Midlands and Lancashire
Commissioning Support Unit

NHS Birmingham Cross City Clinical Commissioning Group
NHS Birmingham South Central Clinical Commissioning Group
NHS 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 a trial explicitly funded by the Clinical Commissioning Group

Version 1.2 – October 2014

1. The policy

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

1.2 Subject to the terms of this policy, the Clinical Commissioning Group will fund access to the treatment which was the subject of the clinical trial after the completion of a clinical trial:

1.2.1 where the Clinical Commissioning Group has agreed explicitly to fund in whole or in part the patient's treatment in a clinical trial;

and

1.2.2 when the treatment which was the subject of the clinical trial has been demonstrated to deliver clinical benefit to the patient.

1.3 The provision of funding to continue a treatment to a patient who leaves a clinical trial where the treatment costs have been funded (wholly or in part) by the Clinical Commissioning Group 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.

1.4 Nothing in this policy commits the Clinical Commissioning Group to funding patients who are either involved or have been involved in any other type of clinical trial.

1.5 Where funding has been provided to a patient under paragraph 1.2 of this policy, the Clinical Commissioning Group reserves the right to seek a formal clinical review of the patient's present and future healthcare needs and to consider whether the decision to provide the patient with on-going funding for the treatment which was the subject of the clinical trial or any other treatment provided to the patient is equitable and appropriate. The Clinical Commissioning Group shall have regard to its other commissioning policies and its ethical framework for priority setting and resource allocation when conducting any such review.

2. Documents which have informed this policy

- The Clinical Commissioning Group's Commissioning Policy: Ethical Framework to underpin 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.statutelaw.gov.uk/SearchResults.aspx?TYPE=QS&Title=medicines+for+human+use+%28clinical+trials%29+regulations+2004&Year=&Number=&LegType=All+Legislation.
Amendment:
http://www.opsi.gov.uk/si/si2006/20061928.htm

- 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/

- Department of Health: HSG(97)32: Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS. (Archived by the Department of Health)

- Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for subvention (April 2009)
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_097627.pdf

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

- Department of Health, The NHS Constitution for England, 2012,
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132961

- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.co.uk/policy/resources/handbook_complete.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

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.
Efficacious	A treatment is *efficacious* where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.
Service Development	A *Service Development* is an application to the Clinical Commissioning Group to amend the commissioning policy of the Clinical Commissioning Group to provide that a particular healthcare intervention should be routinely funded by the 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*.
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.

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. 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:

14. *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.*

33. *At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.*

When the Clinical Commissioning Group (CCG) has either initiated a trial or agreed to provide the funding to allow the patient to enter the clinical trial, the CCG has become a sponsor of the clinical trial and as such should abide by the Declaration of Helsinki.