

Medicines Optimisation Position Statement

Position Statement	Research Trials and NHS Funding: <ul style="list-style-type: none">• Excess treatment costs• Post-trial treatments
Position Statement number	001 (2017)
Date approved by Clinical Executive:	5 th April 2017
Date of issue:	February 2017
Date of review:	February 2019 (Unless new published evidence becomes available before this date OR there is new published national guidance)

This position statement advises on the current status and relative priority of funding drugs for patients at the end of a clinical trial within the Frimley Health local area.

This statement is based on the Thames Valley Priorities Committee Commissioning Policy Statement 38: Research Trials and NHS Funding <http://www.fundingrequests.cscsu.nhs.uk/wp-content/uploads/2016/07/TVPC38-Research-trials-and-NHS-funding-Excessive-treatment-costsPost-trail-treatments-BE.pdf> and has been adopted by all contracted CCGs with commissioning arrangements with Frimley Health.

Post Trial Drug Therapy:

In line with national policy^{1,2,3}, the CCG recommends 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 Frimley Health Area Prescribing Committee where the available evidence of clinical and cost effectiveness will be assessed and considered in line with local policies. The Area Prescribing Committee will then make recommendations on the commissioning of such treatments.

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.^{4,5}

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, the CCG gives 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, e.g., from NICE.

References

- 1 Commissioning Policy: Ongoing treatment following a NHS CB funded trial, NHS Commissioning Board, April 2013. <https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-07.pdf> Accessed 11.02.16
- 2 Commissioning Policy: Ongoing treatment following non-commercially funded clinical trials, NHS Commissioning Board, April 2013. <https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-08.pdf> Accessed 11.02.16
- 3 Commissioning Policy: Ongoing access to treatment following industry sponsored clinical trials or funding, NHS Commissioning Board, April 2013. <https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-13.pdf> Accessed 11.02.16
- 4 Guidance on Excess Treatment Costs, NHS England .November 2015. Guidance on Excess Treatment Costs, NHS England, November 2015 Accessed 11.02.16
- 5 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