

AGENT[™]
Paclitaxel Drug Coated Balloon

**Boston
Scientific**
Advancing science for life[™]

Assign CPT 0931T (Transcatheter Therapeutic Drug-Delivery by Intracoronary Drug Delivery Balloon) to APC 5193

CMS Hospital Outpatient Payment (HOP) Panel Meeting

August 26-27, 2024

Ziad Ali, MD, PhD

Director Interventional Cardiology, St Francis Hospital,
Roslyn, NY

Ta-Yuan Ho

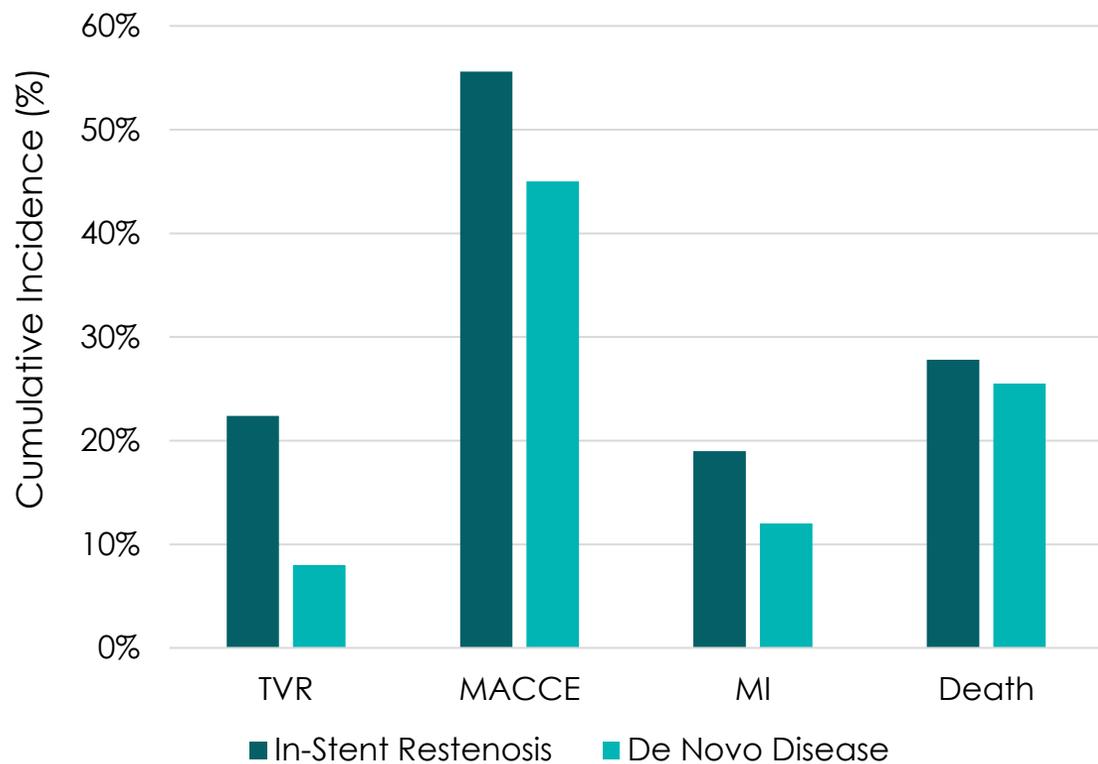
Director, Health Economics & Market Access, Boston
Scientific Corporation



In-Stent Restenosis (ISR) is Clinically Challenging

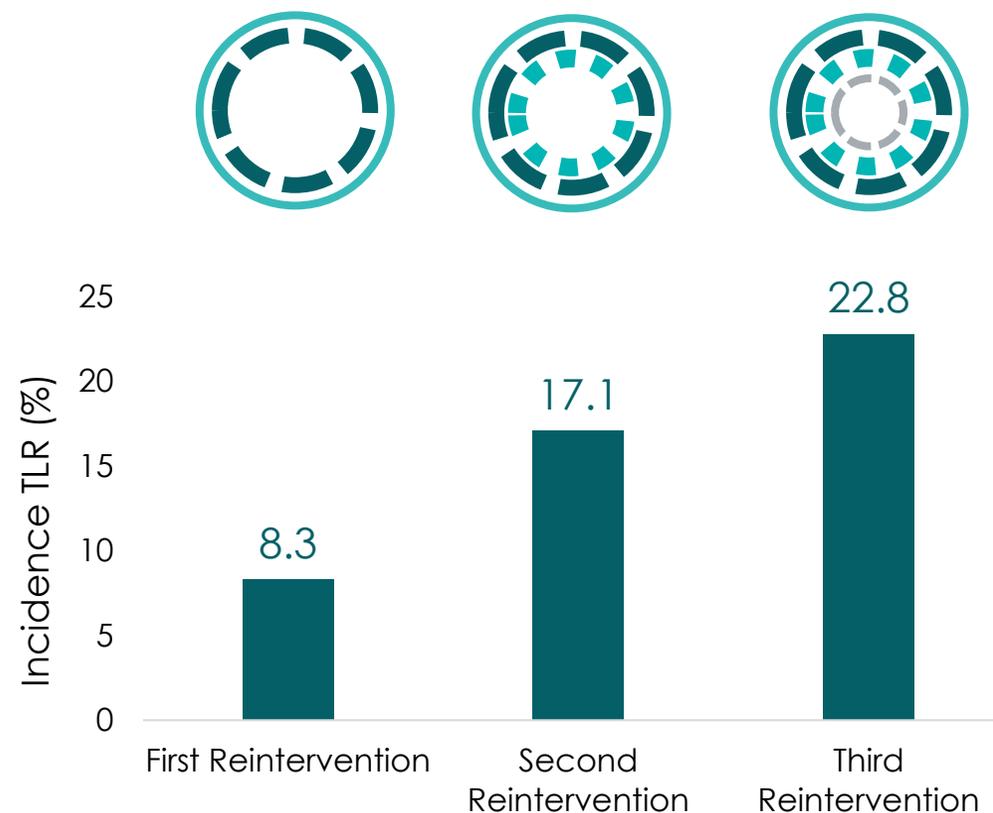
ISR is Associated with Statistically Higher Risk of Adverse Events vs De Novo Disease

Analysis of CathPCI Registry after 48 months
(all P-Values <0.0001)¹



Repeat Interventions in ISR Are Associated with Higher Risk of Target Lesion Revascularization (TLR)

N=30,440 patients at 2 centers in Germany over 15 years²



1. Tamez, H., et al. Eurointervention 17.5 (2021): e380-e387

2. Kastrati, A, and Cassese, S. Journal of the American College of Cardiology 76.13 (2020): 1532-1535.



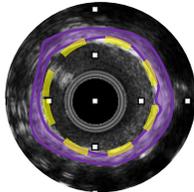
AGENT™ Drug-Coated Balloon (DCB) ISR Procedure Algorithm¹

Step-by-Step

01

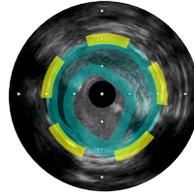
Define Mechanism of ISR with Intravascular Imaging

A. Identify any mechanical issues



e.g. Calcification Behind Struts

B. Understand extent and pattern of disease



e.g. Neointimal Hyperplasia

- Stent
- Neointimal Hyperplasia
- Calcium

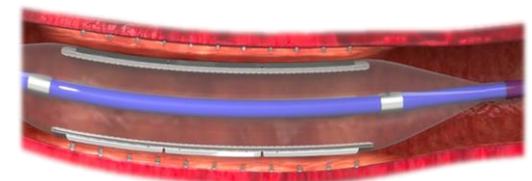
02

Lesion Preparation (Plaque Modification as Needed)

Non-compliant Balloon (NCB) Predilation



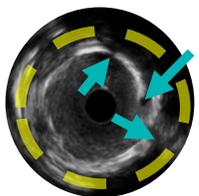
Cutting Balloon for Resistant Lesions



03

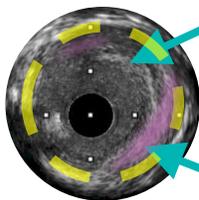
Reassess with Intravascular Imaging for Optimal Result

A. Has calcium been appropriately modified?



Neointimal calcium fractures

B. Has the neointima been appropriately modified?

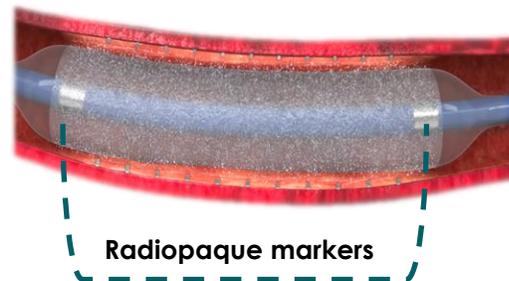


angioplasty effect
more modification can be done

04

Treat the Lesion with AGENT™ Drug-Coated Balloon

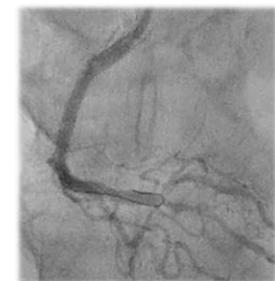
Inflate DCB to 1:1 and keep inflated in position for at least 30 seconds



05

Final Angiographic Assessment

Optional Intravascular Imaging to confirm final results and ensure no flow-limiting dissection





Description of Issue: Coronary DCB APC Assignment

The proposed initial APC assignment for 0913T (XX23T) coronary DCB to APC 5192 would impede Medicare beneficiary access to care by creating a significant financial barrier to utilizing DCB therapy

- In February 2024, AMA CPT Editorial Panel approved a new bundled PCI base code XX23T for transcatheter therapeutic drug delivery by intracoronary drug delivery balloon
- Released 1 July 2024, 0913T (XX23T) will become effective 1 January 2025

- 0913T** Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch
- C9600 & 92978** Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)

- HCPCS C9600 (DES + PTCA) has 2023 GMC of \$11,665¹ and is assigned to APC 5193

Early Cost Analysis Supports Reassignment to APC 5193

Catholic Health Saint Francis Hospital & Heart Center – Roslyn, NY

- Medicare Outpatient claims for coronary DCB were analyzed reflecting experience from the first 2.5 months of commercial availability in 2024

Frequency	Min Cost	Max Cost	Median Cost	GMC	CV
11	\$13,124.80	\$28,297.18	\$17,989.85	\$18,935.69	24.425

Revenue center level costs were analyzed using CCRs from the most recent cost reports from CY 2023 OPPS rate-setting file

- The GMC of these claims would exceed the CY 2025 2x rule cost threshold for procedures in APC 5192 & 5193
 - 91% of these claims would likely qualify for outlier payments in CY 2025 if 0913T remains in APC 5192
- The GMC of these claims is more cost coherent to PCI procedures in APC 5194 than APC 5192

HCPCS	Description	Proposed 2025 APC	Proposed 2025 Payment Rate	2023 Single Frequency	2023 Geometric Mean Cost	Difference
92920	PTCA	51920	\$5,701.38	4,815	\$7,983.85	-\$2,282.47
C9600	DES + PTCA	51930	\$11,292.55	77,356	\$11,665.49	-\$372.94
92928	BMS + PTCA	51930	\$11,292.55	3,076	\$12,449.97	-\$1,157.42
92924	Atherectomy + PTCA	51930	\$11,292.55	481	\$14,932.54	-\$3,639.99
C9602	DES + Atherectomy + PTCA	51940	\$17,680.43	5,539	\$18,812.27	-\$1,131.84
0913T¹	DCB + IVUS/OCT + PTCA	51920	\$5,701.38	11	\$18,935.69	-\$13,234.31
92933	BMS + Atherectomy + PTCA	51940	\$17,680.43	318	\$19,979.92	-\$2,299.49

2025 NPRM CPT Cost Stats.07052024.xls

1. For 0913T, single frequency and geometric mean costs sourced from analysis of 2024 claims from Catholic Health Saint Francis Hospital & Heart Center



Request the HOP Panel recommend CMS reassign CPT 0913T (XX23T) to APC 5193

- APC Reassignment will reduce financial barriers to utilizing coronary DCB and will more appropriately align with the clinical complexity and resource utilization with treating ISR patients
- Costs suggests that resource utilization for coronary DCB procedures would appropriately align with cost of procedures in APC 5193



Summary

CPT/HCPCS Codes	0913T (XX23T) - Transcatheter therapeutic drug delivery by intracoronary drug delivery balloon
APCs Impacted	Endovascular Procedures APC 5192, 5193
Description of the Issue	The proposed initial APC assignment for coronary DCB to APC 5192 would impede Medicare beneficiary access to care by creating a significant financial barrier to utilizing DCB therapy
Clinical Description of Service	Coronary DCB procedure is intended to treat a complex patient population, coronary in-stent restenosis (ISR), and involves both intravascular imaging and mechanical dilation prior to drug delivery.
Recommendation & Rationale	Requesting the Panel recommend CMS reassign CPT 0913T (XX23T) from APC 5192 to 5193. The reassignment more appropriately aligns with the clinical complexity and resource utilization with treating ISR patients. The initial experience at St Francis Hospital demonstrates the resources required for these procedures and supports APC reassignment.

AGENT[™]
Paclitaxel Drug Coated Balloon

**Boston
Scientific**
Advancing science for life[™]



Thank You

Leave the Right
AGENT Behind