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CMS Approves New Technology Add-On Payment for Spiration® IBV Valve System
Approval Recognizes Humanitarian Use of IBV Valve System as a Substantial Clinical Improvement for Controlling Prolonged Post-Operative Air Leaks

Redmond, Wash. – Aug. 3, 2009 – Spiration, Inc., a developer of novel medical devices designed to benefit patients with acute and chronic conditions of the lung, announced today that the Centers for Medicare and Medicaid Services (CMS) has approved a new technology add-on payment (NTAP) for IBV® Valve System use in the hospital inpatient setting to control prolonged air leaks or air leaks likely to become prolonged following lobectomy, segmentectomy or lung volume reduction surgery. The IBV Valve received a Humanitarian Device Exemption (HDE) approval for this indication in October 2008.

The new technology add-on payment is used by CMS as a means to correct for inadequate payment of new technologies under the existing Medicare payment groupings, called Medicare Severity Diagnosis Related Groups (MS-DRGs). CMS regulation considers the NTAP “additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.”¹

“The approval of this NTAP represents a significant accomplishment for Spiration. Only eight products have received an NTAP approval since the payment was implemented in 2001, and this is the only NTAP application approved by CMS in the last two years,” said Rick Shea, president and CEO, Spiration. “We are pleased that CMS recognizes the IBV Valve System as a substantial clinical improvement for controlling certain prolonged post-operative air leaks, which can be a significant and costly complication of lung surgery.”

¹ Centers for Medicare and Medicaid Services:
http://www.cms.hhs.gov/acuteinpatientpps/08_newtech.asp



New technology add-on payment is made when the technology is used in the inpatient setting and meets three criteria: i) newness, ii) substantial clinical improvement to existing therapeutic options, and iii) certain cost thresholds as defined by regulation.

About Humanitarian Device Exemptions

A Humanitarian Device Exemption is a U.S. Food and Drug Administration (FDA) application that is similar to a pre-market approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD). An HUD is a medical device that is intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

About Prolonged Air Leaks

Air leaks are a common complication of surgery caused by lung tissue that has not completely closed and sealed, resulting in an accumulation of air in the chest that can cause breathing difficulties. Prolonged air leaks can contribute to significant morbidity and mortality and affect outcomes after thoracic surgery.

Conventional treatments for prolonged air leaks include further surgical intervention, the insertion of drain tubes into the chest, or lung tissue sealing (pleurodesis). These approaches can result in additional complications, prolonged hospitalization, restricted ambulation, significant pain, and increased costs.

About the IBV Valve System

The IBV Valve System is a minimally invasive treatment that has diverse applications in both acute and chronic conditions of the lung. During the minimally invasive procedure, a catheter is passed through a bronchoscope (a flexible tube passed into the bronchial tubes through the mouth or nose) to deploy the small umbrella-shaped valves into the airways of the lungs. The valves are designed to be easily removed via a similar bronchoscopic procedure.

The device has received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy, or lung volume reduction surgery. The effectiveness of this device for this use has not been demonstrated.



The IBV Valve System is currently under investigation in the U.S. as a new treatment option for the many people with severe emphysema who do not respond well to current medical therapies or are not eligible for or elect not to undergo invasive surgery such as lung volume reduction or lung transplantation.

The IBV Valve System is marketed and distributed by Olympus in Europe, where the system has received market clearance through the CE Mark for the treatment of diseased and damaged lung, an indication that includes the treatment of emphysema and the control of prolonged air leaks. Olympus also has exclusive development and distribution rights for the IBV Valve System in Japan.

About Spiration, Inc.

Spiration, Inc. is committed to improving quality of life for patients with acute and chronic conditions of the lung through the development of novel therapies. Founded in 1999 in Redmond, Wash., the privately held company is backed by prominent investors including Three Arch Partners, New Enterprise Associates, Versant Ventures, New Leaf Ventures (Sprout Group), InterWest Partners, Investor Growth Capital, Saints Capital and Olympus Medical Systems Corp. For more information, visit the company's website at www.spiration.com.

Information about the U.S. pivotal study of Spiration's IBV Valve System may be found at www.emphysematrial.com.

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Cautions: Humanitarian Use Device. Authorized by Federal (or United States) Law for the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy, or lung volume reduction surgery. The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician. IBV Valve is not yet approved for use in emphysema, but is subject to an ongoing clinical investigation in which approval for use in emphysema will be sought.