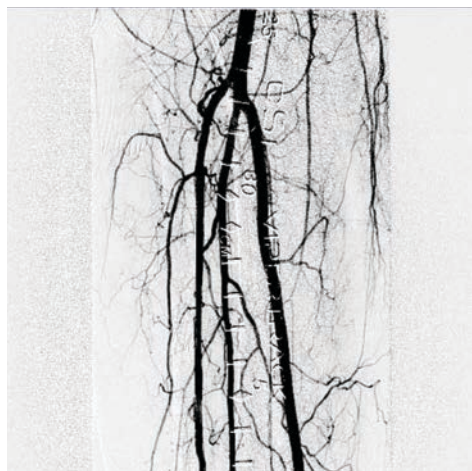


Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



PERIPHERAL INTERVENTIONS

The Use of the Highlander™ 014 PTA Balloon Dilatation Catheter in the Treatment of Peripheral Artery Disease

CLD talks with Vishal Kapur, MD, FACC, FSCAI, RPVI.

What are some of the challenges of treating peripheral artery disease (PAD), particularly below the knee?

PAD is an underappreciated and underdiagnosed disease. It is considered as a coronary artery disease equivalent and hence warrants importance, especially in those patients who have critical limb ischemia (CLI). CLI patients have a significantly higher chance of amputation and of those patients who undergo amputation, half usually die within a year.

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Happy Cardiovascular Professionals Week!
February 11-17, 2024

In This Issue

Do We Need to Withhold Jardiance (SGLT2 Inhibitors) or Ozempic (GLP-1 Agonists) Before Cardiac Cath?

Dr. Morton Kern with Drs. David Cohen, Kirk Garratt, Spencer King, Neal Kleiman, Srihari Naidu, Matthew Price, Steve Ramee, Chet Riha, and Bonnie Weiner.

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Crossing Severely Stenotic and Tortuous Complex Lesions With Ease — Two New Devices Facilitate Successful Outcomes

Eric A. Secemsky, MD, MSc, RPVI; Killian J. McCarthy, MB BCh BAO

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PATIENT CARE

End-Tidal CO₂ Monitoring for Respiratory Adverse Events During Procedural Sedation: An Additional Layer of Safety

CLD talks with Arnold H. Seto, MD, MPA, FSCAI.

In today's cardiac catheterization laboratory environment, why is end-tidal CO₂ monitoring becoming more important?

End-tidal CO₂ (EtCO₂) measures the level of carbon dioxide that is released at the end of exhalation. Since the exhaled CO₂ is much higher than the level in ambient air, EtCO₂ is a sensitive marker of ventilatory effort, much more so than pulse oximetry, which might only decline several minutes after apnea occurs.¹



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CALCIUM CORNER

A Physician's Perspective on New Permanent Reimbursement Pathways for Coronary Intravascular Lithotripsy

CLD talks with Yousif Ahmad, BMedSci, BMBS, MRCP, PhD, FSCAI, FACC.

How did the previous, temporary reimbursement pathways impact intravascular lithotripsy (IVL) utilization within your practice?

The previous IVL codes were temporary pathways as part of a breakthrough technology designation from Centers for Medicare and Medicaid (CMS). The two pathways were New Technology Add-on Payment (NTAP) or Transitional Pass-Through (TPT).

These codes were helpful in that they allowed IVL technology to reach the market and allowed the cost of the device to be accounted for. You weren't losing money by using IVL, so the previous codes were very beneficial from that perspective.

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A Physician's Perspective on New Permanent Reimbursement Pathways for Coronary Intravascular Lithotripsy

CLD talks with Yousif Ahmad, BMedSci, BMBS, MRCP, PhD, FSCAI, FACC.

I work in a larger academic model and many of our cases are referrals that have been unable to be treated elsewhere. There is an acceptance within the institution that certain cases are going to be exceptionally expensive because of the time, resources, and equipment required. It depends on your practice pattern as to how attuned you are to these issues, but we are all aware of an escalating cost when multiple different devices need to be used, such as a case using both atherectomy and IVL. Or perhaps there is an in-stent lesion or a chronic total occlusion, and you perform IVL but don't put in a stent, which is another scenario where the previous reimbursement models would not necessarily have made it a profitable case for the institution.

There are a few important, overarching principles. Number one is you always use the right tool for the right patient to get the most optimal result. Number two, we do have a responsibility to behave responsibly in the way that we use resources. Having an overall awareness of reimbursement costs and health economics is important for physicians. The new IVL reimbursement pathways are cleaner, more straightforward, and easier for both physicians and administrators to understand.

Can you describe the current status of IVL reimbursement?

The two main changes that people need to be aware of are first, for inpatient cases, there are new, dedicated diagnosis-related groups (DRGs) for IVL (Table 1). The new DRG codes are not based on any other technologies, codes, or pathways. What this means for inpatient procedures is that if you use IVL, the new DRG gives you an uplift in reimbursement. The exact amount of uplift depends on specific geographic and other factors, but on average, it appears that it will be around \$8000 per case, which obviously more than offsets the cost of the IVL balloon. That number was reached by Medicare from reviewing the cases where IVL technology was used, which overall tend to be more complex cases. The other thing that is worth mentioning for this inpatient reimbursement is that the code for IVL exists independent of whether a stent is placed. There are two buckets: Percutaneous Coronary Intervention (PCI) With Stent Placement and

PCI Without Stent Placement. For each of those categories, there now exists a separate DRG for IVL. The new DRGs came into effect from October 1st, 2023, so these have already been established.

The other new pathway is physician reimbursement, which came into effect from January 1, 2024. IVL has a new Current Procedural Terminology (CPT) code that is unique to IVL (Table 2). It is an add-on code and not bundled with any other procedures. No matter what else you have done in the case, if you use IVL, there is now an add-on code that you bill in addition to everything else.

The CPT code provides just under three additional work Relative Value Units (RVUs) per case.

Importantly, the new coding pathways are agnostic to the use of any other adjunctive devices. Earlier I mentioned those cases when you need to use multiple devices like atherectomy and IVL, where you are really aware of the cost racking up. Atherectomy and IVL are expensive devices, but at least at the physician level, the new pathway will allow you to get reimbursed for the use of both devices. If there is a case where you do atherectomy, stent placement, etc., there are codes for those. As of January 1, 2024, if you also use IVL, then you add on the CPT code for IVL use. It also counts whether there is stent placement or no stent placement, treatment of a chronic total occlusion, use of imaging, use of atherectomy, and so on. Whatever you do, the CPT code brings an uplift for using IVL as well.

Is there anything specific to non-clinical stakeholders in terms of what they should know about coronary IVL reimbursement?

Cath lab managers, administrators, and people looking at the overheads should be aware of this change because it is going to alter the landscape.

TABLE 1. CMS created new Medicare Severity Diagnosis Related Group (MS-DRG) codes and payments for coronary intravascular lithotripsy in the hospital inpatient setting that became effective October 1, 2023.

MS-DRG	Descriptor	Payment ²
323	Coronary Intravascular Lithotripsy with Intraluminal Device with MCC ¹	\$28,987
324	Coronary Intravascular Lithotripsy with Intraluminal Device without MCC ¹	\$20,785
325	Coronary Intravascular Lithotripsy without Intraluminal Device without CC/MCC ¹	\$18,514

¹ MCC: Major Complications and Comorbidities; CC: Complications and Comorbidities.

² CMS-1785-F; National Average MS-DRG rates shown are based on Medicare Inpatient Prospective Payment System FY2024 Final Rule, National average payment rates assume full update amount for hospitals which have submitted quality data and hospitals have a wage index greater than 1. Site specific payment rates will vary based on regional area wage differences, teaching hospital status, indirect medical education costs, quality data, additional payments to hospitals that treat a large percentage of low income patients ("disproportionate share payments"), etc.

TABLE 2. Effective January 1, 2024, CMS established a new Category I CPT® add-on code for coronary intravascular lithotripsy.

CPT®	Description	Additional Work RVUs ¹	Additional Payment ^{1,2}
+92972	Percutaneous transluminal coronary lithotripsy	+2.97	+\$140

¹ CMS-1784-F; Medicare Physician Fee Schedule Fiscal Year 2024 Final Rule

² Payment rates do not take into account geographical or additional adjustments. Providers should contact their local Medicare Administrative Contractor (MAC) or CMS for specific information as payment rates vary by region.

If you are doing a complex case using multiple devices, there is no longer the potential for a financial penalty from using certain technologies like IVL, either at the institutional level or at the physician level, which means that we are now liberated. You never want to make treatment decisions based on economic implications, but the reality is that you have to be at least aware of the financial and economic implications. Removing these potential barriers to use of IVL is a good thing. The last thing you want is either whoever's running the cath lab or the physician to pause and think, do I want to pull this off the shelf because of the cost? That thinking can go by the wayside because the reimbursement means it should no longer be a factor. As long as physicians document that they used IVL, then reimbursement should be very straightforward.

What do you think about the pairing of the new reimbursement pathways for coronary IVL with

the launch of Shockwave C²⁺?

Occasionally we saw, certainly with the C², that you might finish your 80 pulses in one lesion and it hadn't fully modified the calcium. This should certainly be less of an issue with C²⁺ and the 50% extra pulses. Having 120 pulses rather than 80 does unlock the ability to treat longer lesions. It is also very helpful for treating multiple vessels with one catheter. Let's say you have lesions in the circumflex and left anterior descending coronary arteries. You could ration your pulses between the two, and as long as the catheter can be delivered, the extra pulses allow you to effectively modify multiple lesions and multiple vessels with a single catheter.

The new reimbursement hasn't changed my strategy or practice pattern, but particularly for the combination therapy cases, it is reassuring that you can get reimbursed for atherectomy and lithotripsy, which is a strategy I employ frequently. In complex cases, you often need to use multiple devices to get an optimal result. The new codes will allow for that without potential of it being financially punitive.

Have the 40 additional pulses available with the Shockwave C²⁺ IVL catheter changed how you approach cases?

For a longer lesion that needed calcium modification, I might have previously defaulted to atherectomy because of the challenges in modifying a long lesion with only 80 pulses (and while it is rare, it was certainly not unheard of to use

multiple IVL catheters in a case for a long lesion). There is a huge portion of cases that I still treat with atherectomy for other reasons, but if lesion length was the only reason why I was using an atherectomy device, then I now have the option to use only IVL and just use the C²⁺.

Any final thoughts?

Reimbursement for hospital outpatient procedures will be looked at next by CMS. Inpatient and physician reimbursement have been addressed. The C²⁺ is now available throughout the country. The only other thing to mention about the C²⁺ is that everything else about this device is the same: crossability, deliverability, and ease of use are identical to the C². The cost is the same. The C²⁺ just adds 40 extra pulses. ■

This interview is sponsored by Shockwave Medical. Dr. Ahmad is a paid consultant for Shockwave Medical.

Scan here to view Dr. Ahmad's article online and visit CLD's Calcium Corner:



Yousif Ahmad, BMedSci, BMBS, MRCP, PhD, FSCAI, FACC

Assistant Professor of Medicine (Cardiovascular Medicine); Director, Complex and High-Risk Interventional Procedures (CHIP) Program; Associate Program Director, Interventional Cardiology Fellowship, Yale School of Medicine, New Haven, Connecticut



Shockwave C² and C²⁺ Safety Information

In the United States: Rx only. Please contact your local Shockwave representative for specific country availability.

Indications for Use— The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C² and C²⁺ Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Contraindications— The Shockwave C² and C²⁺ Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings— Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

Precautions— Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anti-coagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

Potential adverse effects consistent with standard based cardiac interventions include— Abrupt vessel closure – Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or nonemergency coronary artery bypass surgery-Emergency or nonemergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)- Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

Risks identified as related to the device and its use: Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. www.shockwavemedical.com/IFU/.

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