

**Excluded: Procedure not routinely funded**

**Thames Valley Priorities Committee Commissioning Policy Statement**

**Policy No. TVPC 37**                      **Excess Treatment Costs (ETCs) for non-commercial clinical trials**

**Recommendation made by the Priorities Committee:**                      **January 2016; updated January 2019<sup>1</sup>**

**Date of issue:**                                      **April 2016 / Update May 2019**

Thames Valley Priorities Committee have considered provision of funding for Excess Treatment Costs (ETCs) for non-commercial clinical research and recommended that funding for ETCs is not routinely available unless they have been agreed for specific named clinical trials in advance with the relevant commissioning CCGs.

Where a trial does not require ETCs and would be cost neutral or cost saving compared to usual care, it should not require approval by Commissioners outside of the statutory Ethical and Trust approval process already in place.

**SUMMARY:**

Excess treatment costs (ETCs) for non-commercial research studies arise when the costs of delivering the treatment or intervention in a trial exceed that of standard treatment. Although often relating to cancer related topics for clinical trials, ETCs also apply to other research areas such as mental health, renal, eye disease and long term chronic conditions.

The need to support high quality, randomised trials to establish and grow a valid evidence base to inform commissioning is of fundamental importance and therefore funding of ETCs should be considered by CCGs. There is NHS England and DH guidance which promotes and supports participation by NHS organisations and NHS patients in research and suggests that CCGs should fund ETCs.<sup>2,3,4</sup>

Thames Valley CCGs support this principle, however competing demands for resources including meeting statutory requirements must be taken into consideration when considering ETC funding requests.

**NOTES:**

- Potentially exceptional circumstances may be considered by a patient's CCG where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living) and there is evidence that the intervention sought would improve the individual's health status.
- This policy will be reviewed in the light of new evidence or new national guidance, e.g., from NICE.
- Thames Valley clinical policies can be viewed at <http://www.fundingrequests.ccsu.nhs.uk/>

<sup>1</sup> No changes have been made to this policy.

<sup>2</sup> NHS England Guidance on Excess Treatment Costs, 2015 <https://www.england.nhs.uk/wp-content/uploads/2015/11/etc-guidance.pdf>

<sup>3</sup> Health Service Guideline - HSG (97) 32

<sup>4</sup> Attributing costs of health and social research and development (AcORD) - Department of Health (October 2012)