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

In-Year Service Developments and the Clinical Commissioning Group's approach to treatments not yet assessed and prioritised

Version 1.2 –October 2014

1. The policy

1.1 This policy applies to any patient for whom the Clinical Commissioning Group is the responsible commissioner.

1.2 A service development is an application to the Clinical Commissioning Group to provide a particular healthcare intervention to be routinely funded by the Clinical Commissioning Group for a defined group of patients. A service development will usually require additional and predictable recurrent funding to be provided by the Clinical Commissioning Group for that healthcare intervention.

1.3 Applications for service developments will generally only be considered and prioritised during the Clinical Commissioning Group's process for developing its commissioning intentions. The Clinical Commissioning Group's Annual Commissioning Plan defines the commissioning position for the Clinical Commissioning Group for each financial year. NHS funded healthcare will only be commissioned by the Clinical Commissioning Group in accordance with the Annual Commissioning Plan or under the Individual Funding Request policy.

1.4 The Clinical Commissioning Group recognises that there will be applications made by provider trusts and/or clinical teams to the Clinical Commissioning Group to commission services which are not in the Clinical Commissioning Group's Annual Commissioning Plan. Such applications will be referred to as "proposed service developments".

1.5 No decision will be made to commission NHS services as part of any proposed service development which is outside the Clinical Commissioning Group's Annual Commissioning Plan until a proposed service development has been assessed, prioritised and a policy decision has been taken as to whether the Clinical Commissioning Group's existing Annual Commissioning Plan should be amended to include the proposed service development.

1.6 **A consequence of this approach is that the Clinical Commissioning Group's default interim policy will be not to fund a proposed service development**.

1.7 The Clinical Commissioning Group shall be entitled to take a decision to amend the Annual Commissioning Plan to include a proposed service development within a financial year. In deciding whether to amend the Clinical Commissioning Group's Annual Commissioning Plan in this way, the Clinical Commissioning Group will apply the principles of priority setting set out in the Clinical Commissioning Group's ethical framework.

1.8 Any application to amend the Clinical Commissioning Group Annual Commissioning Plan to include an in-year service development must be set out in a detailed business plan which describes the proposed policy change, the evidence base to support the policy and sets out the costs of both making the policy change and not making the policy change. The Clinical Commissioning Group will require considerable and compelling evidence of both the clinical and cost effectiveness of the proposed service development before agreeing to a change within a financial year.

1.9 In making such a decision the Clinical Commissioning Group will consider the following factors:

1.9.1 What is the quality and quantity of evidence in support of the treatment? The Clinical Commissioning Group will look for a substantial body of good quality evidence before agreeing to change policy to fund a new treatment in-year.

1.9.2 What are the proven benefits of the treatment? The proven benefits must be substantial.

1.9.3 What is the overall cost of the programme and does it represent good value for money?

1.9.4 How many patients are likely to be treated and what will the part year effect of funding be?

1.9.5 What service development proposals were not funded in the last annual commissioning round or have been refused in-year funding by the Clinical Commissioning Group, and does the proposed treatment have a higher priority than those proposals?

1.9.6 What is the Clinical Commissioning Group's financial position? Can the development be afforded? Can the Clinical Commissioning Group identify opportunities to disinvest in lower priority services or treatments or release funding through efficiency savings?

1.10 An in-year service development will not be approved unless the Clinical Commissioning Group can reach a clear conclusion that the following tests are satisfied:

1.10.1 That the proposed service development would have been highly likely to have been supported by the Clinical Commissioning Group in the last annual commissioning round, in priority to those service developments which could not be afforded by the Clinical Commissioning Group at that time;

1.10.2 The proposed service development is both clinically effective and cost effective; and

1.10.3 The proposed service development is affordable in the current financial year and thereafter.

1.11 Having considered the above and any other relevant factors, the Clinical Commissioning Group can either:

1.11.1 Give approval to the proposed service development; or

1.11.2 Commission such further analysis of, or other work on, the proposed service development as the Clinical Commissioning Group may consider appropriate; or

111.3 Conclude that the proposed service development does not have sufficient merit to justify supporting it and formulate a policy to reflect this; or

1.11.4 Conclude that there is merit in funding the requested treatment, but consider that the Clinical Commissioning Group should delay funding because the development does not have sufficient priority. The proposal in this instance will be considered as part of the next annual commissioning round.

1.12 Until prioritised and funded the default commissioning policy (not to fund) will operate unless otherwise stated.

2. Documents which have informed this policy

- The Clinical Commissioning Group's Commissioning Policy: Ethical Framework to underpin priority setting and resource allocation.

- Department of Health Directions to Clinical Commissioning Groups and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the NHS Institute for Clinical Excellence (NICE) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4083088

- Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006. http://www.legislation.gov.uk/ukpga/2006/41/contents

- 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.co.uk/policy/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
Annual Commissioning Plan	The *Annual Commissioning Plan* is a document prepared by the Clinical Commissioning Group which defines the healthcare interventions that the Clinical Commissioning Group will commission for defined categories of patients in each financial year.
Annual commissioning round	*The annual commissioning round* 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 which involves a series of decisions. This process occurs during the months of October to March for the following financial year.
Budgetary impact	*Budgetary impact* is the total cost to the NHS commissioning body of providing a treatment or service. The greater the budgetary impact, the greater the opportunity cost.
Case by case decision making	*Case by case decision making* 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. If a treatment from which 100 patients could benefit then the Clinical Commissioning Group would either have to offer it to all patients or to none. It would be unacceptable to offer it to 30 unless it was possible to divide the relevant patients into different clinical subgroups. However case by case decision making means that the Clinical Commissioning Group only considers one patient from the 100 patients at a time.
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.
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.
Cost effectiveness analysis	*Cost effectiveness analysis* is a method for assessing or measuring the reasonably anticipated benefits and clinical effectiveness of a particular expenditure. In the health setting this will be the cost of a particular healthcare intervention together with any other costs of delivering the healthcare intervention. Cost effectiveness analysis requires an examination of expenditure to determine whether the money spent could have been used more effectively (and ideally - whether the resulting benefits could have been attained through less financial outlay).
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.
NHS commissioned care	*NHS 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.
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. If for example a commissioner can only afford to fund one of the following: a cancer treatment, a screening programme, or 6 more palliative care beds then the opportunity cost of choosing the cancer treatment is the loss of the opportunity to fund a screening programme and/or palliative care beds.
Policy variation	*A policy variation* occurs when an existing policy is changed. When there is a proposal which would result in increased access to a treatment (for example by lowering the threshold for treatment or adding a new indication for treatment) the policy variation is a service development and will be treated as such.
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 an application to the Clinical Commissioning Group to amend the commissioning policy of the Clinical Commissioning Group to provide that a particular healthcare intervention should be routinely funded by the Group 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. When the treatment meets the regional criteria for supra-CLINICAL COMMISSIONING GROUP policy making, then the similar patient may be in another CLINICAL COMMISSIONING GROUP with which the Clinical Commissioning Group collaborates.

	The existence of one or more similar patients indicates that a policy position is required of the Clinical Commissioning Group.
Singular decision making	*Singular decision making,* in the context of priority setting, occurs when a decision maker assesses a treatment in isolation from the budget and does not compare that proposal with other competing needs.
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.

Guidance note

Service developments and similar patients

Any aspect of health care which the Clinical Commissioning Group has not historically agreed to fund and which will require an additional and predictable commitment of recurrent funding is a potential Service Development.

Any potential Service Development will have to demonstrate that it is clinically effective and cost-effective before being forwarded for prioritisation against competing service developments. Prioritisation will require competing developments to be compared using the factors set out in the Clinical Commissioning Group's *Ethical framework for priority setting and resource allocation*. This is often referred to as making decisions through **the policy route**.

The term Service Development encompasses anything which has the potential to commit the Clinical Commissioning Group to new expenditure for either a cohort of patients or where a second patient might be expected within 3 years including:

- New services
- New treatments including medicines, surgical procedures and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter an existing policy (called a policy variation). This change could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment.
- Pump priming to establish new models of care
- Requests to fund a number of patients to enter a clinical trial.
- Commissioning a clinical trial.

A common error is made by clinicians who make an Individual Funding Request for a patient who is the first of a group of patients they wish to treat with a particular treatment. The patient therefore is representative of a cohort of similar patients. Accordingly, the individual funding request is usually an inappropriate route to seek funding for such treatments. These funding requests will therefore usually be returned to the requesting Clinician, with a request that (s)he follow the normal processes to submit a bid for a service development.

Commissioning for small populations

In addition to requests to fund an experimental treatment in the context of a clinical trial for a single patient, the Individual Funding Request process for *this* Clinical Commissioning Group is designed to deal with two situations.

In the first, the IFR Panel considers funding a treatment, which is not normally commissioned, for a patient who may be considered as exceptional on clinical grounds on the basis that they are demonstrably different to those patients who would normally be denied access to the treatment in question.

In the second the IFR Panel considers funding an experimental treatment outside a clinical trial

(something that is not normally allowed[1]) for an individual patient on the basis that is it not possible to establish the benefit of treatment through the usual mechanisms because of the rarity of the condition or clinical presentation.

While the assessment in each situation is slightly different, they have one major feature in common. In both these circumstances, a key role of the IFR Panel is to make an assessment and decision about individual cases in the absence of normal levels of evidence.

In the second scenario it is important to consider the clinical circumstances which make studying a treatment using normal epidemiological methods difficult. The argument that a treatment cannot be subject to a proper clinical trial on the basis of the rarity of the target patient group is often overstated. A rare disorder (called an orphan disease) is defined by the European Union in its orphan drug legislation as having prevalence of fewer than 5 in 10,000 people. Randomised control trials in most instances should still be the clinical trial of choice in these conditions.

In the UK an ultra-orphan disease (even rarer still) is considered to have a prevalence of fewer than 1 in 60,000 people. For example Gaucher's disease is an ultra-orphan disease with a prevalence of 1 in 100,000 although in one ethnic community the prevalence increases to 1 in 450. There are therefore thousands of patients with the disease. The World Registry for this condition has 4,000 patients listed. In this instance at least, new treatments targeted at the condition, can still be studied through robust clinical trials. This will not necessarily be the case for all very rare diseases, or subgroups of patients with rare conditions.

If one or more well designed trials have been completed for a treatment then the clinical effectiveness of the treatment can be assessed regarding its clinical effectiveness. It also indicates a certain prevalence level. A Clinical Commissioning Group may therefore confidently assume that there are a number of similar patients now or in the near future. On this basis the decision to fund the treatment or not may justifiably be taken through the policy route.

The policy route is considered the ideal because the process allows, if necessary, for a more comprehensive assessment of the evidence, for wider consultation and for the full extent of opportunity costs to the population to be taken into account.

A peculiar problem arises for commissioners who serve very small populations. Because of their small size, individual funding requests which in most other organisations would be screened out on the basis that they represent a potential Service Development are instead referred to the IFR Panel on the grounds of rarity, even though the treatment is not being used in an experimental context. Rarity of itself is not sufficient grounds for exceptionality. In these situations discretion should be allowed both at the screening stage and the IFR Panel stage for a treatment which is the subject of an Individual Funding Request to be redirected for policy development.

[1] See the Clinical Commissioning Group's Policy on *Experimental and unproven treatment*