Arden and Greater East Midlands
Commissioning Support Unit

NHS Birmingham & 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

Implementation and funding of guidance produced by the National Institute for Health and Care Excellence

Version 2.1 – July 2018

1. The policy

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

1.2 The Clinical Commissioning Group will implement the National Institute for Health and Care Excellence's Technology Appraisal Recommendations in line with the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

The Clinical Commissioning Group accepts that it has a legal duty to make treatments available to patients, whose clinical condition falls within the criteria set out in a Technology Appraisal Recommendation, within 3 months of the date of publication of the Technology Appraisal Recommendation, unless a longer time for implementation has been specified by the Institute.

Treatments recommended for use by a Technology Appraisal will receive the highest priority for funding during prioritisation.

1.3 All other NICE Guidance shall be treated as statutory guidance. It will be carefully considered when developing strategies, planning services and prioritising resources. The Clinical Commissioning Group reserves the right to depart from NICE Guidance, other than Technology Appraisals, if the Clinical Commissioning Group has a good reason to do so.

2. Documents which have informed this policy

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

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

- Department of Health, The NHS Constitution for England, 2015, https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england

- National Institute for Health and Care Excellence: https://www.nice.org.uk

- 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

  http://www.nhsconfed.org/resources/2008/12/priority-setting-an-overview

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.
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).
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 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.
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.
NHS Directions	*NHS Directions* are instructions issued by the Secretary of State who has powers under NHS primary legislation to give directions to all NHS Bodies (other than NHS Foundation Trusts) including the Clinical Commissioning Group which place a legal requirement on NHS bodies to act in accordance with the Direction.
NICE's Technology Appraisals	*NICE's Technology Appraisals* are a specific form of Guidance published by NICE which is covered by NHS Directions issued in 2003. The Directions provide that Clinical Commissioning Groups shall make funding available to patients who meet the criteria set out in the Guidance. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless an extension has been authorised by the Secretary of State.
NICE's Clinical Guidelines	*NICE's Clinical Guidelines* are a form of NHS Guidance. They are not covered by NHS Directions.
NICE's Guidance on Interventional Procedures	*NICE's Guidance on Interventional Procedures* are a form of NHS Guidance. They aim to provide information about the safety of new interventional procedures. They are not covered by NHS Directions.
Non- Statutory Guidance	*Non-Statutory Guidance* is written Guidance which is issued by any public or private body other than the Secretary of State or a body authorised by the Secretary of State (or by another part of government which is directly relevant for the relevant decision making process). NHS bodies are not required to have regard to non-statutory guidance in their decision making but are entitled to do so.
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.
Service Development	A *Service Development* is a proposal 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. 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*.

Statutory Guidance	*Statutory Guidance* is written Guidance which is issued by the Secretary of State or a body authorised by the Secretary of State (or by another part of government which is directly relevant for the relevant decision making process). NHS bodies are required to have regard to statutory guidance in their decision making. Statutory Guidance is intended to assist public authorities in the exercise of their statutory duties. It suggests steps which might be taken; factors which could be taken into account and procedures which could be followed to deliver specified steps of administration, or policy delivery. NHS bodies are entitled to depart from statutory guidance if they have a good reason to do so. However: • The NHS body should always record that it has considered the statutory guidance as part of its decision making processes, and • The NHS body should always record the reason or reasons why it has departed from the course of action recommended in the Guidance.
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.

Guidance note

NICE produces the following types of guidance documents:

- Cancer service guidelines
- Clinical guidelines
- Diagnostic guidance
- Interventional procedures guidelines
- Medical technology Appraisals
- Public health guidelines
- Social care guidelines
- Safe staffing guidelines
- Medical practice guidelines
- Technology appraisal guidance
- Highly specialised technologies guidance
- Quality standards

Of these, only technology appraisals impose a mandatory funding requirement upon clinical commissioning groups.

Given that demand for healthcare is greater than the resources available, prioritisation of competing needs cannot be avoided. At present it is not possible to fully implement all NICE guidance, because of unaffordability. This situation also applies to guidance issued by other bodies such as clinical guidelines and standards produced by professional bodies.

It is essential for decision makers to understand the difference between guidance and directions. It is also essential for them to understand the nature of the different types of guidance produced by NICE.

Directions versus guidance

The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 provide that Clinical Commissioning Groups shall make funding normally available to patients who meet the criteria set out in the Guidance. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless a longer period has been specified by the Institute.

Guidance issued to the NHS is non-binding advice which is intended to assist the NHS in the exercise of its statutory duties. It recommends steps which might be taken, factors which could be taken into account and procedures which could be followed to deliver specified steps of administration or policy. NHS bodies are entitled to take decisions which do not follow Guidance (other than NICE's Technology Appraisal Recommendations) if they have a good reason to do so. The availability of resources and competing priorities can be a good reason.

Types of guidance produced by NICE

NICE's Interventional Procedures Programme

This type of guidance is particularly open to being misunderstood.

The Interventional Procedures Programme aims to assess the safety of a particular type of procedure to define the governance framework within which clinicians should use the procedure. The remit of the programme, as defined by NICE, is:

> *The IP Programme assesses the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately. By reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the efficacy and safety of interventions, the Programme enables clinical innovation to be conducted responsibly. No interventional procedure is entirely free from risk; the Programme gauges the extent of risks and benefits and makes recommendations in terms of their implications.*
>
> *To fall within the remit of the IP Programme, a notified interventional procedure must:*
>
> - *involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy, and*
> - *be available within the NHS or be about to be used for the first time in the NHS, outside formal research, and*
> - *be either not yet generally considered standard clinical practice, or a standard clinical procedure, the safety or efficacy of which has been called into question by new information.*

The programme's main focus is safety. It considers efficacy but not cost-effectiveness. The recommendations are largely focused on how a treatment should be delivered within the NHS. There are 4 categories of recommendation as to use of the procedure:

1. *Normal arrangements:* NICE has concluded that the evidence for the efficacy and safety of the procedure is deemed adequate and has recommended that clinicians should observe normal arrangements for governance, consent and audit.

2. *Special arrangements:* NICE has concluded that the procedure needs further evaluation and/or is an emerging technology. Clinicians wishing to use such a procedure are advised to inform their clinical governance lead, make special arrangements for consent and make special arrangements to audit and review their results.

3. *Procedures which are recommended only to be carried out in the context of formal research studies approved by a research ethics committee.* These are procedures which are still considered experimental.

4. *Procedures which should not be used in the NHS.* NICE has concluded that the evidence suggests that the procedure has no efficacy and/or poses unacceptable safety risks.

The classification of procedures into categories 1 and 2 above is not meant to be interpreted as a recommendation for a procedure being made available and funded by the NHS. Many of the procedures falling into these two categories would still be considered to be of unproven clinical effectiveness and/or unproven cost-effectiveness by the Clinical Commissioning Group.

Where NICE has deemed **normal arrangements** apply, decision makers should assess the recommended treatment as it would any potential service development. When the Clinical Commissioning Group has agreed to fund the treatment, consideration should be given as to whether individual prior approval is required in order to ensure that the procedure is undertaken in line with the NICE IPG concerned.

Where NICE has deemed **special arrangements apply** i.e. treatments still considered experimental or whose safety is not certain, the Clinical Commissioning Group will consider the treatment as experimental or unproven. Where consideration is given to funding an experimental treatment, the Clinical Commissioning Group's policy on *Experimental and Unproven Treatments* should be consulted. Where consideration is given to a treatment whose safety is still of concern then funding should only be considered in the context of ongoing national surveillance programmes.

Where NICE has deemed that the treatment should only be made available in the context of a clinical trial **(research only)** then funding the treatment should not be considered. If the treatment is of strategic importance, an option would be to consider funding a clinical trial – possibly in collaboration with the National Institute of Health Research. The Clinical Commissioning Group's policy on *Experimental and Unproven Treatments* should be consulted when this is considered.

Where NICE has taken a view that the treatment **should not be used**, funding should not be sanctioned.

Medical technologies guidance

The medical technologies guidance programme's remit is to:

> *…identif[y] medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them.*

NICE will either state a 'case for adoption' or that more research is required for a particular technology.

> *The 'case for adoption' recommendations are based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice.*

This programme looks at more than safety. A positive case for adoption does not require the Clinical Commissioning Group to fund the technology.