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Ref: LIA MU 84/22

CLASSIFICATION OF CANCER DRUG TREATMENTS WHICH ARE NOT ON THE MOH CANCER DRUG LIST ("NON-CDL CLASSIFICATION FRAMEWORK")

The Non-CDL Classification Framework governs the provision of insurance coverage by IP Insurers for cancer drug treatments which are NOT on the Cancer Drug List approved by the Ministry of Health ("MOH").

1. Background

1.1. The introduction of the MOH Cancer Drug List ("CDL") for approved cancer drug treatments which will be covered by MediShield Life from September 2022 will exclude some cancer drug treatments.

1.2. To provide greater choice for those who prefer broader coverage and are able to afford it, IP Insurers may redesign their Riders to Integrated Shield Plans ("IP Riders") to offer additional coverage beyond the CDL, i.e. to offer coverage for Non-CDL treatments too.

2. Objective of the Non-CDL Classification Framework

2.1. The Non-CDL Classification Framework has been prepared with input and support from the Chapter of Medical Oncologists, College of Physicians, Academy of Medicine, Singapore and the Singapore Society of Oncology. Please refer to Appendix A for full details of the Framework.

2.2. The objective of the Non-CDL Classification Framework is to have in place a standardised classification for different Non-CDL treatments that may be used by IP Insurers for their IP Riders to facilitate a common understanding by various stakeholders, e.g. policyholders, healthcare providers, etc.

2.3. To facilitate product innovation, IP Insurers have the flexibility to select the classes or types of Non-CDL treatments under the Framework that they may cover in their IP Riders.

3. Effective Date

3.1. IP Insurers who wish to extend coverage for treatments beyond CDL for their IP Riders are required to adopt the Non-CDL Classification Framework with effect from **1 April 2023**.

3.2. LIA will monitor and continue to refine the Framework in line with regulatory changes and other related developments.

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LIA MU 84/22 – Appendix A

CLASSIFICATION OF CANCER DRUG TREATMENTS WHICH ARE NOT ON THE MOH CANCER DRUG LIST ("NON-CDL CLASSIFICATION FRAMEWORK")

The introduction of the MOH Cancer Drug List (CDL) for approved cancer drug treatments which will be covered by MediShield Life will exclude some cancer drug treatments. These excluded treatments will have a range of clinical effectiveness, varying levels of inclusions by drug regulators and clinical guidelines. Some treatments may have limited evidence of clinical effectiveness and/or may be experimental in nature.

This Framework proposes standardised classifications for the different treatments and may be used by Insurers to facilitate a common understanding by all stakeholders. This Framework has been prepared with input and support from the Chapter of Medical Oncologists, College of Physicians, Academy of Medicine, Singapore and the Singapore Society of Oncology.

The Framework

Cancer Drug Treatments will be classified according to whether they have received approval by one or more of the following regulatory bodies:

- HSA
- Regulatory drug agencies referenced by HSA, i.e. FDA, EMA, TGA, HC or UK MHRA

Approval by the regulatory body means that the drug label must specify the relevant clinical indication for the drug treatment.

If the cancer drug treatment is not approved by any of the regulatory bodies, then reference will be made to Clinical Guidelines namely NCCN and ESMO.

Table 1: Acronyms and Websites of HSA, Reference Regulatory Bodies and Clinical Guidelines

HSA	Health Science Authority of Singapore (www.hsa.gov.sg/e-services/infosearch)
FDA	US Food and Drug Administration (www.fda.gov/drugsatfda)
EMA	European Medicines Agency for human use (www.ema.europa.eu/en/medicines)
TGA	Therapeutic Goods Administration Australia (https://www.tga.gov.au/)
HC	Health Canada (https://www.canada.ca/en/health-canada/services/drugs-health-products.html)
UK MHRA	United Kingdom Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
NCCN	National Comprehensive Cancer Network (https://www.nccn.org/)
ESMO	European Society for Medical Oncology (https://www.esmo.org/)

Classification of Non-CDL Treatments – Tabular View

This tabular view summarises the classification system. Please refer to the description for full details.

Table 2: Summary View of the Classification of Non-CDL Treatments

	Class A	Class B	Class C	Class D	Class E	Class F
HSA registered drug (✓) or SAR#	✓	✓	SAR	✓	SAR	✓ / SAR
HSA registered indication	✓	X	NA	X	NA	X / NA
Drug and Indication approved by one or more of the reference regulatory agencies*	NA	✓	✓	X	X	X
Guideline recommendations	NA	NA	NA	D1 – NCCN cat 1, ESMO grade A or equivalent D2 – NCCN cat 2A, ESMO grade B or equivalent D3 – NCCN cat 2B, ESMO grade C or equivalent D4 – NCCN cat 3, ESMO grade D/E or equivalent	E1 – NCCN cat 1, ESMO grade A or equivalent E2 – NCCN cat 2A, ESMO grade B or equivalent E3 – NCCN cat 2B, ESMO grade C or equivalent E4 – NCCN cat 3, ESMO grade D/E or equivalent	Clinical indication does not have NCCN or ESMO recommendation

*US FDA, EMA, TGA Australia, Health Canada, UK MHRA. Source: HSA | Evaluation Routes

#SAR, special access route (e.g. named patient access) – note that drugs brought in under SAR have not been evaluated by HSA for safety, quality and efficacy. Source: HSA | Import and supply of unregistered therapeutic products for patient's use

Classification of Non-CDL Treatments – Description

Each cancer drug treatment will be assigned a Class based on its characteristics as described below:

1. Class A
   - 1.1 HSA Registered Drug, AND
   - 1.2 HSA Approved Indication

2. Class B
   - 2.1 HSA Registered Drug, AND
   - 2.2 Indication **NOT** approved by HSA, AND
   - 2.3 Drug and Indication approved by one or more of the reference regulatory bodies

3. Class C
   - 3.1 Non-HSA Registered Drug, but can be brought in via Special Access Route (SAR), AND
   - 3.2 Drug and indication approved by one or more of the reference regulatory bodies

4. Class D
   4.1 HSA Registered Drug, AND
   4.2 Indication **NOT** approved by HSA, AND
   4.3 Drug and indication **NOT** approved by any of the reference regulatory bodies, AND
   4.4 There is an NCCN or ESMO recommendation as described below:

   Class D1
   Drug and indication has Category 1 recommendation at NCCN, Grade A recommendation at ESMO or equivalent, OR

   Class D2
   Drug and indication has Category 2A recommendation at NCCN, Grade B recommendation at ESMO or equivalent, OR

   Class D3
   Drug and indication has Category 2B recommendation at NCCN, Grade C recommendation at ESMO or equivalent, OR

   Class D4
   Drug and indication has Category 3 recommendation at NCCN, Grade D/E recommendation at ESMO or equivalent

5. Class E
   5.1 Non-HSA Registered Drug, but can be brought in via Special Access Route (SAR), AND
   5.2 Drug and indication **NOT** approved by any of the reference regulatory bodies, AND
   5.3 There is an NCCN or ESMO recommendation as described below:

   Class E1
   Drug and indication has Category 1 recommendation at NCCN, Grade A recommendation at ESMO or equivalent, OR

   Class E2
   Drug and indication has Category 2A recommendation at NCCN, Grade B recommendation at ESMO or equivalent, OR

   Class E3
   Drug and indication has Category 2B recommendation at NCCN, Grade C recommendation at ESMO or equivalent, OR

   Class E4
   Drug and indication has Category 3 recommendation at NCCN, Grade D/E recommendation at ESMO or equivalent

6. Class F
   6.1 Treatment does not meet the requirements of any of the Classes above. For example, the drug may be HSA registered or not, but the indications have not been approved by HSA or any of the reference regulators. Furthermore, there is no NCCN or ESMO recommendation.

Hypothetical Examples

Illustration 1

Insurer M chooses to cover Classes A and B non-CDL treatment with their rider and excludes other Classes from coverage.

If the Claimant requires to use Non-CDL treatment, they can only claim for treatment that meets the following conditions:

a) The drug and its intended treatment has been registered and approved by the regulator in Singapore, the Health Science Authority (HSA) [Class A], or
b) The drug has been registered by HSA, but the intended treatment is not approved by HSA. The drug and the intended treatment has been approved or registered by at least one of the 5 approved regulators i.e. USA, Canada, Europe, Australia or UK [Class B].

Any treatment that does not meet the requirements above may not be paid by the Insurer.

Illustration 2

Insurer R chooses to cover Classes A, B, C, D and E and exclude Class F. In addition, Insurer R chooses to provide different levels of coverage according to the Class of treatment with:

- Class A and B and C provided with 90% coverage
- Class D and E provided with 50% coverage