National Institute for Health and Clinical Excellence

IP1025 Insertion of endobronchial valves for persistent air leaks

Consultation Comments table

IPAC date: 17 January 2013

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	I agree with this. The multi disciplinary team is crucial. It should also include a respiratory radiologist in a team who have expertise in this technology. If the team do not have appropriate expertise, they should contact the relevant individuals.	Thank you for your comment. The guidance recommends that the intervention is carried out by a multidisciplinary team with the necessary skills and training.
2	Consultee 2 Manufacturer	**2.1**	The evidence supporting the use of endobronchial valves to treat air leaks is not as limited as it once was, and a growing body of evidence has reduced uncertainty surrounding its efficacy and safety. Evidence as supported by the Humanitarian Device Exemption (HDE) in the United States: The [redacted] has a Humanitarian Device Exemption (HDE) in the United States, based on safety and probable benefit. Safety data from the first 58 patients from the U.S. pilot study in severe emphysema were used for the HDE approval. Â These data are summarized in the Summary of Safety and Probable Benefit for the HDE indication (US. Food and Drug	Thank you for your comment. The Committee considered the comments and no changes were made to the guidance.

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	Consultee 2 Manufacturer		Administration. Summary of Safety and Probable Benefit. N.p.: Food and Drug Administration. Oct. 24, 2008 http://www.accessdata.fda.gov/cdrh_docs/pdf6/H060002b.pdf). In addition, since June 2009 there have been over 500 air leak procedures with the [redacted] with no reportable incidents, CA (Competent Authority) reports, FSCA (Field Safety Corrective Actions) or recalls. There were 4 MDRs submitted to the FDA in the US, generated from use of the IBV Valve in the US market (HDE) to treat air leaks. Â In all cases, it was concluded that the device did not fail or malfunction.	
3	Consultee 2 Manufacturer	**2.1**	Evidence as supported by the Centers of Medicare and Medicaid Services (CMS) in the United States: The Centers for Medicare and Medicaid Services (CMS) in the United States evaluated [redacted] or the New Technology Add-on Payment (NTAP) policy in the hospital inpatient setting of care. CMS determined that, effective fiscal year (FY) 2010, [redacted]System met the substantial clinical improvement, newness, and cost criteria for hospitals to be eligible to receive additional payment under the NTAP for qualified discharges.	Thank you for your comment. Please see response to comment 2. The IP Methods guide states that the evidence used for Guidance development is considered mainly from published peer-reviewed literature.

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			Excerpts from the Federal Register (Vol. 74, No. 165) are included below: ? [redacted] and other bronchial valves produced positive clinical outcomes by resolving air leaks. Â Also the comments we received from the physicians demonstrated a change to the clinical therapy for cases of air leaks by using a bronchial valve such as the [redacted] instead of other alternative treatments such as an invasive surgery to resolve the air leak?.Furthermore, the [redacted] or might even require additional invasive surgeries to resolve the air leak. Â We also note that use of the [redacted]ay lead to more rapid beneficial resolution of prolonged air leaks and reduce recovery time following the three long surgeries mentioned above.?	
4	Consultee 2 Manufacturer	**2.1**	One commenter, an association of thoracic surgeons, expressed support for approving the [redacted] new technology add-on payments. Â The commenter explained that the [redacted] offers a less invasive treatment of the prolonged air leak, whereas the alternative treatment would be a major re-operation which costs more money and poses greater risk to the	Thank you for your comment. Please see response to comment 2.

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			patient.? CMS went on to emphasize that the [redacted] is effective and the importance of the [redacted] as an alternative to more invasive methods:	
5	Consultee 2 Manufacturer	**2.1**	However, we agree that [redacted] can improve clinical outcomes by providing an alternative treatment that is effective and often a less invasive method of treating prolonged air leaks in a small patient population that is properly and carefully selected (as required by the FDA). Additionally, we received positive comments from a major thoracic society and from physicians who indicated that [redacted] and other bronchial valves produced positive clinical outcomes by resolving air leaks. Also, the comments we received from the physicians demonstrated a change to the clinical therapy for cases of air leaks by using a bronchial valve such as the SpirationÂ® IBVÂ® instead of other alternative treatments such as an invasive surgery to resolve the air leak.?	Thank you for your comment. Please see response to comment 2.
6	Consultee 2 Manufacturer	**2.1**	In Fiscal Year 2011, CMS expanded the NTAP to transfer cases that still met the HDE air leak indication. Â CMS uses the NTAP 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	Thank you for your comment. Please see response to comment 2.

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			represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.?[Centers for Medicare and Medicaid Services: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html NTAPs are to be used for ?no less than two years, no more than three years,? until CMS has compiled enough data for the new technology to be reflected in historical claims so that appropriate payment adjustments can be made, as required. Â As anticipated, the IBV Valve System NTAP expired on October 1, 2011, based on the pre-established 2-3 year approval period. Evaluation of substantial clinical improvement compared to existing therapies, and rationale for the NTAP expansion to transfer cases, are detailed in the Federal Register excerpts listed below.	
7	Consultee 2 Manufacturer	**2.1**	42 CFR Parts 412, 413, 415, et al. Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates; and Changes to the Long Term Care Hospital Prospective Payment System and Rate Years 2010 and 2009 Rates; Final Rule, pp 43819-43823.	Thank you for your comment. Please see response to comment 2.
8	Consultee 2 Manufacturer	**2.1**	Evidence as supported by American Medical Association (AMA) editorial review:	Thank you for your comment. Please see response to comment 2.

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			The American Medical Association (AMA) Current Procedural Terminology (CPTÂ®) Editorial Panel has assigned four new Category I CPT codes to report bronchoscopy services for the insertion and removal of bronchial valves in its recently published CPT 2013 Professional Edition. These codes are intended to replace Category III CPT codes that were previously available to describe these services.	
9	Consultee 2 Manufacturer	**2.1**	The process for establishing these codes was supported by the American Thoracic Society and the American College of Chest Physicians. Many factors are considered by the CPT Editorial Panel when grating Category I status; some of the Panel?s criteria require, based on the evidence submitted: ? that the service/procedure has received approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs; ? that the suggested procedure/service is a distinct service performed by many physicians/practitioners across the United States; ? that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature CPT is the most widely accepted coding system used to report medical procedures and services	Thank you for your comment. Please see response to comment 2.

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			under public and private health insurance programs. For more information, see http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-process-faq/code-becomes-cpt.page.	
10	Consultee 2 Manufacturer	**2.1**	We propose that these independent reviews of the safety and probable benefit of endobronchial valves for the treatment of air leaks supports a claim that evidence of its safety and benefit may be less uncertain and more routine than the provisional recommendations suggest.	Thank you for your comment. Please see response to comment 2.
11	Consultee 3 NHS Professional	**2.1.2**	2.1.2 (second line) In cases when surgical repair is not possible (for example in patients with poor cardiopulmonary reserve), talc pleurodesis via the chest drain or thoracoscopic talc poudrage may be an alternative option.	Thank you for your comment. Section 2.1.2 of the Guidance has been changed.
12	Consultee 3 NHS Professional	**2.2.2**	2.2.2 The procedure is done using flexible bronchoscopy with the patient under conscious sedation or general anaesthesia.	Thank you for your comment. Section 2.2.2 of the Guidance has been changed.
13	Consultee 1 NHS Professional	**2.2**	I agree. It is also important ot identify the site of the leak before placement	Thank you for your comment. Section 2.2.2 of the Guidance states site of leak should be identified before placement of the valves.
14	Consultee 4 NHS Professional	**2.2.2**	2.2.2 could be expanded to state: once a suitable segmental bronchus is identified by noting reduction /cessation of the airleak, then a sizing catheter is passed to ensure the optimal valve size is chosen.	Thank you for your comment. The Committee considered the comment but decided not to change the Guidance.

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15	Consultee 2 Manufacturer		In section 2.2.2, the description of the valve and catheter as ?a one-way valve mounted on a flexible catheter?? is not accurate. Â A more accurate and complete description of the procedure in line with its approved Instructions for Use might read as follows: ?The valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus and air movement in the proximal direction. A loader is used to insert the valve into a flexible catheter, which is passed through the bronchoscope, inserted into the target airway, and used to deliver the valve to its target location.?	Thank you for your comment. The Committee considered the comment but decided not to change the Guidance.
16	Consultee 5NHS Professional	**2.3**	[redacted] experience with EBV air leak control in complex patient were presented during SCTS annual meeting 2012 and EACTS in Barcelona 2012.In our experience EBV use made an immediate and significant impact upon the management and prognosis of patients with complex air leaks. They are a valuable tool in the armamentarium of thoracic surgeons dealing with this pathology especially when surgical options have been exhausted or deemed unsuitable. We have successfully controlled air leak in 5 of 6 treated patients.3 patients were ventilated. Two patients had valves successfully removed as a planed procedure few weeks after insertion, presuming that bronchopleural air leak has healed.17:15 Â Â 281	Thank you for your comment. The consultee refers to a non peer-reviewed study. The NICE IP Methods Guide states that efficacy data from non peer-reviewed studies are not normally presented to the Committee

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			THE USE OF ENDOBRONCHIAL VALVES FOR THE MANAGEMENT OF COMPLEX AIR LEAKS G. Elshafie, O. Nawaytou, H. Fallouh, P. Vaughan, M. Kornaszewska (United Kingdom EACTS Barcelona 2012	
17	Consultee 2 Manufacturer	**2.3.1**	In 2.3.1, the authors conclude that patients? condition improved and were considered successful even in cases of partial cessation, such that the overall success rate was 93%. As such, we believe the guidance should clarify that partial cessation accelerates resolution of the air leak.	Thank you for your comment. Section 2.3.1 of the Guidance has presented the results for complete and partial cessation separately.
18	Consultee 2 Manufacturer	**2.3.2**	In 2.3.2, all 8 procedures had improvement in air leak resolution, with median duration of air leak being 4 weeks before and 1 day after treatment. The majority of patients were discharged within 3 days of valve treatment. Additional published literature covering at least 69 cases is listed below, 40 of which were summarized in Travaline et al (Travaline J , McKenna R , De Giacomo T. Treatment of persistent pulmonary air leaks using endobronchial valves. Â Chest 2009; 136:355-60) and another 19 cases since. In addition, many more case reviews have been presented in various abstracts and congresses over this period. Dooms CA, De Leyn PR, Yserbyt J et al. Endobronchial valves for persistent postoperative	Thank you for your comment. Details on duration of air leak and discharge are reported in further detail in the Overview. The Committee agreed to add the following studies to Appendix A: Dooms (2012) [identified in post-consultation search] and Brichon (2012).

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			pulmonary air leak: accurate monitoring and functional implications. Respiration. 2012;84(4):329-33. Epub 2012 Aug 11. Brichon PY, Poquet C, Arvieux C, et al. Successful treatment of a life-threatening air leakage, complicating severe abdominal sepsis, with a one-way endobronchial valve. Interact Cardiovasc Thorac Surg. 2012 Oct;15(4):779-80. Epub 2012 Jul 3.	
19	Consultee 2 Manufacturer	**2.3.2**	Travaline J , McKenna R , De Giacomo T. Treatment of persistent pulmonary air leaks using endobronchial valves. Â Chest 2009; 136:355-60. Gillespie C , Sterman D, Cerfolio R, et al. Â Endobronchial valve treatment for prolonged air leaks of the lung: a case series. Ann Thorac Surg 2011; 91:270-3. Schiavon M, Marulli G, Â Zuin A, et al. Endobronchial Valve for Secondary Pneumothorax in a Severe Emphysema Patient. Thorac Cardiovasc Surg. 2011 Dec;59(8):509-10. Epub 2011 Mar 25. Conforti S, Torre M, Fieschi S, et al. Successful treatment of persistent postoperative air leaks following the placement of an endobronchial one-way valve. Monaldi Arch Chest Dis. 2010; 73:88-91.	Thank you for your comment The following references listed by the consultee are included in the main extraction table in the Overview. Travaline (2009); Gillespie (2011); Schiavon(2011); Conforti (2010); Toma (2007) ; Anile (2006); Snell (2005).

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			Toma T, Kon O, Oldfield W, Â et al. Â Reduction of persistent air leak with endoscopic valve implants. Â Thorax 2007; 62:830-3. Anile M, Venuta F, DeGiacomo T, et al. Â Treatment of persistent air leakage with endobronchial one-way valves. Â J Thorac Cardiovasc Surg 2006; 132:711-2. Snell G, Holsworth L, Fowler S, et al. Â Occlusion of a broncho-cutaneous fistula with endobronchial one-way valves. Â Ann Thorac Surg 2005; 80:1930-32."	
20	Consultee 2 Manufacturer	**2.3.2**	Abu-Hijleh M, Blundin M. Â Emergency use of an endobronchial one-way valve in the management of severe air leak and massive subcutaneous emphysema. Â Lung 2010; 188:253-7. Fischer W, Feller-Kopman D, Shah A, et al. Endobronchial valve therapy for pneumothorax as a bridge to lung transplantation. J Heart Lung Transplant. 2012 Mar;31(3):334-6. Epub 2011 Nov 3. Feller-Kopman D, Bechara R, Garland R, et al. Â Use of a removable endobronchial valve for the treatment of bronchopleural fistula. Chest 2006;	Thank you for your comment. The following references listed by the consultee are included in Appendix A of the Overview: Abu Hijleh (2010); Fischer (2012); Schweigert (2011); Feller-Kopman (2006); Ferguson (2006); Mitchell (2006)

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			130:273-5. Schweigert M, Kraus D, Ficker J, et al. Closure of persisting air leaks in patients with severe pleural empyema - use of endoscopic one-way endobronchial valve. Eur J Cardiothorac Surg 2011; 39:401-3. Ferguson J, Sprenger K, Van Natta T. Closure of a bronchopleural fistula using bronchoscopic placement of an endobronchial valve designed for the treatment of emphysema. Â Chest 2006; 129:479-81. Mitchell K, Â Boley T, Â Hazelrigg S. Â Endobronchial valves for treatment of bronchopleural Â fistula. Ann Thorac Surg, 2006; 81:1129-31.	
21	Consultee 2 Manufacturer	**2.3.2**	Firlinger I, Stubenberger E, Mueller M, et al. Long-term follow-up of patients treated with endobronchial one-way valves for persistent bronchopleural fistuals. Am J Respir Crit Care Med 2012;185:A1108. Wood D, Hogarth K, DellaPona C, et al. Clinical experience with bronchial valves for air leaks of the lung. European Respiratory Society Annual	Thank you for your comment. The following references listed by the consultee refer to non peer-reviewed studies: Firlinger (2012); Wood (2010). There were no new safety events identified in the abstracts. The NICE IP Methods guide states that efficacy data from non peer-reviewed studies are not normally presented to the Committee.

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			Congress 2010; Barcelona; P4145. Venuta F, Rendina E, De Giacomo T, et al. Postoperative strategies to treat permanent air leaks. Thorac Surg Clin 2010; 20:391-7. Wood D , Cerfolio R, Gonzalez X, et al. Â Bronchoscopic management of prolonged air leak. Â Clin Chest Med 2010; 31:127-33. Rosell A, LÃ³pez-Lisbona R, Cubero N, et al. Endoscopic treatment of persistent alveolar-pleural air leaks with a unidirectional endobronchial valve. Arch Bronconeumol. 2011 Jul;47(7):371-3. Fann J, Berry G, Burdon T. Â The use of endobronchial valve device to eliminate air leak. Â Respir Med 2006; 100:1401-06.	The following references listed by the consultee were not added to the overview for the following reasons: - reviews not clinical studies: Venuta (2010); Wood (2010). - foreign-language paper: Rossell (2011). - an animal study: Fann (2006).
22	Consultee 6 Royal College of Physicians	**2.3**	The Royal College of Physicians is aware of and supports the following submission of the British Thoracic Society. Local hospital experience from clinical colleagues using endobronchial valves for protracted air leaks has been positive and the efficacy of the procedure is confirmed.	Thank you for your comment.

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23	Consultee 1 NHS Professional	**2.3**	This data is very encouraging bearing in mind this is a very difficult problem to treat.	Thank you for your comment.
24	Consultee 5 NHS Professional	**2.4**	[redacted] has reported and published a case a valve displacement successfully removed as displacement was diagnoses. Important is to notice that we have achieved an air leak control, drain removal and lung expansion. Valves were displaced few weeks after placement Eur J Cardiothorac Surg. 2011 Nov;40(5):1258-60. Epub 2011 Mar 23. Endobronchial valve migration. Jenkins M, Vaughan P, Place D, Kornaszewska M. Source Department of Thoracic Surgery, University Hospital of Wales, Heath Park, Cardiff, CF14 4XW, UK. melaniejenkins76@hotmail.com	Thank you for your comment. The reference cited by the consultee (Jenkins 2011) is included in the main extraction table of the Overview.
25	Consultee 2 Manufacturer	**2.4**	In 2.4.1-2.4.3, reports of valve migration and expectoration are unique to the Zephyr EBV (Pulmonx), and do not apply to the IBV Valve System (Olympus). The IBV Valve system has demonstrated 0% migration and expectoration in multiple studies (Sterman et al; Respiration 2010; 79:22-223. Bezzi et al; Am J Respir Crit Care Med	Thank you for your comment. The references listed by the consultee refers to studies evaluating the use of valves for a different indication. .

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			2010;181:A542. Eberhardt et al; Chest 2012; 142(4):900-908). We propose the differentiation between the technical successes of these two products may be important for a complete interpretation of the clinical literature and outcomes.	The IP programme issues guidance on procedures rather than efficacy of individual devices.
26	Consultee 1 NHS Professional	**2.4**	The benefits in appropriately selected patients greatly outweigh the risks. It is essential that individuals with expertise in this technology use it. This will signifcantly reduce the incidence of migration and malplacement.	Thank you for your comment. The guidance recommends that the intervention is carried out by a multidisciplinary team with the necessary skills and training.
27	Consultee 5 NHS Professional	**2.5**	I my opinion that EBV should be consider as one of the methods of controlling complex air leak and not only when other treatment have been exhausted. Incretion of valves is a minimal invasive procedure and may be safer comparing to surgical procedure in high risk patients. In our experience cost of the valves was the most limiting factor, however if you camper it with the cost of day of stay on ITU (3 of our patient were ventilated) should be ignored	Thank you for your comment. The evidence for the procedure mainly relates to patients for whom other treatment options have failed. The Committee considered the comment but decided not to change the Guidance. The IP programme looks at the safety and efficacy of procedures and cost effectiveness is not part of the remit of the programme.
28	Consultee 1 NHS Professional	**2.5**	medical pleurodesis rarely works for post-op air leaks- so it is essential we consider this therapy earlier.	Thank you for your comment. Please see response to comment 27.
29	Consultee 2 Manufacturer	**2.5**	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	Thank you for your comment. The remit of the NICE Interventional Procedures programme is to consider safety and efficacy and does not consider comparative effectiveness versus

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			leak (Louis M, Noppen M. Bronchopleual Fistulas. Chest 2005;128:3955-3965). To date, very few of these approaches have been approved. Consequently, for this group with few effective treatment options, there is still a need for a minimally invasive method of treating air leaks. We propose that because of the approval and success of bronchial valves for persistent air leaks, valves should be considered and evaluated for effectiveness and safety compared to other treatment options, and not ?when other treatment options have been exhausted.?	other treatment options. The Committee considered the comment but decided not to change the Guidance.
30	Consultee 1 NHS Professional	**2.5**	May not be the case now in experienced centres- who may be using it earlier. It is essential that ongoing use in expert centres is documented with ongoing audit to help optimise patient selection. With familiarity with the techniques some workers will condier this treatment earlier in the patients illness when appropriate.	Thank you for your comment. The guidance recommends that the intervention is carried out by a multidisciplinary team with the necessary skills and training. Please see response to comment 27.
31	Consultee 5 NHS Professional	**notes**	[redacted]experience with EBV air leak control in complex patient were presented during SCTS annual meeting 2012 and EACTS in Barcelona 2012.In our experience EBV use made an immediate and significant impact upon the management and prognosis of patients with complex air leaks. They are a valuable tool in the armamentarium of thoracic surgeons dealing with this pathology especially when surgical options	Thank you for your comment.

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			have been exhausted or deemed unsuitable. We have successfully controlled air leak in 5 of 6 treated patients.3 patients were ventilated. Two patients had valves successfully removed as a planed procedure few weeks after insertion, presuming that bronchopleural air leak has healed.	
32	Consultee 1 NHS Professional	**notes**	We have been using endobronchial valves, and have free access to the Chartis system from Pulmonx for assessment for collateral ventilation. I have given a talk on COPD at a symposium sponsored by Pulmonx	Thank you for your comment.