Appropriateness and Safety of Coronary Interventions in the OIS/ASC

Rick Snyder, MD
President HeartPlace, P.A.
Dallas, Texas

OUTPATIENT ENDOVASCULAR AND INTERVENTIONAL SOCIETY
OEIS 7TH ANNUAL NATIONAL SCIENTIFIC VIRTUAL MEETING
September 25, 2020

Disclosures

2 Joint Ventured Heart Hospitals

2 OBL/ASC Cath labs:

- Medfinity Health Plano
- Medfinity Health Euless


Medfinity Health
Plano

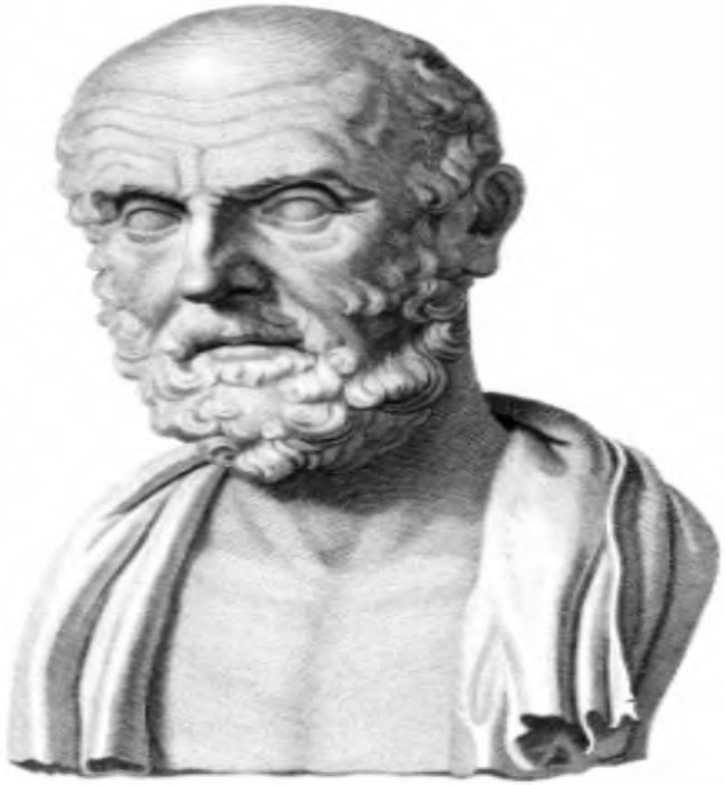

NURSE
STATION
RECOVERY
6
5


2
3


Medfinity
Health
Plano

"First, do no harm."

Hippocrates



OUTPATIENT ENDOVASCULAR AND INTERVENTIONAL SOCIETY

August 28, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
PO Box 8013
Baltimore, MD 21244-1850

**Submitted electronically via
https://www.regulations.gov/comment?D=CMS-2019-0109-0002
and by email to Seema.Verma@cms.hhs.gov**

RE: **"Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc. [CMS-1717-P]"**

Dear Ms. Verma:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 5,000 members representing the majority of practicing interventional cardiologists and cardiac catheterization teams in the United States, including those providing percutaneous coronary interventions (PCI). SCAI promotes excellence in invasive and interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

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CORE CURRICULUM

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SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers

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[12]New York University School of Medicine, New York, New York
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Abstract

The Centers for Medicare & 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.

KEYWORDS
angioplasty, percutaneous coronary intervention, ambulatory surgery center

1 | 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

"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 Writing Group found no substantive data regarding the safety and efficiency of performing PCI in the ASC setting."

expert consensus opinion

PCI w/o onsite surgical back-up: Class III to IIA

PCI Same Day Discharge : Safe

Comparative Study > JACC Cardiovasc Interv. 2019 Aug 12;12(15):1479-1494.
doi: 10.1016/j.jcin.2019.03.030.

Same-Day Discharge After Elective Percutaneous Coronary Intervention: Insights From the British Cardiovascular Intervention Society

Paraskevi Taxiarchi [1], Evangelos Kontopantelis [2], Glen P Martin [1], Tim Kinnaird [3], Nick Curzen [4], Adrian P Banning [5], Peter Ludman [6], Mark De Belder [7], Muhammad Rashid [8], Matthew Sperrin [1], Mamas A Mamas [9]

Affiliations + expand

PMID: 31395218 DOI: 10.1016/j.jcin.2019.03.030

Abstract

Objectives: The aim of this study was to evaluate national temporal trends in same-day discharge (SDD) and compare clinical outcomes with those among patients admitted for overnight stay undergoing elective percutaneous coronary intervention (PCI) for stable angina.

Clinical Investigation

Same-day discharge among patients undergoing elective PCI: Insights from the VA CART Program

Jennifer A. Rymer MD, MBA [a], Colin I. O'Donnell PhD [b], Mary E. Plomondon MSPH, PhD [b], Paul L. Hess MD, MHS [b], Mark Donahue MD [a], Paul L. Hebert PhD [c], Adhir Shroff MD, MPH [d], Rajesh V. Swaminathan MD [a], Stephen W. Waldo MD [b], Arnold H. Seto MD, MPA [e], Christian D. Helfrich MPH, PhD [c], Sunil V. Rao MD [a]

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JAMA Cardiology | Original Investigation

Association of Same-Day Discharge After Elective Percutaneous Coronary Intervention in the United States With Costs and Outcomes

Amit P. Amin, MD, MSc; Duane Pinto, MD, MPH; John A. House, MS; Sunil V. Rao, MD; John A. Spertus, MD, MPH; Mauricio G. Cohen, MD; Samir Pancholy, MD; Adam C. Salisbury, MD, MSc; Mamas A. Mamas, MD; Nathan Frogge, MD, MBA; Jasvindar Singh, MD; John Lasala, MD; Frederick A. Masoudi, MD, MSc; Steven M. Bradley, MD, MPH; Jason H. Wasfy, MD, MPH; Thomas M. Maddox, MD, MPH; Hemant Kulkarni, MD

Supplemental content

IMPORTANCE Same-day discharge (SDD) after elective percutaneous coronary intervention (PCI) is associated with lower costs and preferred by patients. However, to our knowledge, contemporary patterns of SDD after elective PCI with respect to the incidence, hospital variation, trends, costs, and safety outcomes in the United States are unknown.

OBJECTIVE To examine (1) the incidence and trends in SDD; (2) hospital variation in SDD; (3) the association between SDD and readmissions for bleeding, acute kidney injury (AKI), acute myocardial infarction (AMI), or mortality at 30, 90, and 365 days after PCI; and (4) hospital costs of SDD and its drivers.

DESIGN, SETTING, AND PARTICIPANTS This observational cross-sectional cohort study included 672 470 patients enrolled in the nationally representative Premier Healthcare Database who underwent elective PCI from 493 hospitals between January 2006 and December 2015 with 1-year follow-up.

> J Am Heart Assoc. 2019 Jul 2;8(13):e012131. doi: 10.1161/JAHA.119.012131. Epub 2019 Jun 24.

Same-Day Discharge After Elective Percutaneous Coronary Interventions in Ontario, Canada

Mina Madan [1], Akshay Bagai [2], Christopher B Overgaard [3], Jiming Fang [4], Maria Koh [4], Warren J Cantor [5 6], Pallav Garg [7], Madhu K Natarajan [8], Derek Y F So [9], Dennis T Ko [1 4]

Affiliations + expand

PMID: 31498023 PMCID: PMC6662367 DOI: 10.1161/JAHA.119.012131

Free PMC article

Financial Benefits

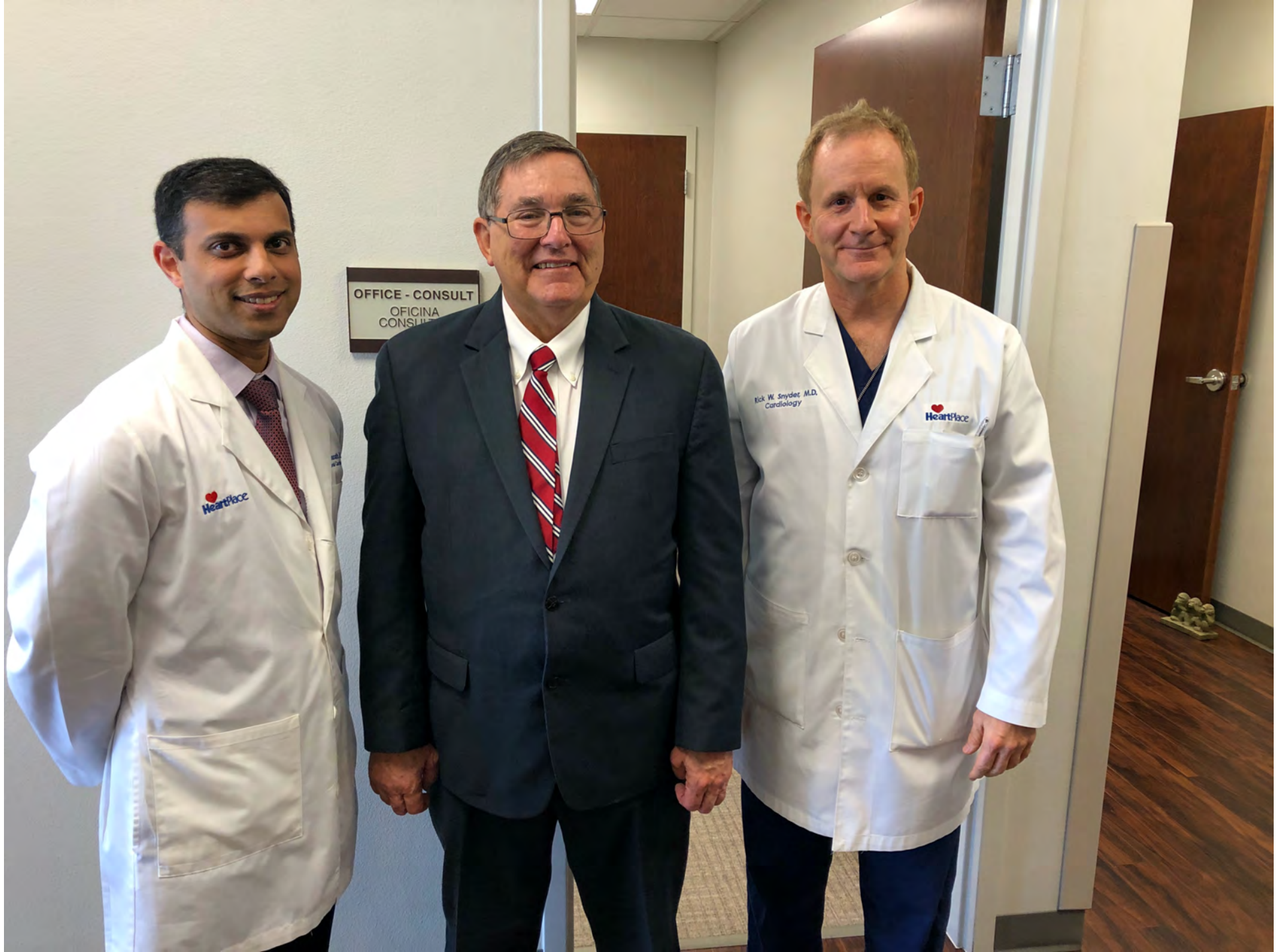
Amin et al.:

- SDD 672,470 pts, 2006 to 2015: average savings of more than $5000 per PCI.

SCAI Position Statement:

- 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.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HeartPlace
Rick W. Snyder M.D.
Cardiology
HeartPlace

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Billing Code 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 414, 416, 419, and 486

[CMS-1717-FC]

RIN 0938-AT74

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.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

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)

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Proposed Additions to the List of ASC Covered Surgical Procedures

First and foremost, SCAI is committed to fiscal responsibility and identifying mechanisms that will bring cost-savings to the healthcare system. We are committed to quality, efficiency, patient experience and preference regarding treatment options, as well as site of service options.

"Therefore, SCAI supports CMS's proposed addition of percutaneous coronary angioplasty and coronary stenting to the list of ASC Covered Surgical Procedures for CY2020."

"*We feel that elective, non-emergent percutaneous coronary angioplasty and coronary stenting procedures have relatively low complication rates and are not expected to pose a significant risk to Medicare beneficiary safety and do not typically require inpatient-level care following the procedure*."

CMS 1717 FR:

Based on our
review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, we believe these three coronary intervention procedures (CPT codes 92920, 92928, and HCPCS code C9600) and three associated add-on procedures (CPT code 92921, 92929, and HCPCS code C9601) ***can be safely performed in the ASC setting, for certain Medicare patients*** and note that the physician should determine whether a particular case would be a good candidate to be furnished in the ASC setting rather than the hospital setting based on the clinical assessment of the patient.

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TABLE 59.— PROCEDURES ON WHICH WE REQUESTED COMMENT FOR ADDITION TO THE ASC LIST OF COVERED SURGICAL PROCEDURES

CY 2020 CPT Code	CY 2020 Long Descriptor
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel

SCAI Comment Letter:

"POTENTIAL PROCEDURES ON WHICH WE REQUEST COMMENT FOR ADDITION TO THE CY 2020 ASC LIST OF COVERED SURGICAL PROCEDURES,

SCAI does not presently support the addition of these more complex PCI procedures to the ASC Covered Surgical Procedural list.

These procedures may be associated with disproportionately higher rates of complications in Medicare populations and at this stage, they should only be performed with the extra support of the hospital setting. This may be revisited as experience with PCI in Medicare beneficiaries in the ASC setting grows."

SCAI Position Statement:

"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. "

Based on the public comments we received, we believe the procedures listed in Table 59 would expose beneficiaries to significant safety risk if performed in an ASC setting at this time and would not meet our criteria established under § 416.166(b). Specifically, we believe that transluminal revascularization of a bypass graft carries an inherent higher risk of complication and may require the assistance of on-site cardiac surgical backup. Additionally, we believe atherectomy procedures carry a greater risk of complication than coronary intervention procedures without an atherectomy procedure. Therefore, at this time, we believe that adding any of the procedures identified in Table 59 of this final rule with comment period to the ASC CPL would expose

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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.

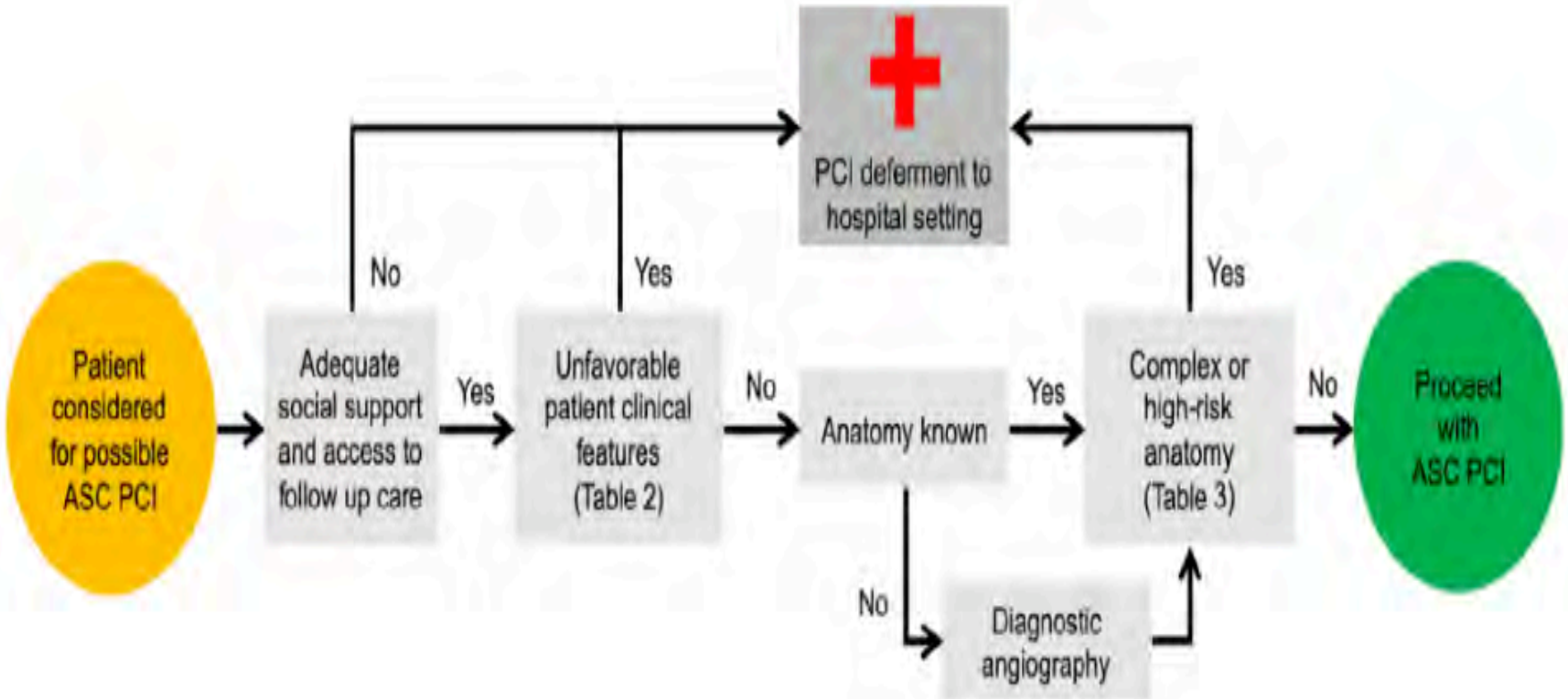

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TABLE 2 Unfavorable patient conditions warranting PCI deferment to the hospital setting

1	Decompensated CHF (NYHA class 3–4)
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 m^2
5	Anemia (Hgb < 9 g/dl) or coagulopathy (e.g., INR >1.5 or platelet count <100 K)
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 noncardiac 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)

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

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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 noncardiac instability during PCI
- At the discretion of the attending physician
- Patient preference to stay overnight

Transfers

A receiving facility should be located within 60 min travel time by ground or air transportation.

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.

Medfinity Plano 2020 Jan.-Aug. Coronary Data

Medicare total patients 194		
DX Only	PCI	Total
136	58	194

ASC Commercial and Medicare Total patients 267		
ASC DX Only	ASC PCI	Total
184	83	267

OBL Commercial Total 103		
OBL DX Only	OBL PCI	Total
76	27	103

Total Coronary patients = 370 in both ASC and OBL

Total Medicare Coronary patients = 194

Total Medicare PCI = 58

Total Medicare DX Only = 136

NCP 2020 Case Counts – LHC and PCI

Case Counts 2020	2020 Cath Lab		2020 ASC		2020 Combined
PCI TOTAL Cases	337		1,365		1,702
PCI Medicare Cases	7		1,120		1,127
LHC TOTAL Cases	1,561		3,869		5,430
LHC Medicare Cases	444		3,054		3,498

Data January 2020 – August 2020

NCP 2020 PCI Safety Data

Variance	2020 Cath Lab	2020 Cath Lab Results		2020 ASC	2020 ASC Results		2020 Combined	2020 Combined Results
Sentinel Events:	**0**	**0.00%**		**0**	**0.00%**		**0**	**0.00%**
Transfers:	**5**	**1.48%**		**14**	**1.03%**		**19**	**1.12%**
Complications	**5**	**1.48%**		**9**	**0.66%**		**14**	**0.82%**
Return to Surgery/Lab	0	0.00%		0	0.00%		0	0.00%
RP Hematoma	0	0.00%		1	0.07%		1	0.06%
MI	0	0.00%		0	0.00%		0	0.00%
Stroke	0	0.00%		1	0.07%		1	0.06%
Hospital Admit w/in 72 hrs	0	0.00%		0	0.00%		0	0.00%
Other	5	1.48%		7	0.51%		12	0.71%
PCIs in 2020: Cath Lab - 337; ASC - 1,365								
Combined PCIs in 2020: 1,702								

Data January 2020 – August 2020

Quality Assurance

There is no current registry specific to PCI in an ASC

Registry suitable for assessing ASC PCI quality metrics is needed.

Leveraging existing national CV registry :

- NCDR Cath PCI registry
- OEIS OIS/ASC Peripheral Registry

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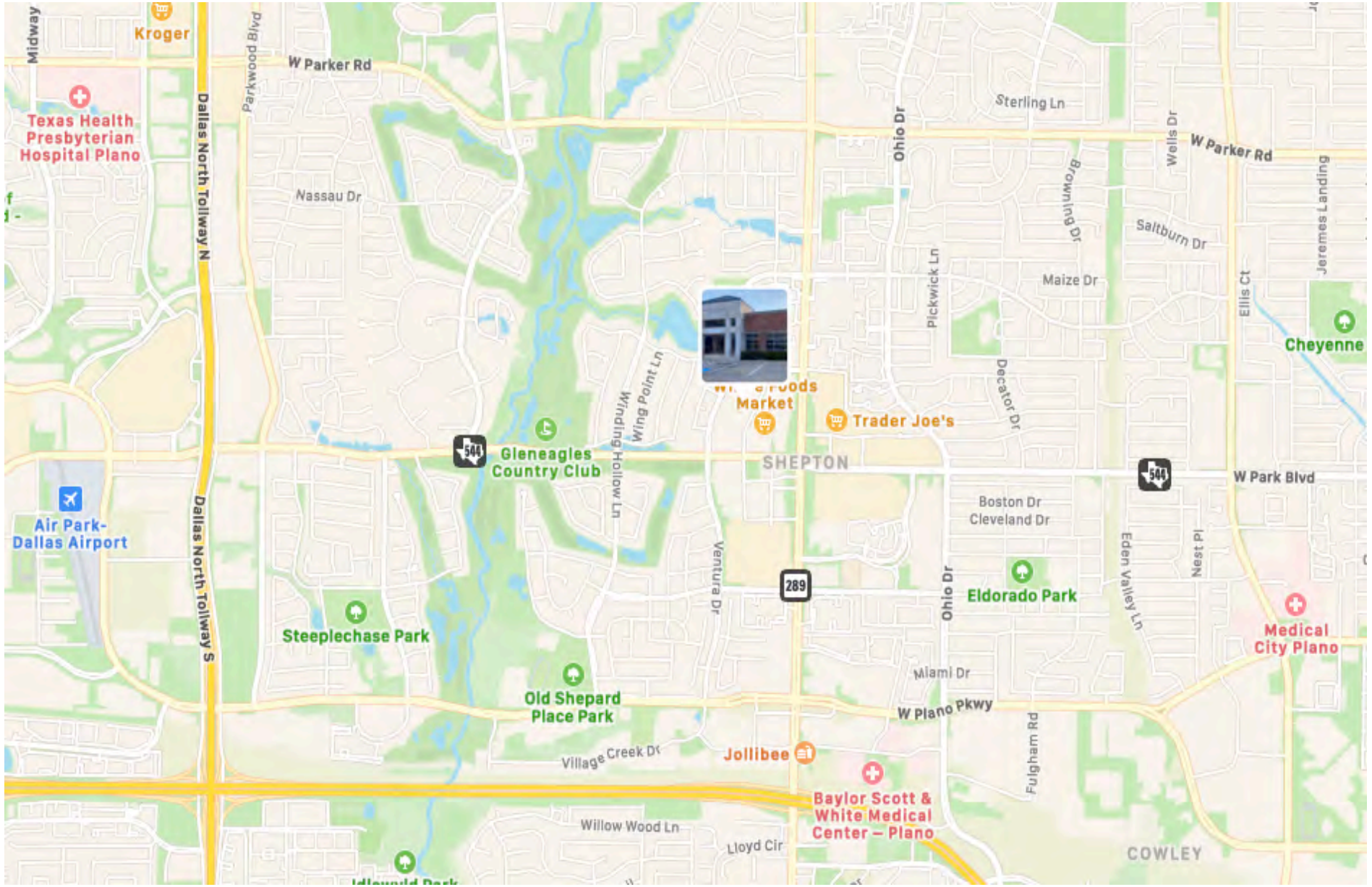
BACK UP SLIDES



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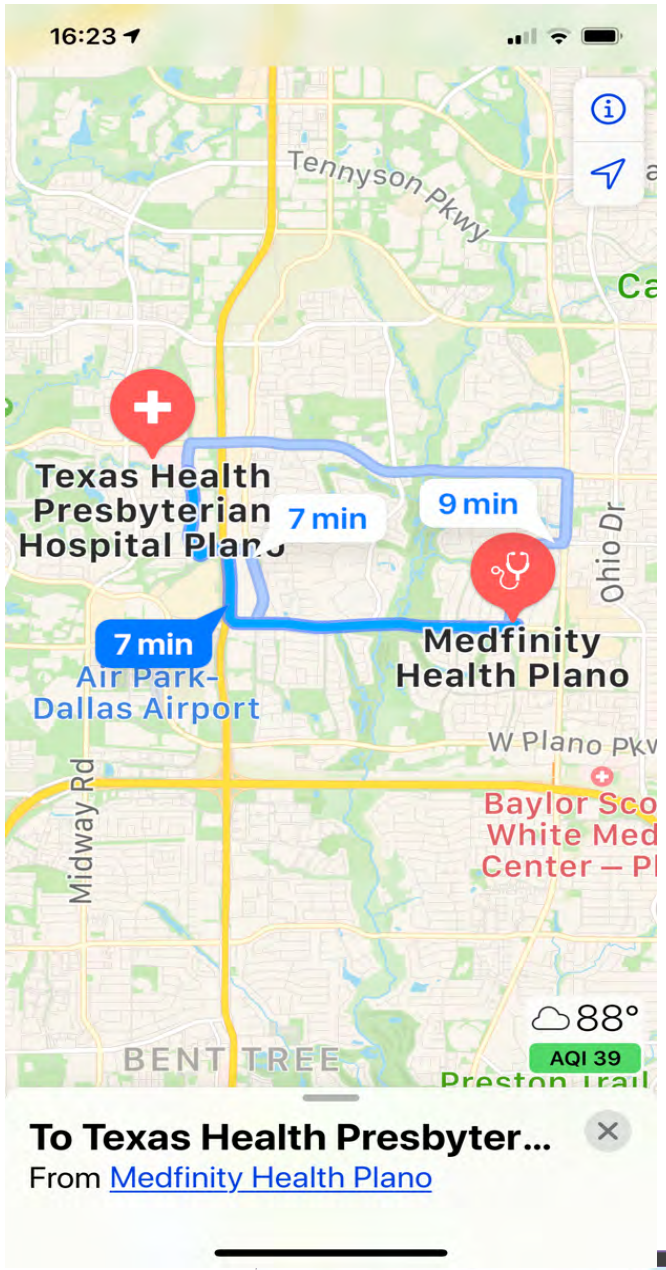
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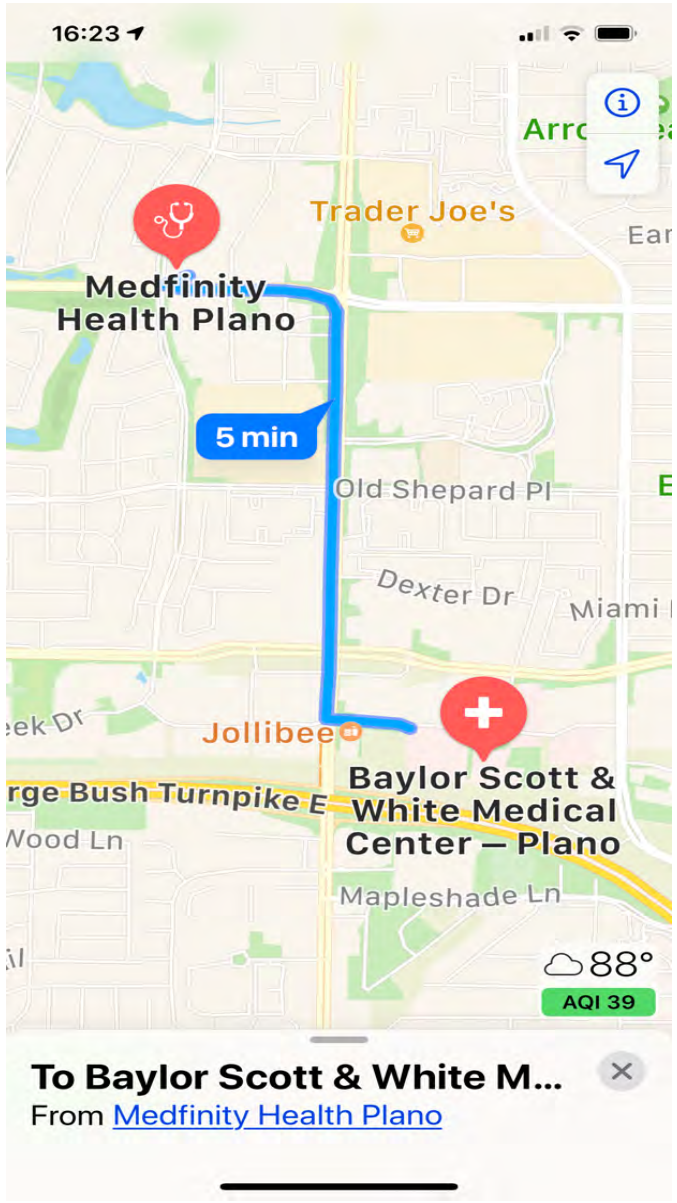
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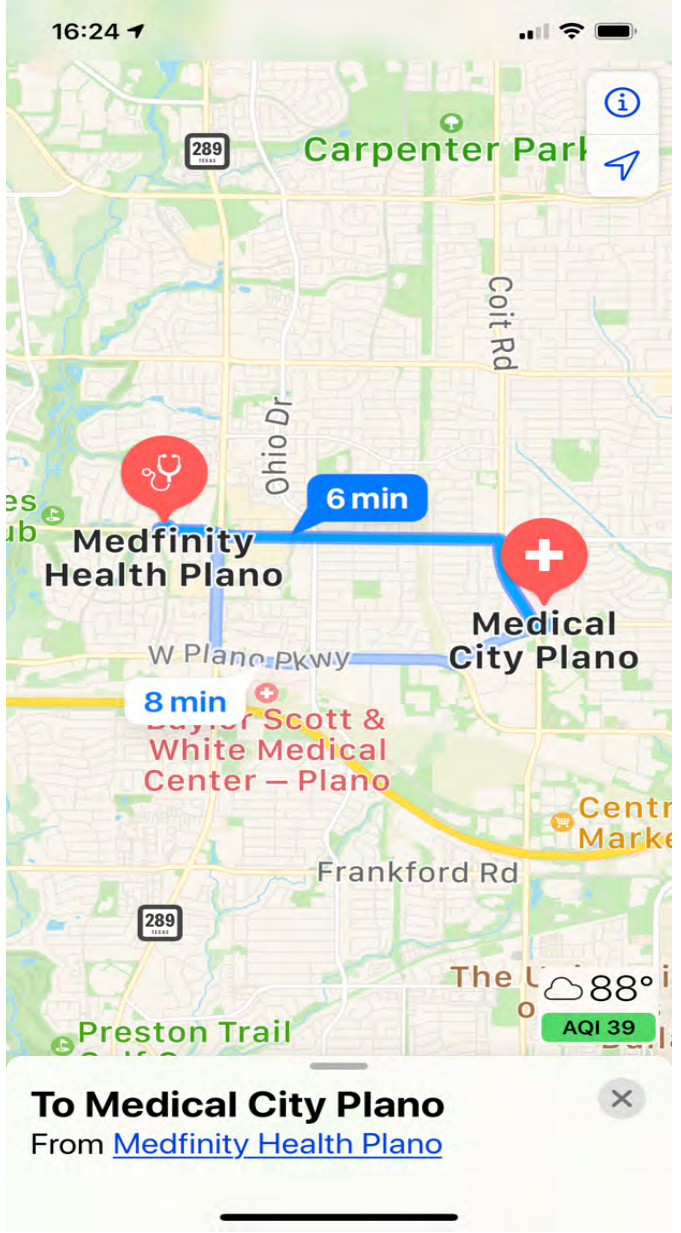
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To Medical City Plano
From Medfinity Health Plano

Comment: One commenter requested separate payment for add-on codes for Fractional Flow Reserve Studies (FFR/iFR) and Intravascular Ultrasound (IVUS). The commenter stated that they believe the packaging of these codes will disincentivize physicians to perform these adjunct procedures because of cost. The codes include:

- 93571 - Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure);
- 93572 - Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure));
- 92978 - Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (list separately in addition to code for primary procedure); and
- 92979 - Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)).

Response: As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66630), we continue to believe that IVUS and FFR are dependent services that are always provided in association with a primary service. Add-on codes represent services that are integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. As we have noted in past rules, add-on codes do not represent standalone procedures and are inclusive to other procedures performed at the same time (79 FR 66818). We continue to believe it is unnecessary to provide separate payment for the previously mentioned add-on codes at this time.

OUTPATIENT ENDOVASCULAR AND INTERVENTIONAL SOCIETY


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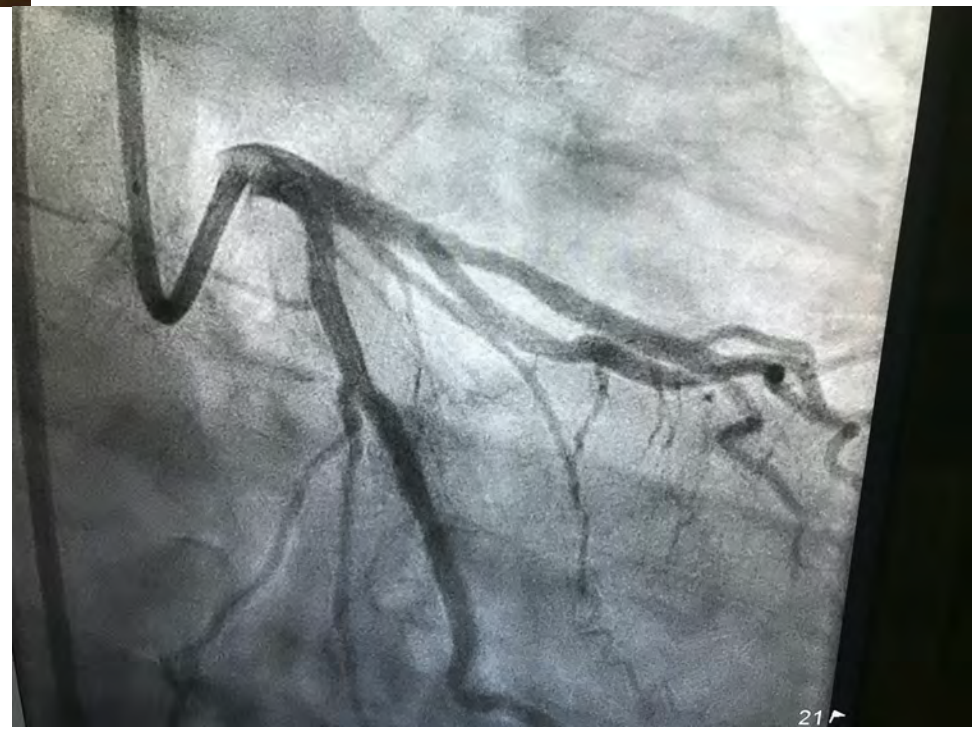
21

Experienced Interventionalists

Board certified

Experienced: >500 PCIs history

SCAI also cautions against newly trained interventional cardiologists performing PCI in the ASC setting.

>50 PCI cases annually

ACCREDITATION

ASCs can seek accreditation from one of several accrediting bodies:

- The Accreditation Association for Ambulatory Health Care, Inc (AAAHC),
- The Joint Commission
- The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF),
- Healthcare Facilities Accreditation Program (HFAP).

Cardiac Procedures have been performed for years in OIS/ASC setting for years for commercial payors.

- Coronary angiography and intervention
- Peripheral angiography and intervention
- Pacemaker and defibrillator insertion
- Loop monitors
- Diagnostic right heart catheterization

Medicare has been slow to adopt reimbursement policy to match commercial payor ASC policies.