MEDICAL POLICY

Medical Policy Title	**Balloon Dilation of the Eustachian Tube (BDET)**
Policy Number	**7.01.101**
Current Effective Date	June 26, 2025
Next Review Date	June 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Balloon dilation of the Eustachian tubes (BDET), unilateral or bilateral, is **medically appropriate** for the treatment of chronic obstructive Eustachian tube dysfunction (ETD) when **ALL** the following **criteria** are met:

A. Age 18 years or older;

B. Comprehensive diagnostic evaluation documents **all** of the following:

1. abnormal tympanogram (Type B or C);
2. abnormal tympanic membrane on examination (e.g., retracted membrane, effusion, or perforation); **and**
3. other causes of aural fullness have been ruled out (e.g., temporomandibular joint disorders, extrinsic obstruction of the Eustachian tube, superior semicircular canal dehiscence, and endolymphatic hydrops);

C. Symptoms of chronic obstructive ETD including **all** of the following:

1. aural fullness and aural pressure;
2. hearing loss or otalgia (earache/pain); **and**
3. symptoms lasting (3) months or longer that are continuous and not episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying);

D. Absence of any contraindication, including but not limited to:

1. patulous ETD;
2. dehiscence of carotid artery canal;

E. No treatment history of prior BDET in the same ear for which the surgery is proposed;

F. Treatment history includes the following, if applicable:

1. failure to respond to appropriate medical management of coexisting conditions (e.g., allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux);
2. symptoms of obstructive ETD must have improved following myringotomy with tympanostomy tube placement (trial is not required for BDET).

II. BDET, unilateral or bilateral, is **investigational** for **ALL** other indications, including but not limited to:

A. As a repeat procedure;

B. Performed concurrent with tympanoplasty (ear drum repair) or other middle ear surgery (e.g., mastoidectomy);

C. Aural fullness but normal examination and tympanogram;

D. Transtympanic BDET;

E. Age 17 years and younger;

F. Extrinsic cause of ETD (e.g., but not limited to enlarged adenoid pads, history of radiation therapy to the nasopharynx, craniofacial syndrome [e.g., cleft palate spectrum], nasopharyngeal or skull base neoplasm, neoplasms causing extrinsic obstruction of the Eustachian tube).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Comprehensive diagnostic evaluation aides in proper patient selection, which may result in successful outcomes of BDET in patients with true primary obstructive ETD. Essential assessments include a history and physical exam, otoscopy, nasal endoscopy, audiometry, and tympanometry. All assessments are inadequate to secure a diagnosis when relied upon in isolation (Tucci et al., 2019).

II. Tympanometry measures the mobility of the tympanic membrane and graphically displays results in tympanograms. Tympanograms are classified by the height and location of the tympanometric peak:

A. Type A indicates normal middle ear and Eustachian tube function;

B. Type B indicates poor tympanic membrane mobility ("flat" tympanogram);

C. Type C indicates the presence of negative middle ear pressure.

III. Failure to relieve symptoms despite a functioning myringotomy or tympanostomy tube suggests a diagnosis other than obstructive ETD (e.g., patulous ETD).

IV. 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.

BDET can only be performed with a balloon dilation device/system that is approved by the U.S. Food and Drug Administration (FDA).

DESCRIPTION

The Eustachian tube (ET) is a fibrocartilaginous duct connecting the nasopharynx to the middle ear space. In adults, the ET is approximately 36 millimeters (mm) in length. It functions primarily to equalize air pressure between the middle ear and atmosphere, crucial to the proper working of the eardrum. The ET opens during yawning, swallowing, and sneezing which aids in equalized air pressure, clearing secretions, and protects the middle ear from infection and nasopharyngeal contents.

Eustachian tube dysfunction (ETD) is a broad diagnostic category that involves the inability of the ET to open and close appropriately. Common ET disorders include:

- Patulous ETD: the functional valve of the ET is pathologically patent, creating an abnormally persistent state of pressure equalization between the middle ear and nasopharynx. Diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations.
- Obstructive ETD: patency of the ET is decreased by a functional or anatomical obstruction.
- Baro-challenge-induced ETD: failure of the ET to adequately open and regulate middle-ear pressure during ambient pressure changes, although ET function may be normal in normobaric situations.

Medical management of obstructive ETD is directed by the underlying etiology. Decongestants and antihistamines can be used for rhinosinusitis to relieve inflammation and secretions. Nasal steroid sprays can also be used to aid in the relief of inflammation. The American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS) clinical consensus statement supports that there is no standard medical therapy for primary obstructive ETD, therefore, in the absence of extrinsic causes, there is no absolute role for a treatment trial of topical or systemic medical therapy in primary OETD (Tucci et al., 2019). Patients who do not find relief with medical management may be treated with surgery.

Available surgical interventions include myringotomy with tympanostomy tube placement, in which a small incision is made to the tympanic membrane and a small tube is placed, to allow for drainage of secretions. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the Eustachian tube. Tympanostomy tube placement may be a repeat procedure for the life of the patient, and the risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

Balloon dilation of the Eustachian tube (BDET) is novel, minimally invasive tuboplasty procedure intended to improve the patency of the cartilaginous Eustachian tube and ease the symptoms of chronic ETD by expanding the Eustachian tube. During this procedure, a saline-filled balloon catheter is introduced into the Eustachian tube trans-nasally using a minimally invasive endoscopic method. Once the balloon is placed, it is inflated. Pressure is maintained for approximately two minutes, followed by deflation and removal. BDET allows for the drainage of secretions and equalization of pressure across the tympanic membrane, providing relief for those suffering from ETD.

This transnasal procedure can be performed unilaterally or bilaterally and done as a stand-alone 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.

Transtympanic approach to accessing the ET is a proposed technique to overcome limitation of the transnasal approach to perform BDET. There is limited and conflicting evidence to support its use.

SUPPORTIVE LITERATURE

For adults with chronic obstruction Eustachian tube dysfunction (ETD) who have not responded to medical management (if applicable) and who undergo balloon dilation of the Eustachian tube (BDET), the evidence is sufficient to conclude that this technology leads to an improvement in net health outcomes. However, there is a lack of published evidence supporting the use of BDET in the pediatric population or for conditions such as patulous ETD, systemic mucosal diseases, or autoimmune inflammatory diseases affecting the nasopharyngeal mucosa. While the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) consensus statement acknowledges that patients with a history of recurrent barochallenge might indicate a diagnosis of obstructive ETD, and that these patients may benefit from BDET, the studies conducted on this subgroup are small and heterogeneous.

Adult Population

Oehlandt et al. (2022) assessed the efficacy and safety of balloon Eustachian tuboplasty (BET) for patients with baro-challenge-induced ETD by conducting a systematic review of the existing literature in November 2020, along with a retrospective cohort study of baro-challenge-induced ETD patients who underwent BET between 2011 and 2020. Additionally, a meta-analysis was performed to evaluate the Valsalva maneuver, ETDQ-7 score, and subjective symptom improvement. The systematic review resulted in inclusion of eight publications and the cohort study included altogether 113 patients. The authors reported an overall improvement in subjective symptoms after BET, showing improvement in 81% of patients, with 22 out of 27 (81%) professionals (professional divers, aviators, or cabin crew members) being able to continue in their profession. Reported complications were rare and mild. Outcome measures appear to be long-lasting based on a mean follow-up period of 4 years and 8 months. Although the authors concluded that BDET seems to be effective in baro-challenged-induced ETD and enables professionals to resume careers (flying or diving), they noted several study limitations (risk of bias was high in all studies, all studies lacked a control group, missing patient data, varied follow-up time and method) and note the need for more controlled and blinded studies on long-term effects.

Froehlich et al. (2020) conducted a systematic review and meta-analysis of balloon dilation for chronic ETD. Twelve studies were included in the meta-analysis, including 3 RCTs, 5 prospective observational studies, and 4 case series. One RCT (Liang et al., 2016) that compared balloon dilation to tympanic paracentesis reported tympanometry and otoscopy scores but not symptoms. The other two RCTs compared balloon dilation plus medical management to medical management alone and used the ETDQ-7 to measure symptoms. Pooled analyses showed improvements in subjective and objective measures including ETDQ-7 scores, tympanograms, otoscopy exams, and ability to perform

a Valsalva maneuver. Improvements appeared to be maintained in studies with longer-term follow-up (3 to 12 months).

Poe et al. (2018) conducted a 2:1 randomized controlled trial (n=323) to assess the safety and efficacy of BDET. Patients included in the study were aged 22 years and older who had persistent ETD and who had failed medical management, which consisted of either a minimum of four weeks of continuous daily usage of any intranasal steroid spray or a minimum of one completed course of an oral steroid within 90 days of study enrollment. A positive diagnosis of persistent ETD was confirmed with both abnormal tympanometry and symptomatic dysfunction, as determined by the Eustachian Tube Dysfunction Questionnaire (ETDQ-7). BDET was performed in the operating room under general anesthesia. Each dilation was done at an inflation pressure of 10-12 atm, with a total time of two minutes. The primary effectiveness endpoint was normalization of tympanometry at six-week follow-up. At the six-week follow-up period, 51.8% of the investigational group had a normal tympanogram versus 13.9% in the control group. At 24-weeks postoperatively, tympanogram normalization in the treatment group was 62.2%, however, the majority of the failed control group subjects had crossed over, so no statistical comparison could be made. Improvement in tympanometry was also associated with normalization of the ETDQ-7 at six-weeks. There were no serious adverse effects noted in the study, but two subjects did develop mild symptoms of patulous ET, one of which resolved by the completion of the study. The authors concluded that the study shows BDET, with adjunctive medical management, is superior to medical management alone. Study limitations include the inability to blind patients, short term follow-up, small sample size, and most patients in the control group (82%) did opt to crossover and receive BDET before their 12-week follow-up. As a result of this crossover, the control group became relatively small and self-selecting in nature, likely biasing any statistical comparison between treatment groups.

Anand et al. (2019) published the 52-week follow up data to the 2017 Poe study. At 52 weeks, the overall results of tympanograms and ETDQ-7 questionnaires of subjects who received balloon dilation remained comparable to the results at the six-week follow-up period. Tympanograms were done at six weeks, 12 weeks, 24 weeks, and 52 weeks. At six weeks, the tympanogram results were 51% normalized; at 52 weeks, 55.5% were normalized. There were many instances in which ears had normalized tympanograms, then reverted to non-normalized tympanograms, then normalized tympanograms again. In total, 63.6% of ears had normalized tympanograms at 52 weeks, either remaining normal throughout the study or converting to normal (failure then becoming normal or temporary failure but return to normal). The authors concluded that the beneficial effects of BDET with medical management at the 52-week follow-up demonstrate a durability that is clinically relevant.

Meyer et al. (2018) conducted a randomized controlled trial to compare BDET to continued medical therapy for treating persistent ETD. Subjects were randomized in a 1:1 ratio to balloon dilation or control (medical management). Of the 60 patients in the study, 31 patients were randomized to the balloon dilation group, and 29 were randomized to the control group. Patients were required to follow-up at six-weeks, and then at three-, six-, and 12-months post-procedure. Patients included in the study were aged 18 years and older, who had been diagnosed with ETD for 12 months or greater, had three or more symptoms, and had failed medical therapy of intranasal steroids or oral steroids. After six weeks, subjects in the control group had the option to undergo the procedure if

their symptoms persisted. Comparison between baseline and post treatment was evaluated using a ETDQ-7. The study found that balloon dilation led to a significant reduction in overall ETDQ-7 scores, as well as statistically significant improvement in ETD symptoms and middle ear functional assessments. The authors concluded that BDET is a safe, effective, and durable treatment for ETD.

Huisman et al. (2018) performed a meta-analysis to evaluate the success of BDET in reducing symptoms in adult patients with ETD. The search yielded 15 studies that met inclusion criteria for a total of 1,155 patients. Inclusion criteria involved studies that were BDET in adults with ETD. The studies evaluated improvement of ETD symptoms to measure effectiveness of treatments such as the Valsalva maneuver, otoscopy, tympanometry, and the ET score. Revisions due to failure of the first ET balloon dilation procedure were reported in three of the 15 studies, including 714 patients. Overall, the results from the studies included in the analysis found that all types of ETD showed an improvement in short-term follow-up, and the number of complications was relatively low. The authors recommended future research in randomized homogenous populations.

Pediatric Population

Aboueisha et al. (2022) published a meta-analysis of BDET in children less than 18 years of age. A database search identified seven studies that examined the safety and efficacy of BDET in pediatric patients (n=408) from the database inception to March 2021. The evidence base included six retrospective cohort studies and one prospective cohort study with a matched retrospective control group. Among these studies, four were designed as single-arm investigations, while three studies compared the outcomes of BDET with ventilation tube insertion (VT). The pooled studies included a total of 408 children, averaging 9.9 years of age, with an average follow-up period of 19.2 months. In all but one study, patients had a history of prior surgeries, including VT plus adenoidectomy or VT alone. Aggregating data from all seven studies, the pooled complications exhibited an incidence rate of 5.1% (95% CI, 3.1 to 8.4), with self-limited epistaxis being the most frequently reported complication. No major adverse events were reported. Type A tympanograms increased from 15.1% to 73.6% (95% CI, 58% to 84.9%) and Type B tympanograms decreased from 64.2% in the pre-operative period to 16.1% (95% CI, 8.5 to 28.4). In the three studies that compared BDET to VT, a significant difference in the rate of failure (need for reoperation, persistent type B tympanogram, or persistence of symptoms) was observed, favoring the BDET group, however, high heterogeneity was observed across the three studies pooled for this estimate.

Although Aboueisha and colleagues noted several limitations (e.g., RCTs, small number of studies, that the BDET technique is not yet standardized, and different types of balloons were used during studies), they concluded that BDET with or without tympanostomy tube placement may produce outcomes that are comparable, if not superior to, tympanostomy tube placement alone in treating chronic otitis medica with effusion. The authors concluded the procedure was safe with no major adverse events, and future prospective RCTs may help better determine the best candidate in the pediatric population.

Saniasiaya et al. (2022) performed a literature review to cover the current literature available on the outcomes of BDET in children. A literature search, conducted from 1990 to 2020, identified only seven articles which included six retrospective cohort case series and one cohort of matched controls. Of the 284 patients included in the review, a total of 463 balloon dilations were performed either

bilaterally or unilaterally. The total number of patients for each study ranged from 1 to 66, with a mean age of 7.8 years. BDET was performed as a second-line treatment in six studies, whereas in one study, BDET was the first-line treatment for ETD. The most common finding of ETD was middle ear effusion, as demonstrated in five studies. No major complications were reported in all seven studies included. Minor complications were noted in four studies, with the most common minor complication includes serous otitis media in 13 patients and epistaxis in five patients. The authors concluded that BDET may be considered as an alternative procedure following failed standard treatment. However, the authors noted that the quality of evidence is inadequate to recommend widespread use of the technique until better quality studies are completed.

Gurberg et al. (2024) conducted a retrospective matched cohort study of 20 pediatric patients, each from two centers in the United States, to report the long-term safety and efficacy of BDET compared with tympanostomy tube (TT) placement in the pediatric population. Inclusion criteria were patients aged less than 18 who were indicated for TT placement. All patients were successfully matched for number of prior TT, prior adenoidectomy, and gender. Of the 20 patients, 17 were matched exactly for age. Charts were retrospectively reviewed for demographics, tympanometry data, adjunctive procedures, and need for additional interventions. A total of 33 Eustachian tubes were dilated in 20 patients with a mean age of 7 years (range 1.2-14). The mean duration of follow-up was 6.7 years (SD 2.6; range 1.4 to 10.8 years). Over the follow-up time period, two patients failed in the BDET group vs. eight patients in the TT insertion group. Patients who underwent BDET had a lower risk of failure than patients who underwent TT insertion (adjusted HR: 0.18; 95=CI: 0.04, 0.81; p=0.03). The probability of being failure free at six years was 88% (95CI, 71- 95%) in the BDET cohort and 53% (95% CI, 33-70%) in the TT insertions cohort. There were no serious injuries reported in either group. Given that these results occurred in the absence of other interventions in the tympanic membrane, authors suggest the possibility that BDET could serve as a standalone procedure for the treatment of chronic otitis media with effusion. The limitations of the study include the small sample size, its retrospective nature, and the differences in location of the cohorts matched. Authors concluded that while the present study bolsters literature support for the use of BDET in patients with ETD refractory to standard surgical treatment, large randomized clinical trials with long term follow up are indicated.

Transtympanic BDET

There is insufficient peer-reviewed evidence to support the safety and efficacy of the transtympanic approach to BDET. The evidence includes a systematic review of studies, which included two case series on human subjects and one case series on human cadavers (Jufas and Patel, 2016). In 2018, Kapadia and colleagues evaluated the safety of transtympanic BDET of the cartilaginous proximal ET on 8 cadavers (15 ears). Kapadia and Tarabichi (2018) conducted a case series study to assess the safety and feasibility of transtympanic dilation of proximal (tympanic-end) of the cartilaginous segment of the Eustachian tube in patients (n=40) undergoing surgery for chronic ear disease. All conclude that further study of the technique is warranted.

PROFESSIONAL GUIDELINE(S)

In 2019, the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) developed clinical consensus statements on BDET (Tucci et al., 2019). The target population was defined as adults ≥18 years who are candidates for BDET because of obstructive ETD in one or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded that BDET is an option for treatment of obstructive ETD and reached consensus of 28 statements related to patient criteria, perioperative considerations, and outcomes. There were 28 other statements that the expert panel did not reach consensus, likely reflecting knowledge gaps regarding the role of BDET in managing OETD. This includes the role for repeat BDET, which was found to lack adequate literature to support the efficacy of repeat BDET if the first BDET has not been successful.

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET. The guidance was based on a rapid review of the evidence 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." The guidance also noted that the procedure was not effective in all patients, there was little evidence on the benefit of repeat procedures, and the procedure is only indicated for chronic ETD refractory to medical treatment.

Although the Food and Drug Administration (FDA) expanded clearance for one dilation system to be used for ages 8-17, there is no clinical practice guideline or consensus statement published for BDET in the pediatric population.

REGULATORY STATUS

In September 2016, the Acclarent AERA Eustachian Balloon Dilation System (Acclarent, Inc.) was granted de novo classification by the FDA. Initially cleared for patients with persistent ETD aged 22 years and older, the system received FDA approval for ages 18 and older (K171761) in January 2018.

Based on real-world evidence, with data from published literature and data provided by established physicians, the FDA expanded the Acclarent AERA's indications for use to include patients ages 8 – 17 years (K230742) in December 2023. The system is indicated for use alone or in combination with adjunctive procedures, to treat objective signs of persistent obstructive ETD from inflammatory pathology, resulting in chronic otitis media with effusion and are refractory to at least one surgical intervention for persistent obstructive ETD.

In December 2016, the XprESS ENT Dilation System (Entellus Medical) was also cleared for marketing by the FDA through the 510(k) process for two indications. Specifically related to ETD, the device is cleared for patients 18 years and older using a transnasal approach. The FDA determined that the device was equivalent to existing devices used for ETD.

In August 2021, the NuVent Eustachian Tube Dilation Balloon (Medtronic Xomed, Inc.) was cleared for marketing through the 501(k) process to treat persistent ETD in patients 18 years and older (K210841).

In August 2023, the TubaVent Balloon Dilatation System (Spiggle & Theis Medizintechnik, Germany) received FDA 510(k) premarket notification clearance (K223542) for the indicated use of dilating the

cartilaginous portion of the Eustachian tube for treatment of persistent obstructive ETD in patients 18 years and older.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
31231	Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)
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
69799	Unlisted procedure, middle ear
92511	Nasopharyngoscopy with endoscope (separate procedure)

HCPCS Codes

Code	Description
None	

ICD10 Codes

Code	Description
H65.00-H65.93	Nonsuppurative otitis media (code range)
H66.001-H66.93	Suppurative and & unspecified otitis media (code range)
H67.1-H67.9	Otitis media in diseases classified elsewhere (code range)
H68.001-H68.029	Eustachian salpingitis and obstruction (code range)
H69.80-H69.93	Other specified and unspecified disorders of Eustachian tube (code range)
H71.00-H71.93	Cholesteatoma of middle ear (code range)
H72.00-H72.93	Perforation of tympanic membrane (code range)

Code	Description
H81.01-H81.09	Meniere's disease (code range)
H81.311-H81.4	Peripheral and Central vertigo (code range)
H91.01-H91.93	Other and unspecified hearing loss (code range)
J30.0-J30.9	Vasomotor and allergic rhinitis (code range)
J31.0-J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis (code range)
J32.0-J32.9	Chronic sinusitis (code range)

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SEARCH TERMS

Balloon dilation, Eustachian tube, Eustachian tube dysfunction, Transnasal, Transtympanic, Acclarent Aera, XprESS, TubaVent

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon our review, balloon dilation of the Eustachian tube is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific

service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
08/15/19, 09/17/20, 09/16/21, 09/15/22, 09/21/23, 08/22/24, 06/26/25	
Date	**Summary of Changes**
06/26/25	• Annual review. Policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
08/15/19	• Original effective date