**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health** **technology evaluation**

### Company decision problem form

Please use this form for submitting information about the pre-invitation scope, which will inform discussion at the decision problem meeting with NICE. This should be used with the relevant company submission template and the ‘[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)’, available on the [NICE website](https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-technology-appraisal-guidance).

*Please note that all commercial in confidence and academic in confidence information in this document must be appropriately highlighted and underlined and justification provided for the confidential nature of the information.*

**Section 1: Questions for NICE**

Please state any specific technical issues or questions about this technology evaluation that need discussing at the decision problem meeting. Please highlight any expected challenges in adhering to the ‘reference case’ (see ‘[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)’).

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**Section 2: Proposal for a cost comparison evaluation *[do not complete this section if not relevant]***

If you think that this technology evaluation should be in the cost comparison evaluation process, in the box below, summarise the evidence and assumptions supporting your proposal (maximum 250 words). The cost comparison process is described in section 5.6.27-5.6.32 of the ‘[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)’.

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**Section 3: NICE pre-invitation scope**

In this section please specify the decision problem that the evidence submission will address. The decision problem should be in line with NICE’s pre-invitation scope and should state the key parameters that the information in the evidence submission will address. Provide a clear rationale if the decision problem differs from the NICE pre-invitation scope.

| **Section** | Company information |
| --- | --- |
| Population |  |
| Intervention (Generic & brand name) |  |
| Comparator(s) |  |
| Outcomes |  |
| Economic analysis |  |
| Subgroups to be considered |  |
| Special considerations, including equity or equality issues |  |

**Section 4a: Comparison with methodology used in previous NICE health technology evaluations in the same disease area**

Please highlight key issues from previous NICE health technology evaluations in the disease area/indication that may be relevant to this evaluation. For example, uncertainties around, and plausibility of, assumptions and inputs in the economic model (such as utility values used). Please comment on how these issues were addressed in previous evaluations, including the committee’s preferred assumptions, and detail the approach planned for this evaluation.

It may be appropriate to apply different assumptions from those in previous health technology evaluations, for example if clinical practice or the understanding of the disease has changed, or if the evidence base necessitates a different model structure or assumptions. Provide a clear rationale if the intended methodology or assumptions differ from the committee’s preferred assumptions in previous evaluations.

| **Previous evaluation** | Issue | How issue was addressed in previous NICE evaluation and committee’s preferred assumptions | Company’s planned approach  and rationale |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
| **[Add more rows as needed]** | | | |

**Section 4b: Relevant outcomes and assumptions *[do not complete this section if there are no published NICE health technology evaluations of the comparators]***

Please compare the outcomes and specific measurement scales that will be included in your evidence submission with those included in the published NICE health technology evaluations of the comparator(s) and justify any differences. This section is particularly relevant if the new technology is likely to have similar clinical efficacy to the comparator. Please focus on the key drivers of cost effectiveness in NICE health technology evaluations of the comparator(s) and highlight the committee’s preferred assumptions about these outcomes.

| **Comparator evaluation** | Outcome and measurement scale used in NICE evaluation of comparator(s) | Committee’s preferred assumptions in NICE evaluation of comparator(s) | Company comments |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
| **[Add more rows as needed]** | | | |

**Section 4c: Resource use *[do not complete this section if there are no published NICE health technology evaluations of the comparators]***

Please highlight the resource costs that will be included in your evidence submission and compare these with the costs included in published NICE health technology evaluations of the comparator(s). Please justify any differences and comment on any uncertainties or potential areas of complexity. This section is particularly relevant if the new technology is likely to be similar in its resource use to the comparator.

| **Comparator evaluation** | Key resource costs associated with comparator(s) | Committee’s preferred assumptions in NICE evaluation of comparator(s) | Company comments |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
| **[Add more rows as needed]** | | | |

**Section 5a: Additional areas of complexity**

When estimating clinical and cost effectiveness, particular emphasis should be given to adhering to the ‘reference case’ (see ‘[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)’). Reasons for deviating from the NICE reference case should be clearly explained in your evidence submission to NICE. Please highlight any expected challenges in adhering to the reference case in the clinical effectiveness and cost-effectiveness tables below.

**Clinical effectiveness**

| **Section** | *Notes* | Company comments |
| --- | --- | --- |
| Clinical evidence sources and potential challenges in interpretation | *Please present information and/or issues relating to the clinical evidence that will be included in your submission. This section should be completed using NICE’s ‘*[*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)*’, sections 3.3.1–3.3.15, 3.3.18–3.3.25, and 3.4.1–3.4.23.* |  |
| EQ-5D data | *If the clinical trial(s) for the technology collected EQ-5D data, please confirm the following and explain your rationale:**The descriptive system used: EQ-5D-3L or EQ-5D-5L?**If the EQ-5D-5L system was used, was the data mapped back to the 3L tool using* *Hernández Alava et al. 2017?**Will your submission include any scenario analyses?**Please refer to section 4.3.16 of the ‘*[*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)*’* |  |
| Relevant evidence that is likely to become available during the evaluation | *Please provide details of any relevant evidence that is likely to become available during the evaluation.* |  |
| Additional information | *Please provide any additional information relating to clinical effectiveness that you believe NICE should be aware of.* |  |

Provide details of the relevant trials (both randomised controlled trials [RCTs] and non-RCTs) that will be included in your evidence submission to NICE. This should be in the tabular format below.

Please note that we expect you to provide the clinical study report(s) for the pivotal trial(s) as part of the appendices or references to your evidence submission.

**RCTs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial no. (acronym)** | **Intervention** | **Comparator** | **Population** | **Primary study ref.** |
| Trial 1 |  |  |  |  |
| Trial 2 |  |  |  |  |
| Etc. |  |  |  |  |

**Non-RCT**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trial no. (acronym)** | **Intervention** | **Population** | **Objectives** | **Primary study ref.** | **Justification for inclusion** |
| Trial 1 |  |  |  |  |  |
| Trial 2 |  |  |  |  |  |
| Etc. |  |  |  |  |  |

**Cost effectiveness**

| **Section** | *Notes* | Company comments |
| --- | --- | --- |
| Cost-effectiveness sources and potential challenges in interpretation e.g. health-related quality-of-life data | *Please present information relating to the cost-effectiveness evidence. This section should be completed using ‘*[*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)***’****, sections 3.3.26–3.3.27, and 4.3–4.7.* |  |
| Potential inclusion and handling of a patient access scheme or commercial access agreement | *Please provide information on any proposed patient access scheme or commercial access agreement.*  *If the patient access scheme or commercial access agreement has not yet been agreed with NHS England, please provide a timescale.* |  |
| Economic model software | *NICE accepts executable economic models using standard software (that is, Excel, DATA, R or WinBUGs) and the company must give NICE full access to the programming code. Please indicate which software will be used. If you plan to submit a model in a non-standard package, NICE, in association with the EAG, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the EAG with temporary licences for the non–standard software for the duration of the evaluation. NICE reserves the right to reject economic models in non-standard software.* |  |
| Additional infomation | *Please provide any additional information relating to cost effectiveness that you believe NICE should be aware of.* |  |

**Section 5b: Additional areas of complexity – Managed Access *[please delete this section if not relevant]***

A managed access proposal may be made for medicines where immature evidence or evidence gaps are likely to result in significant uncertainty for committee decision making.

| **Section** | *Notes* | **Company comments** |
| --- | --- | --- |
| Candidate for the managed access | *Please specify whether you consider the technology to be a candidate for entry into managed access?*  *NICE is able to recommend a technology for managed access if it has the plausible potential to be cost effective, but the clinical evidence is not robust enough for a recommendation in routine use. The drug will then be available through a managed access agreement while more evidence is gathered to resolve the key areas of uncertainty.* |  |
| Provide details of any relevant ongoing or planned studies | *Please list any relevant ongoing or planned studies that are expected to be completed after the evaluation has been published. Provide details of the intervention, comparator, population, outcomes and anticipated timeframe for reporting.* |  |
| Preferred source of data collection | *Please specify the preferred source of data collection to resolve the uncertainty. For example, ongoing or new clinical studies, registries or the Systemic Anti-cancer Therapy (SACT) dataset. If relevant, provide details of any clinical studies or registries.* |  |
| Population included in managed access proposal | *Please specify whether you anticipate that the population included in the managed access proposal is expected to be the population covered by the whole marketing authorisation or a subpopulation of the marketing authorisation. List any proposed details of patient eligibility for treatment, for example (if relevant), disease stage, previous treatment, performance status, mutation status.* |  |
| Proposed outcomes to be collected | *Please specify the proposed outcome data to be collected from each source of data collection that may resolve the key areas of uncertainty.* |  |
| Anticipated timeframe for data collection | *Please specify the anticipated minimum timeframe of data collection for providing meaningful data.* |  |

**Section 6: Regulatory**

*Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.*

| **Section** | *Notes* | Company comments |
| --- | --- | --- |
| Current or proposed marketing authorisation | *What is the proposed indication for the technology?* |  |
| *Which regulatory process are you following?*  *i.e. MHRA/EMA;*  *Centralised or Decentralised Procedure;*  *Full or abbreviated submission;*  *New Active Substance or Type II variation.* |  |
| *What is the target date (mm/yyyy) for regulatory submission?* |  |
| *What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable), regulatory approval and subsequent launch of the technology?* |  |
| *If a regulatory submission has already been made please indicate any discussions currently on-going with the regulator that NICE should be aware of* |  |