

## MEDICAL POLICY – 7.01.606

# Balloon Dilation of the Eustachian Tube

BCBSA Ref. Policy: 7.01.158

Effective Date: May 1, 2026

Last Revised: Apr. 14, 2026


Replaces: N/A

RELATED MEDICAL POLICIES:

None

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [DOCUMENTATION REQUIREMENTS](#) | [CODING](#)  
[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

## Introduction

The eustachian tube is a small, hollow structure that connects the middle ear to the back of the nose. Each ear has an eustachian tube, which is usually filled with air. Its function is to keep pressure inside the ear the same as the pressure outside of the body. It does this by opening and closing, like a valve. These are the tubes that open as a person swallows or yawns, and that make your ears “pop” when you change altitude. If one or both tubes aren’t able to open and close properly, this can lead to symptoms like muffled hearing, a feeling of fullness in the ear, ringing in the ear (tinnitus), and feeling dizzy (vertigo). Over time, ongoing problems with the eustachian tube(s) can lead to inflammation, damage to the eardrum, and possible hearing loss. A technique has been developed in which a small tube containing a balloon is inserted into the nose and then threaded into the eustachian tube. The tiny balloon is then inflated, which opens the tube. The balloon is left in place for a couple of minutes, deflated, and removed. This policy discusses when this technique is considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

Procedure	Medical Necessity
<p><b>Balloon dilation of the eustachian tube</b></p>	<p><b>Balloon dilation of the eustachian tube (BDET) with a device cleared by the US Food and Drug Administration (FDA) for treatment of chronic eustachian tube dysfunction (ETD) may be considered medically necessary when ALL the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Individual is aged 8 years* or older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Symptoms of obstructive ETD (aural fullness, aural pressure, otalgia [earache], and/or hearing loss) are present for 3 months or longer in one or both ears that significantly effects quality of life or functional health status:               <ul style="list-style-type: none"> <li>○ Aural fullness and pressure are present</li> <li>○ Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying)</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• A previous BDET procedure has not been performed</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• A comprehensive diagnostic assessment (which may include tympanometry if the tympanic membrane is intact, nasal endoscopy, and comprehensive audiometry) has been performed with the following findings:               <ul style="list-style-type: none"> <li>○ Abnormal tympanogram (Type B or C) (see <a href="#">Related Information</a>)</li> <li>○ Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on otoscopy exam)</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• If applicable, there was failure to respond to appropriate medical management of potential co-occurring conditions, such as:               <ul style="list-style-type: none"> <li>○ Allergic rhinitis, rhinosinusitis</li> </ul> </li> </ul>



Procedure	Medical Necessity
	<ul style="list-style-type: none"> <li>▪ 4-6 weeks of a nasal steroid spray, if indicated</li> <li>○ Laryngopharyngeal reflux <ul style="list-style-type: none"> <li>▪ Proton pump inhibitor or antacid treatment</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Other causes of aural fullness have been ruled out, such as: <ul style="list-style-type: none"> <li>○ Endolymphatic hydrops (excessive buildup of the endolymph fluid of the inner ear)</li> <li>○ Extrinsic obstruction of the eustachian tube (e.g., adenoid tissue, tumor)</li> <li>○ Superior semicircular canal (SSC) dehiscence (opening in the bone covering the SSC of the inner ear)</li> <li>○ Temporomandibular joint disorders</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• If there is a history of tympanostomy tube placement, symptoms of obstructive ETD improved while tubes were patent</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The individual's eustachian tube dysfunction has been shown to be reversible <ul style="list-style-type: none"> <li>○ The individual states that they are able to relieve the pressure by performing a Valsalva maneuver to "pop" their ears;</li> <li>○ Performing a Valsalva maneuver produces temporary improvement of the individual's tympanogram to Type A tympanogram</li> <li>○ Performing a Valsalva maneuver causes the member's middle ear to aerate, which is indicated by the provider visualizing lateral movement of the tympanic membrane on otoscopy</li> </ul> </li> </ul> <p><b>*Note:</b> Acclarent AERA Eustachian Tube Balloon Dilatation System is the only system labeled for use in those 8 years of age and older</p> <p><b>BDET is considered not medically necessary if the above criteria are not met.</b></p>



Procedure	Medical Necessity
<p><b>Not medically necessary BDET</b></p>	<p><b>BDET is considered not medically necessary for treatment of individuals with any of the following conditions which are considered contraindications to BDET:</b></p> <ul style="list-style-type: none"> <li>• Individuals with patulous ETD (where the eustachian tube stays open)</li> <li>• Extrinsic reversible or irreversible causes of ETD <ul style="list-style-type: none"> <li>○ Craniofacial syndromes, including cleft palate spectrum</li> <li>○ Neoplasms causing extrinsic obstruction of the eustachian tube</li> <li>○ History of radiation therapy to the nasopharynx</li> <li>○ Enlarged adenoid pads</li> <li>○ Nasopharyngeal mass</li> <li>○ Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening</li> <li>○ Systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g. Samter’s triad [aspirin exacerbated respiratory disease], Wegener’s disease, mucosal pemphigus) that is ongoing/active (i.e., not in remission)</li> </ul> </li> <li>• Individuals with aural fullness but normal exam and tympanogram</li> <li>• Individuals with chronic and severe atelectatic ears (retracted tympanic membrane [ear drum])</li> <li>• Dehiscent carotid artery identified on imaging (e.g., preop CT) without appropriate device safeguards (e.g., depth marker)</li> <li>• Active acute infection of the nasopharynx or middle ear</li> <li>• Coagulopathy or bleeding disorders</li> <li>• Trisomy 21</li> </ul>

Procedure	Investigational
<p><b>BDET in individuals aged younger than 8 years of age</b></p>	<p><b>BDET in individuals younger than 8 years of age is considered investigational (See <a href="#">Related Information</a>)</b></p>



## Documentation Requirements

**The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**

- Office visit notes that contain the relevant history and physical that support a diagnosis of and treatment for chronic eustachian tube dysfunction such as:
  - Individual is aged 8 years or older
  - Symptoms of aural fullness and pressure are present
  - Symptoms are continuous rather than episodic
  - Symptoms have been present for  $\geq 3$  months
  - No prior BDET has been performed
  - Tympanogram is abnormal (include tympanometry report)
  - Documentation of tympanic membrane abnormality
  - If a co-occurring condition is present such as allergic rhinitis, rhinosinusitis or laryngopharyngeal reflux, medical management has been tried and failed, including 4-6 weeks of a nasal steroid spray or proton pump inhibitors (PPIs), if indicated.
  - Other causes of aural fullness have been ruled out or are not present
  - If tympanostomy tubes have been previously placed, symptoms of obstructive eustachian tube dysfunction improved while tube(s) were patent
  - The eustachian tube dysfunction has been shown to be reversible
  - No conditions for which treatment with the BDET procedure is considered not medically necessary are present

## Coding

Code	Description
<b>CPT</b>	
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information



Symptoms of obstructive eustachian tube dysfunction (ETD) may include aural fullness, aural pressure, otalgia (earache), and hearing loss. Nearly all individuals will have aural fullness and aural pressure. Many individuals will have otalgia but hearing loss may not be present in all individuals (e.g., individuals with Type C tympanograms).

## Tympanogram Types

**Type A:** is a normal middle ear system, free of fluid or physiological anomalies and looks like a pyramid or teepee shape.

**Type B:** looks like a flat line on the graph and is consistent with middle ear pathology, such as fluid or infection behind the ear drum (e.g., a hole in the ear drum or a perforated ear drum).

**Type C:** is a smaller version of a pyramid or teepee shape that is shifted negatively on the graph. This indicates negative pressure in the middle ear space consistent with sinus or allergy congestion, or a cold or ear infection and is indicative of eustachian tube dysfunction.

## Contraindications to Balloon Dilation of the Eustachian Tube

- The following individuals should not be considered for balloon dilation of the eustachian tube (BDET):
  - Individuals with patulous ETD
    - A diagnosis of patulous ETD (where the eustachian tube stays open) is suggested by symptoms of autophony of voice (loud hearing of a person's own voice), audible respirations, pulsatile tinnitus, and/or aural fullness.
  - Individuals with extrinsic reversible or irreversible causes of ETD including but not limited to:
    - Craniofacial syndromes, including cleft palate spectrum
    - Neoplasms causing extrinsic obstruction of the eustachian tube
    - History of radiation therapy to the nasopharynx
    - Enlarged adenoid pads
    - Nasopharyngeal mass



- Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening
- Systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g. Samter’s triad [aspirin exacerbated respiratory disease], Wegener’s disease, mucosal pemphigus) that is ongoing/active (i.e., not in remission)
- Individuals with aural fullness but normal exam and tympanogram
- Individuals with chronic and severe atelectatic ears (retracted tympanic membrane [ear drum])

### **Reversibility of Eustachian Tube Dysfunction**

Reversibility of ETD can be demonstrated by several means, including any of the following:

- The individual states that they are able to relieve the pressure by performing a Valsalva maneuver to “pop” their ears
- Performing a Valsalva maneuver produces temporary improvement of the individual’s tympanogram to Type A tympanogram
- Performing a Valsalva maneuver causes the member’s middle ear to aerate, which is indicated by the provider visualizing lateral movement of the tympanic membrane on otoscopy

### **Balloon Dilation of the Eustachian Tube Used in Combination with Other Procedures**

- Individuals undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Individuals with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement



## Balloon Dilation of the Eustachian Tube Used in Pediatric Populations

- Individuals between the ages of 8 to 17 are eligible for treatment of persistent obstructive ETD refractory to standard surgical interventions with the Acclarent AERA Eustachian Tube Balloon Dilation System.
- Clinical input from 2 specialty societies provided the following feedback on contraindications for pediatric individuals:
  - Absolute Contraindications
    - Patulous eustachian tube dysfunction
    - Dehiscent carotid artery identified on imaging without appropriate device safeguards
    - Active acute infection of the nasopharynx or middle ear
    - Anatomic obstruction from non-adenoid nasopharyngeal masses requiring alternative management
  - Relative Contraindications
    - Age <8 years
    - Failure to confirm obstructive ETD with objective testing
    - Uncontrolled allergic rhinitis or gastroesophageal reflux
    - Craniofacial anomalies with possible abnormal eustachian tube anatomy
    - Coagulopathy or bleeding disorders
    - Trisomy 21
    - Chronic inflammatory diseases and immunodeficiency

## Evidence Review

---

### Description

Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube (ET) fails to open and/or close properly. This failure is frequently due to inflammation and can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo. Chronic obstructive eustachian tube dysfunction (ETD) can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas (benign skin growth in the middle ear behind the eardrum). Balloon dilation of the ET (BDET) is a procedure intended to improve patency by inflating a balloon in the cartilaginous part of the ET to cause local dilation.



## Background

### *Eustachian Tube Function and Dysfunction*

The ET connects the middle ear space to the nasopharynx. The ET ventilates the middle ear space to equalize pressure across the tympanic membrane, clears mucociliary secretions, and protects the middle ear from infection and reflux of nasopharyngeal contents.<sup>1</sup> Normally, the tube is closed or collapsed and opens during swallowing, sneezing or yawning. ETD occurs when the functional valve of the ET fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. Symptoms of chronic obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia. In milder cases, eustachian tube dysfunction may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions.<sup>2</sup>

### *Diagnosis*

Because the symptoms of ETD are nonspecific, clinical practice guidelines emphasize the importance of ruling out other causes of ETD with a comprehensive diagnostic assessment that includes patient-report questionnaires, history and physical exam, tympanometry, nasal endoscopy, and audiometry to establish a diagnosis.<sup>2</sup>

### *Medical and Surgical Management of Eustachian Tube Dysfunction (ETD)*

Medical management of ETD is directed by the underlying etiology. Treatment of identified underlying conditions, such as systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; or treatment of mass lesions, may be useful in resolving ETD.

Individuals who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the eustachian tube. There is limited evidence and no randomized controlled trials (RCTs) supporting use of these surgical techniques for this indication.<sup>3</sup> Additionally, surgery may be associated with adverse events such as infection, perforation, and otorrhea (fluid drainage from the ear canal). Tympanostomy tube placement may be a repeat procedure for the life of the individual, and the risk of complications from



tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

## ***Balloon Dilatation of the Eustachian Tube***

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous ET to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the ET through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for approximately two minutes or less, after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.<sup>4,5</sup>

Balloon dilation of the eustachian tube can be done as a standalone procedure or in conjunction with other procedures such as adenoidectomy, intranasal surgery (e.g., septoplasty, turbinate procedures or sinus surgery), surgery for obstructive sleep apnea or sleep disturbed breathing, and myringotomy with or without tympanostomy tube placement. This policy addresses BDET as a standalone procedure.

In December 2023, the US Food and Drug Administration (FDA) expanded the indication for the Acclarent AERA Eustachian Tube Balloon Dilation System (K230742), authorizing its use in pediatric patients aged 8 to 17 years with persistent obstructive Eustachian tube dysfunction refractory to medical management.

## **Summary of Evidence**

For individuals who have chronic obstruction ETD despite medical management who receive balloon dilation of the ET, the evidence includes RCTs, prospective observational studies, case series, and systematic reviews of these studies. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Two 6-week RCTs found more improvement with balloon dilation plus medical management than medical management alone on patient-reported symptoms, ability to perform a Valsalva maneuver, proportion of individuals with normalized tympanograms, and otoscopy findings. Durability of these effects was demonstrated at 52 weeks in the uncontrolled extension phase of both RCTs. No serious device- or procedure-related adverse events were reported through 52 weeks of follow-up. Multiple observational studies and case series have reported that individuals experienced improvement when comparing symptoms before and after balloon dilation. Current pediatric data, though largely retrospective and observational, show balloon dilation to be safe and associated with



durable improvements in middle ear function and symptom control. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1** below.

**Table 1. Balloon Dilation of the Eustachian Tube**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT05719207</a>	Efficacy of Balloon Dilation of the Eustachian Tube in Eustachian Tube Dilatory Dysfunction	76	Dec 2025
<a href="#">NCT05998356</a>	Long-term Assessment of Balloon Eustachian Tuboplasty for Obstructive Eustachian Tube Disease: A Multicenter Single-blinded Randomized Controlled Study	96	Jan 2027
<a href="#">NCT07071298</a>	A Real World, Observational Pediatric Registry of the Acclarent AERA Eustachian Tube Balloon Dilation System	300	Feb 2031
<b>Unpublished</b>			
<a href="#">NCT03499015</a>	Balloon Dilation of the Eustachian Tube in Children: a Randomized Side-controlled Clinical Trial	50	Oct 2020 (recruitment status unknown; last update Nov 2018)
<a href="#">NCT04136977<sup>a</sup></a>	XprESS Eustachian Tube Balloon Dilation Registry	169	Aug 2020 (completed; results submitted July 21, 2021, but quality control review process not yet concluded)



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03886740	Tympanostomy Tubes Versus Eustachian Tube Dilation	32	Aug 2021 (withdrawn, difficulty enrolling)
NCT05270031	Balloon Dilation of the Eustachian Tube	58	Feb 2026 (terminated, lack of funding)

NCT: national clinical trial

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2025 Input

Clinical input was sought to help determine whether the use of BDET for pediatric individuals with chronic obstructive ETD refractory to standard surgical interventions would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 2 specialty society-level responses.

For pediatric individuals who have chronic obstructive ETD refractory to surgical interventions who receive BDET, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in appropriately selected patients using the following criteria:

- Individuals 8 years of age or older with symptoms of obstructive ETD with objective evidence of middle ear dysfunction, including abnormal tympanometry (type B or C) or objective



middle ear disease (e.g., retraction, effusion, cholesteatoma) with a history of prior tympanostomy tube placement and/or adenoidectomy;

- BDET can be used as a standard-alone procedure or used with concomitant surgical procedures (e.g., adenoidectomy, tonsillectomy, or endoscopic sinus surgery);
- The patient has undergone a comprehensive diagnostic assessment, including history and physical exam, tympanometry if the tympanic membrane is intact, nasopharyngoscopy, and comprehensive audiometry; and
- Failure to respond to appropriate medical management of alternative or co-occurring conditions that may contribute to symptoms of aural fullness or Eustachian tube dysfunction, if present (e.g., allergic rhinitis, rhinosinusitis, laryngopharyngeal reflux, temporomandibular joint disorder), including a trial of intranasal corticosteroid therapy for 4 to 6 weeks when clinically indicated

## ***2020 Input***

Clinical input was sought to help determine whether the use of BDET for individuals with chronic obstructive ETD despite medical management would provide a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 4 respondents, including 1 specialty society-level response including physicians with academic medical center affiliation and 3 physician-level responses affiliated with an academic medical center, identified by Blue Cross Blue Shield Association.

For individuals who have chronic obstructive ETD who receive BDET, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected individuals using the following criteria:

- Obstructive ETD for 3 months or longer in one or both ears that significantly affects quality of life or functional health status;
- The individual has undergone a comprehensive diagnostic assessment; including history and physical exam, tympanometry if the tympanic membrane is intact, nasopharyngoscopy, and comprehensive audiometry; and



- Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4-6 weeks of a nasal steroid spray, if indicated.

## **Practice Guidelines and Position Statements**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a United States (US) professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### ***American Academy of Otolaryngology-Head and Neck Surgery Foundation***

In 2019, the American Academy of Otolaryngology published a clinical consensus statement on BDET.<sup>2</sup> The target population was defined as adults aged 18 years or older who are candidates for BDET because of obstructive ETD in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded:

- BDET is an option for treatment of individuals with obstructive ETD.
- The diagnosis of obstructive ETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy.
- BDET is contraindicated for individuals diagnosed as having a patulous ETD.
- Further study will be needed to refine individual selection and outcome assessment.

The authors emphasized the importance of identifying other potentially treatable causes of ETD, including allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, and noted that medical management of these disorders is indicated prior to offering BDET. They also noted that potential risks of BDET that are relevant to individual counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.



The society issued a statement in 2025 on BDET: 'The American Academy of Otolaryngology-Head and Neck Surgery considers Eustachian Tube Balloon Dilatation (ETBD) as appropriate treatment for pediatric patients with Obstructive Eustachian Tube Dysfunction resulting in chronic otitis media which is refractory to standard surgical interventions (eg, tympanostomy tube placement and adenoidectomy). Multiple studies have demonstrated the efficacy and safety of ETBD in the pediatric population, with evidence showing improvements in hearing, tympanogram, quality of life, and decreased likelihood for additional surgery. The procedure can be completed safely, as a stand-alone procedure or in combination with other procedures. The American Academy of Otolaryngology-Head and Neck Surgery thus considers ETBD as a proven and effective therapeutic option in a select group of pediatric patients. The recommendation for ETBD should be determined by a qualified Otolaryngology-Head and Neck surgeon. A CT scan is not required preoperatively unless determined to be clinically indicated by the performing physicians. Otolaryngologists should use devices that are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States.<sup>17</sup>

### ***National Institute for Health and Care Excellence (NICE)***

In 2019, the NICE published updated guidance on BDET.<sup>18</sup> The guidance was based on a rapid review of the evidence,<sup>19</sup> and stated, "Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." NICE standard arrangements recommendations mean that there is enough evidence for doctors to consider the procedure as an option.

The guidance also noted:

- The procedure was not effective in all patients, and there was little evidence on the benefit of repeat procedures.
- The procedure is only indicated for chronic ETD refractory to medical treatment.

### **Medicare National Coverage**

There is no national coverage determination.



## Regulatory Status

**Table 2. Devices Cleared by the US Food and Drug Administration (FDA)**

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Acclarent Aera Eustachian Tube Balloon Dilation System	Acclarent, Inc.	01/16/2018	K171761 K230742	Eustachian tube dilation
Xpress ENT Dilation System	Entellus Medical, Inc.	04/05/2017	K163509	Eustachian tube dilation
Nuvent Eustachian Tube Dilation Balloon	Medtronic Xomed, Inc.	08/16/2021	K210841	Eustachian tube dilation
Audion Et Dilation System	Entellus Medical, Inc.	04/12/2022	K220027	Eustachian tube dilation
Vensure Balloon Dilation System	Fiagon GmbH	05/26/2023	K230065	Eustachian tube dilation

Multiple devices have been given a de novo 510(k) classification by the US Food and Drug Administration (FDA) (class II, FDA product code: PNZ)

In December 2023, the US Food and Drug Administration (FDA) expanded the indication for the Acclarent AERA Eustachian Tube Balloon Dilation System (K230742), authorizing its use in pediatric patients aged 8 to 17 years with persistent obstructive Eustachian tube dysfunction refractory to medical management.

## References

1. Schilder AG, Bhutta MF, Butler CC, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. *Clin Otolaryngol*. Oct 2015; 40(5): 407-11. PMID 26347263
2. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. *Otolaryngol Head Neck Surg*. Jul 2019; 161(1): 6-17. PMID 31161864
3. Norman G, Llewellyn A, Harden M, et al. Systematic review of the limited evidence base for treatments of Eustachian tube dysfunction: a health technology assessment. *Clin Otolaryngol*. Feb 2014; 39(1): 6-21. PMID 24438176
4. Poe DS, Hanna BM. Balloon dilation of the cartilaginous portion of the eustachian tube: initial safety and feasibility analysis in a cadaver model. *Am J Otolaryngol*. 2011; 32(2): 115-23. PMID 20392533



5. Schröder S, Lehmann M, Ebmeyer J, et al. Balloon Eustachian tuboplasty: a retrospective cohort study. *Clin Otolaryngol*. Dec 2015; 40(6): 629-38. PMID 25867023
6. Froehlich MH, Le PT, Nguyen SA, et al. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. *Otolaryngol Head Neck Surg*. Nov 2020; 163(5): 870-882. PMID 32482125
7. Aboueisha MA, Attia AS, McCoul ED, et al. Efficacy and safety of balloon dilation of eustachian tube in children: Systematic review and meta-analysis. *Int J Pediatr Otorhinolaryngol*. Mar 2022; 154: 111048. PMID 35085875
8. Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. *Laryngoscope*. May 2018; 128(5): 1200-1206. PMID 28940574
9. Meyer TA, O'Malley EM, Schlosser RJ, et al. A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. *Otol Neurotol*. Aug 2018; 39(7): 894-902. PMID 29912819
10. Anand V, Poe D, Dean M, et al. Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. *Otolaryngol Head Neck Surg*. Apr 2019; 160(4): 687-694. PMID 30620688
11. Cutler JL, Meyer TA, Nguyen SA, et al. Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. *Otol Neurotol*. Dec 2019; 40(10): 1322-1325. PMID 31385858
12. Liu YC, Dean M, Thottam PJ, et al. Balloon Dilation of the Eustachian Tube (BDET)-A Pooled Analysis in Pediatric Patients. *Laryngoscope*. Dec 2025; 135(12): 4887-4893. PMID 40574604
13. Gurberg J, Dean M, Kawai K, et al. Long-term efficacy of balloon dilation of the pediatric Eustachian tube: A six-year matched cohort study. *Am J Otolaryngol*. 2024; 45(3): 104208. PMID 38154198
14. Gürtler N, Honegger F. Eustachian Tube Balloon Dilation in Children: Short- and Long-Term Outcome. *Ann Otol Rhinol Laryngol*. Apr 2024; 133(4): 369-374. PMID 38197378
15. Mukerji S, Rosas Herrera AM, Roachat R, et al. Outcomes and Complications of Pediatric Eustachian Tube Dilation Surgery. *Otolaryngol Head Neck Surg*. Nov 2024; 171(5): 1530-1534. PMID 39033354
16. Ahluwalia J, Babu S, Hauptert M, et al. Outcomes of Concurrent Balloon Eustachian Tuboplasty and Tympanostomy Tube Placement in Children. *Laryngoscope*. Nov 2024; 134(11): 4799-4802. PMID 38872456
17. American Academy of Otolaryngology Head and Neck Surgery. Eustachian Tube Balloon Dilation in the Pediatric Population. 2025; <https://www.entnet.org/resource/eustachian-tube-balloon-dilation-in-the-pediatric-population>. Accessed March 6, 2026.
18. National Institute for Health and Care Excellence. Balloon dilation for chronic eustachian tube dysfunction. *Interventional procedures guidance [IPG665]*. December 2019. <https://www.nice.org.uk/guidance/ipg665>. Accessed March 6, 2026.
19. National Institute for Health and Care Excellence. *Interventional procedure overview of balloon dilation for chronic eustachian tube dysfunction*. <https://www.nice.org.uk/guidance/ipg665/documents/overview-2> December 2019. Accessed March 6, 2026.

## History



Date	Comments
05/01/18	New policy, approved April 10, 2018. Policy created with literature review through October 2017. Balloon dilation of the Eustachian tube for treatment of patients with chronic Eustachian tube dilatory dysfunction is considered investigational.
05/01/19	Annual Review, approved April 18, 2019. Policy updated with literature review through January 2019. references14-15 added. Policy statement unchanged. Removed HCPCS code E1399.
11/01/20	Coding update. Added HCPCS code C9745.
12/01/20	Annual Review, approved November 10, 2020. Policy updated with literature review through July 2020. references added. Policy statement changed: Balloon dilation of the eustachian tube for treatment of patients with chronic obstructive eustachian tube dysfunction may be considered medically necessary when criteria are met.
12/01/21	Annual Review, approved November 2, 2021. Policy updated with literature review through August 3, 2021; no references added. Policy statement unchanged. Remove CPT code 67999.
12/01/22	Annual Review, approved November 7, 2022. Policy updated with literature review through June 20, 2022; no references added. Minor refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed HCPCS code C9745.
12/01/23	Annual Review, approved November 6, 2023. Policy updated with literature review through August 3, 2023; reference added. Policy statements unchanged.
12/01/24	Annual Review, approved November 11, 2024. Policy updated with literature review through August 1, 2024; no references added. Policy statements unchanged.
12/01/25	New policy replaces 7.01.158 Balloon Dilation of the Eustachian Tube, approved November 11, 2025. Policy updated with literature review through July 11, 2025; references added. Policy statements unchanged except for BDET is considered not medically necessary when policy criteria are not met rather than investigational.
05/01/26	Annual Review, approved April 14, 2026. Policy updated with literature review through Dec 15, 2025; references added. Policy statement changed to "The individual is aged 8 years or older" from "The individual is aged 22 years or older," and "symptoms for 3 months or longer" changed from symptoms for 12 months or longer" Added a list of conditions for which treatment with the use of balloon dilation of the eustachian tube is considered not medically necessary. Added policy statement that BDET in individuals less than 8 years of age is considered investigational.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.



CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

