Editorial

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Centers for Medicare & Medicaid Services' decision on drug-coated balloons: No additional reimbursement despite higher cost and highest levels of scientific evidence

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Beyond lifestyle intervention, medical therapy, and supervised exercise, peripheral artery disease (PAD) and its more advanced form, critical limb ischemia (CLI), are commonly treated with endovascular or surgical revascularization. For many years, interventionists commonly used off-label medical devices with little prospective data to guide treatment. Furthermore, professional societies and guidelines struggled to identify class I indications given the paucity of randomized controlled clinical trials. More recently, many third-party payers and the US Food and Drug Administration (FDA) have required 'on-label' indications for use of specific vascular devices. However, these studies have limited follow-up (typically 1 year), are frequently single-arm investigational device exemption (IDE) studies, and lack independent core laboratory adjudication. Fortunately, these realities changed with the introduction of drug-eluting stents (DES) and drug-coated balloons (DCB).

DES were first approved in November 2012 and DCB in February 2015. Since then, 5-year data for DES and 4-year data for DCB have been published. Eight randomized controlled trials have shown DCB to be superior to uncoated percutaneous transluminal angioplasty (PTA) in the femoral-popliteal arteries, with improved patency, decreased need for repeat revascularization, and ultimately lower overall healthcare cost.[1–3] The Centers for Medicare & Medicaid Services (CMS) recognized the clinical effectiveness of DES and DCB and offered special transitional pass-through (TPT) codes so that these novel, clinically proven therapies would be offered to patients without overriding concerns regarding cost. However, on January 1, 2018 the TPT add-on payment for DCB was terminated without creating a new ambulatory payment classification (APC) rate. Effectively, the CMS bundled DCB with uncoated PTA under the same APC rate, implying that the two devices were 'clinically' interchangeable.

This decision concerned many. The decision by the CMS will lead to lower DCB utilization and limit randomized controlled trial-demonstrated superior treatment for elderly and economically disadvantaged patients due to significant cost differences accrued by vascular intervention centers. In a previously published Viewpoint, we raised major concerns and outlined the clinical evidence clearly favoring DCB over uncoated PTA.[4] However, in the July 2018 outpatient hospital rule for CY 2019, the CMS maintained their position of considering DCB and PTA in the same APC category, essentially promoting an inferior reimbursement strategy that does not value efficacy, outcomes, and cost-savings over an episode of care.

The CMS has offered an 8-week open comment period so that all interested parties can express their concerns or support for the recent decision. We ask that all interested individuals provide comments on the CMS website (http://www.regulations.gov) under search term 'CMS-1695-P'. We suggest that clinical and policy experts and researchers indicate the importance of proper reimbursement for the technology that has demonstrated the highest levels of scientific evidence in treating PAD, with multiple publications

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in some of the highest impact factor cardiovascular journals available. We are concerned that the current decision by the CMS will lead to lower DCB use, to the harm of elderly and disadvantaged populations. The impact could even be larger if other third-party payers decide to follow the CMS's decision.

The current policies of the CMS that rely on 'principal of averaging' and 'budget neutrality' are based solely on cost and may lead to rationing of therapies that are not evidence-based or even cost-effective. The intended consequences of this decision are to reduce costs to our national healthcare system, but the unintended consequences are that hospitals operating on razor-thin margins will not be capable of absorbing the cost differences between DCB and uncoated PTA. Furthermore, the concept of 'budget neutrality' creates competing interests among physicians and industry because reimbursement for one procedure must be lowered to allow a higher reimbursement for another. Neither of these principles considers the evidence base and global burden of cost as it relates to DCB for the treatment of PAD. As clinical researchers and experts in the field, we rarely are able to prove causality in comparative effectiveness studies; however, based upon available data, we suspect that this policy change will directly result in significantly lower patency, increased need for repeat revascularization, higher readmission rates, lower quality of life, and higher overall healthcare costs.

We hope that the CMS reconsiders the decision regarding DCB and provides a new and appropriate APC for technologies that have demonstrated superiority to uncoated PTA through rigorous prospective randomized, multicenter, independently adjudicated trials published in major peer-reviewed publications. Policies focused on unit device cost without consideration of clinical benefit and cost-effectiveness over the course of a patient's episode of care will discourage advances in therapy and commitment to rigorous scientific study. These policies will result in inferior treatment for our patients with severe PAD who are at significant risk of major amputation and death, who demand improved quality of life and functional status, and who expect clinicians and federal regulators to work with their best interests in mind.

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