

## CARDIAC CATHETERIZATION SERVICES

### STANDARD ADVISORY COMMITTEE (SAC) Draft Charge Approved by the CON Commission Chairperson as delegated by the CON Commission on January 28, 2014

(original charge in black; **consensus in red**  
**proposal 1 in blue; proposal 2 in green**)

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Determine if elective therapeutic cardiac catheterization's **(limited to PCI's)** should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations.

**Cost and Access do not suggest that there is a need. Research indicates that Quality is not compromised when these services are provided without open heart surgical back up.**

**Vote: Decouple (in favor/opposed)**

If it is recommended that the services should be allowed:

- a. consider the impact of cost, quality and access under the current standards in **determining need** for this service;

Proposal 1	Proposal 2
The following shall replace the existing Section 3(2)(d) respecting requirements for initiation of adult therapeutic cardiac catheterization services:  The applicant shall project a minimum	<b>Launch a PILOT program (Duration 3 years) allowing the 14 primary angioplasty sites (plus any facility with Open Heart Surgery that wants to close their OHS program) that are currently in</b>

<p>of 200 Adult PCI procedures in the category of adult therapeutic cardiac catheterizations (PCI) based on data from the most recent 12-month period preceding the date the application was submitted to the Department.</p> <p>Respecting these projected PCIs, the applicant will further project that either of the following two requirements will be satisfied based on these same data:</p> <ol style="list-style-type: none"> <li>1. That at least 50% of the projected PCI cases will be performed for patients residing at least 60 miles from any existing adult therapeutic cardiac catheterization service, or;</li> <li>2. That at least 75% of the projected PCI cases will be performed for patients residing at most 60 miles from only a single existing adult therapeutic cardiac catheterization service.</li> </ol>	<p>good standing with regards to their quality metrics and outcomes to perform elective angioplasty without surgical back up (This will be determined based on their outcomes reported in BMC2). The current proposal is designed to address topics discussed in CON meetings. Multiple cardiology bodies accept the metrics addressed in this document.</p> <p>Allow current Primary PCI programs (14 institutions), plus any facility with Open Heart Surgery that wants to close their OHS program, to Pilot an elective angioplasty program with the current conditions: (see quality and safety section)</p>
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Vote: Access Criteria (in favor/opposed) If majority vote is in favor of access criteria- Motion to approve proposal 1

Vote: 14 Primary PCI and OHS closing are the only eligible for expansion (Pilot) (in favor/opposed)

b. Provide specific criteria for this service including:

Initiation and Maintenance Volumes;

- i. A minimum of 200 procedures per year to initiate and maintain elective PCI without open heart surgical back up (previously approved through SAC Committee vote)*
- ii. Single operator minimum volume of 50 procedures per year over 2 years (previously approved through SAC Committee vote)*
- iii. Operators must be at least 2 years out of fellowship*

As well as Patient Safety and Quality Criteria

- i. All centers must have a quality program with internal QI processes monitoring patient selection and procedures.*
- ii. All hospitals must have a transfer protocol and emergency plan in place for patient transfers.*
- iii. Each hospital with an approved CON for primary PCI and/or elective PCI (upon upgrade or expansion) shall report to the MDCH as part of their annual hospital survey, the following information from their most BMC2 (or like registry/quality monitoring program) report at its sole expense:*

Proposal 1	Proposal 2
<b>Information collected and utilized internally by this program should include:</b> <ul style="list-style-type: none"><li><b>a. The number of patients treated with and without STEMI</b></li><li><b>b. The proportion of PCI patients with emergency CABG, risk-adjusted acute kidney injury, or post procedure stroke;</b></li><li><b>c. Risk-adjusted patient mortality for both STEMI and non-STEMI procedures;</b></li><li><b>d. PCI in-hospital risk adjusted rate of bleeding events</b></li><li><b>e. Median post-acute LOS for PCI patients with STEMI</b></li><li><b>f. PCI appropriate use in</b></li></ul>	<b>Quality metrics will be determined by the quality sub-committee</b>

<b>elective-non acute MI cases</b>	
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Vote: Quality Sub-Committee determines metrics (in favor/opposed)

Vote: Minimal recommended set approved and updated by BMC2 (or like organization) (in favor/opposed)

iv. Each institution will identify a physician champion as the contact point for the BMC2 or like organization.

v. **Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements will conform with SCAI /ACC consensus document. Each facility will bear the sole expense of demonstrating compliance with these criteria in their application.**

Vote: SCAI/ ACC compliance demonstrated in application for new elective programs and renewals (in favor/opposed)

2. Develop language for a second acquisition, similar to that of other standards.

**Consistent with previous recommendations above.**

3. Develop specific measurable quality metrics in the project delivery requirements similar to that of Open-Heart Surgery (OHS) standards.

<b>Proposal 1</b>	<b>Proposal 2</b>
<p>i. <b>Annually, Michigan Department of Community Health will request of BMC2 (or like organization) a recommendation for a slate of objective quality metrics – to include, but not necessarily be limited to those listed under "Patient Safety and Quality Criteria" section above – together with a threshold value for each metric, representing minimally acceptable performance for the following</b></p>	<p><b>Quality metrics will be determined by the quality sub-committee</b></p> <p><b>Clinical and anatomical consideration to exclude patients from elective angioplasty without surgical backup:</b></p> <ul style="list-style-type: none"> <li><b>a. Patients with decompensated heart failure</b></li> <li><b>b. Patients with advanced</b></li> </ul>

<p>year.</p> <p>ii. If MDCH does not receive the requested slate of objective quality metrics and thresholds within 60 days of request, then MDCH will use the following thresholds and metrics: performance at a level of 25th percentile on each metric listed under "Patient Safety and Quality Criteria" section above.</p> <p>iii. MDCH will notify hospitals who fail to meet any of the minimally acceptable objective quality metric thresholds. MDCH will require these hospitals to:</p> <p>a. Submit a corrective action plan within <u>three (3) months</u> of notification</p> <p>b. Demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds within <u>twelve (12) months</u> of notification.</p> <p>iv. MDCH will revoke the CON of hospitals that fail to meet the requirements set forth in iiib.</p>	<p>malignancy and life expectancy less than 1 year</p> <p>c. Patients with recent hemorrhagic stroke (Less than 8 weeks).</p> <p>d. Patients who are unable to tolerate antiplatelet therapy</p> <p>e. Patients with unprotected Left main disease</p> <p>f. Patients that may require hemodynamic support prior to the start of the procedure as decided by the clinician</p> <p>In case any center fails to provide adequate response or adhere to quality measures as defined by the quality sub-committee, the state will be notified.</p>
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Deliberate and create motion on quality Vote: (in favor/opposed)

Vote: MDCH actions related to those hospitals who fail to meet any of the minimally acceptable quality thresholds: (in favor/opposed)

- iv. If the hospital does not meet minimum state standards with respect to Appropriate Use Criteria, as measured by BMC2 (or like organization), the center will be notified immediately. The

physician champion will be responsible to lead the efforts to develop and submit an action plan as outlined in iiia and iiib.

**Pediatric language will be incorporated as identified in the document distributed by Renee Turner-Bailey.**

4. Consider any technical or other changes from the department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

**These adjustments have previously been recommended and approved by Department of Michigan staff related to definitions and geographies.**

**Table 6. Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery**

High-risk patients	Source
<ul style="list-style-type: none"> <li>• Decompensated congestive heart failure (Killip Class <math>\geq 3</math>) without evidence for active ischemia.</li> <li>• Recent (&lt;8 weeks) cerebrovascular accident.</li> <li>• Advanced malignancy.</li> <li>• Known clotting disorders.</li> <li>• LVEF <math>\leq 30\%</math>.</li> <li>• Chronic kidney disease (creatinine <math>&gt;2.0</math> mg/dL or creatinine clearance <math>&lt;60</math> mL/min).</li> <li>• Serious ongoing ventricular arrhythmias.</li> <li>• Patients with left main stenosis (<math>&gt;50\%</math> diameter) or three-vessel disease unprotected by prior bypass surgery (<math>&gt;70\%</math> stenoses in the proximal or mid segments of all major epicardial coronary arteries), treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure.</li> <li>• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.</li> <li>• Patients undergoing intervention on the last remaining conduit to the heart.</li> </ul>	PCI-GL AHA ECD
High-risk lesions	
<ul style="list-style-type: none"> <li>• Unprotected left main stenosis.</li> <li>• Diffuse disease (<math>&gt;20</math> mm in length).</li> <li>• Extremely angulated segment (<math>&gt;90^\circ</math>) or excessive proximal or in-lesion tortuosity.</li> <li>• More than moderate calcification of a stenosis or proximal segment</li> <li>• Inability to protect major side branches.</li> <li>• Degenerated older vein grafts with friable lesions.</li> <li>• Substantial thrombus in the vessel or at the lesion site.</li> <li>• Any other feature that could, in the operator's judgment, impede successful stent deployment.</li> <li>• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.</li> </ul>	PCI-GL ECD New
<p><i>The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.</i></p>	New
<p>Strategy for surgical backup based on lesion and patient risk</p> <ul style="list-style-type: none"> <li>• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.</li> <li>• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.</li> <li>• Non-high-risk patients with high-risk lesions require no additional precautions.</li> <li>• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.</li> </ul>	PCI-GL

*Italics font:* New or modified recommendation in the document.

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

Table 5. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations—Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis ( <i>Heart Team approach</i> ) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.	PCI-GL ECD New
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such as intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. <i>Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.</i>	PCI-GL ECD New
<b>Recommendations—Case Selection and Management</b>	
Avoid intervention in patients with:	PCI-GL
<ul style="list-style-type: none"> <li>• &gt;50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired.</li> <li>• Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography.</li> <li>• Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms).</li> <li>• Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI.</li> <li>• Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.</li> <li>• Chronic total occlusion.</li> </ul>	ECD New
<i>The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.</i>	
Emergency transfer for coronary bypass surgery patients with	PCI-GL
<ul style="list-style-type: none"> <li>• High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support.</li> <li>• Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.</li> </ul>	ECD

*Italics font: New or modified recommendation in the document.*

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.