

Centers for Medicare & Medicaid Services Creates New Codes That Establish Specific Payment for Intravascular Lithotripsy Performed Below the Knee

December 4, 2020

Four New C-Codes for IVL Performed Below the Knee in Hospital Outpatient Setting

SANTA CLARA, Calif., Dec. 04, 2020 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of Intravascular Lithotripsy (IVL) to treat complex calcified peripheral and coronary artery disease, announced today that as part of the calendar year 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) final rule, the Centers for Medicare & Medicaid Services (CMS) has created four new codes for IVL procedures performed in the tibial and peroneal, or below-the-knee (BTK), arteries in the hospital outpatient setting. These codes will be effective January 1, 2021.

In creating the four new Healthcare Common Procedure Coding System (HCPCS) codes (C9772-C9775), CMS noted that "...resources associated with tibial and peroneal IVL procedures are higher than iliac, femoral and popliteal procedures." Previously, in July 2020, CMS issued four codes C9764-C9767 to describe IVL performed in all lower extremity arteries. As part of the 2021 OPPS final rule, these initial codes have now been redefined to report IVL procedures performed in lower extremity arteries, except tibial and peroneal. Starting in January 2021, there will now be four codes that pertain to below-the-knee IVL procedures and four that pertain to above-the-knee IVL procedures.

In addition, CMS assigned the new HCPCS codes to Ambulatory Payment Classifications (APCs) that determine hospital outpatient payment. These APC assignments are consistent with similar interventional procedures performed in the BTK arteries.

Also effective January 1, 2021, CMS added IVL procedures to the list of services covered in an Ambulatory Surgical Center (ASC) setting.

"We appreciate CMS's swift action in adding these new codes as they acknowledge the differentiation between above-the-knee and below-the-knee procedures and that complex BTK interventions involving IVL require more resources. Importantly, we believe these new HCPCS codes, which now increase payment for IVL procedures performed BTK, will further facilitate access to IVL technology for Medicare patients, while also allowing data collection specific to IVL procedures performed BTK," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "We are grateful for the support that came from multiple medical societies during the public comment period, as well as CMS' Outpatient Physician Advisory panel. We look forward to continued engagement with CMS as the addition of these new codes will enable the collection of cost data on IVL procedures in a more specific way, which we believe will better enable the agency to make appropriate adjustments to procedure payment levels in the future."

For more information, please go to https://shockwavemedical.com/reimbursement/

About Shockwave Medical, Inc.

Shockwave is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

Forward-Looking Statements

This press release contains statements relating to our expectations, projections, beliefs, and prospects, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, market and sell, our products; our expected future growth, including the size and growth potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others. These factors, as well as others, are discussed in our filings with the SEC, and in our other periodic and other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

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Source: Shockwave Medical, Inc.