

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Modular update to NICE manuals

Funding Variation Process Update

Task and finish group report

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1 Executive summary

- 1.1 A funding requirement has applied to NICE technology appraisals since 2001. Regulations provide that ‘a relevant health body must comply with a technology appraisal recommendation’ and ‘NICE must specify in a technology appraisal recommendation the period within which the recommendation ... should be complied with’.
- 1.2 The period must be 3 months unless any of the following circumstances apply, in which case NICE must specify a longer period (a ‘funding variation’) in consultation with stakeholders including Department for Health and Social Care (DHSC) and NHS England (NHSE):
- the health technology cannot be appropriately administered until:
 - training is given to staff involved in the delivery of the health technology to patients
 - certain health service infrastructure needs, including goods, materials or other facilities, are in place
 - other appropriate health services resources, including staff, are in place, or
 - the health technology is not yet available in England.
- 1.3 The current funding variation request (FVR) process has several key challenges linked to the operation, accountability and broader political nature of the mechanism.
- 1.4 Following the approval of the most recent funding variation, improving the approach to funding variations was made a priority project in NICE’s 2025/26 business plan.
- 1.5 This modular update will clarify NICE’s updated process for considering and approving FVRs. This will provide coherent

guidance to stakeholders on how funding variations will be considered.

1.6 The proposed modular update on funding variations will amend the technology appraisal and highly specialised technologies manual to include the new process for considering and approving FVRs from NHSE. The update will include:

- the introduction of an early signal of a funding variation pre-committee from NHSE
- clear expectations on information required for NICE's Guidance Executive (GE) to consider and approve a funding variation
- the creation of an FVR Advisory Group, which will provide advice to GE for FVRs longer than 12 months and include members from the NHS with expert knowledge
- detailed information on the expectations for monitoring and exit strategies during the funding variation period.

2 Background

2.1 A funding requirement has applied to NICE technology appraisals since 2001. Regulations provide that 'a relevant health body must comply with a technology appraisal recommendation' and 'NICE must specify in a technology appraisal recommendation the period within which the recommendation ... should be complied with'.

2.2 The period must be 3 months unless any of the following circumstances apply, in which case NICE must specify a longer period (a 'funding variation') in consultation with stakeholders, including the DHSC and NHSE:

- the health technology cannot be appropriately administered until:

- training is given to staff involved in the delivery of the health technology to patients
- certain health service infrastructure needs, including goods, materials or other facilities, are in place
- other appropriate health services resources, including staff, are in place, or
- the health technology is not yet available in England.

2.3 The Budget Impact Test (BIT) relies on funding variations as a backstop. NHSE may request a longer implementation period where the budget impact of a health technology is more than £40 million in any of the first 3 years of implementation. The BIT threshold was increased from £20 million in January 2025.

2.4 The current FVR process has several key challenges linked to the operation, accountability and broader political nature of the mechanism.

2.5 To date, there have been 4 agreed funding variations:

- Sofosbuvir for hepatitis C (2015) – 2 months
- Hybrid closed loops for type 1 diabetes (2023) – 5 years
- Paxlovid for COVID-19 (2024) – 12 Months
- Tirzepatide for overweight and obesity (2024) – 12 years.

2.6 Following the approval of the most recent funding variation, we made improving the approach to funding variations was a priority project in NICE's 2025/26 business plan.

3 Current approach in the NICE manual

3.1 [NICE's technology appraisal and highly specialised technologies guidance manual \(PMG36\)](#) sets out NICE's current approach to FVRs.

3.2 To date, the FVRs received by NICE have come following applications to vary the funding requirements by NHSE. The 4 requests have all been managed differently and have had differing timescales, but followed the broad process outlined in the manual:

- submission of an FVR to NICE
- a review by NICE's GE
- public consultation
- re-evaluation by GE and final decision
- publication of the NICE guidance alongside confirmation of the variation to funding requirements
- implementation of the technology according to the agreed variation.

4 Thematic analysis to inform the process update

4.1 To understand the strengths and limitations of the current FVR process, NICE conducted a thematic analysis. To do this, we extensively analysed all documents relating to the 4 previous FVRs. These included internal NICE documents, NHSE submissions, responses to consultations and information available to the public on the NICE website. NICE also conducted stakeholder engagement with key stakeholders involved in the previous FVRs. We also undertook 30- to 60-minute interviews with 15 key stakeholders at NICE, NHSE and DHSC.

4.2 A key theme across both streams of research was that people and evidence have been brought into the FVR process at different times, often triggering new streams of work at short notice. This suggests that a key limitation of the existing process is that the need for a funding variation is unknown until late in the NICE

process. In addition, the unrefined, variable process causes inconsistency in what is provided or requested to support GE in its decision making. So, evidence requests are generated at different times, by different stakeholders, for different groups.

4.3 It was also apparent from the document review and interviews, that the infrequency of FVR's to date has led to variation in the recorded documentation, and a lack of familiarity in the process.

4.4 NICE used this feedback to develop an updated and more detailed process to address inconsistencies and stakeholder concerns.

5 Stakeholder engagement

5.1 To ensure the updated manual addresses stakeholder concerns, NICE held roundtable discussions to gather the views of members of DHSC, NHSE, Integrated Care Boards and the Association of the British Pharmaceutical Industry. Participants were broadly supportive of NICE's new process for FVRs, particularly the earlier identification of topics. The participants viewed funding variations as a mechanism to drive system readiness and adoption and considered them to be potentially positive when used effectively.

5.2 During the engagement, stakeholders raised several key issues, including:

- challenges for NHSE in submitting a FVR pre-committee without knowing the final recommendation
- the potential interplay with other ongoing policy developments, such as the recent trade arrangement between the UK and the US
- who will submit funding variations once NHSE and DHSC merge, and questions about how Integrated Care Boards s and other stakeholders can submit FVRs

- the need to monitor and assess ongoing funding variations to ensure a smooth transition out of the funding variation period.

- 5.3 The feedback from the roundtable discussions has directly informed the FVR modular update and the supporting FVR submission template. NICE only requires top-line information on a potential funding request pre-committee and acknowledges that information in the request may change once a final recommendation is made.
- 5.4 It is likely that a national body will continue to submit FVRs on behalf of the system to ensure a consistent rollout nationally. The current regulations do not name a specific national body so this can change from NHSE in the future.
- 5.5 The FVR process has been updated to be clear on requirements for data monitoring and reporting throughout the funding variation period. The manual now outlines the process during a funding variation, including what information should be reported to NICE's GE and options to transition out of a funding variation period.

6 Equality considerations

- 6.1 The funding mandate exists in part to ensure equitable access to new health technologies recommended by NICE. Any deviation from the funding mandate carries a risk of inequitable access because some centres will be able to provide treatment to some people, while other people may miss out in the shorter term.
- 6.2 The reality of funding variations is highly nuanced. Careful use of the funding variation mechanism may encourage faster or more efficient nationwide access to new health technologies than would be achieved through other means. This partly explains the new process's emphasis on the FVR applicant providing detailed plans

describing the expected rollout timelines, and data monitoring the implementation.

- 6.3 Consideration of the equalities impact of a proposed funding variation is included in the FVR template, and detailed explanation of the planned mitigation of those impacts is required.
- 6.4 The improvements to the FVR process will not introduce any additional equalities impacts beyond the current process and will help manage these by having robust data collection and monitoring proposals.

7 Proposed changes to the manual

- 7.1 The FVR modular update aims to provide clarity on and improve the end-to-end FVR process in response to stakeholder feedback on previous FVRs. FVRs will still only be considered for topics that meet the criteria as specified in the regulations.
- 7.2 The FVR modular update will update PMG36. The update will include:
 - the introduction of an early signal of a funding variation pre-committee from NHSE
 - clear expectations on the information required for NICE’s GE to consider and approve a funding variation
 - the creation of an FVAG, which will provide advice to GE for FVRs longer than 12 months and include members from the NHS who have expert knowledge (table 1)
 - detailed information on the expectations for monitoring and exit strategies during the funding variation period.

Table 1 Proposed approach for the Funding Variation Advisory Group

Detail	Funding Variation Advisory Group
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Communication	Communication via email to individual reviewers
Requirement	Input via responding to email questions and flexibility to meet in person or virtually as needed
Term	Appointed for a 3-year term
Membership	Pool of reviewers assigned for each topic
Source	External membership. Staff from the NHS with expert knowledge (clinical, pharmacy, NHS finance, NHS commissioning)
Recruitment	Invitation to colleagues who have relevant knowledge or experience. Potential reviewers are sent a standard invitation inviting them to opt-in
NICE resource required	Current resource within the commercial managed access and policy team
Documentation	Invitation letter Declaration of interests Confidentiality form Equalities monitoring form
Meeting	Confidential input via email, in-person or virtual meeting
Role	Advisory – NICE Guidance Executive is the final decision maker
Contact	NICE project team
Format	Email sent to pool of recipients listing specific questions. Meeting to discuss if required (virtual or in-person) All administrative duties performed by NICE

7.3 It is expected that any health technologies assessed as technology appraisals will follow PMG36 and therefore, this FVR process.

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