



**Warwickshire North
Clinical Commissioning Group**

Commissioning Policy:

On-going access to treatment following a ‘trial of treatment’ which has not been sanctioned by the NHS Clinical Commissioning Group(s) for a treatment which is not routinely funded or has not been formally assessed and prioritised



Quality & Equality First

VERSION CONTROL

| | |
|---------------------------------------|--|
| Version: | 2.0 |
| Ratified by: | Governing Body |
| Date ratified: | 24 th July 2014 |
| Name of originator/author: | Hannah Willetts |
| Name of responsible committee: | Commissioning, Finance and Performance Committee |
| Date issued: | 26 th September 2014 |
| Review date: | July 2015 |

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..... | 4 |
| 2. Equality Statement..... | 4 |
| 3. The Policy..... | 4 |
| 4. Documents that have informed the Policy..... | 5 |
| 5. Glossary..... | 6 |
| 6. Equality Impact Assessment..... | 8 |

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 The Policy of NHS Coventry and Rugby Clinical Commissioning Group, NHS South Warwickshire Clinical Commissioning Group or NHS Warwickshire North Clinical Commissioning Group is that the CCG will not pick up the funding of a patient’s treatment at the end of a ‘trial of treatment’ for treatments which are not normally commissioned by the CCG(s) without the prior written agreement of the CCG(s) or, 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 the trial of treatment was commenced. Provider trusts seeking funding will need to provide evidence of any such agreement.

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. In this Policy a reference to “treatment” is a reference to any healthcare intervention provided, or proposed to be provided, by a clinician of any nature whatsoever.
- 3.3. The Policy of the Clinical Commissioning Group(s) is that it will not pick up the funding of a patient’s treatment at the end of a ‘trial of treatment’ for treatments which are not normally commissioned by the Clinical Commissioning Group(s) without the prior written agreement of the Clinical Commissioning Group(s) or, where commissioning responsibility for a patient transfers from another NHS body to the Clinical Commissioning Group(s), from the NHS commissioning organisation which was the responsible commissioner for the patient at the date that the trial of treatment was commenced. Provider trusts seeking funding will need to provide evidence of any such agreement.

- 3.4. It is the responsibility of the NHS organisation providing the care to the patient, which will usually be the provider trust, and the patient's clinicians to ensure that patients are fully informed and have provided consent before they agree to a trial of treatment. As part of that process, patients must be informed in the event that no written agreement has been secured from the Clinical Commissioning Group to provide for future funding for the treatment. In these situations the patient should be made aware of this policy and the Clinical Commissioning Group's commissioning policy on experimental and not proven treatments.
- 3.5. The Clinical Commissioning Group(s) have no liability to pay the provider under the acute services contract, or otherwise, where the patient has been initiated on treatment before funding approval was sought.
- 3.6. In the event that the prior approval or pick-up funding is not agreed, responsibility for providing on-going access to a treatment is the responsibility of the provider trust in which treatment was initiated.
- 3.7. In the event that the Clinical Commissioning Group(s) make an exception to the policy by agreeing to continue funding for a treatment which has been commenced on a trial basis, this decision does not represent a policy decision by the Clinical Commissioning Group(s) to fund that treatment for other patients who are in the same or similar clinical circumstances. 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. Documents that have informed the Policy

- The CCG's Commissioning Policy (reference): Ethical Framework to underpin priority setting and resource allocation.
- 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 | <p>A <i>clinical trial</i> 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.</p> <p>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.</p> |
| Clinical effectiveness | <p><i>Clinical effectiveness</i> is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.</p> |
| Exceptional | <p><i>Exceptional</i> means out of the ordinary, unusual or special.</p> |
| Exceptional clinical circumstances | <p><i>Exceptional clinical circumstances</i> 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 Clinical Commissioning Group has no policy which provides for the treatment to be provided to patients with that rare medical condition.</p> |
| Experimental and unproven treatments | <p><i>Experimental and unproven treatments</i> 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:</p> <ul style="list-style-type: none"> ▪ 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 treatment | <p>A <i>healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.</p> |
| NHS pick-up of trial of priority setting | <p><i>NHS pick-up of trial of treatment</i> 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</p> |

| | |
|----------------------------|--|
| | <p>regardless of how the treatment has been funded.</p> <p><i>Priority setting</i> 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.</p> |
| Prioritisation | <i>Prioritisation</i> is decision making which requires the decision maker to choose between competing options. |
| Service Development | <p>A <i>service development</i> is an application to the Clinical Commissioning Group(s) to amend the commissioning policy of the CG to provide that a particular healthcare intervention should be routinely funded by the CCG for a defined group of patients.</p> <p>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 <i>in-year service development</i>.</p> |
| Treatment | <i>Treatment</i> 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. |
| Trial of treatment | A <i>trial of treatment</i> refers to a situation where a clinician has exposed a patient to a treatment for the purpose of assessing whether or not the patient is likely to benefit from longer term treatment. |

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 a 'trial of treatment' which has not been sanctioned by the NHS Clinical Commissioning Group(s) for a treatment which is not routinely funded or has not been formally assessed and prioritised |
|------------------------------|--|

| | |
|----------------------------|--|
| Aims of this piece of work | To define access to treatment following a trial of treatment |
|----------------------------|--|

| | | | |
|-------------|--------|--------------------------------------|-----|
| 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 |