



New Medicare pass-through code supports adoption of singleuse duodenoscopes

A new transitional pass-through code (C1748) took effect July 1 for providers using single-use duodenoscopes to treat Medicare patients in the hospital outpatient and Ambulatory Surgical Center (ASC) settings. The pass-through code makes single-use duodenoscopes a financially viable alternative to reusable duodenoscopes.

During a Sept. 30 webinar sponsored by Boston Scientific and hosted by *Becker's Hospital Review*, three physician leaders discussed what's guiding the shift toward singleuse duodenoscopes, as well as what transitional passthrough payment means for organizations using these devices. The speakers were:

- John McInnes, MD, JD, former Director of the Division of Outpatient Care in the Centers for Medicare and Medicaid Services
- Stuart Sherman, MD, of Indiana University Health Physicians Gastroenterology in Indianapolis
- Mark Gromski, MD, of Indiana University Health Physicians Gastroenterology

Three takeaways:

1. The risks of reusable duodenoscopes. Gastroenterologists can't be too vigilant about infection prevention; there's nothing sterile about the upper and lower GI tract, which harbor significant amounts of bacteria, Dr. Gromski said. He pointed to recent reports of multi-drug resistant pathogenic organisms transmitted by reusable duodenoscopes as evidence that ineffective reprocessing may elevate risk.

"The potential for transmission of pathogenic organisms is a problem that is likely to some extent inherent to the design of the current reusable duodenoscopes," he said.

2. Single-use scopes as a possible solution. "Single-use duodenoscopes are designed to prevent infection transmission," Dr. Sherman said. "[The single-use scope] looks remarkably similar to existing reusable

duodenoscopes. It is designed to mimic the performance of gold standard reusable scopes."

This idea was reinforced in August 2019, when the FDA for the first time recommended a transition to "innovative duodenoscope designs" that facilitate or eliminate the need for reprocessing. The advantages of single-use scopes were again underscored in July of this year when a new transitional pass-through payment took effect for single-use duodenoscopes in Hospital Outpatient Departments (HOPD) and ASCs.

3. What transitional pass-through payment means. Transitional pass-through payments are temporary device specific payments meant to allow HOPDs to adopt new technology, Dr. McInnes explained. In the interim, Medicare collects cost data to incorporate costs for these devices into the procedure outpatient payment rate once the pass-through period expires.

"It's a separate payment in addition to and beyond the payment for the associated procedure," he said. "It lasts for three years, and it is available only to certain implantable, insertable medical devices. Routine supplies and capital equipment that's reused cannot get transitional pass-through payment."

Dr. Gromski summarized the significance of pass-through status for single-use duodenoscopes with this key quote: "It signals CMS is invested in finding a solution to the reprocessing of reusable scopes problem and wants people to have access to this new kind of technology."

Boston Scientific played an important role in securing the pass-through payment that led to code C1748 taking effect July 1, according to Dr. McInnes.

"Boston Scientific filed an application for transitional pass-through for the EXALT™ Model D single-use duodenoscope under the new FDA Breakthrough Device Designation pathway and was awarded pass-through status on an expedited basis," Dr. McInnis said. ■

Commercial payers are not required to follow CMS coverage, however, some may choose to do so. It is recommended to reach out to commercial payers to understand commercial payer reimbursement for EXALT Model D.

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