Boston Scientific
Advancing science for life™

ELUVIA™ DRUG-ELUTING STENT

NEW TECHNOLOGY ADD-ON PAYMENT (NTAP)

Effective October 1, 2020, the Centers for Medicare and Medicaid Services (CMS) will provide an add-on payment for the use of Eluvia of up to **$3,646.50** per qualifying Medicare inpatient hospitalization admission to IPPS-participating[1] acute care hospitals. For eligible admissions, this add-on payment will be incremental to the MS-DRG[2] reimbursement.

CMS awarded NTAP status to Eluvia for satisfying these criteria:

NTAP is not applicable to Zilver® PTX ® or any other peripheral device, only Eluvia.

NEWNESS

The product uses a new Mechanism of Action (MOA) to achieve a therapeutic outcome.

COST

The MS-DRG payment for a service involving the product is inadequate based upon CMS case-weighted cost thresholds.

SUBSTANTIAL CLINICAL IMPROVEMENT

The technology must provide a substantial clinical improvement over existing therapies.

IMPERIAL RCT is the world's first Head-to-Head DES SFA Trial[3]

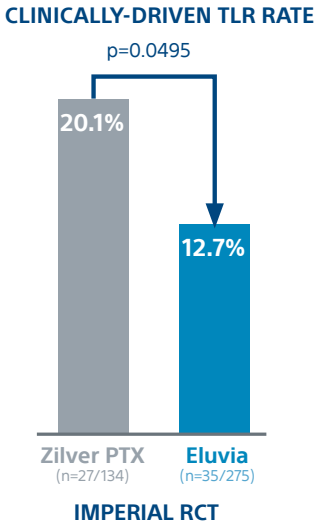
A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia Drug-Eluting Stent against Cook Medical's Zilver PTX Stent

Highest Primary Patency Ever Reported at Two Years for DES or DCB US Pivotal Trial[4]

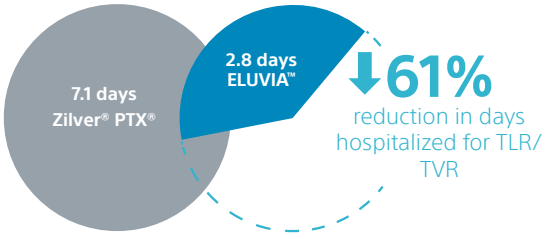
83.0%[5]

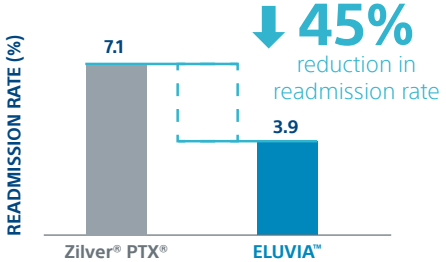
Low Repeat Intervention Rates Through Two Years after Treatment with Eluvia

Eluvia demonstrated a **statistically significant reduction in TLR[5]** vs. Zilver PTX at 24 months



Eluvia **reduces days hospitalized** and **hospital readmissions** vs Zilver PTX at 12 months[5]





For qualified[6] Medicare patients:

IPPS-participating[1] acute care hospitals that report the correct ICD-10-PCS procedure and diagnosis codes will be eligible for the NTAP. The ICD-10-PCS codes (below) associated with the NTAP must be within the first 25 codes on the claim. Hospital may continue utilizing the Eluvia NTAP designation with dates of service beginning October 1, 2021.

How is the NTAP amount[7] calculated?

- The amount of the NTAP is determined by the lesser of either (a) 65% of the total cost of the technology, inclusive of multiple devices [NTAP maximum] or (b) 65% of the costs [Total Hospital Charges for a given admission x Hospital-Specific Operating Cost-to-Charge (CCR) Ratio] in excess of the MS-DRG reimbursement [including adjustments for hospital wage index {HWI}, indirect medical education {IME}, and disproportionate share {DSH}] for the case.
- If the total covered costs of the case do not exceed the MS-DRG payment, then no additional payment is made.

Medicare FY 2022 Hospital MS-DRG Inpatient Reimbursement for SFA (Superficial Femoral Artery) Stenting, Eluvia, Bare-Metal Stents, Covered Stents, non-Sustained Release DES (Drug-Eluting Stents).

MS DRG	Description	FY 2021 Payment[8]
252	Other Vascular Procedures w/ MCC	$21,931
253	Other Vascular Procedures w/ CC	$17,499
254	Other Vascular Procedures w/o CC/MCC	$11,975

ICD-10 PCS[9]	Abbreviated Description
Right Femoral Artery:	
X27H385	Dilation, Right Femoral Artery w/ Sustained Release DES, Perc Approach
X27H395	Dilation, Right Femoral Artery w/ 2 Sustained Release DESs, Perc Approach
X27H3B5	Dilation, Right Femoral Artery w/ 3 Sustained Release DESs, Perc Approach
X27H3C5	Dilation, Right Femoral Artery w/ 4 or > Sustained Release DESs, Perc Approach
Left Femoral Artery:	
X27J385	Dilation, Left Femoral Artery w/ Sustained Release DES, Perc Approach
X27J395	Dilation, Left Femoral Artery w/ 2 Sustained Release DESs, Perc Approach
X27J3B5	Dilation, Left Femoral Artery w/ 3 Sustained Release DESs, Perc Approach
X27J3C5	Dilation, Left Femoral Artery w/ 4 or > Sustained Release DESs, Perc Approach
Proximal Right Popliteal Artery:	
X27K385	Dilation, Proximal Right Popliteal Artery w/ Sustained Release DES, Perc Approach
X27K395	Dilation, Proximal Right Popliteal Artery w/ 2 Sustained Release DESs, Perc Approach
X27K3B5	Dilation, Proximal Right Popliteal Artery w/ 3 Sustained Release DESs, Perc Approach
X27K3C5	Dilation, Proximal Right Popliteal Artery w/ 4 or > Sustained Release DESs, Perc Approach
Proximal Left Popliteal Artery:	
X27L385	Dilation, Proximal Left Popliteal Artery w/ Sustained Release DES, Perc Approach
X27L395	Dilation, Proximal Left Popliteal Artery w/ 2 Sustained Release DESs, Perc Approach
X27L3B5	Dilation, Proximal Left Popliteal Artery w/ 3 Sustained Release DESs, Perc Approach
X27L3C5	Dilation, Proximal Left Popliteal Artery w/ 4 or > Sustained Release DESs, Perc Approach

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1. Hospitals not reimbursed under the IPPS, include but not limited to critical access hospitals, excluded cancer hospitals, long-term acute care hospitals, Veterans Affairs (VA) hospitals, Department of Defense (DoD) facilities, and hospitals in the state of Maryland, are not eligible to receive add-on payments.
2. MS-DRG is a clinically cohesive group of hospital services whose needs run parallel to hospital resources and exhibit similar length-of-stay (LOS) patterns. The CMS goal is to recalibrate appropriate MS-DRG payments to incorporate the use of the new technology.
3. IMPERIAL Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144).
4. Highest-two year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT 2 and Primary Randomization for Zilver PTX RCT. Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
5. 2-Year Results from IMPERIAL Trial; Presented at LINC 2020 Gray WA et al. Lancet. 2018 Oct 27;392(10157):1541-1551. **IMPORTANT:** Economic messages presented above are based on extrapolations of publicly-available data from the IMPERIAL trial.
6. Traditional (fee-for-service) Medicare beneficiaries where the cost of the case exceeds the MS-DRG payment for the case.
7. Hospitals receiving NTAPs are still eligible to receive outlier payments. DRG and outlier payments vary by hospital and are case-dependent. Subsequently, the NTAP amount and total amount of final reimbursement will vary.
8. CMS-1752-F, FY 2022 IPPS Final Rule, https://public-inspection.federalregister.gov/2021-16519.pdf
9. FY 2021 ICD-10-PCS, https://www.cms.gov/medicare/icd-10/2022-icd-10-pcs

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