



MAY 2022

Transitional Pass-Through Payment

Frequently Asked Questions





Transitional Pass-Through (TPT) Payment - **Frequently Asked Questions**

WHAT IS THE TPT PROGRAM?

- The TPT payment program was implemented by CMS to facilitate Medicare beneficiary access to Medical Devices in the Hospital (HOPD) and Ambulatory Surgery Centers (ASC) setting.
- During the TPT period, CMS makes a separate payment for the medical device in addition to the APC payment.
- Data on cost and utilization is collected during the 3-year period of TPT status, which informs CMS's rate-setting for the associated APC when TPT status ends, and the device payment is incorporated into the APC payment.
- The TPT Payment program allows for the collection of data on utilization without increasing HOPD and ASC costs or overall spending in the US health care system.

WHY IS THE TPT PROGRAM IMPORTANT?

- Under Medicare, the cost of a medical device is normally included in a bundled APC payment for the entire procedure. However, when a medical device has been granted TPT status, Medicare makes a separate payment for the cost of the device, minus the portion of the bundled payment that is included in the APC payment for the device.
- This means that physicians and hospitals can use new, innovative medical devices on TPT status without taking a financial loss if the new medical device costs more than older devices.

WHEN AND WHY DID THE TRINAV® INFUSION SYSTEM QUALIFY FOR TPT?

- CMS applied its three-part test — (1) newness, (2) cost impact, and (3) substantial clinical improvement—and determined that TriNav qualified for pass-through payment in HOPD and ASC through December 31, 2022.¹
- TriNav met the narrow program eligibility criteria, including demonstration of substantial clinical improvement compared to existing devices.

WHAT CODES ARE NEEDED FOR TRINAV TPT?

- Facilities must accurately and correctly submit Medicare HOPD and ASC claims. CMS has determined that APC 2025 that is associated with the cost of the device category described by HCPCS code C1982, (*Catheter, pressure-generating, one-way valve, intermittently occlusive*), may be billed with the following CPT Code(s):²
 - 37242 – Pre-Treatment Mapping (*Vascular embolization or occlusion, artery*)
 - 37243 – Treatment (*Vascular embolization or occlusion, organ*)
- Site of Service Codes: Fiscal Intermediaries recognizes two types of settings under the TPT program
 - On Campus-Outpatient Hospital (22)
 - Ambulatory Surgery Centers (24)
- Facilities are encouraged to contact non-Medicare payers prior to using TriNav to confirm coverage and reimbursement, as methodologies and amounts may vary.

¹ Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payments Systems Final Rule, 85 Fed. Reg. 85866, 85988 (Dec. 29, 2020). Please note that TriNav was previously known as the Surefire® Spark™ Infusion System. ² Centers for Medicare & Medicaid Services, CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 4513, Feb. 4, 2020, at 4. Integrated Outpatient Code Editor (22.0.0), Final Summary of Data Changes, (Jan. 2021). CPT copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

HOW LONG WILL TPT LAST? AND WHAT HAPPENS THEN?

- The provision is called “transitional” because it is designed to provide a bridge into the regular payment mechanism. Pass-through status is temporary, lasting at least two but not more than three years.
- TriNav has been granted TPT status through December 31, 2022.
- CMS will incorporate the TriNav Infusion system into the service with which it is used when its pass-through status sunsets (December 31, 2022).
- The Ambulatory Payment Classification (APC) for the related service is increased to reflect the utilization of the TriNav Infusion System during its pass-through period.

TRINAV DESCRIPTION

The TriNav Infusion System is a 0.021-inch lumen microcatheter with SmartValve® self-expanding tip. SmartValve supports pressure generation, which enables delivery of therapeutic agents to selected sites in the peripheral vascular system.^{3,5-7}

INTENDED USE

The TriNav Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.⁴

CONTRAINDICATIONS

TriNav is not intended for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature).⁴

Rx Only. For the safe and proper use of the TriNav Infusion System, refer to the Instructions for Use.

For questions about TriNav reimbursement please contact the TriNav Reimbursement Support at 866-779-0450 or trinavreimbursement@priahealthcare.com. Monday through Friday from 8:30am – 5:00pm ET. After hours calls will be returned the following business day.

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³Titano JJ, et al. *Cardiovasc Intervent Radiol*. 2019 ;42:560-568. ⁴TriSalus™ TriNav™ Infusion System, Instructions for Use. ⁵Kim AY, et al. *PLoS One*. 2017;12(9):e0183861. DOI: 10.1371/journal.pone.0183861. ⁶Pasciak AS, et al. *J Vasc Interv Radiol*. 2015;26:660-669. ⁷Durham E, Jaroch D, Hunter K. Poster presented at: World Conference on Interventional Oncology (WCIO); May 6-9, 2015; New York, NY.