July 27, 2017

Center for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
The Advisory Panel on Hospital Outpatient Payment (The Panel)
Designated Federal Official (DFO): Susan Janeczko, Pharm.D., J.D., DFO
Reference: File Code CMS–1685–N
7500 Security Boulevard
Woodlawn, MD 21244-1850
Sent via Email: APCPanel@cms.hhs.gov

Subject: Assignment of angioplasty procedures using Drug Coated Balloons (HCPCS code: C2623)

Dear Panel Members:

On behalf of the members of the Society for Vascular Surgery (SVS), the Society of Interventional Radiology (SIR) and Vascular Interventional Advances (VIVA), we appreciate the opportunity to submit comments to the Hospital Outpatient Advisory Panel regarding proposed payments for drug coated balloon (DCB) angioplasty procedures, effective CY 2018.

Peripheral arterial disease (PAD) is a chronic, progressive disease associated with significant morbidity and mortality, and higher vascular related hospitalization rates and costs, compared to coronary artery and cerebrovascular disease[1, 2] DCB have emerged as an effective treatment option for patients with symptomatic PAD, combining acute restoration of vessel patency by balloon dilatation with long term maintenance of such patency through the antiproliferative drug.

CMS approved DCBs for both inpatient (effective FY 2016) and outpatient add-on payments via transitional pass through payments (effective April 1, 2015). We believe the add-on payments have been vital to facilitating beneficiary access to an advanced new technology, which has been proven to be clinically effective relative to alternative treatments.

As discussed in the CY 2018 HOPPS proposed rule, the transitional pass through (TPT) status for DCBs will expire on December 31, 2017, after which payment will be packaged into the OPPS payments for associated procedures. As a result, the payment rates for angioplasty procedures with DCB and will be the same as procedures performed with plain balloons.

We are concerned that the proposed payment structure would not adequately reflect the additional costs of DCB and thus would prevent patients from benefiting from a technology that reduces repeat interventions. As a result, patients may end up getting treated with lower cost alternatives but would then be subject to the risks and costs associated with reintervention procedures.

The clinical effectiveness of DCB angioplasty has been established through both randomized controlled trials and large-scale, population based observational studies. Specifically, DCBs have demonstrated improvements as follows:

- DCB therapy offers continued improvement in patency at three years[1],[2], 4, 5
- DCB therapy offers the lowest reported reintervention rate of all available SFA technologies 1-5
- DCB therapy offers better clinical outcomes, reduced reinterventions, and savings in total costs at 2 years.[3]
- A network-metaanalysis of PAD therapies showed that Paclitaxel-coated balloons (i.e. DCBs) offer the best long-term results in occlusive disease of femoropopliteal artery (Katsanos' network analysis).

RECOMMENDATION: The undersigned specialty societies urge the Panel to make a recommendation to CMS to assign a higher APC payment for DCB procedures verses percutaneous transluminal angioplasty (PTA) procedures without DCB.

Thank you for the opportunity to provide comments to the Hospital Outpatient Panel. We look forward to the meeting in August.

Sincerely

Matthew Sideman, MD
Chair, Society for Vascular Surgery Coding Committee

Suresh Vedantham, MD, FSIR
President, Society of Interventional Radiology

John Kaufman, MD
President, Vascular Interventional Advances

[1] Laird JR, Schneider PA, Tepe G, et al. Durability of Treatment Effect Using a Drug-Coated Balloon for Femoropopliteal Lesions: 24-Month Results of IN.PACT SFA. *J Am Coll Cardiol.* 2015;66(21):2329-2338.
[2] Krishnan P. Drug-Coated Balloons Show Superior Three-Year Outcomes vs. Angioplasty: Results from IN.PACT SFA Randomized Trial. Presented at: Vascular InterVentional Advances (VIVA); September 19, 2016; Las Vegas, NV.
[3] Salisbury AC, Li H, Notestein EE, et al. TCT-532 Economic Outcomes of Endovascular Femoropopliteal Intervention using Drug-Coated Balloons vs. Standard PTA: 1-year Results from the IN.PACT SFA II Trial. *Journal of the American College of Cardiology*. 2014;64(11_S).
4. Benenati JF. A Prospective, Global, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated PTA Dilation Catheter. Presented at: Vascular InterVentional Advances (VIVA); September 19, 2016; Las Vegas, NV.
5. Schroeder H, Werner M, Meyer DR et al. Low-dose Paclitaxel-coated Versus Uncoated Percutaneous Transluminal Balloon Angioplasty for Femoropopliteal Peripheral Artery Disease: 1-year Results of the ILLUMENATE European Randomized Clinical Trial. Circulation. 2017;CIRCULATIONAHA.116.026493,