Arden and Greater East Midlands
Commissioning Support Unit

NHS Birmingham & Solihull Clinical Commissioning Group
NHS Dudley Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
NHS Walsall Clinical Commissioning Group
NHS Wolverhampton Clinical Commissioning Group

Collaborative Commissioning Policy

On-going access to treatment following the completion of non-commercially funded clinical trials covered by Department of Health Guidance HSG (97) 32

Version2.1– July 2018

1. The policy

1.1 This policy applies to any patient for whom the Clinical Commissioning Group is the responsible commissioner.

1.1 HSG(97)32 recommends that NHS commissioners should fund excess treatment costs of non-commercial clinical trials, following agreements between the Department of Health and non-commercial research and development organisations. Under these arrangements an NHS commissioner is likely to have already funded part of excess treatment costs associated with these clinical trials. However the Clinical Commissioning Group has no legal obligation to fund excess treatment costs and will therefore exercise discretion with regard to its financial support of clinical trials.

1.2 Where the Clinical Commissioning Group has explicitly agreed to fund one or more patients' treatment in the context of a clinical trial, then on-going care will be funded as outlined in the CCG's policy document *'On-going access to treatment following the completion of a trial explicitly funded by the Clinical Commissioning Group'.*

1.3 For other patients, the Clinical Commissioning Group will exercise discretion to consider providing funding for on-going access to treatment after a non-commercial clinical trial has been completed if:

1.3.1 the clinical trial was wholly funded by non-commercial bodies; and

1.3.2 the trial was sanctioned by the National Institute for Health Research database (https://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/; and

1.3.3 it has been demonstrated that the patient has benefited clinically from the treatment provided as part of the clinical trial; and

1.3.4 the Clinical Commissioning Group determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and the Clinical Commissioning Group can afford that expenditure.

1.4 In the event that the Clinical Commissioning Group agrees to fund treatment under paragraph 1.3, this decision does not represent a policy decision by the Clinical Commissioning Group to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under the Clinical Commissioning Group's service development policy in the normal way.

1.5 Nothing in this policy commits the Clinical Commissioning Group to funding patients who are involved in any other clinical trial.

2. Documents which have informed this policy

- The Clinical Commissioning Group's Commissioning Policy: Ethical Framework for priority setting and resource allocation

- The National Specialised Commissioning Group: Funding of treatments for patients leaving clinical trials (March 2008).

- The Medicines for Human Use (Clinical Trials) Regulations 2004. (Statutory Instrument 2004 Number 1031. *The regulations for clinical trials are set out in the Medicines for Human Use (Clinical Trials) Regulations 2004. The regulations, as originally passed, have been subsequently amended by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and may be further amended. CCGs are advised to seek advice to ensure that they are consulting the current version of the Regulations.*
  Original: http://www.legislation.gov.uk/uksi/2004/1031/contents/made
  Amendment: http://www.opsi.gov.uk/si/si2006/20061928.htm

- Letter from the National Patient Safety Agency, National Research Ethics Service to all UK NHS Research Ethics Committees March 2008.

- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision: 59th WMA General Assembly, Seoul, October 2008.
  http://www.wma.net/en/30publications/10policies/b3/
  https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

- Department of Health: HSG(97)32: Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS.
  http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353?IdcService=GET_FILE&dID=14533&Rendition=Web

- Department of Health, The National Health Service Act 2006, The National Health Service Act 2006.
  http://www.legislation.gov.uk/ukpga/2006/41/contents

- Department of Health, The NHS Constitution for England, 2015,
  https://www.gov.uk/government/publications/the-nhs-constitution-for-england

- Guidance on Excess Treatment Costs – November 2015 :
  https://www.england.nhs.uk/wp-content/uploads/2015/11/etc-guidance.pdf

- NHS Confederation Priority Setting Series, 2008
  - Priority setting: an overview
  - Priority setting: legal consideration
  - Priority setting: strategic planning
  - Priority setting: managing new treatments
  - Priority setting: managing individual funding requests

  http://www.nhsconfed.org/resources/2008/12/priority-setting-an-overview

Glossary

TERM	DEFINITION
Clinical effectiveness	C*linical effectiveness* is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real life population under real life conditions.
Clinical trial	*A clinical trial* is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.
Effectiveness - general	*Effectiveness* means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness - clinical	C*linical effectiveness* is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Experimental and unproven treatments	*Experimental and unproven treatments* are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following: • The treatment is still undergoing clinical trials for the indication in question. • The evidence is not available for public scrutiny. • The treatment does not have approval from the relevant government body. • The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field. • The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body. • The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy. • There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
NHS pick-up of trial of treatment	*NHS pick-up of trial of treatment* refers to the responsible commissioner funding on-going treatment costs for either experimental treatments, those not normally commissioned or those awaiting assessment and prioritisation and where the clinician has initiated a trial of treatment without sanction regardless of how the treatment has been funded.

Priority setting	*Priority setting* is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Service Development	A *Service Development* is a proposal to the Clinical Commissioning Group to provide a particular healthcare intervention to be routinely funded by the Clinical Commissioning Group for a defined group of patients. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an *in-year service development*.
Statutory Guidance	*Statutory Guidance* is written Guidance which is issued by the Secretary of State or a body authorised by the Secretary of State (or by another part of government which is directly relevant for the relevant decision making process). NHS bodies are required to have regard to statutory guidance in their decision making. Statutory Guidance is intended to assist public authorities in the exercise of their statutory duties. It suggests steps which might be taken; factors which could be taken into account and procedures which could be followed to deliver specified steps of administration, or policy delivery. NHS bodies are entitled to depart from statutory guidance if they have a good reason to do so. However: • The NHS body should always record that it has considered the statutory guidance as part of its decision making processes, and • The NHS body should always record the reason or reasons why it has departed from the course of action recommended in the Guidance.
Treatment	*Treatment* means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.
Treatment costs	*Treatment costs*, in the context of clinical trials, are the patient care costs which would continue to be incurred by the NHS if the service in question continued to be provided after the clinical trial had ceased.
Treatment costs - excess	*Excess treatment costs* are incurred where patient care is provided which differs from the standard treatment, in that it is either an experimental treatment or a service in a different location from where it would normally be delivered. The difference between the total Treatment Costs and the cost of the standard treatment (if any) constitutes the *excess treatment costs*.

Guidance note

The World Medical Association
Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Not every clinical trial that is conducted requires on-going treatment of the trial participants. However where the treatment is longer term (for example treatment of blood pressure) the Declaration of Helsinki is unequivocal about the ethical requirements placed on those conducting trials regarding what should happen to patients at the end of a clinical trial:

> *22. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, and other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.*
>
> *In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.*
>
> *37 In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.*

HSG(97)32 Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS (1997)

Guidance HSG(97)32 and the more recent document *Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for subvention (April 2009*) set out the expectation that the NHS (both commissioners and providers of health care) will support the costs associated with delivery of clinical trials though not the costs of data collection, data analysis etc.

It should be noted that the agreement between the Department of Health and non-commercial bodies with an interest in R&D is restricted as set out in the April 2009 guidance document:

> *This document clarifies DH guidance on funding Excess Treatments Costs set out in HSG(97)32. It relates to non-commercial research studies eligible for entry onto the National Institute for Health Research (NIHR) Clinical Research Network Portfolio database or studies funded through the NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), Biomedical Research Centre and Biomedical Research Unit funding schemes. Only studies that meet these criteria are eligible to apply for subvention funding.*

Excess treatment costs associated with clinical trials are largely anticipated to be absorbed through the existing contract between the Clinical Commissioning Group and the Provider (additional outpatient attendances, tests etc.).

Where the excess treatment costs involve a major additional cost (e.g. payment for expensive drugs), the Provider is expected to notify the Clinical Commissioner Group in advance, in order to secure agreement for funding. Because HSG(97)32 is guidance, the Clinical Commissioning Group has some discretion to consider whether or not to fund excess treatment costs, after considering the available resources and competing needs. The prioritisation of clinical trials is covered by the Clinical Commissioning Group's policy *Experimental and unproven treatments.*

This policy deals with the situation where the Clinical Commissioning Group has not been notified in advance about a clinical trial, and is being approached to pick up funding for a patient for on-going treatment after the trial has been completed. In general on-going funding should be provided subject to the patient having benefited from treatment and funding being available. However discretion should be applied, particularly in circumstances where the Provider failed to notify the Clinical Commissioning Group of high costs, as required under the guidance.

In circumstances where the Clinical Commissioning Group was specifically asked by a Provider to fund the treatment cost or the cost of on-going treatment and the request was refused at that stage on affordability grounds, but the patient was nevertheless enrolled in the trial by the Provider, the situation is different. To pick-up the funding of the treatment costs following the completion of the trial in this situation not only puts the Clinical Commissioning Group at considerable financial risk: it would also leave the Clinical Commissioning Group vulnerable to having its funding priorities, identified by reference to the needs of its population in accordance with its statutory duties, destabilised by a third party.

The Clinical Commissioning Group will need to have regard to the individual circumstances of any particular application for ongoing access to treatment following a non-commercially funded trial but even where a patient has been shown to have benefited from treatment, the Clinical Commissioning Group must weigh this against the principle adopted in its *Commissioning Policy: Ethical framework to support priority setting and resource allocation* that third parties cannot determine its funding priorities and the wider and longer term risks associated with picking up funding from a third party.