

Chief Medical Officer
Professor Sir Michael McBride

Circular HSC (SQSD) 12/22

Subject: NICE Technology Appraisals - Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland

For action by:

Chief Executive of Public Health Agency – **for distribution to:**
Director of Public Health and Medical Director – for cascade to relevant staff
Director of Nursing and AHPs – for cascade to relevant staff

Chief Executives of HSC Trusts – **for distribution to:**
Medical Directors – for cascade to relevant staff
Directors of Nursing – for cascade to relevant staff
Heads of Pharmaceutical Services – for cascade to relevant staff
Directors of Acute Services – for cascade to relevant staff
HSC Clinical and Social Governance Leads
Directors of Finance – for cascade to relevant staff

Chief Executive, Regulation & Quality Improvement Authority – **for cascade to:** relevant independent healthcare establishments

Chief Executives of HSC Special Agencies and NDPBs

For Information to:

Chair of Public Health Agency
Chairs of HSC Trusts
Chair of RQIA
Chief Executive Patient and Client Council
Chief Executive/Postgraduate Dean, NIMDTA
Chief Executive, NICPLD
Chief Executive, NIPEC
NICE Implementation Facilitator NI
Members of NI NICE Managers' Forum

Summary of Contents:

The purpose of this circular is to explain the revised arrangements for the endorsement, implementation, monitoring and assurance of NICE Technology Appraisals in NI.

Enquiries:

Any enquiries about the content of this Circular should be addressed to:
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Related documents:

HSC (SQSD) 13/22

Superseded documents

HSC (SQSD) 2/13

Status of Contents:

Action

Implementation:

Effective from 1st April 2022

Additional copies:

Available to download from
<https://www.health-ni.gov.uk/topics/safety-and-quality-standards/national-institute-health-and-care-excellence-nice>

Dear Colleagues

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)
TECHNOLOGY APPRAISALS – PROCESS FOR ENDORSEMENT,
IMPLEMENTATION, MONITORING AND ASSURANCE IN NORTHERN IRELAND**

Introduction

1. This Circular HSC (SQSD) 12/22, updates and replaces Circular HSC (SQSD) 2/13 which sets out the process for the endorsement, implementation, monitoring and assurance of NICE Technology Appraisals in Northern Ireland (NI). The circular has been updated in order to reflect the migration of the Strategic Planning and Performance Group (SPPG), formerly the Health and Social Care Board (HSCB), into the Department of Health. This circular sets out the NI process for Technology Appraisals, where NICE recommends whether or not a drug, medical device or surgical procedure should be funded by the NHS, based on its cost-effectiveness.
2. These arrangements will be effective from **1st April 2022** and will apply to all HSC organisations, including Family Practitioners. It should also be noted by independent health and social care providers.
3. It will be the responsibility of HSC organisations, under the statutory duty of quality as specified in Article 34 of the HPSS (Quality, Improvement and Regulation) (NI) Order 2003, to put in place the necessary systems, which should include adequate and comprehensive dissemination, as part of their clinical and social care governance arrangements, for implementing NICE guidance.

Background

4. NICE is a Non Departmental Public Body tasked with producing national guidance on the promotion of good health and the prevention

and treatment of ill health, as well as having recently taken on responsibility for developing guidance and quality standards in social care.

5. NICE guidance to promote clinical excellence and the effective use of resources for people using the NHS is designed for use in England and, as such, does not automatically apply in NI.
6. The Department established formal links with NICE on 1 July 2006 whereby guidance published by the Institute from that date would be locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in Health and Social Care (HSC). This link has ensured that Northern Ireland has access to up-to-date, independent, professional, evidence-based guidance on the value of health care interventions.

NICE Process

Departmental review of NICE Technology Appraisals for applicability to Northern Ireland

7. Each month NICE publishes its Technology Appraisals, and any costing templates or statements. It also publishes the Final Appraisal Determinations (FADs), near-final versions of Technology Appraisals, approximately 6 weeks prior to the final guidance. Receipt of the FADs for the Technology Appraisals initiates the Departmental review process.
8. The Departmental review is not a reassessment of the clinical and cost evidence used by NICE in forming its advice. NICE guidance will be proofed by the Department only to check for legal, policy and financial consequences related to its implementation in NI. As a result, the guidance may be endorsed with caveats to advise local HSC

organisations of any equivalent legislation/policy or any specific instructions/requirements.

9. As part of the equality screening process and in compliance with Section 75, Northern Ireland Act 1998, the Department will complete an equality screening template which is in addition to NICE's equality screening process.
10. The local Departmental review of NICE Technology Appraisals is expected to be complete within 4 weeks of the final publication by NICE.
11. As soon as the local review is complete, endorsement decisions will be published on the Department's website. Guidance will have links to appropriate caveats where these apply. If a piece of NICE guidance is not applicable to NI, then this will be highlighted and an explanation provided.
12. Following endorsement of a Technology Appraisal the Quality Regulation and Improvement Branch (QRIB) in the Department's Chief Medical Officer's Group will issue the guidance to the SPPG requesting that it prepares a Service Notification.

Commissioning and implementing NICE Technology Appraisals

13. On receipt of endorsement SPPG will confirm to QRIB that it has been received and within 15 weeks from the date of endorsement, the SPPG will issue a **Service Notification** to the HSC Trusts and other relevant providers and stakeholders, including Family Practitioners setting out the expectations for implementation. The Service Notification will be copied to the RQIA for dissemination to the independent sector as appropriate.
14. On receipt of the Service Notification for a Technology Appraisal the HSC Trusts or other provider organisations should disseminate it to

relevant staff and identify a named professional or managerial officer to lead implementation.

15. HSC Trusts will have plans in place to implement Technology Appraisals within 3 months of receiving the Service Notification from the SPPG and that these plans are fully implemented within a further 6 months in the vast majority of cases. The precise timescale, which may be shorter, or longer in exceptional cases, will be specified in the Service Notification. SPPG will seek positive assurance that the required timescales have been met in advance of routine director level Service Issues and Performance meetings with HSC Trusts. By exception, issues identified regarding implementation should be discussed.

16. Where a patient has been receiving treatment with a drug which NICE has appraised and not recommended, the patient should have the option of continuing their therapy until they and their clinicians consider it appropriate to stop. Clinical judgement will continue to have precedence for individual patients to allow for people with complex underlying conditions. Nevertheless, NICE Technology Appraisals are expected to be appropriate for the majority of any clinician's patients. All HSC bodies including Family Practitioners should ensure that drugs not recommended by NICE are not used to start treating a new patient.

17. QRIB will check that Patient Access Schemes apply in NI. It is important for HSC Trusts to claim all reimbursements or discounts where any funding agreements or Patient Access Schemes have been agreed with the manufacturer. Such agreements generally relate to the pharmaceutical industry and have been put in place to allow a drug to meet the NICE threshold for cost-effectiveness. If refunds are not claimed then the drug is not cost-effective. Where there is a Patient Access Scheme a drug should not be used without achieving the appropriate financial savings.

18. NICE guidance can often be associated with new costs. Where the guidance recommends multiple drugs for treating a specific condition, clinicians should follow the NICE recommendations in terms of the order of treatments unless a different order is clinically warranted. NICE guidance also makes recommendations on disinvestment in certain drugs or treatment as well, resulting in savings. It is vital therefore that the Trusts achieve these savings to avoid unnecessary cost pressures.

NICE Implementation Facilitator for Northern Ireland

19. The NICE Implementation Facilitator for Northern Ireland will support the local implementation of NICE guidance. They will work with all HSC organisations to raise awareness of NICE guidance, of NICE implementation support tools and how HSC organisations could utilise them to support quality improvement.
20. In line with the recommendation from the RQIA baseline review of the implementation process in HSC organisations that a network should be established which would include NICE implementation leads from both commissioning and providing organisations, to discuss common issues and share good practice in the implementation of NICE guidance, the NICE Implementation Facilitator for Northern Ireland has established the NI NICE Managers' Forum.

Monitoring and Assurance

21. The SPPG will be responsible for monitoring implementation of NICE guidance within the HSC.
22. The SPPG will hold routine director level Service Issues and Performance meetings with HSC Trusts where the implementation of NICE guidelines is a standing item on the agenda. All HSC Trusts are required to provide positive assurance that the initial required actions of targeted dissemination, identification of a clinical/management lead and

implementation planning have taken place. This is in addition to the positive assurance that will be sought on implementation.

23. Prior to each director level Service Issues and Performance meeting, the SPPG will provide HSC Trusts with a list of the Technology Appraisals where positive assurance is required on the initial actions, and also separately on implementation. The HSC Trust return should provide positive assurance against each Technology Appraisal. The HSC Trust return will be recognised as the HSC Trust formal position.
24. Where the HSC Trust is not in a position to provide positive assurance, the Technology Appraisal be added to agenda of the next director level Service Issues and Performance meeting. Minutes of these meetings will record the implementation issues and key actions required. SPPG will continue to seek positive assurance until implementation is achieved.
25. The SPPG will produce an annual report on the progress made generally in commissioning services in accordance with Departmental endorsed NICE guidance.
26. When a Technology Appraisal is being implemented by Trusts according to plan, then it can be selected for review. The RQIA will extend its support of regional audits to cover some clinically based NICE guidance and will look at a sample of the technology appraisals each year.
27. The RQIA inspections against the 'Quality Standards for Health and Social Care' will include, at a high level, the implementation process for NICE guidance by HSC Trusts.
28. Should any concerns about the implementation of NICE guidance be raised, then the issue will be added to the agenda of the next 6-monthly Accountability meeting with the appropriate organisation.

NICE Consultations and Stakeholder Registration

29. NICE undertakes extensive literature reviews to ensure the robustness of its guidance. In areas where Northern Ireland is at the cutting edge and particularly where services cross health and social care, it is important that we contribute to NICE research at the scoping stage. It is also crucial to comment at the consultation stage as there is no opportunity to influence the guidance once it is published. All HSC Trusts are strongly encouraged to register as stakeholders with NICE so that they can submit any expert comments they may have. The Trusts and healthcare professionals should register to receive the Institute's e-newsletter to be kept informed of all NICE activities and guidance in development.
30. The success of this process depends on everyone playing their part and in particular on good communication and effective clinical leadership. To ensure that endorsed medicines are affordable it is vital that NICE protocols for multiple technologies are fully implemented and that potential savings are achieved in areas that NICE have identified for disinvestment. Through working together co-operatively and making the most of evidence based best practice, we can achieve the best outcomes for the people of Northern Ireland.

Enquiries

31. Any queries relating to this circular should be directed to Quality Regulation and Improvement Branch (QRIB), D1, Castle Buildings, Stormont, Belfast, BT4 3SQ, or e-mail: SGU-NICEGuidance@health-ni.gov.uk



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