

Excluded: Procedure not routinely funded

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. TVPC 38

Research trials and NHS funding:

- Excess treatment costs
- Post-trial treatments

Recommendation made by the Priorities Committee:

January 2016; updated January 2019¹

Date of issue:

April 2016 / Update April 2019

This policy advises on the current status and relative priority of funding drugs for patients at the end of a clinical trial within the Thames Valley.

Post-Trial Drug Therapy:

In line with national policy^{2,3,4}, the Thames Valley Priorities Committee recommend that funding for new drugs where this was initiated as part of a clinical trial is **not normally funded**. CCGs will not routinely make additional funding available (unless this has been agreed in advance).

When a clinical trial is planned, patient expectations should not be raised that NHS funding will be available to enable the patient to continue to receive the trial treatment after the trial has ended. Ethics and Research and Development Committees have a responsibility to ensure that this policy position is included in the trial protocol, Patient Information leaflet and the patient consent form.

Where post-trial treatment is continued by a pharmaceutical company on a “compassionate basis” (and therefore at no cost to the NHS), it may not be assumed that the NHS will subsequently pick up this cost even if the drug under evaluation subsequently receives a marketing authorisation (licence).

The new treatments may be considered by the relevant CCGs or by the Thames Valley Priorities Committee, where the available evidence of clinical and cost effectiveness will be assessed and considered in line with the Thames Valley Ethical Framework. The Priorities Committee will then make recommendations to their CCGs on the commissioning of such treatments.

¹No changes have been made to this policy.

² Commissioning Policy: Ongoing treatment following a NHS CB funded trial, NHS Commissioning Board, April 2013. <https://webarchive.nationalarchives.gov.uk/20170504173034/https://www.england.nhs.uk/commissioning/spec-services/key-docs/> Accessed 11.02.16

³ Commissioning Policy: Ongoing treatment following non-commercially funded clinical trials, NHS Commissioning Board, April 2013. <https://webarchive.nationalarchives.gov.uk/20170504173034/https://www.england.nhs.uk/commissioning/spec-services/key-docs/> Accessed 11.02.16

⁴ Commissioning Policy: Ongoing access to treatment following industry sponsored clinical trials or funding, NHS Commissioning Board, April 2013. <https://webarchive.nationalarchives.gov.uk/20170504173034/https://www.england.nhs.uk/commissioning/spec-services/key-docs/> Accessed 11.02.16

Excess Treatment Costs:

Funding for Excess Treatment Costs (ETCs) for non-commercial clinical research is not routinely available unless they have been agreed for specific named clinical trials in advance with the relevant commissioning CCGs.^{5,6}

In light of the obligation for the NHS to meet national NHS priorities and the requirement for NHS organisations to manage within the resources available, CCGs in the Thames Valley give the highest priority to those treatments that are known to be most cost effective at improving health and a lower priority to those treatments for which the cost is high and the evidence for health improvement is low.

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, eg, from NICE.
- Thames Valley clinical policies can be viewed at <http://www.fundingrequests.ccsu.nhs.uk/>

⁵ Guidance on Excess Treatment Costs, NHS England. November 2015. [Guidance on Excess Treatment Costs, NHS England, November 2015](#) Accessed 11.02.16

⁶ Attributing the cost of health and social care Research & Development (AcoRD), Department of Health, May 2012. [Attributing the cost of health and social care Research & Development \(AcoRD\)](#) Accessed 11.02.16