NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Cancer Drugs Fund Review of TA[XXX]

[Appraisal title and ID number]

Company evidence submission for committee

**[Month year]**

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

Instructions for companies

This is the template you should use for your evidence submission to the National Institute for Health and Care Excellence (NICE) as part of the Cancer Drugs Fund (CDF) review process. This document will provide the appraisal committee with an overview of the important aspects of your submission for decision-making.

This submission should not be longer than 25 pages, excluding the pages covered by this template. If it is too long it will not be accepted.

If applicable provide any supportive and detailed methodological or investigative evidence (additional to the clinical trial and/or Systemic Anti-Cancer Therapy data) in an appendix to this submission.

When cross referring to evidence in the original 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](https://www.nice.org.uk/process/pmg9/chapter/introduction) and the NICE [guide to the processes of technology appraisal](https://www.nice.org.uk/process/pmg19/chapter/introduction).

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Cancer Drugs Fund review submission

# Background

[NICE expect this section to replicate the corresponding section from the 'Terms of engagement' document. If there are differences, please explicitly describe them.]

# Key committee assumptions

[NICE expect this section to replicate the corresponding section from the 'Terms of engagement' document. If there are differences, please explicitly describe them.]

# Other agreed changes

[NICE expect this section to replicate the corresponding section from the 'Terms of engagement' document. If there are differences, please explicitly describe them.]

# The technology

**Table 1 Technology being reviewed**

[Please explcitly describe if there have been any changes since the technology was recommended for use in the CDF (e.g. updates to the wording of the marketing authorisation)]

|  |  |
| --- | --- |
| **UK approved name and brand name** |  |
| **Mechanism of action** |  |
| **Marketing authorisation/CE mark status** | [Describe the marketing authorisation/CE marking for the indications detailed in this submission. Give the date on which this was received.].  |
| **Indications and any restriction(s) as described in the summary of product characteristics** |  |
| **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** |  |
| **Commercial arrangement (if applicable)** | [Indicate if there is a patient access scheme or commercial arrangment agreed which applies for this technology and indication, and whether this is a simple discount or complex arrangement][Note: all cost-effectiveness analyses should only incorporate commercial arrangements that would be operational after the CDF review date, i.e. a commercial arrangement that is operational only during the CDF managed access period should **not** be included.] |
| **Date technology was recommended for use in the CDF** | [Month, Year] |
| **Data collection end date** | [Month, Year] |

# Clinical effectiveness evidence

 [Give details of the data collected during the CDF data collection period that provide evidence that addresses committee’s key uncertainties. NICE expect this section to reflect the corresponding section from the 'Terms of engagement' document. If there are differences, please explicitly describe them.]

**Table 3 Primary source of clinical effectiveness evidence**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study title**  | **[Clinical trial name or primary author surname (year published)]** | **SACT data cohort study** | **[Clinical trial name or primary author surname (year published)]** |
| **Study design** | [for example: RCT, SACT data cohort study, systematic review] | SACT data cohort study |  |
| **Population** |  |  |  |
| **Intervention(s)** |  |  |  |
| **Comparator(s)** |  | Not applicable |  |
| **Outcomes collected that address committee’s key uncertainties**  | [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 appendix** | [for example: B.1.1 (page 5)] |  | [If further columns are required, copy an additional table below] |

[Please delete if not relevant]:

Evidence from [Study name] was not used to update 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].

**Table 3 Secondary source of clinical effectiveness evidence**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study title**  | **[Clinical trial name or primary author surname (year published)]** | **SACT data cohort study** | **[Clinical trial name or primary author surname (year published)]** |
| **Study design** | [for example: RCT, SACT data cohort study, systematic review] | SACT data cohort study |  |
| **Population** |  |  |  |
| **Intervention(s)** |  |  |  |
| **Comparator(s)** |  | Not applicable |  |
| **Outcomes collected that address committee’s key uncertainties**  | [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 appendix** | [for example: B.1.1 (page 5)] |  | [If further columns are required, copy an additional table below] |

[Please delete if not relevant]:

Evidence from [Study name] was not used to update 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 data collection

[Present the key results of the data collected during the CDF data collection period that provide evidence that addresses committee’s key uncertainties. Explicitly describe for each outcome how the collected data compares to that presented at the point of CDF entry. Present each outcome under a separate subheading, and include cross references to the evidence in the appendices where necessary].

[Limit the text under each subheading to around 200 words. Key figures from the appendix should 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 that are used in the economic model. Delete this section if not relevant for this review]

# Incorporating collected data into the model

[Summarise how clinical data collected during the CDF data collection period is incorporated into the economic model in separate subheadings below. Describe where incorporation of collected data results in changes to model assumptions and extrapolations. Provide key figures, such as goodness of fit graphs in this submission. Provide supportive and detailed methodological or investigative evidence in an appendix to this submission.]

## [For example] Overall survival

# Key model assumptions and inputs

[Summarise details of all assumptions and inputs changed in the economic model following the CDF data collection period. Where describing the original parameter / assumption please use those that contributed to the estimate the committee considered demonstrated plausible potential for cost-effectiveness]

**Table 4 Key model assumptions and inputs**

|  |  |  |  |
| --- | --- | --- | --- |
| **Model input and cross reference** | **Original parameter/assumption** | **Updated parameter/assumption** | **Source/Justification** |
| [Progression-free survival source][B.3.6 (page X)]  | [Evidence from study 2] – provide date of data cut | [Evidence from study 2] – provide date of datacut | Further follow-up data from the pivotal trial (study 2) is incorporated into the clinical model |
| [Progression-free survival] extrapolation[B.3.6 (page X)] | Fully fitted log-normal parametric curve | Fully fitted log-logistic parametric curve | Goodness of fit statistics and visual inspection suggests that the log-logistic is the best fitting extrapolation for the updated clinical data |
| [Treatment duration][B.3.6 (page X)] | [X} | [Y]  | [Treatment duration for X was updated using real-world evidence obtained from SACT ] |
| [Add more rows as needed] |  |  |  |

# Cost-effectiveness results (deterministic)

[Present the results from the economic model submitted for the CDF review for the following cost-effectiveness analyses:
(1) Replication of the key cost-effectiveness result(s) considered by committee to demonstrate plausible potential for cost-effectiveness at entry to the CDF;
(2) Cost-effectiveness results that incorporate the data collected during the CDF data collection period, with all model inputs and parameters unchanged from cost-effectiveness analysis (1).
(3) Cost-effectiveness results that incorporate data collected during the CDF data collection period plus any associated changes to the company’s preferred assumptions]
Note: when multiple data sources and/or assumptions are altered following the CDF data collection period, please provide scenario analyses which illustrate the impact of each individual change in the appendix.

**Table 5 Cost-effectiveness results (deterministic)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Technologies** | **Total costs (£)** | **Total LYG** | **Total QALYs** | **Incremental. costs (£)** | **Incremental LYG** | **Incremental QALYs** | **ICER versus baseline (£/QALY)** | **Incremental ICER (£/QALY)** |
| Cost-effectiveness analysis 1: Replication of analysis that demonstrated plausible potential for cost-effectiveness at CDF entry |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Cost-effectiveness analysis 2: Analysis that demonstrated plausible potential for cost-effectiveness at CDF entry – incorporating updated clinical evidence |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Cost-effectiveness analysis 3: New company base-case |
|  |  |  |  |  |  |  |  |  |
| [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 appendices.]

**Table 6 Updated 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. ]

**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] |

# End-of-life criteria

[If a key committee uncertainty was whether the technology meets the end-of-life criteria, please fill out the table below. If not, please delete this section in its entirety]

**Table 8 End-of-life criteria – B.2.13 (page [X])**

|  |  |
| --- | --- |
| 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  |  |

# Key issues and conclusions based on the data collected during the CDF review period