Patient Selection and Referral

Patient Education
PATIENT SELECTION AND REFERRAL

- Introduction
- Patient Pathway Process
- Identifying Patients
- Pre-Authorization Documentation Checklist
Resources for Referring Physicians and Office Staff

Bronchial Thermoplasty (BT), delivered by the Alair™ System, is a safe outpatient procedure for patients with severe asthma proven to provide long-term reductions in asthma exacerbations, lower the risk of hospitalizations and emergency room visits because of asthma, and improve asthma-related quality-of-life measures.

BT Program Activation contains the information you need to identify BT candidates and to communicate with your patients about this treatment option.

BT Program Activation Overview

Patient Selection and Referral
Identify BT candidates and refer appropriate patients to a BT treating physician

Patient Education
Order BT materials from Boston Scientific for your office

Questions? Please contact your local Boston Scientific representative
Identify Bronchial Thermoplasty candidate and conduct initial screen of the patient’s qualifications. BT is appropriate for patients 18 years and older with severe asthma who continue to experience asthma symptoms despite use of inhaled corticosteroids and long-acting beta-agonists.

Discuss BT treatment option with the patient. If a patient meets the criteria for BT, contact him or her to assess interest in the treatment.

Refer patient to a BT Treating Office for a consultation with the BT-trained treating pulmonologist. Complete a BT Patient Consultation Request Form and contact a BT Treating Office. A member of the BT Treating Office will contact the patient to schedule an initial consultation with the BT treating physician. Additional patient documentation from your office may be necessary to confirm asthma diagnosis, medication use, and asthma symptoms.

For a patient consult, visit: www.BTforAsthma.com/physician-locator to find a BT Treating Physician near you.

Receive a patient status follow-up from the BT Treating Office. Once the patient has completed a consultation with the BT treating physician, your office will be notified if he or she is appropriate for BT, and if applicable, when treatment will begin. Depending on the patient’s insurance plan, a pre-authorization of coverage benefits for BT may need to be obtained prior to scheduling the first procedure. This pre-authorization process can take several weeks.

Continue to manage the patient after completion of BT treatment. Immediately after each of the 3 outpatient procedures, the BT treating physician will follow up with the patient to assess post-procedure status and address any clinical needs (phone calls at 1, 2, and 7 days, and a scheduled office visit 2 to 3 weeks following the procedure). Once all 3 procedures are completed, the patient will return to his or her primary asthma physician for continued long-term asthma management. The patient may be evaluated for step-down therapy to determine the lowest level of medication necessary to maintain asthma control.

Questions? Please contact your local Boston Scientific representative.
Identifying Patients

Practices can identify Bronchial Thermoplasty candidates by extracting patient data from health information systems. The target population is patients with severe asthma that is not well controlled with inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA). Please note, the process for pulling data varies depending on the claims, practice management, Electronic Medical Records (EMR), and e-prescribing systems in place.

**Patient Diagnosis and Age**

- Identify patients with asthma diagnosis codes who are 18 years of age or older

**Medications**

- Pair the asthma diagnosis with pharmacy data for specific medications

**Healthcare Utilization**

- Search for patients who have been seen within the last 6 months and have utilized health resources such as:
  (For respiratory related reasons as primary diagnosis)

- Review patient charts for impairments
  (See Criteria Checklist for further guidance)

Schedule patient for evaluation

**PLEASE NOTE:**

It is the responsibility of the user of this tool to ensure any associated processing of health information is performed in compliance with the Health Insurance Portability and Accountability Act (HIPAA).

Boston Scientific does not promote the use of its products outside their FDA-approved label.

For use in physician’s office only.

* J45.51 is provided in this context as a means of identifying patients with severe persistent asthma who may previously have experienced acute exacerbations and may therefore be candidates for Bronchial Thermoplasty. Patients should never be treated with Bronchial Thermoplasty when they are in the midst of acute exacerbations, as this is expressly contraindicated in the directions for use.
Identify patients with asthma diagnosis codes who are 18 years of age or older

**ICD-9 Codes**

- **493.00**: Extrinsic asthma, unspecified
- **493.02**: Extrinsic asthma, with (acute) exacerbation
- **493.10**: Intrinsic asthma, unspecified
- **493.12**: Intrinsic asthma, with (acute) exacerbation
- **493.20**: Chronic obstructive asthma, unspecified
- **493.22**: Chronic obstructive asthma, with (acute) exacerbation
- **493.90**: Asthma, unspecified status
- **493.92**: Asthma, unspecified with (acute) exacerbation

**ICD-10 Codes**

- **J45.50**: Severe persistent asthma, uncomplicated
- **J45.51**: Severe persistent asthma, with (acute) exacerbation
Pair the asthma diagnosis with pharmacy data for specific medications

- Inhaled corticosteroids (ICS)

AND

- Long-acting beta-agonists (LABA)
Search for patients who have been seen within the last 6 months and have utilized health resources such as:
(For respiratory related reasons as primary diagnosis)

• Multiple physician visits or phone calls  OR  • ER visit  OR  • Multiple scripts for oral corticosteroids
Identifying Patients

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- Identify patients with asthma diagnosis codes who are 18 years of age or older
- Pair the asthma diagnosis with pharmacy data for specific medications
- Search for patients who have been seen within the last 6 months and have utilized health resources such as:
  (For Respiratory Related Reasons as Primary Diagnosis)

Review patient charts for impairments
(See Criteria Checklist for further guidance)

Print out a list of BT candidates and pull patient charts. Look for examples of asthma symptoms such as:

- Increased use of rescue inhalers
- Lifestyle modifications
- Nighttime awakenings
- Frequent symptoms during the day
- Poor quality of life
- Additional medications (high dose ICS, OCS, Xolair™ [omalizumab], Nucala™ [mepolizumab], etc)
- Frequent utilization of health services
  (ER visits, hospitalizations, unscheduled office visits)
Identifying Patients

Criteria checklist for patient chart review

To the right is a list of criteria to look for in charts of patients identified by the screening process.

To potentially qualify for BT, the patient must have:

- All boxes under medications checked

  AND

- At least one box checked from healthcare utilization or lifestyle

  **Both boxes should be checked:**
  
  **Medication**
  
  Long-acting beta-agonists (LABA) ___________________ □
  
  Inhaled corticosteroids (ICS) ______________________ □

  **At least one box checked from healthcare utilization or lifestyle:**
  
  **Healthcare utilization**
  
  Exacerbation requiring oral corticosteroids _________ □
  
  Urgent care visit for asthma ________________________ □
  
  ICU/Ventilator ____________________________ □
  
  ER visit for asthma ____________________________ □
  
  Hospitalization ________________________________ □

  **Lifestyle**
  
  Frequent symptoms during the day __________________ □
  
  Nighttime awakenings _____________________________ □
  
  Rescue inhaler use several times a day ____________ □
  
  Normal activity limited __________________________ □
Letter of Medical Necessity and Pre-Authorization Documentation Checklist

Making the case for Bronchial Thermoplasty

Proper documentation demonstrating medical necessity for Bronchial Thermoplasty treatment is critical. Below is a checklist of the key components to consider including in your letter of medical necessity. Please note, the letter of medical necessity should include all the “minimum” criteria listed below. Including additional information and supporting documentation from the “best” section allows for a complete evaluation of the essential elements of the patient’s history.

Template Physician Statement of Medical Necessity

A template document is provided to help physicians develop the written pre-authorization request to make the case for BT. This template can be downloaded from the BT Resource Center.

**Letter of Medical Necessity & Pre-Authorization Documentation Checklist**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Patient Controller Medications</th>
<th>Asthma Impairment</th>
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<tr>
<td>• Documented history of severe persistent asthma, at your office, or patient history as recorded by another physician</td>
<td>• Documented inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) combination</td>
<td>• Evidence of persistent symptoms demonstrating that patient is not well controlled on current medication, such as daily rescue medication use, nighttime awakenings, recent exacerbations, unscheduled office visits, ER visits or hospitalizations</td>
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<td>• Detailed history demonstrating that comorbidities, if present, have been managed (Allergic rhinitis, sinusitis, gastroesophageal reflux disease)</td>
<td>• Clinical history demonstrating prescribed medication represents “maximum medical therapy”</td>
</tr>
<tr>
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<td>• Evidence of patient adherence to medication</td>
<td>• Exhaustive patient history of asthma (6 months minimum) with diagnosis of severe persistent asthma</td>
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<td>• Rationale for not prescribing certain medication (ie, Xolair™) or rationale for reducing medication dose due to side effects, if applicable (eg, obesity, diabetes, interference to quality of life)</td>
<td>• Difficult/extreme/remarkable circumstances patient endures due to disease, particularly as it relates to employment</td>
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**Note:** For any appeal, it is important to include new clinical information, if available. Although it is not mandatory in all cases, and we do not recommend delaying an appeal to await new information, updated information may strengthen the case for your patient.
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**MINIMUM**

**BEST**
Frequently Asked Questions

What is Bronchial Thermoplasty?
Bronchial Thermoplasty, delivered by the Alair™ System, is a safe outpatient bronchoscopy procedure that uses mild heat to reduce excess smooth muscle in the airways, which helps reduce severe asthma attacks.

How does BT work?
People with severe asthma have an excess of smooth muscle tissue lining their airways. During an asthma attack, this muscle constricts the airways, making breathing difficult. BT reduces the amount of excess muscle and helps minimize the narrowing of your airways during an asthma attack.

What are the benefits and risks of BT?
In a clinical trial, almost 79% of patients treated with BT reported significant improvements in their asthma-related quality of life. Patients also reported a reduction in asthma attacks, ER visits and hospitalizations for respiratory symptoms, and fewer days lost from work, school, and other daily activities due to asthma. As with any procedure, there are risks, and individual results may vary. The most common side effect of BT is temporary worsening of respiratory-related symptoms (within 1 to 7 days). There is a small risk (3.4%) of these symptoms requiring hospitalization.

Am I a candidate for BT?
The Alair™ System is approved by the FDA 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 such as Advair™, Symbicort™, and Dulera™. Further evaluation with your physician or a physician trained in BT will help determine whether you are a candidate who may benefit from this procedure.
Frequently Asked Questions

What will happen during the procedure?
To ensure safety and optimal results every step of the way, BT is typically performed under moderate sedation in three separate sessions scheduled three weeks apart. Each session lasts about an hour and focuses on a different part of the lung to ensure all of the affected areas are treated. The device is introduced into your airways through a bronchoscope that is inserted into your mouth or nose, so no incision is required. After the procedure, you will be monitored for 2 to 4 hours and discharged on the same day. The treating physician will provide you with more details on what to expect during and after the procedure.

Who performs BT?
BT is performed at an outpatient hospital facility by a pulmonologist who is specially trained to perform bronchoscopy procedures and BT. To find a BT Clinic and treating physician near you, visit: [www.BTforAsthma.com/physician-locator](http://www.BTforAsthma.com/physician-locator) or call (888) 272-8440.

Will I be able to stop taking my asthma medications?
BT does not replace your current daily maintenance medication, but instead works with it to provide long-term stability in your asthma symptoms and lessen severe asthma attacks requiring oral steroids (prednisone).

Is BT covered by insurance?
Coverage policies and payment vary by payer. Your BT physician/staff will work with you to request coverage of your BT procedure.

How can I learn more about BT?
To learn more about BT, and to find a BT treating physician near you, visit [www.BTforAsthma.com](http://www.BTforAsthma.com) or call (888) 272-8440.
# BT Patient Materials

Boston Scientific offers a number of printed materials for patient education and use in the office. To order any of the following Bronchial Thermoplasty materials, please download the order form from the [BT Resource Center](#).

## Patient education materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Description</th>
<th>Suggestions for use</th>
<th>Pack size</th>
</tr>
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<tbody>
<tr>
<td><strong>BT Patient Pamphlet</strong></td>
<td>Provides a brief overview of BT for patients with severe asthma.</td>
<td>• Include with letter to patients • Office waiting rooms • Pharmacies • Health fairs</td>
<td>Pack of 25</td>
</tr>
<tr>
<td>ENDO-144502</td>
<td></td>
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<tr>
<td><strong>BT Patient Brochure</strong></td>
<td>Provides patients with more details on the clinical benefits and risks of BT.</td>
<td>• Provide to patients who are strongly considering the BT procedure, after physician has explained the details of BT</td>
<td>Pack of 25</td>
</tr>
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<td>ENDO-393403</td>
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<tr>
<td><strong>Reimbursement Brochure</strong></td>
<td>Provides patients with an overview of working with their doctor and health plan to secure coverage for BT.</td>
<td>• Provide to patients who are moving forward with receiving BT</td>
<td>Pack of 5</td>
</tr>
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<td>ENDO-209401</td>
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### Patient education materials

| BT Patient Consultation Form/Pad | Helps collect initial information on patients who may be candidates for BT and would like a consultation. Suggestions for use:  
• Complete form when referring potential patient interested in BT |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ENDO-108605</td>
<td>25 sheets per pad</td>
</tr>
</tbody>
</table>

2 of 2
Patient education materials

BT Patient Pamphlet

Are you ready for a fuller life with fewer asthma attacks?
Perhaps it’s time to look beyond medication alone.

BT Patient Pamphlet

It’s not a medication—it’s revolutionary relief for severe asthma.

Is asthma limiting your life?
You may be a candidate for Bronchial Thermoplasty (BT).
Take a short quiz, hear patient stories, and find a BT Clinic near you by visiting BTforAsthma.com.

BT is indicated for the treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

How BT is performed:
• During the procedure a tiny, carefully controlled device delivers mild heat to the smooth muscle of the airways in your lungs.
• No incision is needed, because the procedure is performed with bronchoscope inserted through the nose or mouth.
• Within your BT treatment is complete, you will return to your regular asthma-treatment doctor to continue managing your asthma.

BT reduces asthma attacks by reducing airway smooth-muscle tissue.
• People who have asthma have more airway smooth-muscle tissue surrounding the airways than people who don’t.
• During an asthma attack, the added tissue can constrict the airways, making it harder to breathe.
• Asthma medicines help open up the airways, but these medicines don’t always work well in people who have severe asthma.
• BT is an add-on therapy that supplements your current asthma medicines.

BT is clinically proven to work. In a clinical study at 1 year, patients with severe asthma who were treated with BT experienced:
• 32% decrease in severe asthma attacks1
• 84% reduction in asthma-related emergency room visits2
• 66% fewer days lost from work, school, and daily activities due to asthma2

Additionally:
• 79% improvement in their airflow-related quality of life3
Reductions in asthma attacks and emergency room visits were shown to extend through a 5-year follow-up period.2

Treatment with BT actually reduces the amount of excess smooth-muscle tissue in the airways. With less of this tissue, the airways conduct less, reducing asthma attacks and making breathing easier.4

Bronchial Thermoplasty (BT), delivered by the Alair System, is a safe outpatient procedure that provides a long-lasting reduction in asthma attacks for people with severe persistent asthma who experience:
• The most common side effect of BT is a temporary worsening of respiratory-related symptoms. These events typically occur within one day of the BT procedure and usually resolve within a week with standard care.
• There is a small risk (0.6%) per procedure that symptoms may require hospitalization.

Bronchial Thermoplasty by the treatment of severe asthma in adults.

REFERENCES:
1. Wechsler ME, Hull KL, de Klerk N, Casteneda A, Woodruff PG, et al. for the AIR2 Trial Study Group. The Alair™ Bronchial Thermoplasty System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. The Alair ™ Bronchial Thermoplasty System is not for use in patients with an active implantable electronic device, and is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. The Alair ™ Bronchial Thermoplasty System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy.
2. Cox PG, et al. Redress restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions, and warnings can be found with product labeling.
3. Castro M, et al, for the AIR2 Trial Study Group. Bronchial Thermoplasty System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. The Alair ™ Bronchial Thermoplasty System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy.

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BSGF. 2004;169:1001-1006.

BSGF. 2004;24:659-663.


BSGF. 2006;27:390-396.


BSGF. 2009;29:211-216.

BSGF. 2009;29:211-216.

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Who is Bronchial Thermoplasty?

The Alair™ System mildly heats your airway walls. This heating reduces some of the extra muscle present in the airways. This may allow your airways to stay more open and help you breathe better.

Who can have this treatment?

(Indication for Use)

The Alair Bronchial Thermoplasty System is indicated 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.

Who cannot have this treatment?

(Contraindications)

You cannot have this treatment if you have:

• An implant with electronics.
  Tell your doctor if you have any implants with electronics, such as a pacemaker. BT may keep the implant from working correctly.

• Problems taking certain medicines.
  Tell your doctor if you have ever had a problem taking any kind of medicine. These medicines do not always work well in patients who have severe asthma.

• Have had this treatment before.
  Tell your doctor if you have had BT before.

• You cannot have this treatment if you are less than 18 years old.
  BT has not been studied in patients younger than 18 years.

A Procedure for Severe Asthma

This brochure describes a procedure for treating severe asthma in adults.

About severe asthma

What happens when you have severe asthma?

Air travels in and out of your lungs through airways. There are tiny muscles in the walls of these airways.

People who have severe asthma have larger muscles in their airways than other people. The airways close down when these muscles contract.

What happens when your airways close down?

When airways close down it can be hard to breathe.

Your chest may feel tight. You may wheeze or cough. Asthma medicines usually open up the airways. These medicines do not always work well in patients who have severe asthma.

Why do doctors do this treatment?

You have severe asthma. Your asthma is severe because the asthma medicines you take now do not control your asthma symptoms.

Your doctor wants to use the Alair™ System to treat your severe asthma. This treatment is called Bronchial Thermoplasty (BT). BT is a procedure and not an asthma medicine. Your doctor thinks your health is good enough to have this treatment.

If you decide to have this treatment, you will need to do what your doctor asks you to do or you may be harmed.

What is the Alair System?

The Alair System is the tool that your doctor will use to perform BT. The Alair System has two main parts:

• A small tube with 4 wires at the end. See Figure 1.

• A machine that heats the wires.

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Patient education materials

BT Reimbursement Brochure

You and your doctor have decided that BT is right for you.

Because Bronchial Thermoplasty (BT) is a relatively new procedure, not all health plans currently cover it. This is normal for a procedure like BT. Even if your insurance company has stated that BT is not covered by your plan, it is possible to request coverage if your doctor considers BT a medical necessity because your asthma is severe and all other options have been exhausted.

Here are some actions you can take to help get the approval you need to move forward with your BT procedure.

1. Request for Coverage

YOUR DOCTOR’S OFFICE will submit a letter of medical necessity to your health plan.

You should provide your doctor’s office with the following information for them to include in this letter. Accurate, detailed information will strengthen your request.

- Describe the impact your asthma has on your quality of life:
  - Do you experience severe asthma attacks?
  - Do you make trips to the emergency room or are you ever hospitalized for asthma symptoms?
  - Do you miss time from work or school due to asthma?
  - Does your asthma give you problems when you perform daily activities such as exercising, walking, or sleeping?

2. Health Plan Response

You should give your doctor’s office a copy of the decision letter or any communication you receive from your insurance company. Discuss appeal options with your doctor if the original request has been denied.

3. Appeals Process

A written appeal is a common next step if your first Request for Coverage is denied. This appeal, submitted by either you or your doctor, will reinforce your need for BT and will address the reasons that coverage for the procedure was denied by your insurer. Note that Member Appeals (appeals submitted by you) are often more effective than Provider Appeals.

YOUR DOCTOR’S OFFICE will help you decide how to proceed with additional appeals, and will provide you with information, such as medical records, that you may need for your appeal.

YOU or your doctor must submit your appeal.

Note: In many cases there is a deadline. Be patient. Your doctor’s office will be a valuable partner as you pursue coverage from your insurance company.

- Be prepared for possible multiple appeals
- Work with your doctor’s office to try every available option

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You should give your doctor’s office a copy of the decision letter or any communication you receive from your insurance company. Discuss appeal options with your doctor if the original request has been denied.

3. Appeals Process

A written appeal is a common next step if your first Request for Coverage is denied. This appeal, submitted by either you or your doctor, will reinforce your need for BT and will address the reasons that coverage for the procedure was denied by your insurer. Note that Member Appeals (appeals submitted by you) are often more effective than Provider Appeals.

YOUR DOCTOR’S OFFICE will help you decide how to proceed with additional appeals, and will provide you with information, such as medical records, that you may need for your appeal.

YOU or your doctor must submit your appeal.

Note: In many cases there is a deadline. Be patient. Your doctor’s office will be a valuable partner as you pursue coverage from your insurance company.

- Be prepared for possible multiple appeals
- Work with your doctor’s office to try every available option
Patient education materials

BT Patient Consultation Form/Pad
Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events:
The Alair™ Bronchial Thermoplasty System is indicated 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 System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair System. Patients should be stable and suitable to undergo bronchoscopy. The most common side effect of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms. Rx Only.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.