PriorityHealth

MEDICAL POLICY
No. 91577-R1

BRONCHIAL THERMOPLASTY

Effective Date: April 15, 2015	**Review Dates: 10/10, 10/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19**
Date Of Origin: October 13, 2010	**Status: Current**

I. POLICY/CRITERIA

Bronchial thermoplasty may be covered when **all** of the following are met:

1. Age 18 years or older
2. Severe persistent asthma (defined below)
3. Poor symptom control (defined below) with either:
   a. inhaled corticosteroids (ICS) and long acting beta agonists (LABA), or
   b. requiring chronic (>3 months) oral corticosteroids
4. At least three emergency department visits or hospitalizations for asthma in the preceding 12 months
5. Participation in Priority Health's asthma case management program for at least 3 months and management by an asthma specialist for at least 6 months
6. Prior authorization by Priority Health.

Definitions:

Patients with severe persistent asthma[1] experience any of the following characteristics in the absence of asthma controller medications:

- Daily symptoms
- Night time awakenings, every night
- Use of rescue medication multiple times per day
- Normal activities are extremely limited
- Impaired lung function (less than or equal to 60% predicted)
- Frequent exacerbations

Patients may not be well controlled[2] if, despite taking high[3] doses of ICS and LABA for at least 3 months[4], they experience at least two or more of the following:

- Asthma exacerbations requiring oral systemic corticosteroids due to respiratory symptoms in the prior year, OR
- Unscheduled physician's office visit due to respiratory symptoms in the prior year, OR
- Emergency room visit due to respiratory symptoms in the prior year, OR
- Hospitalization due to respiratory symptoms in the prior year.

An asthma specialist should have managed the patient for at least six months prior to bronchial thermoplasty to ensure that patient education, environmental factors

and comorbidities have been considered in the management of the patient's severe asthma [5].

Bronchial thermoplasty should be performed by clinicians who are experienced in bronchoscopy and have completed the bronchial thermoplasty training curriculum.

Contraindications to bronchial thermoplasty:

- Presence of a pacemaker, internal defibrillator, or other implantable electronic devices,
- Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines,
- Patients previously treated with the Alair® System should not be retreated in the same area(s). No clinical data are available studying the safety and/or effectiveness of repeat treatments.

One complete thermoplasty procedure is performed in three treatment sessions with a recovery period of 3 weeks or longer between sessions. Repeat procedures, beyond the initial 3 treatments, are not covered because the safety and efficacy of repeat procedures have not been studied.

Footnotes:

[1] Severe persistent asthma as defined in the NHLBI /NAEPP Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma Full Report 2007

[2] Not well controlled as defined in NHLBI /NAEPP Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma Full Report 2007

[3] Maximum combination therapy that the patient can safely and comfortably tolerate

[4] Average of the 1-6 month timeframe provided in the NAEPP Expert Panel Report 3

[5] As described in Proceedings of the ATS Workshop on Refractory Asthma AJRCCM, 2000

Priority Health's Technology Assessment Committee reviewed Bronchial Thermoplasty in September 2010 & December 2011; this policy is based on recommendations of the committee.

II. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required Not Applicable

Note: A complete thermoplasty procedure is performed in three treatment sessions with a recovery period of 3 weeks or longer between sessions. One prior authorization will allow for 3 treatment sessions.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Bronchial thermoplasty is a catheter-based procedure that delivers thermal energy (radiofrequency ablation) through a bronchoscope to reduce smooth muscle mass in airway walls, thus decreasing bronchoconstriction. It is intended as an adjuvant treatment for symptom relief in patients with severe and persistent asthma despite optimal management with current care medication regimens. Approximately 10% of the asthma patient population has true refractory disease that cannot be well controlled despite adherence to treatment.

Bronchial thermoplasty is not a cure for asthma, nor will it obviate the need for continued medical management of the disease.

On April 27, 2010, the Food and Drug Administration (FDA) approved a premarket approval (PMA) application for the Alair System. The Alair System for bronchial thermoplasty is indicated for use in adult patients with severe and persistent asthma not well controlled with inhaled corticosteroids and long-acting beta agonist medications.

The best available published evidence for bronchial thermoplasty is limited to one phase II trial (AIR) and one phase III trial (AIR2). The phase II trial compared this procedure with usual medical care, while the phase III trial was a head-to-head comparison of active versus sham bronchial thermoplasty. The published evidence suggests that a three-course treatment of bronchial thermoplasty with the Alair system may worsen asthma symptoms in the short term, but significantly improve longer-term symptom control. The manufacturer, Asthmatx Inc., funded both AIR and AIR2 trials.

Long term safety of the procedure was evaluated in a clinical trial, Research in Severe Asthma (RISA) Trial. Study results suggested that bronchial thermoplasty is safe for 5 years after treatment in patients with severe refractory asthma.

The Alair System for bronchial thermoplasty has potential to improve symptom control in adults with severe, medically refractory asthma, but the device and procedure have been evaluated in relatively few patients and there are only limited available data on long-term safety and efficacy.

V. CODING INFORMATION

ICD-10 Codes: that *may* apply:

J44.1 Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9 Chronic obstructive pulmonary disease, unspecified
J45.50 Severe persistent asthma, uncomplicated
J45.51 Severe persistent asthma with (acute) exacerbation
J45.52 Severe persistent asthma with status asthmaticus
J45.901 Unspecified asthma with (acute) exacerbation
J45.902 Unspecified asthma with status asthmaticus
J45.909 Unspecified asthma, uncomplicated

CPT/HCPCS Codes:

31660 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

VI. REFERENCES

1. Anthem Blue Cross Medical Policy Bronchial Thermoplasty. http://www.anthem.com/ca/medicalpolicies/policies/mp_pw_c127954.htm (Retrieved January 21, 2015 & December 26, 2017)
2. Castro, Rubin, Laviolette, et. al. Effectiveness and Safety of Bronchial Thermoplasty in the Treatment of Severe Asthma: A multi-center, randomized, double-blind, sham-controlled clinical trial, Am J Respir Crit Care, 2010; 181: 116-124,
3. Castro, M. et.al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. Annals of Allergy, Asthma & Immunology. vol. 107, July 2011 65-70.
4. Bronchial Thermoplasty, Aetna Clinical Policy Bulletin, December 2009. http://www.aetna.com/cpb/medical/data/700_799/0744.html (Retrieved September 9, 2010, August 25, 2011 , January 4, 2013, January 6, 2014, January 21, 2015 , December 29, 2015, December 28, 2016, December 26, 2017, December 27, 2018).
5. Bronchial Thermoplasty, Humana Medical Coverage Policy, May 2010. http://apps.humana.com/tad/tad_new/Search.aspx?searchtype=beginswith&docbegin=B (Retrieved September 9, 2010, August 25, 2011, January 21, 2015, December 26, 2017, December 27, 2018)
   Hayes, Inc. Alair Bronchial Thermoplasty System (Asthmatx Inc.) for Treatment of Asthma. October 7, 2011& December 28, 2012.
6. Hayes, Inc. The Alair® System for Bronchial Thermoplasty, July 13, 2010, October 20, 2010 & September 25, 2013.
7. Hayes, Inc. Bronchial Thermoplasty for Treatment of Asthma, April 7, 2014 and update April 2015, May 2016; Annual Review April 24, 2017 & April 10, 2018.
8. Pavord, ID et al. Research in Severe Asthma Trial Study Group. Safety of bronchial thermoplasty in patients with severe refractory asthma. Ann Allergy Asthma Immunol. 2013 Nov; 111(5):402-7.
9. Wechsler, M., Laviolettem M., Rubin, AS. et.al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. The Journal of Allergy and Clinical Immunology, 03 September 2013 (10.1016/j.jaci.2013.08.009)

AMA CPT Copyright Statement:
All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.