



MAY 2020

# Transitional Pass-Through Payment

Frequently Asked Questions





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

### WHAT IS THE TPT PROGRAM?

- Medicare operates the TPT payment program in order to facilitate patient access to new and truly innovative products that have shown substantial clinical improvement.
- TPT allows the agency to gather the necessary cost and utilization data for a product and assign appropriate codes and rates for long-term payment purposes.
- Medicare makes this special TPT payment while they are collecting data to foster use of new technologies in the outpatient setting amid facility cost concerns.

### WHEN AND WHY DID TriNav QUALIFY FOR TPT?

- Medicare 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 hospital outpatient and ASC settings starting January 1, 2020.<sup>1</sup>
- In support of substantial clinical improvement, CMS considered a number of clinical studies and agreed that the research shows statistically significant improvement when the device is used.<sup>1</sup>

### WHAT CODES ARE NEEDED FOR TriNav TPT?

- In order for Medicare to make a TPT payment, facilities must accurately and correctly submit Medicare outpatient claims.
  - Device Code (C1982): The HCPCS code Medicare created to describe the use of TriNav is C1982 (*Catheter, pressure-generating, one-way valve, intermittently occlusive*).
  - Procedure Code (37243): Medicare has stated that the device code describing TriNav should always be billed with CPT Code 37243 (*Vascular embolization or occlusion*).<sup>2</sup>
  - Site of Service Codes (22 or 24): Medicare recognizes two types of sites for the outpatient TPT program—On Campus-Outpatient Hospital or Ambulatory Surgery Centers.
- While most payers usually follow suit with Medicare Part B coverage policy, the reimbursement methodologies and amounts may vary. Facilities are encouraged to contact payers prior to using a TriNav to confirm coverage and reimbursement policies.

### HOW LONG WILL TPT LAST? AND WHAT HAPPENS THEN?

- Once granted, the law requires Medicare to make TPT payments for at least 2 years. In practice, it takes closer to 3 years to collect sufficient cost and utilization data. TriSalus expects that TPT payments will continue through the end of 2022.
- After TPT, Medicare usually bundles products into the associated ambulatory payment classification (APC) code in direct correlation to the product's utilization during the pass-through period.
- Beginning in 2023, TriSalus expects Medicare will bundle TriNav usage into APC 5193 and increase the payment rate accordingly.

### TRIAL PERIOD REFUND OPTION

- To help alleviate reimbursement concerns during facilities' initial TriNav use, TriSalus is offering a refund up to the full purchase price of any unit if a payor—Medicare Part B or otherwise—denies adequate payment for the product cost.
- Please see Page 2 for full details of the refund offer, including applicable terms and conditions.

The coding information provided above is general in nature, gathered from third-party sources, and subject to change without notice. The provider is solely responsible for determining medical necessity, the appropriate setting for service delivery, and submitting accurate claims for products and services rendered. TriSalus encourages facilities to contact payors for specific information on their coding, coverage, and payment policies.

<sup>1</sup> Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payments Systems Final Rule, 84 Fed.Reg 218, 61142, 61274-76 (Nov.12, 2019). Please note that TriNav was previously known as the Surefire® Spark™ Infusion System. <sup>2</sup> Centers for Medicare & Medicaid Services, CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 4513, Feb. 4, 2020, at 4. CPT copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

## TriNav REFUND TERMS & CONDITIONS

Purchasing hospitals and ambulatory surgery centers (ASC) are eligible for a refund amount up to the purchase price of the entity's first order of TriNav, subject to the following limitations and restrictions:

- Use of the device is consistent with the device's FDA clearance and applicable payor outpatient coverage policy;
- Initial payment denial is sustained at least through the first level of appeal; and
- Hospital or ASC maintains and submits all documentation necessary to establish the applicable conditions of coverage and accurately codes for the services provided.

This refund offer expires on the earlier of (i) the one-hundred and twentieth (120th) day after the first delivery to the facility of purchased TriNav product, or (ii) the hospital's first receipt of notice of a payment denial for an appropriate patient. In other words, the refund offer is limited to the period of the TriNav's initial introduction in each hospital or ASC.

In the event TriSalus provides such a refund, the recipient facility must agree to: (1) report the refund to the appropriate payor and any secondary insurer; (2) return any collected deductibles and copayments to the patient; (3) adjust the statement submitted to the payor or any secondary insurer to reflect the return of any collected cost-sharing amounts; (4) upon request, provide TriSalus with proof of such reports, refunds, or adjustments; and (5) upon request, provide all information related to the refund to federal and state health care officials.

TriSalus reserves the right to limit any such refund amount by deducting either (a) the device offset portion of the APC payment, (b) the difference between the product acquisition cost and the device portion of the APC payment, or (c) a similar amount so as not to unjustly enrich the hospital or ASC.

This refund offer is good only for US hospitals and ASCs. It can be redeemed once per hospital or ASC. The value of this refund offer is limited to each entity's initial order of TriNav or \$46,500, whichever is less. This offer is not transferrable. It cannot be combined with any other offer and has no cash value. No other purchase is necessary. This offer is void where taxed, restricted, or prohibited by law. TriSalus Life Sciences reserves the right to rescind, revoke, or amend this offer at any time with or without notice.

## 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.<sup>1,3-5</sup>

## 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.<sup>2</sup>

## 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).<sup>2</sup>

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

**For further questions about TriNav reimbursement please contact the TriNav Reimbursement Support Hotline at 866-779-0450 or [trinavreimbursement@priahealthcare.com](mailto:trinavreimbursement@priahealthcare.com). The hotline is available Monday through Friday from 8:30am – 5:00pm EST. After hours calls will be returned the following business day.**

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1. Titano JJ, et al. *Cardiovasc Intervent Radiol*. 2019;42:560-568. 2. TriSalus™ TriNav™ Infusion System, Instructions for Use. 3. Kim AY, et al. *PLoS One*. 2017;12(9):e0183861. DOI: 10.1371/journal.pone.0183861. 4. Pasciak AS, et al. *J Vasc Interv Radiol*. 2015;26:660-669. 5. Durham E, Jaroch D, Hunter K. Poster presented at: World Conference on Interventional Oncology (WCIO); May 6-9, 2015; New York, NY.