Managing the Shift to Elective PCI in the ASC Setting

Is your interventional cardiology program prepared?

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After years of debating how interventional cardiology should fit into an ambulatory strategy for the cardiovascular service line (CVSL), we must recognize the clear signaling from the Centers for Medicare & Medicaid Services (CMS) of an expectation to provide lower-cost interventional care in the nonhospital ambulatory setting.

In November 2019, CMS issued its final rule on percutaneous coronary intervention (PCI) in the ambulatory surgical center (ASC) setting by approving the addition of six CPT codes to the ASC-covered procedures list for calendar year (CY) 2020 (Table 1).[1] CMS considers these procedures clinically similar to those that do not require an overnight stay and are currently covered under the Outpatient Prospective Payment System (OPPS). As in the hospital outpatient department/facility setting, "additional branch of a major coronary artery" codes are not reimbursed; however, organizations such as the American College of Cardiology (ACC) encourage continued reporting of these services.

In the comment period before the final rule for CY 2020, the ACC and the Society of Cardiovascular Angiography and Interventions (SCAI) offered comments that were generally supportive of PCI in the ASC setting for a limited subset of patients, with some reservations around patient risk stratification, infrastructure, patient safety, and reimbursement.[2,3]

It's important to recognize that there are challenges to overcome related to cost, regulation, and reimbursement for the ASC environment. State regulations governing ASCs and PCI in the ASC setting vary across the country, and a new ASC will require 12 to 24 months from concept to fully functional. There are some programs with an existing ASC space where adding imaging equipment is possible. However, even in this scenario, structural renovation may be necessary to accommodate PCI services. Although hospital programs will see a substantial reduction in reimbursement for Medicare patients, many markets will see early adopters enter the ASC space to defend market share in the elective outpatient PCI population. Private payers traditionally follow the lead of CMS in coverage determinations and, predictably, will be quick to do so with PCI. They are also likely to emphasize the Medicare coverage determination as evidence that care in the ASC setting is safe for cardiovascular care. Programs that have not determined how and when PCI in the ASC setting will fit into their CVSL ambulatory strategy should act now.

BACKGROUND

In the proposed rule for the CY 2020 Medicare Hospital OPPS and ASC Payment System, CMS indicated its intent to redesign the ASC-covered procedures list to "improve physicians' ability to determine the setting of care as appropriate for a given beneficiary situation."[4] In the final rule,

TABLE 1. APPROVED CPT CODES FOR PCI PROCEDURES IN THE ASC SETTING

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

Abbreviations: ASC, ambulatory surgery center; CPT, Current Procedural Terminology; PCI, percutaneous coronary intervention.

CMS notes the success and safety of programs that have performed peripheral vascular intervention procedures in nonhospital ambulatory settings for more than a decade. In its comments to CMS, the ACC referenced the 2014 SCAI/ACC/American Heart Association (AHA) expert consensus statement that addressed the performance of PCI without surgical backup as a source of guidance for performing PCI in an ASC setting.[5]

PROGRAM ASSESSMENT

As CVSL leaders begin to develop a strategy for PCI in the ASC setting, a comprehensive assessment of existing infrastructure and resources is critical—both within the service line and within the larger organization/system.

Operator Experience

CMS previously required ASCs to have a transfer agreement with an acute care hospital, and physicians practicing at ASCs were required to have privileges at the acute care hospital. Both requirements were eliminated in the final rule for CY 2020.

The published guidance in the 2014 SCAI/ACC/AHA expert consensus statement for performing PCI addresses programs that care for ST-segment elevation myocardial infarction and primary PCI.[5] The recommendations for performing PCI in a setting without surgical backup describe requisite minimum interventional cardiology operator experience, an affiliation with a hospital that performs PCI, and a "working relationship" with cardiac surgeons at another facility who can provide surgical backup in the event of an emergency.

Below are the guidance details for requisite operator experience included in the consensus statement:

- Operators performing PCI in a setting without surgical backup should perform ≥ 50 PCIs annually (averaged over 2 years), including ≥ 11 primary PCIs annually.
- Ideally, the procedures should be in institutions performing > 200 total and > 36 primary PCI procedures annually.

Although patients who will undergo PCI in an ASC will be a lower-risk population collectively, this published guidance should be used as a resource in planning the transition to the ASC setting.

Ambulatory Practice Adaptation: Patient Selection

In the final rule, CMS states the importance of making PCI payable in the ASC setting, acknowledging that "a majority of Medicare beneficiaries may not be suitable candidates to receive these procedures in an ASC setting due to factors such as age and comorbidities."[1] They note that the decision of whether to furnish services in the ASC setting should be based on the physician's clinical assessment of the patient's risk factors.

Processes used in many CVSLs to determine eligibility for PCI in the hospital outpatient setting are often limited to whether an overnight stay will be required. Although this provides a starting point in planning for PCI services in an ASC, a much smaller population of patients will be suitable for it—at least initially. The 2014 consensus statement provides guidance for excluding patients and coronary lesions potentially considered inappropriate for elective PCI in a setting without surgical backup (Table 2). The published guidance may assist programs in planning a formal risk stratification process to guide in assessing which patients are appropriate candidates for care in the ASC setting. Additional clinical considerations, insurance coverage, and socioeconomic factors that may impact same-day discharge (SDD) are also important in determining if the ASC setting is appropriate.

Transradial Access

Transfemoral access has been safely performed and managed in patients undergoing peripheral vascular interventions in the nonhospital outpatient setting for many years. However, planning for the routine use of transradial access in the ASC setting will support better patient experience and reduced postprocedure length of stay. Understanding what percentage of your program's elective outpatient PCIs are likely to be transradial access versus transfemoral access is important in planning infrastructure, care processes, and patient flow for an ASC setting.

Same-Day Discharge

SDD postprocedure is an obvious need for the ASC setting. This practice has also been safely demonstrated in the nonhospital outpatient setting for peripheral vascular interventions. As a result of being pressured for hospital bed space for years, many CVSLs have made progress toward creating an evidence-based approach for SDD in the low-risk, elective, outpatient PCI population. Planning this process for the subset of lower-risk patients eligible to move to the ASC setting should be easily accomplished.

MEDICARE REIMBURSEMENT

Impact on Elective Outpatient PCI Medicare Rates

In the final rule, CMS estimates that if 5% of coronary interventions shift to the ASC setting in 2020, Medicare payments will be reduced by $20 million. The impact on the hospital CVSL revenue line is approximately 50% to 60% reduction in Medicare reimbursement per case moved to the ASC setting—roughly, $6,000 per case (Table 3).

Although more shifts from the hospital outpatient department will result, programs may look to additional strategies for generating revenue in the lower-cost ASC setting.

TABLE 2. PATIENT AND LESION CHARACTERISTICS THAT COULD BE UNSUITABLE FOR NONEMERGENCY PROCEDURES AT FACILITIES WITHOUT ON-SITE CARDIAC SURGERY

High-Risk Patients	Source
Decompensated congestive heart failure (Killip class ≥ 3) without evidence for active ischemia	PCI-GL AHA ECD
Recent (< 8 weeks) cerebrovascular accident	
Advanced malignancy	
Known clotting disorders	
LVEF ≤ 30%	
Chronic kidney disease (creatinine > 2 mg/dL or creatinine clearance < 60 mL/min)	
Serious ongoing ventricular arrhythmias	
Patients with left main stenosis (> 50% diameter) or three-vessel disease unprotected by prior bypass surgery (> 70% 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	
Patients with a single target lesion that jeopardizes an extensive amount of myocardium	
Patients undergoing intervention on the last remaining conduit to the heart	
High-Risk Lesions	**Source**
Unprotected left main stenosis	PCI-GL ECD *New*
Diffuse disease (> 20 mm in length)	
Extremely angulated segment (> 90%) or excessive proximal or in-lesion tortuosity	
More than moderate calcification of a stenosis or proximal segment	
Inability to protect major side branches	
Degenerated older vein grafts with friable lesions	
Substantial thrombus in the vessel or at the lesion site	
Any other feature that could, in the operator's judgment, impede successful stent deployment	
Anticipated need for rotational or other atherectomy device, cutting balloon, or laser	
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.	*New*
Strategy for Surgical Backup Based on Lesion and Patient Risk	**Source**
High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery	PCI-GL
High-risk patients with non–high-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary	
Non–high-risk patients with high-risk lesions require no additional precautions	
Non–high-risk patients with non–high-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery	

Note: Italics indicates new or modified recommendation in the document.

Abbreviations: AHA, American Heart Association; ECD, 2012 expert consensus document on cardiac catheterization standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

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Cardiac rhythm management (CRM) procedures. CRM device implants have been approved for payment in the ASC setting for some time. In the fiscal year 2019, payment rates for CRM device procedures improved, making a move to the ASC setting more attractive from a revenue perspective for some programs. However, patient selection requires the same level of detail as PCI.

Peripheral vascular interventions. Approved for more than a decade, physicians have successfully managed device costs to provide lower-cost interventional peripheral vascular care in a nonhospital outpatient setting. This population will be attractive to CVSLs across several physician specialties. Patient selection criteria for the nonhospital ambulatory setting are well established.

REGULATORY AND ACCREDITATION CONSIDERATIONS

To say that regulatory and accreditation considerations for new ASCs are complex would be an understatement. They are subject to numerous, often overlapping, federal and state regulatory requirements. Certificate of Need laws are in flux in several states. Third-party accreditation is required in some states and voluntary in others; it is also highly valued by third-party payers, some of whom have already approved payment for PCI in the ASC setting. The addition of PCI services to an existing ASC will be subject to many of the same regulations. Accordingly, new construction or renovation will require specific state-dependent planning early in the strategic planning process.

STRATEGIC RELATIONSHIPS

Receiving Hospitals and Surgical Programs

Although CMS eliminated the requirement for ASCs to have a transfer agreement with an acute care hospital in the CY 2020 final rule and the risk of untoward events in the patient population is low, a hardwired process to collaborate with a cardiothoracic surgery team is a need in the early transition of PCI services to the ASC setting. In planning the transition, CVSL programs should create a multidisciplinary team to plan for the possibility of urgent transfer for surgical evaluation. The team should include administrative and clinical leaders of the CVSL and ASC, as well as representation from interventional cardiology, cardiothoracic surgery, cath lab, cardiovascular operating room, transfer services, emergency department, nursing leadership, emergency medical services, and any other representation necessary to plan and execute urgent patient transfer from the ASC for surgical evaluation. Flowcharting the process can provide a simple but consistent guideline, and periodic mock drills may be incorporated into the ASC's quality management program.

TABLE 3. IMPACT ON ELECTIVE OUTPATIENT PCI MEDICARE RATES

Site of Service	Estimated Blended Average
Hospital	$12,000
ASC	$6,200

Abbreviations: ASC, ambulatory surgical center; PCI, percutaneous coronary intervention.

Physician Partners

ASC ownership by physicians and hospitals is on the rise. The decision about whether to partner with physicians in a joint venture model is highly market-driven. Because the joint venture model can implicate federal and state antikickback statutes, knowledgeable legal resources are needed in the strategic planning process if physician partnerships will be considered.

Payers

As programs prepare for Medicare patients, commercial payers will have an interest in providing the ASC site of service as a lower-cost option for their beneficiaries. Strategically, CVSL leaders will need to work with finance to exert influence in contracting to the extent possible. Primary considerations will be patient selection criteria and payment rates.

FACILITY AND PERSONNEL CONSIDERATIONS

The 2014 SCAI/ACC/AHA expert consensus statement provides straightforward recommendations for facilities performing PCI without surgical backup (Table 4). Although the document was aimed at hospitals performing PCI without surgical backup, several recommendations are applicable in the ASC setting and others will require consideration. The equipment and inventory of supplies will be developed as the scope of services to be provided in the ASC setting is developed. Adjunct services, such as intravascular ultrasound and fractional flow reserve, will need to be considered within the restraints of cost.

Nursing and Ancillary Personnel

The shift to PCI in the ASC setting brings the additional challenge of nursing and ancillary staffing. When selecting personnel for the ASC lab, experience in a cath lab is highly recommended as part of the minimum competency criteria. Hospital programs are experiencing critical shortages in the cath lab setting, with most programs relying, to some level, on temporary travel staff to serve in registered nurse and tech roles. There will be fewer team members required to staff the ASC program, and without call and weekend responsibilities, positions in the ASC setting will be attractive to experienced members of the hospital cath lab and recovery teams. These factors put the recruitment and

TABLE 4. FACILITY REQUIREMENTS FOR PCI PROGRAMS WITHOUT ON-SITE SURGERY

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program; program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR, and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely (1) review quality and outcomes of the entire program; (2) review results of individual operators; (3) include risk adjustment; (4) provide peer review of difficult or complicated cases; and (5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS AHA PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of two times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤ 30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery*. Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within < 120 min of an urgent referral*.	PCI-GL AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required*. Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI.	PCI-GL AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment, and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based class I therapies, both acutely and at discharge.	PCI-CS ML
Full-service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing < 200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger-volume facilities. Both physicians and staff should have the opportunity to work at a high-volume center to enhance their skills. The continued operation of laboratories performing < 200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is > 30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL

Note: Italics indicates new or modified recommendation in the document.

Abbreviations: ACC, American College of Cardiology; AHA, American Heart Association; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 expert consensus document on cardiac catheterization standards; IABP, intra-aortic balloon pump; ML, Mission Lifeline; MR, magnetic resonance; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI competency statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention.

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retention of the nursing and ancillary team high on the list of priorities when expanding a program to the ASC setting.

Evidence-Based Care and Patient Education

ASCs bring some welcomed relief by scaling back the administrative processes required in the hospital outpatient department, but it is important to ensure the same level of attention is given to evidence-based care, patient and family education, and access to follow-up care after PCI.

Medication management processes should follow regulatory requirements for the ASC, but planning should accommodate processes to ensure that evidence-based guidelines are used for managing medication in the ACS population, including aspirin, thienopyridine/P2Y12 inhibitors, and statin prescribed at discharge.

Many programs have worked to ensure that patient education is consistent across the physician practice setting and the hospital. Much of that work can and should be duplicated for patient education in the ASC, including:

- Understanding risk factors and reducing the event of a cardiovascular event
- Diet and exercise
- Medication
- Self-care
- Referral to cardiac rehab

OUTCOMES MONITORING AND PEER REVIEW

Hospital-based labs have a substantial amount of data related to coronary angiography and interventions. Many programs participate in the ACC's National Cardiovascular Data Registry (NCDR) CathPCI Registry, which has tracked millions of inpatient and outpatient PCIs and coronary interventions. Physicians and CVSL leaders are accustomed to reports that provide benchmarked, risk-adjusted rates of mortality and complications, appropriate use measures, length of stay, resource use, and cost of care. Currently, there are no registries that support reporting and benchmarking PCI in the ASC setting. In its comments to CMS, the ACC highlighted this void and stated that participation in a national data registry should be required to allow for a similar level of benchmarking, risk adjustment, and outcomes analysis.

ASCs are regulated under the Medicare Conditions for Coverage, which include requiring a program for ongoing assessment and improvement of quality and patient safety. Additionally, monitoring quality and patient safety may vary from one accrediting body to another or from state to state under licensure requirements. However, as the ACC points out, there is an absence of measures specific to the PCI population that have been defined by a national registry or CMS. CVSL leaders will need to plan a strategy to measure clinical and financial performance, appropriateness, and patient experience in the ASC setting. NCDR CathPCI Registry and/or merit-based payment system measures may serve as sources to identify potential measures. It will be important to formally define measures and the means and frequency of data collection, analysis, and reporting. Ideally, these measures will be incorporated into the required CMS, state, and accreditation quality monitoring program.

Consistent with the 2014 SCAI/ACC/AHA expert consensus statement, there should be a mechanism for peer review, including random and individual operator case reviews and review of untoward outcomes. All cases transferred for emergency surgery should be reviewed to identify opportunities for improvement.

CONCLUSION

ASCs are a step forward in providing outpatient elective PCI in a lower-cost setting. This comes as a result of the experience afforded through millions of cases in the hospital setting over more than 4 decades, achieved despite repeated draconian cuts to reimbursement. That clinical experience has prepared us to thoughtfully design and implement safe, evidence-based care in the nonhospital ambulatory setting. However, unless or until CMS revises the payment rates and policies, the shift to the ASC setting will likely be limited in many markets. CVSL leaders will need to be strategic and aggressive to mitigate the level of impact on the structure and margins of our hospital programs. But plan we must, because PCI in the ASC setting will help us ring in the new decade. ■

1. Federal Register. Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; revisions of organ procurement organizations conditions of coverage; prior authorization process and requirements for certain covered outpatient department services; potential changes to the laboratory date of service policy; changes to grandfathered children's hospitals-within-hospitals; notice of closure of two teaching hospitals and opportunity to apply for available slots. https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center. Accessed January 2, 2020.
2. American College of Cardiology. ACC comments on CY 2020 hospital OPPS proposed rule. https://www.acc.org/latest-in-cardiology/articles/2019/09/30/15/06/acc-comments-on-cy-2020-hospital-opps-proposed-rule. Accessed January 2, 2020.
3. Society for Cardiovascular Angiography & Interventions. SCAI Comments to CMS: 2020 HOPPS-ASC proposed rule—PCI in the ambulatory surgical center, non-hospital setting. http://www.scai.org/advocacy/detail.aspx?cid=0a10f247-9715-4249-89bc-2d4b23dab9bc. Accessed January 2, 2020.
4. Centers for Medicare & Medicaid Services. CY 2020 Medicare hospital outpatient prospective payment system and ambulatory surgical center payment system proposed rule (CMS-1717-P). https://www.cms.gov/newsroom/fact-sheets/cy-2020-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center. Accessed January 2, 2020.
5. Dehmer CJ, Blankenship JC, Cilingiroglu M, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol. 2014;63:2624-2641.

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