Potential Impact of the New Universal Definition of Myocardial Infarction on Critical Illness Insurance

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■ ABSTRACT

Objective-The purpose of this article is to discuss how the new recommendation for a universal definition of myocardial infarction (MI) might affect critical illness insurance.

Background-In 2000, the European Society of Cardiology and the American College of Cardiology issued a new definition for MI. Insurers worldwide who sold critical illness insurance changed the wording of the "Heart attack" event on new products to reflect this definition. An update of the MI definition was issued on 27 November 2007. It is likely that this new definition will be adopted by clinicians worldwide. Insurers may need to modify the definition and/or the pricing basis for the "Heart attack" critical illness event.

Results-There are new criteria for MI associated with coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), stent thrombosis, and MI diagnosed via imaging, but the changes are fairly minor. There is greater emphasis on the diagnosis of sudden death due to MI (which could present claims and pricing difficulties for insurers in some markets). The article lists events that are not considered MI. Troponin, and not creatine kinase (CK) or the MB fraction of CK (CKMB), is clearly the preferred cardiac biomarker. Since new assays are able to detect much smaller increases in troponin, many of the infarctions detected in the future will be very small events (micro-infarctions) that were not considered when pricing the product.

Conclusions-This new definition will increase the incidence of MI worldwide. It will also have implications for life and living benefits insurance. The authors state that "Further refinement of the present definition will doubtless occur in the future."

Keywords: Myocardial infarction, troponin, critical illness insurance

In 2000, the Joint European Society of Cardiology and the American College of Cardiology Committee for the Redefinition of Myocardial Infarction issued a new definition for myocardial infarction (MI) that used troponin as the primary cardiac biomarker for diagnosis.(1) Insurers worldwide who sold critical illness (CI) insurance changed the wording of the "Heart attack" event on new products to reflect this definition. An update was issued on 27 November 2007 on behalf of the European Society of Cardiology, American College of Cardiology Foundation, American Heart Association, and World Heart Federation.(2) This update recommends a universal definition of myocardial infarction that would be used worldwide. It also states that "Further refinement of the present definition will doubtless

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occur in the future."

This article summarizes the issues of importance to insurers. The 2007 and 2000 definitions are reproduced in Appendix A and B, respectively.

Minor new criteria

- MI after coronary artery bypass grafting (CABG). "By convention, increases of biomarkers greater than 5 x 99th percentile of the upper reference limit (URL) of a normal population, plus either new pathological Q waves or new LBBB, or angiographically documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium have been designated as defining CABG-related myocardial infarction." For insurers, this change shouldn't affect claim rates because CABG is also a covered event.
- MI due to stent thrombosis. The new definition creates a separate subcategory of MI related to stent thrombosis. These iatrogenic MIs must meet the same criteria that exist for spontaneous MIs.
- Imaging criteria. The 2007 definition states that "Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality" is one of the criteria for MI. For insurers, it may be difficult to decide if an abnormality is old or new since there is usually no baseline imaging test for comparison.
- Prior MI. "Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause."

New criteria for myocardial infarction after percutaneous coronary intervention (PCI)

In patients with normal baseline troponin values, "By convention, increases of biomarkers greater than 3 x 99th percentile URL have been designated as defining PCI-related myocardial infarction." For insurers that include angioplasty as a CI event, these infarctions, which are often very small, will increase the MI incidence rate.

Sudden death

There is greater emphasis on sudden, unexpected cardiac death due to MI. These deaths usually occur before the diagnosis can be confirmed.

"Since these individuals die before pathological changes can develop in the myocardium, it is difficult to say with certainty whether these patients succumbed to a myocardial infarction or to an ischemic event that led to a fatal arrhythmia. The mode of death in these cases is sudden, but the etiology remains uncertain unless the individual reported previous symptoms of ischemic heart disease prior to the cardiac arrest."

"Many patients with myocardial infarction die suddenly. Difficulties in definition of sudden and out-of-hospital death make attribution of the cause of death variable among physicians, regions, and countries. For example, out-of hospital death is generally ascribed to ischemic heart disease in the USA but to stroke in Japan. These arbitrary and cultural criteria need re-examination."

For insurers, there is the possibility that claims could increase because more sudden deaths could be considered MIs. This would not be a problem for acceleration CI products because only the death benefit would be paid. However, for products that pay a CI benefit in addition to the life benefit, and for stand-alone CI products, there is the possibility that the secondary beneficiaries of the policyholder might submit a CI claim after a sudden death (which may or may not have been due to MI). This situation can be avoided by requiring a 30-day survival period after any CI event, or by specifically excluding CI claims in the context of sudden death.

Events that are not considered myocardial infarction

The article states that myocardial cell death associated with mechanical injury is not myocardial infarction.

"It should also be noted that the term myocardial infarction does not include myocardial cell death associated with mechanical injury from coronary artery bypass grafting (CABG), for example ventricular venting, or manipulation of the heart; nor does it include myocardial necrosis due to miscellaneous causes, e.g. renal failure, heart failure, cardioversion, electrophysiological ablation, sepsis, myocarditis, cardiac toxins, or infiltrative diseases."

Events that may or may not be considered myocardial infarction

There are many other situations where troponin can be elevated, such as chest trauma from an automobile accident, hypertrophic cardiomyopathy, atrial fibrillation, severe hypertension, pulmonary embolism, stroke, critically ill patients, and extreme exertion. It will often be difficult to

decide if these cases meet the insurer's criteria for MI.

- The insurer might argue that the event did not meet the criteria of the 2007 definition, namely, "Evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia" because the other main criteria for MI (symptoms of ischemia and ECG changes indicative of new ischemia) were not present. In addition, the text of the 2007 definition emphasizes that "Detection of a rise and/or fall of the measurements is essential to the diagnosis of acute myocardial infarction," so an insurer might argue that chronic troponin elevation (e.g., with hypertrophic cardiomyopathy or severe hypertension) does not meet the criteria for acute MI.
- The policyholder and treating physician might argue that any serious disease that causes an elevation of troponin is evidence of myocardial necrosis, and therefore satisfies the clinical definition of MI.

Troponin issues

Troponin, and not creatine kinase (CK) or the MB fraction of CK (CKMB), is the preferred cardiac biomarker.

Elevated troponin is defined as a value exceeding the 99th percentile of the upper reference limit of a normal population. Since new assays (laboratory tests) are able to detect much smaller increases in troponin, many of the MIs detected in the future will be very small events (micro-infarctions) that were not considered when pricing the product.

For the insurer, there will not be much protective value in defining an abnormal troponin value as some multiple of normal, e.g., "An elevation of 3 times the upper limit of normal," because this value will be a smaller absolute value with each improvement in technology.

Increasing incidence of myocardial infarction

"The use of cardiac troponins will undoubtedly increase the number of events... because of increased sensitivity for detecting infarction. The change in the definition of myocardial infarction will have a substantial impact on the identification, prevention, and treatment of cardiovascular disease throughout the world. The new definition will impact epidemiological data from developing countries relating to prevalence and incidence."

Public policy implications

"An increase in sensitivity of the criteria for myocardial infarction might entail negative consequences for some patients who are not currently labelled as having had an infarction."

"It should be appreciated that the agreed modification of the definition of myocardial infarction may be associated with consequences for the patients and their families with respect to psychological status, life insurance, professional career, as well as driving and pilot licences. Also the diagnosis is associated with societal implications as to diagnosis-related coding, hospital reimbursement, mortality statistics, sick leave, and disability attestation."

Appendix A: 2007 Definition of Myocardial Infarction

Criteria for Acute Myocardial Infarction

The term myocardial infarction should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Under these conditions any one of the following criteria meets the diagnosis for myocardial infarction:

- Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischemia with at least one of the following:
  - Symptoms of ischemia;
  - ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch block [LBBB]);
  - Development of pathological Q waves in the ECG;
  - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
- Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST elevation, or new LBBB, and/or evidence of fresh thrombus by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.
- For percutaneous coronary interventions (PCI) in patients

with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 3 x 99th percentile URL have been designated as defining PCI-related myocardial infarction. A subtype related to a documented stent thrombosis is recognized.

- For coronary artery bypass grafting (CABG) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 5 x 99th percentile URL plus either new pathological Q waves or new LBBB, or angiographically documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium have been designated as defining CABG-related myocardial infarction.
- Pathological findings of an acute myocardial infarction.

Criteria for Prior Myocardial Infarction

Any one of the following criteria meets the diagnosis for prior myocardial infarction:

- Development of new pathological Q waves with or without symptoms.
- Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause.
- Pathological findings of a healed or healing myocardial infarction.

Appendix B: 2000 Definition of Myocardial Infarction

Criteria for Acute, Evolving or Recent Myocardial Infarction

Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:

- Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:
  - ischemic symptoms;
  - development of pathologic Q waves on the ECG;
  - ECG changes indicative of ischemia (ST segment elevation or depression); or
  - coronary artery intervention (e.g., coronary angioplasty).
- Pathologic findings of an acute MI.

Criteria for Established Myocardial Infarction

Any one of the following criteria satisfies the diagnosis for established MI:

- Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed.
- Pathologic findings of a healed or healing MI.

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