NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single technology appraisal

[Appraisal title and ID number]

Company evidence submission

**[Month year]**

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

# Instructions for companies

This is the template for submission of evidence to the National Institute for Health and Care Excellence (NICE) as part of the single technology appraisal (STA) process. Please note that the information requirements for submissions are summarised in this template; full details of the requirements for pharmaceuticals and devices are in the [user guide](http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance).

This submission must not be longer than 250 pages, excluding appendices and the pages covered by this template.

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) and the NICE [guide to the processes of technology appraisal](http://publications.nice.org.uk/guide-to-the-processes-of-technology-appraisal-pmg19/introduction).

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# Tables and figures

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

* + - 1. Executive summary

[The executive summary should include the information listed in sections 1.1 to 1.4 below.]

1.1 Statement of decision problem

[Specify the decision problem that the submission addresses. Present the decision problem in the table below.]

### Table X The decision problem

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Final scope issued by NICE** | **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** |  |  |  |
| **Special considerations including issues related to equity or equality** |  |  |  |

1.2 Description of the technology being appraised

[Describe the technology being appraised in the table below.]

### Table XTechnology being appraised

|  |  |
| --- | --- |
| **UK approved name and brand name** |  |
| **Marketing authorisation/CE mark status** |  |
| **Indications and any restriction(s) as described in the summary of product characteristics** |  |
| **Method of administration and dosage** |  |

## 1.3 Summary of the clinical effectiveness analysis

[Include the studies and any meta-analyses or indirect comparisons that provide evidence of the clinical effectiveness and adverse reactions, a summary of the results and strengths and limitations of the evidence.]

## 1.4 Summary of the cost-effectiveness analysis

[In the table below include an outline of the model structure and the base-case results, the key drivers of the cost-effectiveness results and the strengths and limitations of the analysis. If an incremental analysis is not considered appropriate, explain why.]

### Table X Incremental cost-effectiveness results

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Technology (and comparators)** | **Total costs** | **Total life years** | **Total QALYs** | **Incremental costs** | **Incremental life years** | **Incremental QALYs** | **ICER versus baseline (A)** | **Incremental analysis** |
| **A** | 100 |  | 3 | 0 |  | 0 | N/A | N/A |
| **B** | 200 |  | 6 | 100 |  | 3 | 33.33333 | 33.33333 |
| **C** | 300 |  | 4 | 200 |  | 1 | 200 | Dominated |
| **D** | 400 |  | 8 | 300 |  | 5 | 60 | Extended dominance |
| **E** | 500 |  | 11 | 400 |  | 8 | 50 | 60 |
| ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life years | | | | | | | | |

* + - 1. The technology

2.1 Description of the technology

[Give the brand name, UK approved name, the therapeutic class and a brief overview of the mechanism of action.]

[See section 2.1 of the user guide for full details of the information required here.]

2.2 Marketing authorisation/CE marking and health technology assessment

[Provide details of the (anticipated) indication(s), including the (draft) summary of product characteristics or information for use, expected date of the opinion of the Committee for Human Medicinal Products, marketing authorisation approval or CE marking and launch date.]

[See section 2.2 of the user guide for full details of the information required here.]

2.3 Administration and costs of the technology

[Provide details of the treatment regimen, including the method of administration, healthcare resource use and costs associated with the technology. For pharmaceuticals, complete the table below, indicating whether the acquisition cost is list price or includes a patient access scheme, and the anticipated care setting. For devices, provide the list price and average selling price in a similar table.]

[See section 2.3 of the user guide for full details of the information required here.]

### Table X Costs of the technology being appraised

|  |  |  |
| --- | --- | --- |
|  | **Cost** | **Source** |
| **Pharmaceutical formulation** |  |  |
| **Acquisition cost (excluding VAT) \*** |  |  |
| **Method of administration** |  |  |
| **Doses** |  |  |
| **Dosing frequency** |  |  |
| **Average length of a course of treatment** |  |  |
| **Average cost of a course of treatment** |  |  |
| **Anticipated average interval between courses of treatments** |  |  |
| **Anticipated number of repeat courses of treatments** |  |  |
| **Dose adjustments** |  |  |
| **Anticipated care setting** |  |  |
| \* Indicate whether this acquisition cost is list price or includes an approved patient access scheme. When the marketing authorisation or anticipated marketing authorisation recommends the intervention in combination with other treatments, the acquisition cost of each intervention should be presented. | | |

2.4 Changes in service provision and management

[Provide details of additional tests or investigations needed, other areas of healthcare resource use and costs associated with the technology, and any additional infrastructure requirements.]

[See section 2.4 of the user guide for full details of the information required here.]

2.5 Innovation

[If you consider the technology to be innovative with potential to make a substantial impact on health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculation, identify and present the data used and provide a rationale for your decision.]

[See section 2.5 of the user guide for full details of the information required here.]

* + - 1. Health condition and position of the technology in the treatment pathway

[Provide a brief overview of the disease or condition for which the technology is being used. Include details of the underlying course of the disease.]

[Describe the effects of the disease or condition on patients, carers and society.]

[Explain how the new technology may change the existing treatment pathway.]

[Provide an assessment of whether the use of this technology is likely to raise any equality issues.]

[See section 3 of the user guide for full details of the information required here.]

* + - 1. Clinical effectiveness

4.1 Identification and selection of relevant studies

[Describe the process and methods used to identify and select the studies relevant to the technology being appraised.]

[See section 4.1 of the user guide for full details of the information required here.]

4.2 List of relevant randomised controlled trials

[Provide details of the randomised controlled trials (RCTs) that provide evidence on the clinical benefits of the technology at its licensed dosage within the indication being appraised.]

[See section 4.2 of the user guide for full details of the information required here.]

4.3 Summary of methodology of the relevant randomised controlled trials

[Provide details of the methodology of the RCTs listed in section 4.2.]

[See section 4.3 of the user guide for full details of the information required here.]

4.4 Statistical analysis and definition of study groups in the relevant randomised controlled trials

[State the primary hypothesis or hypotheses under consideration and provide methods used for testing hypotheses for each RCT listed in section 4.2.]

[See section 4.4 of the user guide for full details of the information required here.]

4.5 Participant flow in the relevant randomised controlled trials

[Provide details for each treatment group, the numbers of participants who were (randomly) assigned, received the intended treatment, and were analysed for the primary outcome and safety outcomes.]

[See section 4.5 of the user guide for full details of the information required here.]

4.6 Quality assessment of the relevant randomised controlled trials

[Provide a quality assessment for each RCT listed in section 4.2.]

[See section 4.6 of the user guide for full details of the information required here.]

4.7 Clinical effectiveness results of the relevant randomised controlled trials

[Provide the results for all relevant outcome measures pertinent to the decision problem.]

[See section 4.7 of the user guide for full details of the information required here.]

4.8 Subgroup analysis

[Provide details of any subgroup analyses that were carried out and specify the rationale and whether they were pre-planned or post-hoc.]

[See section 4.8 of the user guide for full details of the information required here.]

4.9 Meta-analysis

[Provide details of the methodology and results of any meta-analyses carried out. If a meta-analysis is not considered appropriate, a rationale must be given and a qualitative overview provided.]

[See section 4.9 of the user guide for full details of the information required here.]

4.10 Indirect and mixed treatment comparisons

[Provide details of the methodology and the results of the indirect and/or mixed treatment comparison. Use the 5 subheadings of: search strategy; study selection; methods and outcomes of included studies; risk of bias; and methods of analysis and presentation of results.]

[See section 4.10 of the user guide for full details of the information required here.]

4.11 Non-randomised and non-controlled evidence

[Provide details of the non-randomised and non-controlled studies that provide additional evidence to supplement RCT data. Provide a list of the relevant studies and summarise the methodology, statistical analyses, participant flow and quality assessment for each. Briefly summarise the results of the non-randomised and non-controlled studies.]

[See section 4.11 of the user guide for full details of the information required here.]

4.12 Adverse reactions

[Provide details of all adverse reactions experienced with the technology in relation to the decision problem.]

[See section 4.12 of the user guide for full details of the information required here.]

4.13 Interpretation of clinical effectiveness and safety evidence

[Briefly conclude the clinical effectiveness and safety of the technology against the comparators specified in the final scope issued by NICE, including any subgroups. If relevant, include a statement on whether this technology meets the end-of-life criteria. Complete the table below and cross reference to where this information is found in the company submission.]

[See section 4.13 of the user guide for full details of the information required here.]

### Table X End-of-life criteria

|  |  |
| --- | --- |
| **Criterion** | **Data available** |
| The treatment is indicated for patients with a short life expectancy, normally less than 24 months | [State mean and/or median life expectancy, and source of the data] |
| There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared with current NHS treatment | [State mean and/or median extension to life, and source of the data] |
| The treatment is licensed or otherwise indicated for small patient populations | [State the cumulative number of patients for all licensed indications in England and source of the data] |

4.14 Ongoing studies

[Provide details of all completed and ongoing studies from which additional evidence is likely to be available in the next 12 months for the indication being appraised.]

* + - 1. Cost effectiveness

5.1 Published cost-effectiveness studies

[Describe and compare the methods and results of any published cost-effectiveness analyses available for the technology and/or the comparator technologies (relevant to the technology appraisal).]

[See section 5.1 of the user guide for full details of the information required here.]

5.2 De novo analysis

### Patient population

[Provide details about the patient population included in the de novo cost-effectiveness analysis.]

[See section 5.2.1 of the user guide for full details of the information required here.]

### Model structure

[Provide details about the model structure of the de novo cost-effectiveness analysis.]

[See sections 5.2.2–5.2.3 of the user guide for full details of the information required here.]

[Summarise the features of the de novo analysis in the table below.]

### Table X Features of the de novo analysis

|  |  |  |
| --- | --- | --- |
| **Factor** | **Chosen values** | **Justification** |
| Time horizon |  |  |
| Were health effects measured in QALYs; if not, what was used? |  |  |
| Discount of 3.5% for utilities and costs |  |  |
| Perspective (NHS/PSS) |  |  |
| PSS, personal social services; QALYs, quality-adjusted life years | | |

### Intervention technology and comparators

[Provide details about the intervention technology and comparator technologies included in the de novo cost-effectiveness analysis.]

[See sections 5.2.4 and 5.2.5 of the user guide for full details of the information required here.]

5.3 Clinical parameters and variables

[Provide details about the clinical parameters and variables included in the de novo cost-effectiveness analysis. This includes describing whether intermediate outcomes were linked to final outcomes, methods of extrapolation, estimation and application of transitional probabilities (when relevant), the use and selection of the most appropriate survival analysis techniques and whether any validation of the clinical parameters has been carried out.]

[See section 5.3 of the user guide for full details of the information required here.]

5.4 Measurement and valuation of health effects

[See section 5.4 of the user guide.]

### Health-related quality-of-life data from clinical trials

[Provide details of the health-related quality-of-life data available from the clinical trials.]

[See section 5.4.1 of the user guide for full details of the information required here.]

### Mapping

[Provide details of any mapping techniques used to estimate health-related quality-of-life data. If health-related quality-of-life data were collected in the clinical trials but not mapped onto a generic outcome measure, explain why.]

[See section 5.4.2 of the user guide for full details of the information required here.]

### Health-related quality-of-life studies

[Provide details of the health-related quality-of-life data available from published (and unpublished) studies.]

[See sections 5.4.3–5.4.5 of the user guide for full details of the information required here.]

### Adverse reactions

[Provide details of how adverse reactions associated with the technology have an impact on health-related quality-of-life.]

[See section 5.4.6 of the user guide for full details of the information required here.]

### Health-related quality-of-life data used in cost-effectiveness analysis

[Provide details of the health-related quality-of-life data used in the cost-effectiveness analysis, including a description of patient experience in the health states of the de novo analysis and whether the utility values have been adjusted and validated.]

[See sections 5.4.7–5.4.13 of the user guide for full details of the information required here.]

[Provide the utility values used in the de novo analysis in the table below.]

### Table X Summary of utility values for cost-effectiveness analysis

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **State** | **Utility value: mean (standard error)** | **95% confidence interval** | **Reference in submission (section and page number)** | **Justification** |
| Health state 1 | HS1 |  |  |  |
| Health state 2 | HS2 |  |  |  |
| [Add more rows as needed] |  |  |  |  |
| Adverse reaction 1 | AR1 |  |  |  |
| Adverse reaction 2 | AR2 |  |  |  |
| HS, health state; AR, adverse reaction | | | | |

5.5 Cost and healthcare resource use identification, measurement and valuation

[See section 5.5.1 of the user guide.]

### Resource identification, measurement and valuation studies

[Provide details of how healthcare resources and unit costs included in the de novo cost-effectiveness analysis were identified.]

[See sections 5.5.2–5.5.4 of the user guide for full details of the information required here.]

### Intervention and comparators’ costs and resource use

[Describe and tabulate the costs and resource use associated with the intervention technology and comparator technologies included in the de novo cost-effectiveness analysis.]

[See section 5.5.5 of the user guide for full details of the information required here.]

### Health-state unit costs and resource use

[Describe and tabulate the unit costs and resource use associated with the health states included in the de novo cost-effectiveness analysis.]

[See section 5.5.6 of the user guide for full details of the information required here.]

### Adverse reaction unit costs and resource use

[Describe and tabulate the unit costs and resource use associated with the adverse reactions included in the de novo cost-effectiveness analysis.]

[See section 5.5.7 of the user guide for full details of the information required here.]

### Miscellaneous unit costs and resource use

[Describe and tabulate any other unit costs and resource use that have been included in the de novo cost-effectiveness analysis.]

[See section 5.5.8 of the user guide for full details of the information required here.]

5.6 Summary of base-case de novo analysis inputs and assumptions

### Summary of base-case de novo analysis inputs

[Summarise and tabulate the inputs and variables of the de novo cost-effectiveness analysis.]

[See sections 5.6.1–5.6.2 of the user guide for full details of the information required here.]

[Summarise the base-case de novo analysis inputs in the table below.]

### Table X Summary of variables applied in the economic model

|  |  |  |  |
| --- | --- | --- | --- |
| **Variable** | **Value (reference to appropriate table or figure in submission)** | **Measurement of uncertainty and distribution: CI (distribution)** | **Reference to section in submission** |
| [Age] | [A years] | [x to y (normal)] | [Patient characteristics section x] |
| [Overall survival] | [B months] | [x to y (Weibull)] | [Trial results section x] |
| [Add more rows as needed] |  |  |  |
| CI, confidence interval | | | |

### Assumptions

[Provide a list of all assumptions in the de novo economic model and justify each assumption.]

5.7 Base-case results

[See section 5.7.1 of the user guide.]

### Base-case incremental cost effectiveness analysis results

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

[See section 5.7.2 of the user guide for full details of the information required here.]

[Present the base-case results in the table below.]

### Table X Base-case results

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Technologies** | **Total costs (£)** | **Total LYG** | **Total QALYs** | **Incremental costs (£)** | **Incremental LYG** | **Incremental QALYs** | **ICER (£) versus baseline (QALYs)** | **ICER (£) incremental (QALYs)** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| ICER, incremental cost-effectiveness ratio; LYG, life years gained; QALYs, quality-adjusted life years | | | | | | | | |

### Clinical outcomes from the model

[Present the estimates of clinical outcomes included in the de novo cost-effectiveness analysis (and compare with the clinical trial results).]

[See sections 5.7.3–5.7.5 of the user guide for full details of the information required here.]

### Disaggregated results of the base case incremental cost effectiveness analysis

[Describe and tabulate the disaggregated results of the base-case incremental cost-effectiveness analysis.]

[See section 5.7.6 of the user guide for full details of the information required here.]

[Present the disaggregated results of the base-case incremental cost-effectiveness analysis in the tables below.]

### Table X Summary of QALY gain by health state

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Health state** | **QALY intervention (X)** | **QALY comparator (Y)** | **Increment** | **Absolute increment** | **% absolute increment** |
| [Health state 1] | [XHS1] | [YHS1] | [XHS1 – YHS1] | [|XHS1 – YHS1|] | [|XHS1 – YHS1|/(Total absolute increment)] |
| [Health state 2] | [XHS2] | [YHS2] | [XHS2 – YHS2] | [|XHS2 – YHS2|] | [|XHS2 – YHS2|/(Total absolute increment)] |
| [Add more rows as needed] |  |  |  |  |  |
| Total | [XTotal] | [YTotal] | [XTotal – YTotal] | Total absolute increment | 100% |
| QALY, quality-adjusted life year; HS1, health state 1; HS2, health state 2  Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee | | | | | |

Table X Summary of costs by health state

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Health state** | **Cost intervention (X)** | **Cost comparator (Y)** | **Increment** | **Absolute increment** | **% absolute increment** |
| [Health state 1 (HS1)] | [XHS1] | [YHS1] | [XHS1 – YHS1] | [|XHS1 – YHS1|] | [|XHS1 – YHS1| / (Total absolute increment)] |
| [Health state 2] | [XHS2] | [YHS2] | [XHS2 – YHS2] | [|XHS2 – YHS2|] | [|XHS2 – YHS2| / (Total absolute increment)] |
| [Add more rows as needed] |  |  |  |  |  |
| Total | [XTotal] | [YTotal] | [XTotal – YTotal] | Total absolute increment | 100% |
| HS1, health state 1; HS2, health state 2  Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee | | | | | |

Table X Summary of predicted resource use by category of cost

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Item** | **Cost intervention (X)** | **Cost comparator (Y)** | **Increment** | **Absolute increment** | **% absolute increment** |
| [Technology cost] | [Xtech] | [Ytech] | [Xtech – Ytech] | [|Xtech – Ytech|] | [|Xtech – Ytech| / (Total absolute increment)] |
| [Mean total treatment cost] | [Xtreat] | [Ytreat] | [Xtreat – Ytreat] | [|Xtreat – Ytreat|] | [|Xtreat – Ytreat| / (Total absolute increment)] |
| [Administration cost] | [Xadmin] | [Yadmin] | [Xadmin – Yadmin] | [|Xadmin – Yadmin|] | [|Xadmin – Yadmin| / (Total absolute increment)] |
| [Monitoring cost] | [Xmon] | [Ymon] | [Xmon – Ymon] | [|Xmon – Ymon|] | [|Xmon – Ymon| / (Total absolute increment)] |
| [Tests] | [Xtests] | [Ytests] | [Xtests – Ytests] | [|Xtests – Ytests|] | [|Xtests – Ytests| / (Total absolute increment)] |
| [Add more rows as needed] |  |  |  |  |  |
| Total | [XTotal] | [YTotal] | [XTotal – YTotal] | Total absolute increment | 100% |
| Tech, technology; treat, treatment; admin, administration; mon, monitoring | | | | | |

5.8 Sensitivity analyses

### Probabilistic sensitivity analysis

[Describe the methods and present the results of the probabilistic sensitivity analysis.]

[See sections 5.8.1–5.8.4 of the user guide for full details of the information required here.]

### Deterministic sensitivity analysis

[Describe the methods and tabulate the incremental cost-effectiveness results of the deterministic sensitivity analysis.]

[See sections 5.8.5–5.8.7 of the user guide for full details of the information required here.]

### Scenario analysis

[Describe the methods and tabulate the incremental cost-effectiveness results of the scenario analyses carried out.]

[See sections 5.8.8–5.8.9 of the user guide for full details of the information required here.]

### Summary of sensitivity analyses results

[Summarise the key results of the sensitivity analyses.]

[See section 5.8.10 of the user guide for full details of the information required here.]

5.9 Subgroup analysis

[Provide details of any subgroup analyses explored in the cost-effectiveness analysis.]

[See sections 5.9.1–5.9.6 of the user guide for full details of the information required here.]

5.10 Validation

### Validation of de novo cost-effectiveness analysis

[Describe any methods used to internally and externally validate the de novo cost-effectiveness analysis.]

[See section 5.10.1 of the user guide for full details of the information required here.]

5.11 Interpretation and conclusions of economic evidence

[Provide a conclusion on the cost effectiveness of the technology.]

[See section 5.11.1 of the user guide for full details of the information required here.]

* + - 1. Assessment of factors relevant to the NHS and other parties

[Provide details of assessment of factors relevant to the NHS and other parties.]

[See section 6 of the user guide for full details of the information required here.]

* + - 1. References

[Use a recognised referencing style, such as Harvard or Vancouver.]

[See section 7 of the user guide for full details of the information required here.]

* + - 1. Appendices

[List the titles of the appendices here. All appendices should be provided as **separate documents to the main submission**.]

[See section 8 of the user guide for examples of appendices that may be used to support the submission.]