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 industry sponsored clinical trials or funding

Version 2.1 – July 2018

1. The policy

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

1.2 Clinical trials

1.2.1 The policy of the Clinical Commissioning Group is that it will not pick up the funding of a patient's treatment at the end of a clinical trial that has been sponsored by a pharmaceutical or medical devices company unless the Group has given its prior written agreement or, where commissioning responsibility for a patient has transferred from another NHS body to the Clinical Commissioning Group, written agreement has been provided by the NHS commissioning organisation which was the responsible commissioner for the patient when the trial was commenced. Provider trusts seeking such funding from the Clinical Commissioning Group will need to provide clear evidence of any such agreement. This is to be considered with the Collaborative Commissioning Policy changing responsible commissioner.

1.2.2 It is the responsibility of the organisation conducting the trial, usually a provider trust, and the patient's clinician to ensure that patients are fully informed before entering the trial that NHS funding for the continuation of treatment delivered as part of a clinical trial that has been sponsored by a pharmaceutical or medical devices company may not be provided unless it has previously been agreed in writing by the patient's responsible NHS commissioner at the outset of the trial.

1.2.3 The Clinical Commissioning Group observes the usual arrangement, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki adopted by the World Medical Assembly that, 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. The Clinical Commissioning Group expects Research Ethics Committees to require that no clinical trial is approved unless funding is identified by those conducting the trial and explicitly approved by the proposed funder to ensure that any patients in a trial who benefit from the treatment in the trial are able to continue the treatment.

1.3 Pharmaceutical company sponsorship [1]: "compassionate funding"

1.3.1 The Clinical Commissioning Group will not continue to fund a patient's treatment when company sponsored funding is withdrawn unless the Group has given its prior written agreement or, where commissioning responsibility for a patient has transferred from another NHS body to the Clinical Commissioning Group, written agreement has been provided by the NHS commissioning organisation which was the responsible commissioner for the patient at the date that funding for the treatment was withdrawn. Provider trusts seeking funding will need to provide evidence of any such agreement from the relevant responsible commissioner.

[1] Pharmaceutical companies frequently provide free treatment to patients in hospital in the period between the end of a clinical trial and licensing. This has been called 'compassionate funding'.

1.3.2 It is the responsibility of the Provider and the patient's clinician to ensure that patients are fully informed about the circumstances in which company funding is being provided, how long this funding will be provided and what will happen when it is withdrawn, and that such arrangements are explicitly approved by the relevant governance body of the provider trust (for example the Drugs and Therapeutics Committee). The patient should agree to their management plan on discontinuation of treatment. This process of obtaining informed consent includes making patients aware of this commissioning policy. The patient's consent should be documented.

1.4 The continued provision of a treatment is the responsibility of those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.

1.5 In the event that the Clinical Commissioning Group makes an exception to the policy under paragraph 1.2 and 1.3 above by providing funding, in the absence of prior written agreement, to continue a treatment to an individual patient who leaves a clinical trial which has been sponsored by a pharmaceutical or medical devices company, 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 for a cohort of patients will be assessed and prioritised under the Clinical Commissioning Group's service development policy in the normal way.

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

1.7 This policy should be read in conjunction with Collaborative Commissioning Policy: Patients changing responsible commissioner.

2. Documents which have informed this policy

- Collaborative Commissioning Policy: Ethical Framework for priority setting and resource allocation
- Collaborative Commissioning Policy: Individual Funding Requests
- Collaborative Commissioning Policy: Patients changing responsible commissioner
- Collaborative Commissioning Policy: In-Year Service Developments and the Clinical Commissioning Group's approach to treatments not yet assessed and prioritised
- Collaborative Commissioning Policy: On-going access to treatment following the completion of industry sponsored clinical trials or funding.
- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) http://www.legislation.gov.uk/uksi/2008/941/contents/made

- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision: 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
  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. (Archived by the Department of Health)
  http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353

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

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

- 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/the-nhs-constitution-for-england

- National Institute for Health and Care Excellence
  https://www.nice.org.uk/Search?q=Highly+specialised+technologies+guidance

- 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.
Company sponsored treatment	*Company sponsored treatment* refers to funding on a named patient basis which allows access to a treatment, usually a drug, in advance of licensing. This is also known as 'compassionate' funding.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money. In this document it does not necessarily imply that this is measured using a specific methodology.
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.
Exceptional	*Exceptional* means out of the ordinary, unusual or special.
Exceptional clinical circumstances	*Exceptional clinical circumstances* are clinical circumstances pertaining to a particular patient which can properly be described as rare or extraordinary. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.

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.
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.
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*.
Similar patient(s)	*A Similar Patient* refers to a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Clinical Commissioning Group collaborates. The existence of one or more similar patients indicates that a policy position is required of the Clinical Commissioning Group.
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 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.*

A third party, such as a Pharmaceutical Company or researchers consenting patients to enter clinical trials, cannot commit the Clinical Commissioning Group to fund on-going treatment of a patient. In assuming that the commissioner will meet that need, those conducting the research have breached a fundamental principle of medical research. Responsibility to redress this failure cannot be made to rest with the Commissioner.

To pick-up funding 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 Declaration of Helsinki requires that participants in clinical trials should share (i.e. have on-going access to) the treatment. The implication of this statement is that it is of application to all participants, regardless of which treatment they received in the trial. Invariably, however, funding applications to a commissioner are limited to supporting the continuation of treatment for those patients who have received the treatment of interest. Nationally there has not, as far as can be determined, been any request for participants in a clinical trial who were in the placebo arm, for example, to receive the trial treatment.

The Clinical Commissioning Group will need to have regard to the individual circumstances of any particular application for ongoing access to treatment following either an industry sponsored trial or 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 for priority setting and resource allocation* that third parties cannot determine its funding priorities and the wider and longer term risks associated with accepting a transfer of responsibility which clearly sits with the original initiator and sponsor of the clinical trial or the provision of free treatment.

Assessing the exceptionality of clinical features of the patient and benefit for trial patients is almost impossible because: the ethical requirement applies to all patients; clinical trials are, by definition, designed to harmonise trial entrants as much as possible; and finally the evidence will not at that point be in the public domain for assessment. However any facts of the specific clinical situation must be weighed against breaching a fundamental principle of the ethical framework. There might be exceptional reasons to set aside the principle but these may well not be clinical in nature. They can be expected to be highly unusual.

When assessing requests to pick up funding following withdrawal of treatment that has been made available to the Provider free of charge by a Pharmaceutical Company, the decision maker should also refer to the Clinical Commissioning Group's policy: *On-going access to treatment following a 'trial of treatment' which has not been sanctioned by the Clinical Commissioning Group for a treatment which is not routinely funded or has not been formally assessed and prioritised.*