



**IN.PACT® Admiral® Drug-Coated Balloon Transitional Pass-Through (TPT) Payment  
 Overview, Examples, and FAQs**

**Overview**

Effective April 1, 2015 Medicare approved a transitional pass-through (TPT) payment for DCB to outpatient hospitals, in addition to the applicable outpatient APC payment rate to cover the cost of treating beneficiaries with the IN.PACT Admiral drug-coated balloon (DCB).<sup>1</sup>

To obtain this incremental payment, hospitals must report the new C-code for DCB, C2623, along with the relevant CPT® code (procedure code).

**The New HCPCS C-Code for DCB Must Be Reported on Outpatient Claims**  
**C2623 = Catheter, transluminal angioplasty, drug-coated, non-laser**

If hospitals do not report C2623, they will **not** receive a TPT payment for DCB and Medicare will not have adequate data to determine an appropriate future reimbursement rate for DCB when TPT status expires in two to three years.

**Medicare determines the TPT payment amount for DCB on a case-by-case basis for each hospital;** it is not a standard amount. The TPT payment amount is *typically* calculated based on:

- **A hospital's charges for DCB**, which includes a hospital's charge adjustment or markup to account for its operating and capital costs;
- **A hospital's average outpatient cost-to-charge ratio (CCR)**, which Medicare publishes and applies to the charges a hospital submits to determine the cost of the DCB to the hospital;<sup>2</sup> and
- ~~X~~ **The device related portion of the relevant APC** payment amount, which is also referred to as the device offset.

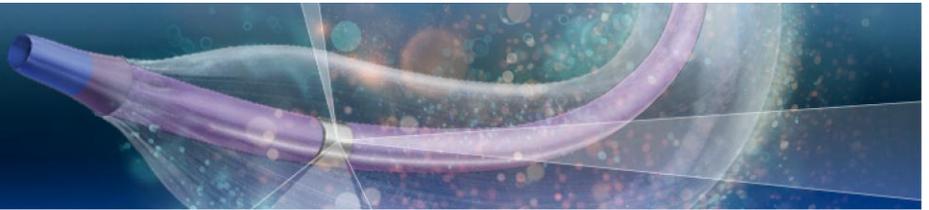
**However, on June 5<sup>th</sup>, CMS published a revised TPT policy for DCB removing the device offset deduction, based on an appeal submitted to CMS by Medtronic explaining the reasons an offset was not appropriate. CMS agreed with our reasoning and removed the offset, retroactive to April 1, 2015. This means the formula for calculating the TPT DCB is now dependent on two factors only, instead of three: the hospital's charges for DCB and the hospital's outpatient CCR.<sup>3</sup>**

**Medicare's <sup>New</sup> Formula for Calculating a Hospital's Total Payment Amount for a DCB Case**

<b>CY 2015 National APC Payment Amount</b>	+	<b>Hospital-Specific TPT Payment Amount</b>	=	<b>Total Amount Hospital Receives for a DCB Case</b>
APC 0083 = \$4,537 APC 0229 = \$9,624 APC 0319 = \$14,841		$\left( \begin{matrix} \text{Hospital's} \\ \text{Charges for} \\ \text{DCB} \end{matrix} \times \begin{matrix} \text{Hospital's} \\ \text{Specific} \\ \text{Outpatient} \\ \text{CCR} \end{matrix} \right) - \begin{matrix} \text{Device Related} \\ \text{Portion of} \\ \text{Relevant APC}^4 \end{matrix}$ 0083 = \$1,083.06 0229 = \$3,892.54 0319 = \$7,127.78		

**Disclaimer:** This document is for general educational purposes only and is not intended to serve as reimbursement advice. The reimbursement scenarios presented herein use a variety of hypothetical charges for DCB. These scenarios are meant to explain how Medicare calculates the TPT and should not be construed as reimbursement advice or guidance on how hospitals should charge for individual cases.

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See below for hypothetical examples illustrating how Medicare calculates the TPT payment for a DCB case and frequently asked questions (FAQs).

### TPT Calculation Examples for DCB

Below are three examples using a fictitious outpatient hospital to help illustrate how Medicare calculates the TPT payment amount for DCB cases. These are hypothetical examples and should not be construed as reimbursement advice or guidance on how hospitals should charge for specific cases.

Overview of Hypothetical Examples of TPT Payment Calculations	
<b>Example 1</b>	Hospital uses <u>one DCB</u> in an <u>angioplasty case</u> (APC 0083)
<b>Example 2</b>	Hospital uses <u>two DCBs</u> in an <u>angioplasty case</u> (APC 0083)
<b>Example 3</b>	Hospital uses <u>one DCB</u> in an angioplasty + atherectomy case (APC 0229)

For simplicity and for illustrative purposes, the examples below assume an acquisition cost of \$1,500 per DCB and a hospital average outpatient cost-to-charge ratio (CCR) of 0.247, which equates to an average outpatient markup of about 400% (1/0.247 x 100). Since each hospital may apply a different charge adjustment or markup to DCB, the examples show how the TPT calculation works for three different hypothetical charge adjustments (200%, 300%, and 400%).

#### Example 1: Hospital uses one DCB for an angioplasty case (APC 0083); TPT payment calculation shown with three different charge adjustments.

APC Payment Amount*	Hospital Specific TPT Payment Amount								Total Payment					
APC 0083 \$4,537	$\left\{ \begin{array}{l} \text{Hospital's Charge Adjustment} \\ \times \\ \text{Acquisition Cost for 1 DCB} \end{array} \right\} = \text{DCB Charge}$				$\times$	Hospital's Outpatient CCR	=	Medicare's Calculated DCB Cost	=	TPT Payment				
\$4,537	+	200% (or 2)	X	\$1,500	=	\$3,000	x	0.247	=	\$741	=	\$741	=	\$5,278
\$4,537	+	300% (or 3)	X	\$1,500	=	\$4,500	x	0.247	=	\$1,112	=	\$1,112	=	\$5,649
\$4,537	+	400% (or 4)	X	\$1,500	=	\$6,000	x	0.247	=	\$1,482	=	\$1,482	=	\$6,019

\*FY 2015 Medicare National Average reimbursement is used in the example; each hospital's APC payment, charge adjustment and CCR will vary

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**Example 2: Hospital uses two DCBs for an angioplasty case (APC 0083); TPT payment calculation shown with three different charge adjustments.**

APC Payment Amount*	Hospital Specific TPT Payment Amount								Total Payment					
APC 0083 \$4,537	$\left\{ \begin{array}{l} \text{Hospital's Charge Adjustment} \\ \times \\ \text{Acquisition Cost for 2 DCBs} \end{array} \right\} = \text{DCB Charge}$				$\times$	Hospital's Outpatient CCR	=	Medicare's Calculated DCB Cost	=	TPT Payment				
\$4,537	+	200% (or 2)	X	\$3,000	=	\$6,000	x	0.247	=	\$1,482	=	\$1,482	=	\$6,019
\$4,537	+	300% (or 3)	X	\$3,000	=	\$9,000	x	0.247	=	\$2,223	=	\$2,223	=	\$6,760
\$4,537	+	400% (or 4)	X	\$3,000	=	\$12,000	x	0.247	=	\$2,964	=	\$2,964	=	\$7,501

\*FY 2015 Medicare National Average reimbursement is used in the example; each hospital's APC payment, charge adjustment and CCR will vary

**Example 3: Hospital uses one DCB for an angioplasty + atherectomy case (APC 0229); TPT payment calculation shown with two different charge adjustments.**

APC Payment Amount*	Hospital Specific TPT Payment Amount								Total Payment					
APC 0229 \$9,624	$\left\{ \begin{array}{l} \text{Hospital's Charge Adjustment} \\ \times \\ \text{Acquisition Cost for 1 DCBs} \end{array} \right\} = \text{DCB Charge}$				$\times$	Hospital's Outpatient CCR	=	Medicare's Calculated DCB Cost	=	TPT Payment				
\$9,624	+	200% (or 2)	X	\$1,500	=	\$3,000	x	0.247	=	\$741	=	\$741	=	\$10,365
\$9,624	+	300% (or 3)	X	\$1,500	=	\$4,500	x	0.247	=	\$1,112	=	\$1,112	=	\$10,736
\$9,624	+	400% (or 4)	X	\$1,500	=	\$6,000	x	0.247	=	\$1,482	=	\$1,482	=	\$11,106

\*FY 2015 Medicare National Average reimbursement for APC 229 is used in the example; each hospital's APC payment, charge adjustment and CCR will vary

If you have additional reimbursement questions, please contact the Medtronic CV Reimbursement Hotline at (877) 347-9662 or [rs.cardiovasculartheconomics@medtronic.com](mailto:rs.cardiovasculartheconomics@medtronic.com)

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**FAQs**
**1. Why did IN.PACT Admiral qualify for TPT payment?**

Medicare provides TPT for qualified technologies that meet pre-established criteria including:<sup>4</sup>

- The technology must represent a “substantial clinical improvement” over the current standard of care
- The technology must be new and not adequately described by existing payment categories or present in hospital claims data
- The technology must meet certain cost thresholds

TPT payment allows Medicare to support patient access to a new technology while evaluating how much the new technology costs the healthcare system and hospital. Since 2005, only 10 devices have received TPT status. The IN.PACT Admiral DCB is one of these 10 devices.<sup>5</sup>

**2. Will TPT apply to all FDA-approved DCBs?**

Yes. The TPT applies to all FDA-approved DCBs.

**Hospital Outpatient Reimbursement for DCB**
**3. What procedure codes are eligible for TPT in the hospital outpatient setting?**

For hospital outpatient cases, C2623 may be billed with the various peripheral transluminal balloon angioplasty codes that are assigned to the three APCs listed below (0083, 0229, 0319).

CPT® CODE & DESCRIPTION	APC ASSIGNMENT & DESCRIPTION	CY15 AVG PAYMENT
37224 – Fem/pop Angioplasty only	0083 – Level I Endovascular Procedures	\$ 4,537
37226 – Fem/pop Angioplasty + Stent	0229 – Level II Endovascular Procedures	\$ 9,624
37225 – Fem/pop Angioplasty + Atherectomy	0229 – Level II Endovascular Procedures	\$ 9,624
37227 – Fem/pop Angioplasty + Stent + Atherectomy	0319 – Level III Endovascular Procedures	\$ 14,841

**4. Where can a hospital find the hospital specific outpatient cost-to-charge-ratio (CCR) used in the TPT payment calculation?**

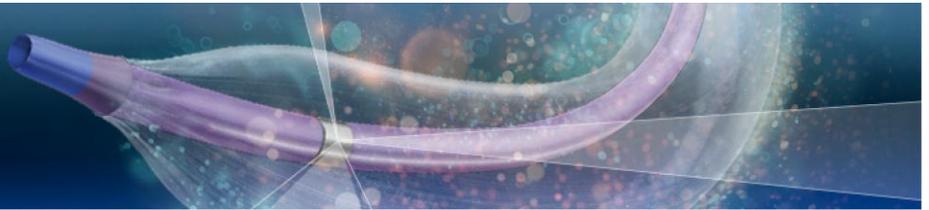
The CY 2015 Outpatient CCRs by provider number are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-CN.html?DLPage=1&DLSort=2&DLSortDir=descending>. Download the CY-2015-OPPS-CN Facility-Specific-Impacts file and search the excel file by Medicare provider number. The Outpatient CCR is listed in Column J. If you do not know your Medicare provider number, please contact us via email at [rs.cardiovascularhealthconomics@medtronic.com](mailto:rs.cardiovascularhealthconomics@medtronic.com) with the name and location of your hospital and we can look it up for you.

**5. What to do if a hospital encounters claims edits/issues requiring resubmission of the claim or other issues with claims using the C2623 code (including denial)?**

The best source of information regarding claims processing issues is the payer – either the patient’s private insurance company or, the Medicare Administrative Contractor (for traditional Medicare A/B patients). Providers should contact the appropriate payer to report the problem and seek clarification about the issue.

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Please also contact us at the Medtronic CV Reimbursement Hotline (877-347-9662) or send us an email at [rs.cardiovascularhealththeconomics@medtronic.com](mailto:rs.cardiovascularhealththeconomics@medtronic.com) with the details of the issue for additional support and guidance.

**6. When will the claims processing systems be updated to remove the device offset deduction from the TPT payment calculation?**

Medicare updates its claims processing systems quarterly; since the offset removal was decided after the April update, the next update will occur effective July 1, 2015. Starting July 1, a claim submitted appropriately should be processed without an offset deduction.

**7. What is the process for obtaining retroactive TPT payments for Medicare DCB cases from April 1, 2015 to July 1, 2015, until the claims processing systems are updated with the offset removal?**

Providers should work with their respective Medicare Administrative Contractors (MACs) for information on how to obtain payments for cases prior to July 1, 2015 as each MAC may have different processes in place for this. Lookup your hospital's MAC and contact information at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/#tx>.

**8. How should a hospital bill a DCB case in the outpatient hospital setting?**

We offer the following suggested best practices for submitting a hospital outpatient DCB case to Medicare:

- Ensure that the correct CPT procedure code (37224, 37225, 37226 or 37227) is submitted with C2623 as well as the appropriate device codes for other devices used (for example, at least one of the following: C1725, C1874, C1876, C1724 must be included on the claim).
- Specify the number of units of DCB catheters used
- Submit the appropriate revenue code from the 027X series
- Ensure the charges reflect the number of DCB catheters used in the procedure

**Physician Reimbursement**

**9. How are physician payments impacted by using DCB?**

Physician professional payments are not impacted when using DCB. The physician will continue to use the same CPT code to describe the work of performing a peripheral angioplasty with a DCB or other balloon angioplasty catheter.

CPT® CODE & DESCRIPTION	CY15 MEDICARE FACILITY UNADJUSTED FEE SCHEDULE PAYMENT
37224 – Fem/pop Angioplasty only	\$ 481.97
37226 – Fem/pop Angioplasty + Stent	\$ 566.00
37225 – Fem/pop Angioplasty + Atherectomy	\$ 651.09
37227 – Fem/pop Angioplasty + Stent + Atherectomy	\$ 783.03

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## **Reimbursement for DCB Cases in the Hospital Inpatient Setting, ASC, and Physician Office Setting**

### **10. Does the TPT payment apply to DCB cases performed in the inpatient setting, an ambulatory surgery center (ASC), or in physician office-based labs?**

#### ***Hospital Inpatient Setting***

TPT payment does not apply to the inpatient setting. However, Medtronic submitted an application for a New Technology Add-on Payment (NTAP) for DCB in November 2014. Medicare will notify us of their decision in early August 2015 with an effective date of October 1, 2015. If approved, hospital inpatient cases using a DCB will receive an additional payment above the applicable MS-DRG payment.

#### ***Ambulatory Surgery Centers***

Providers in the ASC setting of care are eligible for TPT payment for DCB cases when C2623 is billed with CPT Code 37224 (Fem/pop Angioplasty only) or CPT Code 37226 (Fem/pop Angioplasty + Stent).<sup>6</sup>

Providers in the ASC setting are not eligible for TPT payment for DCB cases when C2623 is billed with CPT Code 37225 (Fem/pop Angioplasty + Atherectomy). TPT payment for DCB when used in an angioplasty + atherectomy case is only available in the acute hospital outpatient setting (OPPS). Medicare's formula for determining the TPT payment amount is different than the formula used for the hospital outpatient setting. For more information, please contact the Medtronic CV Reimbursement Hotline at (877) 347-9662 or [rs.cardiovascularhealthconomics@medtronic.com](mailto:rs.cardiovascularhealthconomics@medtronic.com).

#### ***Physician Office-Based Labs***

TPT payment does not apply to physician office-based labs. Unfortunately, for physician office-based labs, there is no separate coding or payment mechanism to capture the additional DCB technology cost.

## ***Reimbursement for Non-Medicare DCB Cases***

### **11. Does the TPT apply to non-Medicare patients treated with a DCB**

TPT payment only applies to Medicare fee-for-service (FFS) claims for DCB cases. While commercial and Medicare Advantage plans often use Medicare FFS payment rates as a reference when establishing their own payment rates, the coding and payment policies of commercial payers may vary for DCB. Providers should work with these payers to ensure appropriate reimbursement for non-Medicare FFS patients.

#### **References**

<sup>1</sup> CMS. April 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS). Transmittal #: R3217CP. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3217CP.pdf>. Accessed March 17, 2015.

<sup>2</sup> CY 2015 Outpatient CCRs by provider number available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-CN.html?DLPage=1&DLSort=2&DLSortDir=descending>. Download the CY-2015-OPPS-CN Facility-Specific-Impacts file and search the excel file by provider number.

<sup>3</sup> CMS. July 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS). Transmittal #: R3280CP. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3280CP.pdf>. Accessed June 25, 2015.

<sup>4</sup> CMS. Process and Information Required to Apply for Additional Device Categories for Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System. Available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/catapp.pdf>. Accessed March 17, 2015.

<sup>5</sup> CMS. List of Device Category Codes for Present or Previous Pass-Through Payment and Related Definitions. Available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Compleat-list-DeviceCats-OPPS.pdf>. Accessed March 17, 2015.

<sup>6</sup> CMS. April 2015 Update of the Ambulatory Surgical Center (ASC) Payment System. Transmittal #: R3214CP. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3214CP.pdf>. Accessed March 17, 2015.

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## Indications for Use:

The IN.PACT Admiral Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

### Contraindications

The IN.PACT Admiral DCB is contraindicated for use in:

- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

### Warnings

- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP (14 atm [1419 kPa]) is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of implanting multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 20,691 µg of paclitaxel in a patient has not been clinically evaluated in the IN.PACT SFA Trial.

### Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the *Instructions for Use* (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events

### Potential Adverse Events

Adverse events that may occur or require intervention include, but are not limited to the following: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.

Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.

Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.

Refer to the Physician's Desk Reference for more information on the potential adverse events observed with paclitaxel. There may be other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse events. This content is available electronically at [www.manuals.medtronic.com](http://www.manuals.medtronic.com).

**CAUTION:** Federal (USA) law restricts the use of this device to sale by or on the order of a physician.

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