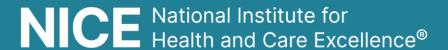
Changes to NICE's cost effectiveness threshold: next steps

December 2025

NICE National Institute for Health and Care Excellence®



## Introduction and overview



## Government support for the pharmaceutical sector includes changes to the NICE threshold

- Changes to improve pharmaceutical operating environment announced as part of US – UK economic prosperity deal and UK industrial strategy.
- Aims to support the sector, while preserving patient access.
- NICE approves 91% medicines that we evaluate (~70 a year). We estimate 3-5 additional approvals per year due to changes.

#### **NICE will deliver two commitments:**

- 1. Change to NICE's cost-effectiveness thresholds used to develop Technology Appraisal (TA) guidance to £25,000 £35,000.
- 2. Govt. support for NICE to **implement a new value set** used to value health related quality of life in health technology comparisons.

## What is changing?



### NICE's cost effectiveness threshold

### **Background**

- NICE uses thresholds to decide which health technologies are cost-effective for use in NHS.
- Standard threshold will change to £25,000 to £35,000 per QALY.
- Preserves patient access and emphasises NICE's role supporting innovation.

#### **Delivery**

- Applies to NICE's Technology Appraisals (TA) guidance.
- NICE proposes new threshold applies across all NICE guidance (Digital, HealthTech, Guidelines). We await further detail from government.
- We are not aware of any proposals to change the thresholds used to evaluate Highly Specialised Technologies (HSTs) for ultra-rare diseases.
- DHSC will consult on powers to direct NICE to enact this, subject to regulation change, from April 2026.

## What is changing?



**New value set to quantify health states** 

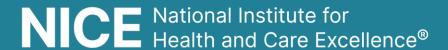
### **Background**

- A 'value set' allows us to quantify health-related quality of life, to help compare treatments.
- Converts patient-reported health states into numerical values.
- New value set will **better capture the views of the public today**, with more sensitive, cutting-edge methodology and replacing 1990s data underpinning current approach.

#### **Delivery**

- Value set being developed by asking 1,200 members of the public to judge different health states.
- Following ongoing independent peer review of the value set and subsequent publication in 2026, we will consult on changes to the methods Manual.

## Implementation and next steps



## New threshold will be introduced following DHSC direction from April 2026

- DHSC plans to consult on powers to direct NICE to implement a new cost-effectiveness threshold.
- This requires a targeted change to regulations.
- Change clarifies the status quo that Ministers
   are responsible for the medicines budget, while
   NICE is responsible for methodology.
- Will not permit broader intervention in NICE methods or decisions.

### Anticipated timeline (subject to consultation)

- Dec 2025 DHSC consult on proposed regulations change.
- Early 2026 In anticipation of regulations change, prior to March, NICE plan to conduct a short consultation on <u>how</u> the change will be implemented.
- March 2026 Regulation change gives DHSC power to direct NICE on threshold.
- March 2026 NICE directed to implement new threshold.
- April 2026 NICE methods Manual updated.

## What does this mean for ongoing TAs?

### For all new and ongoing TAs

- All topics will continue as planned. Current threshold will apply until a direction by DHSC is received. Subject to parliamentary process, a new threshold will apply from April at the earliest.
- From point of a DHSC direction, new threshold will apply regardless of when TA was initiated.
- Historic TA guidance will not routinely be revisited.

# Ongoing TAs with scheduled committees prior to NICE implementing new threshold

In the period before DHSC direct NICE:

- i. If a topic is found cost-effective under the current threshold it will be recommended as usual.
- ii. If a topic is not found cost-effective using current thresholds but where applying new thresholds could result in a positive recommendation:
  - We will not publish a negative decision. Publication of final draft guidance will be paused until NICE can apply the new thresholds.
  - Once new threshold comes into force, the threshold will be increased by £5,000 automatically and will not require further committee discussion.
  - Publication processes and commercial discussions will then continue as usual.
- iii. If a topic is not found cost effective and would not be recommended even under a new threshold, the topic will proceed to negative recommendation as usual.

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### NICE will consult on new value set in 2026

- NICE welcomes support for implementing new value set for measuring health-related quality of life, using NICE's preferred "EQ-5D-5L" instrument.
- Will best reflect how the public values different health states in NICE evaluations.
- Developed using up-to-date UK preference data from 1,200 individuals and state-of-the-art methodologies.
- Delivery follows NICE's standardised process for modular Manual updates.

### **Delivery**

- Academic peer review and publication (ongoing). To ensure quality, this step must be independent of NICE. Publication is likely to be between c. Feb – May 2026.
- 2. Post publication (c. 16 weeks):
  - NICE consultation on impact of value set.
    Exact timeframes depend on the nature of the consultation response.
  - Integration into NICE's methods Manual.

### Next steps

- For those with questions:
  - Further information is available online: https://indepth.nice.org.uk/changes-to-nices-cost-effectiveness-thresholds/index.html
  - If not answered via the above, NICE stakeholders can contact: nice@nice.org.uk
- Stakeholders involved in ongoing medicines evaluations with questions regarding their NICE appraisal should direct questions to the relevant Associate Director or Principal Technical Adviser.
- NICE will continue to engage stakeholders throughout the implementation process outlined. We will also be discussing these plans at the upcoming NICE public Board meeting on 10<sup>th</sup> December.