Midlands and Lancashire
Commissioning Support Unit

NHS Birmingham Cross City Clinical Commissioning Group
NHS Birmingham South Central Clinical Commissioning Group
NHS Solihull Clinical Commissioning Group
NHS Dudley Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
NHS Walsall Clinical Commissioning Group
NHS Wolverhampton Clinical Commissioning Group

Collaborative Commissioning Policy

Ethical framework for priority setting and resource allocation

Version 1.2 – October 2014

1. Introduction

The Secretary of State has a duty to continue to promote a comprehensive health service.

The Clinical Commissioning Group receives a fixed budget from Central Government and must arrange for the provision of healthcare to the extent it consider necessary to meet the reasonable requirements of its patients, subject to the duty to stay within its allocated resources.

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

The mechanism through which investment and disinvestment decisions are taken is through a range of Clinical Commissioning Group processes. The Clinical Commissioning Group undertakes strategic planning, which leads to decisions made in its annual commissioning round. All decision making within the Clinical Commissioning Group is underpinned by this ethical framework. The Clinical Commissioning Group 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 patients 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, the Clinical Commissioning Group cannot meet every healthcare need of all patients within its areas of responsibility. The fact that the Clinical Commissioning Group takes a decision not to commission a service to meet a specific healthcare need due to resource constraints is an inevitable fact of life in the NHS and does not indicate that the Clinical Commissioning Group is breaching its statutory obligations.

This ethical framework underpins priority setting processes and informs decision making by the Clinical Commissioning Group and its associated committees. In particular, it supports 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; and to
- provide a means of expressing the reasons behind decisions that have been taken.

The ethical framework has two parts:

1. Core principles

These are the principles which guide all decision making by the Clinical Commissioning Group both at the service and individual level. As with all Clinical Commissioning Group policies, this policy should be reviewed at regular intervals. However, core principles will guide all decision making unless and until the Clinical Commissioning Group decides to amend this policy.

The core principles will 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 these principles:

1. The first is that, as budget holder for a defined population and the responsible commissioner for a defined range of clinical services, the Clinical Commissioning Group and its committees should ensure that all decisions are framed and considered in such a way that all options for investment 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 the Clinical Commissioning Group already allow for high priority service developments to be considered as a matter of urgency and for individuals who have unusual and high priority clinical needs to be funded.

   The principles that require the Clinical Commissioning Group to consider competing demands when committing resources avoid the situation in which patients, patient groups and services who lobby, being given undue priority.

2. The second theme is that a commissioner should not give preferential treatment to a patient who is but one of a number of patients with the same clinical needs. Either a treatment or service is made available to all patients with equal clinical need or, if this cannot be afforded, it should not be commissioned for any patient. A decision to treat only some of the patients may be unfair because the decision about whom to treat would potentially be arbitrary and risks being discriminatory.

   The Clinical Commissioning Group considers 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 discriminate on a rational basis between different sub-groups of patients on clinical grounds*.

   A treatment policy approved by the Clinical Commissioning Group should therefore not be approved unless the Clinical Commissioning Group has made funds available to allow all patients within the clinical group identified in the policy to access treatment.

3. The need to demonstrate that a treatment is clinical effective or that a service development represents value for money is only the first stage in assessing priority.

   It is important to appreciate that being effective (or providing value for money) is *a minimum requirement* in order to be subject to prioritisation for funding and not **the** sole criteria that have to 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. While there might be instances where a commissioning body may choose to take on that responsibility for a number of reasons, another important principle is that the Clinical Commissioning Group 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. 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.

2. Factors to be taken into account when prioritising competing needs for healthcare

The NHS cannot possibly provide a service that meets the "best interests" of every patient and, indeed, does not have a legal obligation to do so. The Clinical Commissioning Group recognises that commissioners do not have a duty of care to the patients they serve but have an obligation to provide a fair system for deciding which treatments to commission, recognising that the Clinical Commissioning Group does not have the budget to fulfil every single need of the patients for whom it is responsible.

This means that the key task of priority setting is to choose between competing claims on the Clinical Commissioning Group's budget. This requires the Clinical Commissioning Group 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. However the Clinical Commissioning Group recognises that its internal resources will not allow every service to be assessed and ranked within every annual commissioning round.

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

The Clinical Commissioning Group will seek, within the resources available to it, to take rational decisions about which services to commission. As part of that process the Clinical Commissioning Group 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.

2. The policy

2.1 Core principles

Principle 1
The values and principles driving priority setting at all levels of decision making should be consistent.

Principle 2
The Clinical Commissioning Group has a legal responsibility to commission healthcare, within the areas for which it has commissioning responsibility, in a manner which is consistent with its legal duty not to overspend its allocated budget.

Principle 3
The Clinical Commissioning Group has a responsibility to make rational decisions in determining the way it allocates resources to the services it directly commissions and to 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 the Clinical Commissioning Group should have a fair chance of being considered, subject to the capacity of the Clinical Commissioning Group 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 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 disadvantaged or unjustifiably advantaged or 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 health needs in sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 6
The Clinical Commissioning Group should only invest in treatments which are of proven cost-effectiveness unless it does so in the context of well designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and clinical effectiveness of a healthcare intervention. Other forms of service developments must represent value for money.

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 / value for money, and then prioritised in a way which supports consistent and affordable decision making.

Principle 8
The Clinical Commissioning Group must ensure that the decisions it takes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

Principle 9
No other body or individual, other than those authorised to take decisions under the policies of the Clinical Commissioning Group, has a mandate to commit the Clinical Commissioning Group to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

Principle 10
The Clinical Commissioning Group should strive, as far as practicable, to provide equal treatment to individuals in the same clinical circumstance. The Clinical Commissioning Group should therefore not 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 have to be subject to normal prioritisation processes.

Principle 13
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. The responsibility for this lies with the party initiating and funding the trial and not the Clinical Commissioning Group unless the Clinical Commissioning Group has either itself funded the trial or agreed in advance to fund aftercare for patients entering the trial.

Principle 14
Unless the requested treatment is approved under existing policies of the Clinical Commissioning Group, the Clinical Commissioning Group will not, save 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.

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

1. Whether there is a Direction or other legal requirement which mandates the Clinical Commissioning Group to fund a particular proposed service development or an element of any proposed service development.

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 the Clinical Commissioning Group'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 of the proposed service development 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 the Clinical Commissioning Group 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 the Clinical Commissioning Group 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:

    a. An assessment of the total budgetary impact of funding the proposed service development; and

    b. 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 the Clinical Commissioning Group has at the time that it makes the decision and the affordability of the proposed service development.

15. Whether or not extraordinary circumstances are operating which justify variance from any original funding plan (e.g. the management of a major outbreak)

3. Documents which have informed this policy

- Department of Health, The NHS Health Service Act 2006, The NHS Health Service (Wales) Act 2006 and The NHS Health Service (Consequential Provisions) Act 2006. NHS Act - **http://www.legislation.gov.uk/ukpga/2006/41/contents** consequential provisions - **http://www.publications.parliament.uk/pa/ld200506/ldbills/138/2006138.pdf**

- Department of Health, The NHS Constitution for England, 2012 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132961

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

- NHS Confederation Priority Setting Series, 2008

  Priority setting: an overview
  Priority setting: legal consideration
  Priority setting: strategic planning
  Priority setting: managing new treatments
  Priority setting: managing individual funding requests

Glossary

TERM	DEFINITION
Clinical effectiveness	C*linical effectiveness* is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real life population under real life conditions.
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. In this document it does not necessarily imply that this is measured using a specific methodology.
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.
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 there is too great a measure of uncertainty over 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.
Healthcare need	*Healthcare need* is a health problem which can be addressed by a known clinically effective intervention. Not all health problems can be addressed.

In-year service development	An *in-year service development* is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Clinical Commissioning Group 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.
Normally commissioned care	*Normally commissioned care* is healthcare which is routinely funded by the patient's responsible commissioner. The Clinical Commissioning Group has policies which define the elements of healthcare it is and is not prepared to commission for defined groups of patients.
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 *Service Development* is a proposal to amend what is normally commissioned by the Clinical Commissioning Group. 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 a patient within the CCGs 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 is required of the Clinical Commissioning Group.
Strategic planning	*Strategic planning* 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. Strategic plans should be updated through an annual process, with major re-assessments occurring at the end of the planning cycle. Strategic planning directs how resources are allocated.
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.