

Ethical framework for priority setting and resource allocation

(Adapted from NHS Commissioning Board Interim Commissioning Policy: NHSCB cp-01)

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Version:	V4
Approval Date:	November 2021
Review Date:	September 2025



Document Control Sheet

Title:	Ethical framework for priority setting and resource allocation		
Electronic File Name:	\\10.201.56.151\Shared\New SCCG Medicines Management\Policies, Procedures & Guidelines\Policies		
Placement in Organisational Structure:	NHSSTW Medicines Management Team		
Consultation with stakeholders:	Mills and Reeve Solicitors, UKHSA		
Approval Level:	Strategic Commissioning Committee		
Dissemination Date:	23/11/21	Implementation Date:	23/11/21
Method of Dissemination:	Website, Mills and Reeve Training Session, Presentation to Providers, Newsletter		

Document Amendment History

Version No.	Date	Brief Description
1	Oct 2013	Approved at Board
2	May 2019	Amended to Joint
3	Sept 2021	Updated due to 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 ethical framework should underpin and be applied to priority setting processes carried out by NHS Shropshire, Telford and Wrekin (NHSSTW) with delegated authority. In particular it should be the basis for decision-making in:

- the development of strategic plans for individual services
- making investment and disinvestment decisions during the annual commissioning cycle
- making in-year decisions about service developments or disinvestments
- the management of individual funding requests

The purpose of setting out the principles and considerations to guide priority setting is to:

- provide a coherent framework for decision making
- promote fairness and consistency in decision making
- ensure that the reasons behind decisions that have been taken are clear and comprehensive

2 Equality Statement

NHSSTW has 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 is 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 Guidance Note

NHSSTW receives a fixed budget from Central Government and have specific areas in which it is required to directly commission healthcare for specified groups of NHS patients.

NHSSTW has a concurrent duty that is direct to Parliament, with the Secretary of State, to provide a comprehensive healthcare service. Within that duty the NHS must meet all reasonable requirements for healthcare, subject to the duty to live within its allocated resources. NHSSTW has a responsibility to commission appropriate healthcare to meet the clinical needs of individual patients within the area of their responsibility and within their overall budget.

Commissioned services include those provided through primary, secondary and tertiary care NHS providers, the independent sector, voluntary agencies and independent NHS contractors.

Investment and disinvestment decisions are guided by a range of NHSSTW processes. NHSSTW undertakes strategic planning which leads to decisions made in their annual commissioning rounds. All decision-making within NHSSTW should be underpinned by this ethical framework. NHSSTW seeks to take decisions about which services to commission through a systematic approach, which is centred on the needs of patients but which fairly distributes services across different patient groups. It can only do so if all decision-making is based on clearly defined evaluation criteria and follows clear ethical principles.

Given resource constraints, NHSSTW cannot meet every healthcare need of all patients within their area of responsibility. NHSSTW may take a decision not to commission a service to meet a specific healthcare need due to resource constraints. This does not indicate that NHSSTW is breaching their statutory obligations.

This ethical framework should underpin and be applied to priority setting processes carried out by NHSSTW and their associated committees. In particular it should be the basis for decision-making in:

- the development of strategic plans for individual services
- making investment and disinvestment decisions during the annual commissioning cycle
- making in-year decisions about service developments or disinvestments
- the management of individual funding requests

The purpose of setting out the principles and considerations to guide priority setting is to:

- provide a coherent framework for decision-making
- promote fairness and consistency in decision-making
- provide clear and comprehensive reasons behind decisions that have been taken

The ethical framework has two parts: Core Principles and Factors which are taken into account when prioritising competing needs for healthcare.

4 A - Core Principles

These are the principles that should guide all decision-making by NHSSTW. As with all NHSSTW policies, this policy should be reviewed at regular intervals. However, these core principles should guide all decision-making unless and until NHSSTW decides to amend this policy.

The core principles should be applied when dealing with individual funding requests, in conjunction with other general or treatment-specific commissioning policies, which might be relevant to the case.

Five important themes can be found within the above principles.

1. The first is that, as budget holder for a defined population and a range of clinical services, NHSSTW and their committees should ensure that all decisions are framed and considered in such a way that all options for investments are considered. This means that there should not be a parallel system operating, which allows individual treatments or patients to bypass prioritisation. The commissioning and operating policies that have been adopted by NHSSTW allow for the funding of high priority service developments or of individuals who have unusual and high priority clinical needs. This principle prevents patients, patient groups or services who lobby being given undue priority
2. The second theme is that a commissioner should not give preferential treatment to an individual patient who is one of a group of patients with the same clinical needs. Either a treatment or service is funded in order to create the opportunity for all patients with equal need to be treated or, if this cannot be afforded, it should not be commissioned as part of NHS treatment for any patients. NHSSTW consider that if funding for a treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some of the patients unless it is possible to differentiate between groups of patients on clinical grounds. A decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory.

A treatment policy approved by NHSSTW should therefore not be approved unless NHSSTW have made funds available to allow all patients within the clinical group identified in the policy to have equal access to treatment.

Individual patients may be considered for funding through the individual funding request process if their clinician can demonstrate that the patient is clinically exceptional.

3. The need to demonstrate clinical effectiveness and value for money is only the first stage in assessing priority. Effectiveness and value for money are minimum requirements to enable prioritisation for funding but are not the sole criteria that must be met for funding to be agreed.
4. Commissioners are frequently asked to take on funding commitments made by another statutory body or other type of organisation (including pharmaceutical companies, research bodies or acute trusts) or indeed an individual who has funded the treatment themselves. NHSSTW, like any other organisation, cannot

assume responsibility for a funding decision in which it played no part, unless there is a legal requirement to do so.

5. Related to point 4 is the issue of financial support provided to research and development (R&D). Commissioner support for R&D is highly desirable but it needs to be placed within appropriate constraints. These constraints should protect high priority treatments and services of established value.

5 B - Factors taken into account when prioritising competing needs for healthcare

NHSSTW has an obligation to provide a fair system for deciding which treatments to commission, recognising that NHSSTW does not have the budget to fulfil all the needs of all patients within its areas of responsibility.

This means that the key task of priority setting is to choose between competing claims on NHSSTW's budget. This requires NHSSTW to adopt policies that allow potential and existing demands on funds to be ranked, preferentially in the context of a strategic plan for the service. NHSSTW recognises that their internal resources will not allow every service to be assessed and ranked within every annual commissioning round. NHSSTW will therefore have to allocate its own resources to decide which services to assess and rank each year as part of the annual commissioning round. In undertaking this work NHSSTW will decide which factors to take into account to decide which services to focus upon and which work to undertake to help define the relative priority of a service development or an Individual Funding Request.

When prioritising both within and across healthcare programmes a commissioner has to make complex assessments and trade-offs. Section 2 sets out the common factors which are taken into account when making these decisions. This list is not exhaustive.

NHSSTW will seek, within the resources available to them, to take rational decisions about which services to commission. As part of that process NHSSTW is committed to examining existing services and reserves the right to withdraw funding from existing services which are not determined to justify their funding since this will release resources to fund other services which have a higher ranking.

6 Core Principles

Principle 1

The values and principles driving priority setting at all levels of decision-making must be consistent.

Principle 2

NHSSTW has a duty to provide a comprehensive healthcare service. Within that duty the NHS must meet all reasonable requirements for healthcare, subject to the duty to live within its allocated resources.

Principle 3

NHSSTW has a responsibility to make rational decisions in determining the way it allocates resources to the services they directly commission. It must act fairly in balancing competing claims on resources between different patient groups and individuals.

Principle 4

Competing needs of patients and services within the areas of responsibility of NHSSTW should have an equal chance of being considered, subject to the capacity of NHSSTW to conduct the necessary healthcare needs and services assessments. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process. Services, clinicians and individual patients should not be allowed to bypass normal priority setting processes.

Principle 5

Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be unjustifiably advantaged or disadvantaged on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual / cognitive function or physical functions.

There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting the needs of sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 6

NHSSTW should only invest in treatments and services which are of proven cost-effectiveness unless they do so in the context of well-designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and/or value for money of a treatment or other healthcare intervention.

Principle 7

New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness and then prioritised in a way which supports consistent and affordable.

Principle 8

NHSSTW must ensure that the decisions they take demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

Principle 9

All NHS commissioned care for which NHSSTW is responsible should be provided as a result of a decision made by NHSSTW. No other body or individual, other than those authorised to take decisions under the policies of NHSSTW have a mandate to commit NHSSTW to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

Principle 10

NHSSTW should strive, as far as is practical, to provide equal treatment to individuals in the same clinical circumstance where the healthcare intervention is clearly defined. NHSSTW should not, therefore, agree to fund treatment for one patient which cannot be afforded for and openly offered to, all patients with similar clinical circumstances and needs.

Principle 11

Interventions of proven effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

Principle 12

Because the capacity of the NHS to fund research is limited, requests for funding to support research on matters relevant to the health service have to be subject to normal prioritisation processes.

Principle 13

If a treatment is provided within the NHS which has not been commissioned in advance by NHSSTW save for those treatments approved by another responsible commissioner, the responsibility for ensuring on-going access to that treatment lies with the organisation that initiated treatment.

Principle 14

Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. They should be fully informed of the arrangements for continuation of treatment after the trial has ended. The responsibility for this lies with the party initiating and funding the trial and not NHSSTW unless NHSSTW has either funded the trial themselves or agreed in advance to fund aftercare for patients entering the trial.

Principle 15

Unless the requested treatment is approved under existing policies of NHSSTW in general it will not, except in exceptional circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.
that initiated treatment.

7 Key Factors

Key factors that will be taken into account when assessing the relative priorities of competing needs for healthcare

1. Whether there is a Direction made by the Secretary of State or other legal requirement which mandates NHSSTW to fund a particular proposed service development or an element of any proposed service development, including having due regard to the Equality Act 2010.
2. Whether or not the proposed service development and/or the benefits anticipated to be derived from the proposed service development have been identified as a priority within the strategic plan for that service. This includes the extent to which the proposed service development supports the delivery of NHSSTW's Quality, Innovation, Productivity and Prevention Plan.
3. The anticipated effectiveness of the proposed service development particularly in reference to patient-oriented outcomes.
4. The specific nature of the health outcome or benefit expected from the proposed service development.
5. The anticipated impact on the population affected by the proposed service development.
6. Potential impacts of the proposed service development on one or more other services funded as part of NHS treatment (positive or negative).
7. The level of confidence NHSSTW has in the evidence underpinning the case for the proposed service development or the Individual Funding Request (i.e. the quality of the evidence).
8. The level of confidence NHSSTW has in the robustness of the business case for the proposed service development.
9. Value for money anticipated to be delivered by the proposed service development (this includes cost-effectiveness where available).
10. The anticipated budgetary impact of the proposed service development including:
 - an assessment of the total budgetary impact of funding the proposed service development; **AND**
 - whether the proposed service development is cost saving in the short, medium or long term or cash releasing
11. Any anticipated risks related to the proposed service development.
12. Whether the proposed service development will improve access to healthcare and for whom.
13. The effect of the proposed service development on patient choice.

- 14.** The level of uncommitted funds that NHSSTW has at the time that it makes the decision and the affordability of the proposed service development.
- 15.** Whether or not extraordinary circumstances exist, which would justify variance from any original funding plan e.g. the management of a major outbreak.

8 Documents which have informed this policy

- Department of Health, The NHS Health Service Act 2006 (amended by Health and Social Care Act 2012), The NHS Health Service (Wales) Act 2006 and The NHS 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 NHS Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009
https://www.engage.england.nhs.uk/consultation/af642939/supporting_documents/genericcommissioningpolicies.pdf
- NHS Confederation Priority Setting Series, 2008
<https://www.nhsconfed.org/publications/priority-setting-strategic-planning>

9 Glossary

TERM	DEFINITION
Annual Commissioning Plan	The <i>Annual Commissioning Plan</i> is a document prepared by NHSSTW which defines the healthcare interventions that they will commission for defined categories of patients in each financial year.
Annual commissioning round	<i>The annual commissioning round</i> is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involves a complex process of prioritisation informed by a series of decisions. This process occurs during the months of October to March for the following financial year.
Case by case decision making	<i>Case by case decision-making</i> in the context of priority setting is when the decision maker opts to allocate resources for a specified treatment and for specified patients in the absence of policy or as a substitute to policy-making. A fundamental principle of the NHS is that if a treatment is made available to one patient by an NHS commissioner, it should be made available to all other patients for whom the commissioner is responsible and who have an equal need for that treatment. However case by case decision-making means that NHSSTW only, consider an individual patient.
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>
Cost effectiveness	<i>Cost effectiveness</i> is an assessment as to whether a healthcare intervention provides value for money.
Effectiveness - general	<i>Effectiveness</i> means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.

Effectiveness - clinical	<i>Clinical effectiveness</i> is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
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 different way to previous studies 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 <i>healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.
Healthcare need	<p><i>Healthcare need</i> is a health problem which can be addressed by a known clinically effective intervention.</p> <p>Not all health problems can be addressed.</p>
In-year service development	<i>An in-year service development</i> is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which NHSSTW agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

NHS commissioned care	<i>NHS commissioned care</i> is healthcare which is routinely funded by the patient's responsible Integrated Care Board (ICB) or by the NHS Commissioning Board (NHS CB). The ICB and the NHS CB have policies which define the elements of healthcare which each ICB and the NHS CB is and is not prepared to commission for defined groups of patients.
NHS Directions	The Secretary of State has powers under NHS primary legislation to give Directions to all NHS Bodies (other than NHS Foundation Trusts) including NHSSTW. <i>NHS Directions</i> are instructions which place a legal requirement on NHS bodies to act in accordance with the Direction.
Opportunity cost	<i>Opportunity cost</i> is the loss of the ability for the NHS to fund other healthcare interventions when a decision is made to apply NHS resources to a particular healthcare intervention.
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>A <i>service development</i> is an application to the NHSSTW to amend their commissioning policy to enable a particular healthcare intervention to 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 investment is made outside of the annual commissioning round, such investment is referred to as an <i>in-year service development</i>.</p>

Similar patient(s)	<p><i>A similar patient</i> is one 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.</p> <p>The existence of one or more similar patients indicates that a policy position is required of NHSSTW.</p>
Strategic planning	<p><i>Strategic planning</i> is the process by which an organisation determines its vision, mission, and goals and then maps out measurable objectives to accomplish the identified goals. The outcome is a strategic plan which sets out what needs to be done and in what time scale. Strategic planning focuses on what should be achieved in the long term (3, 5, 7, or 10 year time span) while operational planning focuses on results to be achieved within one year or less.</p> <p>Strategic plans should be updated through an annual process, with major re-assessments occurring at the end of the planning cycle. <i>Strategic planning</i> directs how resources are allocated.</p>
Value for money	<p><i>Value for money</i> in general terms is the utility derived from every purchase or every sum spent.</p>