

# STANDARD ON DISCLOSURES FOR CRITICAL ILLNESS PRODUCTS

Effective from 1 July 2022



#### 1. INTRODUCTION

Critical Illness products are designed to pay out a benefit when a policyholder has a serious illness or suffers a traumatic event which results in financial difficulty. In order for the product to be practical and affordable, the illness or trauma needs to be sufficiently serious before the sum insured is paid out. If this were not the case, there would be many benefits paid which would make the product expensive and therefore less accessible.

To ensure that consistent and objective claims decisions can be made, the definitions used to determine whether a policyholder qualifies for a benefit need to be sufficiently detailed. Some level of medical terminology is required which can be difficult for many people to understand.

It is acknowledged that this is a necessarily complex product that requires some definitions to be standardised, and this formed the objective of, the Standardised Critical Illness Definitions Project (SCIDEP). The project focused on standard definitions for the four "core" diseases which make up more than half of all critical illness claims. However, medical conditions change from time to time and this requires this document to be periodically updated. Updates made are recorded in the amendment schedule at the end of this document.

The quotation or contract provided by the insurer must state what percentages the insurer will pay out for the standard definitions at the various severity levels in a 4 x 4 grid. This allows customers to easily compare the benefits of different insurance companies. The standardised definitions form the technical underpin for the 4 x 4 disclosure grid. The necessary detail in these standardised definitions also allows for consistency in claims assessment and therefore decisions.

Below is an example of what this grid could look like. It will differ depending on the insurer and the type of critical illness product which is taken out:

Disease	Severity Level			
	A (most severe)	B (moderate	C (mild	D (least severe)
		impairment)	impairment)	
Stroke	100%	75%	50%	25%
CABG	100%	75%	50%	25%
Heart Attack	100%	75%	50%	25%
Cancer	100%	75%	50%	25%

## 2. SCOPE AND APPLICATION

The SCIDEP definitions apply to any critical illness product that covers any of the four core diseases. The definitions apply to all ASISA member companies and adherence to the disclosures later on in this document is mandatory.

It is not necessary for insurers to change their product philosophy or marketing material. The purpose of the standardised definitions is that it will provide some "underpin" to the product therefore providing policyholders and intermediaries with:

- (a) the comfort that they can get their claim assessed on industry approved definitions, and
- (b) that they can get a better understanding of when and at what level different insurers will pay out.

The process does not attempt to stifle competition as insurers are not restricted in terms of the number of diseases covered, the percentage paid out, the number of payments that can be



made, or the rates that they charge. It is possible for insurers to keep all of their documentation the same, except for the fact that they must state clearly in the contract what percentage they would pay out for the SCIDEP definitions. Hence insurers merely need to map their current pay-outs to the SCIDEP definitions.

Changes to the definitions do not need to be applied retrospectively. They only need to be applied to new policies sold after the effective date of the current version of the Standard.

The standard definitions apply to the following four "core" diseases, which make up more than half of all Critical Illness claims:

- Heart attack
- Cancer
- Stroke
- Coronary Artery By-pass Graft (CABG).

The definitions for each of these diseases must be read with the criteria for the four tiers, A, B, C, and D, with A being the most severe and D being the least severe.

Although the sixteen definitions (four diseases with four severities) are standardised, the percentage benefit paid for each of the definitions is up to the discretion of each insurance company. Therefore, an insurer can pay between 0% and 100% for each severity of each disease. An insurer cannot pay a lower percentage for a more severe definition, although they can pay the same percentage. Examples of possible pay-outs could be:

	Insurer 1	Insurer 2	Insurer 3	Insurer 4	Insurer 5
Severity A	100%	100%	100%	100%	100%
Severity B	75%	0%	100%	100%	100%
Severity C	50%	0%	10%	0%	100%
Severity D	25%	0%	10%	0%	100%

#### **Contract Wording**

Although it would be ideal for all insurers to use the standardised definitions in their quotations and contracts, there are some practical restrictions that may make this difficult to implement. Hence insurers must state that they will honour claims according to the SCIDEP definitions, for at least one severity level of each of the four core diseases that they cover. This means that no insurer can have 0% cover for all four severity levels of any given condition. If a claim is declined on the insurer's definition, the policyholder will have the right to insist that it is also assessed according to the SCIDEP definitions.

#### STROKE

#### 3.1 DEFINITION FOR SCIDEP FOR TIERED PRODUCTS

Death of brain tissue due to inadequate blood supply or haemorrhage within the skull resulting in neurological deficit, confirmed by neuro-imaging investigation and appropriate clinical findings by a specialist neurologist. Symptoms and signs as well as imaging must confirm a new stroke.

## For the above definition, the following are not covered:

- Transient ischaemic attack; this is defined as a transient episode of neurologic dysfunction (irrespective of duration) caused by focal brain, spinal cord, or retinal ischemia, without acute infarction (on neuroimaging investigations)
- Vascular disease affecting the eye or optic nerve;
- Migraine and vestibular disorders;
- Traumatic injury to brain tissue or blood vessels.

Severity levels will be assessed by a full neurological examination by a specialist neurologist any time after three months.

# Level A: Stroke with severe impairment

Needs constant assistance, as measured by:

- the inability to do 3 or more basic ADL's, or
- a Whole Person Impairment (WPI) of greater than 35%.

## Level B: Stroke with moderate impairment

Cannot function independently, as measured by:

- the inability to do 6 or more advanced ADL's, or
- a WPI of 21% to 35%.

# Level C: Stroke with mild impairment

Can function independently, but has impairment as measured by:

- the inability to do 3 or more advanced ADL's, or
- a WPI of 11% to 20%.

#### Level D: Stroke with almost full recovery

Almost full recovery, with minor residual symptoms or signs, as measured by:

- a permanent objective neurological deficit that is evident on physical examination that has persisted for a continuous period of at least three months after the onset of the stroke, or
- a WPI of 1% to 10%.

WPI figures are calculated as per the latest American Medical Association Guides to the Evaluation of Permanent Impairment.

## **Basic activities of Daily Living**

- Bathing the ability to wash/bathe oneself independently
- Transferring the ability to move oneself from a bed to a chair or from a bed to a toilet independently
- **Dressing** the ability to take off and put on ones clothes independently
- Eating the ability to feed oneself independently. This does not include the making of food
- Toileting the ability to use a toilet and cleanse oneself thereafter, independently
- Locomotion on a level surface the ability to walk on a flat surface, independently
- Locomotion on an incline the ability to walk up a gentle slope, or a flight of steps independently

#### Advanced activities of Daily Living

- Driving a car the ability to open a car door, change gears or use a steering wheel
- **Medical care:** the ability to prepare and take the correct medication
- Money management the ability to do one's own banking and to make rational financial decisions
- Communicative activities: the ability to communicate either verbally or written
- **Shopping:** the ability to choose and lift groceries from shelves as well as carry them in bags
- Food preparation the ability to prepare food for cooking as well as using kitchen utensils
- Housework the ability to clean a house or iron clothing
- Community ambulation with or without assistive device, but not requiring a mobility device the ability to walk around in public places using only a walking stick if necessary
- Moderate activities: activities like moving a table, pushing a vacuum cleaner, bowling, golf
- Vigorous activities: able to partake in running, heavy lifting, sports

**Note:** All activities of daily living (ADL's) will be assessed with the use of assistive devices where appropriate.

#### 3.2 SCIDEP DEFINITION FOR NON-TIERED PRODUCTS

It is recommended that the primary definition of stroke with its exclusions are used for non-tiered products, as defined in 1.1 above, in combination with any one of the 4 severity levels. The decision on which severity level to use will be a pricing and product philosophy issue.

## 4. CABG DEFINITIONS

#### 4.1 DEFINITION FOR SCIDEP FOR TIERED PRODUCTS

The undergoing of surgery, regardless of method of surgical access, to correct the narrowing of, or blockage to, one or more coronary artery(ies) by means of a by-pass graft.

#### For the above definition, the following are not covered:

Closed coronary artery procedures, including but not limited to coronary angioplasty, stent insertion and all other intra-vascular catheter-based procedures.

#### Level A

The undergoing of surgery to correct the narrowing of, or blockage to, three or more coronary arteries, by means of a by-pass graft.

#### Level B

The undergoing of surgery to correct the narrowing of, or blockage to, two coronary arteries, by means of a by-pass graft.

#### Level C

The undergoing of surgery to correct the narrowing of, or blockage to, the left main or proximal left anterior descending coronary artery, by means of a by-pass graft.

#### Level D

The undergoing of surgery to correct the narrowing of, or blockage to, any one coronary artery, by means of a by-pass graft.

#### 4.2 DEFINITON FOR SCIDEP FOR NON-TIERED PRODUCTS

Any of the 4 severity level definitions can be used on its own for non-tiered products. The SCIDEP disclosure grid should indicate correctly that severity levels below the chosen definition will have a zero-percentage pay-out.



## 5. HEART ATTACK DEFINITIONS

#### 5.1 DEFINITION FOR SCIDEP FOR TIERED PRODUCTS

A Heart Attack or Acute Myocardial Infarction (MI) is defined as acute myocardial injury confirmed by a certified physician as having occurred as a direct consequence of acute myocardial ischemia resulting from inadequate blood supply to the heart.

Not all clinical myocardial infarctions are covered by the SCIDEP definitions set out below. Only the specified severities as set out in Level A to D are covered.

## Level A: Heart attack with severe permanent impairment in function

A Heart attack that meets the criteria as defined under Level C, with permanent impairment in one or more of the following functional criteria, as measured 6 weeks post-infarction:

Criterion	Value
NYHA classification	Class 4
METS	1 or less
LVEF	< 30%
LVEDD	> 72
Ultrasound FS in %	< 16%

## Notes:

- 1. If more than one functional criterion is impaired, but their values do not conform to one severity level (for example one impaired value is Level A and another Level B), the final severity level should be determined by giving preference to the more objective criteria, i.e. in the following order:
  - 1. LVEF
  - 2. LVEDD
  - 3. Ultrasound FS
  - 4. METS
  - 5. NYHA

#### Level B: Heart attack with mild permanent impairment in function

A heart attack that meets the criteria as defined under Level C, with permanent impairment in one or more of the following functional criteria, as measured 6 weeks post-infarction:

Criterion	Value
METS	2-7
LVEF	30%-50%
LVEDD	59-72
Ultrasound FS in %	16%-25%

## Notes:

- 1. If more than one functional criterion is impaired, but their values do not conform to one severity level (for example one impaired value is Level A and another Level B), the final severity level should be determined by giving preference to the more objective criteria, i.e. in the following order:
  - 6. LVEF
  - 7. LVEDD
  - 8. Ultrasound FS
  - 9. METS
  - 10. NYHA

## Level C: Moderate heart attack of specified severity

This is defined as the death of heart muscle, due to inadequate blood supply, as evidenced by any of the following combinations of criteria:

1. Compatible clinical symptoms AND raised cardiac biomarkers

OR

2. Compatible clinical symptoms AND new pathological Q-waves on ECG as defined in Annexure A (b)

OR

3. New pathological Q-waves on ECG as defined in Annexure A (b) AND raised cardiac biomarkers

OR

4. ST-segment and T-wave changes on ECG indicative of myocardial injury as defined in Annexure A (a) **AND** raised cardiac biomarkers

Where raised cardiac biomarkers are referenced above, they are defined as any **one** of the following Troponin or Non-Troponin Markers:

## **Sensitive Troponin Markers**

Marker		Value**	
*Assay (test)	Troponin Type	Unit: ng/L	Unit: ng/ml
Roche hsTnT	TnT	> 1000	> 1,0
Abbott ARCHITECT	Tnl	> 3000	> 3,0
Beckman AccuTnl	Tnl	> 5000	> 5,0
Siemens Centaur Ultra	Tnl	> 6000	> 6,0
Siemens Dimension RxL	Tnl	> 6000	> 6,0
Siemens Stratus CS	Tnl	> 6000	> 6,0

<sup>\*</sup> Use the relevant manufacturer's assay (test) or equivalent as it appears on the laboratory report.

# **Conventional Troponin Markers:**

Marker		Value	
Assay (test)	Troponin	Unit: ng/L	Unit: ng/ml
	Туре		
Conventional TnT	TnT	>1000	>1,0
Conventional AccuTnl***	Tnl	>500	>0,5

<sup>\*\*\*</sup> or equivalent threshold with other Troponin I methods

## **Non-Troponin Markers**

Marker	Value
Raised CK-MB mass	Raised 2 times or more the upper limit of normal
	laboratory reference range in acute presentation phase
Total CPK elevation	Raised 2 times or more the upper limit of normal
	laboratory reference range in acute presentation phase,
	with at least 6% being CK-MB

## Level D: Mild heart attack of specified severity

This is defined as the death of heart muscle, due to inadequate blood supply, as evidenced by all three of the following criteria:

- 1. Compatible clinical symptoms AND
- 2. Characteristic ECG changes indicative of myocardial ischaemia or myocardial infarction as per Annexure A (a) **AND**
- 3. Raised cardiac biomarkers defined as any **one** of the following Troponin or Non-Troponin Markers:

<sup>\*\*</sup>Values represent multiples of the World Health Organisation (WHO) MI rule in levels and not the 99th percentile values (upper limit of normal) as quoted on the laboratory result.

# **Sensitive Troponin Markers:**

Marker		Value**	
*Assay (test)	Troponin Type	Unit: ng/L	Unit: ng/ml
Roche hsTnT	TnT	>500	>0,5
Abbott ARCHITECT	Tnl	>1500	>1,5
Beckman AccuTnl	Tnl	>2500	>2,5
Siemens Centaur Ultra	Tnl	>3000	>3,0
Siemens Dimension RxL	Tnl	>3000	>3,0
Siemens Stratus CS	Tnl	>3000	>3,0

<sup>\*</sup> Use the relevant manufacturer's assay (test) as it appears on the laboratory report.

## **Conventional Troponin Markers:**

Marker	Value		
Assay (test)	Troponin Type	Unit: ng/L	Unit: ng/ml
Conventional TnT	TnT	>500	>0,5
Conventional AccuTnl***	Tnl	>250	>0,25

<sup>\*\*\*</sup> or equivalent threshold with other Troponin I methods

## **Non-Troponin Markers:**

Marker	Value
Raised CK-MB mass	Raised above the upper limit of normal laboratory reference range but not meeting the severity C definition (i.e. below 2 times the upper limit of normal laboratory reference range) in acute presentation phase
Total CPK elevation	Raised above the upper limit of normal laboratory reference range but not meeting the severity C definition (i.e. below 2 times the upper limit of normal laboratory reference range) in acute presentation phase, with at least 6% being CK-MB

The evidence must show a definite acute myocardial infarction due to obstructive coronary heart disease. Other acute coronary syndromes, including but not limited to angina, are not covered by this definition.

<sup>\*\*</sup>Values represent multiples of the World Health Organisation (WHO) MI rule in levels and not the 99<sup>th</sup> percentile values (upper limit of normal) as quoted on the laboratory result.



Post coronary artery intervention Myocardial Infarction (MI)

# 1) LEVEL D BENEFIT REQUIRES ALL OF THE FOLLOWING:

- a) Percutaneous coronary intervention (PCI)
- b) Confirmed acute MI, \*occurring within 24 hours post PCI
- c) Raised Cardiac Markers as specifically set out in the table below

Marker	Parameter
Cardiac troponin	As it appears in the definition of at least a heart attack of mild
assay	severity (Level D) post intervention, OR
Raised CK-MB	Raised above the upper limit of normal laboratory reference range
mass reference	but below 4 times the upper limit of normal laboratory
range post	
intervention	

# 2) LEVEL C BENEFIT REQUIRES ALL OF THE FOLLOWING:

- a) Coronary Artery By-Pass Graft (CABG)
- b) Confirmed acute MI, \*occurring within 24 hours post CABG
- c) Raised Cardiac Markers as specifically set out in the table below

Marker	Parameter
Cardiac troponin	As it appears in the definition of at least a heart attack of moderate
assay	severity (Level C) post intervention, OR
Raised CK-MB	Raised 4 times or more the upper limit of normal laboratory
mass	reference range post intervention



#### **Annexure A**

## **Definitions of ECG changes**

- a. ECG changes indicative of Myocardial Ischaemia that may progress to Myocardial Infarction:
  - Patients with ST-segment elevation:
    - New or presumed new ST segment elevation at the J point in two or more contiguous leads with the cut-off points greater than or equal to 0.2mV in leads V1, V2,or V3, and greater than or equal to 0.1mV in other leads.
    - o Contiguity in the frontal plane is defined by the lead sequence AVL, I and II, AVF, III.
  - Patients without ST-segment elevation:
    - o ST-segment depression of at least 0.1 mV;
    - o T-wave abnormalities only.

## b. Definition of new pathological Q-waves:

- Any new Q-wave in leads V1 through V3;
- A Q-wave greater than or equal to 40 ms (0.04s) in leads I, II, AVL, AVF, V4, V5 or V6;
- The Q-wave changes must be present in any two contiguous leads, and be greater than or equal to 1mm in depth;
- Appearance of new complete bundle branch block.

## Reference:

Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction: "Myocardial Infarction Redefined – A Consensus Document"; Journal of the American College of Cardiology, Vol. 36, No 3, 2000, p959-968. Table 3 & 4, p962.

## 5.2 DEFINITION FOR SCIDEP FOR NON-TIERED PRODUCTS

Any of the 4 levels of severity may be used on its own for the definition of a heart attack for non-tiered products. The final choice will be determined by price and company philosophy.

It needs to be noted that:

Levels C and D are diagnosis-based and do not require permanent impairment. It will therefore pay a benefit even if full recovery has taken place.

Levels A and B are impairment based and do require some degree of permanent impairment. Full recovery will not qualify for a claim under these definitions.

It is also important to note that the definitions of levels A and B are based on the basic definition of level C, with some impairment criteria added. Therefore, if either levels A or B are to be used as a standalone non-tiered benefit, the level C criteria (and ECG changes description) should be used as a starting basis, to which the criteria of either A or B are added.



#### 6. CANCER

#### 6.1 DEFINITION FOR SCIDEP FOR TIERED PRODUCTS

A malignant tumour positively diagnosed with histological confirmation and characterised by the uncontrolled growth of malignant cells and invasion of tissue. The term malignant tumour includes leukaemia, lymphoma and sarcoma. The classifications are based on the latest edition of the AJCC Cancer Staging Manual. Pathological staging overrides the clinical staging.

#### The following conditions are excluded from this definition:

- Tumours which are histologically described as benign, pre-malignant, low malignant potential. Any tumour classified as carcinoma in-situ (Tis) or (Ta) by the latest edition of the AJCC Cancer Staging Manual
- All tumours of the prostate unless histologically classified as having a Gleason score of 7
  or more or having progressed to at least clinical TNM classification T2N0M0.
- All non-melanoma skin cancers are excluded. A malignant melanoma that has been histologically classified as TINOMO or higher is covered under this definition.
- All myelodysplastic syndromes and myeloproliferative neoplasms including but not limited to, essential thrombocythemia, primary myelofibrosis, polycythemia vera
- Primary cutaneous lymphoma and dermatofibrosarcoma which are confined to the skin and which have not spread to the lymph nodes or distant sites
- All cancers only identified from tumour cells, pieces of DNA, or any other biomarkers, any
  of which may be present in the blood, saliva, urine, or other bodily fluids, including, but
  not limited to, tests known as "liquid biopsies".

Cancers are generally classified by severity into four stages. However, brain and prostate cancer, leukaemia and lymphoma do not conform to this general classification. Therefore, additional tiering levels are provided for these cancers.

#### Tiering of all Cancers except prostate, leukemia, lymphoma and brain tumours

The levels are correlated to the general classification used by the American Joint Committee for Cancer for the type of cancer involved:

Level A - Stage 4 cancer

Level B - Stage 3 cancer

Level C - Stage 2 cancer

Level D - Stage 1 cancer



## Tiering of prostate cancer

Stage 1	T1a, N0, M0, Gleason ≤ 4	Excluded
Stage 2	T1a, N0, M0, Gleason 5-6	Excluded
	T1b-c, N0, M0, Gleason 2-6	Excluded
	T1a-c, N0, M0 Gleason ≥7	Level D
	T2, N0, M0 any Gleason	Level D
Stage 3	T3, N0, M0 any Gleason	Level C
Stage 4	T4, N0, M0 any Gleason	Level B
	Any T, N1 – 3, M0 any Gleason	Level A
	Any T, any N, M1, any Gleason	Level A

#### Tiering of leukemia and lymphoma

## Level A:

#### This benefit will pay for any one of the following diagnoses:

- Acute Myeloid Leukaemia;
- Chronic Lymphocytic Leukaemia, (stage III or IV on the Rai classification, Binet C, Very High risk CLL-IPI);
- Chronic Myeloid Leukaemia (requiring bone marrow transplant);
- Acute Lymphocytic Leukaemia (adults);
- Hodgkins/Non Hodgkins lymphoma Stage IV on Ann Arbor classification system;
- Multiple Myeloma Stage III on the Durie-Salmon Scale.

## Level B:

#### This benefit will pay for the following diagnoses:

- Hodgkins and Non Hodgkins lymphoma Stage III on Ann Arbor classification system
- Chronic Lymphocytic Leukaemia (High Risk CLL IPI)

#### Level C:

## This benefit will pay for any one of the following diagnoses:

- Chronic Lymphocytic Leukaemia (stage I or II on the Rai classification, Binet B, intermediate risk requiring treatment CLL-IPI);
- Acute Lymphocytic Leukaemia (children);
- Chronic Myeloid Leukaemia (no bone marrow transplantation);
- Hodgkins/Non Hodgkins lymphoma Stage II on Ann Arbor classification system;
- Multiple myeloma Stage I and II on the Durie-Salmon scale.

## Level D:

#### This benefit will pay for any one of the following:

- Chronic Lymphocytic Leukaemia (Stage 0, Binet A, Low Risk CLL-IPI);
- Hairy cell leukaemia;
- Hodgkins/Non Hodgkins lymphoma Stage 1 on Ann Arbor classification



# Tiering of brain tumours

WHO grade II	Without neurological deficit	Severity D
WHO grade II	With neurological deficit	Severity C
WHO grade III	On diagnosis	Severity B
WHO grade IV	On diagnosis	Severity A

**Grade I** brain tumours will be considered under the Benign Brain Tumour benefit should a life office contract such a benefit in their critical illness product.

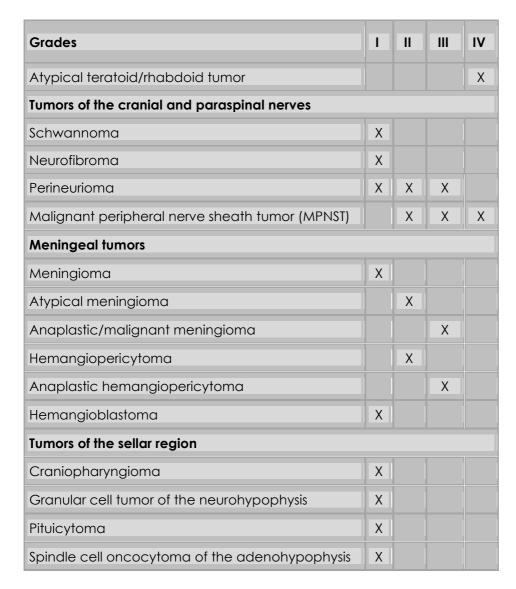
A table of the WHO grading for specific tumours has been included for reference purposes.

## **WHO Grades of CNS Tumors**

Grades	1	II	III	IV
Astrocytic tumors				
Subependymal giant cell astrocytoma	X			
Pilocytic astrocytoma	X			
Pilomyxoid astrocytoma		Χ		
Diffuse astrocytoma		Χ		
Pleomorphic xanthoastrocytoma		Χ		
Anaplastic astrocytoma			X	
Glioblastoma				Χ
Giant cell glioblastoma				Χ
Gliosarcoma				Χ
Oligondendroglial tumors				
Oligodendroglioma		Χ		
Anaplastic oligodendroglioma			Х	
Oligoastrocytic tumors				
Oligoastrocytoma		Χ		
Anaplastic oligoastrocytoma			X	
Ependymal tumors				
Subependymoma	X			
Myxopapillary ependymoma	X			
Ependymoma		X		
Anaplastic ependymoma			X	

# ASIS

Grades		Ш	III	IV
Choroid plexus tumors				
Choroid plexus papilloma	X			
Atypical choroid plexus papilloma		Х		
Choroid plexus carcinoma			Х	
Other neuroepithelial tumors				
Angiocentric glioma	X			
Chordoid glioma of the third ventricle		Χ		
Neuronal and mixed neuronal-glial tumors				
Gangliocytoma	X			
Ganglioglioma	X			
Anaplastic ganglioma			Х	
Desmoplastic infantile astrocytoma and ganglioglioma	X			
Dysembryoplastic neuroepithelial tumor	X			
Central neurocytoma		Χ		
Extraventricular neurocytoma		Χ		
Cerebellar liponeurocytoma		Χ		
Paraganglioma of the spinal cord	X			
Papillary glioneuronal tumor	X			
Rosette-forming glioneural tumor of the fourth ventricle	X			
Pineal tumors				
Pineocytoma	X			
Pineal parenchymal tumor of intermediate differentiation		X	X	
Pineoblastoma				X
Papillary tumor of the pineal region		Χ	Х	
Embryonal tumors				
Medulloblastoma				Х
CNS primitive neuroectodermal tumor (PNET)				X



#### Notes:

- Histological confirmation is required.
- There is no requirement to undergo current recommended treatment.
- Prophylactic mastectomy for carcinoma in situ will not qualify under this definition as the cancer is not invasive.
- The committee tried to avoid using classification or staging terms but could not in the case of prostate. This was because staging definitions may change over time and are complex for the consumer.
- The committee decided not to exclude any HIV related cancers.

## 6.2 DEFINITION FOR SCIDEP FOR NON-TIERED PRODUCTS

The cancer definitions all have two components:

- The basic definition of cancer, with the standard exclusions, as defined under the tiered product definitions (4.)
- A severity level definition (A-D) comprising of two elements:
  - o General severity levels for all cancers



o Separate severity levels for brain and prostate cancer, leukaemia and lymphoma.

The severity levels (A-D) of all cancers, and those for brain and prostate cancer, leukaemia and lymphoma, are more or less comparable across all 4 levels.

For non-tiered definitions any severity level can be chosen depending on pricing and product philosophy. It however needs to be noted that the definition should start with the generic definition of cancer and its' standard exclusions as defined in 4.1. This needs to be followed by the definitions under the chosen severity level, including the definition for all cancers, as well as for brain and prostate cancer, leukemia and lymphoma.

The SCIDEP grid should reflect the payment per benefit appropriately.



# **ANNEXURE B: DETAIL ON CANCER STAGING**

## **Lymphoma**

HODGKIN'S and NON-HODGKIN'S LYMPHOMA

## **Ann Arbor Staging System**

Stage I	The lymphoma is in a lymph node or nodes in only 1 region The lymphoma is found only in 1 area of a single organ outside of the lymphatic system(E)*
Stage II	The lymphoma is in 2 or more groups of lymph nodes on the same side of the diaphragm  The lymphoma extends locally from a single group of lymph nodes into a nearby organ (IIE). It may also affect other groups of lymph nodes on the same side of the diaphragm.
Stage III	The lymphoma is found in lymph node areas on both sides of the diaphragm  The lymphoma may also have extended into an area or organ next to the lymph nodes (IIIE), into the spleen (IIIS), or both (IIE,S)
Stage IV	The lymphoma has spread outside of the lymph system into an organ that is not right next to an involved node  The lymphoma has spread to the bone marrow, liver, brain or spinal cord or the pleura

<sup>\*</sup>The designation "E" generally refers to extranodal contiguous extension (ie, proximal or contiguous extranodal disease)

# **Burkitt's lymphoma staging**

A – Single solitary extra-abdominal site

AR – Intra-abdominal, more than 90% tumour resected

B – Multiple extra abdominal tumours

C – Intra abdominal tumour

D – Intra-abdominal plus one or more extra-abdominal sites

# <u>Leukaemia</u>

# CLL International Prognostic Index (CLL-IPI)

Level A (equivalent to stage IV	RAI III	Binet C	Very high risk CLL IPI
cancer)	and IV		
Level B (equivalent to stage III			High Risk CLL IPI
cancer)			
Level C (equivalent to stage II	RAH	Binet B	intermediate risk
cancer)	and II		requiring treatment
Level D (equivalent to stage I	RAI 0	Binet A	Low risk
cancer)			



- If more than one criteria/staging is given, but their values do not conform to one severity level (for example Rai is level 1 which equates to SCIDEP level C, but CLL-IPI is high risk which equates to SCIDEP level B), the final severity level should be determined by giving preference to the more objective criteria, i.e. in the following order:
  - 1. CLL-IPI
  - 2. Binet
  - 3. Rai

# Modified Rai clinical staging system for chronic lymphocytic leukaemia

Risk	Stage	Description	
Low	0	Lymphocytosis in blood or bone marrow	
Intermediate	I	Lymphocytosis + enlarged lymph nodes	
	II	Lymphocytosis + enlarged liver or spleen with or without	
		lymphadenopathy	
High	III	Lymphocytosis + anaemia (Hgb <11 g/dL) with or without enlarged	
		liver, spleen or lymph nodes	
	IV	Lymphocytosis + thrombocytopenia (platelet count <	
		100,000/microL) with or without anaemia or enlarged liver, spleen,	
		or lymph nodes	

# **Binet Clinical staging system**

Stage	Clinical features at	Median survival (years)
	diagnosis	
Α	Lymphocytosis and <3 areas	>7
	of palpable lymph nodes	
В	Lymphocytosis and >3 areas	<5
	of palpable lymph nodes	
С	Same as stage B with	<2
	anaemia or	
	thrombocytopenia	

# **Durie-Salmon classification**

Stage	Durie-Salmon Criteria	ISS Criteria	Prognosis
1	All of the following		
	<ul> <li>Hemoglobin value &gt; 10g/dL</li> <li>Serum calcium value normal or ≤ 12 mg/dL</li> <li>Bone x-ray, normal bone structure (scale 0) or solitary bone plasmacytoma only</li> <li>Low M - component production rate - IgG value &lt;5 g/dL; IgA value &lt;3 g/dL</li> </ul>	β <sub>2</sub> -M < 3.5 mg/dL and albumin ≥3.5 g/dL	60 months Median Survival
	Bence Jones protein < 4 g/24 h		



*	Neither stage I or III	Neither stage I nor stage III	41 months
III	On or more of the following: - Haemoglobin value <8.5 g/dL - Serum calcium value >12 mg/dL - Advanced lytic bone lesions (scale 3) - High M-component production rate lgG value >7 g/dL; lgA value >5 g/dL - Bence Jones Protein >12g/24 h	$\beta_2$ -M $\geq$ 5.5 mg/dL	23 months

Durie-Salmon sub classification (either A or B)

A: Relatively normal renal function (serum creatinine value <2.0 mg/dL (<177 µmol/l)

B: Abnormal renal function (serum creatinine value  $\geq$  2.0 mg/dL (> 177  $\mu$ mol/ $\ell$ ) – Stage B worse outcome

\* Stage II =  $\beta_2$ -M <3.5 or  $\beta_2$ -M 3.5 – 5.5 mg/dL, and albumin <3.5 g/dL

Stage	Clinical features at diagnosis	Median survival (years)
A	Lymphocytosis and <3 areas of palpable lymph nodes	>7
В	Lymphocytosis and >3 areas of palpable lymph nodes	<5
С	Same as stage B with anaemia or thrombocytopenia	<2



# **HISTORY OF AMENDMENTS**

Effective date	Amendments
1 September 2009	First version of the Standard
1 January 2011	Version 2- Addition of Non-tiered definitions.
1 June 2012	Version 3-Changes of semantic nature. Instructions on how the tiered definitions should be adapted for use in a stand-alone format for a non-tiered product was included.
1 January 2015	Version 4 -Changes to introduction and definitions- almost entirely of a technical and cosmetic nature

Responsible Senior Policy Advisor: Point Person for the Life & Risk Board Committee