

## **FINAL Key Questions and Background**

### **Bronchial Thermoplasty**

#### **Medical Background**

The National Asthma and Education and Prevention Program Expert Panel Report recommends add-on therapy with long-acting beta agonists, leukotriene modifiers, theophylline, and omalizumab in patients with difficult-to-treat asthma who take inhaled corticosteroids. These therapies reduce inflammation or decrease airway narrowing by relaxing airway smooth muscles. Unfortunately, therapeutic options for patients with severe asthma remain limited and adjunctive therapies (like those listed above) targeting other mediators of the inflammatory pathway have yielded variable results.

Bronchial thermoplasty is designed to reduce the smooth muscle that constricts the airway during asthma attacks. This procedure relies on a catheter that has an expandable array of electrodes that is delivered to the airway via a bronchoscope, which allows the physician to see inside the lung. After the catheter is threaded into the airway, a wire leading out of the back end of the catheter is attached to a radiofrequency generator and a lever is operated that causes the electrodes to curl into a ball shape around the front end of the catheter. The curved electrodes are held against the bronchial walls and an electrical current is applied to generate heat that destroys the smooth muscle underneath the lining of the bronchial passages. Bronchial thermoplasty is performed in 3 separate procedures in which all accessible airways located beyond the mainstream bronchi (average of 3-10 mm in diameter) except for the right middle lobe are treated. The delivery of energy during bronchial thermoplasty uses continuous feedback to tightly control the degree and time of tissue heating to decrease airway smooth muscle mass without airway perforation or stenosis. Dividing the treatment into three procedures allows shorter procedure times and obviates the risks associated with widespread irritation of the airways in patients with severe asthma. Bronchial thermoplasty is typically performed by a pulmonologist with the patient under moderate sedation or general anesthesia.

#### **Policy Context**

Bronchial thermoplasty is a procedure used to treat asthma that is not well-controlled by medication. Smooth muscle in the lungs is altered by placement of a radiofrequency catheter that heats the muscle tissue, reducing the likelihood of bronchoconstriction during an asthma reaction. The specific catheter for the procedure was approved for marketing by the FDA in 2010. There are high concerns related to the safety and efficacy of bronchial thermoplasty, and medium concerns for the cost-effectiveness of the procedure.

**Scope of This HTA**

**Population:** Adults diagnosed with moderate or severe asthma

**Interventions:** Bronchial thermoplasty

**Comparators:** Medical management; sham treatment; no comparator

**Outcomes:** Quality of life; asthma control including medication use; asthma exacerbations; lung function; safety; emergency department visits; hospitalizations; mortality; cost and cost-effectiveness .

**Key Questions**

1. What is the clinical effectiveness of bronchial thermoplasty for treatment of asthma?
  - a. Is there clinically meaningful improvement for patients with severe asthma?
2. What are the harms associated with bronchial thermoplasty?
3. Does the effectiveness of bronchial thermoplasty or incidence of adverse events vary by clinical history or patient characteristics (e.g., age, sex, prior treatments)?
4. What are the cost implications and cost-effectiveness of bronchial thermoplasty?

**Public Comment & Response**

See *Draft Key Questions: Public Comment & Response* document published separately.