Boston Scientific

CMS Grants Additional Reimbursement For EXALT™ Model D Single-Use Duodenoscope

New Technology Add-on Payment can increase patient access to ERCP procedures with reduced infection risks

MARLBOROUGH, Mass., Aug. 2, 2021 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announced that the U.S. Centers for Medicare & Medicaid Services (CMS) granted a New Technology Add-on Payment (NTAP) for single-use duodenoscopes, applicable to the EXALT™ Model D Single-Use Duodenoscope, as part of its Fiscal Year 2022 Hospital Inpatient Prospective Payment System. NTAP was created to facilitate patient access for qualifying new medical technologies that substantially improve the diagnosis or treatment of Medicare beneficiaries. Beginning October 1, 2021, CMS will provide hospitals with additional device reimbursement when the EXALT Model D Single-Use Duodenoscope is used for eligible cases in the hospital inpatient setting.

The EXALT Model D Single-Use Duodenoscope is designed to eliminate the risk of infection due to ineffective reprocessing of traditional reusable duodenoscopes. Duodenoscopes are used to diagnose and treat various pancreatic and biliary conditions during endoscopic retrograde cholangiopancreatography (ERCP) procedures. Every year, more than 700,000 ERCP procedures are performed in the U.S. and approximately 1.5 million are completed worldwide.[i] In 2019 the U.S. Food and Drug Administration (FDA) recommended that providers utilize duodenoscopes with disposable components or fully disposable devices, when available.[ii]

The EXALT Model D Single-Use Duodenoscope previously received Breakthrough Device Designation from the FDA as well as transitional pass-through (TPT) payment by CMS, the latter of which allows for incremental device reimbursement for Medicare cases performed in the hospital outpatient setting. Further, in response to a Boston Scientific request, CMS created two unique ICD-10 procedure codes for hospitals to facilitate reporting the use of single-use duodenoscopes when used in the hospital inpatient setting beginning October 1, 2021.

"Securing NTAP, in addition to TPT, for the EXALT Model D Duodenoscope will support health care providers in accessing this device for Medicare patients – a group that represents over 40% of all ERCPs performed in the U.S. each year," said Dave Pierce, executive vice president and president, MedSurg and president, Endoscopy, Boston Scientific. "Adequate reimbursement is key for the adoption of any new technology, and this decision from CMS will help provide hospitals with the means to treat Medicare patients with this device."

The EXALT Model D Duodenoscope is part of the Boston Scientific single-use device portfolio, which includes technologies within the gastrointestinal, pancreaticobiliary, surgical, urological and airway spaces such as the LithoVue™ Digital Flexible Ureteroscope, SpyGlass™ DS Direct Visualization System, SpyGlass™ Discover Digital Catheter, and EXALT™ Model B Single-Use Bronchoscope.[iii]

For additional information, please visit the EXALT Model D Single-Use Duodenoscope page on the Boston Scientific website.

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 more than 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 business plans, clinical trials 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, political, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; 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 IA - 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 statement 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 press release.

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[i] Internal estimate

[ii] 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

[iii] The EXALT Model B Single-Use Bronchoscope is currently pending FDA 510(k) review and is not yet available for sale in the United States

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