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VIEWPOINT

Public Health Impact of the Centers for Medicare and Medicaid Services Decision on Pass-Through Add-On Payments for Drug-Coated Balloons

A Call to Action

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ABSTRACT

On Wednesday, November 1, 2017, the Centers for Medicare and Medicaid Services (CMS) made a public decision to end the transitional pass-through add-on payment for drug-coated balloons beginning January 1, 2018, without creating a new ambulatory payment classification rate for these devices. In this Viewpoint, the authors highlight the disconnect between the CMS's decision not to create a new ambulatory payment classification category for drug-coated balloons despite demonstrated clinical superiority. The authors believe this decision is more in line with a rigid fee-for-service payment system than a value-based system that encourages quality over quantity, and disadvantages both the elderly and the poor. They call on all who advocate for patients with peripheral artery disease to action, encouraging their engagement on CMS decisions regarding payment. (J Am Coll Cardiol Intv 2018;11:496–9)

On Wednesday, November 1, 2017, the Centers for Medicare and Medicaid Services (CMS) made a public decision to end the transitional pass-through (TPT) add-on payment for drug-coated balloons (DCBs) beginning January 1, 2018, without creating a new ambulatory payment classification (APC) rate for these devices (1). The outpatient hospital TPT add-on payment program is

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designed to support patient access to new technologies that meet stringent approval criteria regarding clinical effectiveness and that are not included in the existing APC rates. By offering an "add-on" payment, CMS has the opportunity to facilitate access to new and innovative devices that are too new to be covered in existing payments while CMS collects data on the costs of the technology to hospitals (2). After sufficient cost data has been collected, a process that typically requires 2 to 3 years, a decision can be made to incorporate the cost of these devices into a new APC, if applicable. DCBs became commercially available in February 2015. In April 2015, the hospital outpatient TPT add-on payment was initiated and in October 2015 inpatient new technology add-on payments (NTAPs) for DCB became effective.

CMS should be applauded for approving additional DCB coverage through NTAPs and TPT add-on payments, recognizing the incremental clinical benefits afforded by DCB compared with traditional uncoated angioplasty for patients with peripheral artery disease (PAD). This decision enabled thousands of patients to be treated with the most clinically effective technology available for reducing lifestyle limiting ambulatory symptoms and reducing the likelihood of limb loss. However, in the calendar year 2018 Outpatient Prospective Payment System (OPPS) Final Rule (effective January 1, 2018), CMS made the determination to end TPT payments and NTAPs and instead package DCB device costs into the currently available payment for uncoated balloon angioplasty. The decision to neither create a new APC category nor assign DCB angioplasty a more appropriate APC category surprised professional societies, physicians, public policy organizations, and medical centers who argued against doing so during the 2018 OPPS Proposed Rule Open Comment Period, out of concern over unintended patient consequences. Furthermore, there is an extensive body of clinical trial evidence showing the clinical superiority of femoropopliteal DCB versus uncoated balloon angioplasty. These studies include 3 large randomized controlled trials and a number of comparative analyses that confirmed the cost effectiveness of DCB in both the United States and Europe (3–9).

In this Viewpoint, we highlight the disconnect between CMS's decision not to create a new APC category for DCBs despite demonstrated clinical superiority. We believe this decision is more in line with a rigid fee-for-service payment system than a value-based system that encourages quality over quantity, and disadvantages both the elderly and the poor. We call on all who advocate for patients with PAD to action, encouraging their engagement on CMS decisions regarding payment.

Although decisions regarding TPT add-on payments are based on rigorous pre-specified clinical and cost criteria and are clearly outlined by CMS, the process for assigning procedures to payment categories after expiration of add-on payments does not incorporate value-based judgments. Instead, the fate of new technology reimbursement is left to a system that is based on the "principal of averaging," which has inherent drawbacks. In the CY2018 Final Outpatient Hospital Rule, the CMS response to stakeholder requests for a separate procedure code was as follows: "We believe that procedures with which the drug-coated balloons are used, specifically the procedure described by CPT code 37224, are appropriately described by the existing procedure codes and do not believe it is necessary at this time to establish a Healthcare Common Procedure Coding System C-code or G-code to distinguish an angioplasty procedure with a drug-coated balloon from an angioplasty procedure without a drug-coated balloon. The OPPS is a prospective payment system that relies on the principles of averaging, with some cases in an APC being more costly than others (and some cases being less costly)."

We disagree with this description. Because lower extremity angioplasty with more expensive DCBs is superior to uncoated balloon angioplasty, we assert that angioplasty with an uncoated balloon should rarely be used as standalone or definitive therapy (10,11). The comments from CMS about averaging the costs implies that both procedures have similar clinical efficacy and are interchangeable; therefore, the costs will balance out over time. This assumption by CMS is erroneous; indeed, angioplasty with uncoated balloons alone is broadly considered as substandard care given the superior 5-year outcomes with drug-eluting stents (DES) and 4-year outcomes with DCBs (12–14). It is therefore difficult to understand CMS's decision to consider DCB and angioplasty equal and interchangeable from a reimbursement perspective. In doing so, CMS risks unintended consequences resulting from reduced use of DCBs that will negatively impact patient outcomes.

This decision by CMS regarding hospital outpatient reimbursement for DCB procedures on the expiration of the add-on payment raises the issue of how CMS perceives "value." If value is determined by patient outcomes, plus access to necessary medical care, divided by cost, then the superior clinical outcomes associated with femoropopliteal DCB use appear to be overlooked in a system that bases decisions only on

costs. This is troubling, because decisions made solely on cost criteria may lead to rationing of effective health care therapies independent of the patient's best option. In this specific case, elderly Medicare patients would be disadvantaged, by the insufficient reimbursement available for more expensive, but more beneficial, treatment with DCBs.

Considering the disconnect between the current fee-for-service system and the available evidence base, the bigger question is, will this ruling by CMS have an impact on the health of patients with PAD? If the goal of the CMS program with novel technology is to nudge hospitals to swallow the cost differences, then this is unfortunate, as many hospitals that are currently experiencing financial distress will not be able to assume the additional cost of DCBs resulting from the significant reduction in reimbursement. This will likely incent physician operators toward lower DCB use and have a negative impact on patient outcomes while increasing repeat procedures, especially in more financially disadvantaged environments.

Although physicians, allied health professionals, and hospitals have a duty to provide the best evidence-based care to every patient, the financial impact of providing optimal care for patients remains a reality that must be addressed. We feel the current CMS decision will have a negative impact on DCB use, resulting in poorer vessel patency and quality of life, and higher readmission rates and overall health care costs for CMS beneficiaries (3,5,7–9).

Despite the many letters submitted during the 60-day comment period, CMS's agreement to continue to track C2623 codes and wait for panel review of the APCs for endovascular procedures is disappointing. Furthermore, CMS's decisions appear arbitrary when considered against evidence-based guidelines written in collaboration with multiple professional societies (15). It is difficult to understand a decision that severely underpays for the most innovative and effective technologies supported by level 1 evidence of clinical benefit (10,15,16).

The current fee-for-service system used by CMS does not align with patients' best interests and ignores value-based care. We would ask that this CMS reimbursement decision be updated to place more emphasis on data and clinical outcomes. CMS should instead seek direct input on the merits of each technology from knowledgeable, independent, multidisciplinary teams of content experts who consider data on patient health impact, including cost, safety, and efficacy.

We hereby issue a call to action to professional societies, representing thousands of physicians and the millions of patients they treat, patient advocacy groups, and patients themselves to partner with CMS on how to improve payment systems so that incentives are appropriately aligned, supporting therapies based on their patient and societal value. Representatives from major societies can provide guidance and expertise from a clinical perspective, to help CMS make important payment decisions that has an impact on the health of thousands of patients. We hope that this document facilitates the opening of a dialogue among Congress, CMS, professional societies, and medical professionals.

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