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| GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR INCLUSION ON THE CANCER DRUG LIST  |
| The [Cancer Drug List (CDL)](https://safe.menlosecurity.com/https%3A/www.moh.gov.sg/home/our-healthcare-system/medishield-life/what-is-medishield-life/what-medishield-life-benefits/cancer-drug-list) outlines all cancer drugs and indications that are subsidised under the Standard Drug List (SDL) or Medication Assistance Fund (MAF) and/or are claimable under MediShield Life and MediSave. PROCESSFrom 2022 onwards, companies are responsible for providing evidence submissions and price proposals for their cancer drugs to be assessed for inclusion on the CDL in parallel with their assessment for regulatory approval by HSA. More information can be found on: [www.ace-hta.gov.sg/resources/process-methods#company-submissions](http://www.ace-hta.gov.sg/resources/process-methods#company-submissions). Clinicians can also request ACE to evaluate treatments for potential inclusion on the list. For example, a treatment not submitted for HSA’s approval due to the small patient pool in Singapore but considered standard of care for a very rare cancer or for a specific subgroup of patients with no suitable registered treatment alternatives. Prior to submitting an application, please check with the company about its status. An unregistered drug/indication should only be submitted for evaluation if it fulfils these 3 criteria:

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| No. | Criteria |
| 1 | Approved by at least one reference overseas regulatory authority e.g. FDA, EMA or TGA |
| 2 | Sufficient evidence available to assess safety, clinical effectiveness and cost-effectiveness |
| 3 | Lack of treatment alternatives on the CDL for the specified indication.  |

All drug applications should be submitted to the Chairman of the Medical Board (or equivalent body, see section 7) of each institution for endorsement before sending to MOH\_DAC\_Secretariat@moh.gov.sg. EVALUATION CRITERIAIt remains the decision of MOH Committees whether the drug applied for will be included on the CDL. Applicants shall not lobby MOH or departmental officers. Lobbying activities are defined as *‘communications in an effort to influence government decision making, including … the allocation of funding’.*Generally, the following core criteria are taken into consideration:

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| *Clinical need of patients and role of treatment* | The drug preparation has a clinical role in the management of the requested indication in Singapore. |
| *Clinical effectiveness and safety* | Sufficient published evidence should be available to enable a robust evaluation of the clinical effectiveness and safety of the drug preparation.The incremental benefit offered by the drug preparation over other treatments used in routine clinical practice for the intended indication(s) should be clinically significant and offer meaningful outcomes to patients.The drug preparation has an acceptable safety profile, comparable to other treatments used in routine clinical practice for the intended indication(s). |
| *Cost effectiveness (Value for money)* | The incremental benefit and cost of the drug preparation compared to existing treatments. For each therapeutic group, the most cost-effective drug preparation, which fulfils the above criteria, would be considered favourably by the DAC. |
| *Budget impact* | The annual cost to the Government to fund the drug preparation for the patients with the intended indication(s). |

USE OF UNREGISTERED DRUGS/INDICATIONSAn unregistered drug/indication should only be used after informed consent from the patient has been obtained. The patient should be made aware that an unregistered drug/indication is being used and that both the treating clinician and patient accept full responsibility that the drug has not been evaluated for quality, safety and efficacy by HSA. Off-label use should be discussed at an institution’s appointed tumour board with documentation of recommendations and approval by the institution’s Chairman of the Medical Board (or equivalent body). All documentation, including informed consent forms, should be retained. MOH reserves the right to periodically audit clinics or clinicians for compliance. Patients and clinicians should be aware that accepted applications do not guarantee that a treatment will be included onto the CDL. **ENQUIRIES**The MOH DAC Secretariat may be contacted at MOH\_DAC\_Secretariat@moh.gov.sg if you require any assistance and/or if you wish to check if a treatment is under evaluation prior to completing the form.

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| **FORM FOR NEW DRUG OR NEW INDICATION APPLICATIONS***For any application for a new active ingredient or new indication of existing active ingredients in the Cancer Drug List* Please ensure that all fields are completed. MOH reserves the right to reject an application if it is considered incomplete.  |
| Section 1 (Drug preparation, indication and dosing information)  |
| 1. Product name [generic name, trade name, dosage form (s) and strength(s)]
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| 1. What is the proposed indication?
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| 1. Is this indication approved by the Health Sciences Authority (HSA)?

If it is not HSA approved, please state the regulatory authority which has approved it (e.g. US FDA, EMA).  |  |
| 1. What is approved dosage of the drug and median treatment duration for the proposed indication?
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| 1. Please list any existing treatments that would be used in combination with this drug for this indication.
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| Section 2 (Clinical need) |
| 1. What is the clinical need for the proposed treatment?
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| 1. Describe how this treatment fits in the local treatment algorithm.
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| 1. Please list any existing treatments that would likely be replaced by this treatment.
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| 1. Please estimate the number of patients eligible for this treatment in Singapore?
2. (Please provide references or the assumptions underpinning the estimate if available)
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| Section 3 (Clinical evidence) |
| 1. Has this treatment been included in clinical practice guidelines and if yes, what is the category of the recommendation? (e.g. NCCN Category 1, 2A or 2B)
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| 1. What is the key evidence / trial supporting the use of this treatment?
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| 1. Please elaborate on the comparative clinical effectiveness and safety versus the existing treatments?
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| 1. Please provide the ESMO-MCBS score[[1]](#footnote-1) for the treatment.

If scored manually, please attach the completed ESMO-MCBS form with the application.  |  |
| Section 4 (Cost) |
| 1. Are there any patient assistance programs funded by the manufacturer? If yes, please provide details including eligibility criteria, level of assistance and any bonusing schemes in place.
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| Please provide the information below for all the proposed drug preparation(s) and its comparators. |
| Drug preparation | Unit cost price | Unit selling price | Selling price to patient (per cycle/course) | Volume dispensed to all patients over last 12 months |
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| Section 5 (Details of Applicant & Contact staff) |
| Name of applicant: |  |
| Designation: |  |
| Department: |  |
| Institution: |  |
| Email address: |  |
| Telephone number: |  |

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| Section 6 (Review and endorsement by 1. the institution’s tumour board or
2. in the absence of a tumour board, a cancer specialist with the same sub-specialty and at least 12 years of clinical practice following specialist registration who is not involved in the direct care of the patient being treated)
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| 1. Uniform consensus that there is a clinical need for this treatment (Yes/No, please elaborate briefly)
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| 1. Uniform consensus that the evidence supports the routine use of this treatment in local clinical practice (Yes/No, please elaborate briefly)
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| 1. Endorsement by the reviewer or tumour board (Yes/No)
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| Name of reviewer or representative from the tumour board: |  |
| Designation: |  |
| Department: |  |
| Institution: |  |
| Email address: |  |
| Telephone number: |  |
| Section 7 (Endorsement by Chairman of the Medical Board, or equivalent body, of the institution. If not available, endorsement may be obtained by another cancer specialist with at least 12 years of clinical practice following specialist registration) |
| Chairman of the Medical Board or equivalent bodySignature, Stamp & Date: |  |

1. [ESMO-MCBS (ESMO-Magnitude of Clinical Benefit Scale)](https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-scorecards) facilitates improved decision-making regarding the value of anti-cancer therapies, promotes accessibility and reduces iniquity of access to high value cancer treatments [↑](#footnote-ref-1)