

# Amended and Additional Definitions for the Indian Market

**FICCI Health Insurance Committee:  
Task Force on Critical Illness**

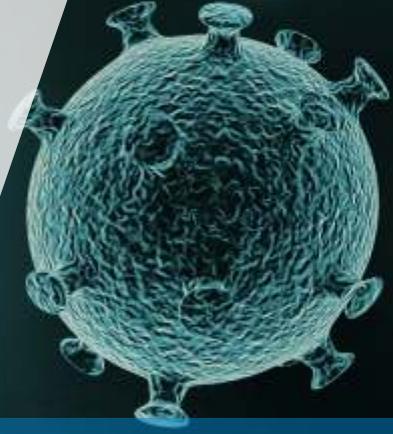
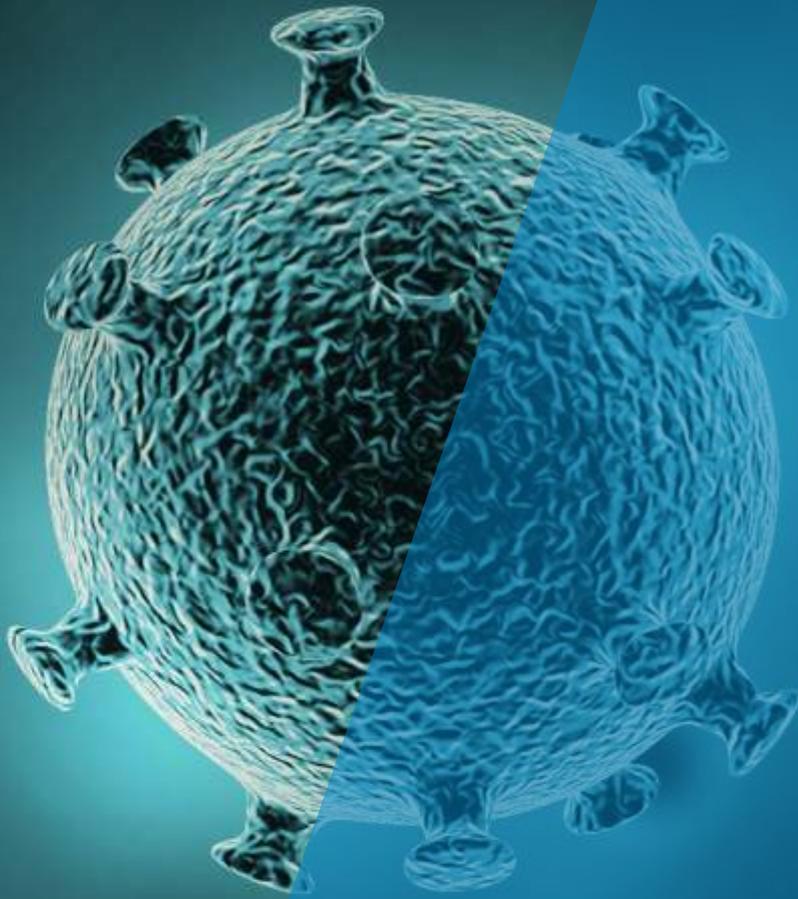


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FICCI Health Insurance Committee: Task Force on Critical Illness



# Foreword by FICCI



**Mr Antony Jacob**  
Co-Chair  
FICCI Health Insurance  
Committee &  
CEO, Apollo Munich  
Health Insurance



**Mr G Srinivasan**  
Chair  
FICCI Health Insurance  
Committee &  
CMD, The New India  
Assurance



**Mr Girish Rao**  
Co-Chair  
FICCI Health Insurance  
Committee & CMD  
Vidal Healthcare  
Services

India has the challenge of triple burden of disease – in which rising Non Communicable Diseases (NCDs) threaten development, infectious diseases are still dominant, and injuries remain a cause for concern against the backdrop of other health and development challenges.

Cardiovascular diseases, cancers, chronic respiratory diseases, kidney failure, and other Non-Communicable Diseases (NCDs) are estimated to account for 60% of all deaths in India, making them the leading cause of death. Furthermore, NCDs account for about 40% of all hospital stays and roughly 35% of all recorded outpatient visits\*. Stress, poor diet and lack of exercise, all banes of modern life, are now exposing more and more Indians to critical illnesses (CIs) each year. This, coupled with the increasing cost of treatment, has made recovery an expensive journey. Hence, we believe that CI plans will become more relevant in the coming years.

However, the reality today is that people still identify Health Insurance with Indemnity or 'Mediclaime' plans. The main cause of limited take up of CI plans is lack of awareness and complexity in communication of benefits. With technological advancements, there is a change in type of procedures and treatment done and this needs to be reflected in the definitions of diseases/conditions. Products have to be made easier to understand for both customers and distributors. We need to tackle these issues as an Industry.

In 2009, the FICCI sub-committee had standardized definitions for 11 most impactful CIs. These were adopted by the Health Insurance industry in India following the IRDA Circular on "Standardization in Health Insurance" - February 2013.

FICCI put forward the following standard definitions of Critical Illnesses –

1. *Cancer of Specified Severity*
2. *First Heart Attack – Of Specified Severity*
3. *Open Chest CABG*
4. *Open Heart Replacement or Repair Of Heart Valves*
5. *Coma of Specified Severity*
6. *Kidney Failure Requiring Regular Dialysis*
7. *Stroke Resulting In Permanent Symptoms*
8. *Major Organ /Bone Marrow Transplant*
9. *Permanent Paralysis of Limbs*
10. *Motor Neuron Disease with Permanent Symptoms*
11. *Multiple Sclerosis with Persisting Symptoms*

In 2015, as per the mandate of IRDA, FICCI constituted a Task Force to review the existing definitions of critical illness and also to identify and define new conditions.

The task force, led by **Dr Himanshu Bhatia – Senior Medical Officer (Asia), Gen Re Support Services**, comprised of a specialized group of experts with representation from key stakeholders including Reinsurance companies, life / non –life and specialist health insurance companies, TPA's, and medical technology company, who after several brain-storming meetings and conference calls, prepared the first draft of the report, by reviewing four earlier existing definitions, and identifying and defining eleven new conditions.

Before finalizing the report and as part of the review process, two drafts of the report were presented to the FICCI Health Insurance Committee Members, for review and inputs. The Task Force, taking into consideration the inputs of the Committee Members, further refined the document and sent it to select senior people in the industry for a final review.

After 6 months of rigorous work, which included carrying out extensive research of various markets and consideration of technical dynamics of Critical Illness, we are pleased to present FICCI's Report on Critical Illness 2015. The report also contains the Task Force's recommended roadmap for implementation of the definitions. We would also like to thank IRDA who have been an integral part of the Committee and has continuously guided & supported us in this endeavor.

# 1 Executive Summary

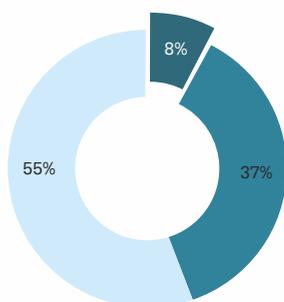
The FICCI sub-committee had, in 2009, recommended standard definitions for the 11 conditions covered under most Critical Illness Products. These were adopted by the Health Insurance industry in India following the IRDA Circular on “Standardization in Health Insurance” - February 2013 (IRDA/HLT/CIR/036/02/2013). Eleven conditions were covered- including the 'core' Critical Illnesses - Cancer, Heart Attack, CABG, Kidney Failure and Stroke.

In February 2015, the IRDA suggested that the Insurance Committee of FICCI review the existing definitions and suggested to review the list for additional conditions (with appropriate definitions). Since the task of reviewing definitions requires a mix of clinical and insurance skills, the FICCI Insurance Committee chose to set up a specialized task-force with representation from key stakeholders including Reinsurance companies as well as life / non –life and specialist health insurance companies.

The market context to the Critical Illness Product should also be kept in mind. Health insurance in India is sized at Rs 21,000 cr (March 2015); but the main product that is sold is hospitalization indemnity cover (sold as a generic “Mediclaim” category of product). Critical Illness products are sold as both stand alone and rider benefits- by life, non-life and specialist health insurance companies. While the market statistics on the number of CI policies and sum insured are not available, a recent 2014 market research survey estimated that 8% of health insurance buyers purchased critical illness<sup>1</sup>. However, the most common causes of claims include conditions which are financially debilitating for the consumer.

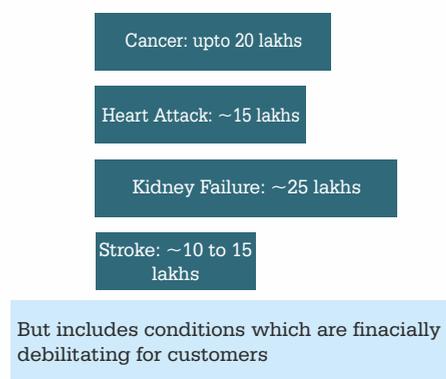
8% of health policies sold are Critical illness Covers

**Health Insurance Ownership 2014**  
 ■ Critical Illness ■ Other Health Insurance policies  
 ■ Don't own health insurance



Source: ICICI Lombard 2014 Survey on Health and Tobacco Consumption, Sample size of 1111 across 5 cities - Mumbai, Kolkatta, Hyderabad, Lucknow, Ahmedabad

Typical costs of care - main conditions claimed under Critical Illness Insurance



<sup>1</sup>Source: ICICI Lombard Survey on Health & Tobacco Consumption, March 2014. Survey of 1111 consumers across 6 cities on health insurance purchase and tobacco consumption / disclosure habits

## OBJECTIVES OF TASK FORCE

1. Overall, the objective is to **standardize** the definitions of Critical Illness while balancing the interests of both consumers and insurance providers.
2. For consumers, offering **clear and consistent** coverage across the industry enhances consumer confidence in the CI product by allowing comparison on price and other value added benefits and eliminates the challenge of comparing technical aspects of CI definitions used by different insurers.
3. Bring **consistency during claims assessment** across the industry by reducing the incidences of one insurer paying a claim and another rejecting due to differences in definition. Going forward, it builds a platform where true incidence of CI conditions in the Indian insured population can be accurately assessed.
4. Align the key existing definitions with **advances made in medical technology and clinical practice** as well as to address areas of practical constraints based on insights gained from past experience.

### 1.1 Key recommendations of the task-force

In line with the terms of reference, and given the need to 'demystify' critical illness – the following graphic summarizes the impact of change in the definitions on key stakeholders:

Recommendation	Impact on			
	Consumer	Distributor	Provider	Insurer
Cancer - Clarification on exclusions	▲	▲		▲
Inclusion of Angioplasty	▲	▲	▲	■
Heart Attack - In line with the 'universal' definition	▲	■	▲	
Multiple Sclerosis - Changes in line with developments in clinical practice	▲		▲	
Additional conditions - Blindness, deafness, loss of speech, loss of limbs etc	▲	▲		▲

▲ Positive Impact

▼ Negative Impact

■ Natural Impact

### 1.1.1 Review of Existing Definitions

- Existing Definitions were reviewed – and changes have been recommended to four conditions – Cancer, Heart Attack (Myocardial Infarction), Open Chest Coronary Arterial Bypass Surgery (commonly known as Open Heart Surgery) and Multiple Sclerosis.
- Changes are aimed at providing greater clarity to the consumer and the distributor, (e.g. changes in Cancer definition), and/or to upgrade definitions to the latest medical updates (e.g. Myocardial infarction, Multiple Sclerosis).

### 1.1.2 Additional 11 conditions included in CI list

- Inclusion of 11 conditions –Major Head Trauma, Benign Brain Tumor, End Stage Lung Disease, End Stage Liver Disease, Angioplasty, Blindness, Deafness, Loss of Speech, Loss of limbs, Primary (Idiopathic) Pulmonary Hypertension, Third Degree Burns.
- Many of the new conditions included in the extended list are those where the **financial impact in terms of future income earning ability is high.**

### 1.1.3 Inclusion of Angioplasty

- Coronary Angioplasty is generally not a part of the “major” critical illness benefit. Customers who have undergone Angioplasty but do not show evidence of Heart Attack as defined by existing definition do not qualify under any CI benefit, leading to customer grievance. Insurance companies are therefore offering more and more products covering Angioplasty with a smaller benefit amount.
- Given this situation the task force felt that standardizing the definition to be used by the market would lead to orderly growth and the market's movement in this direction can be calibrated by a standard definition.
- Unlike other conditions, the definition allows for a **partial payout** of the sum insured for Angioplasty – this is to ensure that insurers do not overextend cover and insurance policies are closer to actual costs of care. It will also reduce any incentive for over-utilization and anti-selection.

### 1.1.4 Amendments to the Cancer definition

- To include emerging clinical terminology - such as “pre-malignant”, “borderline malignant”, “low malignant potential”. These terms refer to non-invasive forms of malignancies which are excluded from the scope of critical illness covers. **However the use of the word “malignant” by the doctors at the time of diagnosis can create confusion in the mind of the consumer, who would expect to claim under the Cancer benefit. To ensure greater transparency to the consumer the definition of cancer clarifies the conditions which are specifically excluded.**
- Exclusion wording on some cancers are liberalized to widen the coverage of such cancers, e.g. inclusion of metastatic skin cancer apart from malignant melanoma.

### **1.1.5 Amendments to Heart Attack definition**

- To include NSTEMI as part of Heart Attack definition in line with Universal definition of Myocardial Infarction
- To exclude isolated Troponin elevations purely due to undergoing of cardiac procedures without evidence of myocardial infarction.

### **1.1.6 Amendments to Multiple Sclerosis definition**

- Definition has been aligned to remove the requirement of CSF evidence, or two or more episodes of MS in line with current technological advances and clinical criteria.

### **1.1.7 Amendments to Coronary Artery Bypass definition**

- Coronary artery bypass grafting procedure has undergone innovation and evolution in the past few years. Minimally invasive surgical procedures or key-hole procedures are now being done in some centers. Innovative procedures include minimally invasive direct coronary artery bypass grafting (MIDCAB), Port-Access Coronary Bypass Grafting, Hybrid Surgery and Totally Endoscopic assisted coronary artery bypass grafting (TECAB).
- These are indicated for similar severity of the coronary artery disease and are equally expensive.
- Current definition has therefore been amended to allow for such procedures under the CABG benefit.

## **1.2 Implementation: Impact on existing products**

- New definitions can come into force after a "X" date (eg June 1 2016) across the whole industry
- If there is no change in product features except update on definitions- only certification plus file and use process is recommended. This will avoid the operational and transaction intensity on insurers and the Regulator. This is also common practice in all markets where CI definitions are reviewed.
- With change in product features (Eg addition of new condition) or any price implication (even for existing definitions)- Product refiling would be required
- The above is subject to acceptance by the IRDAI and subsequent notification

# 2 Terms of Reference

## 2.1 Terms of Reference

The Task force was appointed by the FICCI Committee on Insurance to:

1. Review the existing Critical Illness standard definitions; suggest appropriate changes in view of changes in clinical, technological or market forces;
2. Add conditions to the standard list of Critical Illnesses; based on feedback from insurers and consumers.
3. For each of the added conditions, suggest appropriate definitions, as well as a rationale for the recommended definition.

The output of the task force is structured accordingly.

## 2.2 Composition of the Task Force

The task force comprised the following members:

Name	Role	Designation	Company
Dr Himanshu Bhatia	LEADER	Senior Medical Officer, Asia	Gen Re Support Services
Ms Vidya Hariharan	MEMBER	Director - Group Strategy	Vidal Healthcare
Mr Mahaveer Chandiwala	MEMBER	Head of Underwriting and Claim - Development and Services	Munich Re India Services Private Limited
Dr Sheetal Salgaonkar	MEMBER	Medical Director - Medical Services	RGA Services India Pvt. Ltd.
Dr Asha Sapre	MEMBER	External Medical consultant	Swiss Re Services India Private Ltd
Mr Dinesh Pant	MEMBER	Product Actuary Team	LIC of India
Mr Sarang Gokhale	MEMBER	Senior Vice President & Head - Underwriting, Claims & Business Solutions Group	ICICI Prudential
Mr Burugupalli Madhu	MEMBER	VP - Products	ICICI Prudential
Ms Asha Nair	MEMBER	Director & General Manager	United India Insurance
Mr Rajagopal Rudraraju	MEMBER	Vice President - Claims and Group Underwriting	Apollo Munich Health Insurance Company Limited
Dr Manisha Kalaver	MEMBER	Associate Director - Medical Services	RGA Services India Pvt. Ltd.
Mr Sanjay Datta	MEMBER	Head - Underwriting & Claims	ICICI Lombard General Insurance

- Representation was sought from reinsurance companies providing capacity for CI in the Indian market in order to capitalize their knowledge / experience of other markets.
- Since Critical Illness insurance is provided by Life / Non-Life and Stand-alone health companies – all three segments were represented.

# 3 Review of existing definitions

## 3.1 Cancer of specified severity

### 3.1.1 Current Definition

A malignant tumor characterized by the uncontrolled growth & spread of malignant cells with invasion & destruction of normal tissues. This diagnosis must be supported by histological evidence of malignancy & confirmed by a pathologist. The term cancer includes leukemia, lymphoma and sarcoma. The following are excluded -

- (1) Tumors showing the malignant changes of carcinoma in situ & tumors which are histologically described as pre-malignant or non-invasive, including but not limited to: Carcinoma in situ of breasts, Cervical dysplasia CIN-1, CIN -2 & CIN-3.
- (2) Any skin cancer other than invasive malignant melanoma
- (3) All tumors of the prostate unless histologically classified as having a Gleason score greater than 6 or having progressed to at least clinical TNM classification T2N0M0.
- (4) Papillary micro - carcinoma of the thyroid less than 1 cm in diameter
- (5) Chronic lymphocytic leukaemia less than RAI stage 3

### 3.1.2 Amended Definition

A malignant tumor characterized by the uncontrolled growth & spread of malignant cells with invasion & destruction of normal tissues. This diagnosis must be supported by histological evidence of malignancy & confirmed by a pathologist. The term cancer includes leukemia, lymphoma and sarcoma.

The following are excluded - (1) All tumors which are histologically described as carcinoma in situ, benign, pre-malignant, borderline malignant, low malignant potential, neoplasm of unknown behavior, or non-invasive, including but not limited to: Carcinoma in situ of breasts, Cervical dysplasia CIN-1, CIN -2 & CIN-3. (2) Any non-melanoma skin carcinoma unless there is evidence of metastases to lymph nodes or beyond; (3) Malignant melanoma that has not caused invasion beyond the epidermis; (4) All tumors of the prostate unless histologically classified as having a Gleason score greater than 6 or having progressed to at least clinical TNM classification T2N0M0(5) All Thyroid cancers histologically classified as T1N0M0 (TNM Classification) or below; (6) Chronic lymphocytic leukaemia less than RAI stage 3 (7) Non-invasive

<p>(6) All tumours of the urinary bladder histologically classified as T1N0M0 (TNM Classification) or below</p>	<p>papillary cancer of the bladder histologically described as TaN0M0 or of a lesser classification, (8) All Gastro-Intestinal Stromal Tumours</p>
<p>(7) All tumors in the presence of HIV infection.</p>	<p>histologically classified as T1N0M0 (TNM Classification) or below and with mitotic count of less than or equal to 5/50 HPFs; (9) All tumors in the presence of HIV infection.</p>

### 3.1.3 Key discussion points / Rationale for change

A. Reduce ambiguity on what defines “non-cancerous” conditions in the existing definition which are to be excluded :

1. Clinicians have begun using terms such as “borderline malignant”, “low malignant” to describe non-invasive and carcinoma in situ conditions. The insurance definition of “Cancer of a specific severity” therefore must include these new terms to the definition and remove ambiguity by specifying that such diagnosis are excluded.

Edited version : The following are excluded – “(1) All tumors which are histologically described as carcinoma in situ, benign, pre-malignant, borderline malignant, low malignant potential, neoplasm of unknown behavior, or non-invasive, including but not limited to: Carcinoma in situ of breasts, Cervical dysplasia CIN-1, CIN -2 & CIN-3”

B. Some cancers were intended to be covered in existing definition but due to gaps in wordings, these were considered as being excluded. Exclusion wording on such conditions are being liberalized to widen the coverage of such cancers and are expected to have no material impact on pricing.

1. In the existing definition, all non-melanoma skin cancers are excluded, e.g. BCC with metastasis is also excluded when this is as severe as any other cancer and has high morbidity and mortality. Therefore Non-melanoma with metastasis has been included in revised definition.

Edited version: “Any non-melanoma skin carcinoma unless there is evidence of metastases to lymph nodes or beyond; (3) Malignant melanoma that has not caused invasion beyond the epidermis”

2. In the existing definition, both Ta and T1NoMo of bladder cancers are excluded while the original intention was to exclude only Ta since these represent the non-invasive papillary carcinoma. Exclusion has been modified in revised definition to exclude only Ta (and to provide coverage for T1NoMo)

Edited version: “Non-invasive papillary cancer of the bladder histologically described as TaN0M0 or of a lesser classification”

C. Manage the new threat of early Thyroid and GIST cancers due to technological advances

1. Exclusion on GIST with mitotic count of less than or equal to 5/50 HPFs- GIST fulfilling both criterion has very good prognosis and minimal recurrence rate, which do not fit into the spirit of Major Cancers coverage and therefore must be excluded {For low malignant potential (low risk) GIST, the 5-year survival rate (at approximately 95%) is similar to the normal population – (Source: Bucher P, Taylor S, Villiger P, Morel P, Brundler M. For small intestinal stromal tumours are there any prognostic factors. Source: Am J Surg 2004)

Edited version : “ (8) All Gastro-Intestinal Stromal Tumours histologically classified as T1N0M0 (TNM Classification) or below and with mitotic count of less than or equal to 5/50 HPFs”

2. Similarly, early Thyroid cancers are often incidental findings due to screening, have very low morbidity or mortality. Thyroid cancer exclusion needs to be revised to align with TNM classification rather than follow old classification which is now outdated.

Edited version: “(5) All Thyroid cancers histologically classified as T1N0M0 (TNM Classification) or below”

## 3.2 Multiple Sclerosis

### 3.2.1 Current Definition

The definite occurrence of multiple sclerosis. The diagnosis must be supported by all of the following:

- Investigations including typical MRI and CSF findings, which unequivocally confirm the diagnosis to be multiple sclerosis;
- There must be current clinical impairment of motor or sensory function, which must have persisted for a continuous period of at least 6 months, and
- Well documented clinical history of exacerbations and remissions of said symptoms or neurological deficits with at least two clinically documented episodes at least one month apart.

Other causes of neurological damage such as SLE and HIV are excluded.

### 3.2.2 Amended Definition

The unequivocal diagnosis of Definite Multiple Sclerosis confirmed by a Consultant Neurologist. The diagnosis must be evidenced by all of the following:

- investigations including typical MRI findings which unequivocally confirm the diagnosis to be multiple sclerosis and
- there must be current clinical impairment of motor or sensory function, which must have persisted for a continuous period of at least 6 months.

Other causes of neurological damage such as SLE and HIV are excluded.

### 3.2.3 Key discussion points / Rationale for change

1. **Reduce ambiguity in diagnosis of Multiple Sclerosis:** The Current CI definition demanded both MRI and CSF findings. Given medical advances with non-invasive imaging techniques, CSF analysis is rarely carried out for diagnosis of Multiple sclerosis. This required is therefore removed from revised definition.
2. **Technological advances:** Magnetic Resonance Imaging (MRI) of the central nervous system (CNS) can support, supplement, or even replace some clinical criteria as most recently emphasized by the McDonald Criteria of the International Panel on Diagnosis of MS. The use of imaging for demonstration of dissemination of central nervous system lesions in space and time has been simplified, and in some circumstances dissemination in space and time can be established by a single scan.
3. Clinical definition no longer demands two or more clinical episodes. The definite diagnosis of MS can be made without multiple clinical episodes. Hence it is preferable to reword existing definition to add that a Specialist must make the unequivocal diagnosis of Definite Multiple Sclerosis basis objective neurological impairment, involvement of white matter long tracks and involvement of two or more areas of CNS in space and time. Removal of this requirement of 2 or more clinical episodes therefore would have no material impact on pricing

## 3.3 Myocardial Infarction

(First Heart Attack of specific severity)

### 3.3.1 Current Definition

The first occurrence of myocardial infarction which means the death of a portion of the heart muscle as a result of inadequate blood supply to the relevant area.

The diagnosis for which will be evidenced by all of the following criteria:

- a) a history of typical clinical symptoms consistent with the diagnosis of Acute Myocardial Infarction (for example typical chest pain)
- b) new characteristic electrocardiogram changes

### 3.3.2 Amended Definition

The first occurrence of heart attack or myocardial infarction, which means the death of a portion of the heart muscle as a result of inadequate blood supply to the relevant area. The diagnosis for Myocardial infarction should be evidenced by all of the following criteria:

- a) A history of typical clinical symptoms consistent with the diagnosis of acute myocardial infarction (For e.g typical chest pain)
- b) New characteristic electrocardiogram changes

c) Elevation of infarction specific enzymes; Troponins or other specific biochemical markers.

The following are excluded

- (1) Non-ST – Segment Elevation Myocardial Infarction (NSTEMI) with elevation of Troponin I or T
- (2) Other acute Coronary Syndromes
- (3) Any type of Angina Pectoris.

c) Elevation of infarction specific enzymes, Troponins or other specific biochemical markers.

The following are excluded:

- (1) Other acute Coronary Syndromes
- (2) Any type of angina pectoris
- (3) A rise in cardiac biomarkers or Troponin T or I in absence of overt ischemic heart disease OR following an intra-arterial cardiac procedure.

### 3.3.3 Rationale for change

1. Include the word "Heart attack "in the definition for clarity of the consumer.

Edited version : “The first occurrence of heart attack or myocardial infarction, which means the death of a portion of the heart muscle as a result of inadequate blood supply to the relevant area”

2. Align with current clinical definition of Myocardial Infarction ( 3RD Universal Definition ) by removing the exclusion for NSTEMI from existing definition of Myocardial Infarction

- Universal definition of Myocardial Infarction does not differentiate between STEMI and NSTEMI as both include death of cardiac muscle and impact morbidity/ mortality.
- Interventions if carried out early can reverse STEMI ECG changes and produce a NSTEMI appearance (which would lead to inappropriate declination under existing Myocardial Infarction definition).
- The task force does not anticipate pricing implications as technically NSTEMI are part of Universal definition of Myocardial Infarction and are included in current costing process.
- Add an exclusion- “A rise in cardiac biomarkers or Troponin T or I, in absence of overt ischemic heart disease or following an intra-arterial cardiac procedure”. Conditions other than ischemia can cause rise in cardiac biomarkers including Troponin especially with highly sensitive assays now available in the market. Examples include pulmonary embolism, cardiac injury, myocarditis, renal disorders etc. cause Increase in Troponins. Also, post cardiac procedures like angiography or revascularization procedures like PCI or CABG, cardiac biomarkers may rise. This exclusion would guard against invalid claims due to increase in values of cardiac biomarkers or Troponins in absence of heart attack or following intra-arterial cardiac procedures.

- There was extensive discussion on whether absolute cutoffs or percentile cutoffs for Troponin should be mentioned in the definition to be in line with the third universal definition of MI. The absence of standardization of the type of Troponin test, the variety of kits with different laboratory, the high cost of both the qualitative and quantitative test and lack of availability of Trop T test all over India would not it make it practical to insist on this requirement. It was therefore decided not to include an absolute cut off for Trop T levels anywhere in the definition.

Edited version of exclusions: “The following are excluded:

- (1) Other acute Coronary Syndromes
- (2) Any type of angina pectoris
- (3) A rise in cardiac biomarkers or Troponin T or I in absence of overt ischemic heart disease OR following an intra-arterial cardiac procedure.

## 3.4 Open Chest Coronary Artery Bypass Surgery

### 3.4.1 Current Definition

The actual undergoing of open chest surgery for the correction of one or more coronary arteries, which is/are narrowed or blocked, by coronary artery bypass graft (CABG). The diagnosis must be supported by a coronary angiography and the realization of surgery has to be confirmed by a specialist medical practitioner.

Excluded are:

- (1) Angioplasty and/or any other intra-arterial procedures
- (2) Any key-hole or laser surgery.

### 3.4.2 Amended Definition

The actual undergoing of heart surgery to correct blockage or narrowing in one or more coronary artery(s), by coronary artery bypass grafting done via a sternotomy (cutting through the breast bone) or minimally invasive keyhole coronary artery bypass procedures. The diagnosis must be supported by a coronary angiography and the realization of surgery has to be confirmed by a cardiologist.

Excluded are: Angioplasty and/or any other intra-arterial procedures

### 3.4.3 Key discussion points / Rationale for changes recommended:

- Coronary artery bypass grafting procedure has undergone innovation and evolution in the past few years. Minimally invasive surgical procedures or key-hole procedures are now being done in some centers.

- These are indicated for similar severity of the coronary artery disease and are equally expensive. The procedures reduces the risks associated with the use of the heart-lung machine cardiopulmonary bypass (CPB) and offer the same benefits as open-heart coronary artery bypass grafting (CABG) surgery with shorter hospitalization, less blood loss and a faster recovery.
- Innovative procedures include minimally invasive direct coronary artery bypass grafting (MIDCAB), Port-Access Coronary Bypass Grafting, Hybrid Surgery and Totally Endoscopic assisted coronary artery bypass grafting (TECAB). Definition has therefore been amended to allow for such procedures under the CABG benefit.

Edited version: “.....grafting done via a sternotomy (cutting through the breast bone) or minimally invasive keyhole coronary artery bypass procedures”

# 4 Additional Definitions

## 4.1 Angioplasty

4.1.1 Current Definition	4.1.2 Amended Definition
<p>NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.</p>	<p>Coronary Angioplasty is defined as percutaneous coronary intervention by way of balloon angioplasty with or without stenting for treatment of the narrowing or blockage of minimum 50 % of one or more major coronary arteries. The intervention must be determined to be medically necessary by a cardiologist and supported by a coronary angiogram (CAG)</p> <p>Coronary arteries herein refer to left main stem, left anterior descending, circumflex and right coronary artery.</p> <p>Diagnostic angiography or investigation procedures without angioplasty/stent insertion are excluded.</p> <p>A payment benefit equal to xxx % of the Critical Illness sum assured subject to a maximum of INR xxx shall be paid under this benefit.</p>

**4.1.3 Key discussion points / Rationale for change**

Coronary Angioplasty is generally not a part of the “major” critical illness benefit. Customers who have undergone Angioplasty but do not show evidence of Heart Attack as defined by existing definition do not qualify under any CI benefit, leading to customer grievance. Insurance companies are therefore offering more and more products covering Angioplasty with a smaller benefit amount.

Given this situation the task force felt that standardizing the definition to be used by the market would lead to orderly growth and the market's movement in this direction can be calibrated by a standard definition.

### Design considerations

**Number of arteries with lesions:** The commonly used definitions differ in the number of arteries with lesions, as given in some examples below:

- a. One or more of the coronary arteries
- b. Two or more of the coronary arteries
- c. In Left Main Stem or definition as b.

The proposed definition is designed to avoid complexity and “one or more coronary arteries” corrected is considered under the standardized definition

**Extent of blockage:** Most definitions have a requirement of 60% or more blockage for the procedure to be considered under this benefit. Angioplasty is not performed on mild obstructions that narrow the artery by less than 50%, because such lesions seldom cause symptoms. In addition, angioplasty may actually accelerate progress of such lesions (Source: Popma, J. J., Donald S. Baim, and Frederic S. Resnic. "Percutaneous Coronary and Valvular Intervention." Also refer Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine. Eds. Peter Libby, et al. 8th ed. W.B. Saunders, 2007. 1419-1449).

We recommend a requirement of “minimum 50 % narrowing or blockage” as a cut off. This also reduces payout for inappropriate angioplasties.

**Definition of coronary arteries :** It is proposed to consider the following major coronary arteries

- Left main stem
- Left Anterior Descending (LAD)
- Left circumflex (LCX)
- Right Coronary Artery (RCA)

**Quantum of payment:** It is recognized that Angioplasty is not part of the “major” Critical Illness conditions and does not warrant the same level of payout. Each insurer should clearly mention the maximum payout so as to enable to customer to compare the benefit. In order to ensure the same, the definition includes a statement at the end which allows each insurer to customize the payout to their risk appetite and target customer segment.

## 4.2 Benign Brain Tumor

4.2.1 Current Definition	4.2.2 Amended Definition
<p>NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.</p>	<p>Benign brain tumor is defined as a life threatening, non-cancerous tumor in the brain, cranial nerves or meninges within the skull. The presence of the underlying tumor must be confirmed by imaging studies such as CT scan or MRI.</p> <p>This brain tumor must result in at least one of the following and must be confirmed by the relevant medical specialist.</p> <ol style="list-style-type: none"> <li>1. Permanent Neurological deficit with persisting clinical symptoms for a continuous period of at least 90 consecutive days or</li> <li>2. Undergone surgical resection or radiation therapy to treat the brain tumor.</li> </ol> <p>The following conditions are <b>excluded</b>: Cysts, Granulomas, malformations in the arteries or veins of the brain, hematomas, abscesses, pituitary tumors, and tumors of skull bones and tumors of the spinal cord.</p>

4.2.3 Key discussion points / Rationale for change
<ol style="list-style-type: none"> <li>1. The imaging studies such as CT scan or MRI are needed to establish presence and exact location of the tumor.</li> <li>2. <b>Permanent Neurological Deficit with Persisting Clinical Symptoms:</b> Permanent neurological deficit with Persisting Clinical Symptoms is defined as signs and symptoms of dysfunction in the nervous system that are present on clinical examination by a Specialist and <b>expected to last throughout the insured person's life</b>. The following neurological symptoms are covered under this definition: numbness, paralysis, localized weakness, dysarthria (difficulty with speech), aphasia (inability to speak), dysphagia (difficulty in swallowing), visual impairment, difficulty in walking, lack of coordination, tremor, seizures, dementia, cognitive impairment, delirium and coma. An abnormality seen on brain or other scans without definite related clinical symptoms, neurological signs occurring without symptomatic abnormality such as brisk reflexes without other symptoms and symptoms of psychological or psychiatric origin will not qualify as Permanent neurological deficit with Persisting Clinical Symptoms. Majority of benign brain tumors that have any functional neurological deficit or any likelihood of functional neurological deficit will get a procedure like surgery or radiation therapy.</li> </ol>

3. Surgery, also called surgical resection, is often indicated for primary brain tumors. A surgeon removes some or the entire tumor without causing severe damage to surrounding tissues. Although some will not be operable for technical reasons or by virtue of site within the brain like diffuse benign astrocytoma etc. Biopsy will not be considered as surgical resection.
4. These un-resectable and non-surgical tumors will get some other modality of treatment like radiation therapy. In the past two decades, researchers have developed new techniques of delivering radiation that target the brain tumor while protecting nearby healthy tissues. These treatments include Gamma Knife Radiosurgery or Stereotactic radiosurgery, Intensity-modulated radiation therapy (IMRT) and Brachytherapy. Types of radiation therapy include:
  - **Gamma Knife Radiosurgery or Stereotactic Radiosurgery:** is a very precise form of therapeutic radiology. Even though it is called surgery, a Gamma Knife procedure does not involve actual surgery, nor is the Gamma Knife really a knife at all. It uses beams of highly-focused gamma rays to treat small to medium size lesions, usually in the brain. Many beams of gamma radiation join to focus on the lesion under treatment, providing a very intense dose of radiation without a surgical incision or opening. A highly precise form of radiation therapy that directs narrow beams of radiation to the tumor from different angles. For this procedure, the patient may wear a rigid head frame. Computed tomography (CT) or magnetic resonance imaging (MRI) help the doctor identify the tumor's exact location and a computer helps the doctor regulate the dose of radiation. Stereotactic radiotherapy is similar physically to radiosurgery but involves fractionation (multiple treatments). This modality would be recommended for tumors within or close to critical structures in the brain that cannot tolerate a large single dose of radiation or for larger tumors.
  - **Three-dimensional conformal radiation therapy (3D-CRT):** a conventional form of radiation treatment delivery that uses a specific arrangement of x-ray beams designed to conform to the shape of the tumor to maximize tumor dose and minimize normal surrounding tissue dose. This form of treatment is tailored to the patient's specific anatomy and tumor location. CT and/or MRI scan is often required for treatment planning.
  - **Intensity-modulated radiation therapy (IMRT):** an advanced mode of high-precision radiotherapy that utilizes computer-controlled x-ray accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. The radiation dose is designed to conform to the three-dimensional (3-D) shape of the tumor by modulating—or controlling—the intensity of the radiation beam to focus a higher radiation dose to the tumor while minimizing radiation exposure to healthy cells. Arc therapy is an advanced treatment technique that builds on the advantages of IMRT. The potential advantages of arc therapy over IMRT have not been fully established. This technique is not yet widely available.
  - Brachytherapy the temporary placement of radioactive materials within the body, usually employed to give an extra dose- or boost- of radiation to the area of the excision site.

## 4.3 Blindness

4.3.1 Current Definition	4.3.2 Amended Definition
<p>NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.</p>	<p>Total, permanent and irreversible loss of all vision in both eyes as a result of illness or accident.</p> <p>The Blindness is evidenced by</p> <ol style="list-style-type: none"> <li>corrected visual acuity being 3/60 or less in both eyes or ;</li> <li>the field of vision being less than 10 degrees in both eyes.</li> </ol> <p>The diagnosis of blindness must be confirmed by an ophthalmologist and must not be correctable by aides or surgical procedure</p>

### 4.3.3 Key discussion points / Rationale for change

Different definitions considered for arriving at the Insurance definition –

**WHO definition** - 'Blindness' is defined as visual acuity of less than 3/60, or a corresponding visual field loss to less than 10 degrees, in the better eye with the best possible correction.

#### **National Program for Control of Blindness (NPCB) – India - Technical Definition**

- Vision 6/60 or less with the best possible spectacle correction
- Diminution of field vision to 20° or less in better eye

**Key discussion points** – Various diseases and accidents may lead to totally permanently impaired vision in both eyes. The visual acuity and the visual fields are used to measure the degree of impairment.

Profound vision loss (total blindness) is defined as visual acuity of 3/60 or less (0.05 or less in the decimal notation) or a visual field of 10° diameter or less in the better eye. A visual acuity of 3/60 (or 0,05) is the ability to see an object only at 3 metres what the normal eye can see at 60 metres. Constriction of the visual field to less than 10° means that only objects in the centre of the visual field can be seen (tunnel or tubular vision).

In addition, the visual impairment must be permanent, i.e. cannot be improved any further by medical intervention (e.g. surgery) or by optimized vision aids. As per clinical evaluation NPCB definition would result in low vision and does not have clear trigger points.

The Disability certification issued by chief commissioner-Government of India considers 100% disability for individuals with visual disability of Category III and beyond. The category III definition is in line with the proposed definition of visual acuity of 3/60 to 1/60 or field of vision 10°.

The proposed insurance definition has clear and precise claims trigger and is in line with clinical evaluation of total blindness.

## 4.4 Deafness

### 4.4.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.4.2 Amended Definition

Total and irreversible loss of hearing in both ears as a result of illness or accident. This diagnosis must be supported by pure tone audiogram test and certified by an Ear, Nose and Throat (ENT) specialist. Total means “the loss of hearing to the extent that the loss is greater than 90 decibels across all frequencies of hearing” in both ears.

### 4.4.3 Key discussion points / Rationale for change

There are multiple causes of deafness –age related, genetic, neurological, medication, chemical, physical trauma etc.

The diagnosis will be ascertained by an audiogram wherein a thorough test is conducted by an ENT specialist.

Since definition states total and irreversible loss of hearing in both ears hence profound deafness of greater than 90db is considered.

## 4.5 End Stage Lung Failure

### 4.5.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.5.2 Amended Definition

End stage lung disease, causing chronic respiratory failure, as confirmed by a physician and evidenced by all of the following:

- 1) FEV1 test results consistently less than 1 litre measured on 3 occasions 3 months apart; and
- 2) Requiring continuous permanent supplementary oxygen therapy for hypoxemia; and
- 3) Arterial blood gas analysis with partial oxygen pressure of 55mmHg or less (PaO<sub>2</sub> < 55mmHg); and
- 4) Dyspnea at rest

### 4.5.3 Key discussion points / Rationale for change

- End stage lung disease refers to chronic respiratory failure due to chronic lung diseases such as COPD ,pulmonary fibrosis ,cystic fibrosis etc.
- The main feature of respiratory failure is hypoxemia which would be evidenced by the 3 main criteria:

- o Requiring continuous permanent supplementary oxygen therapy for hypoxemia; and
- o Arterial blood gas analyses with partial oxygen pressures of 55mmHg or less (PaO<sub>2</sub> < 55mmHg);
- o Dyspnea at rest: The criteria of FEV<sub>1</sub> < 1 would indicate advanced /severe category of lung disease The requirement of 3 readings 3 months apart ensures that the drop is not during an exacerbation.

## 4.6 End stage Liver Failure

### 4.6.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.6.2 Amended Definition

Permanent and irreversible failure of liver function that has resulted in all three of the following:

- permanent jaundice; and
- Ascites; and
- hepatic encephalopathy.

Liver failure secondary to drug or alcohol abuse is **excluded**.

### 4.6.3 Key discussion points / Rationale for change

- End stage liver disease mainly refers to decompensated cirrhosis. Decompensated cirrhosis is defined by the presence of ascites, variceal bleeding, encephalopathy and/or jaundice.
- The addition of gastrointestinal varices would add more weight to the other three but many times upper GI scopy is not available.

Note – End stage failure due to substance or alcohol abuse is specifically **excluded**.

## 4.7 Loss of Speech

### 4.7.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.7.2 Amended Definition

Total and irrecoverable loss of the ability to speak as a result of injury or disease to the vocal cords. The inability to speak must be established for a continuous period of 12 months. This diagnosis must be supported by medical evidence furnished by an Ear, Nose, Throat (ENT) specialist.

All psychiatric related causes are excluded.

### 4.7.3 Key discussion points / Rationale for change

Given Loss of Sight and Loss of Hearing are part of the new conditions; Loss of Speech has also been added.

## 4.8 Loss of Limbs

### 4.8.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.8.2 Amended Definition

The physical separation of **two** or more limbs, at or above the wrist or ankle level limbs as a result of injury or disease. This will include medically necessary amputation necessitated by injury or disease. The separation has to be permanent without any chance of surgical correction. Loss of Limbs resulting directly or indirectly from self-inflicted injury, alcohol or drug abuse is excluded.

### 4.8.3 Key discussion points / Rationale for change

The current list of standardized definitions by IRDAI does not have a definition for loss of limbs. However, the loss of functional use is covered within the definition for 'Permanent Paralysis of Limbs' which reads –*“Total and irreversible loss of use of two or more limbs as a result of injury or disease of the brain or spinal cord. A specialist medical practitioner must be of the opinion that the paralysis will be permanent with no hope of recovery and must be present for more than 3 months.”*

On the other hand, the intention of the "Loss of Limbs" condition is to cover "severance" (mainly due to injury and amputation) which currently does not fulfill the existing Permanent Paralysis of Limbs definition. . Having "loss of limb by severance" will provide wider scope for the customer than currently available. Both definitions are shown below:

#### Number of limbs

The definition required two or more of the limbs to be severed and is consistent with:

- The existing wording
- Guidelines for evaluation of permanent physical impairment where loss of one limb is considered at 55% (lower limb at heel)-60% (upper limb at wrist)

#### Coverage for disease and injury

The coverage for this includes disease and injury to keep it consistent with the definition for Permanent Paralysis of Limbs.

## 4.9 Major Head Trauma

### 4.9.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.9.2 Amended Definition

Accidental head injury resulting in permanent Neurological deficit to be assessed no sooner than 3 months from the date of the accident. This diagnosis must be confirmed by a relevant medical specialist and supported by unequivocal findings on Magnetic Resonance Imaging, Computerized Tomography, or other reliable imaging techniques. The accident must be caused solely and directly by accidental, violent, external and visible means and independently of all other causes.

The Accidental Head injury must result in an inability to perform at least three (3) of the following Activities of Daily Living either with or without the use of mechanical equipment, special devices or other aids and adaptations in use for disabled persons. For the purpose of this benefit, the word “permanent” shall mean beyond the scope of recovery with current medical knowledge and technology.

The Activities of Daily Living are:

1. Washing: the ability to wash in the bath or shower (including getting into and out of the bath or shower) or wash satisfactorily by other means;
2. Dressing: the ability to put on, take off, secure and unfasten all garments and, as appropriate, any braces, artificial limbs or other surgical appliances;
3. Transferring: the ability to move from a bed to an upright chair or wheelchair and vice versa;
4. Mobility: the ability to move indoors from room to room on level surfaces;
5. Toileting: the ability to use the lavatory or otherwise manage bowel and bladder functions so as to maintain a satisfactory level of personal hygiene;
6. Feeding: the ability to feed oneself once food has been prepared and made available.

The following are excluded:

- (a) Spinal cord injury;

### 4.9.3 Key discussion points / Rationale for change

The definition is added to the list of critical illness with and objective to cover major head trauma resulting from an accident with evidence of permanent neurological deficit.

## 4.10 Primary (Idiopathic) Pulmonary Hypertension

### 4.10.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.10.2 Amended Definition

An unequivocal diagnosis of Primary (Idiopathic) Pulmonary Hypertension by a Cardiologist or specialist in respiratory medicine with evidence of right ventricular enlargement and the pulmonary artery pressure above 30 mm of Hg on Cardiac Cauterization. There must be permanent irreversible physical impairment to the degree of at least Class IV of the New York Heart Association Classification of cardiac impairment.

The NYHA Classification of Cardiac Impairment are as follows.

- Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms.
- Class IV: Unable to engage in any physical activity without discomfort. Symptoms may be present even at rest.

Pulmonary hypertension associated with lung disease, chronic hypoventilation, pulmonary thromboembolic disease, drugs & toxins, diseases of the left side of the heart, congenital heart disease and any secondary cause are specifically excluded.

## 4.11 Third Degree Burns

### 4.11.1 Current Definition

NA – this condition has been included in the extended list of Critical Illness Conditions for the first time, therefore no current definition is shown.

### 4.11.2 Amended Definition

There must be third-degree burns with scarring that cover at least 20% of the body's surface area. A certified physician must confirm the diagnosis and the total area involved using standardized, clinically accepted, body surface area charts covering 20% of the body surface area.

### 4.11.3 Key discussion points / Rationale for change

Only third degree burns which involve full depth to underlying tissue are covered as this has very significant impact on morbidity.

Two common methods used for assessing total percentage of body surface area in adults are “Rule of Nines “ and “Lund Browder”.

# 5 Additional discussion points

The following conditions were discussed / reviewed – but were not included in the final list:

## 5.1 Septicemia / Multi Organ Dysfunction:

The task force examined the request to see if following definition could be included in the list of conditions:

Septicemia/ Multi Organ dysfunction - “Systemic disease associated with the presence and persistence of pathogenic micro-organisms or their toxins in the blood resulting in organ dysfunction, tissue hypo-perfusion and septic shock”.

### 5.1.1 Discussion points:

- Septicemia and Multiple organ dysfunction are two separate conditions at different ends of the clinical spectrum. Septicemia- Sepsis is defined as system inflammatory whole body reaction in response to an infectious process. This is often a very acute process and does not fall in the spirit of "critical illness with certain irreversible damage" which is the core focus of CI products.
- Also Septicemia has very wide range and therefore cannot be accurately defined for insurance purpose – i.e. specific metrics which can create an objective claims definition.
- Multiple organ dysfunction syndrome refers to progressive deterioration of organ function in an acutely ill patient. It is the most severe end of the spectrum for sepsis and mortality rate can be as high as 25-30% or higher.
- The definition given above is intends to cover a stage of Multi-organ failure, which as very high in-hospital mortality. Mortality rates vary from 20-76% with 2 organs failure, 30-90% with 3 organs. Majority of studies showed mortality of 100% with  $\geq 4$  organ failure. In other words, many individuals afflicted with Multi-organ failure will not be able to use the critical illness benefit as they will not survive.
- Market precedent: Most CI products in India do not include Septicemia / multi order dysfunction because of the lack of clear claims triggers on the one hand and low survival rates on the other.
- Therefore, while this is a critical condition – the task force recommends that the same not be included in the list of conditions.

## 5.2 Consideration of pricing impact of definitions

- Existing core definitions: Definitions were constructed to ensure that for "existing" conditions, there is no material impact on pricing. For detailed explanation, kindly refer to the "key discussion point/rationale for change" section of the existing core definitions (Cancer, Heart Attack, CABG, and Multiple Sclerosis).

If the insurers require price increases due to change in existing core definitions, each company can justify the need to increase the price by providing IRDAI with evidence that their existing CI rate specifically excluded the above in their current pricing assumption (and not just in the definition). The final decision will be made by IRDAI on basis of the evidence provided.

- For new conditions, eg. Angioplasty, there is pricing implication which has to be considered by the insurer as they would do with adding any new condition.

## 5.3 Inclusion of mental health conditions

Feedback from the committee suggested that there was a need to include mental health conditions – namely, Senile Dementia, Parkinson's and Alzheimer's. The task force was of the below view:

- This is a valid recommendation, however, mental health a sensitive issue. Many versions of definitions (eg with Activities of Daily Living (ADL), without ADL) exist in the market
- Wordings chosen can have significant pricing implications and the mental health conditions requires significant deliberations within wider group

The task force suggested that CI mental health conditions be evaluated as a separate project by a larger task force.

# Acknowledgements

FICCI is grateful to the following eminent professionals for their immense contribution in preparing this report.

- **Dr Himanshu Bhatia** – Senior Medical Officer (Asia), Gen Re Support Services.
- **Ms Vidya Hariharan** - Director (Group Strategy), Vidal Healthcare
- **Mr Mahaveer Chandiwala** - Head of Underwriting and Claim - Development and Services, Munich Re India Services Private Ltd.
- **Dr Sheetal Salgaonkar** - Medical Director (Medical Services), RGA Services India Pvt. Ltd.
- **Dr Asha Sapre** - External Medical consultant, Swiss Re Services India Pvt. Ltd
- **Mr Sarang Gokhale** - Senior VP & Head (Underwriting, Claims & Business Solutions Group), ICICI Prudential
- **Mr Burugupalli Madhu** - VP (Products), ICICI Prudential
- **Mr Rajagopal Rudraraju** - VP (Claims and Group Underwriting), Apollo Munich Health Insurance
- **Dr Manisha Kalaver** - Associate Director (Medical Services), RGA Services India Pvt. Ltd.
- **Mr DVS Ramesh** - Dy Director (Health Policy), IRDAI
- **Mr Sandeep Patel** - CEO & Managing Director, CignaTTK Health Insurance
- **Mr Manish Jain** – Director (Health Policy), Johnson & Johnson
- **Mr Dinesh Pant** - Secretary (Product Development Actuarial Core Group/ Product Actuary), LIC of India
- **Ms Asha Nair** – Former Director & General Manager, United India Insurance Company Ltd.
- **Mr Sanjay Datta** – Head (Underwriting & Claims), ICICI Lombard General Insurance

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## **FICCI HEALTH INSURANCE TEAM**

### **Ms Shobha Mishra Ghosh**

Senior Director

Federation of Indian Chambers of Commerce and Industry

T: +91-11-2348 7468

E: [shobha.mishra@ficci.com](mailto:shobha.mishra@ficci.com)

### **Mr Anirudh Sen**

Deputy Director

Health Services | Health Insurance

Federation of Indian Chambers  
of Commerce and Industry

T: +91-11-23487445

E: [anirudh.sen@ficci.com](mailto:anirudh.sen@ficci.com)

### **Mr Syed Quasim Ali**

Assistant Director

Health Services | Health Insurance

Federation of Indian Chambers  
of Commerce and Industry

T: +91-11-23487220

E: [quasim.ali@ficci.com](mailto:quasim.ali@ficci.com)









**Federation of Indian Chambers of Commerce and Industry**

Federation House, Tansen Marg, New Delhi - 110 001

T : +91-11-2373 8760 (11 Lines) | F : +91-11-2332 0714, 2372 1504

E: [ficci@ficci.com](mailto:ficci@ficci.com), W: [www.ficci.com](http://www.ficci.com)

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