Boston Scientific

Boston Scientific Receives Medicare Transitional Pass-Through Payment for the EXALT™ Model D Single-Use Duodenoscope

MARLBOROUGH, Mass., June 8, 2020 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced that the Centers for Medicare & Medicaid Services (CMS) has approved its application for a transitional pass-through (TPT) payment category to describe single-use endoscopes, including the EXALT™ Model D Single-Use Duodenoscope, under the Medicare hospital outpatient prospective payment system (OPPS). The intent of TPT payment is to facilitate Medicare beneficiary access to the advantages of new and innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure Ambulatory Payment Classifications (APC) rate.

The new device transitional pass-through code (C1748) may be used to bill for EXALT Model D when it is used in treatment of Medicare beneficiaries in the hospital outpatient setting starting July 1, 2020.

The EXALT™ Model D Single-Use Duodenoscope is the world's first and only single-use, flexible duodenoscope currently cleared by the US. Food and Drug Administration (FDA). Duodenoscopes are used in endoscopic retrograde cholangiopancreatography (ERCP) procedures to diagnose and treat various pancreatic and biliary conditions. Every year, more than 700,000 ERCP procedures are performed in the U.S. and approximately 1.5 million are completed worldwide.[1]

Notably, the FDA has recommended that providers transition to duodenoscopes with disposable components or fully disposable devices, when they are available.[2]

The FDA granted EXALT Model D its Breakthrough Devices Designation through a program intended to expedite the development and prioritize the review of certain medical devices that provide for more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Breakthrough Device Designation provides patients more timely access to novel medical devices such as Exalt Model D.

Since January 2020, CMS has provided an alternative pathway for innovative technologies that have received FDA marketing authorization and Breakthrough Devices Designation to qualify for device pass-through payment. EXALT Model D is among the first devices to receive TPT approval by CMS via this pathway.

"The approval of this new payment category in the outpatient setting will help ensure healthcare providers have access to EXALT Model D at a time when there is heightened awareness of the need to eliminate infection risk for patients, physicians, and hospital staff. With EXALT Model D, physicians can use a new, sterile duodenoscope for every procedure," said Brian Dunkin, M.D., chief medical officer, Endoscopy, Boston Scientific. "Boston Scientific has been dedicated to advancing the care of pancreaticobiliary diseases for over 30 years, and we are proud that the Centers for Medicare & Medicaid Services, the country's largest payer for health care, recognizes the importance of our technology to its beneficiaries."

The EXALT™ Model D Single-Use Duodenoscope received FDA clearance in December 2019 and has been commercially launched as an alternative to reusable duodenoscopes, eliminating the need for duodenoscope reprocessing and repairs, and allowing physicians to use a new, sterile scope for every procedure.

Please visit www.bostonscientific.com/EXALT for more information about the EXALT Model D Single-Use Duodenoscope.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for 40 years, we advance science for life by providing a broad range of high-performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our product launches and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; the closing and integration of acquisitions; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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1. Internal Estimate
2. United States Food and Drug Administration website: " The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication" April 10, 2020

SOURCE Boston Scientific Corporation

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