SUPPLEMENTARY EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021

Purpose of supplementary explanatory statement
The purpose of this supplementary explanatory statement is to provide information on the Duke Treadmill Score, SYNTAX Score and New York Heart Classification, including where these tools can be publicly accessed online, for the *Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021* (the Regulations).

Amendments to the explanatory statement

Repeal and substitute Item 51 in Schedule 1 Amendments – Part 3 – Cardiac Services

Item 51 inserts new clauses 5.10.17A, 5.10.17B, 5.10.17C and 5.10.17D after clause 5.10.17 in the GMST.

Clause 5.10.17A provides patient eligibility and timing requirements for new cardiac items 38244, 38247, 38307, 38308, 38310, 38316, 38317 and 38319.

A service under these items applies if the service has not been provided to the patient in the previous 3 months, unless the patient experiences a new acute coronary syndrome or angina in that period or requires staging of the initial percutaneous coronary intervention procedure under items 38316, 38317 or 38319, and one of the following indications apply to the patient:

a) the patient has an acute coronary syndrome evidenced by any of the following:
    i. ST segment elevation;
    ii. new left bundle branch block;
    iii. troponin elevation above the local upper reference limit;
    iv. new resting wall motion abnormality or perfusion defect;
    v. cardiogenic shock;
    vi. resuscitated cardiac arrest;
    vii. ventricular fibrillation;
    viii. sustained ventricular tachycardia; or
b) the patient has unstable angina or angina equivalent with a crescendo pattern, rest pain or other high-risk clinical features, such as hypotension, dizziness, pallor, diaphoresis or syncope occurring at a low threshold; or
c) the patient has either of the following detected on computed tomography coronary angiography:
    i. significant left main coronary artery disease with greater than 50 per cent stenosis or a cross-sectional area less than 6mm2
    ii. severe proximal left anterior descending coronary artery disease

Clause 5.10.17B provides patient eligibility requirements for new cardiac items 38248 and 38249.

A service under these items applies if the patient is recommended for coronary angiography as a result of a heart team conference, or has one of the following indications:

a) the patient has limiting angina or angina equivalent despite an adequate trial of optimal medical therapy; or
b) the patient has high risk features, including at least one of the following:
    i. myocardial ischaemia demonstrated on functional imaging;
    ii. ST segment elevation, sustained ST depression, hypotension or a Duke treadmill score of minus 11 or less, demonstrated by stress electrocardiogram testing;
    iii. computed tomography coronary angiography evidence of one or more coronary arteries with stenosis of 70 per cent or more; or
    iv. left ventricular dysfunction or segmental wall motion abnormality at rest.

A heart team conference must be conducted by a team of specialists or consultant physicians practising in the speciality of cardiology or cardiothoracic surgery, and must include each of the following:
    i. an interventional cardiologist;
    ii. a non-interventional cardiologist;
    iii. a specialist or consultant physician.

The team must assess the patient's risk and technical suitability to receive the service and make a recommendation about whether or not the patient is suitable for invasive coronary angiography

A record of the conference must be created and include the following:
    i. the particulars of the assessment of the patient during the conference;
    ii. the recommendations made as a result of the conference;
    iii. the names of the members of the team making the recommendations.

Clause 5.10.17C provides patient eligibility requirements for new cardiac items 38311, 38313, 38314, 38320, 38322 and 38323.

A service under these items applies if the patient is recommended for coronary angiography as a result of a heart team conference, or:
a) if the patient has any of the following indications:
    i. limiting angina or angina equivalent despite an adequate trial of optimal medical therapy;
    ii. myocardial ischaemia demonstrated on functional imaging;
    iii. high risk features such as ST segment elevation, sustained ST depression, hypotension or a Duke treadmill score of minus 11 or less, demonstrated by stress electrocardiogram testing; and
b) if the patient has either of the following in the vascular territory treated:
    i. a stenosis of 70 per cent or more;
    ii. a fractional flow reserve of 0.80 or less, or non-hyperaemic pressure ratios distal to the lesions of 0.89 or less

In relation to the requirements under subparagraph 5.10.17B(2)(b)(ii) and subparagraph 5.10.17C(2)(a)(iii), the Duke Treadmill Score is a weighted index combining treadmill exercise time using standard Bruce protocol, maximum net ST segment deviation (depression or elevation), and exercise-induced angina. It was developed to provide accurate diagnostic and prognostic information for the evaluation of patients with suspected coronary heart disease. The Duke Treadmill Score is available on the helio website at https://www.healio.com/cardiology/learn-the-heart/cardiology-review/topic-reviews/duke-treadmill-score, as at 1 July 2021.

A service under items 38314 and 38323 is to be provided if either the patient does not have diabetes mellitus and the multi-vessel coronary artery disease of the patient meets the criteria outlined in subclause 5.10.17C(3), or despite a recommendation that surgery is preferable, the patient has expressed a preference for catheter-based intervention.

Subclause 5.10.17C(3) provides the criteria for the multi-vessel coronary artery disease which includes that it does not involve stenosis of more than 50 per cent in the left main coronary artery, bifurcation lesions involving side branches with a diameter of more than 2.75 mm, chronic vessel occlusions for more than three months, severely angulated or calcified lesions or a SYNTAX score of more than 23. The SYNTAX score is a grading system that evaluates the complexity and prognosis of patients undergoing percutaneous coronary intervention (PCI). The SYNTAX Score can be accessed on the SYNTAX Score website at http://syntaxscore.org/index.php, as at 1 July 2021.

Subclause 5.10.17C(4) provides the requirements for a heart team conference, relating to procedural items for coronary artery disease. The conference must be conducted by a team of specialists or consultant physicians practising in the speciality of cardiology or cardiothoracic surgery, and must include each of the following:

i. an interventional cardiologist;
ii. a specialist or consultant physician;
iii. for items 38314 and 38323 – a cardiothoracic surgeon;
iv. for items 38311, 38313, 38320 and 38322 – a cardiothoracic surgeon or a non-interventional cardiologist.

The team must assess the patient's risk and technical suitability to receive the service and make a recommendation about whether or not the patient is suitable for percutaneous coronary intervention.

A record of the conference must be created and include the following:

i. the particulars of the assessment of the patient during the conference;
ii. the recommendations made as a result of the conference;
iii. the names of the members of the team making the recommendations.

Clause 5.10.17D provides that a report or clinical note is to be created for a service under items 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38320, 38322, 38323, 38316, 38317 and 38319. The report or clinical note must include documentation that demonstrates how the item applies to the service, including how the patient is eligible for the service.

Repeal and substitute Item 59 in Schedule 1 Amendments – Part 3 – Cardiac Services

Item 59 repeals items 38365 to 38393 to amend items 38365 and 38368, and to repeal items 38371, 38384, 38387, 38390 and 38393. These items have been repealed to clarify inclusion criteria and allow for the provision of a complete medical service under items 38365, 38368 and new item 38471 (refer to item 61 in the Regulations).

Item 38365, which is for the insertion, removal or replacement of a permanent cardiac synchronisation device, is amended to provide that the service is not to include a cardiac synchronisation device that is capable of defibrillation.

The amended item descriptor provides that the service is to be performed on a patient who has chronic heart failure aligning with clinical guidelines and is not be performed in association with item 38212. This service has also been amended to be provided in association with an assistance item due to the complexity of the procedure.

Item 38368, which is for the insertion, removal or replacement of a permanent transvenous left ventricular electrode through the coronary sinus, is amended to provide that the service is for a patient who has chronic heart failure aligning with clinical guidelines. This service has also amended to include assist due to the complexity of the procedure. A service under this item cannot be performed in association with a service under items 35200, 38200 or 3212.

One of the requirements of items 38365 and 38368 is that the patient has chronic heart failure, which is classified under the New York Heart Association (NYHA). The NYHA classification is an internationally recognised classification system for heart failure. The NYHA classification can be accessed on heart online website at https://www.heartonline.org.au/media/DRL/New_York_Heart_Association_(NYHA)_classification.pdf, as at 1 July 2021.

Repeal and substitute Item 61 in Schedule 1 Amendments – Part 3 – Cardiac Services

Item 61 repeals items 38470 to 38483 to insert new items 38471, 38472, 38474 and 38484, to amend item 38477, and to repeal items 38470, 38473, 38475, 38478, 38480, 38481 and 38483. These items have been repealed to remove obsolete items and to allow for the provision of a complete medical service under items 38467, 38516 and 38517.

Amended item

Item 38477, which is for a valve annuloplasty with insertion of ring, is amended to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38516, 38517, 38806 or 45503.

New items

New item 38471 is for the insertion of an implantable defibrillator including the insertion of patches for the insertion of one or more transvenous endocardial leads in a patient. The patient must have at least a history of haemodynamically significant ventricular arrhythmias in the presence of structural heart disease, documented high-risk genetic cardiac disease, ischaemic heart disease or chronic heart failure aligning with clinical guidelines. This service consolidates items 38384 and 38390 which will be repealed, and it cannot be performed in association with a service under item 38212.

New item 38472 is for the insertion, replacement or removal of an implantable defibrillator generator for a patient who has at least a history of haemodynamically significant ventricular arrhythmias in the presence of structural heart disease, documented high-risk genetic cardiac disease, ischaemic heart disease, or chronic heart failure aligning with clinical guidelines. This service consolidates items 38387 and 38393 which will be repealed, and it cannot be performed in association with a service under item 38212.

One of the indicators for the provision of a service under items 38471 and 38472 is that the patient has chronic heart failure, which is classified under the New York Heart Association (NYHA). The NYHA classification is an internationally recognised classification system for

heart failure. The NYHA classification can be accessed on heart online website at https://www.heartonline.org.au/media/DRL/New_York_Heart_Association_(NYHA)_classification.pdf, as at 1 July 2021.

New item 38474 is for the repair, augmentation or replacement of the branch pulmonary arteries, with cardiopulmonary bypass for patients with congenital heart disease. This is a complex surgery which is not well described under existing items. A service under item 38474 cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

New item 38484 is for aortic or pulmonary valve replacement with bioprosthesis or mechanical prosthesis. It is for a complete medical service according to valve location, and cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.