NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology appraisal

[Appraisal title and ID number]

Company budget impact analysis submission

[Month year]

|  |  |  |  |
| --- | --- | --- | --- |
| **File name** | **Version** | **Contains confidential information** | **Date** |
|  |  | **Yes/no** |  |

# Instructions for companies

This is the template for submission of the budget impact analysis to the National Institute for Health and Care Excellence (NICE). It needs to be completed as part of the technology appraisal process for the application of the budget impact test, and the analysis that supports budget impact calculations. It explains what information NICE requires and the format in which it should be presented. It should be read alongside these NICE guides:

* [NICE Health Technology Evaluation Manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation)
* [Assessing resource impact process Manuel](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/budget-impact-test)

This document should provide an analysis of any factors relevant to the NHS and other parties that will allow the evaluation of the budget impact for the technology. The budget impact analysis will not influence the appraisal committee’s consideration of the clinical and cost effectiveness of a technology.

The submission should be as brief and informative as possible.

The submission should be sent to NICE electronically in Word or a compatible format, and not as a PDF file. The budget impact analysis must be a stand-alone document. Budget impact analyses are not normally presented to the appraisal committee, but will be available to them on request.

When making a budget impact analysis submission, companies must ensure that all confidential information is highlighted and underlined in the electronic version sent to NICE. See section 5 of the [NICE Health Technology Evaluation Manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) for information about all aspects of information handling.

### Highlighting in the template (excluding the contents list)

Square brackets and grey highlighting are used in this template to indicate text that should be replaced with your own text or deleted. These are set up as form fields, so to replace the prompt text in [grey highlighting] with your own text, click anywhere within the highlighted text and type. Your text will overwrite the highlighted section.

To delete grey highlighted text, click anywhere within the text and press DELETE.

Grey highlighted text in the footer does not work as an automatic form field, but serves the same purpose – as prompt text to show where you need to fill in relevant details. Replace the text highlighted in [grey] in the header and footer with appropriate text. (To change the header and footer, double click over the header or footer text. Double click back in the main body text when you have finished.)

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# Tables and figures

[Include a list of all tables and figures here with page references]

* + - 1. Technology being appraised
	1. Complete the table 'Technology being appraised’ below, including details of the treatment regimen and method of administration. Specify the sources of information and data used to complete the table, for example the summary of product characterisitcs or trial data. For more information see the NICE Health Technology Evaluation Manual.

### Table X Technology being appraised

|  |  |
| --- | --- |
| **UK approved name and brand name**  |  |
| **Indications and any restriction(s) as described in the summary of product characteristics (SmPC)** | Give the (anticipated) indication(s) in the UK. For devices, provide the date of (anticipated) CE marking, including the indication for use. |
| **Optimisation of population** | Provide details of any optimisation of the population (compared to the marketing authorisation) in this submission or state if no optimisation is proposed. |
|  |  | **Source** |
| **Acquisition cost (including VAT)\*** |  |  |
| **Method of administration (including homecare provision and if appropriate, any funding arrangements for homecare provision)** |  |  |
| **Dosage**  |  |  |
| **Average length of a course of treatment** |  |  |
| **Anticipated average interval between courses of treatments** |  |  |
| **Anticipated number of repeat courses of treatments** |  |  |
| **Dose adjustments** |  |  |
| \* Indicate whether this acquisition cost is a confirmed or anticipated list price. When the marketing authorisation or anticipated marketing authorisation recommends the intervention in combination with other treatments, the list price of each intervention should be presented. |

* 1. Provide details of any commercial arrangements, for example a patient access scheme, that have been approved for inclusion in the technology appraisal. For more information see section 5 of the NICE Health Technology Evaluation Guide. If a commercial arrangement has been proposed but is not yet approved, please provide the anticipated date of approval.
		+ 1. Health condition and position of the technology in the treatment pathway
	2. State the disease or condition for which the technology is indicated.
	3. Present the clinical pathway of care that shows the context of the proposed use of the technology within the pathway. This information should be summarised in a diagram.

* Describe established clinical practice for the population eligible for treatment with the technology.
* State the line of treatment the technology will be used in, for example, ‘second-line treatment’ or ‘second-line and third-line treatment’
* Explain how the new technology may change this existing pathway including any impacts on subsequent treatments.

* State the comparator technologies being considered.
* Where benefits/savings are achieved or capacity is released, show these per each relevant year
	1. Provide details of other clinical guidelines (for example, UK guidance from the royal societies or European guidance) and national policies.
	2. Describe any issues relating to current clinical practice, including any variations or uncertainty about established practice.
		+ 1. Eligible population
	3. Briefly describe the incidence and prevalence of the condition and life expectancy for people with the condition.
	4. State how many people are eligible for treatment with the technology in England for the full (anticipated) marketing authorisation or CE marking and for any subgroups considered. Include data for the next 5 years.
	5. Provide details of any assumptions used and include all steps taken to calculate the eligible population.
		+ 1. Resources
	6. Identify the resource use to the NHS associated with the technology being appraised and specify whether this is different to current clinical practice.
* Describe the location or setting of care (that is, primary and/or secondary care, commissioned by NHS England specialised services and/or clinical commissioning groups).
* Specify if the technology needs additional infrastructure in the NHS to be put in place.
* Provide information on the administration costs, staff costs, costs of monitoring and tests and the rate of adverse events associated with the technology. Include details of additional tests or investigations needed and other areas of healthcare resource.
* State whether any concomitant therapies are specified in the (anticipated) marketing authorisation or were administered in the key clinical trials (for example, for managing adverse reactions) with the technology.
* State if and to what extent the technology will affect patient monitoring compared with established clinical practice in England.
	1. Provide a table that clearly sets out all relevant costs for the technology.
* This should include any commercial arrangements if applicable (see section 1.2), the costs of administration, monitoring, managing adverse events, and any other costs that should be taken into account when assessing the budget impact of the technology.
* Provide information (source data, calculations, basis for assumptions) on the unit costs used. If unit costs used in the economic analysis were not based on national reference costs or the payment-by-results tariff, explain how the cost for the activity was calculated.
	1. Provide a table that clearly sets out the relevant costs for the comparator technologies (identified in section 2). This should include all costs and the information described in section 4.2.
		+ 1. Uptake and market share
	2. Provide information to support estimates of market share for the current treatment options and for the technology for the next 5 years.

### Table X Uptake and market share

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Technology** | **Current practice** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| Eligible population | x | x | x | x | x | x |
| Technology being appraised  | x% | x% | x% | x% | x% | x% |
| [Comparator 1] | x% | x% | x% | x% | x% | x% |
| [Comparator 2] | x% | x% | x% | x% | x% | x% |
| [Comparator 3] | x% | x% | x% | x% | x% | x% |

* + - 1. Benefits and savings
	1. Describe any clinical benefits leading to resource savings that may be expected from using the technology (including those that are not quantifiable).
	2. State if there are any services (for example tests, investigations) the NHS may disinvest in as a result of adopting the technology and any areas where resources may be redirected.
	3. Quantify any clinical benefits leading to resource savings in England where possible (if not included in section 7 below).
		+ 1. Estimated annual budget impact
	4. Provide a table setting out the expected budget impact (see example table below). Indicate whether the eligible population is in line with the final scope and/or the company’s decision problem. If there is a commercial arrangement please provide a table using the list price and a table using the commercial arrangement.

### Table X Expected budget impact

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| Eligible population for treatment with [technology] |  |  |  |  |  |
| Population expected to receive [technology] |  |  |  |  |  |
| Cost (saving) of treatment pathway without [technology]  |  |  |  |  |  |
| Cost (saving) of treatment pathway with [technology]  |  |  |  |  |  |
| Net budget impact |  |  |  |  |  |

* 1. State if the net budget impact is expected to exceed the budget impact test of £20 million per year in any of the first 3 years of its use in the NHS (see the [budget impact test procedure](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/budget-impact-test)). This should take into account the cumulative effect of people having treatment for more than 1 year when recommendations allow.
	2. Include different scenarios as applicable.
		+ 1. Limitations of the budget impact assessment

Highlight any limitations of the budget impact assessment, including any assumptions not already discussed.

* + - 1. References

[Please use a recognised referencing style, such as Harvard or Vancouver. Trials should be identified by the first author or trial ID, rather than by relying on numerical referencing alone (for example, ‘TrialNCT123456/Trial ACRONYM/Jones et al.126' rather than ‘One trial126’).]