



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, heart failure, and atrial fibrillation.

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

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

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 one 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.

- ₁ Troponin at least 2x upper limit of normal
- ₂ Troponin greater than upper limit of normal but less than 2x upper limit of normal
- ₃ Troponin within normal limits
- ₉ Other

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

→ Continue on the next page.

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 below.**

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 Yes Unknown

₀ ₁ 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 Yes Unknown

₀ ₁ 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

Yes ₁ No ₀


5. **Coronary revascularization**

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)

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
 - ₁ Yes
 - ₉ Unknown
- 

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

Yes ₁ No ₀

6. **Carotid artery disease requiring and/or occurring during hospitalization.** Disease must be symptomatic and/or requiring intervention (i.e., vascular or surgical procedure).

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 (≥ 50% stenosis) on carotid angiogram, MRA, or Doppler flow study
- ₃ Vascular or surgical procedure to improve flow to the ipsilateral brain

- Yes ₁ No ₀
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).
- 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
- Yes ₁ No ₀
8. **Congestive heart failure requiring and/or occurring during hospitalization.** (Physician diagnosis of new-onset or worsened congestive heart failure on this admission.)
- 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

- Yes ₁ No ₀ 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).
- 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: _____
- ₉ Unknown, not specified

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

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 → **Go to Question 12 on the next page.**
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

Yes ₁ No ₀

12. Atrial Fibrillation (AF) requiring and/or occurring during hospitalization (includes but is not limited to new-onset AF)

AF is confirmed if it is new onset (as stated in the available medical records), acute, worsening (e.g., with rapid ventricular response), associated with complications (e.g., peripheral embolus* or stroke), or requires new or additional treatment by intervention or medication adjustment during the hospital stay of one night or more. Do not include chronic, stable AF not meeting any of the previously listed criteria. AF does not have to be the reason for the admission. The diagnosis of AF is confirmed by a 12-lead ECG, a clearly diagnostic rhythm strip, a therapeutic procedure to treat AF (cardioversion or ablation), or other similar clear-cut documentation in the discharge summary or clinical notes. Atrial flutter is not adjudicated, but may be noted in the comments section of the Investigation Documentation Summary (IDS). (OAC, February 27, 2013)

*A peripheral embolus is defined as any non-cerebral arterial embolus and is recorded in question 12.12 – *Peripheral embolus*. This would include an embolus to the extremities or to the visceral organs. This definition of “peripheral embolus” is only used in the context of atrial fibrillation; it is a more inclusive definition than the one WHI uses to code peripheral arterial disease. A cerebral embolus is coded under question 12.13 – *Embolic stroke*. Note a TIA is not recorded under either peripheral embolus or embolic stroke. Rather, it is treated as a separate outcome to be reviewed and adjudicated by the Stroke Committee. (OAC, April 24, 2013)

12.1. Date of Admission: - - (M/D/Y)

	No	Yes	Unknown
12.2. Available medical records indicate first diagnosis of AF (new onset) or recent outpatient diagnosis of AF and this is the first hospitalization for treatment.	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉

Medications: Medication management of AF during this Hospitalization. (*Mark each item.*)

	No	Yes	Unknown
12.3 Rate control with medications (e.g., calcium channel blockers, digoxin, beta-blockers, etc.)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.4 Rhythm control with medications (e.g., sotalol, dofetilide, propafenone, flecainide, amiodarone, dronedarone, etc.)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.5. Anticoagulation (warfarin [Coumadin]; thrombin inhibitor, dabigatran [Pradaxa], etc., excluding aspirin and other antiplatelet drugs)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉

Procedures attempted and/or done on this admission:

	No	Yes	Unknown
12.6. Pharmacologic cardioversion	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.7. Electrical cardioversion	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.8. Catheter ablation	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.9. Surgical ablation (MAZE procedure or similar)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.10. AV node ablation and pacemaker	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.11. Other procedure or intervention, specify:	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉

Complications for this AF:

12.12. Peripheral embolus	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉
12.13. Embolic stroke (<i>If Yes, forward to Stroke Committee.</i>)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₉

Responsible Adjudicator Signature

Table 1
Definition of Criteria for Diagnosis of Myocardial Infarction

ECG Pattern/Symptoms	Cardiac Enzyme Interpretation (see Table 2 below)			
	Abnormal	Equivocal	Incomplete	Normal
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.