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Balloon Dilation of the Eustachian Tube

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) **may be considered medically necessary** under the following conditions:

- Adults (age 22 years and older) with symptoms of obstructive ETD (aural fullness, aural pressure, otalgia, and/or hearing loss) for 12 months or longer in one or both ears that significantly affects quality of life or functional health status:
  - Aural fullness and pressure must be present (see Policy Guidelines); **AND**
- The individual has undergone a comprehensive diagnostic assessment; including patient-reported questionnaires, history and physical exam, tympanometry if the tympanic membrane is intact, nasal endoscopy, and comprehensive audiometry, with the following findings:
  - Abnormal tympanogram (Type B or C); and
  - Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam); **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; **AND**
- Other causes of aural fullness such as temporomandibular joint disorders, extrinsic obstruction of the eustachian tube, superior semicircular canal dehiscence, and endolymphatic hydrops have been ruled out; **AND**
- If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent; **AND**
- The individual does not have patulous ETD or another contraindication to the procedure (**s**ee Policy Guidelines); **AND**
- The individual's ETD has been shown to be reversible (see Policy Guidelines); **AND**
- Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying); **AND**
- The individual has not had a previous BDET procedure.

Balloon dilation of the eustachian tube **is considered experimental, investigational and/or unproven** if the above criteria are not met.

Policy Guidelines

Symptoms of obstructive eustachian tube dysfunction may include aural fullness, aural pressure, otalgia, 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., patients with Type C tympanograms).

Contraindications to Balloon Dilation of the Eustachian Tube
The following individuals should not be considered for balloon dilation of the eustachian tube:

- Individuals with patulous eustachian tube dysfunction (ETD).
  - A diagnosis of patulous ETD is suggested by symptoms of autophony of 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, 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.

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 balloon dilation of the eustachian tube (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.

Description

Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube 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 ETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the eustachian tube (BDET) is a procedure intended to improve patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

Eustachian Tube Function and Dysfunction
The eustachian tube connects the middle ear space to the nasopharynx. It 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. (1) Normally, the tube is closed or collapsed and opens during swallowing, sneezing or yawning. Eustachian tube dysfunction occurs when the functional valve of the eustachian tube 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, ETD may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions. (2)

<u>Diagnosis</u>
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. (2)

Medical and Surgical Management of Eustachian Tube Dysfunction

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.

Patients 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. (3) Additionally, surgery may be associated with adverse events such as infection, perforation, and otorrhea. 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

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for 2 minutes or less, after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia. (4, 5)

Balloon dilation of the eustachian tube can be 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. This medical policy addresses balloon dilation of the eustachian tube as a stand-alone procedure.

Regulatory Status

Multiple devices have been given a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ) (Table 1).

Table 1. Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) Number	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

Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Balloon Dilation for Chronic Obstructive Eustachian Tube Dysfunction

Clinical Context and Therapy Purpose

The purpose of balloon dilation of the eustachian tube (BDET) is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic obstructive eustachian tube dysfunction (ETD) despite medical management.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with chronic obstructive ETD despite medical management.

Eustachian tube dysfunction occurs when the functional valve of the eustachian tube fails to open and/or close properly, frequently due to inflammation. Symptoms may include ear fullness, recurrent barochallenge (difficulty clearing the ears with changes in ambient pressure), hearing loss, otalgia, and tinnitus.

Interventions
The therapy being considered is BDET.

Balloon dilation of the eustachian tube is a procedure intended to improve the patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for 2 minutes or less after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

Comparators
Medical management of ETD is directed by the underlying etiology: treatment of viral or bacterial rhinosinusitis; systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; and treatment of mass lesions. Treating underlying conditions, if identified, may be useful in resolving ETD. Patients who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes, methods of eustachian tube dilation other than balloon dilation, or mechanical pressure equalization devices.

Outcomes
The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity. Specific outcome measures are described in Table 2. Initial follow up examinations are typically done at 4 to 6 weeks to judge early efficacy. Follow-up should be at least 1 year to appropriately establish a clinically meaningful improvement.

Table 2. Outcome Assessment of Chronic Obstructive Eustachian Tube Dysfunction

Outcome Measure	Description	MCID, if known
Eustachian Tube Dysfunction Questionnaire (ETDQ-7)	Validated, standardized, 7-item patient-reported questionnaire to assess symptom severity associated with ETD. Pressure, pain, feeling clogged, cold/sinusitis problems, crackling/popping, ringing, and muffled hearing. Patients rate the severity of seven symptoms on a scale ranging from 1 (no problem) to 7 (severe	0.5-point improvement Normalization is defined as a mean item score <2.1 or a total score <14.5

	problem). Dividing the total score by seven yields the mean item score. A total score of ≥14.5 and mean item score of ≥2.1 indicate ETD. Scores in the range of 1-2 indicate no to mild symptoms, 3-5 moderate symptoms, and 6-7 severe symptoms.	
Valsava maneuver	Patient breathes out while closing the nose and mouth to direct air to the eustachian tube and help them open. Modified: gentle nose blow with simultaneous swallow	Positive (ability to perform the maneuver when needed) Negative (unable to perform the maneuver)
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. Type A indicates normal middle ear and eustachian tube function; type B indicates poor tympanic membrane mobility ("flat" tympanogram), and type C indicates the presence of negative middle ear pressure.	Type A (normal)
Otoscopy findings	Visual examination of the tympanic membrane using an otoscope. Classifies tympanic membrane as abnormal (retracted membrane, effusion, perforation, or any other abnormality identified on exam) or normal	Normal tympanic membrane

ETD: eustachian tube dysfunction; MCID: minimal clinically important difference.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Froehlich et al. (2020) conducted a systematic review and meta-analysis of balloon dilation for ETD (Tables 3 and 4). (6) 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 2 RCTs compared balloon dilation plus medical management to medical management alone and used the ETDQ-7 to measure symptoms. Table 3 summarizes results at 6 weeks. Pooled analyses showed improvements in subjective and objective measures including Eustachian Tube Dysfunction Questionnaire (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).

Aboueisha and colleagues (2022) published a meta-analysis of balloon dilation for eustachian tube dysfunction (BDET) in children. (7) The authors searched PubMed, Embase, Web of Science, Cochrane, Clinicaltrials.gov, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases and identified 7 studies that examined the safety and efficacy of BDET in pediatric patients from database inception to March 2021. The evidence base encompassed 6 retrospective cohort studies and 1 prospective cohort study with a matched retrospective control group. Among these studies, 4 were designed as single-arm investigations, while 3 studies compared the outcomes of BDET with ventilation tube insertion (VT). Utilizing the methodological index for non-randomized studies (MINORS) criteria, two reviewers evaluated the potential bias in the included studies. The overall quality assessment revealed a moderate quality level, with the comparative studies achieving an average score of 17.3 and the non-comparative studies achieving 10.6.

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 almost all cases (except for one study where data was not available on pre-treatment), patients had a history of prior surgeries, including VT plus adenoidectomy or VT alone. Aggregating data from all 7 studies, the pooled complications exhibited an incidence rate of 5.1% (95% confidence interval [CI], 3.1 to 8.4), with self-limited epistaxis being the most frequently reported complication. Following BDET, the proportion of patients with Type A tympanogram increased from 15.1% to 73.6% (95% CI, 58% to 84.9%) and the number of patients with Type B tympanogram decreased from 64.2% in the pre-operative period to 16.1% (95% CI, 8.5 to 28.4) post-operatively pooling data from 5 studies. All pooled post-operative outcomes had high heterogeneity with the exception of complication rate, which had a low level of heterogeneity. In the 3 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 (odds ratio [OR], 0.24; 95% CI, 0.1 to 0.4; I^2, 80.9%); however, high heterogeneity was observed across the 3 studies pooled for this estimate.

Several earlier systematic reviews of observational studies have been published. Case series included in these reviews consistently reported that patients experienced improvement when

comparing symptoms before and after balloon dilation. The studies varied in the type of medical management used to treat ETD before and after balloon dilation.

Table 3. Systematic Review Characteristics

Study	Search End Date	Included Studies	Participants	N (range)	Study Designs	Duration
Froehlich et al. (2020) (6)	January 2019	35 total, 12 included in quantitative meta-analysis	Adults with ETD	448 patients (2-202), 445 ears (2-234)	3 RCTs, 5 prospective observational, 4 case series	6 weeks-12 months

ETD: eustachian tube dysfunction; N: number; RCTs: randomized controlled trials.

Table 4. Systematic Review Results

Study	ETDQ-7 Normalization (Proportion with score <2.1)	ETDQ-7 Mean Score	Valsalva Maneuver (Proportion able to perform)	Tympanometry Normalization (Proportion with Type A)[1]	Tympanometry Improvement (Proportion with change from Type B to Type A or from Type C to Type B)[1]	Otoscopy Findings (Proportion with a normal finding)
Froehlich et al. (2020) (6)						
N studies /patients Study designs	2/245 RCTs	3/2261 RCT, 1 prospective observational, 1 case series	6/436 ears RCTs	12/606 ears RCTs, prospective observational, case series	4/287 ears	7/252 ears
Baseline % (95% CI)	N/A	NR	13.2% (0.7-37.5%)	13.9% (1.5-35.6)	N/A	22.1% (2.0-55.0)
6 weeks % (95% CI)	53.5% (47.0, 59.8)	NR	71.2% (58.8% - 82.1%)	58.9% (40.4-76.2)	53.0% (29.1-76.2)	53.8% (31.1-75.7)
Pooled Difference Pre-Post (95% CI):	N/A	-2.13 (-3.02 to -1.24); p=.0004	58.0% (52.0%-63.3%); p<.001	45.0% (39.9-49.8); p<.0001	N/A	31.7% (22.5-40.4); p<0001
I^2 (p-value)	NR	87% (.0004)	NR	NR	NR	NR

[1] Type A indicates normal middle ear and eustachian tube function; type B indicates poor tympanic membrane mobility ("flat" tympanogram), and type C indicates the presence of negative middle ear pressure.

CI: confidence interval; ETDQ-7: 7-item Eustachian Tube Dysfunction Questionnaire; N: sample size; N/A: not applicable; NR: not reported; RCT: randomized controlled trial.

Randomized Controlled Trials

Two randomized controlled trials have evaluated BDET for obstructive ETD (Tables 5 to 7). (8, 9) Both compared BDET plus medical management to medical management alone for 6 weeks. Following the 6-week follow-up period, patients who were randomized to medical management alone could elect to receive BDET and were followed up to 52 weeks in an extension phase.

The balloon catheter used in Poe et al. (2017) was a custom-designed eustachian tube balloon catheter (ETBC) (Acclarent). Eligible patients had persistent patient-reported symptoms of ETD (ETDQ-7 mean item score ≥2.1) and abnormal tympanometry (type B or type C) and failed medical management including either a minimum of 4 weeks of daily use of an intranasal steroid spray or a minimum of 1 course of an oral steroid. (8) Each investigator was required to perform 3 successful balloon dilation procedures in nonrandomized "lead-in" patients who were then followed for durability and safety outcomes. Randomization and analyses were performed at the person-level whether or not the patient had unilateral or bilateral ETD. The primary efficacy outcome (normalization of tympanometry) was assessed by both site investigators and a blinded, independent evaluator; discrepancies were resolved by a second independent evaluator. For bilaterally treated patients, both ears had to be rated as normalized for that patient to be considered normalized for the primary outcome.

Anand et al. (2019) reported 52-week data on 128 patients who received an ETBC, including those randomized to the intervention and those who crossed over following the 6-week randomized phase. (10) Of 128 patients with normalized tympanogram at 6 weeks, 71 remained normalized at 52 weeks and 71 of 124 had normalized scores on the ETDQ. Some ears failed to normalize at earlier visits but converted at subsequent follow-up visits. Overall, 119 of 187 (63.6%) ears had type A tympanograms at 52 weeks, either remaining normal throughout the study or converting to normal. There were no device- or procedure-related serious adverse events during the 52-week follow-up period.

Meyer et al. (2018) conducted a RCT evaluating BDET versus continued medical therapy for treating 60 participants with persistent ETD. The primary efficacy outcomes were symptoms as measured by the ETDQ-7 score and the primary safety outcome was rate of complications. (9) Mean (standard deviation) change in overall ETDQ-7 score at 6 weeks was 2.9 (1.4) for balloon dilation compared with 0.6 (1.0) for medical management: balloon dilation was superior to medical management ($p<.0001$). No complications were reported in either study arm. Among participants with abnormal baseline assessments, improvements in tympanogram type ($p<.006$) and tympanic membrane position ($p<.001$) were significantly better for balloon dilation than control. Improvements in the ETDQ-7 scores were maintained through 12 months after balloon dilation. Cutler et al. (2019) reported longer-term follow-up data from this trial. (11) Of 58 patients from the original study who were eligible for the extension study, 47 were enrolled (81.0%) The mean follow-up time was 29.4 months post-procedure (range 18 to 42 months). Changes from baseline at the end of the longer-term follow-up period were similar to improvements observed at 1 year on outcome measures including the ETDQ-7, normalized tympanogram, ability to perform the Valsalva maneuver, and patients' satisfaction with the outcome of the procedure. One patient underwent a revision eustachian tube dilation after 362

days, performed concurrently with balloon dilation for recurrent sinus disease. No other surgeries or adverse events were reported.

Study limitations are summarized in Tables 8 and 9. Limitations included a lack of blinding which could bias reports of patient-reported symptoms, and short (6-week) comparative follow-up period.

Table 5. Randomized Controlled Trials of Balloon Dilation of the Eustachian Tube: Study Characteristics

Study name (NCT Number) Publications	Coun-tries	Dates	Key Eligibility Criteria	Outcome Measures and Duration of Follow-up	Intervention	Comparator
The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150) Poe et al. (2017) (8); NCT02087150 (10)	U.S., 21 sites	2014-2016	Inclusion: 22 years or older, persistent ETD, failure of medical management, positive diagnosis of ETD Exclusion: • Anatomy that requires an adjunctive surgical procedure • Concomitant nasal or sinus procedures planned on the same day as surgical procedure • Concomitant ear procedures planned on the same day as surgical procedure • History of major surgery of the head or neck within 4 months prior to surgery • History of patulous ET • History of fluctuating	Primary: Tympanogram normalization (Type A) in all indicated ears at 6 weeks Secondary: Improvement of 0.5 points on ETDQ-7 at 6 weeks Exploratory: Tympanogram normalization (Type A) at 12, 24, and 52 weeks ETDQ-7 Improvement at 12, 24, 52 weeks Work and activity impairment at 6, 12, 24, 52 weeks	BDET plus medical management (daily nasal steroid spray for 6 weeks) 162 patients (234 ears)	Medical management alone (daily nasal steroid spray for 6 weeks) 80 patients (117 ears)

			sensorineural hearing loss • Active acute otitis media • Tympanic membrane perforation • Tympanosclerosis • Acute upper respiratory infection • Temporomandibular joint disorder • Cleft palate • Craniofacial syndrome • Cystic fibrosis • Ciliary dysmotility syndrome • Systemic mucosal or immunodeficiency disease • Intolerance of medication for ETD • Prior intervention of eustachian tube			
XprESS Eustachian Tube Dilation Study (NCT02391584) Meyer et al. (2018) (9, 11)	U.S., 5 sites	2015-2017	Inclusion:18 years or older, diagnosed with symptoms of chronic ETD for at least 12 months, ETDQ-7 score ≥3.0, record of failed medical management Exclusion: • Require concomitant procedures at the time of the study enrollment or procedure • Have patulous eustachian tube	Primary: Mean change in overall ETDQ-7 at 6 weeks, complication rate through 6 months post-procedure Secondary: technical success rate, revision rate at 12 months, mean change in ETDQ-7 at 3 months, 6	BDET • 31 patients	Continued medical management • 29 patients

			• Have ear tubes in place or perforation of the tympanic membrane • Have evidence of internal carotid artery dehiscence • Be pregnant at the time of enrollment • Be currently participating in other drug or device studies	months, and 12 months		

BDET: balloon dilation of the eustachian tube; ET: eustachian tube; ETDQ-7: Eustachian Tube Dysfunction Questionnaire; ETD: eustachian tube dysfunction; NCT: National Clinical Trial; U.S.: United States.

Table 6. Randomized Controlled Trials of Balloon Dilation of the Eustachian Tube: Results at 6 Weeks

Study name (NCT Number) Publications	ETDQ-7 Normal-ization (Score <2.1)	ETDQ-7 Mean Change	Valsalva Maneuver Positive	Normalized Tympanogram (Type A)	Otoscopy Results (Tympan-ic Mem-brane position normal)	Adverse Events
The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter NCT02087150 Poe et al. (2017) (8)						
BDET plus medical management	77/137 (56.2%)		32.8% increase in number of ears	72/139 (51.8%)	Not assessed	4 serious adverse events No device- or procedure-related serious adverse events
Medical management alone	6/71 (8.5%)		3.1% increase in number of ears	10/72 (13.9%)		1 serious adverse event

						No medication-related serious adverse events
P-value	<.001		<.001	<.0001		
XprESS Eustachian Tube Dilation Study NCT02391584 Meyer et al. (2018) (9)						
BDET plus medical management		-2.9 (1.4)	8/17 (47.1%)	8/14 (57.1%)	10/15 (66.7%)	No complica-tions
Medical management alone		-0.6 (1.0)	2/14 (1.3%)	1/10 (10.0%)	0/12 (0.0%)	No complica-tions
P-value		<.0001	.068	.006	.001	

BDET: balloon dilation of the eustachian tube; ETDQ-7: Eustachian Tube Dysfunction Questionnaire; NCT: National Clinical Trial.

Table 7. Randomized Controlled Trials of Balloon Dilation of Eustachian Tube - Uncontrolled Extension Phase Results (52 weeks)

Study name (NCT Number) Publications	ETDQ-7 Normal-ization (Score <2.1) at 52 Weeks	ETDQ-7 Mean Change	Valsalva Maneuver Positive at 52 Weeks	Normalized Tympano-gram (Type A) at 52 weeks	Otoscopy Results (Tympanic Membrane position normal)	Adverse Events
The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150) (10)						
Number analyzed	124		230 (Ears)	128 (187 ears)		219
BDET plus medical management	71/124 (57.3%)		Ears: 185/230 (80.4%)	Patients: 71/128 (55.5%) Ears: 119/187 (63.6%)	Not assessed	No device- or procedure-related serious adverse events Two occurrences of patulous ET, both

						described as mild.
XprESS Eustachian Tube Dilation Study (NCT02391584) Meyer et al. (2018) (9, 11)						
N		49	47	80	49	49
BDET plus medical management		2.1 (SD reported in graph only)	31/47 (66.0%)	70/80 (87.5%)	42/49 (85.7%)	No complica-tions

BDET: balloon dilation of the eustachian tube; ET: eustachian tube; ETDQ-7: Eustachian Tube Dysfunction Questionnaire; NCT: National Clinical Trial; SD standard deviation.

Table 8. Randomized Controlled Trials: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Poe et al. (2017) (8)				1. Limited information on harms provided in the primary publication vs. FDA dossier	1. Only 6 weeks of comparative data; longer follow-up of BDET to 52 weeks in subset of patients.
Meyer et al. (2018) (9)	1. Study enrollment criteria did not require abnormal middle ear functional assessments				1. Compar-ative outcomes limited to 6 weeks; longer follow-up of BDET in subset of patients.

BDET: balloon dilation of the eustachian tube; FDA: Food and Drug Administration.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Randomized Controlled Trials: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Poe et al. (2017) (8)		1. Blinding of patients not possible; may bias patient-reported measures				1. Treatment effects and CIs not reported.
Meyer et al. (2018) (9)		1. Blinding of patients not possible; may bias patient-reported measures				

CI: confidence interval

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Summary of Evidence

For individuals who have chronic obstructive eustachian tube dysfunction (ETD) despite medical management who receive balloon dilation of the eustachian tube (BDET), the evidence includes randomized controlled trials (RCTs), prospective observational studies, case series, and systematic reviews of these studies. 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 patients 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 patients experienced improvement when comparing symptoms before and after balloon dilation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input From Physician Specialty Societies And Academic Medical Centers

2020

For individuals who have obstructive ETD 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 a subgroup of appropriately selected patients 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 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 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

American Academy of Otolaryngology-Head and Neck Surgery Foundation

In 2019, the American Academy of Otolaryngology published a clinical consensus statement on BDET. (2) The target population was defined as adults ≥18 years 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 patients 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 patients diagnosed as having a patulous ETD.
- Further study will be needed to refine patient 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 patient counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET. (12) The guidance was based on a rapid review of the evidence, (13) 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 10.

Table 10. Unpublished Clinical Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT05719207	Efficacy of Balloon Dilation of the Eustachian Tube in Eustachian Tube Dilatory Dysfunction	76	Dec 2024
NCT05998356	Long-term Assessment of Balloon Eustachian Tuboplasty for Obstructive Eustachian Tube Disease: A Multicenter Single-blinded Randomized Controlled Study	96	Jan 2027
NCT03499015	Balloon Dilation of the Eustachian Tube in Children: a Randomized Side-controlled Clinical Trial	50	Oct 2020 (recruitment status unknown; last update Nov 2018)
NCT04136977[a]	XprESS Eustachian Tube Balloon Dilation Registry	169	Aug 2020 (completed; results submitted July 21, 2021, but quality control review process not yet concluded)
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.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	69705, 69706
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2025	Document updated. Coverage unchanged. No new references added; some removed.
02/01/2025	Document updated with literature review. Coverage unchanged. Added references 11-20.
01/01/2024	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. No new references added.
01/01/2022	Reviewed. No changes.
01/15/2021	Document updated with literature review. Coverage has changed from experimental, investigational and/or unproven to Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube

	dysfunction may be considered medically necessary when criteria are met. NOTEs 1-4 added. References added: 2, 6, 9-12. Some references were removed.
04/15/2000	New Medical document. Balloon Dilation of the Eustachian Tube was previously housed on medical policy SUR706.001 Nasal and Sinus Surgery. Intent of the Coverage is unchanged. Balloon dilation of the eustachian tube for treatment of patients with chronic eustachian tube dilatory dysfunction is considered experimental, investigational and/or unproven.