

## **Establishment of new arrangements for funding the reimbursement of excess treatment costs from 1 October 2018**

### **December 2018 update**

Commencing 1 October 2018 there are a number of changes in the way CCGs, NHS England Specialised Commissioning and NHS providers are expected to manage excess treatment costs (ETCs) related to non-commercial research.

The response to the consultation, [Supporting research in the NHS](#), set out how NHS England, the National Institute for Health Research, the Department of Health and Social Care and the Health Research Authority, working together, would implement changes to simplify arrangements for managing ETCs. These can be found [here](#).

NHS England, HRA and NIHR recognised the complexity and variation in processes for commissioners and providers agreeing these costs. Research has been held up for many months or years because of difficulties arranging for ETCs to be agreed and paid. This has caused real problems in the setting up of clinical research, thus impacting the speed of patient access to research. The new system is aimed at making it simpler and less bureaucratic for ETCs to be identified and reimbursed, which should be better for everyone involved.

We are currently in a pilot phase (until March 2019) to test the new model.

### **ETC funding arrangements for new research funding applications from 1 October 2018**

- Research teams are required to complete a Schedule of Events Cost Attribution Tool (SoECAT) at research funding application stage to attribute the research study activity and calculate the likely ETCs associated with the study. The NIHR Local Clinical Research Network (LCRN) AcORD specialists will support this activity and validate the attribution of activity in the tool.
- Once a study has secured research funding and where NHS England Specialised Commissioning is the responsible commissioner for the study activities an additional finance template must be completed to identify which ETCs may be automatically paid under core NHS contracts. Specialised commissioning's finance team will support the lead research team if needed to complete this to calculate the ETCs that will be reimbursable.
- The NIHR Clinical Research Network (CRN) now manages ETCs on behalf of all CCGs, and every CCG has made a contribution to a central budget for ETCs.

### **Changes for providers from 1 October 2018**

- Providers are now expected to absorb ETCs to the level of 0.01% of their total operating income, or a minimum of £10,000 per year, whichever is higher. These thresholds have been set in partnership with NHS Improvement, and any agreed ETCs incurred beyond these will be reimbursed. For the pilot period the threshold applies to all ETCs relating to CCG-commissioned services only and has been pro-rated for a 6-month period.
- Once the provider threshold has been reached, LCRNs will reimburse providers for ETCs relating to CCG commissioned services without the need for an invoice, based on recruitment data held in the central portfolio management system.

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- NHS Health Research Authority

- NHS England Specialised Commissioning will reimburse providers directly for agreed ETCs as part of existing contractual arrangements, again based on recruitment data provided.
- The provider thresholds have been set to limit the financial exposure providers face in participating in research. Providers can make substantial savings on treating patients in research studies. The new system is not asking providers to identify these savings separately, but there is an assumption that providers will be able to offset any excess treatment costs from savings generated. It is important that providers take this portfolio approach when considering the thresholds rather than considering them on a study by study basis. Once a provider has reached the threshold, an ETC per patient value will be reimbursed based on recruitment into studies with payments made for each patient recruited upfront irrespective of whether they continue participating in the study.
- NHS E has reiterated the requirement for NHS providers to cover the threshold values for CCG studies in a formal letter to NHS provider trust Directors of Finance on 5 November and will continue to review NHS provider willingness to fund ETCs up to the threshold.

### **Ensuring continued payment of ETCs for existing studies where CCGs are the responsible commissioner**

To ensure that providers are appropriately reimbursed and to apply the provider threshold for recruitment to studies after 1 October we are transitioning existing CCG funded studies into the new system. In order to ensure we have an ETC value for each study that has been transitioned we:

- have collated information on existing ETC commitments from CCGs and research sponsors
- have contacted key research funders for information on ETCs that were defined in research funding applications
- are calculating the ETC value for studies from existing HRA Schedule of Events in the HRA approval submissions for studies where there was no ETC value available from the CCG returns.
- may ask sponsors to complete a Schedule of Events Cost Attribution Tool (SoECAT) for those transitioning studies with ETCs where we have been unable to identify or calculate a per patient ETC value through the above sources.

This collated information will be added to the relevant NIHR Central Portfolio Management System (CPMS) study records and will be used to determine the reimbursement to providers from the ETC CCG funding allocation based on patient recruitment from 1 October. We aim to make the first payment to providers in February 2019 for patients recruited between 1 October and 31 December 2018 subject to the confirmation of a per patient ETC value.

By using a number of sources to establish an ETC value for existing studies we hope that we will capture data for all CCG funded studies. Once the first payment schedules have been released should we be made aware of ETCs for existing studies that have not been included in this exercise we will expect sponsors to complete a SoECAT to establish the ETC per patient value.

Specialised Commissioning is retaining current arrangements for existing studies already recruiting or which received funding approval prior to 1<sup>st</sup> October and will therefore not look to

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revisit historic funding agreements. The new arrangements for Specialised Commissioning study ETC payments will only apply to studies newly funded on or after 1 October 2018.

### **Further information**

For further clarification or questions regarding individual studies, please:

- Refer to the dedicated NIHR webpage [www.nihr.ac.uk/nhs-england-consultation](http://www.nihr.ac.uk/nhs-england-consultation)
- Contact [supportmystudy@nihr.ac.uk](mailto:supportmystudy@nihr.ac.uk) or 0113 34 34 555