CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1786)

June 1st, 2023

Attendees:

David Kenigsberg, MD, FACC, FHRS, Florida Heart Rhythm Specialists, PLLC

Donald "Buck" Cross, MD, MBA, National Medical Director, National Cardiovascular Partners

Jerry Niedzwiecki, MD, FSIR, DFOEIS, Past President, Outpatient Endovascular and Interventional Society

Kelly Bemis, Chief Clinical Officer, National Cardiovascular Partners

Stacey Fahrner, Vice President, Government Affairs, Fresenius Medical Care on behalf of National Cardiovascular Partners

Jason McKitrick, Principal, Liberty Partners Group on behalf of OEIS

Meeting Objective and Agenda

Meeting Objective:

- Discuss continued expansion of the ASC site of service for cardiac procedures
- Provide rationale and data to support adding cardiac ablation procedures –
 93650, 93653, 93654, 93656, 93613, 93621, 93622, 93623 to the ASC CPL

Agenda:

- 1) Background: Recent CMS actions to move cardiac procedures into the ASC site of service
- 2) Description of cardiac ablation
- 3) Potential savings to Medicare program and beneficiaries
- 4) Discuss safety and appropriateness of cardiac ablation with same day discharge
- 5) Provide rationale and data to support adding these procedures on the ASC CPL

About Us





- Multispecialty medical society
 - Interventional cardiology, interventional radiology, and vascular surgery
- Focused on enhancing the safety, quality, and efficacy of outpatient (ASC and office-based) interventional procedures
- National Cardiovascular Partners is the market leaders in independent, outpatient cardiac catheterization and vascular labs operated in partnerships with physicians.
- NCP has partnered with over 300 physicians in 25 outpatient cardiac catheterization & vascular labs in Texas, Arizona, California, Louisiana, South Carolina and Kansas.
- NCP physician partners perform over 94,000 outpatient cases each year

History: Expanding Access to ASCs for Cardiology Treatments

- CMS has expanded access to ASCs for cardiology services in recent years:
 - In 2019, CMS expanded the definition of "surgery" to include "surgery-like" procedures that are assigned codes outside of the CPT surgical range, and added 12 diagnostic codes
 - In 2020, CMS added certain interventional cardiac cath procedures to the ASC CPL, ensuring parity in access between Medicare FFS patients and patients with Medicare Advantage and commercial coverage
- CMS noted that if new evidence, clinical studies, or data become available that
 may support adding procedures to the ASC CPL, "we will consider the
 commenters' recommendations in future rulemaking"
- CMS recognized that "ongoing review is necessary to determine if changes in technology and/or medical practice affect the clinical appropriateness" of procedures for the ASC setting

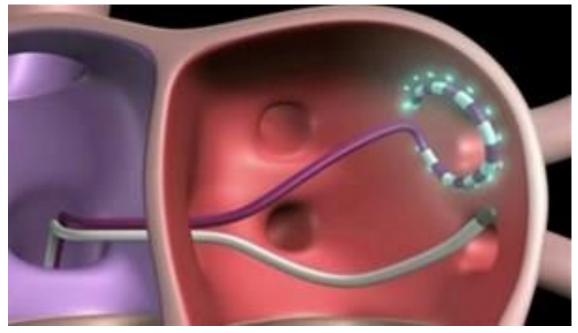
Recommendation for CY 2024 ASC CPL

For CY 2024, we recommend CMS expand access to the ASC site of service for Medicare FFS patients by adding <u>cardiac ablation</u> procedures to the CPL

RATIONALE	
Provides Comprehensive Point of Service	 Provides a more comprehensive and convenient point of service for diagnosis and treatment of cardiac conditions
Meets Covered Surgical Procedures Definition	 Procedures are "surgery-like" under the definition as expanded in 2019 Meets the definition of "Covered surgical procedure"
Poses No "Significant Safety Risk"	 Pose no significant safety risk when performed in an ASC Supported by clinical studies and data
Reflects Technology Advancement	 Like percutaneous coronary intervention (added in 2020), cardiac ablation procedures evolved from open surgery to safer, minimally invasive surgeries through the adoption of catheter-based technologies
Aligns with State Regulations and Commercial Payors	Better aligns Medicare with state and commercial payors
Creates Economic Efficiencies	 Need for ablation services is likely to continue growing (60% increase from 2017 to 2021) Estimated 1 year savings of \$45M

What is Cardiac Ablation?

- Cardiac ablation is a procedure that scars tissue in your heart to block irregular electrical signals. It is used to treat heart rhythm problems (arrhythmias). Long flexible tubes (catheters) are threaded through blood vessels to the heart. Sensors on the tips of the catheters transmit heat or cold energy to destroy (ablate) the tissue.
- <u>Video explanation of procedure:</u> https://pulse.cardiovisual.com/video/?id=265



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Substantial Savings for Medicare and Beneficiaries - \$450M+ Over 10 Years

				HOPI)	ASC			
HCPCS	Short Descriptor	Status Indicator	APC	Volume	"	Total Payment for 5% of Volume	Volume from HOPD		Payment Differential from HOPD
93650	Ablate heart dysrhythm focus	J1	5212	8,179	\$ 6,733	\$ 2,753,460	409	\$ 1,514,403.19	\$ 1,239,057.16
93653	Ep & ablate supravent arrhyt	J1	5213	22,500	\$ 23,481	\$ 26,416,125	1,125	\$14,528,868.75	\$ 11,887,256.25
93654	Ep & ablate ventric tachy	J1	5213	5,456	\$ 23,481	\$ 6,405,617	273	\$ 3,523,089.24	\$ 2,882,527.56
93656	Tx atrial fib pulm vein isol	J1	5213	55,869	\$ 23,481	\$ 65,592,999	2,793	\$36,076,149.70	\$ 29,516,849.75
		Movement of Volume from HOPD	5%	4,600	Sum of HOPD Total	\$ 101,168,202	4,600	\$ 55,642,511	\$ 45,525,691

One Year Savings Assumptions:

- Modeled 5% of HOPD volume moving to the ASC in the first year
- Used 2021 claims data for utilization
- Used 2023 HOPD payment rates
- Assumed ASC payment are approx. 55 percent of HOPD

Additional Considerations for Savings Projections:

- Migration in the first year is likely to be low but would pickup quickly in years 2 and beyond as practices make investment in technology
- For example, Cardiac Cath procedures in the ASC are approx. 10-12 percent of total volume in 2021

Cardiac Ablation Meets "Covered Surgical Procedures" Criteria

- Cardiac ablation procedures do not pose a significant safety risk when performed in an ASC
- Hospital Without Walls experice provided a unique opportunity to gather Medicare FFS safety data in an ASC

No Significant Safety Risk

• Not expected to pose a significant risk to beneficiary safety when performed in an ASC

No Active Medical Monitoring

 Not expected to require active medical monitoring and care of beneficiary at midnight following the procedure

Separately Paid Under OPPS

Separately paid under OPPS

No Significant Safety Risk

Claims analysis shows little evidence of hospital admission, emergency room visit, or death

Recent evidence supports provision of these services in nonhospital settings for appropriate patients

Clinically similar procedures are already covered in the ASC

Aligns with CMS CY2019 policy to expand access for cardiac services

Claims Analysis Shows No Significant Safety Risk

- Claims analysis shows little evidence of hospital admission, emergency room visit, or death from cardiac ablation procedures when performed in an HOPD
 - Despite increase in utilization, claims data reflects consistently low incidence of hospitalization, emergency room visits, and mortality

HCPCS	Description	Number of Procedures		Inpatient admission within 1 day		Emergency room visit within 1 day		Mortality within 30 days	
		2017	2021	2017	2021	2017	2021	2017	2021
93650	Intracardiac Ablation of AV Node	8,086	8,179	0.6	0.7	0.3	0.3	0.8	1.0
93653	Comp EP Evaluation w/RA & RV Pacing/Recording, His Bundle Recording; w/SVT Ablation	24,180	22,500	0.7	0.8	*	*	0.2	0.2
93654	Comp EP Evaluation w/RA & RV Pacing/Recording, His Bundle Recording; w/ VT Ablation and LV Pacing/Recording	4,220	5,456	1.1	1.4	*	*	0.5	0.4
93656	Comp EP Evaluation w/RA & RV Pacing/Recording, His Bundle Recording w/Transseptal Cath; w/ Atrial Fib Ablation and LA Pacing/Recording	34,514	55,869	1.0	1.0	*	*	0.2	0.2

Electrophysiology Studies, Mapping and Add-on Elements of Cardiac Ablation Procedures are Safe

These procedures are elements of cardiac ablation procedures that are packaged in the HOPS and would need to be added to the ASC CPL

HCPCS	HOPPS Status Indicator	Description	Number of Procedures		Inpatient admission within 1 day		Emergency room visit within 1 day		Mortality within 30 days	
			2015	2021	2015	2021	2015	2021	2015	2021
93613	N (packaged)	Intracardiac 3-D Mapping	40,592	76,055	0.9%	1%	0.3%	0.4%	0.2%	0.2%
93621	N	Comp EP Evaluation w/ LA Pacing/Recording	16,024	22,500	0.9%	0.9%	0.6%	*	0.3%	0.2%
93622	N	Comp EP Evaluation w/ LV Pacing/Recording	2,018	5,456	0.9%	2.0%	*	*	*	0.2%
93623	N	Programmed Stimulation and Pacing after IV Drug Infusion	22,331	55,869	0.7%	1.3%	0.3%	*	0.1%	0.2%

Hospital Without Walls - Medicare FFS Data

Interventional Electrophysiology In The Ambulatory Surgical Center During SARS-CoV-2 Pandemic

Background:

• EP procedures and Catheter ablative therapy have been historically restricted to the hospital setting. During the SARS-CoV-2 pandemic the Center for Medicare and Medicaid Services (CMS) created the Hospitals Without Walls program and authorized Ambulatory Surgical Centers (ASC) to provide services as a hospital.

Results:

- Complications from cardiac ablations (5/1072; 0.46%) included: 1 pericardial effusion req. paracentesis, 2 large groin hematoma requiring hospitalization, 1 protamine anaphylactic rxn, 1 episode of
- hemoptysis after intubation that required discontinuation of the procedure and hospital observation. A total of four ablations req. overnight hospitalization (0.37%).

• Hold:

 Cardiac ablations can be safely performed as an outpatient same day procedure in the ambulatory surgical center.

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National Cardiovascular Partners Data

Variance	2015 Results	2016 Results	2017 Results	2018 Results	2019 Results	2020 Results	2021 Results	2022 Results	ASC Totals 2015 thru 2022	ASC Results 2015 thru 2022
Sentinel Events:	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0	0.00%
Transfers:	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0	0.00%
Falls	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0	0.00%
Infections	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0	0.00%
Complications	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0	0.00%

^{*}ASC Ablation Cases Performed: 4 in 2015; 3 in 2016; 0 in 2017; 7 in 2018; 69 in 2019; 53 in 2020; 28 in 2021; 29 in 2022 - TOTAL 193 cases

Large Multi-Center Studies, Claims Analyses, and Survey Data Support the Safety and Feasibility of Same Day Discharge

Author	Publication	Description
Deyell et al.	JACC Clin. Electrophysiol 2020	 Multicenter cohort study of 3,054 patients undergoing AF ablation from 2010 to 2014 at two major centers in Canada to evaluate the efficacy, health care utilization, and safety of a same-day discharge (SDD) protocol. Primary outcome was the proportion of patients who achieved successful same-day discharge after AF ablation. Same-day discharge was achieved in 79.2% (2,418 of 3,054) of patients. Conclusion: Same-day discharge after AF ablation is feasible in the majority of patients with use of a standardized protocol.
Field et al.	Heart Rhythm O2 2021	 Retrospective cohort study examined administrative claims and billing data in a commercial claims database from January 1, 2016, to June 30, 2020 to investigate the safety and efficacy of same-day discharge (SDD) after catheter ablation (CA) for atrial fibrillation (AF). 1610 SDD and 4637 overnight stay patients with mean age 56.1 (6 7.6) years. No significant difference in composite 30-day postprocedural complication rate between SDD and ONS groups (2.7% vs 2.8%, respectively; P 5 .884). Conclusion: In a large, propensity-matched, real-world sample, SDD appears to be safe and have similar outcomes compared with overnight observation following CA for AF.
Konig et al.	EP Europace 2021	 European Heart Rhythm Association (EHRA) survey was designed to (1) assess to what extent SDD is currently utilized with respect to institutional differences, (2) describe experiences with SDD, and (3) record clinicians' perceptions and opinions concerning the possibility of future implementation and expansion of this practice. In total, 218 participants (6.5% response rate) from 49 countries completed the survey. Overall, SDD was implemented in 77.5%, whereas this proportion was significantly higher in tertiary and high-volume centers (83.8% and 85.3%, both P < 0.01). The concept of SDD was most commonly used following implantations of cardiac event recorders (97%), diagnostic EP procedures (72.2%), and implantations of pacemakers with one or two intracardiac leads (50%), while the lowest SDD utilization was observed after catheter ablations of left atrial or ventricular arrhythmias.

Conclusion & Discussion

For CY 2024, we recommend CMS expand access to the ASC site of service for Medicare FFS patients by adding cardiac ablation procedures to the CPL

- Growing demand for ablation surgeries
- ASC site of service is safe and efficient
- How can we help?
- What additional information or data do you need?