SOP21
Review and Implementation of NICE Guidance

Appendices

Appendix	Details
Appendix 1	The Identification and Implementation process for NICE Guidance (exc. TAGS)
Appendix 2	The Identification and Implementation process for NICE Technology Appraisal Guidance (TAGs) only
Appendix 3	Implementation of NICE Approved Drug form

1.0 Procedure Statement

The purpose of this procedure is to ensure that there are robust processes in place for the review and implementation of best practice of new and existing NICE Guidelines to satisfy the following requirements.

- The Trust database is kept up to date and monitored appropriately.
- The Trust can provide assurance to commissioners of due process.
- There will be a standardised approach to the review, implementation, and compliance of NICE recommendations.

2.0 Definitions

2.1 National Institute for Health and Care Excellence (NICE) guidance.

NICE guidelines are evidence-based recommendations for health and care in England. They set out the care and services suitable for most people with a specific condition or need, and for people in particular circumstances or settings. NICE guidelines help health and social care professionals to prevent ill health.

3.0 Accountabilities

3.1 Trust Board

The Trust Board is responsible for ensuring that the Trust complies with relevant national best practice and mandatory standards published by NICE.

3.2 The Chief Executive (CEO)

The CEO is responsible for ensuring that NICE Guidance recommendations are effectively and efficiently managed.

3.3 Trust NICE Implementation Leads

The Trust NICE Implementation Leads are responsible for the review of the internal NICE register, for assessing the relevance of NICE guidance the Trust and ensuring that there is an

appropriate nominated lead for a review and response to all guidance identified as applicable. For receiving information from other responsible groups on the implications. They are also responsible for providing a report and an exception report to the Medicines Management Group, Quality and Safety Advisory Group and for ensuring guidance is implemented as fully as possible. Appropriate NICE guidance (assessed on a risk-based approach) will be allocated to the Annual Directorate Clinical Audit Plans

3.4 **Divisional Medical Directors** are responsible for assessing the relevance of NICE guidance to the Trust and ensuring that there is an appropriate nominated lead for all guidance identified as applicable.

3.5 **The Divisional Management Team** is responsible for the scrutiny and challenge of assurance given for each piece of NICE guidance at Divisional level. They are also responsible for approval or submission of business case for the Implementation of NICE Approved Drugs form within timescales in relation to any NICE Technology Appraisal Guidance (TAG) adopted by the Trust. See appendix 2**.**

All of the above should be reflected in the minutes of the relevant meeting. Divisions are accountable to produce any evidence and assurance of guidance status as required.

3.6 **The Directorate Management Team** (Clinical Director/Directorate Manager/Group Manager)

For NICE Guidance (NG) and Clinical Guidelines (CG) a baseline assessment tool produced by NICE is to be completed by the nominated lead and held locally.

For NICE TAGs an Implementation of NICE Approved Drug Form (See section 4.4 for further detail about completion of this form)

All of the above should be reflected in the minutes of the relevant meeting. Directorates are accountable to produce any evidence and assurance of guidance status as required.

Directorates to present NICE guidance that hit a barrier initially to Divisional Management Team, NICE Implementation Group and NICE TAG Assurance Group.

3.7 **The Nominated Lead** is responsible for reviewing the NICE guideline and submitting a response within timescales and for providing timely updates for monitoring to completion. The initial response to Governance Officer must identify any gaps, rationale or assurance of planned actions required either on the NICE proforma, in an email or an action plan/gap analysis.

3.8 **The Quality Assurance Administrator** will be alerted to or will search NICE websites for new publications and must disseminate the NICE guidance, and relevant documents to nominated leads for a response.

3.9 **Governance Team Leader** are responsible for overseeing implementation processes at directorate level and for providing timely compliance and exception reports to Division (via the Healthcare Governance Managers). They must ensure that appropriate guidance is proposed for inclusion on directorate Clinical Audit Plans.

3.10 **Governance Officers** are responsible for supporting directorates in understanding their position and progress with NICE guidance implementation. They must provide exception reports for review at the appropriate directorate governance meetings. They must keep the Trust central database system updated with information regarding implementation and audit status.

3.11 **NICE Implementation Group** is chaired by the Trust NICE Implementation Lead (exc.

NICE TAGs) and provides assurance on NICE guidance to Quality and Safety Advisory Group

3.12 **NICE TAG Assurance group (NAG)** is chaired by the Trust NICE Implementation Lead for TAGs only and will report to the Medicines Management Group (MMG) as a standing agenda item and provides assurance in NICE TAGs to Quality and Safety Advisory Group.

3.13 **Quality and Safety Advisory Group (QSAG)** is responsible for the monitoring and review of NICE implementation, providing assurance to the Quality Committee (QC).

4.0 Procedure Detail / Actions

This procedure refers to central monitoring of all NICE Guidelines

Directorates will escalate any local guidance that may require review by Divisional Management Team, and, if required, the Divisional Management Team will escalate to Quality and Safety Advisory Group

4.1 Implementing guidance NOT supported/recommended by NICE

- Clinicians must escalate via directorate/Division/NIG that details:
- The proposed procedure.
- How they will ensure that patients understand the risks/uncertainty about the procedure's safety and efficacy.
- What clear written information and counselling support both before and after the procedure will be offered to the patient.
- How audit and review of the clinical outcomes of all patients undergoing NICE non approved procedures will be completed.
- Risk assessment scoring (as per OP10).

For implementation of a new procedure refer to –

OP95 Introduction of New Clinical Techniques and Interventional Procedures

http://intranet.xrwh.nhs.uk/pdf/policies/OP_95_Policy_printable_version.pdf

4.2 Non implementation recommended by NICE

Where the nominated lead feels that the NICE guidance cannot be implemented, the NICE proforma must be completed identifying the reasons for non-implementation. An update to be provided to the NICE Implementation Group and NICE TAGs Assurance Group

4.3 Intervention Procedure Guideline (IPG)

If the procedure is to be implemented or implemented at a later date, the nominated lead must advise Governance, following the NICE Process and the Implementing New Procedures Policy. See OP95 Introduction of New Clinical Techniques and Interventional Procedures

4.4 Assessing the financial implications

Where the service is required to be compliant with the NICE TA, the nominated lead with the support of the directorate pharmacist, the directorate management team and the clinical finance accountant) must ensure an Implementation of NICE Approved Drug form is completed and submitted for approval. Refer to Appendix 3 (Implementation of NICE Approved Drugs form).

The formulary process for the addition of a medicine to the Black Country Formulary is managed by the Black Country Joint Formulary Group, independent of the trust process for the approval of NICE TAs. Therefore, regardless of the formulary status of the medicine on the Black Country Formulary, an Implementation of NICE Approved Drug form must be completed, submitted and approved at trust level before the medicine can be made available to the service and eligible patients.

NICE TAGs, where appropriately applied to the patient population, will be funded by the responsible commissioner within three months from the date of publication. For certain NICE TAs, funding may be made available within 30 days from the date of publication.

Where a business case is required for the implementation of the NICE guidelines including NICE TAG, standard trust processes for business cases should be followed.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation of this policy require additional revenue resources	No
3	Does the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	No

6.0 Equality Impact Assessment

This Procedure has been assessed as not affecting the equality and diversity of any one group or person. Implementation of accountabilities and responsibilities applies to all staff.

7.0 Maintenance

It is the responsibility of the Trust NICE Implementation Lead and the Quality Assurance Officer to review the Procedure every 3 years.

8.0 Communication and Training

Communication of this Procedure will be through the following routes:

- Trust Intranet policies and procedures available to staff.

9.0 Audit Process

All guidance status will remain partially compliant until the necessary actions have been completed or the guidance has been signed off at Directorate / Divisional / NICE Implementation Group/NICE TAG Assurance Group

Criterion	Lead	Monitoring	Frequency	Committee / Group
NICE Guidance	Trust NICE Lead/s	Central database system	Bi-annual	Quality and Safety Advisory Group

10.0 References

- RWT Risk Management Assurance Strategy
- OP10 Risk Management and Patient Safety reporting Policy
- OP 95 Introduction of New Clinical Techniques and Interventional Procedures
- Care Quality Commission – CQC Key Question – Effective and Well Led
- NICE Website: **http://www.nice.org.uk/**

Part A - Document Control

Operational Procedure reference: SOP21 (Previously OP56)	**Operational Procedure Title:** Review and Implementation of NICE Guidance	**Status:** Final	**Author:** Trust NICE Leads- Dr R McCathie/ Dr B Ramakrishna **Chief Officer Sponsor:** Chief Medical Officer

Version / Amendment story	**Version**	**Date**	**Author**	**Reason**
	3.0	August 2025	Trust NICE Implementation Leads	Full review of SOP21, rewording of NICE Guidelines, update to include new TAG process and update of associated Appendices The removal of National Guidance NCEPOD procedure
	2.2	May 2025	Trust Clinical NICE Implementation Lead	Extension
	2.1	Jan 2022	Trust Clinical NICE Implementation Lead	Appendix 3 Implementation of NICE Approved Drugs (Minor amendment to headings Drug costs, Activity cost and Finance approval added)
	2.0	December 2021	Trust Clinical NICE Implementation Lead	Change in NICE audit process Minor wording amendments
	1.3	September 2020	Trust Clinical NICE Implementation Lead	Change to the number of TA NICE audits to be undertaken by Oncology & Haematology Removal of commissioners NICE Assurance Group Minor wording amendments
	1.2	Sept 2019	Trust Clinical NICE Implementation Lead	Change to the number of TA NICE audits to be undertaken by Oncology & Haematology
	1.1	March 2019	Trust Clinical NICE Implementation Lead	Changes to the NICE audit process, Technology Appraisal Guidance (TAG) implementation of NICE approved drugs template and review of divisional exception reports
	1	March 2018	Trust Clinical NICE Implementation Lead	OP56 Review and Implementation of NICE Guidance and OP64 Guidance to a combined standard operating procedure

OP56	V5.2	May 2016	Compliance Officer	NICE TAG Proforma Revised TAG process and financial impact
	V5.1	Dec 2015	Compliance Officer	Updated NICE proforma
	V5	October 2014	Quality Assurance Officer	Scheduled Review
	V4.1	June 2013	Governance Standards Lead	NICE Proforma Appendix 4 updated to include reference to Quality Standards throughout form
	V4	October 2011	Governance Standards Lead	Minor amendment
	V3	October 2009	Governance Standards Lead	Review
	V2	March 2008	Governance Standards Lead	Review
	V1	April 2006	Governance Standards Lead	Introduction

Intended Recipients: All staff	
Consultation Group / Role Titles and Date: June 2025 Dr Ramakrishna, Trust NICE Lead Dr R McCathie, Trust NICE Lead Tajender Athwal, Quality Assurance Lead Justin Samuels, Principal Pharmacist - Clinical Commissioning, Homecare and Blood-borne Viruses Joanne Colgan, Division 1 Governance Healthcare Manager Kelly Emmerson, Division 2 Governance Healthcare Manager Joanne Hughes, Division 3 Governance Healthcare Manager	
Name and date of Trust level committee where reviewed	August 2025
Name and date of final approval committee	Trust Policy Group - August 2025
Date of Procedure issue	September 2025

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	August 2028 (3 years)

Training and Dissemination:

Communication of this procedure will be through the following routes:

Management Team Members: to agree and advise all Directorates and Departments of its implementation.

Trust Intranet Policies – Available to staff.

Publishing Requirements: Can this document be published on the Trust's public page:

Yes

If yes you must ensure that you have read and have fully considered it meets the requirements outlined in sections 1.9, 3.7 and 3.9 of OP01, Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines, as well as considering any redactions that will be required prior to publication.

To be read in conjunction with:

RWT Integrated Governance Strategy

OP10 Risk Management and Patient Safety Reporting Policy

OP 95 Introduction of New Clinical Techniques and Interventional Procedures

Initial Equality Impact Assessment (All policies): Completed Yes

Full Equality Impact Assessment (as required): Completed No

If you require this document in an alternative format e.g., larger print please contact Central Assurance Team

Contact for Review	Trust Clinical NICE Implementation Lead / Trust NICE TAG Lead/Quality Assurance Officer
Implementation plan / arrangements (Name implementation lead)	Trust Clinical NICE Implementation Lead / Trust NICE TAG Lead/Quality Assurance Officer
Monitoring arrangements and Committee	NICE Implementation Group/ NICE TAG Assurance Group Quality and Safety Advisory Group (QSAG)

Document summary / key issues covered:

This procedure document states the Royal Wolverhampton NHS Trust requirements for review and implementation of NICE

Key words for intranet searching purposes	NICE Guidance

High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g., contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk, it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee	**No**

VALIDITY STATEMENT

This document is due for review on the latest date shown above. After this date, policy and process documents may become invalid. The electronic copy of this document is the only version that is maintained. Printed copies must not be relied upon to contain the latest updates and amendments.

Process for Identification & Implementation of NICE Guidance (Exc. Technology Appraisals Guidelines (TAGs))

NICE Guidance is published monthly on NICE website - Link - Published guidance, NICE advice and quality standards | Guidance | NICE

Quality Assurance Team issues guidance list to the Trust NICE Leads/Divisional Medical Director(s) monthly to assess relevance and allocation of Trust leads.

Relevant

Not Relevant to Trust

Quality Assurance updates database with response

Quality Assurance Administrator sends email with response timescales plus links to relevant documents to nominated Lead

Nominated Lead completes relevant NICE documents indicating implementation status, gaps and actions required and returns to their Governance Officer within timescales
Any risks identified due to non-compliance with the recommendations must be considered for entry onto the appropriate Risk Register (Directorate/Divisional/Trust)

NICE Implementation status and action required

Not Applicable

Provide rationale for status

Not Implemented-Other

If guidance NOT implemented but recommended OR Implemented and NOT recommended by NICE – nominated Lead must provide rationale and assurance to Division, NIG, NAG

Partial - actions required to achieve compliance

Provide assurance to Governance Officer of the planned actions with action timescales for implementation

For Interventional Procedure guidelines (IPG) implementation of a new procedure. Lead must refer to OP95 Introduction of New Clinical Techniques and procedures

A Risk Evaluation Form must be produced by the guidance lead for all NICE Guidance open >12 months

Compliant – Gaps in Compliance Accepted.

Complete appropriate form to provide rationale of not being able to fully implement. To be taken to Division for approval of gaps in compliance accepted following which to be taken to Trust NICE Implementation Group for approval of gaps in compliance accepted.
A request may be made for a review of status in 12 months

Fully Implemented

Maintain evidence of implementation & ensure guidance is reviewed and prioritised on a risk based approach for audit within 2 years

NICE status change following an audit outcome of 'moderate non-compliance' or 'significant non-compliance' must be approved by the NICE guidance Lead, a re-audit to be undertaken within 12 months

NICE guidance monitoring of action status is via Directorate, Divisional governance meetings, NICE Implementation Group (NIG), NICE TAG Assurance Group (NTAG) and Quality Standards Advisory Group (QSAG)
Governance Officers update database and monitor actions to completion. Governance Officers/Governance Team Leader to produce compliance status reports to relevant Division, Directorate groups and NIG. Trust NICE Lead/s to Quality Standards Advisory Group

TIMELINE	ACTION
1st working day of each month	Quality Assurance Team download list of previous month's published Guidance AND circulate the list of NICE Technology Appraisals (TAGs) to Divisional Medical Directors (DMDs), Trust NICE Lead and Principal Pharmacist- Clinical Commissioning
External deadline: 90+ days or 30 day from publication Internal deadlines (no later than): - **Directorate approval-** Day 1 to 30 - **Divisional approval** – Day 31 to day 60	Trust NICE Lead, DMDs and Principal Pharmacist assign nominated consultant/service leads for a response AND Directorate pharmacist (awareness only); Data system to be updated by Quality Assurance Team
	Quality Assurance Team share paperwork, approval process and deadline for response to the service leads; directorate management team, pharmacist and Governance Officer (GO) to be cc'd in; GO to update data system
	Nominated consultant and directorate pharmacist completes NICE TA Proforma and forwards to Directorate management team and GO cc'd in; GO to update Inphase
	Directorate management team and Finance review and submit for approval at Divisional Governance or appropriate forum (by exception depending upon urgency); GO to update data system
	Division to determine if NICE TAG can be implemented within current resources or requires additional business case to implement; If no business case is required, NICETAG approved by Division, Pharmacy can make drug available. OR If Business case is required , NICE proforma submitted to CIG and GMC for approval; GO cc'd in to update data system
Day 61 to 90	Submit business case to pre-screen CIG for review and submission to GMC; GO cc'd in to update data system
	If agreed at CIG, business case team will forward on NICE TA to GMC for financial approval and outcome from GMC to be shared with Pharmacy and Assurance team (operational). Queries/challenges to be fed back to Division. GO to update data system with outcome

Implementation of NICE Approved Drugs

Section 1:						
NICE TA Title & Number						
NICE TA Published Date:						
NICE TA Implementation Due Date:						
Contact Details	**Name of nominated lead submitting:**		**Name of supporting directorate pharmacist:**		**Name of directorate finance manager:**	
	Job Title:		**Job Title:**		**Job Title:**	
	Directorate:		**Directorate:**		**Directorate:**	
	Tel:		**Tel:**		**Tel:**	
	Email:		**Email:**		**Email:**	

Section 2: To Be Completed by Nominated Lead		
NICE Recommendations:		
Is this drug a: NB: If a drug is a 'replacement' or 'alternative option', provide the name of the current lead/comparator drug in line with national or local guidance/ treatment pathways.	**Replacement**	☐ Yes ☐ No
	If yes, what is this replacing?	
	Alternative option	☐ Yes ☐ No
	If yes, please provide details:	
	New indication:	☐ Yes ☐ No
	Additional option	☐ Yes ☐ No
Number of Patients requiring treatment: NB: this is an estimate based on data in the TA and local knowledge.	**Number of Patients eligible to start treatment at baseline:**	**Number of Patients Per Year (cumulative):** Year 1 – Year 2 – Year 3 –
Is this drug only available as part of a commissioned service?	☐ Yes ☐ No ☐ TBC If TBC, this should be confirmed at Divisional Governance	
If yes to the above, is RWT commissioned to provide this service?	☐ Yes ☐ No ☐ TBC If TBC, queries relating to RW-commissioned services should be raised with the RWT Contracts and Commissioning (rwh-tr.contractqueries@nhs.net) and/or this should be confirmed at Divisional Governance.	
Are the estimated number of patients eligible for treatment different to NICE TA estimates?	☐ Yes ☐ No	
	If yes, please explain the reasoning for this:	

Section 3:To Be Completed by Directorate Pharmacist	
How is this drug dispensed/supplied?	☐ Inpatient Pharmacy ☐ Outpatient Pharmacy ☐ Homecare ☐ Pharmacy Aseptics ☐ Other (please specify):

What is the dosage, frequency and duration/number of treatment cycles for this drug?	***Please show workings out:***	
What is the mode of delivery?	☐ IV ☐ SC ☐ IM ☐ Oral ☐ Other (please specify):	
Is this drug a pass-through cost to Commissioners?	☐ **Yes** ☐ **No** If Yes: a) which commissioners: ☐ NHSE ☐ ICB ☐ CDF b) what is the funding arrangement ☐ C+V ☐ Block c) is prior approval (Blueteq) required ☐ Yes ☐ No ☐ TBC	
What is the cost of this drug? **NB:** - Apply the maximum associated drug cost for dose, frequency and treatment duration - Pharmacy Procurement team to confirm trust contract prices - Costs must be calculated to **exclude VAT** but VAT will be applied by RWT Finance team where applicable	**Cost of Medicinal Form per pack (£):**	
	Cost per Treatment per patient per year or cycle (£):	
	Please show workings out:	
Cost of drug being replaced or alternative option: The costs provided must be based on the current lead/comparator drug in line with national or local guidance/ treatment pathways.	**Cost of Medicinal Form per pack (£):**	
	Cost per Treatment per Year or cycle (£):	
	Please show workings out (£):	

Section 4: Resource Assessment- To Be Completed by Directorate Management Team (including Finance)		
Is there any impact on activity or resource required? *i.e. Does this guidance have significant impact on the patient pathway or require additional resource in order to implement?*	☐ Yes	☐ No
	If yes, please provide details:	
Resource Impact *(finance to complete)*		

Section 5: Submission		
Submitted by:	**Clinical Director**	**Date:**
	Directorate Manager	**Date:**
Section 6: Approval		
Outcome (see status and description below)	☐ Approved- full implementation * ☐ Action Required**	
Approved by:	**Divisional Sign Off**	**Date:**
	Contracting and Investment Group	**Date:**
	Trust Management Committee	**Date:**

Status	Description
***Fully Implemented**	All aspects of the guidance are applicable and to be implemented within the Trust. Pharmacy will make available any medicines which are prescribed as part of a commissioned/approved service and in line with a positive NICE Technology Guidance within the timeframe of implementation.
****Action Required**	There are issues preventing implementation i.e. funding, staffing, equipment or other resources. Complete TAGS NICE proforma/process (appendix 2) as per trust procedure[1]

References

1. SOP21 Review and Implementation of NICE Guidance