NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single technology appraisal

[Evaluation 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) as part of the single technology appraisal (STA) process. This document will provide the evaluation 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 [health technology evaluation guidance development manual](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

### 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.

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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.)

Contents

[A.1 Health condition 5](#_Toc94095918)

[A.2 Clinical pathway of care 5](#_Toc94095919)

[A.3 Equality considerations 5](#_Toc94095920)

[A.4 The technology 5](#_Toc94095921)

[A.5 Decision problem and NICE reference case 6](#_Toc94095922)

[A.6 Clinical effectiveness evidence 9](#_Toc94095923)

[A.7 Key results of the clinical effectiveness evidence 10](#_Toc94095924)

[A.8 Evidence synthesis 10](#_Toc94095926)

[A.9 Key clinical issues 10](#_Toc94095927)

[A.10 Overview of the economic analysis 11](#_Toc94095928)

[A.11 Incorporating clinical evidence into the model 11](#_Toc94095929)

[A.12 Key model assumptions and inputs 11](#_Toc94095930)

[A.13 Base-case ICER (deterministic) 12](#_Toc94095931)

[A.14 Probabilistic sensitivity analysis 13](#_Toc94095932)

[A.15 Key sensitivity and scenario analyses 13](#_Toc94095933)

[A.16 Benefits not captured in the QALY calculation 15](#_Toc94095934)

[A.17 Severity 15](#_Toc94095935)

[A.18 Budget impact 15](#_Toc94095937)

[A.19 Interpretation and conclusions of the evidence 16](#_Toc94095939)

Tables and figures

[Table 1 Technology being evaluated – B.1.2 (page [X]) 5](#_Toc94095831)

[Table 2 The decision problem – B.1.1 (page [X]) 7](#_Toc94095832)

[Table 3 Clinical effectiveness evidence 9](#_Toc94095833)

[Table 4 Key model assumptions and inputs 11](#_Toc94095834)

[Table 5 Base-case results (deterministic) – B.3.7 (page [X]) 12](#_Toc94095835)

[Table 6 Base-case results (probabilistic) – B.3.8 (page [X]) 13](#_Toc94095836)

[Table 7 Key scenario analyses 14](#_Toc94095837)

[Table 9 Budget impact – [Document] (page [X]) 15](#_Toc94095838)

[Figure 1 Model diagram – B.3.2 (page [X]) 11](#_Toc478402523)

[Figure 2 Scatterplot of probabilistic results – B.3.8 (page [X]) 13](#_Toc478402524)

[Figure 3 Tornado diagram – B.3.8 (page [X]) 13](#_Toc478402525)

Submission summary

# Health condition

[Provide a brief overview of the disease or condition for which the technology is indicated (no more than 250 words).]

# Clinical pathway of care

Present a diagram summarising the clinical pathway of care that shows the context of the proposed use of the technology.]

# 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.]

# The technology

**Table 1 Technology being evaluated – 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 granted. If not, state the current UK regulatory status, with relevant dates. [(For example, date of application and/or expected date of approval from the MHRA)] |
| **Indications and any restriction(s) as described in the summary of product characteristics** | [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 infomation for use (IFU) for devices in appendix C. Provide the (draft) UK 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 NHS England, and whether this is a simple discount or complex arrangement] |

# 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 focuses on part of the technology’s marketing authorisation [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 because: [please include the relevant option from the list below]

* 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 |  |  |  |
| Perspective for outcomes | [All direct health effects, whether for patients or, when relevant, carers] |  |  |
| Perspective for costs | [NHS and personal social services (PSS)] |  |  |
| Time horizon | [Long enough to reflect all important differences in costs or outcomes between the technologies being compared] |  |  |
| Synthesis of evidence on health effects | [Based on systematic review] |  |  |
| Measuring and valuing health effects | [Health effects should be expressed in QALYs. The EQ-5D is the preferred measure of health-related quality of life in adults.] |  |  |
| Source of data for measurement of health-related quality of life | [Reported directly by patients or carers, or both] |  |  |
| Source of preference data for valuation of changes in health-related quality of life | [Representative sample of the UK population] |  |  |
| Equity considerations | [An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit, except in specific circumstances] |  |  |
| Evidence on resource use and costs | [Costs should relate to NHS and PSS resources and should be valued using the prices relevant to the NHS and PSS] |  |  |
| Discounting | [The same annual rate for both costs and health effects (currently 3.5%)] |  |  |

# 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.]

[It is anticipated that this will be limited to the data that are used in your economic model; if not please explain this clearly using the wording below]

**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** | [Please mark in bold the outcomes that are incorporated into the model’s base-case results] |  | [Please delete columns if not required] |
| **Reference to section in submission** | [for example: B.2.1 (page 40) and F.1.1 (page 5)] |  | [If further columns are required, copy an additional table below] |

[Please delete if not relevant]:

[Study name] was not used to populate the economic model. The results of this study support [please include details of why it is relevant]. This study was not included in the economic model because [please add rationale].

# Key results of the clinical effectiveness evidence

[Present the key results of the relevant studies. 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 results that are used in the economic model.]

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

# Key clinical issues

[Please provide a bullet list of the key assumptions and limitations that should be considered when interpreting these results. It is expected there would be no more than 5 key issues. Examples are included below.]

* [Crossover in study 1 means that overall survival benefit is underestimated.]
* [The impact of crossover cannot be accounted for in all studies in the mixed treatment comparison because we do not have access to the data.]

# Overview of the economic analysis

[Provide an annotated diagram of the model structure used in the cost-effectiveness analysis. Annotations should include cycle length, time horizon, and summarised transition probabilities.]

**Figure 1 Model diagram – B.3.2 (page** **[X])**

# Incorporating clinical evidence into the model

[Please summarise the key clinical parameters and variables included in the cost-effectiveness analysis. For example, describe methods of extrapolation, survival analysis techniques, estimation and application of transition probabilities, and whether any validation of the clinical parameters has been carried out.]

# Key model assumptions and inputs

[Briefly summarise details of the key assumptions and inputs used in the economic model, including any assumptions that do not align with the reference case (maximum 100 words each).] [Focus should be given to inputs and assumptions where there is plausible uncertainty (for example, an assumption identified by clinical opinion) and where identified uncertainty substantially affects the ICER.]

**Table 4 Key model assumptions and inputs**

|  |  |  |
| --- | --- | --- |
| **Model input and cross reference** | **Source/assumption** | **Justification** |
| [Progression-free survival][B.3.6 (page X)]  | [Evidence from study 2] | [The baseline patient characteristics of the included trials were heterogeneous so a meta-analysis would be inappropriate. Data from the larger phase III trial rather than the exploratory phase II trial were used]. |
| [Administration costs][B.3.6 (page X)] | [No administration costs] | [Both regimens are oral and taken by patients at home. It has been assumed that administration costs are not incurred]. |
| [Treatment duration][B.3.6 (page X)] | [Treatment duration for X was derived from study 1, but for the comparator it was assumed that treatment continued until progression] | [Mean time on treatment (and 95% confidence intervals) was reported from study 1, whereas clinical expert opinion was that treatment with the comparator is continued until progression.] |
| [Add more rows as needed] |  |  |

# Base-case ICER (deterministic)

[Present the results of the cost-effectiveness analysis for your base-case scenario and preferred set of assumptions. Present results in ascending order of incremental ICER, and mark the results for the technology under consideration in bold.]

**Table 5 Base-case results (deterministic) – B.3.7 (page** **[X])**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Technologies** | **Total costs (£)** | **Total LYG** | **Total QALYs** | **Incremental. costs (£)** | **Incremental LYG** | **Incremental QALYs** | **ICER versus baseline (£/QALY)** | **Incremental ICER (£/QALY)** |
|  |  |  |  |  |  |  |  |  |
| [Add more rows as needed] |  |  |  |  |  |  |  |  |
| Abbreviations: ICER, incremental cost-effectiveness ratio; LYG, life years gained; QALYs, quality-adjusted life years |

# Probabilistic sensitivity analysis

[Provide, as one table and accompanying scatterplot, the key probabilistic sensitivity analysis. Present table results in ascending order of incremental ICER, and mark the results for the technology under consideration in bold.]

[Include a cross reference to the discussion of the underlying methodology, including the specific distribution of all parameters, in the main submission.]

**Table 6 Base-case results (probabilistic) – B.3.8 (page [X])**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Technologies** | **Total costs (£)** | **Total LYG** | **Total QALYs** | **Incremental. costs (£)** | **Incremental LYG** | **Incremental QALYs** | **ICER versus baseline (£/QALY)** | **Incremental ICER (£/QALY)** |
|  |  |  |  |  |  |  |  |  |
| [Add more rows as needed] |  |  |  |  |  |  |  |  |
| Abbreviations: ICER, incremental cost-effectiveness ratio; LYG, life years gained; QALYs, quality-adjusted life years |

**Figure 2 Scatterplot of probabilistic results – B.3.8 (page [X])**

# Key sensitivity and scenario analyses

[Provide a summary of the sensitivity analyses as a Tornado diagram]

**Figure 3 Tornado diagram – B.3.8 (page [X])**

[Summarise the scenario analyses that have the most substantial impact on the cost-effectiveness results and that you consider plausible. Do not include scenarios that do not follow the NICE reference case. It is anticipated this summary would include no more than 5 different scenarios]

**Table 7 Key scenario analyses**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario and cross reference** | **Scenario detail** | **Brief rationale** | **Impact on base-case ICER** |
| **Base case** | **[Add base case ICER for reference]** |
| [higher baseline age][B.3.6 (page X)] | [Anon 2015; Mean X, CI a-b)] | [The ICER is sensitive to age because it affects mortality, and Anon 2015 is a more recent study from a non-UK country.] | [+£X,XXX] |
|  |  |  |  |
|  |  |  | [Add more rows as needed] |

# Benefits not captured in the QALY calculation

[Provide a brief explanation (no more than 200 words) about why you consider the technology to have potential to make a substantial impact on health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculation, and therefore misrepresent the health utility gained.]

[For further information see the section on innovation in the main submission: B.2.12 (page X).]

# Severity

[If relevant, include a statement on whether this technology meets the criteria for a severity weight.]

### Table 8 summary of QALY shortfall analysis – B.3.6 (page [X])

|  |  |  |
| --- | --- | --- |
| **Expected total QALYs for the general population**  | **Total QALYs that people living with a condition would be expected to have with current treatment** | **QALY shortfall** |
|  | Comparator A |  |
| [Add more rows as needed] | Comparator B |  |

# Budget impact

[Provide summary values of the budget impact in the table below. Provide cross references to the assumptions and methods used in calculating the values]

Table 9 Budget impact – [Document] (page [X]**)**

|  |  |  |
| --- | --- | --- |
|  | Company estimate  | Cross reference |
| Number of people in England who would have treatment |  |  |
| Average treatment cost per person  |  |  |
| Estimated annual budget impact on the NHS in England |  |  |

# Interpretation and conclusions of the evidence

[Briefly summarise the clinical and cost-effectiveness evidence, including any health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculations (no more than 300 words, excluding cross references).]