

**On-going access to treatment following a
‘trial of treatment’ which has not been
sanctioned by NHS Shropshire, Telford and
Wrekin for a treatment which is not
routinely funded or has not been formally
assessed and prioritised**

(adapted from NHS Commissioning Board Interim Commissioning Policy: NHSCB cp-09)



Document Control Sheet

Title:	On-going access to treatment following a 'trial of treatment' which has not been sanctioned by NHS Shropshire, Telford and Wrekin for a treatment which is not routinely funded or has not been formally assessed and prioritised		
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Document Amendment History

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1	Oct 2013	Approved at Board
2	May 2019	Amended to Joint
3	Sept 2021	Updated due to Merger

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/>

Printed copies or those saved electronically must be checked to ensure they match the current online version.

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Policy Statement

This policy applies to any patient in circumstances where NHS Shropshire, Telford and Wrekin (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 NHS Shropshire, Telford and Wrekin is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

The policy of NHS Shropshire, Telford and Wrekin 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 NHSSTW without the prior written agreement of NHSSTW or where commissioning responsibility for a patient transfers from another NHS body to NHSSTW 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

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.

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 NHSSTW is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.
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. The policy of NHSSTW 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 NHSSTW without the prior written agreement of NHSSTW or, where commissioning responsibility for a patient transfers from another NHS body to NHSSTW, 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.
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 NHSSTW to provide for future funding for the treatment. In these situations the patient should be made aware of this policy and NHSSTW’s commissioning policy on experimental and not proven treatments.
5. NHSSTW 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.
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.
7. In the event that NHSSTW make an exception to the policy under paragraph 2 above 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 NHSSTW 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 NHSSTW’s service development policy in the normal way.

Documents which have informed this policy

- NHSSTW 's Generic Commissioning Policy: Ethical Framework for priority setting and resource allocation
- Department of Health, The National Health Service Act 2006, 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>

Glossary

TERM	DEFINITION
Clinical trial	<p><i>A 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>
Effectiveness - clinical	<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 NHSSTW have 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

	<ul style="list-style-type: none"> 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	<i>A healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.
NHS pick-up of trial of treatment	<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 regardless of how the treatment has been funded.
Priority setting	<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.
Prioritisation	<i>Prioritisation</i> is decision making which requires the decision maker to choose between competing options.
Service Development	<p><i>A service development</i> is an application to NHSSTW to amend the commissioning policy of NHSSTW to provide that a particular healthcare intervention should be routinely funded 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 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	<i>A 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.