NHS
Warwickshire North
Clinical Commissioning Group

Commissioning Policy:

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

Quality & Equality First

VERSION CONTROL

Version:	2.0
Ratified by:	Governing Body
Date ratified:	24th July 2014
Name of originator/author:	Hannah Willetts
Name of responsible committee:	Commissioning, Finance and Performance Committee
Date issued:	26th September 2014
Review date:	July 2015

VERSION HISTORY

Date	Version	Comment / Update
March 2014	1.0	Based on NHS England policy
June 2014	2.0	EIA added

Contents

1. Policy Statement

1.1. This policy applies to any patient in circumstances where NHS Coventry and Rugby Clinical Commissioning Group, NHS South Warwickshire Clinical Commissioning Group or NHS Warwickshire North Clinical Commissioning Group (the "CCGs") 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 one of the CCGs is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

1.2. The CCGs will implement the National Institute for Health and Care Excellence (NICE)'s Technology Appraisals in line with the Secretary of State's Directions.

1.3. The CCGs accept that they have a legal duty normally to make treatments available to patients whose clinical condition(s) come within the definitions listed in a Technology Appraisal within 3 months of the date of the appraisal's publication unless the treatments have been exempted by the Secretary of State. These treatments will receive the highest priority for funding during prioritisation.

1.4. All other NICE Guidance shall not be treated as statutory guidance, including medical technologies guidance. It will be carefully considered when developing strategies, planning services and prioritising resources. The CCGs reserve the right to depart from NICE Guidance, other than Guidance which relates to treatments for patients that are within the specific remit of the Secretary of State's Directions, if the CCGs have a good reason to do so.

2. Equality Statement

2.1. The CCGs have 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. The CCGs are 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 their functions, the CCGs 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.

2.2. In the case that the publication of a NICE clinical guideline triggers the review of a CCG commissioning policy, the need to conduct an Equality Impact Assessment will be considered.

3. Guidance Note

NICE produces the following types of guidance documents:

- Cancer service guidance
- Clinical guidelines
- Diagnostic guidance
- Interventional procedures guidance
- Medical Technologies guidance
- Public health guidance
- Technology appraisals guidance

Of these only technology appraisals are subject to guidance from the Secretary of State.

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 on the grounds of affordability. 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
NHS Directions are legally binding instructions to CCGs, health authorities, special health authorities and NHS trusts issued by the Secretary of State under section 8 of the National Health Service Act 2006.

NICE's Technology Appraisals are a specific form of Guidance published by NICE which are covered by NHS Directions issued in 2003. The Directions provide that CCGs 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 an extension has been authorised by the Secretary of State.

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 Appraisals) 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

The Interventional Procedures (IP) 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. Recommendation as to use of the procedure fall into 4 categories:

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 CCG(s).

Where NICE has deemed **normal arrangements** apply decision-makers should assess the recommended treatment in the same way as any other potential service development. When the CCG(s) 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 that are still considered experimental or whose safety is not certain, the CCG(s) 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 on-going 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 (NIHR). The CCG'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 save in the most exceptional circumstances.

4. The Policy

4.1. This policy applies to any patient in circumstances where the NHS Coventry and Rugby Clinical Commissioning Group, the NHS South Warwickshire Clinical Commissioning Group or the NHS Warwickshire North Clinical Commissioning Group (the "CCG(s)") 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 Clinical Commissioning Group(s) is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

4.2. The Clinical Commissioning Groups will implement the National Institute for Health and Care Excellence (NICE)'s Technology Appraisals in line with the Secretary of State's Directions.

4.3. The Clinical Commissioning Group(s) accept that it has a legal duty normally to make treatments available to patients whose clinical condition(s) come within the definitions listed in a Technology Appraisal within 3 months of the date of appraisal's publication unless the treatments have been exempted by the Secretary of State. These treatments will receive the highest priority for funding during prioritisation.

4.4. 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(s) reserve the right to depart from NICE Guidance, other than Guidance which relates to treatments for patients that are within the specific remit of the Secretary of State's Directions, if the Clinical Commissioning Groups have a good reason to do so.

5. Documents that have informed the Policy

- The CCG's Commissioning Policy (reference): Ethical Framework to underpin priority setting and resource allocation.

- Department of Health: Directions concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE).

- 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.legislation.gov.uk/ukpga/2006/41/contents

- Department of Health: The NHS Constitution for England, July 2009.

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

- NHS Confederation Priority Setting Series, 2008.

6. Glossary

TERM	DEFINITION
Budgetary impact	*Budgetary impact* is the total cost to the CCG of providing a treatment or service. The greater the budgetary impact, the greater the opportunity cost.
Exceptional	*Exceptional* means out of the ordinary, unusual or special.
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.
NHS commissioned care	*NHS commissioned care* is healthcare which is routinely funded by the patient's responsible Clinical Commissioning Group or by NHS England. Both CCGs and NHS England have policies which define the elements of healthcare which each CCG and NHS England is and is not prepared to commission for defined groups of patients.
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 CCG(s) which place a legal requirement on NHS bodies to act in accordance with the Direction.
NICE's Technology Appraisals	*NICE* publish a specific form of Guidance termed *Technology Appraisals*. This Guidance 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.
NICE Guidance on Medical Technologies	*NICE's Guidance on Medical Technologies* is a form of NHS Guidance. They aim to provide information about the cost benefits of specific medical technologies. 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 directly relevant part of government). NHS bodies are not required to have regard to non-statutory guidance in their decision- making but are entitled to do so.
Statutory Guidance	*Statutory Guidance* is written guidance issued by the Secretary of State or a body authorised by the Secretary of State (or by another directly relevant part of government). 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.

Equality Impact Assessment

Arden Commissioning Support

Organisation	Coventry and Rugby CCG, Warwickshire North CCG and South Warwickshire CCG	Department		Name of lead person	Hannah Willetts EIA Jennifer Weigham

Piece of work being assessed	Commissioning Policy: Implementation and funding of guidance produced by the National Institute for Health and Care Excellence
Aims of this piece of work	To define the implementation of guidance produced by NICE

Date of EIA	6.6.14	Other partners/stakeholders involved	CSU

Who will be affected by this piece of work?	Patients in Coventry & Warwickshire in need of packages of care

Protected characteristic		**Is there likely to be a differential impact?** Yes, no, unknown
All		No
Gender		No
Race		No
Disability		No

Religion/ belief		No
Sexual orientation		No
Age		No
Social deprivation		No
Carers		No
Human rights		No