

South Central Priorities Committees (Buckinghamshire & Milton Keynes Priorities Committee)

Policy Statement 62a: Excess Treatment Costs (ETCs) for non-commercial clinical trials

Date of Issue: Updated January 2010, issued December 2007

Priorities Committees across South Central 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 PCTs.

The Priorities Committees also recommended that a South Central wide process for ETCs to be considered should be established. This process will include consideration of ETCs for individual trials, monitoring of ETCs and provision of information about trials that save costs. It was noted that 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 approval 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.

There is Department of Health guidance (1994) which suggests that PCTs should fund ETCs. Since it was first issued, the DH has promoted adherence to it by re-issuing it periodically. However, competing demands for resources, including meeting statutory requirements, has meant that funding for ETCs has sometimes prevented Trusts in South Central from entering patients into clinical trials.

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 PCTs.

NOTES:

1. *Exceptional circumstances may be considered where there is evidence of significant health impairment and there is also evidence of the intervention improving health status.*
2. *This policy will be reviewed in light of new evidence or guidance from NICE.*
3. *Buckinghamshire/Milton Keynes Priorities Committee policy statements can be viewed at <http://www.miltonkeynes.nhs.uk/default.asp?ContentID=548>*