Draft Benefit Definition: Ischaemic Heart Disease – PMB DTP code: 907E

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Contents

907E	Acute and sub-acute ischemic heart disease including myocardial infarction and unstable angina.
Treatment:	Medical management; surgery; percutaneous procedures

This benefit definition does not endorse explicitly one medicine/medical device within a particular therapeutic class over another. Schemes may utilize treatment protocols and formularies to ensure appropriate evidence based and cost-effective choice of treatment. If a scheme should, however, choose to make use of a restricted protocol or formulary, such protocols/formularies must be communicated **in advance** to the member and service providers who will be responsible for the provision of the restricted/limited interventions. This is important to avoid events where a service provider unknowingly provides an intervention that will not be covered by the scheme or incur a co-payment to the member. This applies even in situations where there may not be time to do pre-authorization of services.

1 Introduction

1.1 Scope

The scope of this benefit definition will be in particular on coronary revascularization by means of coronary bypass grafting (CABG) or percutaneous coronary interventions (PCI's) in order to relief ischaemia.

1.2 Burden of disease

According to results of the INTERHEART study, the five most important risk factors for myocardial infarction operate similarly in different ethnic groups and geographical locations worldwide. These risk factors are smoking history, diabetes history, hypertension, abdominal obesity and the ration of apolipoprotein B to apolipoprotein A-1 (1). The emergence of risk factors for atherosclerotic vascular disease in South Africa has been noted for several decades (2). Population based surveys in the early 1990s showed that 13-31% of the population have at least one risk factor for atherosclerotic disease (2). Later in the 2000s, surveys confirmed high population prevalence of hypertension, diabetes, smoking as well as a high prevalence of obesity affecting about 50% of the female population in Limpopo and Mpumalanga provinces (2). Heart disease, diabetes and stroke together constitute the second most important cause of death in the adult population in South Africa (3). Cardiovacular disease is increasing amongst all age groups in South Africa and is predicted to become the prime contributor to overall morbidity and mortality in the over 50-year age group (4).

1.3 Percutaneous procedures – PMB level of care

As this component of the treatment of the DTP 907E is not only specified in general terms i.e. "medical management" or "surgery", but also in specific terms i.e. "percutaneous procedures", the latter component it is not subject to the provision made in the explanatory note (2) to Annexure A in the regulations. Percutaneous coronary interventions (PCIs) as prescribed minimum benefits are therefore not restricted to availability of this intervention in the Public sector. A protocol should be developed on the basis of the principles stated in Regulation 15D(b) and 15H namely, evidence based medicine, taking into account considerations of cost-effectiveness and affordability.

2 Abbreviations

ASA	–	acetylsalicylic acid
BMS	–	Bare metal stent
CABG	–	coronary artery bypass grafting
CAD	–	coronary artery disease
CDL	–	chronic disease list
CHF	–	chronic heart failure
CVD	–	cardiovascular disease
DAPT	–	Dual antiplatelet therapy
DES	–	Drug eluting stent
DSP	–	Designated Service Providers
ECG	–	electrocardiogram
FFR	–	fractional flow reserve
IVUS	–	Intravascular Ultrasound Imaging
LAD	–	left anterior descending
LV	–	left ventricle
MVD	–	multivessel disease
MRI	–	magnetic resonance imaging
NSTE-ACS	–	non-ST-segment elevation acute coronary syndrome
OCT	–	Optical Coherence Tomography
OMT	–	optimal medical therapy
PCI	–	percutaneous coronary intervention
PET	–	positron emission tomography
PMB	–	prescribed minimum benefit
PTCA	–	Percutaneous transluminal coronary angioplasty
SPECT	–	single photon emission computed tomography
STEMI	–	ST-segment elevation myocardial infarction
UA	–	Unstable angina
UFH	–	Unfractionated heparin

3 Evaluation and diagnostic work-up

3.1 Diagnostic work-up

Documentation of ischaemia using functional testing is strongly recommended before elective invasive procedures (5). The proposed utilization of diagnostic utilities per event that should be seen as PMB level of care is listed in Annexure A under the heading: Diagnostic services.

In patients with chronic stable angina or low risk non ST segment acute coronary syndrome, the use of non-invasive stress imaging as a screening is preferred before angiography (6). It should however be recognized that some cases may be complicated and provision should be made for exceptions on the grounds of acceptable clinical motivation through an official appeals process. The scheme may indicate during the pre-authorization process what the preferred setting should be for any particular diagnostic procedure especially if the patient is not already admitted to hospital. Limitation of the setting should be based on current best practice and cost-effectiveness.

3.2 Additional invasive diagnostic tools

3.2.1 Intravascular ultrasound imaging (IVUS)

IVUS allows tomographic assessment of the lumen area, plaque size and distribution (5). Although IVUS may be a valuable adjunct to angiography, there has been no properly designed randomized controlled trial comparing the clinical value of IVUS-guided stent inplantation in the DES area (5). *This technique will therefore not fall within the scope of prescribed minimum benefits*.

3.2.2 Optical coherence tomography (OCT)

OCT is a light-based modality of intravascular imaging with higher spatial resolution than IVUS but at present is recommended as a valuable research tool by the European Society Task Force (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) (5). *OCT will not fall within the scope of prescribed minimum benefits at this time.*

4 Multidisciplinary team and risk assessments

4.1 Multidisciplinary team

A collaborative team effort including the patient in the decision making process should be followed. The patient needs to understand the risks and benefits of each treatment option. A multidisciplinary team serves the purpose of a balances multidisciplinary decision making process and usually includes general practitioners, cardiologists, cardiac surgeons, anaesthesiologists, intensivists, and other specialties as required such as geriatricians, pulmonologists etc. (5). See Annexure A, page 11, Professional services) for a list of the multidisciplinary team potentially involved in diagnosis and treatment of this condition on an outpatient as well as an inpatient basis. Reasonable exceptions need to be considered by schemes.

4.2 Risk assessment

Risk assessment and stratification should be done by the multidisciplinary team. This may guide the intervention to be carried out and also provides information regarding the prognosis of a patient and the surgical risk. There are a number of international well-published risk stratification scores that may be used. This forms part of prescribed minimum benefits.

5 Treatment

The mode of revascularization should be based on the severity and distribution of the CAD.

5.1 Stable coronary artery disease

Optimal medical therapy in accordance with the relevant treatment algorithms related to cardiac conditions are the first-line evidence based cost-effective way of treating stable coronary artery disease. However, there are instances where it would be clinically appropriate to combine it with PCI or CABG.

The SYNTAX score may serve as a guideline for clinical practice to choose between PCI and CABG as an appropriate intervention (6):

<23	=	PCI indicated
23 to 32	=	Clinical judgment (PCI or surgery)
≥33	=	Surgery indicated (except when there is severe co-morbidity)

5.1.1 Indications (entry criteria) with Class 1 evidence for revascularization in a patient with stable angina or silent ischaemia (5).

- Significant Left Main stenosis (>50%)
- LAD disease (>50%)
- 2VD or 3VD with impaired LV function
- Proven large area of ischaemia (>10%LV)
- Single remaining patent vessel >50% stenosis (Level C evidence)
- Any stenosis >50% with limiting angina or angina equivalent, unresponsive to OMT

(Class 1 evidence : Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.)

5.1.2 Contra-indications for stenting in patients with stable angina (5)

- Unfavourable anatomy
- Contra-indication for use of DAPT
- Better outcomes/survival benefit with CABG in particular prognostic indication

5.1.3 When is CABG preferred to stenting (6)?

It is not possible to provide specific recommendations for the preferred method of revascularization for every possible clinical scenario as there are many individual patient clinical characteristics that need to be taken into consideration.

5.2 Non-ST-segment elevation acute coronary syndromes (5)

The goal of treatment in this group of patients is symptom relief and improvement in prognosis in the short and long term. Evidence shows that an early invasive strategy reduces cardiovascular death and MI.

5.2.1 Entry criteria for stenting

- As with patients suffering from stable CAD, the mode of revascularization should be based on the severity and distribution of the CAD so the same criteria may be used to determine the most effective mode of revascularization.

5.2.2 Contra-indications

- Unfavourable anatomy
- Contra-indication for use of DAPT
- Better outcomes/survival benefit with CABG in particular prognostic indication

5.2.3 Notes

- Patients with high risk NSTE-ACS (GRACE score >140) should undergo urgent angiography and revascularization within 24 hours of admission.
- In patients with lower risk NSTE-ACS (GRACE score <140), angiography and revascularization can be delayed but should be performed within 72 hours of hospital admission and preferably during the same hospital stay.
- The type of revascularization can only be determined after an angiography has been performed. FFR measurement can also provide important information in the decision making process.
- The benefit from PCI in patients with NSTE-ACS is related to its early performance.

5.3 ST-segment elevation myocardial infarction (5)

In this setting primary PCI is indicated as first line therapy as a reperfusion strategy. When PCI is not possible within 2 hours of the onset of symptoms, then immediate fibrinolysis is indicated. In the latter group of patients, delayed PCI is indicated as required unless fibrinolysis is unsuccessful and there is persistent ST-elevation.

Only in cases of unfavourable anatomy for PCI or in PCI failure, emergency CABG should be considered when a very large myocardial area is in jeopardy and surgical revascularization can be completed before this area becomes necrotic (i.e. in the first 3-4 hours)

5.3.1 Entry criteria for stenting

- All patients with STEMI should qualify for PCI as first-line therapy if logistically possible.

5.3.2 Contra-indications

- Unfavourable anatomy
- Contra-indication for use of DAPT

5.4 Drug-eluting stents (DES) versus Bare metal stents (BMS) (6)

5.4.1 Indications for DES

- Chronic Stable Angina
- <3mm vessel diameter
- >15mm vessel length

- Diabetics
- Left Main or Bifurcation or Proximal LAD
- Chronic Total Occlusions (CTO's)
- In-stent restenosis
- Ostial lesions
- Saphenous Graft lesions

5.4.2 Contra-indications for DES

- Diabetics with triple vessel disease including LAD stenosis should be referred for surgery rather than the deployment of multiple drug eluting stents unless surgery is contra-indicated due to co-morbidities.

5.4.3 Indications for BMS

- Lesions of 3.5mm or greater and shorter than 15mm
- High risk of bleeding (With BMS - reduced duration needed for dual antiplatelet therapy)

According to the South African Society of Cardiovascular Intervention, the use of bare metal stenting should occur in 20%-40% of patients (6).

5.5 Medical management related to PCI

The published algorithm for Coronary Artery Disease, Hypertension and Hyperlipidaemia makes provision for evidence based optimal medical management of high risk patients. All relevant medicines use in hospital before, during and after a revascularization procedure also forms part of the PMB level of care. These include antiplatelet and antithrombotic pharmacotherapy. For the purpose of this benefit definition only long-term antiplatelet therapy post PCI will be discussed.

5.5.1 Antiplatelet therapy post PCI

Table 1

Medicine description	Dose and duration of treatment
Clopidogrel	75mg daily for 1 month post BMS; and 6-12 months post DES
Prasugrel	When clopidogrel is not available or not appropriate/contra-indicated.
Acetylsalicylic acid	Co-administered with thienopyridines. 150-300mg.

5.6 Thrombectomy (6)

Aspiration or mechanical thrombectomy is recommended when large thrombus load is identified or total occlusion is present.

5.7 Special conditions

5.7.1 Diabetes

Patients with diabetes and coronary artery disease are at increased risk compared to non-diabetic patients (5). All trials have also shown an increased risk of repeat revascularization procedures after

PCI compared with CABG and it could therefore be anticipated that there will be a higher rate of CABG versus PCI in diabetic patients. The antithrombotic therapy in diabetic patients should not differ from that in non-diabetic patients (5).

5.7.2 Chronic Kidney Disease (CKD)

There is consistent evidence that in patients with mild to moderate CKD CABG is better than PCI. In patients with severe CKD there is evidence of either method being superior (5). All patients with CKD undergoing diagnostic catheterization should receive preventive hydration 12 hours before and 24 hours after the procedure to prevent contrast-induced nephropathy (5).

5.7.3 Patients requiring valve surgery

Combining CABG and aortic valve replacement surgery reduces the rates of perioperative MI, mortality and morbidity (5). If patients risk for combining the CABG with valve replacement surgery, PCI or transcatheter aortic valve implantation (TAVI) may be considered (5). The use of TAVI should however be clinically motivated by a team of specialists.

- Chronic heart failure

There is weak evidence suggesting that CABG is superior to PCI in patients with ischaemic heart failure (5).

- Crossed revascularization procedures
    - Graft failure

In acute early graft failure post CABG, PCI may be an alternative to re-operation unless the graft or native artery appears unsuitable for PCI or if several important grafts are occluded (5). Patients with a previous CABG have worse long-term outcomes when they undergo PCI or repeat CABG than those without prior CABG (5). In late graft failure, PCI or redo CABG is indicated with severe symptoms or extensive ischaemia despite optimal medical therapy although PCI is the first choice (5).

    - PCI failure

In early PCI failure due to symptomatic restenosis, repeat PCI is indicated unless failed PCI is likely to cause a large MI. CABG will be required in late failure following PCI in cases where lesions are unsuitable for PCI, there is additional non-discrete disease progression in other vessels or restenosis are repetitive (5).

- Arrhythmias in patients with ischaemic heart disease

Concomitant ablative treatment may be required for patients with atrial fibrillation scheduled for CABG (5).Beta-blockers are recommended to decrease the incidence of atrial fibrillation after CABG (5). Other medicines with some evidence that may decrease the incidence of AF after CABG are sotalol, amiodarone, statins, and corticosteroids (5).

5.8 Drug-eluting stents

Drug-eluting stents (DES) should be made available according to recommendations based on pivotal trials. In native vessels, DES has been proven to reduce restenosis and its proven efficacy should be

considered by default in nearly all clinical conditions and lesion subsets, except if there is a contraindication for long-term use of dual antiplatelet therapy (DAPT) (5).

5.9 Access sites for cardiac catheterization

Both the transfemoral and transradial access sites are acceptable for cardiac catheterisation.

5.10 Setting for revascularization

In hospital procedures will include surgery and care in ICU, high care and general ward.

In a medical emergency treatment may not be limited to designated service providers (DSP's). In non-emergency cases a scheme may limit the preferred providers by having DSP arrangements. The scheme should however ensure that there is parity between the services of the multidisciplinary team and the hospitals in their DSP lists. A patient should be able to have continuity of treatment from the diagnosis through to the treatment and care without being penalised during the process as a result of unpaired DSP arrangements.

5.11 Follow-up

The objectives of follow-up strategies are to detect restenosis or graft occlusion, the functional status of the patient and strategies for secondary prevention. Physical examinations, resting ECG and routine laboratory tests will also be needed.

Long-term medical treatment includes **ACE-inhibitors** or **angiotensin receptor blockers** in patients intolerant to ACE-inhibitors. **Beta-blockers** should be continued in all patients after MI or ACS or LV dysfunction, unless contraindicated (5). High dose **statins**, unless contraindicated, are indicated in all patients regardless of the lipid levels (5). In these patients, the limitations on statin dosages as per the algorithm for lipid lowering medicines, does not apply.

Annexure A

6 Coding related to PMB DTP code: 907E

6.1 ICD-10 codes

I20.0	Unstable angina
I20.1	Angina pectoris with documented spasm
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I21.0	Acute transmural myocardial infarction of anterior wall
I21.1	Acute transmural myocardial infarction of inferior wall
I21.2	Acute transmural myocardial infarction of other sites
I21.3	Acute transmural myocardial infarction of unspecified site
I21.4	Acute subendocardial myocardial infarction
I21.9	Acute myocardial infarction unspecified
I22.0	Subsequent myocardial infarction of anterior wall
I22.1	Subsequent myocardial infarction of inferior wall
I22.8	Subsequent myocardial infarction of other sites
I22.9	Subsequent myocardial infarction of unspecified site
I23.0	Haemopericardium as current complication following acute myocardial infarction
I23.1	Atrial septal defect as current complication following acute myocardial infarction
I23.2	Ventricular septal defect as current complication following acute myocardial infarction
I23.5	Rupture of papillary muscle as current complication following acute myocardial infarction
I23.6	Thrombosis of atrium auricular appendage and ventricle as current complications following acute myocardial infarction
I23.8	Other current complications following acute myocardial infarction
I24.1	Dressler's syndrome
I24.8	Other forms of acute ischaemic heart disease
I24.9	Acute ischaemic heart disease, unspecified
I25.0	Atherosclerotic cardiovascular disease, so described
I25.1	Atherosclerotic heart disease
I25.2	Old myocardial infarction
I25.6	Silent myocardial ischaemia
I25.8	Other forms of chronic ischaemic heart disease
I25.9	Chronic ischaemic heart disease, unspecified
I51.0	Cardiac septal defect, acquired
I51.3	Intracardiac thrombosis, not elsewhere classified
P29.4	Transient myocardial ischaemia of newborn

6.2 Codes for professional services

6.2.1 Consultations outpatient

Practice	Description	Codes	Nr/year
014,015	GP	0190 or 0191	4
018	Physician	0192	1
021	Cardiologist		2
019 (only when indicated)	Pulmonologist		1
044	Cardio Thoracic Surgery		1

6.2.2 Consultations inpatient

Practice	Description	Codes	Nr/year
014,015	GP	0190 or 0191	4
018	Physician	0192	1
021	Cardiologist		2
019 (only when indicated)	Pulmonologist		1
044	Cardio Thoracic Surgery		1
010	Anaesthetists		1

6.2.3 Procedural inpatient

Practice	Description	Codes	Nr/year
021	Cardiologist		2
044	Cardio Thoracic Surgery		1
010	Anaesthetists		1

6.2.4 NHRPL surgical procedure codes

NHRPL code	Procedure
1251	Transeptal puncture
1252	Left heart catheterisation with coronary angiography (with or without biopsy)
1253	Right heart catheterisation (with or without biopsy)
1254	Catheterisation of coronary artery bypass grafts and/or internal mammary grafts
1276	Percutaneous transluminal angioplasty: First cardiologist: Single lesion
1277	Percutaneous transluminal angioplasty: Second cardiologist: Single lesion
1278	Percutaneous transluminal angioplasty: First cardiologist: Second lesion
1279	Percutaneous transluminal angioplasty: Second cardiologist: Second lesion
1280	Percutaneous transluminal angioplasty: First cardiologist: Third or subsequent lesions (each)
1281	Percutaneous transluminal angioplasty: Second cardiologist: Third or subsequent lesions (each)
1282	Use of balloon procedures including: First cardiologist: Atrial septostomy; Pulmonary valve valvuloplasty; Aortic valve valvuloplasty; Coarctation dilation; Mitral valve valvuloplasty
1283	Use of balloon procedure as in item 1282: Second cardiologist
1284	Atherectomy: Single lesion: First cardiologist
1285	Atherectomy: Single lesion: Second cardiologist
1286	Insertion of intravascular stent: First cardiologist *
1287	Insertion of intravascular stent: Second cardiologist *
1346	Aorta-coronary bypass operation (including interpretation of angiogram): Harvesting of saphenous veins: Unilateral (modifier 0005 not applicable)
1347	Aorta-coronary bypass operation (including interpretation of angiogram): Harvesting of saphenous veins: Bilateral (modifier 0005 not applicable)
1348	Aorta-coronary bypass operation (including interpretation of angiogram): Utilizing saphenous veins
1349	Aorta-coronary bypass operation (including interpretation of angiogram): Additional arterial implant: Any artery
1350	Aorta-coronary bypass operation (including interpretation of angiogram): Additional double arterial implant: Any artery
1351	Aorta-coronary bypass operation with valve replacement or excision of cardiac aneurysm
1356	Insertion and removal of intra-aortic balloon pump (modifier 0005 not applicable)
1358	Harvesting of radial artery

*The insertion of a stent(s) (item 1286 & 1267) may only be charged once per vessel regardless of the number of stents inserted in this vessel.

6.2.5 Diagnostic services

Type	*Description of the test*	*Codes*	*Proposed utilization per event*
Pathology	CKMB	4152,4153,4138	1 of
	Troponin	4161	1
	Full Blood Count	3755 (Incl. 3739,3762,3783,3785,3791)	1
	Platelet count	3797	1
	Glucose	4057	1
	Lipogram	4025	1
	CRP	3947	1
	U & E	4171	1
	Creatinine	4032	1
Radiology	Chest X-Ray	30110,30100	1 of
	CT angiography for coronary arteries	33310,33300	1 of
Procedures			
	Exercise electrocardiogram (ECG)	1232 or 1233 or 1234 or1235 or1236	1 of
	Specialist interpretation of ECG	1230 or 1231	1 of
	Performance of ECG by GP	1228 or 1229	1 of
	ECHO	3620,3621,3622,3623,3624,3625	1 of
Invasive procedures	Left heart catheterization with coronary angiography (with or without biopsy)	1252	1
	Fractional Flow Reserve (FFR)	1186 or 1188	1

6.2.6 Additional costs to be funded related to hospital admission

- Theatre
- ICU
- General ward
- High care
- Consumables
- Medicines
- Medical appliances and devices

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