

COMMENTS	-Affix label here-
	Member ID: _____ - _____ - _____
<i>To be completed by Physician Adjudicator</i>	
Date Completed: _____-_____-_____ (M/D/Y)	Central Case No.: _____
Adjudicator Code: _____	Case Copy No.: _____

(For items 1-12, each question specifies “mark one” or “mark all” that apply.)

Complete Q1 - ECG, Q2 - Cardiac enzyme, and Q3 - Cardiac pain information for the following WHI Extension Study outcomes: Myocardial infarction (MI), coronary revascularization, and heart failure.

1. ECG pattern (Mark the one category that applies best.)

- ₁ Evolving Q-wave and evolving ST-T abnormalities*
- ₂ Equivocal Q-wave evolution; or evolving ST-T abnormalities; or new left bundle branch block
- ₃ Q-waves or ST-T abnormalities suggestive of an MI and not classified as code 1 or 2 above
- ₈ Other ECG pattern, ECG uncodable, or normal ECG pattern
- ₉ ECG not available

***Mark if ECG formal interpretation report clearly indicates evidence for acute ST-segment elevation myocardial infarction (STEMI) when the actual ECG tracing cannot be obtained.**

2. Cardiac enzyme information available?

- ₀ No → **Skip to Question 3 on page 2.**
- ₁ Yes

2.1 Serum creatine kinase (CK): (Mark all that apply.) (Always record % or index if available.)

If CK-MB available:

CK-MB expressed as a % or index: **(Record peak results only.)**

- ₁ CK-MB at least 2x upper limit of normal for % or index
- ₂ CK-MB greater than upper limit of normal but less than 2x upper limit of normal for % or index
- ₃ CK-MB within normal limits for % or index

CK-MB expressed in units (usually ng/ml): **(Record peak results only.)**

- ₄ CK-MB at least 2x upper limit of normal for units
- ₅ CK-MB greater than upper limit of normal but less than 2x upper limit of normal for units
- ₆ CK-MB within normal limits for units

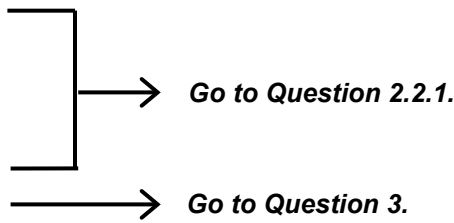
AS355 COSMOS only	2.1.1 CK-MB peak result _____ . _____	2.1.2 CK-MB upper limit of normal _____ . _____
------------------------------	---------------------------------------	---

If CK-MB not available:

- ₉ Total CK at least 2x upper limit of normal
- ₁₀ Total CK greater than upper limit of normal but less than 2x upper limit of normal
- ₁₁ Total CK within normal limits
- ₉₉ CK result not available

AS355 COSMOS only	2.1.3 Total CK peak result _____	2.1.4 Total CK upper limit of normal _____
------------------------------	----------------------------------	--

2.2 Troponin lab test. **(Mark the one category that applies best.) (If more than one test was conducted, record the type with the most elevated lab result.)**

- ₁ Troponin C
 - ₂ Troponin I
 - ₃ Troponin T
 - ₄ Troponin, not specified
 - ₉ Troponin not available
- 

2.2.1	Results (Mark the <u>one</u> category that applies best.) Troponin values should be coded using the upper limit of normal (ULN) and not upper limit of indeterminate/indecisive as the reference value. Thus, if 2 cutpoints are given, choose the lower cutpoint for the upper limit of normal.
	<ul style="list-style-type: none"> <input type="checkbox"/>₁ Troponin at least 2x upper limit of normal <input type="checkbox"/>₂ Troponin greater than upper limit of normal but less than 2x upper limit of normal <input type="checkbox"/>₃ Troponin within normal limits <input type="checkbox"/>₉ Other

AS355 COSMOS only	
Most elevated Troponin:	
2.2.2	Troponin peak result _____ . _____
2.2.3	Troponin upper limit of normal _____ . _____

3. **Cardiac pain** defined as: an acute episode of pain, discomfort or tightness in the chest, arm, throat or jaw. **(Mark the one category that applies best.)**

- ₁ Present
- ₂ Absent
- ₉ Unknown/Not recorded

Yes ₁ No ₀

4. Definite, probable, or aborted myocardial infarction (See Table 1 – Definition of Criteria for Diagnosis of Myocardial Infarction and Table 2 – Algorithm for Enzyme Diagnostic Criteria on the last page of this form.)

4.1 Date of admission: - - (M/D/Y)

4.2 Diagnosis: (Mark one.)

₁ Myocardial infarction not occurring as a result of or during a procedure. (Skip to Question 4.3.)

₂ Myocardial infarction during or resulting from a procedure, i.e., within 30 days of any procedure.



4.2.1 Type and timing of Procedure (Mark one.)

- ₁ A myocardial infarction that followed a cardiac procedure within 24 hours (for example, diagnostic coronary catheterization, percutaneous coronary intervention (PCI), CABG, pacemaker insertion, or cardioversion).
- ₂ A myocardial infarction that followed a cardiac procedure within 2-30 days (for example, diagnostic coronary catheterization, PCI, CABG, pacemaker insertion, or cardioversion).
- ₃ A myocardial infarction that followed a non-cardiac procedure within 30 days (for example, any elective or emergency non-cardiac vascular procedure regardless of type of anesthesia, or any elective or emergency surgical procedure requiring more than local anesthesia). (Go to Question 4.3 below.)

Answer both questions:

4.2.2 Was the cardiac procedure a PCI?

₀ No

₁ Yes →

4.2.3 Were enzyme levels at least 3X ULN (99th percentile)?

No ₀

Yes ₁

Unknown ₉

4.2.4 Was the cardiac procedure a CABG?

₀ No

₁ Yes →

4.2.5 Were enzyme levels at least 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found for CABG?

No ₀

Yes ₁

Unknown ₉

4.3 Was a thrombolytic agent administered or emergent* revascularization procedure (e.g., angioplasty or stent) performed? (Mark one.)

*An emergent revascularization is conducted within 12 hours of symptom onset; code both here and in Q5. Non-emergent revascularization procedures are coded only under Q5. Examples of thrombolytic agents are streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

₀ No

₁ Yes

₉ Unknown

AS355 COSMOS only

4.4 Universal criteria of MI classification (Mark one.)

- ₁ Type 1: Spontaneous MI
- ₂ Type 2: Secondary MI
- ₃ Type 3: MI resulting in death (no biomarkers available)
- ₄ Type 4a: Post-PCI MI
- ₅ Type 4b: MI related to stent thrombosis
- ₆ Type 5: Post-CABG MI

Yes No 5. Coronary revascularization. Categories A, C, D

₁ ₀ 5.1 Date of Admission/Procedure: - - (M/D/Y)

5.2 Type of procedure: Any one of the following procedures aimed at improving cardiac status (Mark all that apply.)

- ₁ Coronary artery bypass graft (CABG)
- ₂ Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy, percutaneous coronary intervention (PCI)

AS355 COSMOS only

5.2.1 Coronary artery interventions (Mark all that apply.)

- ₁ Left main coronary artery
- ₂ Left anterior descending artery or branches
- ₃ Left circumflex artery or marginal branches
- ₄ Right coronary artery or branches
- ₅ Any vein bypass graft treated by PCI
- ₆ Internal thoracic (left or right internal mammary) artery (RIMA or LIMA) graft treated by PCI
- ₈ Other (Specify: _____)
- ₉ Information not available

5.3 Second myocardial infarction (MI) (i.e., second MI not already reported in Question 4) occurring as a result of or during the revascularization procedure. (Mark one.)

₀ No ₉ Unknown

₁ Yes



5.3.1 For PCI, were enzyme levels at least 3X ULN (99th percentile)?

₀ No ₁ Yes ₉ Unknown

5.3.2 For CABG, were enzyme levels at least 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found?

₀ No ₁ Yes ₉ Unknown

Categories A, C, D

Yes **No** **6.** **Carotid artery disease requiring and/or occurring during hospitalization.** Disease must be symptomatic and/or requiring intervention (i.e., vascular or surgical procedure).

₁ ₀

6.1 Date of Admission: - - (M/D/Y)

6.2 Diagnosis: **(Mark one.)**

₁ Carotid artery occlusion and stenosis without documentation of cerebral infarction

₂ Carotid artery occlusion and stenosis with documentation of cerebral infarction

6.3 Carotid artery disease based on (Hospitalization plus one or more of the following):
(Mark all that apply.)

₁ Symptomatic disease with carotid artery disease listed on the hospital discharge summary

₂ Symptomatic disease with abnormal findings ($\geq 50\%$ stenosis) on carotid angiogram, MRA, or Doppler flow study

₃ Vascular or surgical procedure to improve flow to the ipsilateral brain

Categories A, C, D

Yes **No** **7.** **Peripheral arterial disease (iliac arteries or below) requiring and/or occurring during hospitalization.** Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be symptomatic and/or requiring intervention (e.g., vascular or surgical procedure for arterial insufficiency in the lower extremities).

₁ ₀

7.1 Date of Admission: - - (M/D/Y)

7.2 Diagnosis: **(Mark the one category that applies best.)**

₂ Atherosclerosis of arteries of the lower extremities

₃ Arterial embolism and/or thrombosis of the lower extremities

7.3 Peripheral arterial disease based on (hospitalization plus one or more of the following):
(Mark all that apply.)

₁ Ultrasonographically, angiographically, or MRI-demonstrated obstruction, or ulcerated plaque ($\geq 50\%$ of the diameter or $\geq 75\%$ of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below

₂ Absence of pulse by Doppler in any major vessel of lower extremities

₃ Exercise test that is positive for lower extremity claudication

₄ Surgery, angioplasty, or thrombolysis for peripheral arterial disease

₅ Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene

₆ Exertional leg pain relieved by rest and at least one of the following:

(1) claudication diagnosed by physician, or

(2) ankle-arm systolic blood pressure ratio ≤ 0.8

Categories A, C, D, E

Yes **No** **8.** **Congestive heart failure requiring and/or occurring during hospitalization.** (Physician diagnosis of new-onset or worsened congestive heart failure on this admission.)

₁ ₀

8.1 Date of Admission: - - (M/D/Y)

- 8.2 Congestive heart failure based on one or more of the following: **(Mark all that apply.)**
- ₁ Congestive failure diagnosed by physician and receiving medical treatment for CHF on this admission (e.g., diuretic, digitalis, vasodilator and/or angiotensin-converting enzyme inhibitor)
 - ₂ Congestive failure diagnosed by physician and receiving medical treatment on this admission **plus** current medical record documents a history of an imaging procedure showing impaired systolic or diastolic LV function
 - ₃ Pulmonary edema/congestion by chest X-ray on this admission
 - ₄ On this admission, dilated ventricle or poor left (or right-side) ventricular function (e.g., wall motion abnormalities) by echocardiography; radionuclide ventriculogram (RVG)/multigated acquisition (MUGA), or other contrast ventriculography, or evidence of left ventricular diastolic dysfunction

Categories A, C, D

Yes **No** **9.** Aortic aneurysm **Requires a hospitalization of one night or more. Disease must be symptomatic and/or requiring intervention (e.g., vascular or surgical procedure).**
₁ ₀

9.1 Date of Admission: - - (M/D/Y)

9.2 Diagnosis: **(Mark one.)**

- ₁ Ultrasonographically- or angiographically-demonstrated (by any imaging modality) aortic aneurysm
- ₂ Surgical or vascular procedure for aortic aneurysm

9.3 Location: **(Mark one.)**

- ₁ Ascending aortic aneurysm (arising anywhere from the aortic valve to the left subclavian artery)
- ₂ Descending aortic aneurysm (thoracic aorta from the left subclavian artery to the diaphragm)
- ₃ Thoracoabdominal aortic aneurysm (descending aorta extending below the diaphragm)
- ₄ Abdominal aortic aneurysm (AAA) (abdominal aorta below the renal arteries only)
- ₈ Other (Specify: _____)
- ₉ Unknown, not specified

Categories A, C, D

Yes **No** **10.** Aortic dissection **Requires a hospitalization of one night or more.**
₁ ₀

10.1 Date of Admission: - - (M/D/Y)

10.2 Diagnosis: **(Mark one.)**

DeBakey Classification

- ₁ Type I (Dissection of the ascending and descending thoracic aorta)
- ₂ Type II (Dissection of the ascending aorta)
- ₃ Type III (Dissection of the descending aorta)

If DeBakey classification cannot be determined, complete the following:

- ₄ Stanford Type A (Dissection involving the ascending aorta, regardless of the site of the primary tear)
- ₅ Stanford Type B (Dissection of the descending aorta)
- ₆ Not able to be classified with available documents

Category A, C

Yes ₁ No ₀

11. **Heart Valve Disease** Requires a hospitalization of one night or more. Moderate to severe valvular disease involving one or more valves that requires medical treatment; surgical repair or replacement; or interventional procedure to treat stenosis or regurgitation.

11.1 Date of Admission: - - (M/D/Y)

11.2 Which valve(s) involved (causing symptoms, hospitalization, treatment, or complications) are specified?

Which valves? *(Mark No or Yes for each valve. If valve not known, mark Valve NOS (Not Otherwise Specified - i.e., not identified in available records). If you mark Yes, mark the one corresponding diagnosis.*

				Diagnosis					
		No	Yes		Stenosis	Insufficiency	Both	Unknown	
11.2.1	Aortic	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	→	11.2.1.1	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉
11.2.2	Mitral	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	→	11.2.2.1	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉
11.2.3	Pulmonic	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	→	11.2.3.1	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉
11.2.4	Tricuspid	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	→	11.2.4.1	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉
11.2.5	Valve NOS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	→	11.2.5.1	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉

11.3 Was a procedure or operation performed?

₀ No

₁ Yes



11.3.1 On which valve was the procedure or operation performed? *(Mark all that apply.)*

₁ Aortic

₂ Mitral

₃ Pulmonic

₄ Tricuspid

₉ Unknown

Responsible Adjudicator Signature

Table 1
Definition of Criteria for Diagnosis of Myocardial Infarction

	Cardiac Enzyme Interpretation (see Table 2 below)			
	Abnormal	Equivocal	Incomplete/ Absent	Normal
ECG Pattern/Symptoms				
Cardiac pain present:				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Definite MI
Equivocal Q wave evolution; or evolving ST-T abnormalities, or new left bundle branch block	Definite MI	Definite MI	Probable MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Definite MI	Probable MI	No MI	No MI
Other ECG, ECG absent or uncodable	Definite MI	No MI	No MI	No MI
Cardiac Pain absent:				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Probable MI
Equivocal Q wave evolution; or evolving ST-T abnormalities; or new left bundle branch block	Definite MI	Probable MI	No MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Probable MI	No MI	No MI	No MI
Other ECG, ECG absent or uncodable	No MI	No MI	No MI	No MI

Table 2
Algorithm for Enzyme Diagnostic Criteria***

Cardiac Enzyme	Interpretation		
	Abnormal*	Equivocal	Normal
Creatine kinase MB fraction (CK-MB)	≥ 2x ULN (as %, index, or units)	1-2x ULN (as %, index, or units)	WNL
Troponin (C, I, or T)**	Troponin ≥ 2x ULN	Troponin 1-2x ULN	Troponin is WNL
Total creatine kinase (CK) (no MB available)	N/A	Total CK ≥ 2x ULN	Total CK is 1-2x ULN or WNL

ULN = upper limit of normal

WNL = within normal limits

* If both CK-MB and Troponin are available, Troponin must be elevated to be considered abnormal; if only CK-MB is available, abnormal levels are enough to code enzymes as abnormal, i.e., WHI considers Troponin as the most accurate indicator of myocardial injury.

** Code Troponin levels using the ULN and not Upper limit of undeterminate/indecisive as the reference value. Thus, if 2 cut points are given, choose the lower cut point for the ULN.

*** For procedure related MI – also code 5.3.1 or 5.3.2 with these definitions: 3X ULN (99th percentile) for PCI and 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found for CABG.

AS355 COSMOS only

Table 3
Universal Classification of Myocardial Infarction

Type 1: Spontaneous myocardial infarction

Spontaneous myocardial infarction related to atherosclerotic plaque rupture, ulceration, fissuring, erosion, or dissection with resulting intraluminal thrombus in one or more of the coronary arteries leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. The patient may have underlying severe CAD but on occasion non-obstructive or no CAD.

Type 2: Myocardial infarction secondary to an ischaemic imbalance

In instances of myocardial injury with necrosis where a condition other than CAD contributes to an imbalance between myocardial oxygen supply and/or demand, e.g., coronary endothelial dysfunction, coronary artery spasm, coronary embolism, tachy-/brady-arrhythmias, anemia, respiratory failure, hypotension, and hypertension with or without LVH.

Type 3: Myocardial infarction resulting in death when biomarker values are unavailable

Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB, but death occurring before blood samples could be obtained, before cardiac biomarker could rise, or in rare cases cardiac biomarkers were not collected.

Type 4a: Myocardial infarction related to percutaneous coronary intervention (PCI)

Myocardial infarction associated with PCI is arbitrarily defined by elevation of cTn values $>5 \times$ 99th percentile URL in patients with normal baseline values (\geq 99th percentile URL) or a rise of cTn values $>20\%$ if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial

Type 4b: Myocardial infarction related to stent thrombosis

Myocardial infarction associated with stent thrombosis is detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarkers values with at least one value above the 99th percentile URL.

Type 5: Myocardial infarction related to coronary artery bypass grafting (CABG)

Myocardial infarction associated with CABG is arbitrarily defined by elevation of cardiac biomarker values $>10 \times$ 99th percentile URL in patients with normal baseline cTn values (\geq 99th percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.