

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

(Adapted from NHS Commissioning Board Interim Commissioning Policy: NHSCB cp-08)

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## Document Control Sheet

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## Document Amendment History

Version No.	Date	Brief Description
1	Oct 2013	Approved at Board
2	May 2019	Amended to Joint
3	Aug 2021	Updated following CCG Merger
4	Sept 2022	Updated following transition to ICB

The formally approved version of this document is that held on the NHS Shropshire, Telford and Wrekin website: <https://www.shropshiretelfordandwrekin.nhs.uk/about-us/how-we-are-run/policies-procedures-and-governance/medicines-management/medicines-management-commissioning-policies/>

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## 1 Policy Statement

This policy applies to any patient in circumstances where NHS Shropshire, Telford & Wrekin 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 ICB's are the responsible commissioners for the provision of that medical treatment as part of NHS care to that person.

If NHS has explicitly agreed to funding patients in a clinical trial, then on-going care will be funded as outlined in NHSSTW policy document '*On-going access to treatment following the completion of a trial explicitly funded by NHS Shropshire, Telford and Wrekin*'

For other clinical trials, NHSSTW 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

NHSSTW 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. NHSSTW 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 its functions, NHSSTW 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

1. This policy applies to any patient in circumstances where NHSSTW 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 ICB is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.
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. NHSSTW, however, 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. If NHSSTW has explicitly agreed to fund patients in a clinical trial, then on-going care will be funded as outlined in NHSSTW's policy document *'On-going access to treatment following the completion of a trial explicitly funded by NHS Shropshire, Telford and Wrekin.'*
4. For other clinical trials, NHSSTW 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**
  - NHSSTW determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and NHSSTW can afford that expenditure.
5. In the event that NHSSTW agrees to fund treatment under paragraph 4, this decision does not represent a policy decision by NHSSTW 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 NHSSTW service development policy in the normal way.
6. This policy does not in any way commit NHSSTW to fund patients who are involved in any other clinical trial.

## 4 Documents which have informed this policy

- NHSSTW Generic Commissioning Policy: Ethical Framework for 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. PCTs are advised to seek advice to ensure that they are consulting the current version of the Regulations.* Original: <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. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
- 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. <https://www.legislation.gov.uk/ukpga/2006/41/contents>
- Department of Health, The NHS Constitution for England, July 2009, <https://www.gov.uk/government/publications/the-nhs-constitution-for-england>
- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009,
- NHS Confederation Priority Setting Series, 2008 <https://www.nhsconfed.org/publications/priority-setting-strategic-planning>

## 5 Glossary

TERM	DEFINITION
<b>Clinical trial</b>	<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 which 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>
<b>Cost effectiveness</b>	<i>Cost effectiveness</i> is an assessment as to whether a healthcare intervention provides value for money.
<b>Effectiveness - clinical</b>	<i>Clinical effectiveness</i> is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
<b>Healthcare intervention</b>	A <i>healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.
<b>Priority setting</b>	<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.
<b>Prioritisation</b>	<i>Prioritisation</i> is decision making which requires the decision maker to choose between competing options.
<b>Service Development</b>	<p>A <i>service development</i> is an application to NHSSTW to amend the commissioning policy of NHSSTW to request that a particular healthcare intervention should be routinely funded by NHSSTW 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</p>

	investment is made outside of the annual commissioning round, such investment is referred to as an <i>in-year service development</i> .
<b>Treatment</b>	<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.