



SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers

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Short Title: SCAI position on PCI in an ASC

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ABSTRACT:

The Centers for Medicare and Medicaid Services (CMS) began reimbursement for percutaneous coronary intervention (PCI) performed in ambulatory surgical centers (ASC) in January 2020. The ability to perform PCI in an ASC has been made possible due to the outcomes data from observational studies and randomized controlled trials supporting same day discharge (SDD) after PCI. In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation are comparable without any difference in short-term or long-term adverse events. Furthermore, a potential for lower cost of care without a compromise in clinical outcomes exists. These studies provide the framework and justification for performing PCI in an ASC. The Society for Cardiovascular Angiography and Interventions (SCAI) supported this coverage decision provided the quality and safety standards for PCI in an ASC were equivalent to the hospital setting. The current position paper is written to provide guidance for starting a PCI program in an ASC with an emphasis on maintaining quality standards. Regulatory requirements and appropriate standards for the facility, staff and physicians are delineated. The consensus document identified appropriate patients for consideration of PCI in an ASC. The key components of an ongoing quality assurance program are defined and the ethical issues relevant to PCI in an ASC are reviewed.

INTRODUCTION:

Interventional cardiology has undergone tremendous evolution since the initial percutaneous coronary intervention (PCI) was performed in 1977. In the early stages of procedural development, acute vessel closure occurred in almost 10% of patients, and therefore onsite cardiothoracic surgical support was required for provision of interventional coronary procedures. Over the ensuing years, advancements in procedural technique, devices and pharmacotherapy have led to a high proportion of procedural success with a low rate of major complications. [1, 2] During this time, the complexity of patients and procedures has increased. [2, 3] PCI without cardiothoracic surgical backup has transitioned from a Class III indication to a Class IIa indication [4, 5] and is routinely performed in the outpatient hospital setting. Furthermore, the high safety profile of the procedure and success of same-day discharge (SDD) programs have made it possible to perform elective PCI in non-hospital outpatient facilities. [6] Performance of PCI in lower acuity settings reduces its cost. [6, 7] Because of the excellent safety profile of elective PCI and the opportunity for lowering cost, the Centers for Medicare & Medicaid Services (CMS) initiated reimbursement for PCI performed in ambulatory surgical centers (ASC) on January 1, 2020. [8]

The Society for Cardiovascular Angiography and Interventions (SCAI) supported CMS' proposal to reimburse elective PCI in the ASC setting during the public comment period in 2019. [9] This support is contingent on the maintenance of high-quality standards as patients undergoing PCI in an ASC should

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receive the same quality of care as those receiving PCI as an outpatient in the hospital. This is a companion document to the SCAI Optimal PCI Therapy for Complex Coronary Artery Disease Consensus Statement differentiating appropriate patient care for PCI in the hospital and ASC setting.[3] It is intended to provide guidance for the development of an ASC-based PCI program, and for established programs seeking to maintain a high standard of care.

METHODS:

The need for a SCAI position paper on PCI performed in an ASC was identified by a working group of the SCAI Government Relations Committee. The writing group included members of the SCAI Government Relations Committee, the SCAI Quality Committee, the SCAI Executive Committee and SCAI members with significant prior experience with PCI in an ASC.

Before appointment, members of the writing group were asked to disclose financial relationships from the 12 months prior to their nomination. Author disclosures are included in Supplemental Table I. Consistent with the SCAI Publications Manual of Standard Operating Procedures, <50% of the writing group had any relevant conflict of interest.[10] Disclosures were periodically reviewed during document development and updated as needed. Writing group members with a current financial interest were recused from primary authorship of any relevant section of the document. The work of the writing committee was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

The Writing Group found no substantive data regarding the safety and efficiency of performing PCI in the ASC setting. Therefore, this document primarily reflects expert consensus opinion. The writing group reviewed relevant clinical guidelines and consensus papers [4, 11-17] as were available regarding performing PCI in an outpatient site of service and issues relevant to SDD after outpatient PCI.

The draft manuscript was peer reviewed in February 2020 and the document was revised to address pertinent comments. The writing group unanimously approved the final version of the document. The SCAI Publications Committee and Executive Committee endorsed the document as official society guidance in May 2020.

PERCUTANEOUS CORONARY INTERVENTION IN AN AMBULATORY SURGERY CENTER:

The ability to perform PCI in an ASC has been made possible due to the outcomes data from observational studies and randomized controlled trials supporting SDD after PCI. [7, 18-23] In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation were comparable without any difference in short-term or long-term adverse events. No safety signals were observed [7, 18-23] and SDD was associated with a lower cost of care in both the Early Discharge After Transradial Stenting of Coronary Arteries (EASY) randomized clinical trial and observational registries. [7, 22, 24, 25] These studies provide the framework and justification for performing PCI in an ASC.

Potential Benefits

The value proposition for performing outpatient PCI in an ASC versus the hospital outpatient environment, while dependent on consistent procedural efficacy and safety, offers improved efficiency of care, increased access to care, better patient satisfaction, and reduced cost. Advances in clinical decision-making, adjunctive pharmacotherapy, and procedural technology have continuously improved the safety profile of outpatient PCI. Data from the National Cardiovascular Data Registry (CathPCI) from 1612 hospitals (n=667,424) reveal that major complications after PCI are rare, and exceedingly so for elective PCI.[1] Cautious case selection based on patient and lesion characteristics can further reduce the risk of complication in the ASC setting.

A single randomized controlled trial from Canada and an observational registry in the United States show some cost savings with SDD after elective PCI, primarily by eliminating the cost of an overnight hospital stay.[7, 22, 25] The 2020 CMS-approved PCI reimbursement rates for the ASC setting are reduced by 30% as compared to the hospital outpatient setting. CMS anticipates \$20 million saved in cost, and \$5 million saved in copays, if just 5% of PCIs shift to ASCs. [26]

Potential Drawbacks of Outpatient PCI in the ASC setting

While there are potential benefits of outpatient PCI in the ASC setting, it is important to consider the drawbacks. There are extensive published data on the safety of outpatient PCI in a hospital setting, but none available for outpatient PCI safety in an ASC setting. The shift in procedural volume from hospitals to ASCs will have financial implications for hospitals that could potentially impact their ability to provide other necessary services. Although it is expected that PCI in an ASC would decrease overall expenditure, it is possible that the actual number of PCI procedures performed may increase. It is

the goal of this document to provide guidance on reducing the possibility of any negative clinical or financial outcomes.

REGULATORY CONSIDERATIONS:

Outpatient PCI can be currently performed in four different types of outpatient environments as defined by the CMS Place of Service (POS) Code system: POS 11 Office (i.e. Office Based Lab-OBL); POS 19 Off Campus-Outpatient Hospital; POS 21 On Campus-Outpatient Hospital; and POS 24 Ambulatory Surgical Center(ASC).[27] Prior to the new rule, Medicare only provided reimbursement for PCI in hospital-based settings. The rule enacted by CMS adds Medicare payment for PCI in the ASC setting but not in office-based labs (OBLs). An ASC must meet the criteria outlined by Medicare found in the Code for Federal Regulations (CFR) Title 42: Public Health, Part 416: ASCs.[28] The ASC must also meet any additional state level requirements, which are typically more stringent than those for OBLs.[29] The CMS rule has added coronary angioplasty and coronary stenting codes to the ASC Covered Procedure List establishing payment for six PCI Current Procedural Terminology (CPT) codes (Table 1).[8] Notably, PCI for coronary artery bypass grafts, chronic total occlusions (CTO), myocardial infarction or coronary atherectomy will not be reimbursed in an ASC site of service. It was the expressed written opinion by SCAI to CMS that these higher risk lesion subsets not be reimbursed in the ASC setting until more safety data are available regarding PCI in an ASC for lower-risk lesions. [8] However, SCAI strongly endorses reimbursement for physiologic and intravascular imaging studies, such as fractional flow reserve (FFR), intravascular ultrasound (IVUS) and Optical Coherence Tomography (OCT), respectively, in an ASC. The

reimbursement, availability and utilization of these studies would likely lead to reduced inappropriate PCI and improved clinical outcomes.

Before an ASC can serve governmental payor beneficiaries, the entity must have an agreement with CMS to participate in Medicare as an ASC. Specific federal conditions for coverage can be found on the CMS website.[30] The first condition for coverage states that “The ASC must comply with State licensure requirements,” and, therefore, to be eligible for CMS ASC Certification, the Catheterization Laboratory (Cath Lab) must first be licensed as an ASC in that individual state. Furthermore, regulation of the performance of PCI is under state jurisdiction and state licensing criteria that ASCs must meet prior to certification. Not all states allow the performance of PCI in the ASC setting. Some states require a certificate-of-need for a new Cath Lab, which is issued based on proof that the facility fulfills an unmet need in the community. Those considering starting an ASC-based PCI program should understand the legal requirements within their state.

Many ASCs choose to go through voluntary accreditation processes. Accreditation is sometimes referred to as a “third party survey” and is not mandatory for ASCs by federal regulations or to be contracted with CMS Medicare/Medicaid. However, accreditation may be mandatory in some states and with some payers. ASCs can seek accreditation from one of several accrediting bodies: The Accreditation Association for Ambulatory Health Care, Inc (AAAHC), The Joint Commission, or The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), and Healthcare Facilities Accreditation Program (HFAP).

Finally, the ASC's governing body must appoint an individual who has appropriate qualifications in accordance with State and Federal regulations to provide oversight of radiation issues.

STANDARDS:

This writing group believes that a PCI Cath Lab in an ASC needs to meet the standards outlined in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards.[11] The document describes facility design and standards for safe performance of PCI with assurance of staff safety. The document also addresses the requirement of adequate staffing to provide the required level of procedural and peri-procedural care and operator competency standards.

Facility and Equipment Standards:

Cath Labs must be designed in accordance with industry standards. National organizations, such as the Facilities Guidelines Institute, may be used as a resource to evaluate Cath Lab design and construction.[6, 31] Proper safety precautions including adequate radiation shielding for patients and personnel and personal radiation monitoring devices must be maintained.[32] There must be a distinct room within the ASC where patients recover immediately post-procedure. A "room" consists of an area with at least semi-permanent walls from floor to ceiling separating it from other areas of the ASC. Adequate equipment for post-procedure monitoring such as telemetry, automated blood pressure cuffs, and pulse oximetry must be available.

The ASC must be equipped with the necessary supplies for PCI. Equipment must also be available to address potentially catastrophic complications, including:

- pericardiocentesis tray
- echocardiography/ultrasound capable of assessing for pericardial effusions
- temporary transvenous pacemaker
- covered stents
- mechanical circulatory support (e.g. intra-aortic balloon pump)
- Advanced Cardiac Life Support (ACLS) supplies, medications, and equipment including a defibrillator and a ventilator.
- On-site ASC provider with expertise in endotracheal intubation and airway management.

In addition to emergency equipment, the facility should be capable of performing physiologic lesion assessment. Either IVUS or OCT should also be available for anatomic lesion and stent assessment. Peripheral vascular ultrasound availability is important for safe access and the ability to measure point-of-care activated clotting time is essential.

Procedural and Periprocedural Standards:

The SCAI 2016 Best Practices in the Cardiac Catheterization Laboratory document should serve as a guide for clinical management.[14] All staff involved in direct patient care should be ACLS certified. The ASC must ensure that the nursing service is directed under the leadership of an RN. There must be sufficient nursing staff with the appropriate qualifications to address the nursing needs of all the patients. A mechanism to notify other health care personnel in the ASC of any patient emergency should be in place. Finally, the ASC must follow the American Society of Anesthesiology guidelines for sedation.

[33]

Transfer Protocols:

For medical emergencies requiring care beyond the capabilities of the ASC, an efficient procedure must be in place to facilitate immediate patient transfer from the ASC to an appropriate receiving hospital. A receiving facility should be located within 60 minutes travel time by ground or air transportation.[13] Ideally, a written transfer agreement would be in place between the ASC and the receiving facility even though this formality is not mandated by CMS.[34] The local receiving hospital must be either a Medicare-participating hospital, or a non-participating hospital meeting emergency services payment requirements per CMS guidelines. An “effective procedure” for immediate emergency transfers includes having an established written policy that addresses the circumstances warranting transfer, parties involved in the transfer decision on both the transferring and receiving end, accompanying documentation, emergency medical services (EMS) communication, and communication with the receiving facility at both a physician and nursing level. The ASC must also have an effective protocol with ambulance services and/or medical flight services to transfer patients requiring emergency services to a management capable hospital in an expedited fashion. An appropriate communication plan must be in place between the ASC and emergency transfer services. There must be evidence that the staff are aware of, and can implement the ASC’s policy immediately upon development of, a medical emergency. The ASC must provide emergency care within its capabilities and initiate stabilizing treatment until the patient is transferred.

Operator Standards:

The interventional cardiologist performing the PCI procedure must be licensed in the state in which the ASC is located and must practice within the scope of his/her license. Each physician performing procedures in the ASC must have been determined to be qualified and have been granted privileges under rules established by the governing body of the ASC. The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials, determining whether to grant privileges and defining the scope of privileges for each physician. Although all credentialing decisions are local, SCAI strongly endorses interventional fellowship training, board certification, and a minimum annual volume of at least 50 PCI procedures per operator.[16] SCAI also cautions against newly-trained interventional cardiologists performing PCI in the ASC setting. The initial guideline for PCI without on-site surgical backup suggested >500 interventions as a primary operator.[35] It is recognized that this number may be difficult to reach in the current era, but it is the opinion of SCAI that PCI in an ASC be performed by experienced operators with an established record of acceptable outcomes. These concerns are of even greater importance in an ASC where additional providers may not be available to assist as the clinical need of the patient dictates.

The governing body is required to solicit the opinion of qualified medical personnel on the competence of the applicant for privileges. ASCs should consider seeking the recommendation of qualified outside physicians when they do not have the appropriate in-house expertise to evaluate the competency of the applicant for privileges. Medical staff privileges must be periodically reappraised by the ASC.

An explicit written policy should indicate how the medical staff is held accountable by the governing body. It is possible for an ASC to be owned and operated by one physician who is both the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases, the physician owner must still implement a formal process for complying with all medical staff regulatory requirements.

SCOPE OF PROCEDURES:

Although many cardiovascular procedures can potentially be performed in an ASC, this position paper addresses adult PCI and diagnostic cardiac procedures only. Previously, procedures that may be unsuitable for PCI without on-site cardiac surgery have been described[11, 13] and similar cautions apply to ASCs. As in the hospital setting, PCI may be performed "ad hoc" with a similar decision-making process.[12] However, there are additional concerns unique to the ASC setting that must be considered when proceeding to PCI.

Appropriate Patients and Procedures:

A concurrent SCAI document detailing state-of-the-art practice for complex CAD provides guidance regarding site performance locations for such patients.[3] PCI in patients with high-risk clinical features should be avoided in the ASC setting (Table 2). Lesions with complex features and those associated with higher complication rates should also be avoided in an ASC setting (Table 3). Elective procedures possibly requiring mechanical circulatory support should not be performed in ASCs, although the ability to emergently insert an intra-aortic balloon pump should be readily available.

Diagnostic procedures (e.g. left and right heart catheterization, coronary and graft angiography) are appropriate for ASCs. Invasive diagnostic testing that involves intravascular imaging (IVUS and/or

OCT) or functional evaluation (FFR and/or resting indices) and coronary angioplasty and stenting are appropriate in an ASC. As discussed earlier, bypass graft PCI, coronary atherectomy, CTO PCI and PCI for acute coronary syndromes have higher complication rates and should be avoided in the ASC setting. These procedures are also not reimbursed by CMS when performed in an ASC. Until safety for lower risk PCI in an ASC can be demonstrated across the country in large populations, these and other more complex interventions should be restricted to a hospital environment.[3]The SCAI PCI risk calculator may be a useful tool for guiding decisions regarding the most appropriate setting for a specific patient. The calculator can be accessed at www.scaipciriskapp.org" www.scaipciriskapp.org.

Only patients who are appropriate for SDD should be considered for intervention in an ASC. The 2018 SCAI Expert Consensus Document on Length of Stay Following PCI provides guidance on patient suitability for SDD.[17] However, not all patients that might be suitable for SDD in the hospital setting are appropriate for ASC-based PCI. The ASC setting does not provide the option of easily converting a patient to overnight observation. For example, a bifurcation intervention might be suitable for SDD but if there is side branch loss it would need to be converted to an overnight stay. The probability of such an event must be carefully considered in the ASC setting. Another consideration is the lack of ancillary support in the ASC setting. Patients that might require additional resources post procedure (e.g. respiratory therapy, dialysis) would not be appropriate for the ASC setting. Patients must also have transportation home, adequate social support and reliable follow up.

It is recommended that all ASC PCI facilities have a protocol in place that guides patient selection and procedural decision-making. All operators should be educated on the protocol and monitored for adherence. Copies of the protocol should be kept on-site and readily accessible to all operators and staff. A suggested protocol is depicted in Figure 1 and Table 4. It is also encouraged that a “radial first” approach be utilized for ASC PCI. Radial access is ideal in the ASC setting to minimize bleeding, access site complications, reduce staff workload, and decrease the risk of an overnight observation for femoral access site concerns.[15]

ONGOING QUALITY:

PCI in the ASC site of service should be performed with the same expectations for quality as in the hospital. A quality program must be in place to evaluate procedure appropriateness, technical performance, and assurance of quality of care. The SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup contains recommendations applicable in the ASC setting.[13] In addition, key components of a recommended quality program have been recently outlined by SCAI but would need to be modified to account for the ASC environment.[14] Key topics to cover for ASCs are outlined in Table 5.

Participation in a PCI registry that is specifically designed or modified for the ASC setting will be necessary for ongoing quality assurance. This can be accomplished by the creation of a new outpatient PCI registry or through leveraging existing national cardiovascular registries, such as the NCDR CathPCI registry. Registry data should be used to monitor PCI operator and institutional volumes, outcomes, and procedural appropriateness.[36] This would allow benchmarking, establishment of performance standards and appropriate risk adjustment for evaluation of outcomes. There is no current registry specific to PCI in an ASC. The Outpatient Endovascular and Interventional Society (OEIS) has developed a national registry that is a Qualified Clinical Data Registry (QCDR) focused on outcomes within outpatient interventional suites (OIS) and ASCs.[37, 38] While this QCDR only supports a peripheral vascular interventional module, the OEIS plans to offer a single cardiac module specifically focused on all cardiac interventions performed in the OIS and ASC. The NCDR CathPCI registry is well established but does not yet accept submission of data from ASCs and does not include metrics specific to the ASC site of service. The development of a registry suitable for assessing ASC PCI quality metrics is needed. It is imperative

that such a registry be developed with consideration of the potential administrative burden that participation might have on an ASC and should only include essential quality assurance metrics. Data abstraction teams, as are typically found in the hospital setting, may not be financially sustainable in the ASC environment at the current reimbursement rates.

CMS is finalizing the Ambulatory Surgical Center Quality Reporting (ASCQR) Program to enhance the quality of care in the outpatient surgical setting. The ASCQR Program is a pay-for-reporting quality program for the ASC setting that requires an ASC to meet quality reporting requirements or else undergo a 2.0 percentage point reduction in its annually updated fee schedule. Relevant patient safety measures that are currently reported to CMS include all-cause hospital transfer/admission.[37] These measures for ASCs were developed because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting could be an indication of a complication, serious medical error or other unplanned negative patient outcome. The ASCQR program should be improved with specific SCAI-recommended measures that would help better evaluate the safety of PCI in the ASC setting.

ETHICAL CONSIDERATIONS:

All ASC operations and clinical care must be conducted consistent with The American Medical Association Code of Medical Ethics.[39] The physician and the ASC have an ethical duty to place patient's interests first. This core value should guide the ASC's code of conduct. Ownership in an ambulatory surgical center presents a potential conflict of interest that requires active guidance, policy development

and approaches to address this issue. ASC ownership may include a combination of physician investors and/or a regional/national business enterprise. In addition to the ownership of the ASC, physician-owned intermediaries (POI) have been developed to provide additional potential financial compensation via the sale of medical devices to the ASC. This provides a potential conflict as medical decision making could be impacted by implanting devices that result in a financial benefit to the physician and/or ASC. The three types of POI include the distributor POI, manufacturer POI and the group purchasing organization.

Important principles to consider in order to address this issue are as follows:

- A. Remuneration should not be based on utilization and/or referrals. Neither the ASC, nor other investors, should provide loans to potential new physician investors.
- B. Fee splitting is illegal. Payment by a physician to another physician/clinician for referrals should not occur.
- C. A robust quality assurance and utilization review program should be implemented to monitor physician self-referral.
- D. Referral to the ASC versus hospital should be determined by medical policy developed on evidence- or consensus-based principles.
- E. Administrators/management should not pressure physician investors who select alternative sites for patients to receive care.

- F. Policies should be developed that support the ability of physicians to care for patients more likely to experience disparities in care based on social demographics and/or insurance status.

Federal law, including Stark Law exceptions and Anti-Kickback Statute safe harbors, coupled with ethical principles, dictate that the physician must disclose both ownership and additional compensation factors to patients making informed choices. Ideally, disclosures would be performed before the patient arrives at the ASC for a procedure. Best practices would include:

- a. Disclosure to the patient of ownership interest
- b. Disclosure to the patient of additional structure which impacts physician compensation
- c. Disclosure, when requested by the patient, of a full list of investors
- d. Information regarding alternative choices including other ASCs and hospitals for patients

CONCLUSION:

Interventional cardiology continues to be an innovative and rapidly evolving field that offers increasing safety for selected patients undergoing PCI. As performing PCI in an ambulatory environment can be performed safely and is now reimbursed, it is important to establish the optimal strategy and model to keep doing so. The decision to perform PCI in an ASC must be made in the context of the local healthcare environment, while initiation of an ASC PCI program requires transparent adherence to state and federal regulations and operational

standards. Patients should receive the same quality of care regardless of the procedural site of service and ongoing quality assurance monitoring will be imperative for the long-term success of this endeavor. This SCAI writing group believes that it has laid a foundation of principles to promote safe performance of elective PCI in ambulatory surgery centers.

Table 1. CPT Codes Approved for Reimbursement by CMS

Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting

Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

Table 4. Ambulatory Surgical Center PCI Performance Checklist

Table 5. Key Features of a High-Quality ASC PCI Program

Figure 1. Patient Pathway for ASC PCI

Supplemental Table 1. Author Disclosure Information

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Table 1. CPT Codes Approved for Reimbursement by CMS

CY 2020 Procedural Code	CY 2020 Procedural Code Long Descriptor
CPT Code 92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch
CPT Code 92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
CPT Code 92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
CPT Code 92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
HCPS Code C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
HCPS Code C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)

CPT = Current Procedural Terminology; HCPCS = Healthcare Procedure Coding System

Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting

1. Decompensated CHF (NYHA Class 3 to 4)
2. Recent TIA/stroke (<8 weeks)
3. Left Ventricular Ejection Fraction <30%
4. Chronic Kidney Disease with an estimated Glomerular Filtration Rate < 45 mL/min/1.73 m²
5. Anemia (Hgb < 9 g/dL) or coagulopathy (e.g. INR >1.5 or platelet count < 100K)
6. Acute coronary syndrome
7. Severe pulmonary hypertension or disease (advanced COPD or patients on supplemental oxygen)
8. Unprotected left main stenosis or three-vessel CAD
9. Any cardiac or non-cardiac signs of clinical instability.
10. Significant PAD limiting femoral and radial access.
11. Severe aortic stenosis
12. Severe contrast allergy
13. Operator judgment on other condition(s)

CHF = Congestive Heart Failure; TIA = Transient Ischemic Attack; Hgb = Hemoglobin; INR = International Normalized Ratio; COPD = Chronic Obstructive Pulmonary Disease; CAD = Coronary Artery Disease; PAD = Peripheral Artery Disease

Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

1. Bifurcation lesions with significant side branch involvement
2. Severe lesion calcification
3. Extremely angulated segment or excessive proximal tortuosity
4. Bypass graft lesions
5. Chronic total occlusions
6. Other vessel characteristics that the operator judges would impede stent deployment
7. Thrombus in target vessel or lesion
8. Unprotected left main lesions
9. Last remaining conduit
10. Possible need for upfront mechanical circulatory support

Table 4: Ambulatory Surgical Center PCI Performance Checklist**Pre-Scheduling Assessment:**

- Confirmed transportation after procedure
- Adequate social support at home. Adequate caregiver at home the evening of discharge
- Patient resides or stays in close geographic proximity (≤ 30 minutes driving time) to a hospital capable of providing emergency care for complications that could occur after discharge
- No unfavorable patient clinical features or PCI indications (Table 2)
- No known complex/high-risk anatomical features (Table 3)
- Patient fully understands plans for ASC PCI and same day discharge

Morning of Procedure Assessment:

- Transportation, social support and post discharge geographic location confirmed
- Patient signed informed consent and disclosures regarding relevant financial interests of the interventional physician
- Patient evaluated by physician and confirmed to be appropriate for ASC PCI

Post-PCI Assessment:

- Favorable PCI features:
 - Successful PCI: $<30\%$ residual stenosis with final TIMI 3 flow
 - Transradial approach (preferred but not mandatory)
 - Successful access site hemostasis
- Unfavorable PCI features (consider patient transfer to hospital setting if present)
 - Loss of side branch > 1 mm in diameter
 - Significant no-reflow during the procedure
 - NHLBI Type B-F dissection in the target vessel at the end of the procedure
 - Intracoronary thrombus that arose during the procedure
 - Transient vessel closure during the procedure likely to precipitate significant infarction
 - Vascular access complication
 - Any cardiac or non-cardiac instability during PCI
 - At the discretion of the attending physician
 - Patient preference to stay overnight

Pre-Discharge Assessment:

- Absence of chest pain, access site hematoma and cardiac rhythm abnormalities
- Four hours of observation completed
- ECG prior to dismissal reviewed and without significant change
- Follow up appointment scheduled within 1-2 weeks
- Patient is able to obtain DAPT and other prescriptions by the following morning
- Patient accompanied by an adult at the time of discharge and at home

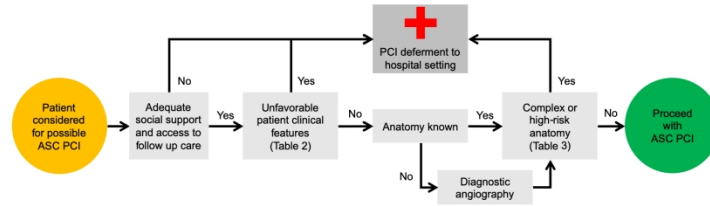
PCI = Percutaneous Coronary Intervention; ASC = Ambulatory Surgical Center; TIMI = Thrombolysis In Myocardial Infarction; NHLBI = National Heart Lung and Blood Institute; ECG = Electrocardiogram; DAPT = Dual Antiplatelet Therapy

Table 5. Key Features of a High-Quality ASC PCI Program

Pre-Procedural	Procedural	Post-Procedural
Appropriate informed consent including risk of transfer for complications	Established criteria for high-risk coronary anatomy that require transfer for safe PCI performance	Appropriate documentation of required data elements for cath and PCI reporting
Appropriately trained staff and PCI operators	Appropriate training/supplies for conscious sedation	Registry participation to evaluate procedural outcomes and appropriateness
Established quality insurance program for continuous peer review of quality and outcomes	Emergency preparedness protocols in place	Established criteria for clinical indications for transfer to acute care facility
Written transfer agreements with hospitals and surgeons	Mock transfer drills with EMS and “receiving” hospital	Evaluation of acute care required within one month after discharge
Established clinical criteria for determination of high-risk patients	Ability for real-time image review for CT surgical consultation	Appropriate clinical follow up scheduled within 1-2 weeks of PCI

PCI=Percutaneous Coronary Intervention; EMS= Emergency Medical Services

Figure 1. Patient Pathway for Ambulatory Surgical Center Percutaneous Coronary Intervention



ASC=Ambulatory Surgical Center; PCI=percutaneous coronary intervention; Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting; Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

Figure 1. Patient Pathway for Ambulatory Surgical Center Percutaneous Coronary Intervention. ASC=Ambulatory Surgical Center; PCI=percutaneous coronary intervention; Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting; Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

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