NHS
Warwickshire North
Clinical Commissioning Group

Commissioning Policy:

On-going access to treatment following the completion of non-commercially funded clinical trials

Quality & Equality First

VERSION CONTROL

Version:	2.0
Ratified by:	Governing Body
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Name of originator/author:	Hannah Willetts
Name of responsible committee:	Commissioning, Finance and Performance Committee
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VERSION HISTORY

Date	**Version**	**Comment / Update**
March 2014	1.0	Based on NHS England policy
June 2014	2.0	EIA added

Contents

1. Policy Statement

1.1 This Policy applies to any patient in circumstances where NHS Coventry and Rugby Clinical Commissioning Group, NHS South Warwickshire Clinical Commissioning Group or NHS Warwickshire North Clinical Commissioning Group (the "CCG(s)") is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that one of the Clinical Commissioning Groups is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

1.2 If NHS Coventry and Rugby Clinical Commissioning Group, NHS South Warwickshire Clinical Commissioning Group or NHS Warwickshire North Clinical Commissioning Group has explicitly agreed to funding patients in a clinical trial, then on-going care will be funded as outlined in the Clinical Commissioning Groups' policy document *'On-going access to treatment following the completion of a trial explicitly funded by the Clinical Commissioning Group(s)'.*

1.3 For other clinical trials, the Clinical Commissioning Groups will exercise discretion to consider whether or not to provide funding for on-going access to treatment after a non-commercial clinical trial. This policy outlines the criteria to be used when considering such funding.

2. Equality Statement

2.1. The CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out their functions, the CCGs will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

3. The Policy

3.1. This Policy applies to any patient in circumstances where NHS Coventry and Rugby Clinical Commissioning Group, NHS South Warwickshire Clinical Commissioning Group or NHS Warwickshire North Clinical Commissioning Group (the "CCG(s)") is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that the Clinical Commissioning Group(s) is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

3.2. HSG(97)32 recommended that NHS commissioners should fund excess treatment costs of non-commercial clinical trials, following concordats which were agreed 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 the treatment costs associated with these clinical trials. However the Clinical Commissioning Group(s) has no legal obligation to fund such treatment and will therefore exercise discretion as to whether and when research and development will be funded.

3.3. If the Clinical Commissioning Group(s) has explicitly agreed to fund patients in a clinical trial, then on-going care will be funded as outlined in the Clinical Commissioning Group(s)

policy document *'Ongoing access to treatment following the completion of a trial explicitly funded by the Clinical Commissioning Group(s)'*

3.4. For other clinical trials, the Clinical Commissioning Group(s) will exercise discretion to consider providing funding for on-going access to treatment after a non-commercial clinical trial has been completed if:

- The clinical trial was wholly funded by non-commercial bodies, and
- The trial was sanctioned by the National Institute for Health Research (NIHR) database (http://public.ukcrn.org.uk/search/Portfolio.aspx), and
- It has been demonstrated that the patient has benefitted clinically from the treatment provided as part of the clinical trial, and
- The Clinical Commissioning Group(s) determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and the Clinical Commissioning Group(s) can afford that expenditure.

3.5 In the event that the Clinical Commissioning Group(s) agree to fund treatment under paragraph 4, this decision does not represent a policy decision by the Clinical Commissioning Group(s) 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.

3.6. This policy does not in any way commit the Clinical Commissioning Group(s) to fund patients who are involved in any other clinical trial.

4. Documents that have informed the Policy

- The CCG's Commissioning Policy (reference): 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.
  Original:
  http://www.legislation.gov.uk/uksi/2004/1031/contents/made
  Amendment:
  http://www.legislation.gov.uk/uksi/2006/1928/contents/madehtm

- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision: 59th WMA General Assembly, Seoul, October 2008.

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

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

- Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for subvention (April 2009)

- Department of Health: The National Health Service Act 2006 (amended by NHS Health and Social Care Act 2012), The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006.
  http://www.legislation.gov.uk/ukpga/2006/41/contents

- Department of Health: The NHS Constitution for England, July 2009.

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

- NHS Confederation Priority Setting Series, 2008.

5. Glossary

TERM	DEFINITION
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.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money.
Clinical effectiveness	C*linical effectiveness* is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
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.
Prioritisation	*Prioritisation* is decision making which requires the decision maker to choose between competing options.
Service Development	A s*ervice development* is an application to the Clinical Commissioning Group(s) to amend the commissioning policy of the CCG(s) to provide that a particular healthcare intervention should be routinely funded by the CCG(s) 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.

Equality Impact Assessment

Arden Commissioning Support

Organisation	Coventry and Rugby CCG, Warwickshire North CCG and South Warwickshire CCG	Department		Name of lead person	Hannah Willetts EIA Jennifer Weigham

Piece of work being assessed	Commissioning Policy: On-going access to treatment following the completion of non-commercially funded clinical trials
Aims of this piece of work	To define access to treatment following completion of non-commercially funded trials

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Date of EIA	6.6.14	Other partners/stakeholders involved	CSU

Who will be affected by this piece of work?	Patients in Coventry & Warwickshire in need of packages of care

Protected characteristic		**Is there likely to be a differential impact?** Yes, no, unknown
All		No
Gender		No
Race		No
Disability		No

Religion/ belief		No
Sexual orientation		No
Age		No
Social deprivation		No
Carers		No
Human rights		No