

BIA response to Budget Impact Test threshold consultation

Background

NHS England has published a [consultation document](#) which sets out proposals for raising the Budget Impact Test (BIT) threshold from £20 million to £40 million.

The consultation is open until 25 September 2024. You can access the consultation [here](#).

Consultation questions

Q1: To what extent do you agree or disagree that the BIT threshold should be increased from its current level of £20 million?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

The BIA strongly supports increasing the BIT threshold. This will be the first increase to the threshold since the BIT was introduced in 2017. An increase to the threshold is necessary to reflect both inflationary factors and the changing nature of the medicines pipeline, which is increasingly made up of innovative medicines which provide significant clinical benefit. Increasing the threshold will help to ensure that the BIT only applies to those medicines with a significant budget impact, while also reducing the administrative burden for NHS England.

There are multiple layers of cost control in the system in addition to the BIT, including the VPAG which limits the total cost of NHS expenditure on branded medicines, as well as Patient Access Scheme (PAS) discounts and commercial access agreements (CAAs). These mechanisms help to manage the affordability of new medicines in the NHS. In this context, NICE's remit should not be to add a further layer of cost containment by ensuring its methods and processes are cost neutral.

Q2: To what extent do you agree or disagree that, as set out in the VPAG agreement, the BIT threshold should be increased to £40 million?

- Strongly agree
- Agree
- **Neither agree nor disagree**
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

We understand through engagement with NHS England that the £40 million figure is based on 80/20 analysis, with 20% of products expected to trigger the BIT at the new threshold. However, no information has been published on the analysis of the pipeline and the estimated impact of the £40 million threshold on patient access to new medicines in the coming years. It is therefore difficult to say the extent to which we agree or disagree with the £40 million figure.

Regular reviews of the BIT threshold should take place to ensure that it remains at an appropriate level. As part of these reviews, NHS England should provide metrics to monitor how the BIT is applied and its impact on patient access to new medicines. These reviews should also consider the broader methodology and application of the BIT to ensure it remains fit for purpose.

On the broader methodology and application of the BIT, we recommend that:

- There should be greater transparency of BIT processes to enable greater understanding of the reasons behind decisions on the application of the BIT. Companies should be provided with a full understanding of the evidence sources used to inform NHS England decisions, and there should be a clear process for companies to engage with NHS England on the assumptions and modelling used.
- The BIT threshold should not be applied to medicines upon exit from the Innovative Medicines Fund (IMF) or Cancer Drugs Fund (CDF). The BIT is intended to “manage the affordable introduction of higher cost technologies to the NHS”, and it is not clear why the managed access period is not considered as the first use of a medicine’s use in the NHS. These medicines are also subject to the expenditure control mechanism while in the IMF or CDF.
- Flexibility is required in the application of the BIT to support patient access to innovative medicines in areas of unmet need. This should include alternative approaches to manage the entry of high-cost innovative medicines such as cell gene therapies into the NHS in order to ensure timely patient access to these transformative treatments. This should include the use of innovative payment models which allow the cost of a treatment to be spread over a number of years. The commitment in the 2024 VPAG to pilot two innovative payment models provides a good opportunity to introduce these alternative approaches in the NHS.