NHS
Warwickshire North
Clinical Commissioning Group

Commissioning Policy:

On-going access to treatment following the completion of industry sponsored clinical trials or funding

Quality & Equality First

VERSION CONTROL

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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 Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.

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. Guidance Notes

Requests for pick-up funding based on the assumption that the NHS should take responsibility for funding treatment once it is licensed.
Commonly the timing of requests for funding for patients who have been in clinical trials is around the time that a license for the drug/indication is granted. There is an assumption by some clinicians conducting clinical trials that once the drug is licensed then the NHS should assume responsibility for funding the drug. This is incorrect. The NHS has a responsibility to consider and prioritise new treatments being made available, but this in no way places any obligation on the commissioner to fund patients already on treatment funded by Industry by whatever route. Requests for the routine pick-up of funding should therefore be rejected. The appropriate time for a commissioner to assume responsibility for on-going funding is if, and when, a decision has been made to fund the service development, and access to the treatment is opened to all patients meeting treatment criteria under the policy.

Requests for pick-up funding made on the basis that a patient's response to the treatment should be considered as exceptional and should be considered under the Clinical Commissioning Group's Individual Funding Request (IFR) policy.

Although this type of request is more typical when patients have funded themselves privately, they can occur following industry funding e.g. compassionate use.
Critical to assessing these cases is an understanding of some key aspects of priority setting and commissioning policy development.

A hypothetical cancer drug X will be used to illustrate key principles.

In deciding whether or not to fund drug X the commissioner will aim to consider the range of clinical presentations, natural histories and responses to treatment that might be exhibited by the patient group of interest (the "target group").

Clinical trials suggest that, on average, drug X extends life by 2 - 3 months, although there is naturally a range of responses amongst the target group.

The evidence from trials suggests that, out of every 100 patients that receive treatment, most will not get any benefit from drug X. Some will get a few weeks' benefit and 3 patients are observed to live 12 months longer than expected and with a reasonable quality of life.

In this instance, the normal range of response of the target group is from no benefit, to one year's extension of life, to life at a reasonable quality.

The commissioner must take a policy decision on the basis of this evidence.

Having assessed the cost-effectiveness of treating all patients in the target group, the commissioner reaches the decision that drug X is not cost-effective and should not be funded. However, the commissioner does a sub-group analysis on the three patients who get the most benefit and decides that for this group the treatment is cost-effective and does present good value for money and therefore ideally should be considered for funding during the annual commissioning round.

The final commissioning position will depend on whether or not this sub-group of 3 out of 100 patients can be identified in advance of treatment.

If it is possible to clinically distinguish this subgroup before starting treatment, the treatment is likely to be funded.

If the patients in this subgroup cannot be identified in advance, then it would be necessary to treat 100 patients for 3 people to derive benefit. This would not represent good value for money and so drug X would not be funded for any patient. This position could be reviewed if new evidence came to light.

An alternative option which may be open to the commissioner is to fund all patients to a point where the 3 can be clearly identified. However this option could only be considered for interventions which involved a series of treatments (e.g. a course of chemotherapy) or on-going treatment. Furthermore, this approach could only be justified if it delivered value for money. Whether it was value for money would be influenced by:

- The cost of each dose or course of treatment.
- The speed with which responders could be identified.
- The availability of a valid measure which reliably linked response to outcome. A particular problem relating to outcome is the fact that proxy measures are frequently used in clinical trials and also in clinical practice. In the case of cancer treatments, disease-free progression is frequently used as a marker of long-term survival, but the correlation between these two measures has been seriously questioned by Bowater, Bridge and Lilford.

Commissioners frequently get requests to fund patients who have either received third party funding or who have funded themselves privately for treatments not normally commissioned by the commissioners on the basis that they have responded exceptionally well to the treatment.

Let us say that a patient seeks funding for drug X because the drug has proved to be clinically effective in his or her particular case, and that they are likely to be one of the 3 patients who benefit the most.

At first glance, the decision maker may be tempted to vary its policy to permit drug X to be funded in those instances where response has been demonstrated. However, except in those circumstances where funding is provided for the initial stages by another NHS body, such a policy would mean only allowing NHS funding to be made available to patients who can either afford to fund the early stages of the treatment themselves or are fortunate enough to access drug-company supported initial treatment. It would thus involve making

the NHS's willingness to provide treatment contingent on a prior private investment by the individual patient or a commercial investment by an interested party.

Section 1(3) of the NHS Act 2006 provides that all NHS treatment should be provided free of charge unless Regulations have been made to permit charging. The policy stance set out above would not involve direct charging, but may be considered by a decision maker to offend against the spirit of the NHS, in that a policy variation of this nature would make treatment dependent on an individual's ability to fund (a prior) part of their own care or have that care funded by a party that was hoping to use the investment to persuade the NHS to fund further treatment.

A commissioning body would therefore be acting entirely rationally (and thus lawfully) in refusing to make either a policy variation to provide drug X to patients who had, by virtue of funding treatment outside of the NHS, been identified as the 3 patients who benefit more from treatment or to fund them as an individual patient on grounds of exceptionality.

Reference

J Bowater, L Bridge and R Lilford: The relationship between progression-free and post-progression survival in treating four types of metastatic cancer, Elsevier, Cancer Letters, Volume 262, Issue 1, Pages 48-53.

4. The Policy

4.1. 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.

Clinical trials

4.2. The policy of the CCG(s) is not to 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, without prior written agreement between the CCG(s) and the sponsoring organisation concerned. The CCG(s) will also not assume funding responsibility in those cases where commissioning responsibility for a patient transfers from another NHS body to the CCG(s), from the NHS commissioning organisation which was the responsible commissioner for the patient when the trial commenced. Provider trusts seeking funding from the CCG(s) will need to provide clear evidence of any such agreement.

4.3. It is the responsibility of the pharmaceutical/medical device company, the organisation conducting the trial (usually a provider trust), and the patient's clinician, to ensure that patients are fully informed that CCG(s) 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 is agreed in writing by the CCG(s) and the sponsoring pharmaceutical/medical devices company at the outset of the trial.

4.4. The CCG(s) observe that 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, is that at the conclusion of the study, patients are entitled to be informed about its outcome 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 CCG(s) expect 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 patient in a trial who benefits from a treatment is able to continue that treatment once the trial has finished.

Drug company sponsorship

4.5. The CCG(s) will not pick up the funding of a patient's treatment when company sponsored funding is withdrawn without the prior agreement of the CCG(s). The CCG(s) will also not assume funding for a patient's treatment in those circumstances where commissioning responsibility for a patient transfers from another NHS body to the CCG(s), from 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 prior funding agreement from the relevant responsible commissioner.

4.6. It is the responsibility of the provider trust 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 for; and what will happen when it is withdrawn. It is also the responsibility of the provider trust and the patient's clinician to ensure 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. Patients should be made aware of this commissioning policy in advance of treatment commencing and their consent should be documented.

4.7. Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.

4.8. In the event that the CCG(s) makes an exception to the policy under paragraph 1.2 above, by providing funding to continue a treatment once a patient has left a clinical trial, sponsored by a pharmaceutical or medical devices company, this decision does not represent a policy decision by the CCG(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.

4.9. Nothing in this policy commits the CCG(s) to funding patients who are involved in any other clinical trial.

5. 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: 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.

6. 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.
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.
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.
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 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.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
Healthcare need	*Healthcare need* is a health problem which can be addressed by a known clinically effective intervention. Not all health problems can be addressed.
NHS pick-up of trial of treatment	*NHS pick-up of trial of treatment* refers to the responsible commissioner funding on-going treatment for either experimental, not normally commissioned or awaiting assessment and prioritisation and where the clinician has initiated a trial of treatment without sanction regardless of how the treatment has been funded.
Outlier	*An outlier* is a clinical observation of a patient or group of patients that lies outside the normal clinical picture. The outlier may be different from the patient group of interest in one of two ways. Their response to treatment may be very different to the rest of the group or their clinical presentation / natural history might be very different to the rest of the group. In order for an outlier to be identified it is necessary to characterize the patient subgroup of interest.
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 to amend the commissioning policy of the CCG to provide that a particular healthcare intervention should be routinely funded by the CCG 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 the existence of 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. The existence of one or more similar patients indicates that a policy position is required of the CCG.
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 industry sponsored clinical trials or funding
Aims of this piece of work	To define access to treatment following completion of industry sponsored trials

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