Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Balloon Dilation of the Eustachian Tube (BDET)

Description/Background

Eustachian Tube Function

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, 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.[2]

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.[2]

Medical and Surgical Management of Eustachian Tube Dysfunction

Medical management of eustachian tube dysfunction (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 Dilatation of the Eustachian tube
Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube. 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 approximately 2 minutes 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 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 our without tympanostomy tube placement. This evidence review addresses BDET as a standalone procedure.

*The treatment of patulous eustachian tube is not addressed in this policy.

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

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
Acclarent Aera Eustachian Tube Balloon Dilation System	Acclarent, Inc	12/13/2023	K230742	Eustachian tube dilation

Medical Policy Statement

Eustachian tube dilation devices that are FDA approved are established. They are considered a useful therapeutic option in the treatment of chronic obstructive eustachian tube dysfunction when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions

Balloon dilation of the eustachian tube for treatment of chronic obstructive eustachian tube dysfunction may be considered **established** under the following conditions:

- Adults (age 18 years and older) with symptoms of obstructive eustachian tube dysfunction (aural fullness, aural pressure, otalgia, and/or hearing loss) for 3 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

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) OR
    - Symptoms consistent with baro-challenge induced Eustachian tube dysfunction (that is: recurrent aural fullness, popping, or pain that reproducibly occurs with changes in pressure). This means eustachian tube dysfunction is not reversible.

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 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 eustachian tube dysfunction should have improved while tubes were patent

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.

In certain situations, consideration may be given to individuals younger than 18 years of age. The most likely scenario is older children and/or adolescents who have failed standard treatment with grommet (ventilation or tympanostomy tube insertion), adenoidectomy or both.

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

Exclusions

- BDET has been proposed for the treatment of other conditions. But the evidence is insufficient to support BDET for the following conditions (this list is not all-inclusive):
  - 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 patulous eustachian tube dysfunction
- Individuals with aural fullness but normal exam and tympanogram
- Individuals with chronic and severe atelectatic ears
- BDET is considered investigational for all other indications

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

69705 69706

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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 OBSTRUCTION EUSTACHIAN TUBE DYSFUNCTION

Clinical Context and Test 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 review.

Populations

The relevant population of interest are 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 balloon dilation of the eustachian tube.

Balloon dilation of the eustachian tube is a procedure intended to improve the patency by inflating a balloon in the cartilaginous part of the ET 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 eustachian tube dysfunction 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 one 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 eustachian tube dysfunction. 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 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.	0.5 point improvement Normalization is defined as a mean item score <2.1 or a total score <14.5
Valsava maneuver	Patient breathes out while closing the nose and mouth to direct air to the ET 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 ET 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

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. 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 eustachian tube dysfunction (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 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 (3-12 months).

Aboueisha and colleagues (2022) published a meta-analysis of balloon dilation for eustachian tube dysfunction (BDET) in children.[11] 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 (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 eustachian tube dysfunction 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 eustachian tube dysfunction	448 patients (2-202) 445 ears (2-234)	3 RCTs, 5 prospective observational, 4 case series	6 weeks-12 months

ETD: eustachian tube dysfunction; 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)
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)	NA	NR	13.2% (0.7-37.5%)	13.9% (1.5-35.6)	NA	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):	NA	-2.13 (-3.02, -1.24); P =.0004	58.0% (52.0%-63.3%); P<.001 4	45.0% (39.9-49.8); P <.0001	NA	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 ET 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; NA: not applicable; NR: not reported; RCT: randomized controlled trial

Randomized Controlled Trials

Two randomized controlled trials have evaluated BDET for obstructive eustachian tube dysfunction (Tables 5-7).[7,8] 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 eustachian tube dysfunction (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.[7] 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 a ETBC, including those randomized to the intervention and those who crossed over following the 6-week randomized phase.[9] 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 eustachian tube balloon dilation versus continued medical therapy for treating 60 participants with persistent eustachian tube dysfunction. The primary efficacy outcomes were symptoms as measured by the ETDQ-7 score and the primary safety outcome was rate of complications.[8] 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.[10] 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 18-42 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 ET 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	Countries	Dates	Key Eligibility Criteria	Outcome Measures and Duration of Followup	Intervention	Comparator
The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150)Poe et al (2017)[7];NCT02087150[9]	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 four (4) months prior to surgery • History of patulous ET • History of fluctuating 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	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 weeksETDQ-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)
XprESS Eustachian Tube Dilation StudyNCT02391584Meyer et al (2018)[8,10]	U.S., 5 sites	2015-2017	Inclusion:18 years or older, diagnosed with symptoms of chronic eustachian tube dysfunction 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 • 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	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 months and 12 months	BDET • 31 patients	Continued medical management • 29 patients

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

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

Study name (NCT Number) Publications	ETDQ-7 Normalization (Score <2.1)	ETDQ-7 Mean Change	Valsalva Maneuver Positive	Normalized Tympanogram (Type A)	Otoscopy Results (Tympanic Membrane position normal)	Adverse Events
The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150)Poe et al (2017) [7];NCT02087150						
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)[8]						
BDET plus medical management		-2.9 (1.4)	8/17 (47.1%)	8/14 (57.1%)	10/15 (66.7%)	No complications
Medical management alone		-0.6 (1.0)	2/14 (1.3%)	1/10 (10.0%)	0/12 (0.0%)	No complications
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 Normalization (Score <2.1) at 52 Weeks	ETDQ-7 Mean Change	Valsalva Maneuver Positive at 52 Weeks	Normalized Tympanogram (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)[9]						
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 StudyNCT02391584Meyer et al (2018)[8,10]						
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 complications

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

Table 8. Randomized Controlled Trials: Study Relevance Limitations

Study	Population	Intervention	Comparator	Outcomes	Follow-Up
Poe et al (2017)[7]				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) [8]	1. Study enrollment criteria did not require abnormal middle ear functional assessments				1. Comparative outcomes limited to 6 weeks; longer follow-up of BDET in subset of patients.
Key	1. Intended use population unclear 2. Clinical context for treatment is unclear 3. Study population unclear 4. Study population not representative of intended use 5. Study population is subpopulation of intended use	1. Not clearly defined 2. Version used unclear 3. Delivery not similar intensity as comparator	1. Not clearly defined 2. Not standard or optimal 3. Delivery not similar intensity as intervention 4. Not delivered effectively	1. Key health outcomes not addressed 2. Physiologic measures, not validated surrogates 3. Not CONSORT reporting of harms 4. Not established and validated measurements 5. Clinically significant difference not prespecified 6. Clinically significant difference not supported	1. Not sufficient duration for benefits 2. Not sufficient duration for harms

BDET: balloon dilation of the eustachian tube
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. Clinical significant difference not prespecified; 6. Clinical 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	Blinding	Selective Reporting	Follow-Up	Power	Statistical
Poe et al (2017)[7]		1. Blinding of patients not possible; may bias patient-reported measures				1. Treatment effects and CIs not reported.
Meyer et al (2018)[8]		1. Blinding of patients not possible; may bias patient-reported measures				
Key	1. Participants not randomly allocated 2. Allocation not concealed 3. Allocation concealment unclear 4. Inadequate control for selection bias	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician	1. Not registered 2. Evidence of selective reporting 3. Evidence of selective publication	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)	1. Power calculations not reported 2. Power not calculated for primary outcome 3. Power not based on clinically important difference	1. Test is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event 2. Test is not appropriate for multiple observations per patient 3. Confidence intervals and/or p values not reported 4. Comparative treatment effects not calculated

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] Data Completeness 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. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis 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 despite medical management who receive balloon dilation of the eustachian tube, 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.

SUPPLEMENTAL INFORMATION

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.

2020 Input

Clinical input was sought to help determine whether the use of balloon dilation of the eustachian tube for individuals with chronic obstructive eustachian tube dysfunction despite medical management 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 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 BCBSA.

For individuals who have obstructive eustachian tube dysfunction who receive balloon dilation of the eustachian tube, 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 patients using the following criteria:

- Obstructive eustachian tube dysfunction 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 balloon dilation of the eustachian tube (BDET).[2,] The target population was defined as adults ≥ 18 years who are candidates for BDET because of obstructive eustachian tube dysfunction (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 (NICE)

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET.[11] The guidance was based on a rapid review of the evidence,[12] 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 eustachian tube dysfunction refractory to medical treatment.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 10.

Table 10. Unpublished Clinical Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05719207	Efficacy of Balloon Dilation of the Eustachian Tube in Eustachian Tube Dilatory Dysfunction	76	Dec 2024
Unpublished			
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.

Government Regulations
National/Local:

There is no national or local Medicare coverage determination on balloon dilation of the Eustachian tube.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Balloon Ostial Dilation for Treatment of Chronic and Recurrent Rhinosinusitis

References

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11. 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
12. 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 October 2020.
13. 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.
14. Blue Cross Blue Shield Association. Balloon Dilation of the Eustachian Tube. Medical Policy Reference Manual. MPRM 7.01.158. Published October 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through October 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/17	6/20/17	6/20/17	Joint policy established
9/1/18	6/19/18	6/19/18	Policy re-written to mirror new BCBSA coverage policy. No changes to policy status.
9/1/19	6/18/19		Routine policy maintenance. No change in policy status.
3/1/20	12/17/19		Added code 0583T, effective 1/1/20 as E/I and added statement “the treatment of patulous eustachian tube is not addressed in this policy”.
3/1/21	12/15/20		Policy status changed to established with coverage criteria. Rationale re-written, references 2, 6, 7, 9,10, 13, 14 added, some deleted. Codes 69705 and 69706 added. Code C9745 deleted effective 1/1/2021.
3/1/22	12/14/21		Routine policy maintenance. No change in policy status.
3/1/23	12/20/22		Routine policy maintenance. No change in policy status. Minor refinements to MPS – the word patient updated to individual. (ky)
3/1/24	12/19/23		• MPS statement updated to: The safety and effectiveness of United States Food and Drug Administration (FDA) approved balloon dilation devices have been established. They may be considered a useful therapeutic option in the treatment of chronic obstructive eustachian tube dysfunction when criteria are met. • Moved previous MPS to the inclusion and exclusion section. • Inclusion statement below updated to 3 months or longer from 12 months. o Adults (age 18 years and older) with symptoms of obstructive eustachian tube dysfunction (aural fullness,

			aural pressure, otalgia, and/or hearing loss) for 3 months or longer in one or both ears that significantly affects quality of life or functional health status • Added the below language to Inclusions section: o In certain situations, consideration may be given to individuals younger than 18 years of age. The most likely scenario is older children and/or adolescents who have failed standard treatment with grommet (ventilation or tympanostomy tube insertion), adenoidectomy or both. • The American Academy of Otolaryngology-Head and Neck Surgery Foundation supports 3 months or longer. BCBSA received clinical input in 2020 which did support 3 months duration as clinically appropriate. BCBSA will consider making this correction on their policy as well. • Vendor: N/A (ky)
3/1/25	12/17/24		• Routine Maintenance • Code 0583T is removed from the policy as it represents the Tula system which is not an eustachian tube dilation device. • The medical policy statement is reworded. There is no change to the intent. • Literature review request from Integra Life Sciences requesting coverage for patients 8 to 17 years of age with persistent OETD resulting in chronic OME, refractory to at least one surgical intervention for persistent OETD. • Added Acclarent Aera Eustachian Balloon Tube Dilation System

			under the Regulatory Section. The policy already includes language under the inclusions to support under 18 age group. • Vendor: N/A (ky)
5/1/25	2/18/25		• Summary/comments: • Policy coming early to review due to Michigan Ear Institute's inquiry. • Policy reviewed and updates made accordingly to the Inclusions/Exclusions section. • This policy will go back to its original date of December, 2025 JUMP. • BCBSA reviewed their policy 7.01.158: Balloon Dilation of the Eustachian Tube on 10/2024. Our JUMP policy is in alignment with BCBSA's policy; however clarification was required regarding the language of reversibility of symptoms by the Valsalva maneuver (baro-challenge). • Vendor: N/A (ky)

Next Review Date: 4th Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BALLOON DILATION OF THE EUSTACHIAN TUBE (BDET)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	See policy criteria
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A