**Company Pre-Submission Form**

This form should be used by companies who wish to register their intent to provide an evidence submission for funding consideration to the Agency for Care Effectiveness (ACE). Companies should indicate the type of submission, anticipated submission timelines and the proposed evaluation framework, which will inform discussions with ACE at the pre-submission meeting.

**All** sections in this form should be completed with the intention of submitting either a full or expedited evaluation. Please refer to *Part 2: Guidelines for preparing an evidence submission for funding consideration* in *Procedures and guidelines for company submissions to the Agency for Care Effectiveness for funding consideration*, which is available on the [*ACE website*](https://go.gov.sg/company-guidelines)*.*

**Section 1:**

**Specific questions for ACE to be addressed at the pre-submission meeting**

Please state any specific technical issues, process enquiries or questions about this evaluation that you wish to discuss with ACE at the pre-submission meeting. Please highlight any anticipated difficulties in following the submission guidelines or any expected deviations from the reference case.

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**Section 2: Proposed evaluation framework and type of submission**

In the table below, please define the scope of the evaluation by presenting the PICO elements - proposed population, intervention, comparator(s), key effectiveness and safety outcome(s), subgroups to be considered, and the overall clinical claim that the submission aims to address.

| **Element** | *Notes* | Company information |
| --- | --- | --- |
| Population | *In this section please specify the evaluation framework that the evidence submission will address. It should state the key parameters that the information in the evidence submission will address.* | [Briefly describe the target health condition and population to be treated] |
| Intervention | [State the intervention under evaluation] |
| Comparator(s) | [State the comparator(s), which may include proprietary (branded) and non-proprietary (generic) drugs and biosimilar products that represent the current alternative therapy routinely prescribed for the target health condition in Singapore and would most likely be replaced by the intervention.] |
| Outcomes | [Briefly state the key patient-relevant clinical effectiveness and safety outcomes] |
| Subgroups | [Briefly state any subgroups of the population which will be considered in the evaluation] |
| Clinical claim | [State the clinical claim that the submission presents as follows: ‘In [population with health condition], [intervention] is no worse than/as effective as/more effective than [main comparator] at improving/reducing [outcome(s)]’] |

Please indicate the type of evidence submission to ACE (full or expedited evaluation): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

In the table below, please include the proposed clinical criteria for listing on the Medication Assistance Fund (MAF), Cancer Drug List (CDL) and Cell, Tissue and Gene Therapy Product (CTGTP) List and state whether these criteria are consistent with the indication(s) that have been submitted for HSA approval and the target population and health condition in the evaluation framework.

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**Section 3: Clinical need and local clinical practice**

Briefly describe the current clinical treatment algorithm (or pathway) for the health condition in the target Singapore population and how the medicine will impact clinical practice (i.e. what is the clinical need for this medicine?).

If the intervention under evaluation has a related pathology test that may help to determine the population group eligible for that medicine (e.g. companion diagnostic), please describe how testing fits within the current and future clinical treatment algorithm (e.g. population who will be tested, what prior tests have been undertaken or what clinical signs are present, testing frequency), and how that leads to changes in clinical management.

**Section 4a: Companion diagnostic (if applicable)**

Please provide details of the test(s) (currently used or expected to be used in future) in the table below.

|  |  |
| --- | --- |
| **Test details** | **(add more columns if there are multiple tests)** |
| Name of test |  |
| Commercial or lab-developed test? |  |
| Manufacturer (if commercial test) |  |
| HSA-approved (Yes/No)? (or anticipated date of approval, if approval is still pending) (if commercial test) |  |
| Biomarker(s) tested |  |
| Prevalence of the biomarker within the tested population (please provide supporting evidence) |  |
| Type of test (e.g. single variant, single gene, gene panel, whole exome sequencing), *please list all the genes tested in the gene panel* |  |
| Molecular technique of test (e.g. IHC, NGS) |  |
| Specimen required (e.g. blood, tissue biopsy) |  |
| Sensitivity and specificity (please provide supporting documents) |  |
| Name of the lab performing or expected to perform the test (and accreditations), state if this is a local or overseas provider |  |
| Total cost per test (in SGD) to the patient |  |

**Section 4b: Administration and costs of the intervention**

Please provide details of the treatment regimen, including method of administration and the costs (if available) associated with the intervention.

|  |  |
| --- | --- |
| **Parameter** | **[Intervention, strength, formulation]** |
| Method of administration |  |
| Dose |  |
| Dosing frequency |  |
| Average length of a course of treatment |  |
| Is treatment given in an inpatient or outpatient setting? |  |
| Proposed cost per unit |  |
| Average cost of a course of treatment |  |
| Anticipated number of repeat courses of treatments |  |

**Section 5: Clinical effectiveness**

Please highlight any expected challenges in adhering to the reference case in the clinical effectiveness table below.

| **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.* |  |
| Relevant evidence that is expected to become available during the evaluation |  |
| Additional information | *Please provide any additional information relating to clinical effectiveness that you believe ACE 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 ACE. This should be in the tabular format below.

Please note that companies are required to provide the clinical study report(s) for the pivotal trial(s) as part of the appendices or references to an evidence submission.

**RCT evidence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study No. (acronym)** | **Intervention** | **Comparator** | **Population** | **Primary study reference** |
| Study 1 |  |  |  |  |
| Study 2 |  |  |  |  |
| [Add more rows as required] |  |  |  |  |

**Non-RCT evidence**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study No. (acronym)** | **Intervention** | **Population** | **Objectives** | **Primary study reference** | **Justification for inclusion** |
| Study 1 |  |  |  |  |  |
| Study 2 |  |  |  |  |  |
| [Add more rows as required] |  |  |  |  |  |

**Section 6: Economic evaluation and budget impact assessment**

Please describe the proposed approach for the economic evaluation in the submission. Highlight any expected challenges in adhering to the reference case or any other technical questions relating to the proposed economic analysis under “additional information” in the table below.

|  |  |  |
| --- | --- | --- |
| **Section** | *Notes* | Company comments |
| Type of economic evaluation | *Please describe whether a cost-minimisation (CMA) or cost-utility analysis (CUA) will be presented. If a CUA which was originally developed to inform funding decisions in another country is being adapted for ACE, please provide this information.* |  |
| Estimated patient numbers and budget impact | *Please complete and submit the costing template. Ensure reference sources and assumptions are included.* |  |
| Proposed patient assistance programme or other arrangements | *Please provide information on any proposed patient assistance programme (either existing or newly developed) or other arrangements for subsidy consideration which may be included in the evidence submission.* |  |
| Type of economic model | *Please state the type of economic model describing whether it is a cohort or individual-level simulation* |  |
| Components of the economic model | *Please describe broadly, components of the model, such as information related to:*   1. *Time horizon;* 2. *Cycle length;* 3. *Health states (including method(s) of estimating state membership or transition probabilities, whichever is relevant);* 4. *HRQoL sources;* 5. *Key model assumptions; and* 6. *Key scenario analyses*   *Please provide transition state diagrams to complement the description of the economic model structure and also describe, if applicable, the type of extrapolation techniques (e.g. standard parametric) that will be used if the time horizon applied in the model extends beyond the duration of the studies/trials.* |  |
| Economic model software | *ACE only accepts executable economic models using standard software and the company must give ACE full access to the programming code. Web-based models are not acceptable. Please indicate which software will be used. If you plan to submit a model in a non-standard package, ACE, in association with the ERC, will investigate whether the requested software is acceptable. ACE reserves the right to reject economic models in non-standard software.* |  |
| Additional information | *Please provide any additional information relating to the economic evaluation that you believe ACE should be aware of.* |  |

Please highlight the resource costs that will be included in your evidence submission. Costing information that is not in the [*Singapore Healthcare Resource Sheet*](https://go.gov.sg/sg-resourcesheet) should be obtained from clinicians/Public Healthcare Institutions (PHIs) as required.

| **Key resource costs associated with intervention** | Key resource costs associated with comparator(s) | Company comments |
| --- | --- | --- |
| *Notes: please state whether the intervention will be associated with any additional resource costs relative to its comparator(s). Please also comment on any uncertainties or potential areas of complexity.* | | |
|  |  |  |
|  |  |  |
| [Add more rows as required] | | |

**Section 7: Regulatory timelines**

Please indicate the date of submission to HSA and whether the intervention has already obtained HSA regulatory approval for the condition under evaluation, or state the anticipated timelines to receiving approval.

Please provide the date of regulatory approval and the approved indication(s) from overseas reference agencies (e.g. US FDA, EMA, TGA etc). If approval is still pending, please provide the anticipated date of approval and the proposed wording of the indication(s).

| **Regulatory agency** | Date of submission and regulatory approval for condition under evaluation(or anticipated date of approval, if approval is still pending) | Approved indication(s)(or anticipated wording of indication(s) if approval is still pending) |
| --- | --- | --- |
| Health Sciences Authority (HSA) |  |  |
| US FDA |  |  |
| EMA |  |  |
| [Add more rows as required] | | |

Please indicate your anticipated date to provide an evidence submission to ACE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section 8: Evaluations conducted by overseas HTA agencies**

Please indicate whether the intervention has already been evaluated by other overseas HTA agencies (e.g. NICE UK, PBAC Australia, CDA Canada, PHARMAC NZ etc.) or the anticipated timeline to a recommendation if an HTA evaluation is ongoing. Where possible, please provide the PICO framework for the evaluations considered by the overseas HTA agencies.

| **HTA agency** | Date of recommendation(or date of submission and anticipated date of recommendation, if evaluation is still ongoing) | Recommended indication(s)(or anticipated wording of subsidy criteria, if evaluation is still ongoing) | PICO framework that the evaluation addresses |
| --- | --- | --- | --- |
| NICE, UK |  |  |  |
| PBAC, Australia |  |  |  |
| CDA, Canada |  |  |  |
| [Add more rows as required] | | |  |

**Section 9: Any other issues for discussion**

Please indicate any other issues for discussion that you would like ACE to address at the pre-submission meeting.

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