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Approved by

OCQC

Policy for the Implementation and Monitoring of NICE Guidance

Oxfordshire PCT is now part of the NHS Buckinghamshire and Oxfordshire Cluster; this policy sets out the arrangements for NICE Implementation within Oxfordshire PCT.

1) Introduction and background

The National Institute for Health and Clinical Excellence (NICE) provides guidance, sets quality standards and manages “NHS Evidence” (the national database) to improve people’s health and prevent and treat ill health. NICE makes recommendations to the NHS on:

- new and existing medicines, treatments and procedures
- treating and caring for people with specific diseases and conditions.

NICE makes recommendations to the NHS, local authorities and other organisations in the public, private, voluntary and community sectors on:

- how to improve people's health and prevent illness and disease.

(Source: www.nice.org.uk/aboutnice/about_nice.jsp)

This revised policy is being issued because of changes to Oxfordshire PCT’s role. Until April 2011, the PCT had dual commissioning and provider roles and was subject to inspection, in respect of NICE implementation, by the NHS Litigation Authority (NHSLA) through the Risk Pooling Scheme for trusts and the Care Quality Commission (CQC) through Standards for Better Health. NHS providers continue to be monitored by the NHSLA and the CQC in respect of how they implement NICE guidance.

The PCT is not now subject to these monitoring mechanisms in its commissioning-only role. However, the PCT must still fulfil its responsibilities in relation to NICE guidance and, in accordance with sound governance principles, have systems in place to demonstrate that it is doing so. Failure to ensure that Technology Appraisal Guidance (TAGs) are implemented and that due account is taken of other NICE guidance would expose the board to significant risk.

PCTs and NHS trusts are obliged by statutory Direction, to ensure that funding is made available for treatments recommended by NICE Technology Appraisal Guidelines (**TAGs**) within three months of publication, unless otherwise directed by the Secretary of State. TAGs make recommendations on the use of new and existing drugs and treatments in the NHS.

Whilst other NICE guidance is not mandatory, it must be taken into account when commissioning and delivering services.

Regulatory framework

In managing NICE implementation and monitoring, Oxfordshire PCT must take account of relevant Department of Health and NHS directions and guidance in addition to NICE guidance itself, because of the direct and indirect references to NICE guidance which they contain. These include:

- NHS directions/guidance (see “*Good Practice Guidance on Managing the Introduction of New Healthcare Interventions and Links to NICE Technology Appraisal Guidance*,” Dept. of Health, December 2006)
- NHS Constitution
- NHS Operating Framework
- NHS Outcomes Framework
- The Quality, Innovation, Productivity and Prevention programme (QIPP)

2) Purpose

This policy provides a framework so that the Board can be assured that systems are in place:

- For the evaluation of NICE guidance;
- To ensure that due weight is given to NICE guidance as part of the PCT’s work in meeting its statutory obligations, its core aims and in delivering on objectives set by the Department of Health;
- Which enable the PCT to meet its specific statutory obligation to facilitate the implementation of TAGs by its providers. The NHS Constitution describes the right of patients to have access to drugs in line with NICE TAG recommendations;
- To agree with providers a suitable level of monitoring and auditing of NICE guidance;
- To survey forthcoming NICE guidance to assist the PCT in its financial planning.

PCT activities which need to take account of NICE include:

- Service re-design
- Clinical Pathways
- Referral guidelines
- ‘Lavender’ Policy Statements
- Contracts with providers
- Partnership working with non-NHS organisations

3) Definitions

There are currently seven types of **NICE guidance**

- **Cancer Service Guidance (CSG)**: Guidance on the way services are organised for the treatment of different types of cancer.

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- **Clinical Guidelines (CG):** Guidance on the treatment and care of people with a specific disease or condition in 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.
- **Diagnostics Guidance (DG):** DGs are designed to help the NHS adopt efficient and cost effective medical diagnostic technologies more rapidly and consistently. The PCT's Policy Statement on [Diagnostics Guidance](#) can be found in Appendix 1 of this document.
- **Interventional Procedures Guidance (IPG):** IPGs indicate whether an interventional procedure is safe enough and works well enough to be used in the NHS. The term 'interventional procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or a body cavity. The PCT's Policy Statement on [IPG Implementation](#) can be found in Appendix 1 of this document.
- **Medical Technologies Guidance (MTG):** MTGs are 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. The PCT's Policy Statement on [Medical Technologies Guidance](#) can be found in Appendix 1 of this document.
- **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). Guidance produced by other NICE guidance programmes occasionally makes recommendations that could improve health or prevent disease.
- **Technology Appraisals Guidelines (TAG):** TAGs makes recommendations on the use of new and existing drugs and treatments in the NHS. If NICE recommends a drug or treatment for a particular condition, the NHS has to make it available for patients with that condition if it is suitable for them. PCTs and NHS trusts are obliged by statutory Directions, to ensure that funding is made available for treatments recommended by NICE TAGs within three months of publication, unless otherwise directed by the Secretary of State. This obligation is restated in the NHS Constitution, published in March 2010. The PCT Policy on [TAG implementation](#) can be found in Appendix 1

- **Quality Standards** NICE also now publishes Quality Standards (QS). These are sets of specific, concise statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions. Whilst QSs are not requirements or targets, the care system is obliged to have regard to them in planning and delivering services.

4) Accountability and responsibility

Chief Executive Officer

The Chief Executive Officer (CEO) holds ultimate accountability for adherence to the NICE Policy and ensuring that there are sufficient resources for the implementation of this policy. The CEO is responsible for ensuring this policy is consistent with statutory legislation and is implemented. Operational responsibility is delegated.

Director of Finance

The Director of Finance is responsible for ensuring that:

- Funds are available to meet the PCT's responsibilities to implement NICE
- There is financial scope for in year contract variations for new NICE guidance

Consultant in Public Health Medicines (Healthcare Priorities)

The Consultant in Public Health Medicines (Healthcare Priorities) has delegated authority and manages the work of the NICE Implementation Principal.

NICE Implementation Principal

The NICE Implementation Principal is responsible for:

- Monthly dissemination of new NICE guidance within the organisation;
- providing specialist knowledge and strategic advice to the PCT on NICE guidance and, where relevant the implications for financial planning, the commissioning process and contract monitoring;
- providing strategic updates to the PCT on forthcoming NICE Guidance to inform its commissioning agenda;
- ensuring that timely and relevant advice is given to the Director of Finance regarding the financial implications of published and anticipated guidance for incorporation in the PCT's financial planning;
- producing an Annual Report on PCT activity in relation to NICE implementation and monitoring.

Commissioning Managers:

Those commissioning services have an obligation to demonstrate that due cognisance is taken of NICE guidance when drawing up service specifications and negotiating contracts. They must also ensure that specifications and contracts allow for an appropriate level of monitoring and auditing of compliance with NICE Guidance.

The Oxfordshire PCT Commissioning Quality Sub-Committee (CQSC)

The Oxfordshire PCT Commissioning Quality Sub-Committee is accountable to the Board for ensuring that the PCT fulfils its obligations regarding NICE guidance and Quality Standards.

Oxfordshire PCT NICE (Implementation) Group

Oxfordshire PCT NICE (Implementation) Group is an operational committee. It reports to the CQSC on its remit:

- To receive and appraise formal updates from the NICE Implementation Principal on forthcoming and newly published NICE guidance –the potential cost or savings potential and the commissioning implications
- To recommend areas for the monitoring and auditing of NICE guidance by the PCT's providers on an annual and ongoing basis
- To appraise audits carried out by the PCT's providers of NICE Guidance and to make recommendations arising from its appraisals

5) Process for monitoring compliance and effectiveness of the policy

The processes described in this policy will be reviewed on an annual basis at the NICE Implementation Group meeting. Discuss at next meeting. The review will comprise a range of potential sources of assurance including the NimpG minutes, the Implementation of NICE annual report, the programme of audits undertaken and the NIMPg review of audit outcomes.

6) Process for review of this policy

This policy will be reviewed every three years or where necessary for example, in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance.

7) Equality Impact of policy

NHS Oxfordshire NICE Group considers that the due regard has been given to the requirements of the Equality Duty as defined in the Equality Act, 2010 in drawing up this policy. It recognises its responsibility to ensure that no-one is unlawfully discriminated against on the following grounds

- *age*
- *disability*
- *gender reassignment*
- *pregnancy and maternity*
- *race – this includes ethnic or national origins, colour or nationality*
- *religion or belief – this includes lack of belief*
- *sex*
- *sexual orientation*

The Group does not consider that the policy unlawfully discriminates against the above groups either directly or indirectly. The Group considers that the

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policy does not infringe the other responsibilities NHS Oxfordshire has under the Act namely to;

- *advance equality of opportunity and*
- *foster good relations across all of the protected characteristics*

Appendix 1

PCT Policy Statement 115a: Implementation of NICE Interventional Procedures Guidance (IPGs)

PCT Policy Statement 143: Funding of NICE Technology Appraisals within three months of publication

PCT Policy Statement 200: Implementation of NICE Medical Technologies Guidance (MTGs) and Diagnostic Technologies Guidance (DTGs)

**Oxfordshire Priorities Forum
(NHS Oxfordshire)****Policy Statement 115a: Implementation of NICE Interventional Procedures
Guidance (IPGs)****Clinical Executive decision: Approved March 2008, May 2010****Date of issue: March 2008, updated May 2010**

The use of any intervention assessed by NICE under their IPG programme is a LOW PRIORITY and not normally funded by the Oxfordshire PCT unless:

- *the intervention has been categorised by NICE as 'safe and efficacious' and the clinical governance arrangements have been described as 'Normal';*

AND

- *funding has been agreed by commissioners through the funding route detailed below.*

Funding route

PCTs have no statutory duty to fund the use of interventions assessed under NICE's IPG programme. Oxfordshire PCT will only consider funding of interventions categorised by NICE IPGs as requiring 'Normal' clinical governance arrangements (see *categorisation below*). To obtain funding, a business case must be submitted to Oxfordshire PCT in advance of the intervention's use OR an evidence review must be taken through the Priorities Committee. This requirement applies even if the intervention is included in Tariff.

Regardless of equivalent cost, the PCT will not commission the use of interventions that are less effective or pose a greater risk to patients than standard interventions.

Trusts wishing to undertake research associated with the use of IPG interventions must apply for research funds in the usual way.

Oxfordshire PCT will not usually accept business case applications for IPGs categorised other than 'Normal'.

NICE IPGs take account of safety and efficacy but do not consider the cost or cost-effectiveness of a procedure. NICE IPGs indicate the circumstances in which an intervention *might* be used and provide a process as to *how* it might be used (which must be followed if the IPG is implemented). However, NICE IPGs do not make recommendations as to whether the intervention *should* be used.

Interventional Procedure Guidance Categorisation

NICE IPGs assess the evidence of safety and efficacy and categorise the clinical governance arrangements required if an intervention is to be used, as follows:

1. Normal
2. Special
3. Other
4. Research only
5. Do not use

1. Potentially exceptional circumstances may be considered by the patient's PCT where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living.)

2. This policy will be reviewed in the light of new evidence or guidance from NICE.

3. The Oxfordshire Priorities Forum lavender papers can be viewed at www.oxfordshire.nhs.uk/oxfordsetting.asp

South Central Priorities Committee
(Oxfordshire PCT)

Policy Statement 143: Funding of NICE Technology Appraisals within three months of publication

Clinical Executive decision: September 2009

Date of issue: September 2009

NICE TAGs will normally be funded by Oxfordshire PCT three months from the date of publication, in line with National Health Service Act (1977) Directions (2003).

Decisions to provide funding earlier may be made, as an exception, by the PCT's Clinical Executive, after consideration of the specific circumstances and taking into account the South Central Ethical Framework.

Directions under *The National Health Service Act 1997* are in force, stating that Primary care Trusts have a statutory duty to provide funding for NICE Technology Appraisals (TAGs) not later than three months from the date of publication.

Occasionally, additional Directions relating to a specific TAG are published, which modify this requirement by removing the funding direction altogether or extending it for a varying period of time.

Horizon scanning and the publication of the NICE consultations documents, including the Final Appraisal Document, alert Oxfordshire PCT and NHS-funded health care providers to the probability of a positive recommendation by NICE. However, draft documents cannot provide the basis for timing changes in services and policies. In some cases the appraisal consultation leads to significant changes in the final guidance. Also, it is not uncommon for the publication of the final TAG to be delayed following consultations and appeals.

NOTES:

1. Potentially exceptional circumstances may be considered by the patient's PCT where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living.)
2. This policy will be reviewed in the light of new guidance from the Department of Health.
3. The Oxfordshire Priorities Forum minutes and policies can be viewed at www.oxfordshire.nhs.uk/ordthysetting.asp

**NHS Oxfordshire
Commissioning policy**

Policy Statement 200: Implementation of NICE Medical Technologies Guidance (MTGs) and Diagnostic Technologies Guidance (DTGs)

Clinical Executive decision: Approved February 2011

Date of issue: March 2011

NHS Primary Care Trusts have no statutory duty to fund the use of the technologies assessed under the National Institute for Health and Clinical Excellence (NICE) Medical Technologies Guidance (MTG) and Diagnostic Technologies Guidance (DTG) programmes.

*NHS Oxfordshire has considered these types of NICE guidance, and agreed that the use of any medical or diagnostic technology assessed by NICE under their MTG and DTG programmes is a **LOW PRIORITY** and not normally funded by NHS Oxfordshire unless:*

- 1. NICE has stated "The case for adoption within the NHS as described is supported by the evidence"*
- AND*
- 2. funding has been agreed by commissioners through either of the funding routes detailed below.*

Funding – provision of a business case

NICE MTGs and DTGs review the clinical and cost impact evidence for a technology compared with currently available technologies. NICE indicates the circumstances in which a technology *might* be used; they do not make recommendations as to whether the technology *should* be used, and do not override clinical judgement for any individual patient.

To obtain funding, in advance of the use of a medical or diagnostic technology supported by NICE:

- the provider must submit a business case to NHS Oxfordshire for approval

OR

- NHS Oxfordshire agrees to commission the technology following consideration of an evidence review and positive recommendation by the Priorities Committee.

NB This approval process applies even if the technology is included in tariff.

1. Potentially exceptional circumstances may be considered by the patient's PCT where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living.)
2. This policy will be reviewed in the light of new guidance from NICE or other relevant national body
3. Minutes of the Priorities Committee meetings can be viewed at <http://www.oxfordshirepct.nhs.uk/professional-resources/default.aspx>.

NICE Quality Standards Process Flowchart

Buckinghamshire and Oxfordshire Cluster

NICE Quality Standards released

1 week

Quality standards added to NICE update and sent to Priorities Group. QCS NICE rep to check NICE update for new standards

2 weeks after QCS informed

QCS Identify a PCT/OCCG Lead and report back to NICE group

PCT/OCCG leads Identify provider lead e.g. Medical Director/Consultant Lead

Clock stopped if lead not found. Max 3 months

If no PCT/OCCG lead identified or a significant amount of work required then Executive Team alerted for a decision. Decision to OCCG TB for ratification.

4 weeks after QCS informed

PCT/OCCG leads work with provider lead to Identify work required to meet standard

2 months after QCS informed

PCT/OCCG Lead develops action plan including timescales, outcomes and monitoring arrangements. Plan submitted to
 a) NICE group for comment, then
 b) OCQC for agreement.
 Progress monitored via OCQC

Once all actions in place OCQC closes plan apart from ongoing monitoring.

Adherence to Quality Standard will be monitored through

- ▶ performance indicators
- ▶ targeted audits.
- ▶ 6-monthly updates to OCCG TB.
- ▶ Annual report to OCQC/OCCG TB.

LC to report back to NICE Group.