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**Inclusion/Exclusion Criteria for Non-Emergency Angioplasty Patients in Non-Surgery-on-Site Hospitals that Participated in the MASS COMM Trial**

**Effective August 1, 2013 (Revised)**

**Inclusion Criteria: the patient must meet all of the following criteria:**

1. Patient is  $\geq 18$  years old.
2. Patient requires single- or multi-vessel percutaneous coronary intervention (PCI) of *de novo* or restenotic target lesion (including in-stent restenotic lesions), in native coronary artery(s) and/or coronary artery bypass graft(s).
3. Patient has clinical evidence of ischemic heart disease in terms of a positive functional study, documented ischemic symptoms or other clinical indication for PCI.

*Angiographic Inclusion Criteria:*

4. The target lesion(s) is (are) *de novo* or restenotic (including in-stent restenotic) native coronary artery lesion(s) or bypass graft with  $\geq 50$  stenosis (visual estimate), and is:
  - amenable to PCI; and
  - meets guideline-driven evidence of hemodynamic significance by angiography, FFR, IVUS or other modality.

**Exclusion Criteria: non-emergency PCI may not be performed at the non-SOS site if any of the following conditions apply to the patient:**

1. The patient is pregnant.
2. Left ventricular ejection fraction less than 20%.

- As LVEF less than 30% is a high risk feature for PCI, those patients with LVEF less than 30% undergoing non-emergency PCI will undergo an adjudication process as defined by DPH;
- As current national guidelines are revised over time, this document will be amended to reflect those changes specifically for this high risk patient group.

*Angiographic Exclusion Criteria:*

3. Unprotected left main coronary artery disease (stenosis >50%).
4. Any target lesion that requires treatment with a debulking or ablative device such as rotational atherectomy.
5. The target vessel is in a “last remaining” epicardial vessel (e.g., >2 non-target epicardial vessels and the bypass grafts to these territories [if present] are totally occluded).
6. Known or suspected chronic total occlusion.

## Changes to Inclusion/Exclusion Criteria for Non-Emergency PCI at Former MASS COMM non-SOS Sites

This document lists each of the inclusion/exclusion criteria in effect during the MASS COMM Trial, and indicates whether or not the criterion has been maintained, deleted, or revised. For a list of only those criteria in effect starting August 1, 2013, please see pages 1-2 of this document.

The following criteria for the performance of non-emergency PCI in non-SOS hospitals are contingent upon a tight working relationship and collaborative agreement between a SOS hospital and the non-SOS hospital that addresses:

- consideration of potential candidacy for CABG as part of the decision-making process regarding the optimal patient management strategy/treatment,
- the provision of rapid transport for patients for whom a procedural complication warrants surgical intervention,
- the SOS hospital's agreement to accept without delay any patient referred emergently, and
- specific responsibilities for the physician and nursing staffs in addressing emergent situations.

Please refer to 105 CMR 130.975 for the regulatory requirements related to collaboration agreements.

These criteria are also contingent upon participation in a QA and Peer Review process which includes both non-SOS and SOS hospital interventionalists and SOS hospital cardiac surgeons, and which will include evaluation of Appropriate Use Criteria, mortality and complications of these procedures, as required by 105 CMR 130.975.

<u>Inclusion Criteria</u> Patient must meet all of the following criteria:	Check as applicable:			Revised Language
	Keep	Delete	Revise	
1. Subject is $\geq$ 18 years old.	<b>X</b>			
2. Subject requires single- or multi-vessel percutaneous coronary intervention (PCI) of <i>de novo</i> or restenotic target lesion (including in-stent restenotic lesions). N.B. staged procedure will not be considered to meet the endpoint component of repeat revascularization if either of the following pre-catheterization procedure qualifying clinical laboratory values are met:			<b>X</b>	Patient requires single- or multi-vessel percutaneous coronary intervention (PCI) of <i>de novo</i> or restenotic target lesion (including in-stent restenotic lesions), in native coronary artery(s) and/or coronary artery bypass graft (s).

• eGFR < 60 ml/min or • creatinine > 1.5 mg/dl				
3. Subject's lesion(s) is (are) amenable to stent treatment with currently available FDA-approved bare metal or drug eluting stents, or angioplasty		<b>X</b>		
4. Subject is an acceptable candidate for non-emergency, urgent or emergency CABG.		<b>X</b>		
5. Subject has clinical evidence of ischemic heart disease in terms of a positive functional study, or documented symptoms.			<b>X</b>	Patient has clinical evidence of ischemic heart disease in terms of a positive functional study, documented ischemic symptoms or other clinical indication for PCI.
6. Documented stable angina pectoris [Canadian Cardiovascular Society Classification (CCS) 1, 2, 3, or 4], unstable angina pectoris with documented ischemia (Braunwald Class IB-C, IIB-C, or IIIB-C), non-ST segment elevation myocardial infarction, or documented silent ischemia.		<b>X</b>		
7. Subject and the treating physician agree that the subject will comply with all follow-up evaluations.		<b>X</b>		
8. Subject has been informed of the nature and purpose of the study and agrees to its provisions and has provided written informed consent as approved by the Institutional Review Board/Ethics Committee of the respective clinical site.		<b>X</b>		
<b>Angiographic Inclusion Criteria:</b>				
9. The target lesion(s) is (are) <i>de novo</i> or restenotic (including in-stent restenotic) native coronary artery lesion(s) with $\geq 50$ and $< 100\%$ stenosis (visual estimate), or the target lesion is an acute (less than 1 month) total occlusion as evidenced by			<b>X</b>	The target lesion(s) is (are) <i>de novo</i> or restenotic (including in-stent restenotic) native coronary artery lesion(s) or bypass graft with $\geq 50$ stenosis (visual estimate), and is: -amenable to PCI, and -meets guideline-driven evidence of

clinical symptoms.				hemodynamic significance by angiography, FFR, IVUS or other modality. See new exclusion criterion #22 for known or suspected chronic total occlusion.
10. If Fractional Flow Reserve (FFR) is measured, target lesion(s) has (have) evidence of a hemodynamically significant stenosis determined by FFR measurement ( $FFR \leq 0.8$ ).		<b>X</b>		
11. Target lesions(s) is (are) located in an infarct (if not treated with primary PCI) or non-infarct-related artery with a 70% or greater stenosis (by visual estimate) > 72 hours following the STEMI.  Lesions treated with PCI > 72 hours following STEMI would be subject to the same protocol inclusion/exclusion criteria listed above and below with the exception that a target lesion of 70% or greater stenosis may be treated with or without symptoms or abnormal stress test).		<b>X</b>		
<b><u>Exclusion Criteria</u></b> <b>Non-emergency PCI may not be performed at the non-SOS site if any of the following conditions apply to the patient:</b>	<b>Keep</b>	<b>Delete</b>	<b>Revise</b>	<b>Revised Language</b>
1. The patient is pregnant or breastfeeding.			<b>X</b>	The patient is pregnant.
2. Evidence of ST segment elevation myocardial infarction within 72 hours of the intended treatment on infarct related or non-infarct related artery.		<b>X</b>		
3. Cardiogenic shock on presentation or during current hospitalization.		<b>X</b>		
4. Left ventricular ejection fraction less than 20%.			<b>X</b>	Left ventricular ejection fraction less than 20%. <ul style="list-style-type: none"> <li>as LVEF less than 30% is a high risk feature for PCI, those patients with LVEF</li> </ul>

				<ul style="list-style-type: none"> <li>As current national guidelines are revised over time, this document will be amended to reflect those changes specifically for this high risk patient group.</li> </ul>
5. Known allergies to: aspirin, clopidogrel (Plavix <sup>®</sup> ), prasugrel (Effient <sup>®</sup> ), and ticlopidine (Ticlid <sup>®</sup> ), heparin, bivalirudin, stainless steel, or contrast agent (which cannot be adequately premedicated).		<b>X</b>		
6. A platelet count <75,000 cells/mm <sup>3</sup> or >700,000 cells/mm <sup>3</sup> or a WBC <3,000 cells/mm <sup>3</sup> .		<b>X</b>		
7. Acute or chronic renal dysfunction (creatinine >2.5 mg/dl or >150µmol/L).		<b>X</b>		
8. Subject is currently participating in an investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints. (Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials).		<b>X</b>		
9. Prior participation in the MASS-COMM Trial, unless the patient has completed the 12-month follow-up for the Trial, and/or prior participation in the Cohort Study, unless the patient has completed the 30-day follow-up for the Cohort Study.		<b>X</b>		
10. Within 30 days prior to the index Cohort Study procedure, the subject has undergone a previous coronary interventional procedure of any kind. Note: This		<b>X</b>		

exclusion criterion does not apply to post-STEMI patients.				
11. Stroke or transient ischemic attack within the prior 3 months.		<b>X</b>		
12. Active peptic ulcer or upper GI bleeding within the prior 3 months.		<b>X</b>		
13. Subject has active sepsis.		<b>X</b>		
14. Unprotected left main coronary artery disease (stenosis >50%).	<b>X</b>			
15. Subject has evidence of a hemodynamically insignificant stenosis determined by FFR measurement (FFR > 0.8).		<b>X</b>		
16. In the investigator's opinion, subject has a co-morbid condition(s) that could limit the subject's ability to participate in the study or comply with follow-up requirements or impact the scientific integrity of the study.		<b>X</b>		
<b>Angiographic Exclusion Criteria:</b>				
17. Subject has normal or insignificant coronaries (i.e., coronary lesion(s) < 50% stenosis).		<b>X</b>		
18. Any target vessel has evidence of: a. excessive thrombus (e.g., requires target vessel thrombectomy) b. tortuosity (>60 degree angle) that makes it unsuitable for proper stent delivery and deployment, c. heavy calcification.		<b>X</b>		
19. Any target lesion requires treatment with a device other than PTCA prior to stent placement (e.g. but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc.).			<b>X</b>	Any target lesion that requires treatment with a debulking or ablative device such as rotational atherectomy.
20. Any lesion that is located in a saphenous vein graft, however, lesions located within the native		<b>X</b>		

vessel but accessed through the graft are eligible.				
21. The target vessel is in a “last remaining” epicardial vessel (e.g., >2 non-target epicardial vessels and the bypass grafts to these territories [if present] are totally occluded).	<b>X</b>			
22. Known or suspected chronic total occlusion.				Added subsequent to revision to angiographic inclusion criterion #9.