



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2009

1. Technology Name:

Endobronchial Valve

2. Manufacturer Name:

Emphasys Medical, Inc.

3. Trade Brand of Technology:

Emphasys Medical Zephyr® Endobronchial Valve (Zephyr EBV)

4. Brief Description of Service or Device:

The Zephyr® Endobronchial Valve (Zephyr EBV) is a novel implantable device developed by Emphasys Medical as a new treatment option for patients with advanced emphysema. Zephyr EBV treatment offers relief to emphysema patients by achieving targeted volume reduction and enhancing breathing dynamics, enabling patients to breathe better. The therapy reduces volume in the diseased portions of the lung and improves function in the healthier areas of the lung without the risks and complications of more complex and invasive procedures. Treatment with the Zephyr EBV consists of placing several small, one-way valves in patients' airways leading to the most diseased portion of the lungs to control the flow of air into and out of diseased portions of the lung.

New Criteria

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 Zephyr EBV has not yet received pre-market approval. The pre-market application (PMA #P070025) for the Zephyr EBV was received by the FDA on September 21, 2007.

Expedited review for the PMA was granted on October 29, 2007.

The expected approval date is proprietary information contained in the full application.

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

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

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).

We anticipate making the product available immediately after FDA approval.

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?

Yes.

- 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.

ICD-9-CM Procedure Code: 33.71 - Endoscopic insertion or replacement of bronchial valve(s)

- 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#TopOfPage 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.

N/A

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://cms.hhs.gov/providers/hopps/apc.asp> for more information.)

An outpatient application for pass-through payments under the Medicare outpatient prospective payment system has not been submitted for the Zephyr EBV.

Cost Criteria

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#TopOfPage.

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.

Proprietary information contained in full application.

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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).

Proprietary information contained in full application.

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

- 190 Chronic Obstructive Pulmonary Disease with MCC
- 191 Chronic Obstructive Pulmonary Disease with CC
- 192 Chronic Obstructive Pulmonary Disease without CC/MCC

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

Proprietary information contained in full application.

Clinical Improvement

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:

Medicare patients with advanced emphysema require access to less invasive procedures that provide a substantial improvement over current standard of care medical therapy. These patients suffer from the inability to breathe and perform everyday activities and experience an uninterrupted deterioration of their lung function and an associated increasing disability. The VENT Pivotal Trial conclusively established the Zephyr EBV as a new point on the continuum of care and demonstrated significantly and substantially improved clinical outcomes compared to the current standard of care for advanced emphysema patients.

Through the VENT Pivotal Trial and as detailed in the full application, treatment with the Zephyr EBV has been demonstrated to significantly improve clinical outcomes (FEV1, 6MWT, SGRQ, MMRC, Cycle Ergometry and BODE) compared to medical therapy for patients with advanced emphysema. Furthermore, the VENT Pivotal Trial identified a selectable subset of patients with a greater magnitude of clinical improvement.

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

1. Fann, J.I., G.J. Berry, and T.A. Burdon, Bronchoscopic Approach to Lung Volume Reduction Using a Valve Device. *J Bronchol*, 2003. 10: p. 253-259.
2. Snell, G., et al., The Potential for Bronchoscopic Lung Volume Reduction Using Bronchial Prostheses: A Pilot Study. *Chest*, 2003. 124(3): p. 1073-1080.
3. Toma, T., et al., Bronchoscopic volume reduction with valve implants in patients with severe emphysema. *Lancet*, 2002. 361: p. 931-933.
4. Venuta, F., et al., Bronchoscopic Lung-Volume Reduction With One-Way Valves in Patients With Heterogeneous Emphysema. *Ann Thorac Surg*, 2005. 79(2): p. 411-417.
5. Yim, A.P., et al., Early results of endoscopic lung volume reduction for emphysema. *J Thorac Cardiovasc Surg*, 2004. 127(6): p. 1564-1573.
6. de Oliveira, H., et al., Transbronchoscopic Pulmonary Emphysema Treatment: 1-Month to 24-Month Endoscopic Follow-up. *Chest*, 2006. 130(1): p. 190-199.
7. Hopkinson, N.S., et al., Effect of Bronchoscopic Lung Volume Reduction on Dynamic Hyperinflation and Exercise in Emphysema. *Am. J. Respir. Crit. Care Med.*, 2005. 171(5): p. 453-460.
8. Wan, I.Y., et al., Bronchoscopic Lung Volume Reduction for End-Stage Emphysema: Report on the First 98 Patients. *Chest*, 2006. 129(3): p. 518-526.
9. Toma, T., et al., Methodological Aspects of Bronchoscopic Lung Volume Reduction with a Proprietary System. *Respiration*, 2003. 70: p. 658-664.
10. Hillier, J.E., T.P. Toma, and C.E. Gillbe, Bronchoscopic Lung Volume Reduction in Patients with Severe Emphysema: Anesthetic Management. *Anesth Analg*, 2004. 99(6): p. 1610-1614.
11. Brown, M.S., et al., CAD in clinical trials: Current role and architectural requirements. *Computerized Medical Imaging and Graphics*, 2007. 31: p. 332-337.
12. Bouros, D. and M.E. Froudarakis, Bronchoscopic Lung Volume Reduction: A Window for the Future? *Respiration*, 2004. 71: p. 214-215.

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13. Hopkinson, N.S., Bronchoscopic lung volume reduction: indications, effects and prospects. *Curr Opin Pulm Med*, 2007. 13: p. 125-130.
14. Maxfield, R.A., New and Emerging Minimally Invasive Techniques for Lung Volume Reduction. *Chest*, 2004. 125(2): p. 777-783.
15. McKenna, R.J., Bronchial Blockers for Lung Volume Reduction Surgery: Where Are We and Where Are We Going? *J Bronchol*, 2005. 12(2): p. 67-68.
16. Polkey, M.I. and N.S. Hopkinson, Bronchoscopic lung volume reduction. *Eur Respir Rev*, 2006. 15(100): p. 99-103.
17. Toma, T.P., D.M. Geddes, and P.L. Shah, Brave new world for interventional bronchoscopy. *Thorax*, 2005. 60: p. 180-181.
18. Venuta, F., et al., Bronchoscopic procedures for emphysema treatment. *European Journal of Cardio-thoracic Surgery*, 2006. 29: p. 281-287.
19. Cetti, E.J., A.J. Moore, and D.M. Geddes, Collateral ventilation. *Thorax*, 2006. 61: p. 371-373.
20. Fessler, H.E., Collateral Ventilation, the Bane of Bronchoscopic Volume Reduction. 2005. 171(5): p. 423-424.
21. Salanitri, J., et al., 133Xenon ventilation scintigraphy applied to bronchoscopic lung volume reduction techniques for emphysema: relevance of interlobar collaterals. *Internal medicine Journal*, 2005. 35: p. 97-103.
22. Noppen, M., et al., Successful Treatment of a Giant Emphysematous Bulla by Bronchoscopic Placement of Endobronchial Valves. *Chest*, 2006. 130(5): p. 1563-1565.
23. Strange, Charlie., et al., Design of the Endobronchial Valve for Emphysema Palliation Trial (VENT): a non-surgical method of lung volume reduction. *BMC Pulmonary Medicine* 2007 7:10

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