



## Transitional Pass-Through Payment - Frequently Asked Questions

### WHAT IS TRANSITIONAL PASS-THROUGH (TPT) PAYMENT?

- The Centers for Medicare & Medicaid Services' (CMS) [TPT payment program](#) facilitates patient access to new and innovative device technologies that have shown substantial clinical improvement by allowing for adequate payment while CMS collects cost data necessary to incorporate the cost of these technologies into existing ambulatory payment classification (APC) payment rates.
- The TPT program applies to devices used in procedures reimbursed by Medicare under its Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. TPT payment does not apply outside of these settings or to payment from non-Medicare payers.

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

- On November 12, 2019, CMS approved the Surefire® Spark™ Infusion System (now known as the TriNav™ Infusion System) for TPT payment beginning in the 2020 Calendar Year (CY) in the [CY 2020 Medicare Hospital OPPS and ASC Payment System Final Rule \(CMS-1717-FC\)](#).<sup>1</sup>
- To secure TPT payment, CMS requires that a new product meet specific criteria: Newness, Substantial Clinical Improvement, and Cost.<sup>2</sup> CMS determined that TriNav™ met all three criteria for pass-through payment approval:
  - **Newness:** CMS stated that TriNav™ met the Newness criterion, having been recently granted 510(k) premarket clearance by the Food and Drug Administration (FDA) on April 3, 2018 and not appropriately described by another existing category (i.e., code).
  - **Substantial Clinical Improvement:** CMS stated that TriNav™ met the Substantial Clinical Improvement criterion based on four clinical studies submitted by TriSalus.
  - **Cost:** CMS also agreed that TriNav™ met the CY2020 cost significance requirement. TriSalus™ set the cost of TriNav™ according to a standard set of cost considerations, including cost of goods, research and development costs, and relative value.

### WHAT DOES TPT MEAN FOR HOSPITALS / HOW LONG WILL IT LAST?

- Beginning on January 1, 2020, hospital outpatient departments and ambulatory surgery centers using the TriNav™ device will be eligible to receive an offset payment amount equal to the difference between the current device portion of the APC payment rate and the cost of the device, in addition to the CY 2020 APC payment amount.
- CMS may make pass-through payments for a period of at least 2 years, and not more than 3 years.<sup>3</sup> CMS may therefore make pass-through payments for procedures using the TriNav™ device until December 31, 2022.
- The TPT payment is available when a device described by the below C-code is used in the hospital outpatient or ASC setting and reimbursed by Medicare.

### WHAT IS THE CODE NEEDED FOR TriNav™ TPT?

HCPCS Code	Description
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive

- CMS will recognize the above C-code when used in conjunction with appropriate procedure code(s) both during and subsequent to the pass-through payment period.

### DISCLAIMER

These codes are not all-inclusive; appropriate codes can vary by patient setting of care and payer. Correct coding is the sole responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. TriSalus™ Life Sciences does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

For further questions about TriNav™, please contact TriSalus™ Life Sciences at +1.888.321.5212 or [info@trinavinfusion.com](mailto:info@trinavinfusion.com)

<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).

<sup>2</sup> 42 USC 1395l(t)(6) as implemented in 42 CFR 419.66

<sup>3</sup> 42 USC 1395l(t)(6)(C)