NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Fast track appraisal: cost-comparison case

[Appraisal title and ID number]

Document A

Company evidence submission summary for committee

**Company** confirm that all information in the submission summary is an accurate summary or replication of evidence in the main submission and accompanying appendices and that wherever possible a cross reference to the original source is provided.

**[Month year]**

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

Instructions for companies

This is the template you should use to summarise your evidence submission to the National Institute for Health and Care Excellence (NICE) when a cost-comparison case is made as part of the fast track technology appraisal process. This document will provide the appraisal committee with an overview of the important aspects of your submission, for decision-making.

This submission summary must not be longer than 25 pages, excluding the pages covered by this template. If it is too long it will not be accepted. Please submit a draft summary with your main evidence submission. The NICE technical team may request changes later.

When cross referring to evidence in the main submission or appendices, please use the following format: Document, heading, subheading (page X).

For all figures and tables in this summary that have been replicated, cross refer to the evidence from the main submission or appendices in the caption in the following format: Table/figure name – document, heading, subheading (page X).

Companies making evidence submissions to NICE should also refer to the NICE [guide to the methods of technology appraisal](http://publications.nice.org.uk/guide-to-the-methods-of-technology-appraisal-2013-pmg9/introduction), the NICE [guide to the processes of technology appraisal](http://publications.nice.org.uk/guide-to-the-processes-of-technology-appraisal-pmg19/introduction) and the NICE [process and methods addenda](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/process).

### 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 footer with appropriate text. (To change the footer, double click over the footer text. Double click back in the main body text when you have finished.)

Tables and figures

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

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Submission summary

# The technology

### Table 1 Technology being appraised – B.1.2 (page [X])

|  |  |
| --- | --- |
| **UK approved name and brand name** |  |
| **Mechanism of action** |  |
| **Marketing authorisation/CE mark status** | [Indicate whether the technology has a UK marketing authorisation/CE marking for the indications detailed in this submission. If so, give the date on which this was received. If not, state the current UK regulatory status, with relevant dates (for example, date of application and/or expected date of approval from the Committee for Human Medicinal Products)]. |
| **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.]  [If a submission is based on the company’s proposed or anticipated marketing authorisation, the company must advise NICE immediately of any difference between the anticipated and the final marketing authorisation approved by the regulatory authorities.]  [Include the (draft) SmPC for pharmaceuticals or information for use (IFU) for devices in appendix C.]  [Provide the (draft) European public assessment report for pharmaceuticals or a (draft) technical manual for devices in appendix C.] |
| **Method of administration and dosage** |  |
| **Additional tests or investigations** | [State whether additional tests or investigations are needed (for example, diagnostic tests to identify the population for whom the technology is indicated in the marketing authorisation)] |
| **List price and average cost of a course of treatment** |  |
| **Patient access scheme (if applicable)** | [Indicate if there is a patient access scheme agreed with the Department of Health, and whether this is a simple discount or complex arrangement] |

# Clinical pathway of care

[Summarise the clinical pathway of care in a diagram showing the context of the proposed use of the technology. Describe and explain any changes since the NICE technology appraisal(s) of the comparator(s) specified in the final scope.]

# Equality considerations

[Briefly summarise whether the use of this technology is likely to raise any equality issues. If there are none, please delete this section.]

# Key drivers of the cost effectiveness of the comparator(s)

## Clinical outcomes and measures

[Summarise the clinical outcomes and measures that were used in the cost-effectiveness analysis of the NICE technology appraisal(s) of the comparator(s) specified in the final scope for this appraisal.]

[Highlight the key clinical drivers of the cost-effectiveness results and include any preferred assumptions from the committee that are relevant to the consideration of these outcomes.]

## Resource use assumptions

[Summarise the committee’s preferred assumptions about resource use and the associated costs from the NICE technology appraisal(s) of the comparator(s).]

# Decision problem and NICE reference case

[Please choose the text below that is most applicable to your submission and adapt as needed.]

The submission covers the technology’s full marketing authorisation for this indication. The submission covers the full population for the comparator, as recommended by NICE.

The submission focuses on part of the technology’s marketing authorisation or part of the population for the comparator as recommended in NICE guidance [for example, explain if this affects details of the pathway position or population, such as ‘people with 2 previous relapses only’ or ‘people with severe disease’]. The proposed [position in the treatment pathway/population] is narrower than [the marketing authorisation/the population for the comparator as recommended by NICE] because: [please include the relevant option from the list below].

* The published NICE technology appraisal guidance for the comparator(s) specified in the NICE scope recommends the [comparator] for a subgroup of the population in the marketing authorisation, and therefore a cost-comparison case can be made only for this population [add details of the population for whom the comparator is recommended in NICE guidance].
* This is relevant to NHS clinical practice; it would not be used [elsewhere/in a wider population].
* The evidence base on [technology] is limited to [this position/population].
* This [position/population] optimises the cost effectiveness of [technology], because [please provide rationale].
* This [position/population] reflects where [technology] provides the most clinical benefit.
* [Technology] is not [clinically/cost] effective in [add position/population].

The company submission [is consistent with/differs from] the final NICE scope and the NICE reference case. [If the submission is different from the NICE reference case or scope, provide details and a rationale in the table below. Please delete rows, or if applicable the entire table, when the decision problem is consistent with the final NICE scope and the NICE reference case.]

### Table 2 The decision problem – B.1.1 (page [X])

|  |  |  |  |
| --- | --- | --- | --- |
|  | Final scope issued by NICE/reference case | Decision problem addressed in the company submission | Rationale if different from the final NICE scope |
| Population |  |  |  |
| Intervention |  |  |  |
| Comparator(s) |  |  |  |
| Outcomes |  |  |  |
| Economic analysis |  |  |  |
| Subgroups to be considered |  |  |  |

# Clinical effectiveness evidence

[Give details of the randomised controlled trials and non-randomised and non-controlled evidence that provide evidence of the clinical benefits of the technology and are relevant to the submission.]

### Table 3 Clinical effectiveness evidence

|  |  |  |  |
| --- | --- | --- | --- |
| **Study title** | **[Clinical trial name or primary author surname (year published)]** | **[Clinical trial name or primary author surname (year published)]** | **[Clinical trial name or primary author surname (year published)]** |
| **Study design** | [for example RCT, cohort study, systematic review] |  |  |
| **Population** |  |  |  |
| **Intervention(s)** |  |  |  |
| **Comparator(s)** |  |  |  |
| **Outcomes specified in the decision problem** |  |  |  |
| **Superiority, equivalence or non-inferiority trial?** |  |  | [Please delete columns if not required] |
| **Reference to section in submission** | [for example: B.3.1 (page 40) and F.1.1 (page 5)] |  | [If further columns are required, copy an additional table below] |

# Key results of the clinical effectiveness evidence

[Present the key results of the clinical trials, limited to the outcomes and measures that were included in the NICE technology appraisal(s) of the comparator(s) specified in the final scope.]

[Present each outcome under a separate subheading, and include cross references to the evidence in the main submission or appendices].

[Limit the text under each subheading to 200 words. Key figures from the submission may be included in addition to this.]

## [For example] Overall survival

# Evidence synthesis

[Present the results of any meta-analysis or indirect and mixed treatment comparisons. Please focus on the outcome measures that were used in the cost-effectiveness analysis of the NICE technology appraisal(s) of the comparator(s).]

[Summarise the results as clearly and briefly as possible – multiple forest plots are not appropriate for a submission summary.]

# Overview of the cost-comparison analysis

[In the table below, briefly summarise the costs and assumptions used in the cost-comparison analysis, including your rationale and supporting references (maximum 100 words each).]

[Include the time horizon, method for calculating acquisition costs and assumptions about resource use (for example, the frequency and costs associated with drug administration, patient monitoring and adverse events).]

### Table 4 Costs and assumptions in the cost-comparison analysis

|  |  |  |
| --- | --- | --- |
| **Costs and assumptions** | **Source** | **Justification** |
|  |  |  |
|  |  |  |
|  |  |  |
| [Add more rows as needed] |  |  |

# Base-case results

[Describe and tabulate the base-case cost-comparison results.]

### Table 5 Base-case results – B4.3 (page [X])

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Technologies** | **Acquisition costs (£)** | **Resource costs (£)** | **Adverse event costs (£)** | **Other costs (£)** | **TOTAL COSTS (£)** |
| **Intervention** |  |  |  |  |  |
| **Comparator 1** |  |  |  |  |  |
| **Comparator 2** |  |  |  |  |  |
| **[Add more rows as needed]** |  |  |  |  |  |
| [state the time horizon] | | | | | |

# Key sensitivity and subgroup analyses

[Give details of any sensitivity analyses or subgroup analyses.]

# Interpretation and conclusions of the evidence

[Briefly summarise the evidence supporting comparable costs and health benefits of the technology and its comparators (no more than 300 words in total, excluding cross references).]