NHS
Shropshire
Clinical Commissioning Group

Experimental and Unproven Treatments

(Adapted from NHS Commissioning Board Interim Commissioning Policy: NHSCB cp-06)

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Contents

Policy Statement

This policy applies to any patient in circumstances where NHS Shropshire Clinical Commissioning Group (NHSSCCG) 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 CCG is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

It is standard practice for commissioners not to fund treatments which are still considered experimental, irrespective of the 'potential' health benefit for either individuals or groups of patients. It is difficult to justify funding an experimental treatment with outcomes which are either unproven or unclear when many proven interventions and important elements of healthcare remain either unfunded or are not fully accessed by sections of the population.

Except for those circumstances set out in this policy, where a commissioner may wish to fund an experimental treatment, interventions which are judged to be experimental or not to be of proven effectiveness will not routinely be funded.

Equality statement

NHSSCCG 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. NHSSCCG 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, NHSSCCG 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.

Guidance note

There are a number of organisations shaping and funding medical research, each of which has its own goals, interests and perspectives. The wider NHS has been an active player in research and development (R&D) since its beginning. Historically, those funding healthcare services have also funded research in specific instances. This position was strongly supported in the Peckham Report (circa 1990) that recommended that NHS organisations (both providers and 'purchasers') spend about 1-2% of their budget on R&D. In July 2009, a letter from the Department of Health set out the framework for entering more patients into clinical trials. The notion that commissioners should fund research is therefore not unusual, although the explicit commissioning of research by those commissioning health care services remains a relatively uncommon event.

In an environment where the demand and need for healthcare is greater than the ability of healthcare systems, including the NHS, to supply services, experimental treatments and the evaluation of treatment have to be undertaken judiciously, responsibly and for clearly defined purposes.

Despite the emphasis and importance placed on the need to ensure that clinical practice and public policy is based on sound evidence, the NHS is under increasing pressure to introduce treatments earlier, based upon less evidence, as a result of demands made by patients or lobby groups.

NHSSCCG will ensure that any new healthcare intervention is not implemented through the guise of a short-term study, without plans to cease provision once the study ends. If this route is funded under the guise of research, the intervention can become established without going through proper prioritisation processes.

Clinical researcher time is a scarce resource as are the funds to support trials. As a result it is highly likely that important and desirable trials cannot be carried out because of resource constraints. The failure to prioritise a treatment for study cannot be used as grounds for the NHS to fund the experimental treatment.

Commissioners have always differentiated between efficacy and clinical effectiveness although there is no agreed definition of these words in the commissioning context. Decision makers may find the following definitions of assistance:

- *effectiveness* means the degree to which objectives that have been identified in advance are achieved. In the NHS c*linical effectiveness* is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
- a treatment which is *efficacious* has been shown to have a beneficial effect in a carefully controlled and optimal environment. It is not always possible to have confidence that data from clinical trials will translate in clinical practice into the

anticipated benefits or that any meaningful health gain for the target patient population of interest will be achieved. This is the difference between disease-orientated outcomes and patient-orientated 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.

There are four main reasons why a treatment might be considered efficacious but not clinically effective:

1. the trial is poorly designed so that it cannot answer the question of interest. The lack of head to head studies that are available to those funding healthcare is of particular concern
2. use of invalid proxy outcome measures. A proxy outcome measure is a measure used as an alternative to the clinical outcome of interest
3. adoption of inappropriate short follow-up periods for the study, which makes it impossible to establish whether the long-term clinical outcomes claimed are actually realised and whether other effects, that had not been predicted, do occur – this is particularly important in the context of patient safety
4. treatments often perform less well in practice than under trial conditions. The reasons for this include: clinical expertise, patient selection, variable clinical practice, and loss of the Hawthorne effect (a placebo effect specific to trials). While it is not always possible to anticipate the likelihood of a discrepancy between trials and a routine NHS setting in advance, it is sometimes possible to anticipate the circumstances in which this might be a problem.

Licensing processes (such as drug licensing, the Medicines and Healthcare products Regulatory Agency approval for medical devices, and the National Institute for Health and Clinical Excellence's interventional procedures programme for invasive procedures) are designed to assess safety and efficacy. They do not address either effectiveness or cost-effectiveness.

It is also possible for a treatment to be clinically effective in theory but for this potential to be unrealisable. Evaluation of what *actually* happens once a treatment is released into the NHS is necessary in many areas of care but rarely happens. It is therefore possible that the NHS is paying for treatments which have been established for years without the NHS really knowing the true extent of their effectiveness.

For many treatments only time, experience and proper formal evaluation can establish the *optimum use* of the treatment.

EXPERIMENTAL TREATMENTS

What is an experimental treatment?

Those commissioning health seek to provide as comprehensive a healthcare service as possible across all patient groups and across the entire patient pathway, within an overriding legal obligation to stay within the financial budget allocated to them. Given that demand for healthcare will always exceed the resources available to fund treatment, it is justifiable to give the funding of experimental treatments a lower priority than funding the provision of core services and treatments of proven benefit.

Criteria for considering a treatment as experimental include:

the treatment is still undergoing clinical trials and/or yet to undergo a phase III clinical trial for the indication in question

- there are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question
- the treatment does not have approval from the relevant government body
- the treatment does not conform to usual 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 that 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 authoritative evidence of safety and efficacy.

From the position of those funding healthcare two other criteria can be added:

- the evidence is not yet available for public scrutiny
- the decision maker does not have confidence in the evidence base that has been presented (i.e. in the interpretation of the evidence).

Primary policy position of commissioners on experimental treatments

It is standard practice for commissioners not to fund treatments which are still considered experimental, irrespective of the ‘potential’ health benefit for either individuals or groups of patients.

The primary reason for adopting this policy is that it is difficult to justify funding an experimental treatment with outcomes which are either short term, unproven or unclear when many proven interventions and important elements of healthcare remain either unfunded or are not fully accessed by sections of the population.

Exceptions to the general rule

On occasion, however, a commissioner may wish to fund an experimental treatment.

Before doing so, decision-makers need to reassure themselves of two things:

1. that the decision to agree to an exception to the general rule is made for very clear and explicit reasons which are consistent with the organisation's priority setting principles
2. that funding experimental treatments is done in a way that will contribute to the knowledge base.

There are a number of common scenarios in which explicit funding of an experimental treatment might be considered.

Scenario 1: Experimental treatment for rare clinical situations and where the commissioner judges that trials will be impossible to carry out

Commissioning bodies often receive funding requests for experimental treatments supported by an argument that trials are impossible. It is recognised that there are circumstances where the potential for trials is restricted because of the nature of the treatment and/or the epidemiology of the disease. The case is, however, often overstated, even for rare disorders. Robust multicentre international trials, whilst a major challenge, are possible. Rarity is therefore not always sufficient ground for accepting a lack of evidence. There are many other types of interventions which, historically, have not been subject to adequate trials, including surgical procedures and medical devices.

It is important for decision makers to distinguish between those instances where trials are either impossible or improbable and those where the research community and industry have not prioritised a trial.

Having ruled out those treatments where trials are possible, decision-makers, are then left to justify a funding request in which there is either:

- no evidence, or;
- only anecdotal evidence, or;
- evidence from small and often heterogeneous case reports, or;
- evidence solely of short term outcomes, or;
- evidence of effectiveness in a similar condition to the clinical circumstance under consideration.

Here decision-makers have to approach the decision as though it were any other service development (whether for one or more patients). This is done by:

- judging the potential benefit and risks;
- estimating value for money; and
- prioritising the patient's need against other competing demands.

The main difference between this and normal service development assessment is that the judgment about benefit rests on the biological plausibility of benefit by seeking a view on the biological mechanism and/or extrapolating information from unrelated cases.

If, after having considered the issue, decision -makers are minded to fund *and* can afford to do so – then there are three options open to the commissioner:

1. fund on the condition that the patient enters a properly conducted *'n of 1'* trial (including the adequate blinding of recipients, providers and assessment and having objective and relevant outcome measures). England does not currently have such a trial unit and so this option is not currently open to the commissioner.
2. fund the treatment for a period of time and make on-going treatment subject to demonstration of benefit for an individual patient using locally agreed criteria. Under these circumstances there should be agreement about the timescales of the trial and the measurable outcomes against which to determine on-going treatment. Such an approach is often *erroneously* referred to as an *n of 1 trial.* It is more appropriately called a *trial of treatment*. This is only an option where there is a course of treatment or long-term treatment. It is not suitable for, example, a surgical intervention.
3. fund with no additional conditions. A report providing an update on the patient's progress should be requested from the clinician.

In all instances where a clinical database or a population registry operates, data should be submitted to this as a condition of funding.

Scenario 2: Experimental treatments that are currently being studied but require the commissioner to sponsor either one or more individual patients to enter into a trial

Most research is industry-sponsored and, therefore, this scenario does not commonly arise. However, those commissioning healthcare do regularly fund excess service costs of non-industry trials such as those conducted by the Medical Research Council. This funding arises out of the Concordat that exists between the Department of Health and research bodies. It is a memorandum of understanding and as such it is guidance rather than a direction to the NHS to support such research. In reality commissioners are rarely aware of the fact that they are supporting a trial because additional hospital activity related to the trial is logged under routine contract activity such as a diagnostic or chemotherapy episode. There are some areas of clinical practice – most notably in the treatment of haematological and childhood cancers – where routine treatment is commonly delivered within the context of trials.

Trials which come under the auspices of this arrangement are listed on the National Institute of Health Research (NIHR) Clinical Trials Register:

http://public.ukcrn.org.uk/search/Portfolio.aspx

In addition, local professional bodies may also support trials. So for example there are some trials in Blood and Marrow Transplantation (BMT) which may be NIHR supported but have not been supported by the British Society of BMT although they may be supported by the European equivalent.

It is important to establish what the status of a trial is, who has sponsored it and which bodies contribute to funding the trial.

The Government has set a target to double patients being entered into trials in the next few years. As a result of the increased trials activity and also the nature of the trials taking place under the umbrella of the Concordat, those commissioning health care have become increasingly aware of trial costs. This is because there are an increasing number of requests to fund high cost elements of trials.

Those commissioning health care may be asked to explicitly fund trials in two ways:

1. A request to support a trial by funding a number of patients or any qualifying patient to enter the trial. In these instances the request should be treated as a service development. If it is a very large trial with considerable budgetary consequence it is more likely that prioritisation should be through the annual commissioning process
2. A request to support a single patient to enter a trial. This request should be managed under the organisation's Individual Funding Request (IFR) policy and process.

In both these instances the following should be considered:

- the potential strategic importance of the treatment. This is essentially a judgment as to whether the trial will address the key goals and priorities of the programme area. The collective experience of commissioners suggests that opportunities of this kind are rare, as most funding requests for experimental treatments are for second, third and fourth line treatments for the seriously ill, as a last resort. Equally uncommon are requests to fund patients in trials which address specific questions for an existing and established treatment
- the quality of the trial and whether or not it is going to generate the sort of information needed to come to a view on the treatment
- ownership of the data. Public funds should not be used to support trials where there is no guarantee that the results will be put into the public domain and the data subject to external scrutiny
- whether the trial can be afforded and whether it should be prioritised over competing needs.

Commissioners most commonly receive requests to fund on-going treatment once a trial has ended. Generally trial pick-up should not be funded. Very occasionally funding is sought before a patient is entered into a trial. In these instances a patient's participation in the trial is dependent on NHSSCCG picking up funding at the end of the trial. Here the assessment is the same. Because these requests relate to industry-sponsored trials, the second and third bullet points above play a particularly important role in the assessment.

Scenario 3: Potentially important treatments which are of great interest to public authorities but not to other stakeholders

Very rarely those funding healthcare services may consider an experimental treatment so important that they wish to see a publicly funded trial established. Given the lack of R&D and industry support for these types of trials, it may be necessary for commissioners to initiate and fund the whole trial themselves. However, in the first instance advice should be sought from the NIHR.

Treatments for which there are adequate trials and which have demonstrated effectiveness but for which concerns remain over the true value of the treatment

It is not uncommon to have a situation where a treatment is supported by reasonably good trials but important questions still remain about the treatment. In these instances the requirement for on-going evaluation is legitimate. Unfortunately, treatments associated with high risks (e.g. high budgetary impact, potential for widening clinical scope, uncertainties about risks and true benefits) are all too often released into the NHS without a robust plan for review of the treatment some years ahead. This is an area where the NHS Commissioning Board needs to expand its formal evaluation of treatments.

Non-drug interventions often have a sparse evidence base and present a particular challenge to commissioners.

Issues that might result in a commissioner deeming that a treatment should only be made available if there is on-going evaluation include, but are not limited to:

- where there are concerns about the true nature of the benefit and/or risks and/or long term outcomes
- where a treatment's true place in managing a clinical condition has yet to be established
- where there is potential for significant variation in clinical practice (which might otherwise be difficult to control)
- where it is not known how best or where to deliver the treatment (e.g. dose, frequency, sequencing, concurrent treatment, duration of treatment, location)

- where there is a good chance that real-life effects and/or costs may differ from those seen in clinical trials because of difference in context, patient mix, treatment delivery, service provision etc.

Decision makers should, therefore, be able to apply conditions when funding treatments in this category. NICE is considering the use of an 'Only in Research' recommendation. The place of this category of recommendation and how such a recommendation is then translated into a trial is only now starting to be considered nationally, although commissioners have been using this as a policy option for years (although very rarely initiating and funding the trial themselves). A key difficulty has been that trials need clinicians who are interested and willing to carry out the trial and a system for national or multicentre co-ordination as well as achieving consensus on research priorities amongst large numbers of commissioners. There is also debate about the research methodologies that could be informative enough in these circumstances; in particular there is debate about the potential of disease registers and audit to improve the evidence base for individual treatments.

Existing treatments

The NHS has not always built in routine evaluation of treatments as they are introduced into the NHS there are a number of treatments which are in current practice and routinely commissioned but whose benefits, and sometimes risks, are not sufficiently understood and quantified. This is particularly so for treatments whose use has expanded without any underpinning evidence.

There are times, therefore, when commissioners may wish to review an existing treatment.

Using research to address value for money and affordability issues

There are treatments which present a different set of considerations. These are:

- effective treatments which provide significant health benefits and which fall above the accepted cost-effectiveness threshold[a]
- effective treatments which fall below the threshold but whose budgetary impact is considered too high to be affordable (i.e. the opportunity costs are too great).

The question, in both these instances, is "How does the NHS approach potentially useful treatments which are not cost effective or not affordable although they are clinically-effective?"

Price negotiation is one option.

[a] Note there are three categories of treatments which fall above the threshold: those that are not cost-effective because they are poor treatments (such treatments need no further attention and should not be funded), those that are not-cost effective because of pricing but which provide valued health benefits in the opinion of the commissioner and whose costs might be brought down to acceptable levels, and finally treatments which provide valued health benefits but which will always stay above the threshold (biological ultra-orphans being a case in point). Each has its own decision path and it is the second group which is referred to here.

Another option is to explore ways of obtaining a similar outcome at lower cost. This is particularly pertinent to new biological drugs which are often licensed at a dose higher than that which is needed to deliver a clinical effect. In this context research to explore more cost effective solutions for patients has a legitimate role.

The above illustrates a number of instances where commissioners could fund research directly. Such research could be justified by a public body, as the return on the investment will accrue to society generally rather than the licence or patent holders of the technology under investigation.

The Policy

This policy applies to any patient in circumstances where NHSSCCG 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 CCG is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

Except for those circumstances set out below, treatments which are judged to be experimental or not to be of proven effectiveness will not routinely be funded.

Clinical trials

NHSSCCG will strive to fulfil the requirements placed upon those commissioning health services as set out in the Department of Health letter to the NHS (Gateway number 12153), provided that:

- NHSSCCG has satisfied itself that the clinical trial is supported by the NIHR and other relevant national bodies;
- support for the trial can be afforded by NHSSCCG across the period of the trial; and
- NHSSCCG considers that trial to represent a good use of the resources that have been allocated to it having taken account of the competing demands upon its budget.

Requests to enter a single patient into a clinical trial will be managed through the IFR policy and process.

Requests to support recruitment of more than one patient into a clinical trial will be treated as a proposed service development. The decision to fund may be through an in-year service development route or through the normal annual commissioning round.

In assessing requests to sponsor one or more patients to enter a clinical trial, or to pick up funding following completion of a trial, NHSSCCG will consider:

- the potential strategic importance of the treatment for the health of the population. This requires an informed judgment to be made on whether the trial will address key national priorities for the health issues for a particular patient group or programme area (e.g. cancer, cardiovascular disease)
- the status of the clinical trial including whether or not the trial has been ratified by the NIHR and other relevant professional and research bodies
- the quality of the trial and whether or not it is reasonably expected to generate the sort of information needed to enable those funding healthcare to reach a view on the clinical effectiveness and cost effectiveness of the treatment. Specialist advice may need to be sought on the methodology to be adopted within any trial

- ownership of the data. Trials which do not guarantee that the data will be made available to public authorities and research communities for independent evaluation will not be considered for funding
- affordability and priority when compared to competing unmet needs.

Where an application is made the clinician will be expected to provide as much information as possible about the patient(s) including, where relevant: patient numbers, costs, potential on-going costs, the treatment and the trial. A copy of the trial protocol should also be included with the application.

In all circumstances where funding is granted, the provider must keep a record of acceptance to ensure pick up funding after a trial is carried out either for an individual patient or for the trial.

Use of an existing treatment experimentally for rare clinical circumstances

NHSSCCG will give consideration to supporting an existing treatment in an experimental context for rare clinical situations provided that the clinician making the application is able to demonstrate that running a good quality clinical trial for the treatment in the clinical situation in question is impossible.

This type of request will be considered under NHSSCCG's IFR policy and process.

In assessing these cases NHSSCCG will make a decision having regard to the following factors:

- the potential benefit and risks of the treatment;
- the biological plausibility of benefit based on other evidence;
- an estimate of cost of the treatment and the anticipated value for money;
- the priority of the patient's needs compared to other competing needs and unfunded developments.

The clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based, costs, as well as clinically relevant information on the patient. In addition, the clinician will identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

The options for consideration by NHSSCCG in these instances are:

- not to fund
- fund on the condition that the patient enters a properly conducted *'n of 1'* trial (if and when this option is open to the NHS)
- fund a trial of treatment but make on-going treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team

- fund with no evaluation requirements, although an outcomes report may be requested.

In all instances, contribution to any relevant clinical database or population registry which is operating will be an additional condition before NHSSCCG gives approval of funding for the treatment.

Novel treatments not previously studied at all

Primary research into novel treatments will not be funded through this funding source. The funding of these trials should come through a different route.

Documents which have informed this policy

NHSSCCG's Commissioning Policy: Ethical Framework for priority setting and resource allocation

Department of Health letter, Requirements to support research in the NHS, Gateway number 12153, July 2009.
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_102101

Department of Health: HSG(97)32:Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS.
http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4016456

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.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103

Department of Health, The NHS Constitution for England, July 2009,
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093419

The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009,
http://www.npc.co.uk/policy/resources/handbook_complete.pdf

NHS Confederation Priority Setting Series, 2008,
http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx

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.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money.
Effectiveness - general	*Effectiveness* means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness - clinical	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 specific 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 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 at the same stage of development. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional.

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 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.
Opportunity cost	*Opportunity cost* 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	*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 NHSSCCG to amend the commissioning policy of NHSSCCG to provide that a particular healthcare intervention should be routinely funded by NHSSCCG 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 NHSSCCG.
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.
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.