Bronchial Thermoplasty
Clinical Coverage Criteria

Overview

Asthma is a chronic disease of the lungs in which inflammation causes the bronchi to swell and narrow the airways creating mild to severe chest tightness, coughing, shortness of breath and wheezing. Treatment is dependent on the severity and recurrence of symptoms and usually consists of inhaled corticosteroids and long-acting beta-agonists.

Bronchial thermoplasty is a minimally invasive procedure that involves the delivery of radiofrequency energy during bronchoscopy to the airway smooth muscles. The main evidence for bronchial thermoplasty consists of three randomized controlled trials. Two compared bronchial thermoplasty to usual care (Cox et al, 2007, Pavord et al., 2007) and the other compare bronchial thermoplasty to a sham bronchoscopic procedure (Castro et al., 2010). The only sham-controlled trial of bronchial thermoplasty (Castro et al., 2010) failed to achieve its primary end-point and has left many unanswered questions about the results reported in that trial. In 2014, the American Thoracic Society (ATS)/ European Respiratory Society (ERS) Task Force recommended that bronchial thermoplasty be performed on in the context of an IRB-approved clinical trial (Chung et al., 2014), while the American College of Chest Physicians recommended bronchial thermoplasty for those adult patients with severe persistent, poorly-controlled asthma who continue to experience asthma exacerbations, emergency department visits and hospitalizations despite maximal medical treatment.

The Alair® Bronchial Thermoplasty System (Boston Scientific, Natick, MA, USA), was FDA-approved on April 27, 2010 (P0800032) for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. The Alair® Bronchial Thermoplasty system remains the only FDA-approved device for the treatment of severe persistent asthma.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for Medicare Advantage, NaviCare and PACE plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have a National Coverage Determination (NCD) for bronchial thermoplasty. National Government Services, Inc. does not have a Local Coverage Determinations (LCD) or Local Coverage Article (LCA) for bronchial thermoplasty at this time.

Bronchial Thermoplasty requires prior authorization. Requests must be supported by the treating provider(s) medical records. All the below criteria must be met:

1. The member must be 18 years of age or older.
2. The member has been diagnosed with severe persistent asthma with daily symptoms resulting in the use of a rescue inhaler such as the below:
   - Wheezing, coughing, chest tightness, and shortness of breath.
   - Persistent nighttime symptoms.
3. The severe symptoms are limiting the member's daily physical activities.
4. The member's symptoms have been treated and medically managed by an Asthma Specialist for a minimum of 6 months.
5. Evidence in the medical records supporting the member's symptoms are not responding to high dose inhaled corticosteroids and long-acting-beta-agonists for a minimum of 3 months for severe asthma exacerbations 2 or more times requiring oral steroids or being considered for chronic oral steroids or requiring hospitalizations.
6. The member is a non-smoker for at least 1 year.
7. The member does not have a contraindication to bronchial thermoplasty:
   - Presence of a pacemaker, internal defibrillator or other implantable electronic device.
   - Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine and benzodiazepines.
   - Patients previously treated with bronchial thermoplasty should not be retreated. There is no clinical data on the safety and/or effectiveness of repeat treatments.

Exclusions

- Any use of Bronchial Thermoplasty other than outlined above.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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

References

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Policy history

Origination date:	06/01/2018
Approval(s):	Technology Assessment Committee: 05/15/2018 (Introduced as a new policy), 05/22/2019 (updated references), 10/27/2020 (updated criteria to include additional contraindications, updated references). *06/15/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).*

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.