Board meeting

18 September 2025

Proposed update to PMG36 manual

Purpose of paper

For approval

Board action required

The Board is asked to:

* Consider this manual update and approve it for public consultation
* Delegate to Guidance Executive approval of any subsequent changes to the manual post-consultation and response to consultation comments.

Brief summary

This paper provides proposed updates to the [PMG36 manual](https://www.nice.org.uk/process/pmg36) to facilitate greater production of technology appraisal guidance on HealthTech, as set out in the NHS 10-year plan.

Board sponsors

Mark Chapman, Director of Medical Technology

Helen Knight, Director of Medicines Evaluation

Nick Crabb, Chief Scientific Officer

Introduction

NICE has been working with system partners on the Rules Based Pathway to agree a mechanism to identify and support automatic funding for HealthTech products evaluated through the pathway. The agreed funding mechanism to deliver this is through the existing NICE technology appraisal recommendations with associated funding requirement. The 10 year health plan includes the Rules Based Pathway and expands the NICE technology appraisal process to cover devices, diagnostics and digital products.

The existing manual for technology appraisals, PMG36, can be used to develop technology appraisal guidance on HealthTech; however, technology appraisal guidance has predominantly focused on medicines. This manual will therefore be updated to provide the processes and methods to develop technology appraisal guidance more suited to the HealthTech landscape.

A presentation at the last Board meeting ([item 7](https://www.nice.org.uk/about-us/our-board/public-board-meetings/2025/public-board-meeting-agenda-and-papers-july-2025), slide 9) gave timescales to launch technology appraisals in HealthTech, including that by October 2025 we will launch a consultation to our technology appraisals manual to guide HealthTech developers through this process.

Background

The proposed changes to PMG36 are to support production of technology appraisals on HealthTech (that is, medical devices, diagnostics, digital technologies) and not to change the assessment of medicines. The proposed changes also better align with the manual for NICE HealthTech guidance ([PMG48](https://www.nice.org.uk/process/pmg48/chapter/introduction); with no associated funding requirement).

[NICE-wide topic prioritisation: the manual](https://www.nice.org.uk/process/pmg46/chapter/eligibility-criteria-for-using-the-prioritisation-framework-and-direct-routing-to-guidance) has been reviewed and will not be updated because it already includes provision for the prioritisation board to route HealthTech topics to technology appraisal guidance, subject to ministerial referral.

Overview of key proposed changes

Most proposed changes are to improve clarity. Below sets out an overview of the key proposed changes.

Title and introductory text

For clarity, the title of PMG36 is proposed to be changed from ‘NICE health technology evaluations: the manual’ to ‘NICE Technology Appraisal and Highly Specialised Technologies guidance: the manual’.

Requests for information

In line with the approach for HealthTech guidance there will be requests for information made to companies rather than a requirement for company submissions. HealthTech companies often are small and medium sized enterprises (SMEs) and have much less experience of NICE and Health Technology Assessment. So, a more targeted request for information (with direct questioning) is considered important to support companies and obtain the important and relevant information. Requests for information allow companies to highlight studies, data or economic analyses they consider relevant, but do not require companies to prepare a submission (e.g. conduct a systematic review or produce an economic model).

Technical engagement

For clarity and to simplify the process as much as possible, it is proposed that the optional step of technical engagement for appraisals of single technologies in medicines will not be used for technology appraisals for HealthTech. This aligns with the approach to develop HealthTech guidance and is more appropriate for the HealthTech landscape because HealthTech assessments predominantly include multiple technologies.

Commercial opportunities

Many of the aspects related to commercial activities described in PMG36 cite and are related to the NHS commercial framework for new medicines. For clarity, these sections are proposed to be designated as for ‘medicines only’. The update proposes to add a further section to PMG36 to describe commercial opportunities for HealthTech during the technology appraisal process.

Severity modifier

The update proposes that the severity modifier will not be applied to technology appraisals done on HealthTech at this time. The severity of the condition should be captured within the QALY benefits and then deliberatively within decision making. The proposed text also notes that we are currently exploring approaches for how the severity modifier could be applied for technology appraisals of HealthTech. This is consistent with the approach taken for NICE clinical guidelines:

“Initially, the severity modifiers introduced by the Centre for Health Technology Evaluation (CHTE) for technology appraisal guidance will not be applied to NICE guideline health economic analyses. For NICE guidelines, the severity of the condition should be captured within the QALY benefits and then deliberatively within decision making. However, to enable consistent decision making across NICE guidelines and technology appraisals and to foster better integration of NICE recommendations across these programmes, we are currently exploring approaches on how the severity modifier could be applied within NICE guidelines. We would consult with stakeholders ahead of any implementation.” (see section 7.8 of Developing NICE guidelines: the manual [PMG20](https://www.nice.org.uk/process/pmg20))

Next steps

Subject to approval, this manual will be released for public consultation for 4 weeks.

Clear communications will be provided for stakeholders to explain our approach to the manual update and an implementation plan will be developed for enacting the changes operationally.

Following consultation, and conditional on addressing consultation comments received, we aim to update the manual as quickly as possible to allow use for technology appraisals on HealthTech. To this end, we are proposing that the Board delegates to Guidance Executive approval of any subsequent changes to the manual post-consultation and response to consultation comments to avoid a delay in guidance delivery. An update on the final manual and feedback from consultation will be provided to the Board for information in December.

Finance / HR / legal implications

Technology appraisals on HealthTech will be subject to the standard appeal process used for medicines.

To develop and establish with partners the mechanics and foundation of the rules-based pathway for more value-driven decision making across procurement and adoption, NICE will start selective and small in scale for Technology Appraisals in HealthTech. The number of technology appraisals in HealthTech will be delivered within the existing portfolio of guidance for the HealthTech programme and NICE will not impose a charge to companies in relation to technology appraisal guidance at this time.

Board action required

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September 2025