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

Definitions:

Patients with severe persistent asthma 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 if, despite taking high doses of ICS and LABA for at least 3 months, 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


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](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](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.

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.

Long term safety of the procedure is being evaluated in an ongoing clinical trial, http://clinicaltrials.gov/ct2/show/NCT00401986?term=RISA&rank=1

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

Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma, Michael E. Wechsler, Michel Laviolette, Adalberto S. Rubin, et.al., The Journal of Allergy and Clinical Immunology, 03 September 2013 (10.1016/j.jaci.2013.08.009)
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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.

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