Consultation stage impact assessment

Title: NICE cost effectiveness threshold regulations

Type of measure: Secondary

Stage: Consultation

Source of intervention: Domestic

Department or agency: Department of Health and Social Care

Other departments or agencies: NHS England, NICE

IA number: N/A

RPC reference number: N/A

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Date: 9 December 2025

Summary: intervention and options

Cost of preferred (or more likely) option (base year = year of IA)

Total net present social value (in £m): N/A

Business net present value (in £m): N/A

Net cost to business per year (in £m): N/A

What is the problem under consideration? Why is government action or intervention necessary?
The National Institute for Health and Care Excellence (NICE) develops authoritative, evidence-based guidance for the NHS on whether new medicines and other treatments should be routinely funded by the NHS in England based on their costs and benefits. NICE evaluates treatments against a cost-effectiveness threshold. Its methods and decisions centre on whether a specified product is a cost-effective use of the health budget compared to other potential uses of that budget. Wider public and economic policy considerations are outside of NICE's remit. Currently, this threshold can be changed only by decision of the NICE Board. It is important that decisions on critical elements of UK medicines policy which can make a strategic contribution to delivery of wider government objectives, or which need to be determined taking into account wider considerations outside health economics, such as the cost-effectiveness threshold, are subject to democratic control and accountability. This allows the government to balance health objectives with other government objectives to deliver on its overall agenda.

What are the policy objectives of the action or intervention and the intended effects?

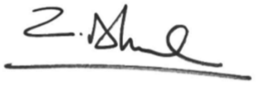
The policy objective is to confer on the Secretary of State a power to direct NICE with respect to the value of the cost-effectiveness threshold used by NICE in evaluating medicines and other treatments, in order to increase democratic control and accountability. Ministers may use the power to decrease or increase the cost-effectiveness threshold used by NICE to support government objectives.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Non-regulatory options such as the NICE cost-effectiveness threshold being set by the NICE board were deemed insufficient to ensure the Secretary of State is accountable for decisions which impact on delivery of wider government objectives. It is, in the view of HMG, for the elected government to determine how best to achieve the appropriate balance between affordability, patient access to medicines, and a flourishing economy, while preserving the independence of NICE in making decisions on individual products within the framework set out by ministers.

Will the policy be reviewed? N/A. If applicable, set review date:				
Is this measure likely to impact on international trade and investment?		N/A		
Are any of these organisations in scope?	Micro **N/A**	Small **N/A**	Medium N/A	Large **N/A**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		Traded: N/A	Non-traded: N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY:  Date: 09/12/2025

Summary: Analysis and Evidence

Policy Option 1

Description: Amend the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 to allow the Secretary of State to set the cost-effectiveness threshold used by NICE in its evaluations.

Full economic assessment

Price Base N/A	PV Base N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** N/A

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	N/A

Description and scale of key monetised costs by 'main affected groups'

There is no monetised impact of the proposed powers as the Secretary of State would continue to implement any desired changes via direction to NICE. As the direction itself, rather than the amendment to regulations, would have impacts, no quantified impacts are assessed here.

Other key non-monetised costs by 'main affected groups'

N/A

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	N/A

Description and scale of key monetised benefits by 'main affected groups'

N/A

Other key non-monetised benefits by 'main affected groups'

N/A

Distributional impacts

N/A

Key assumptions/sensitivities/risks	Discount rate
N/A	

Business assessment (Option 1)

Direct impact on business (Equivalent Annual) £m:		
Costs: N/A	Benefits: N/A	Net: N/A

Evidence base

Problem under consideration and rationale for intervention

The National Institute for Health and Care Excellence (NICE) is the executive, non-departmental public body responsible for developing evidence-based guidance for the health and care system on value for money and best practice. Through its technology appraisal and highly specialised technologies programmes, NICE makes recommendations for the NHS on whether new medicines and other technologies should be routinely funded by the NHS based on clinical and cost effectiveness. The NHS in England is statutorily required to make funding available for medicines and treatments recommended by NICE in its technology appraisal and highly specialised technologies guidance, normally within three months of the publication of final guidance.

In developing its guidance, NICE uses a cost-effectiveness threshold which is an expression of how much of the public sector purse should be spent on medicines and other technologies. When NICE was established in 1999, it was not given an explicit threshold for cost-effectiveness. In 2004, NICE formally adopted a cost-effectiveness threshold range of £20,000 - £30,000 per QALY. This range reflected patterns in past decisions made by its Appraisal Committees and was considered a pragmatic compromise between affordability and access. The Government's view on this has evolved, such that this threshold should now be set taking into account factors wider than health economics that are beyond NICE's remit (delivering the Life Sciences Sector Plan and the 10 Year Health Plan).

No government since NICE's creation 26 years ago has changed the thresholds used to evaluate medicines and other innovations, despite huge changes in the economic, commercial, and healthcare environment it operates in. It is, therefore, the government's view that it is the right time to review and update the NICE frameworks used, where necessary, in order to ensure that NICE is able to continue its world leading approach to assessing drugs and treatments, and keep pace with the needs and realities of the globally competitive life sciences sector we are operating in today.

The Secretary of State does not currently have the legal power to direct NICE to amend the cost-effectiveness threshold used in its programmes. The threshold can only be changed by a decision from the NICE Board and any change to the threshold would have to be grounded in NICE's general duties which are focused on health and social care impacts. It is important that critical elements of UK medicines policy which either impact on delivery of wider government objectives or need to be determined taking into account factors wider than health cost-effectiveness, are subject to Ministerial control. This will support the government to deliver on its agenda and to enable direct accountability for deciding how much of the public sector purse should be spent on medicines and other technologies.

This impact assessment covers the costs and benefits of the regulatory changes (see "summary and preferred option with description of implementation plan").

One example of how government may wish to use a power to direct NICE with respect to the value of the cost-effectiveness threshold it uses in evaluating medicines and other treatments, are proposals to increase the cost-effectiveness threshold alongside an announced deal on medicines pricing with the US Administration (announced on 1 December 2025[1]). Drivers of this change include improving the commercial environment for the life sciences sector and supporting both the Life Sciences Sector Plan and the 10 Year Health Plan.

[1] Landmark UK-US pharmaceuticals deal to safeguard medicines access and drive vital investment for UK patients and businesses - GOV.UK – accessed 2 December 2025

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

It is expected that impacts will be associated with ministers' exercise of the power of direction not by the change to the regulations itself.

Description of options considered

1. **Do nothing** - regulations provide that NICE is responsible for the methods that it uses in the development of its guidance and recommendations, including the cost-effectiveness threshold that NICE uses.

2. **Confer a power of direction on ministers to set the cost-effectiveness threshold** – the government has stated that if a policy is of national importance, then ministers should have appropriate oversight and control of its development [2]. This is the preferred option.

Policy objective

The policy objective is to confer on Secretary of State a power to direct NICE as to the cost-effectiveness threshold that it uses in the development of its guidance and recommendations, in order to increase accountability to a broader range of objectives than health cost-effectiveness.

Summary and preferred option with description of implementation plan

The Preferred Option we are consulting on is to give the Secretary of State for Health and Social Care the legal power to direct NICE to amend the cost-effectiveness threshold used in its programmes[3]. It requires an amendment to the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013. As this cost-effectiveness threshold is set out in NICE Methods and Process Manual (PMG36)[4], and not in legislation, the legislation will not directly affect the NICE cost-effectiveness threshold. Rather, it will provide the Secretary of State the authority to direct NICE to make changes to the cost-effectiveness threshold, who agree any updates to the methods manual via weekly Guidance Executive. Under this proposal, the primary legislation that allows for this change to be made would be the Health and Social Care Act 2012. The proposed amendment to the regulations would be subject to a public consultation and the amended regulations would then be drafted and laid before Parliament to come into force in March 2026.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

None of the options will have any direct monetisable costs or benefits. Any monetisable costs and benefits will be associated with ministers' exercise of the power of direction. If the Preferred Option is implemented, any decisions that are taken to amend the cost-effectiveness threshold will follow the normal government value for money decision processes.

Direct costs and benefits to business calculations

While the power conferred on the Secretary of State through the preferred option does not stipulate in-itself how the threshold might change (i.e. raised or lowered), the preferred option will be more likely to benefit businesses by enabling decisions on the cost-effectiveness

[2] https://www.gov.uk/government/news/hundreds-of-quangos-to-be-examined-for-potential-closure-as-government-takes-back-control
[3] Implemented through amending the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013
[4] 6 Committee recommendations | NICE health technology evaluations: the manual | Guidance | NICE – accessed 28 October 2025

threshold used in NICE evaluations to take into account wider economic and industrial policy factors, such as the economic impact of life sciences investment.

Enabling ministers to change the NICE cost effectiveness threshold could however create business uncertainty. The standard NICE threshold being fixed for many years provides a stable environment for company decision-making, and there is a risk that a power of direction may be perceived by businesses as enabling the threshold to be changed with more frequency making the UK a more unpredictable access market. However, it is anticipated that changes to the NICE cost-effectiveness threshold will be very infrequent, which will provide a stable business environment.

Risks and assumptions

There is a risk that conferring direction-giving powers on ministers with respect to the way in which NICE develops guidance could be perceived to undermine NICE's independence. To mitigate this risk, the proposed direction-giving power would be very tightly defined, and ministers would remain unable to direct NICE as to the substance of its guidance, maintaining its independence in decision making.

Distributional and wider impacts

Any impacts will be associated with ministers' exercise of the power of direction not by the change to the regulations itself.

Impact on small and micro businesses

Any impacts will be associated with ministers' exercise of the power of direction not by the change to the regulations itself.

Other impacts (consider the impacts of your proposals)

Any impacts will be associated with ministers' exercise of the power of direction not by the change to the regulations itself. For more information on potential behavioural changes resulting from this measure, see "Risks and assumptions" above.

A summary of the potential trade implications of measure

Any impacts will be associated with ministers' exercise of the power of direction not by the change to the regulations itself.

Monitoring and evaluation

Plans for monitoring and evaluation would be put in place for any exercise of the power to give directions.

Conclusion

This impact assessment sets out the rationale for conferring a power of direction on the Secretary of State to determine the cost-effectiveness threshold used by NICE in its programmes. The measure reflects the government's commitment to ensuring that decisions on the allocation of public funds for medicines take account of wider objectives beyond health, including patient access, trade, and economic investment, as articulated in the Life Sciences Sector Plan and the 10 Year Health Plan. While the regulatory change itself does not create direct costs or benefits, its exercise will have significant implications for the commercial environment, patient outcomes, and the UK's global competitiveness in life sciences. The preferred option provides a mechanism for accountability and alignment with national priorities, while maintaining NICE's independence in the substance of its guidance. Monitoring and evaluation will be essential to assess impacts, recognising the complexity and uncertainty inherent in modelling counterfactual scenarios. This approach seeks to balance value for money in public spending with the ambition to make the UK a leading destination for life sciences innovation and patient access to medicines.