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

(Adapted from NHS Commissioning Board Interim Commissioning Policy: NHSCB cp-05)

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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.

NHSSCCG will implement the National Institute for Health and Clinical Excellence (NICE)’s Technology Appraisals in line with the Secretary of State’s Directions.

NHSSCCG accepts 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 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.

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. NHSSCCG reserves 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 NHSSCCG has a good reason to do so.

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

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
- Quality Standards

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 NHS organisations 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 NHS Commissioners 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

Cancer Service Guidance

Cancer service guidance supports the implementation of The NHS Cancer Plan for England, and the NHS Plan for Wales Improving Health in Wales. The focus of the cancer service guidance is to guide the commissioning of services and is therefore different from clinical practice guidelines.

Health professionals should take the NICE cancer service guidance into account when planning, commissioning and organising services for cancer patients. This guidance can be used to identify gaps in local provision and to check the appropriateness of existing services.

Clinical Guidelines

Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills.

Aim of clinical guidelines

Good clinical guidelines aim to improve the quality of healthcare. They can change the process of healthcare and improve people's chances of getting as well as possible. Clinical guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional

Versions of clinical guidelines

NICE produces four versions of its clinical guidelines:

- the **full guideline** contains all the recommendations, plus details of the methods used and the underpinning evidence
- the **NICE guideline** presents the recommendations from the full version in a format suited to implementation by health professionals and NHS bodies
- the **NICE pathway** is an online tool for health and social care professionals that brings together all related NICE guidance, quality standards and implementation tools on a topic in a set of interactive flowcharts
understanding NICE guidance is written using suitable language for people without specialist medical knowledge

Diagnostic Guidance

As part of NICE's work on evaluating medical technologies, the Diagnostics Assessment Programme (DAP) focuses on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS is able to adopt clinically and cost effective technologies rapidly and consistently.

Diagnostics includes all types of measurements and tests that are used to evaluate a patient's condition, such as physiological measurements, laboratory tests and pathology tests, imaging tests, and endoscopy.

Diagnosis is the process of identifying whether the patient has a disease at the time of testing. It is performed for patients with specific complaints or in whom signs or symptoms have been noted that may indicate a disease. Tests can have several different uses in the process of diagnosis, for example:

- Ruling in or out a specific disease
- General examination looking for clues to the cause of the symptoms
- Staging, or additional testing to assess how advanced or severe the disease is
- Monitoring a patient over time to determine changes in their condition
- Screening tests to look for conditions in patients without signs or symptoms of the specific condition.

The Diagnostics Assessment Programme (DAP) provides specialist capacity for undertaking complex assessments of diagnostic technologies. In many cases, the meaningful assessment of diagnostic technologies requires detailed knowledge of the post diagnosis care pathways, which results in considerable complexity.

The programme is closely linked to NICE's Medical Technologies Evaluation Programme (MTEP) and the Medical Technologies Advisory Committee (MTAC). MTAC undertakes topic selection for all medical technologies and routes appropriate diagnostics topics to the DAP.

Interventional Procedures Programme

NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use.

An interventional procedure is a procedure used for diagnosis or treatment that involves one of the following:
• making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel.
• gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth.
• using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems

Where NICE has taken a view that a treatment **should not be used**, funding should not be sanctioned save in the most exceptional circumstances.

**Medical Technologies Guidance**

Medical technologies guidance is designed to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.

The types of products which might be included are medical devices that deliver treatment such as those implanted during surgical procedures, technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions.

**Public Health Guidance**

Public health guidance makes recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health. The guidance may focus on a particular topic (such as smoking), a particular population (such as schoolchildren) or a particular setting (such as the workplace).

**Technology Appraisal Guidance**

Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales, such as:
• medicines
• medical devices (for example, hearing aids or inhalers)
• diagnostic techniques (tests used to identify diseases)
• surgical procedures (for example, repairing hernias)
• health promotion activities (for example, ways of helping people with diabetes manage their condition).
Quality Standards

NICE quality standards are a concise set of prioritised statements designed to drive measurable quality improvements within a particular area of health or care.

NICE quality standards are derived from high quality guidance such as that from NICE or other sources accredited by NICE. Quality standards are developed independently by NICE, in collaboration with healthcare professionals and public health and social care practitioners, their partners and service users. Information on priority areas, people's experience of using services, safety issues, equality and cost impact are also considered during the development process.

NICE quality standards are central to supporting the Government's vision for a health and social care system focussed on delivering the best possible outcomes for people who use services, as detailed in the Health and Social Care Act (2012).

NICE quality standards enable:
- **Health professionals and public health and social care practitioners** to make decisions about care based on the latest evidence and best practice.
- **People receiving health and social care services, their families and carers and the public** to find information about the quality of services and care they should expect from their health and social care provider.
- **Service providers** to quickly and easily examine the performance of their organisation and assess improvement in standards of care they provide.
- **Commissioners** to be confident that the services they are purchasing are high quality and cost effective and focussed on driving up quality.
The Policy

1. 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.

2. NHSSCCG will implement the National Institute for Health and Clinical Excellence (NICE)’s Technology Appraisals in line with the Secretary of State’s Directions.

   NHSSCCG accepts 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.

3. All other NICE Guidance shall not be treated as statutory guidance. It will be carefully considered when developing strategies, planning services and prioritising resources. NHSSCCG reserves 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 NHSSCCG has a good reason to do so.
Documents which have informed this policy

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

Department of Health Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE)

http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103

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/policy/resources/handbook_complete.pdf

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

<table>
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<tr>
<th>TERM</th>
<th>DEFINITION</th>
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<tr>
<td>Budgetary impact</td>
<td><em>Budgetary impact</em> is the total cost to NHSSCCG of providing a treatment or service. The greater the budgetary impact, the greater the opportunity cost.</td>
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<tr>
<td>Exceptional</td>
<td><em>Exceptional</em> means out of the ordinary, unusual or special.</td>
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| 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 (CCG) or by the NHS Commissioning Board (NHSCB). Both CCGs and the NHSCB have policies which define the elements of healthcare which each CCG and the NHSCB 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 NHSSCCG 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 primary care trusts 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 Intervventional Procedures | *NICE’s Guidance on Intervventional 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. |