better. Taking into consideration the feedback from the consultation responses NHS England and partners have developed a new model by which the NIHR CRN will manage ETCs on behalf of CCGs. This document outlines the policy under which ETCs will be managed.

3 Scope

This policy relates only to the management of ETCs relating to CCG commissioned services in England.

4 Roles and responsibilities

NIHR CRN and LCRNs

1. LCRN will manage ETCs on behalf of the CCG in line with the commissioning policy
2. LCRNs will reimburse provider organisations in line with the commissioning policy
3. CRN will provide a quarterly update on how monies are being spent to the Lead CCG
4. CRN will provide an annual report on how monies have been spent and any exceptions that have occurred in that period

Lead CCG for the LCRN region:

1. The CCG undertakes the commissioning function for ETCs on behalf of the other CCGs within the LCRN region
2. The CCG enters into agreement with LCRN, via the host organisation, that ETCs will be managed by CRN under the commissioning policy
3. The CCG/nominated individual will be called upon for any decisions regarding ETCs requests or resolution of any issues that fall outside the commissioning policy.

NHS England

1. Monitor the implementation and operation of this policy and amend and refine as necessary

5 Distribution and implementation

This policy document will be distributed to CCGs in England and will be published by NHS England and partners alongside operational guidance for the ETC management model. The audience for this guidance includes:

- NHS Commissioners
- Provider organisations
- Research Funders and Sponsors
- Researchers

6 Monitoring

Implementation of the policy will be monitored by the Innovation, Research and Life Sciences Group, NHS England.
Evaluation of implementation will be undertaken to ensure that the policy enables CRN and LCRNs to manage ETCs on behalf of CCGs efficiently and effectively. The policy will be refined and updated as necessary.

The policy will be reviewed after 6 months initially and then on an annual basis.

7 Equality and Health Inequalities Analysis

This procedural document forms part of NHS England's commitment to create a positive culture of respect for all individuals including staff, patients, their families and carers as well as community partners. The intention is to identify, remove or minimise

discriminatory practice in the areas of race, disability, gender, sexual orientation, age and ‘religion, belief, faith and spirituality’ as well as to promote positive practice and value the diversity of all individuals and communities.