

NON-FATAL PURE DEFINITIONS

NON-FATAL PURE ADJUDICATION DEFINITIONS

Cardiovascular Events - Definitions

10.00 NON-FATAL CARDIOVASCULAR EVENTS

10.10 Non-Periprocedural Myocardial Infarction (MI)

MI is considered either definite, probable or possible according to the following characteristics:

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.11: <u>Definite</u>	<ol style="list-style-type: none"> ECG showing new and definite sign of MI (Minnesota code 1-1-1) or Symptoms typical or atypical or inadequately described but attributed to cardiac origin lasting at least 20 minutes and by troponin or cardiac enzymes (CKMB, CK, SGOT, SLDH) above center laboratory ULN ECG with new ischemic changes (new ST elevation/depression or T wave inversion ≥ 2 mm) and by troponin or cardiac enzymes (CKMB, CK, SGOT, SLDH) above center laboratory ULN <p>Please note that increased markers may occur in trauma (CK, AST, myoglobin and CK MB to a lesser degree); renal insufficiency, heart failure, pulmonary embolism.... (troponin), cardioversion (all)</p>	I21-I22
10.12: <u>Probable</u>	<ol style="list-style-type: none"> ECG with new and probable sign of MI (Minnesota code 1-2-1), or Typical symptoms lasting at least 20 minutes considered of cardiac origin, with only new ST-T changes (new ST elevation/depression or T wave inversion ≥ 1 but < 2mm) without documented increased cardiac markers as in PURE definition 10.11 (above), or Increased cardiac enzymes showing a typical pattern of MI as above without symptoms or significant ECG changes. 	
10.13: <u>Possible</u>	<ol style="list-style-type: none"> ECG with new and possible sign of MI (Minnesota code 1-3-1), or Typical symptoms lasting 20 minutes and more considered to be of cardiac origin without documented ECG or cardiac marker. 	

10.20 Periprocedural Myocardial Infarction

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.21: <u>Definite</u>	<ol style="list-style-type: none"> ECG showing new and definite sign of MI (Minnesota code 1-1-1), or Increased cardiac markers within 48 hours of procedure: <ul style="list-style-type: none"> percutaneous coronary intervention: CKMB should be ≥ 5 X ULN or troponin ≥ 5 X above lower level of necrosis OR $> 20\%$ increase in cardiac markers if elevated at the beginning of the procedure in a patient with symptoms suggestive of myocardial ischemia Coronary surgery: Increased cardiac markers CKMB should be ≥ 10X ULN or troponin ≥ 10X above lower limit of necrosis. 	I21-I22
10.23: <u>Possible</u>	Physician report of a Coronary procedure-related MI ≤ 48 hours after the index procedure (PCI or CABG surgery) in the absence of available supporting documentation of any definite criteria, i.e., ECG tracing, cTn values or other imaging evidence of new myocardial necrosis.	I21-I22

The **Minnesota codes** for MI is taken from Rose and Blackburn and published in their book "Evaluation Methods of Cardiovascular Disease WHO 1969".

- Definite MI** is Q/R ratio $\geq 1/3$ and Q duration ≥ 0.03 second in one of the following leads: I, II, V2, 3, 4, 5, 6. (code 1-1-1)
- Probable MI** is Q/R ratio $\geq 1/3$ and Q duration between 0.02 and 0.03 second in one of the following leads: I, II, V2, 3, 4, 5, 6. (code 1-2-1)
- Possible MI** is Q/R ratio between 1/5 and 1/3 and Q duration between 0.02 and 0.03 second in one of the following leads: I, II, V2, 3, 4, 5, 6. (code 1-3-1)

10.30 Stroke/Transient Ischemic Attack (TIA)

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.31: <u>Definite</u>	Stroke is defined as an acute focal neurological deficit <i>diagnosed by a physician</i> and thought to be of vascular origin (without other case such as brain tumor) with signs and symptoms lasting ≥ 24 hrs. N.B. <ul style="list-style-type: none"> Subarachnoid hemorrhage manifested by sudden onset headache with/without focal signs and imaging (CT or MRI or lumbar puncture) showing evidence of bleeding primarily in the subarachnoid space is considered a stroke in absence of trauma or brain tumor or malformation Subdural hematoma is <u>not</u> considered as a stroke and may be related to previous trauma or other cause. 	I60-I64, I69
10.33: <u>Possible</u>	Stroke is possible if there is a history of sudden onset of focal neurological deficit of one or more limbs, loss of vision or slurred speech lasting about 24 hours or more	
10.34: <u>TIA</u>	The diagnosis of TIA requires the presence of acute focal neurological deficit thought to be of vascular origin with signs and symptoms lasting less than 24 hours	G45

10.40 Congestive Heart Failure

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.41: <u>Definite</u>	The diagnosis of congestive heart failure requires signs (rales, increased jugular venous pressure or ankle edema) or symptoms (nocturnal paroxysmal dyspnea, dyspnea at rest or ankle edema) of congestive heart failure <u>and</u> one or both of the following: <ul style="list-style-type: none"> radiological signs of pulmonary congestion, Treatment of heart failure with diuretics. 	I50
10.42: <u>Probable</u>	Progressive shortness of breath on lying down or at night, improving on sitting up AND any of the following signs or symptoms: swelling of feet, distension of abdomen, progressive cough in a person with known hypertension or a history of previous MI/angina or other heart disease	
10.43: <u>Possible</u>	Congestive heart failure is considered possible when there is progressive shortness of breath on lying down or at night, improving on sitting up AND any of the following signs or symptoms: swelling of feet, distension of abdomen, progressive cough	

10.50 Effort Angina with documented Ischemia

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.51: <u>Definite</u>	Stress test with ECG with new ST depression >1 mm or positive imaging (ECHO, Scan) compatible with ischemia	I20
10.52: <u>Probable</u>	Typical effort angina (i.e. Squeezing, pressure or burning type pain touching the sternum occurring on exertion and relieved by rest or nitroglycerin)	

10.60 Unstable Angina

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.61: <u>Definite</u>	1. Hospitalization for typical symptoms with new ECG changes (T wave inversion < 2mm) <u>OR</u> 2. Coronary revascularization within one week of admission, and treated as unstable angina.	I20
10.62: <u>Probable</u>	1. Hospitalization for typical symptoms lasting at least 10 but less than 20 minutes without ECG or cardiac enzyme elevation	
10.63: <u>Possible</u>	Not hospitalized for typical symptoms of angina occurring at rest and treated as unstable angina: rest, anti-platelets, nitrates, beta blockers and/or calcium channel blockers.	

10.80 Other Non-Fatal Cardiovascular Events

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
10.81	Rheumatic Heart Disease	I01, I05-I09
10.82	Other valvular heart diseases (excluding Rheumatic Heart Disease)	I34-I37
10.83	Pericarditis	I30-I32
10.84	Endocarditis	I33, I38, I39
10.85	Myocarditis	I40, I41
10.86	Congenital heart disease	Q20-Q28
10.87	Atrial fibrillation/flutter Atrial Fibrillation and Flutter are due to an abnormal cardiac rhythm at the atrial level, and the diagnosis is made on the electrocardiographic (ECG) tracing or monitor.	I48
10.88	Peripheral artery disease (lower limb iliac to popliteal and carotid)	I73
10.90	Pulmonary embolism	I26
10.91	Other cardiac or arterial diseases: <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	I00, I02, I10-I13, I15, I23-I25, I27, I28, I42-I47, I49, I51, I52, I65-I68, I70-I72, I74, I77-I83, I85-I89, I95, I97-I99

11.00 Cancer by primary site and may be either definite, probable or possible based on described characteristics

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
11.01	Mouth	C00-C06, C10, C12, C14
11.02	Esophagus	C15
11.03	Stomach	C16
11.04	Small Intestine	C17
11.05	Large Intestine including rectum	C18-C20
11.06	Pancreas	C25
11.07	Liver	C22, C24
11.08	Lung/Pleura	C33-C34, C38-C39, C45
11.09	Breast	C50, D05
11.11	Prostate	C61
11.13	Head and neck	C31-C32, C70
11.14	Skin	C43-C44, D03-D04
11.15	Multi-site	C97
11.16	Other, specify	C07-C09, C11, C13, C23, C26, C30, C37, C46-C49, C57-C58, C63, C68-C69, C74-C79, C96, D00-D02, D07, D09, D37-D45 , D47, D48
11.17	Cervical	C53, D06
11.18	Uterine/Ovarian	C54-C56
11.19	Vaginal/Vulva	C51-C52
11.20	Kidney	C64, C65
11.21	Bladder	C66-C67
11.22	Anus	C21
11.23	Testis	C62
11.24	Penis	C60
11.25	Brain/Spinal Cord	C71-C72
11.26	Leukemia	C91-C95, D46
11.27	Lymphoma	C81-C85, C88, C86
11.28	Multiple Myeloma	C90
11.29	Musculoskeletal (muscle, bones, tendons, ligaments, joints, cartilage)	C40-C41
11.30	Thyroid	C73
11.40	Unknown Site	C80
A: Definite	Diagnosis made on histopathology	
B: Probable	<ol style="list-style-type: none"> 1. Imaging proof and therapeutic intervention, or 2. Physician diagnosis followed by therapeutic intervention 	
C: Possible	<ol style="list-style-type: none"> 1. Symptoms and signs (weight loss without other cause) suggestive of cancer, or 2. Diagnostic imaging (the participant dies before histological proof or therapeutic intervention) 	

NON-FATAL PURE ADJUDICATION DEFINITIONS

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12.00 NON-FATAL INFECTIONS

12.10 Pulmonary Tuberculosis

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
12.11: <u>Definite</u>	<p>1. Positive bacteriology (sputum or body fluid microscopy) or positive histopathology</p> <p>OR</p> <p>2. Chronic cough of long duration (> 4 weeks) with fever and any one of the following signs or symptoms</p> <ul style="list-style-type: none"> • Evening rise in fever • Blood in sputum • Chest pain • Breathlessness • Loss of appetite • Chronic weight loss <p>AND reported history of TB diagnosis by physician based on evidence and started on anti-tuberculosis treatment</p>	A15, A16, A19
12.12: <u>Probable</u>	<p>Chronic cough of long duration (> 4 weeks) with fever and any one of the following signs or symptoms</p> <ul style="list-style-type: none"> • Evening rise in fever • Blood in sputum • Chest pain • Breathlessness • Loss of appetite • Chronic weight loss <p>AND one of the following:</p> <ul style="list-style-type: none"> • diagnosis based on positive radiology OR • Family history of diagnosed TB OR • Positive TB serology or positive past Mantoux test 	
12.13: <u>Possible</u>	<p>At least one of the symptoms below</p> <p>Chronic cough of long duration (> 4 weeks) with fever and any one of the following signs or symptoms</p> <ul style="list-style-type: none"> • Evening rise in fever • Blood in sputum • Chest pain • Breathlessness • Loss of appetite • Chronic weight loss <p>AND Empirical diagnosis by clinician</p>	

12.20 AIDS

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
12.21: <u>Definite</u>	1. Positive serology plus symptoms 2. H/o severe weight loss in less than 3 months AND 3. History of prolonged unexplained fever, or diarrhoea or persistent cough for more than 1 month (intermittent or continuous) OR 4. HIV Positive serology 5. Possibly with Mouth sores / white patches in mouth, Skin rash, Generalized swelling of nodes in armpits, neck, groin, history of ulcers in genital area, history of spouse/partner with similar illness/ death of spouse partner from illness	B20-B24
12.22: <u>Probable</u>	One of the above	

12.30 COVID-19

Clinical Criteria

At least two of the following symptoms: fever, chills, rigor, myalgia, headache, sore throat, new olfactory and taste disorder **OR** at least one of the following symptoms: cough, shortness of breath/difficult breathing **OR** severe respiratory illness with at least one of the following: clinical/radiological evidence of pneumonia and/or ARDS

Laboratory criteria

Confirmatory: Molecular testing: real-time reverse-transcription polymerase chain reaction (rRT-PCR)

Presumptive: Serology testing – specific antibody/specific antigen.

Epidemiological Linkage

Close contact [within 6 feet for at least 10-30 minutes] exposure within 14 days before onset of symptoms, with a confirmed or probable case **OR** travel to an area with sustained ongoing community transmission

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
12.31: <u>Definite</u>	Confirmed by molecular testing: real-time reverse-transcription polymerase chain reaction (rRT-PCR) irrespective of severity of clinical criteria	U07
12.32: <u>Probable</u>	1. Meets clinical criteria and epidemiological evidence with no confirmed laboratory testing OR 2. Meets presumptive laboratory testing and either clinical criteria or epidemiological evidence	

12.90 Other Non-Fatal Infections

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
12.90	Other Non-Fatal Infections <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	A00-A09, A17-A18, A20-A99, B00-B19, B25-B99

13.00 NON-FATAL DISEASES OF THE RESPIRATORY SYSTEM

13.10 Asthma

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
13.11: <u>Definite</u>	<p>Symptoms of episodic wheeze or shortness of breath or chest tightness for more than 3 months of the year <u>AND evidence of variable airflow limitation EITHER as</u></p> <ol style="list-style-type: none"> 1. Abnormal spirometry and 12% improvement from baseline FEV1 15 minutes after inhaled short acting broncho-dilator <u>OR</u> 2. If spirometry is normal, diagnosis may be established by methacholine challenge test. <p>(aka: symptoms + demonstrated variable airflow obstruction)</p>	J45-J46
13.12: <u>Probable</u>	<ol style="list-style-type: none"> 1. Episodic symptoms of wheezing or shortness of breath or chest tightness for more than 3 months of the year AND onset before age 40 years AND physician's diagnosis <p>(aka symptoms + no demonstrated variable obstruction + physician diagnosis)</p> <p><u>OR</u></p> <ol style="list-style-type: none"> 2. If symptoms unknown <u>EITHER</u> <ul style="list-style-type: none"> • abnormal spirometry and 12% improvement from baseline FEV1 15 minutes after inhaled short acting broncho-dilator + physician's diagnosis, without confirmation of airflow limitation <u>OR</u> • abnormal spirometry and 12% improvement from baseline FEV1 15 minutes after inhaled short acting broncho-dilator + Therapy with bronchodilators, including inhaled steroids <u>OR</u> • If spirometry is normal, diagnosis may be established by methacholine challenge test + Physician diagnosis <u>OR</u> • If spirometry is normal, diagnosis may be established by methacholine challenge test + Therapy with bronchodilators, including inhaled steroids <p>(aka no symptoms, but demonstrated variable airflow obstruction + physician diagnosis/ treatment)</p>	
13.13: <u>Possible</u>	<p>Episodic symptoms of wheezing or shortness of breath or chest tightness for more than 3 months of the year AND onset before age 40 years</p> <p>AND</p> <p><u>WITHOUT</u> history of significant exposure to smoking (<10 pack-years) and/or other risk factors (including inhaled noxious particles or gases)</p> <p>AND</p> <p>Therapy with bronchodilators, including inhaled steroids</p> <p>(aka symptoms + negative exposure history + therapy)</p> <p><i>Pack-years= number of tobacco sticks per day x duration of tobacco use in years divided by 12</i></p>	

13.20 COPD (Obstructive Airway Disease)

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
13.21: <u>Definite</u>	<ol style="list-style-type: none"> 1. Symptoms of chronic cough, sputum production, shortness of breath for >3 months of year AND 2. History of significant exposure to smoking (>10 pack-years) and/or other risk factors (include inhaled noxious particles or gases) AND 3. Confirmatory laboratory: post-bronchodilator FEV1/VC < 70%. <p>(aka symptoms + exposure history + fixed airflow obstruction)</p> <p><i>Pack-years= number of tobacco sticks per day x duration of tobacco use in years divided by 12</i></p>	
13.22: <u>Probable</u>	<ol style="list-style-type: none"> 1. Confirmatory laboratory: post-bronchodilator FEV1/VC < 70% AND <p><u>EITHER</u></p> <ol style="list-style-type: none"> 2. Symptoms of chronic (> 3 months of the year) cough, sputum production and shortness of breath OR 3. History of exposure to smoking (> 10 pack-years) and/or other risk factors (Include inhaled noxious particles or gases) OR 4. Physician diagnosis OR 5. Therapy with bronchodilators <p>(aka fixed airflow obstruction + symptoms/ exposure history/ physician diagnosis/ treatment)</p> <p><i>Pack-years= number of tobacco sticks per day x duration of tobacco use in years divided by 12</i></p>	J44
13.23: <u>Possible</u>	<p>Individual >= 40 years of age and</p> <ul style="list-style-type: none"> • Symptoms of chronic cough, sputum production and shortness of breath for more than 3 months of the year for at least 2 years AND history of exposure to smoking (>10 pack-years) and other risk factors (including inhaled noxious particles or gases) (aka symptoms + exposure history but no demonstrable fixed airflow obstruction) <p>OR</p> <ul style="list-style-type: none"> • Symptoms of chronic cough, sputum production and shortness of breath AND Physician diagnosis of COPD (aka symptoms + physician diagnosis but no demonstrable fixed airflow obstruction) <p>OR</p> <ul style="list-style-type: none"> • Symptoms of chronic cough, sputum production and shortness of breath AND Therapy with bronchodilators with history of exposure to smoking and other risk factors (including inhaled noxious particles or gases) (aka symptoms + COPD therapy but no demonstrable fixed airflow obstruction) <p>OR</p> <ul style="list-style-type: none"> • No symptoms but with History of exposure to smoking and other risk factors (including inhaled noxious particles or gases) AND Physician diagnosis of COPD (aka no symptoms + exposure history + diagnosis) <p>OR</p> <ul style="list-style-type: none"> • No symptoms but with History of exposure to smoking and other risk factors, (Include inhaled noxious particles or gases) AND Therapy with bronchodilators (aka no symptoms + exposure history + therapy) <p>OR</p> <ul style="list-style-type: none"> • Physician diagnosis of COPD AND Therapy with bronchodilators (aka no symptoms + diagnosis + therapy) <p><i>Pack-years= number of tobacco sticks per day x duration of tobacco use in years divided by 12</i></p>	

13.30 Other Non-Fatal Respiratory Diseases

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
13.30	Other Non-Fatal Respiratory Diseases <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	J00-J43, J47-J99, Q30-Q34

14.00 Non-Fatal Accident or Injury:

Specific details should be provided on the Adjudication Form

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
14.00	Non-Fatal Accident or Injury <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	V01-V99, W00-W99, X00-X99, Y00-Y98

17.00 Other Non-Fatal Diseases (Excluding Other Cardiovascular Diseases, Cancer, Other Infections, Other Respiratory Diseases and Injury)

PURE Adjudication Code	Event Type	Acceptable ICD-10 codes
17.10	Diseases of the Nervous System: <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	G00-G44, G46-G99, Q00-Q07
17.20	Diseases of the Digestive System: <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	K00-K93, Q39-Q45
17.30	Diseases of the Genito-Urinary System: <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i>	N00-N99, Q50-Q64
17.50	Other diseases: <i>Please refer to the PURE ICD-10 Code Listing and PURE Non-Fatal Adjudication Code Sheet.</i> Valid ICD-10 Codes include the following: 'D' - Benign Neoplasm and Blood disorders 'E' - Endocrine 'F' - Mental 'H' - Eye/Ear 'L' - Skin, or 'M' - Musculoskeletal 'Q' - Congenital not already classified above <i>ICD-10 Codes that should never be indicated: Any 'P' (Perinatal) code or 'R' (Signs/Symptoms)</i>	D10-D36, D50-D89, E00-E90, F00-F99, H00-H95, L00-L99, M00-M99, O00-O99, Q00-Q18, Q35-Q99, R00-R94