Addendum to IESCCG & WSCCG policy titled “On-going access to treatment following third party funding including clinical trials and excess treatment cost”.

Public Health Suffolk on behalf of Ipswich & East Suffolk and West Suffolk Clinical Commissioning groups

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This addendum is in reference to the West Suffolk CCG and the Ipswich and East Suffolk CCG Commissioning policy, June 2015: On-going access to treatment following third party funding including clinical trials and excess treatment cost\(^1\). Following the approval of this Commissioning policy\(^1\), NHS England then released further guidance in relation to excess treatment costs\(^2\) and released new information on the early access to medicine scheme\(^3\).

The purpose of this addendum is to:

1. Summarise and highlight any significant points from the NHS England: Guidance on Excess Treatment Costs\(^2\) and to ensure that we have taken this guidance into consideration.
2. Explain and raise awareness of the early access to medicine scheme (EAMS).

The NHS England: Guidance on Excess Treatment Costs was published on the 16/11/2015. It provides guidance on ‘how (excess treatment) costs should be identified and how the payment of these costs can be managed by NHS bodies, in accordance with the established policy’\(^1\).

- A diagram in section 2 of the guidance illustrates a broad overview of the research funding process and those involved. See Appendix 1.

- Section 4 of the guidance categorises and defines the areas of cost in research. Although similar definitions are included in the West Suffolk and East Suffolk and Ipswich CCG policy, the updated definitions are included below for absolute clarity.

  ‘Researchers wishing to access funding for their research must therefore attribute the costs across the three categories:
  
  o **Research Costs:** research costs are met by the research funder
  
  o **Support Costs:** resources are generally provided by the NIHR usually via the Local Clinical Research Networks

  o **NHS Treatment Costs:** NHS Treatment costs are funded by the NHS through normal commissioning arrangements for patient care’ (Section 4, page 7).

**‘Terminology explained:**

**Research costs** are the costs of the research and development itself that end where the research ends. They relate to activities that are being undertaken to answer the research question.

**Support costs** are the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided.
**NHS treatment costs** are the costs of patient care, which would be incurred if the care/treatment under review became standard care. For the purpose of attributing costs during a research study, an assumption is made that the care/treatment under review will become standard, but whether this happens in practice is dependent on the results of the research and on the NHS’ desire to commission it (Section 4, page 7-8).

• Section 5 of the guidance has an additional explanation to the definition provided in the West Suffolk and Ipswich and East Suffolk policy.

‘Terminology explained:

**Excess Treatment Costs** are the difference between the total treatment costs and the cost of standard treatment.

Excess Treatment Costs are part of treatment costs and therefore normal commissioning arrangements apply.

Excess Treatment Costs should be identified at an early stage of a study preferably prior to an application for research funding being submitted. Researchers should seek to minimise these through study design and management of costs’ (Section 5, page 8).

• Section 7 of the guidance is entitled ‘Subvention funding’. It is important to note that in exceptional circumstances where there is a very high Excess treatment cost, the Department of Health Research and Development Directorate may provide contribution towards funding. This is referred to as subvention funding and this may only be applied for by the chief investigator of the study.

• Section 8 of the guidance is entitled ‘Accessing funding for Excess Treatment Costs’. It is important that those requesting funding for research understand that there are multiple organisations involved with commissioning and that early contact with an advising authority can ensure that the appropriate commissioners are approached. It is recognized that early contact is not always possible, like in the case of multi-centre studies, and this will not affect funding for legitimate requests approved by the NIHR or one of its research partners*. This section only applies to NIHR or one of its research partners’ funded trials. However the provider Trusts should make all efforts to inform the commissioners at the earliest possible opportunity.

* It relates specifically to non-commercial research (i.e. research funded by the National Institute of Health Research (NIHR), other areas of central Government including Research Councils, NIHR non-commercial Partners and also Investigator-initiated, commercial-collaborative studies (Industry-funded, non-industry sponsored studies).
Early Access to Medicine Scheme (EAMS)

The Medicine and Healthcare regulatory Authority (MHRA) launched EAMS so that patients could be treated with certain promising unlicensed medications. This scheme allows additional treatment options to patients, allows companies to gain more information on the medication and gives those in the NHS more experience with the medication. This scheme was primarily used for oncology medications; however, for the first time a non-oncology medication has been approved through the EAMS. As this medication is for heart failure, the EAMS will now be accessed by those not only in primary care but secondary care as well. NHS services should thus become familiar with the process of submitting medications and accessing medications on the EAMS. Funding for medications on the EAMS will initially be provided by the pharmaceutical company until the CCG and Trusts implement the relevant NICE TA. Further information is available from https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams and in the letter written by David Geddes dated October 12th, 2015 available from https://www.england.nhs.uk/wp-content/uploads/2015/10/eams-letter-oct15.pdf.

Conclusion

The aim of this paper was to provide transparent guidance for the researchers and the providers where the research will be carried out. Commissioning authorities understand the invaluable part research plays in advancing medicine and the quality of patient care, as well as the potential for cost savings.

The NHS Guidance on Excess Treatment does not introduce any new policies or principles but reflects those previously stated in the Health Service Guideline (97) and the AcoRD document (May 2012). There are no changes needed to the West Suffolk CCG and the Ipswich and East Suffolk CCG Commissioning policy; however it is advised that the NHS Guidance on Excess Treatment Costs and the points discussed in this addendum are used to support the original policy.

As the EAMS expands to include a variety of medications, NHS services are encouraged to become familiar with the scheme.
References

1. West Suffolk CCG and Ipswich and East Suffolk CCG Commissioning Policy: On-going access to treatment following third party funding including clinical trials and excess treatment cost. June 2015
4. GOV.UK Apply for the early access to medicines scheme (EAMS). Available from: [https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams](https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams)
7. Department of Health: Attributing the costs of health and social care Research & Development (AcoRD), May 2012