

OPPS PAYMENT FOR DRUG-COATED BALLOON (DCB) ANGIOPLASTY PROCEDURES IN CY 2018

Advisory Panel on Hospital Outpatient Payment
August 21-22, 2017

SUMMARY OF PRESENTATION

Presenters*

Gary M. Ansel, MD, FACC
Carrie Bullock
Dave Parr

System Medical Chief, Vascular: OhioHealth Heart & Vascular Physicians
Director, Health Policy & Reimbursement: Medtronic
Vice President, Global Reimbursement: CR Bard

CPT and HCPCS Codes Involved

37224 Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
C2623 Catheter, transluminal angioplasty, drug-coated, non-laser

APCs Affected

5192 Level 2 Endovascular Procedures
5193 Level 3 Endovascular Procedures

Description of the Issue

Following expiration of transitional pass-through payment at the end of CY 2017, costs of drug-coated balloon (DCB) angioplasty procedures will far exceed OPPS payment in CY 2018 based on current assignment of CPT code 37224 to APC 5192.

Clinical Description of the Service

Use of DCBs in revascularization procedures results in superior clinical and economic outcomes relative to use of plain balloons only. CPT 37224 is assigned to APC 5192, while other femoropopliteal revascularization procedures that frequently involve DCBs are in APC 5193.

Recommendations and Rationale for Change

In order to recognize the higher up-front costs associated with DCB and to improve clinical homogeneity, we respectfully request that DCB angioplasty procedures (37224+C2623) be assigned to APC 5193 instead of 5192, and that CMS consider amending its complexity adjustment criteria so that this combination will qualify for a complexity adjustment.

Potential Consequences of Not Making the Change

Unless CMS reassigns DCB angioplasty procedures to a higher level APC, Medicare payment will be inadequate to ensure continued patient access to this important technology.

*Disclosures: Dr. Ansel is a paid consultant to CR Bard and Medtronic. Ms. Bullock is an employee and shareholder of Medtronic. Mr. Parr is an employee and shareholder of CR Bard.

A CLINICAL PERSPECTIVE ON THE ROLE OF DRUG- COATED BALLOONS

Gary M Ansel MD FACC

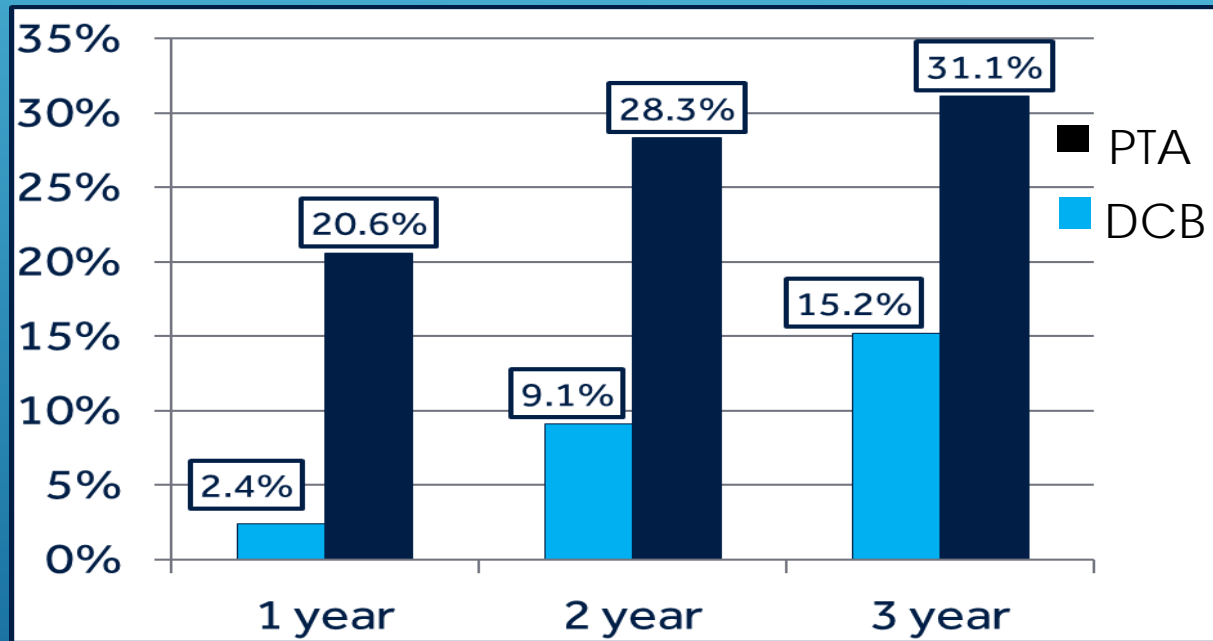
System Medical Chief: Vascular

OhioHealth Heart & Vascular Physicians

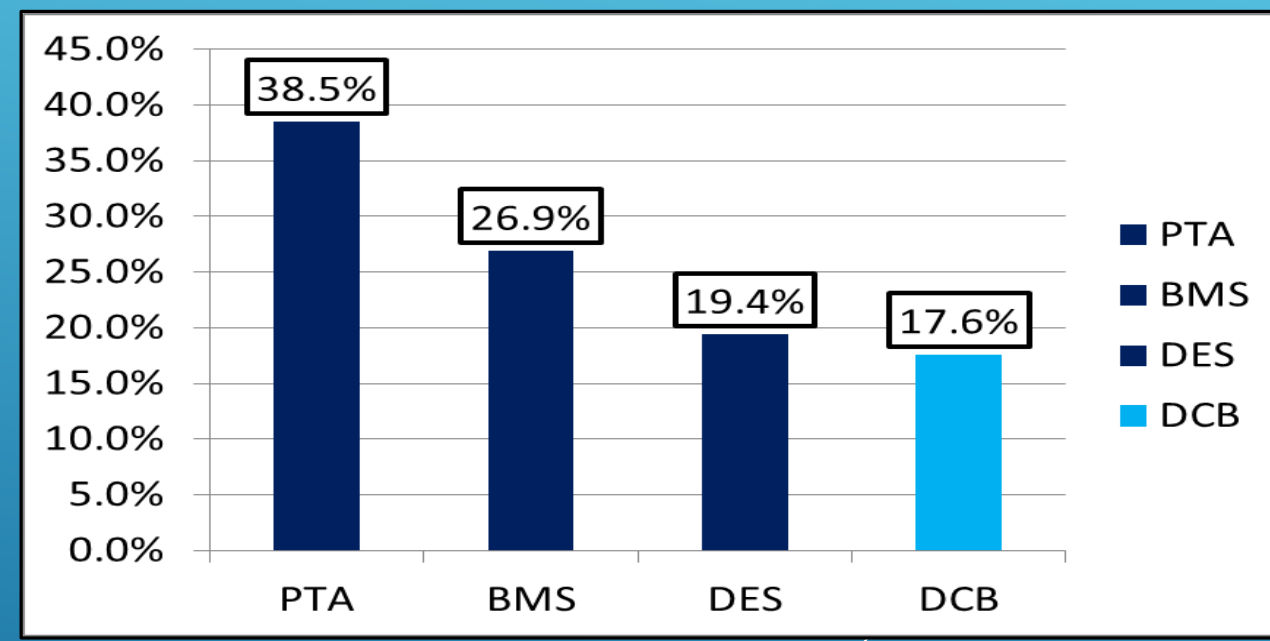
Columbus, Ohio

SUSTAINED, LONG-TERM IMPROVEMENTS IN PATENCY AND SUBSTANTIALLY REDUCED REPEAT PROCEDURES AT 1, 2 AND 3 YEARS

- DCBs have been a major therapeutic change in the treatment of PAD in the US
- Long-term follow-up data confirm the significant improvement in patient outcomes^{1,2,3,4}
- DCB therapy is associated with the lowest reintervention rate among SFA technologies⁵



SIGNIFICANTLY FEWER REPEAT INTERVENTIONS WITH DCB VS PTA



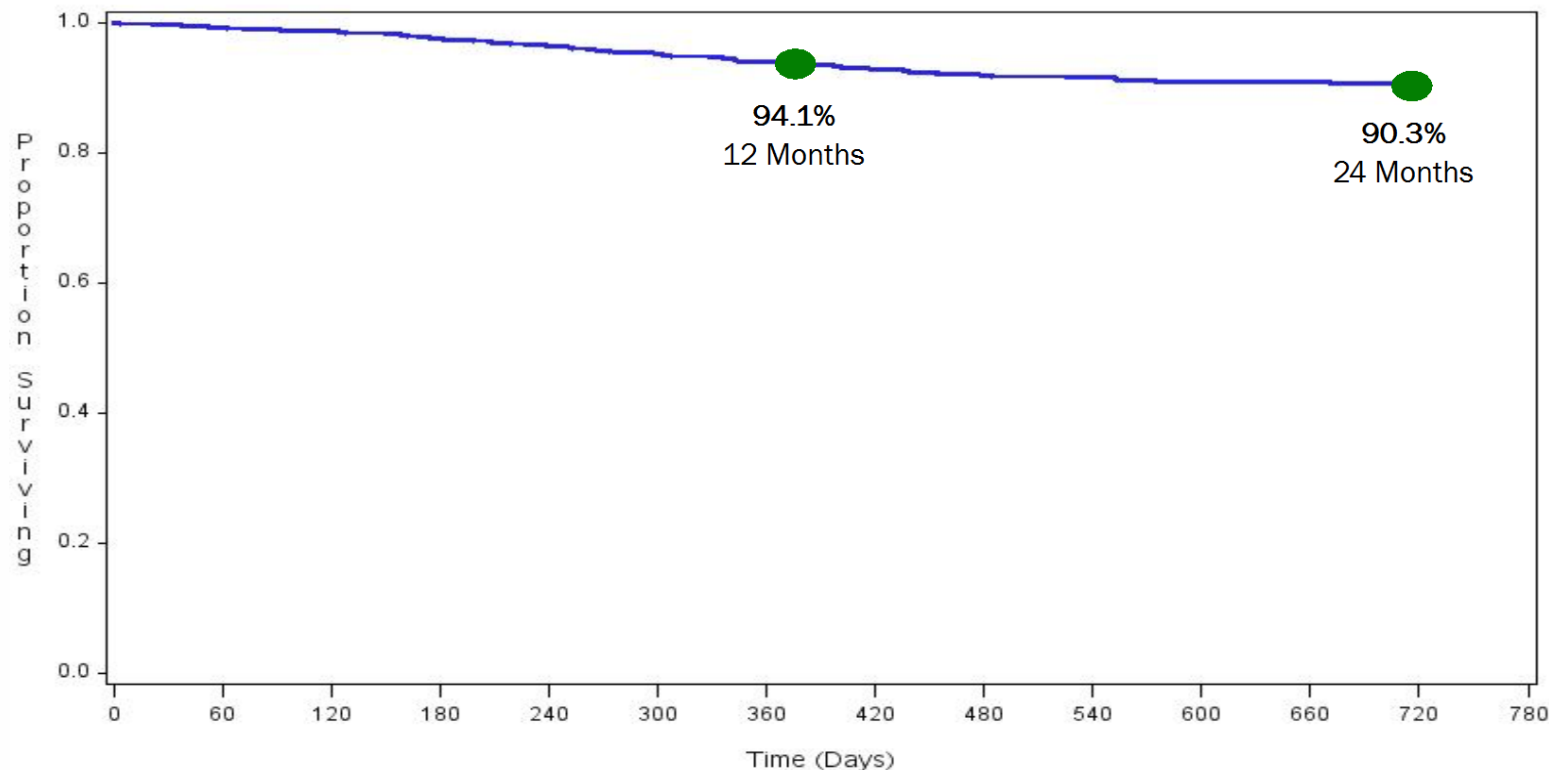
SUBSTANTIALLY LOWER REPEAT INTERVENTIONS WITH DCB VS OTHER THERAPIES AT 2 YEARS (Pooled 24 month TLR rates)

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) Sept 2016; Las Vegas, NV.
3. Benenati JF. A Prospective, Global, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated PTA Dilatation Catheter. Presented at: VIVA; Sept, 2016; Las Vegas, NV.
4. 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 ILLUMINATE European Randomized Clinical Trial. *Circulation*. 2017;CIRCULATIONAHA.116.026493.
5. Adapted from: JB, Geisler, BP, Garner, AM et al. Economic Analysis of Endovascular Interventions for fem-pop Arterial Disease: A systematic review and Budget Impact Model for the US and Germany, *Catheterization and Cardiovascular Interventions* 2014, 84:546-554.

LUTONIX[®] Global SFA Real-World Registry

TLR Free Survival

Time	N	Survival % [95% CI]	P-value ¹	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	628	94.1% [92.0%, 95.6%]	<.001	40	34	617
Month 24 (730 Days)	527	90.3% [87.7%, 92.3%]		63	318	310



¹ Primary efficacy analysis based on Kaplan-Meier estimates ($H_0: s \leq 78\%$ vs $H_1: s > 78\%$) where s is the survival rate

VERY LOW REPEAT INTERVENTION RATES ARE CONSISTENT ACROSS DIVERSE PATIENT POPULATIONS

Comparison of 12-month Outcomes¹

	IN.PACT SFA (DCB ARM) (N=220)	IN.PACT Global Long Lesion Imaging Cohort (N=157)	IN.PACT Global ISR Imaging Cohort (N=131)	IN.PACT Global CTO Imaging Cohort (N=126)	IN.PACT Global Clinical Cohort (N=1406)
Lesion Length (Mean ± SD, cm)	8.94 ± 4.89	26.40 ± 8.61	17.17 ± 10.47	22.83 ± 9.76	12.09 ± 9.54
Primary Patency (KM @ 360 days)	86.6%*	91.1%	88.7%	85.3%	N/A
CD-TLR	2.4%	6.0%	7.3%	11.3%	7.5%
Thrombosis	1.4%	3.7%	0.8%	4.3%	2.9%
Major Amputation Target Limb	0.0%	0.0%	0.0%	0.0%	0.2%

*KM Day 360 rate of 87.5% using 2-year data

STELLAREX ^{2, 3}	ILLUMENATE EU RCT ¹ (DCB ARM) (N=222)	ILLUMENATE US RCT ² (DCB ARM N= 200)
Lesion Length (Mean ± SD, cm)	7.2 ± 5.2	8.0 ± 4.5
In-stent Restenosis (ISR) %	0.0%	0.0%
Chronic Total Occlusion (CTO) %	19.2%	19.0%
Primary Patency (KM @ 360 days)	89.0%	82.3%
CD-TLR	5.9%	7.9%
Major Amputation Target Limb	0.0%	0.0%

1. Jaff, M. Drug-Coated Balloon Treatment for Patients with Intermittent Claudication: Insights from the In.Pact Global Full Clinical Cohort ; Presented at VIVA 2016, Las Vegas, NV.
2. Schroeder H, Werner M, Meyer DR, et al. Low-Dose Paclitaxel-Coated Versus Uncoated Percutaneous Transluminal Balloon Angioplasty for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial (Randomized Trial of a Novel Paclitaxel-Coated Percutaneous Angioplasty Balloon). *Circulation*. 2017;135(23):2227-2236.
3. Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation*. 2017.

DCB THERAPY OFFERS SUPERIOR CLINICAL OUTCOMES AND LONG TERM SAVINGS TO HEALTH SYSTEMS AND PAYERS

- Prospective cost-effectiveness study with 2 year follow-up
- Initial procedure costs \$1,129 higher per patient in DCB arm
- Discharge to 24 months target limb-related costs - \$1,212 lower per patient treated with DCB
- DCB therapy offers better outcomes and no added cost after two years compared to PTA, creating cost savings to the health care system^{1,2}

JACC Cardiovasc Interv. 2016 Nov 28;9(22):2343-2352. doi: 10.1016/j.jcin.2016.08.036.

Cost-Effectiveness of Endovascular Femoropopliteal Intervention Using Drug-Coated Balloons Versus Standard Percutaneous Transluminal Angioplasty: Results From the IN.PACT SFA II Trial.

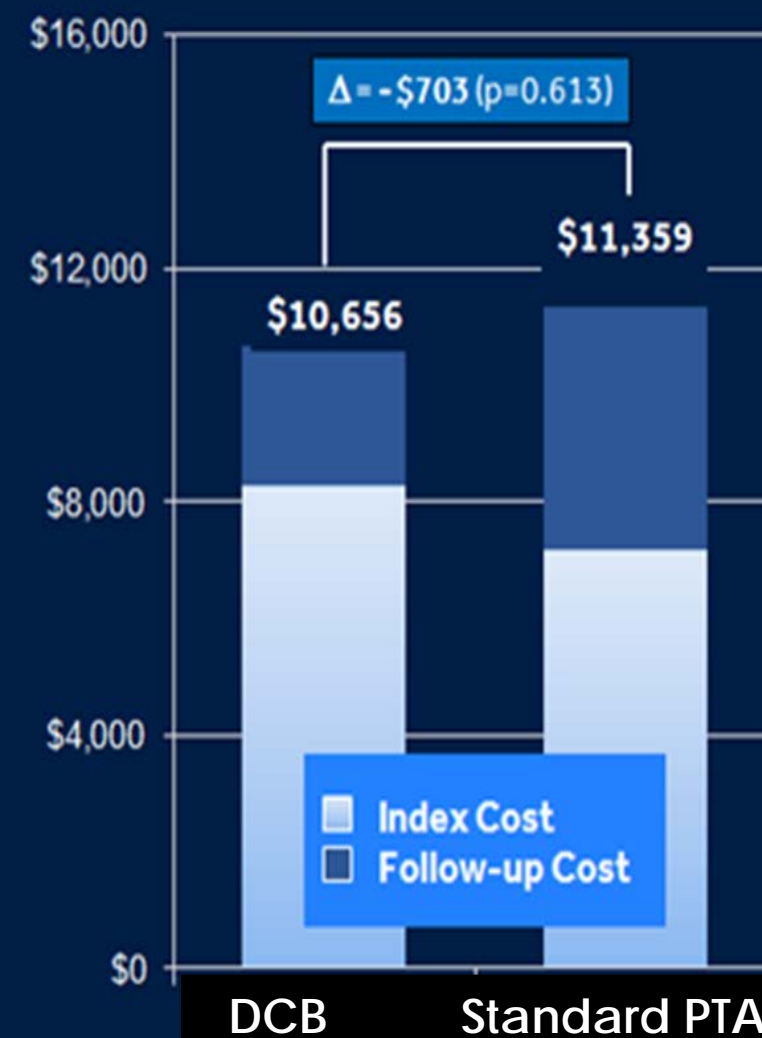
Salisbury AC¹, Li H², Vilain KR², Jaff MR³, Schneider PA⁴, Laird JR⁵, Cohen DJ⁶.

Author information

Abstract

OBJECTIVES: The aim of this study was to evaluate the cost-effectiveness of drug-coated balloon (DCB) angioplasty versus standard percutaneous transluminal angioplasty (PTA).


Cost-Effective: Lower follow-up costs after DCB offset higher upfront costs of DCB




1. Salisbury AC, Li H, Vilain, KR et al. Cost-effectiveness of Endovascular Femoropopliteal Intervention using Drug Coated Balloons vs Standard Percutaneous Transluminal Angioplasty: Results from the IN.PACT SFA II Trial. JACC Cardiovasc Interv. 2016 Nov 28; 9 (22): 2343-2352.

2. Pietzsch JB, Geisler, BP, Garner, AM et al. Economic Analysis of Endovascular Interventions for fem-pop Arterial Disease: A systematic review and Budget Impact Model for the US and Germany, Catheterization and Cardiovascular Interventions 2014, 84:546-554.

SUMMARY OF UPDATED CLINICAL EVIDENCE

- DCBs have significantly changed the treatment landscape for femoropopliteal artery disease based on the superior outcomes including:
 - ▶ Reduction in loss of patency and recurrent symptoms
 - ▶ Lower rates of revascularization (51% relative reduction at 3 years), and
 - ▶ Lower target limb related treatment costs at 2 years
 - Long term follow-up data confirm that clinical benefits extend through 3 years
 - Consistent results across diverse patient populations
 - DCB are a cost-effective strategy due to fewer repeat procedures
- 
- A series of three parallel white diagonal lines extending from the bottom right towards the top right of the slide.

WHAT IS HAPPENING IN THE COMMUNITY

- Increasing uptake of DCB devices
 - Far fewer stent procedures
 - Less radiation
 - Less repeat procedures (Riverside Methodist Hospital down 16%)
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- A series of white diagonal lines of varying lengths and thicknesses are positioned in the bottom right corner of the slide, creating a modern, abstract graphic element.

OPPS PAYMENT FOR DCB
ANGIOPLASTY PROCEDURES
BEGINNING IN CY 2018

CODING FOR DCB ANGIOPLASTY PROCEDURES

- DCB devices received their own HCPCS code when they were approved for transitional pass-through payment, effective April 1, 2015

Code	Descriptor
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser

- The CPT code for femoropopliteal artery angioplasty does not distinguish between DCB procedures (involving both a plain balloon and a DCB) and non-DCB procedures (involving only a plain balloon)

Code	Descriptor
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty

PROPOSED CY 2018 OPPTS APC AND PAYMENT

- Separate pass-through payment for C2623 for the DCB device will expire on December 31, 2017; payment will be packaged into the associated procedure
- 37224 is proposed to be assigned to Comprehensive APC 5192 (Level 2 Endovascular Procedures):

APC	APC Descriptor	CY 2018 Proposed Payment
5191	Level 1 Endovascular Procedures	\$2,845
5192	Level 2 Endovascular Procedures	\$4,999
5193	Level 3 Endovascular Procedures	\$10,218
5194	Level 4 Endovascular Procedures	\$15,573

DESCRIPTION OF ISSUE

- Costs of DCB angioplasty procedures will far exceed OPPS payment in CY 2018 based on current assignment of CPT code 37224 to APC 5192 (Level 2 Endovascular Procedures)
- The mean cost for cases involving DCB is 25% higher than the mean cost of cases involving only a plain balloon, and nearly 40% higher than the mean cost of APC 5192
- Despite significant uptake (43% of 37224 cases involved DCB), the costs of DCB have negligible impact on the APC payment because of the high volume of other procedures assigned to APC 5192

CY 2018 OPPS Proposed Rule Data				
	Single Frequency	Geometric Mean Cost	Difference Relative to DCB Cases	
			\$	%
37224 with C2623 (DCB)	4,575	\$8,483	---	---
37224 without C2623 (non-DCB)	6,057	\$6,396	-\$2,087	-25%
37224 (all claims)	10,695*	\$7,153	-\$1,330	-16%
Overall APC 5192	92,029	\$5,200	-\$3,283	-39%

Sources: Analysis by Direct Research, CMS 2018 OPPS Proposed Rule CPT and APC Cost Statistics

* Does not equal the sum of prior two lines because derived from CMS' CPT Cost Statistics file rather than from modeled results.

RECOMMENDATION AND RATIONALE FOR CHANGE

- DCB angioplasty procedures should qualify for a complexity adjustment and be reassigned to APC 5193 to improve alignment between payment and costs
- In the CY 2018 OPPS proposed rule, CMS proposed a similar approach for cystoscopy procedures involving blue light technology (82 *Federal Register* 33579-33580)
- Qualifying claims would include 37224 as the primary HCPCS code, and C2623 as the secondary HCPCS code
- Analysis of the subset of CY 2016 claims with 37224+C2623 indicates a mean cost of \$8,483, which is 3% less than the complexity adjustment threshold for APC 5193 of \$8,743

Primary HCPCS	Primary APC	Secondary HCPCS	Complexity Adjustment APC Assignment	Evaluation Subset Combination Frequency	Meet Volume Threshold?	Evaluation Subset Geometric Mean Cost	Cost Threshold	Difference Between Subset Cost and Threshold (\$ / %)
37224	5192	C2623	5193	4,575	Yes	\$8,483	\$8,743	-\$260 / -3%

Sources: Analysis by Direct Research, CMS 2018 OPPS Proposed Rule Appendix J

RECOMMENDATION AND RATIONALE FOR CHANGE (CONT.)

- The cost of DCB angioplasty procedures (\$8,483) is much more in line with the proposed payment for APC 5193 (\$10,218) than it is for the proposed payment for APC 5192 (\$4,999), and higher than other procedures already assigned to APC 5193
- Other peripheral revascularization procedures are assigned to APC 5193, including those commonly billed with C2623 (e.g., 37225 and 37226)
- Allowing a complexity adjustment for 37224+C2623 will improve payment accuracy at the procedure level, with negligible impact at the APC level (less than 3%)
 - Final 2018 payment rates would remain slightly higher than final 2017 payment rates

CY 2017 OPPS Final Rule		CY 2018 OPPS Proposed Rule		Modeled CY 2018 OPPS Final Rule with Complexity Adjustment for DCB (37224+C2623)	
APC	Payment	APC	Payment	APC	Payment
5191 Level 1	\$2,834	5191 Level 1	\$2,845	5191 Level 1	\$2,845
5192 Level 2	\$4,825	5192 Level 2	\$4,999	5192 Level 2	\$4,877
5193 Level 3	\$9,752	5193 Level 3	\$10,218	5193 Level 3	\$10,174
5194 Level 4	\$14,782	5194 Level 4	\$15,573	5194 Level 4	\$15,573

Sources: Analysis by Direct Research, CMS 2017 Final Rule Addendum A, CMS 2018 Proposed Rule Addendum A

ABSENT A CHANGE IN THE FINAL RULE, PAYMENT FOR DCB ANGIOPLASTY PROCEDURES WILL BE INSUFFICIENT TO ENSURE PATIENT ACCESS

- The current proposed payment rate for DCB angioplasty procedures of \$4,999 based on assignment to APC 5192 is significantly lower than the historical costs for these cases of \$8,483
- The mean cost for cases involving DCB is 25% higher than the mean cost of cases involving only a plain balloon, and nearly 40% higher than the mean cost of APC 5192
- If a change in APC assignment is not made, payment for these procedures will be inadequate to ensure that patients have continued access to DCB angioplasty procedures, which CMS has determined provide superior clinical benefit to Medicare beneficiaries compared to plain balloon angioplasty procedures

The manufacturers of DCB technology respectfully request the Panel recommend to CMS that DCB angioplasty procedures (37224+C2623) be assigned to APC 5193 instead of 5192, and that CMS consider amending its complexity adjustment criteria so that this combination will qualify for a complexity adjustment