



**Tracking Form for Applicants for New Technology Add-on Payments  
under the Acute Inpatient Prospective Payment System (IPPS) for  
Federal Fiscal Year (FY) 2010**

1. Technology Name: **Bronchial Valve**
2. Manufacturer Name: **Spiration, Inc.**
3. Trade Brand of Technology: **Spiration® IBV® Valve System**
4. Brief Description of Service or Device:

The Spiration IBV Valve System is a device to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS).

The IBV Valve, a small umbrella-shaped valve, is designed to limit airflow to the portions of the lungs distal to airway in which the valve is deployed, while still allowing mucus, fluids, and air to flow past the valve in the proximal direction. For the treatment of air leaks, the valve limits airflow to the injured tissue, reducing air flow through the leaking tissue, which may enable healing.

During the minimally invasive procedure, a deployment catheter is passed through a bronchoscope (a tube passed into the bronchial airways through the mouth or nose) to deploy the small umbrella-shaped valves into the target areas of the lungs.

IBV Valves are to be removed no longer than 6 weeks after implantation when used for the control of air leaks. The IBV Valve has design features to aid removal using standard bronchoscopic techniques.

**Newness Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

The Spiration IBV Valve System received FDA Humanitarian Device Exemption approval on October 24, 2008.

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

No. Under the conditions of an HDE approval, no sales can take place until IRB approvals are obtained at individual sites. In addition, a post-approval study protocol is being developed, as required in the approval order, for implementation with first sales of the product.

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

- a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

The ICD-9 procedure code 33.71, *Endoscopic insertion or replacement of bronchial valve(s)* is currently used to define the procedure.

There is a separate request pending before the ICD-9 Coordination Committee to revise current ICD-9 procedure coding to address bronchial valve placement in a single lobe or multiple lobes.

- b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to [http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01\\_overview.asp](http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp) for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.

Not applicable. See answer to Question 7a.

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to [http://www.cms.hhs.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp](http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp) for more information.)

No.

**(For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)--.**

**Note: The information provided on this tracking form will be made publicly available.**

## **Cost Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at: [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp)

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

[Spiration considers this proprietary information not available for public disclosure. Cost information is provided in the application to CMS for New Technology Add-On Payment.](#)

9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**-breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

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10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

[MS-DRG 163 Major Chest Procedure with MCC](#)  
[MS-DRG 164 Major Chest Procedure with CC](#)  
[MS-DRG 165 Major Chest Procedure without CC/MCC](#)

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2010 (by DRG)?

[Up to a maximum of 4,000 patients per year, pursuant to FDA regulations.](#)

## **Clinical Improvement Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services.

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

- a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

Management of air leaks due to persistent bronchopleural fistula involves chest drainage and occasionally pleurodesis with more difficult cases requiring surgical pleurectomy and surgical repair. Because the patients included in the HDE approval have already had thoracic surgery and may also have other medical problems, they are generally considered high risk to undergo further surgery.

Complications associated with prolonged air leaks and some of the currently available management techniques include 1) prolonged use of chest tubes, which can increase the risk of pneumonia, deep venous thrombosis, pulmonary embolus, atelectasis, subcutaneous emphysema and infections; 2) restricted ambulation due to chest tubes, increasing the risk associated with inactivity; 3) prolonged requirements for pain medication; and 4) extended post-operative length of stay, increasing the potential for hospital acquired infections [Cerfolio RJ, Surg Clin N Am 82 (202) 833-848]. It has been demonstrated that air leaks lasting more than three days have a significant impact on length of hospital stays [Bardell T, Petsikas D Can Respir J Vol 10 No 2 March 2003].

Many previous bronchoscopic approaches to the problem of prolonged air leaks have been tried. These include glues and many different materials in an attempt to occlude the airway feeding the air leak. To date none of these approaches have been approved.

Consequently, for this group with few effective treatment options, there is still a need for an alternative, less invasive method of treating air leaks. The Spiration IBV Valve System is a minimally invasive technology that includes a one-way bronchial valve and a deployment catheter. The IBV Valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus, fluid and air movement in the proximal direction. For the control of air leaks, the valve limits airflow to injured tissue which may enable healing.

No device comparable to the IBV Valve System is approved to treat prolonged air leaks in post-surgical LVRS, lobectomy, or segmentectomy patients in the US.

- b. List all published peer-review articles relevant to the new service or technology.

Two articles were published in 2005 and two in 2006 regarding the use of bronchial valves for air leaks. These are relevant since the valve used is also a one-way valve. Notable is the uniformly positive experience reported.

*Snell GI, Holsworth L, Fowler S, Eriksson L, Reed A, Daniels FJ, Williams TJ. Occlusion of a broncho-cutaneous fistula with endobronchial one-way valves. Ann Thorac Surg 2005; 80:1930-1932.*

*Fann JJ, Berry GJ, Burdon TA. The use of endobronchial valve device to eliminate air leak. Respir Med 2006; 100:1401-1406.*

*Feller-Kopman D, Bechara R, Garland R, Ernst A, Ashiku S. Use of a removable endobronchial valve for the treatment of bronchopleural fistula. Chest 2006; 130:273-275.*

*Ferguson JS, Sprenger K, Van Natta T. Closure of a bronchopleural fistula using bronchoscopic placement of an endobronchial valve designed for the treatment of emphysema. Chest 2006; 129:479-481.*

Two relevant articles have been published regarding the clinical experience with the IBV Valve. These results are from patients with severe emphysema rather than air leaks but the results are relevant for safety and effectiveness in air leak patients. Analogous to blocking air feeding an air leak, the bronchial valves block air flow to the areas of most severe emphysema, resulting in decreased air volume in the treated lung lobes. The air volume is redirected to lung lobes with less disease and this inhaled volume shift is associated with improved health-related quality of life.

*Wood DE, McKenna RJ, Yusen RD, Sterman DH, Ost DE, et al. A multicenter trial of an intrabronchial valve for treatment of severe emphysema, Journal of Thoracic and Cardiovascular Surgery. 133(1):65-73, 2007*

*Coxson HO, Fauerbach PVN, Storness-Bliss C, Müller NL, Cogswell S, et al. The computed tomography assessment of lung volume changes after bronchial valve treatment. In Press*

Also published are the abstracts for presentations at major meetings regarding the recent experience with the IBV Valves and air leaks.

*Wood D, Gonzalez X, Sirokman W, Dillard D, Springmeyer S: Reduction of severe air leaks using an intra-bronchial valve delivered via flexible bronchoscopy. Am J Respir Crit Care Med 2004; 169:A480.*

*Cerfolio R, Gonzalez X, Springmeyer SC. Evaluation of the Spiration IBV<sup>®</sup> Valve to control air leaks case report. Proceedings World Congress of Bronchology 2008; Tokyo, Japan.*

*Sterman D, Gillespie C, Cerfolio R, Mularski R, Gonzalez X, Springmeyer S. Multicentre experience with bronchial valve treatment of life-threatening prolonged air leaks. Euro Resp J 2008; 262s*

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