7.01.158	Balloon Dilation of the Eustachian Tube		
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Section:	7.0 Surgery	**Page:**	Page 1 of 40

Policy Statement

I. Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered **medically necessary** for **all** of the following:
   A. 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
      1. Aural fullness and pressure must be present
      2. 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 **all** of the following:
         a. Abnormal tympanogram (Type B or C)
         b. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam)
      3. Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated
   B. Documentation that 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
   C. If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent
   D. The individual does not have patulous ETD or another contraindication to the procedure
   E. The individual's ETD has been shown to be reversible
   F. Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying)
   G. The individual has not had a previous BDET procedure

II. Balloon dilation of the eustachian tube is considered **investigational** if the above criteria are not met.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

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).

Superior Semicircular Canal Dehiscence syndrome is also known as Superior Canal Dehiscence Syndrome or less often Minor's syndrome. It is very rare but causes hearing and balance symptoms due to either absence or a very thin temporal bone over the superior semicircular canal. Although symptoms may be similar to ETD there are often differences that can help distinguish between the two. CT or other diagnostic tests can be used if needed to help make the diagnosis.

Endolymphatic Hydrops occurs when there is an excessive buildup of endolymph fluid that flows through the inner ear. It is treated by dietary changes and medications.

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Patulous Eustachian Tube occurs when the eustachian tube is intermittently open (it is normally closed). It is a physical problem and when advanced needs surgical correction.

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;
    - Enlarged adenoid pads
    - History of radiation therapy to the nasopharynx
    - Nasopharyngeal mass
    - Neoplasms causing extrinsic obstruction of the eustachian tube
    - 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

The following CPT codes will **replace HCPCS code C9745** for dilation of the eustachian tube with a balloon:

- **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

The following codes may be used for this service:

- **69799**: Unlisted procedure, middle ear

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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.

Related Policies

- Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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	Eustachian tube dilation
Xpress ENT Dilation System	Entellus Medical, Inc.	04/05/2017	K163509	Eustachian tube dilation

In September 2016, the AERA® (Acclarent) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ). The new classification applies to this device and substantially equivalent devices of this generic type. The AERA® is cleared for dilating the eustachian tube in patients ages 22 and older with persistent ETD.

In December 2016, the XprESS™ ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by the FDA through the 510(k) process (K163509). The FDA determined this device was substantially equivalent to existing devices for use in ETD. The predicate devices are XprESS™ Multi-Sinus Dilation System (K152434) and AERA® Eustachian Tube Balloon Dilation System.

Rationale

Background

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

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(ETD) 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,]

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 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 our without tympanostomy tube placement. This evidence review addresses balloon dilation of the eustachian tube as a stand alone procedure.

Literature Review

Evidence reviews 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

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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 review.

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	Validated, standardized, 7-item patient-reported questionnaire to assess symptom severity associated with ETD.	0.5 point improvement Normalization is defined as a mean item score <2.1 or a total score <14.5

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Outcome Measure	Description	MCID, if known
Questionnaire (ETDQ-7)	Pressure, pain, feeling clogged, cold/sinusitis problems, crackling/popping, ringing, and muffled hearing. Patients rate the severity of 7 symptoms on a scale ranging from 1 (no problem) to 7 (severe problem). Dividing the total score by 7 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 to 2 indicate no to mild symptoms, 3 to 5 moderate symptoms, and 6 to 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.

Review of Evidence

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 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).

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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 (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 to 202) 445 ears (2 to 234)	3 RCTs, 5 prospective observational, 4 case series	6 weeks to 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	6/436 ears RCTs	12/606 ears RCTs, prospective	4/287 ears	7/252 ears

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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)
		observational, 1 case series		observational, case series		
Baseline% (95% CI)	NA	NR	13.2% (0.7 to 37.5)	13.9% (1.5 to 35.6)	NA	22.1% (2.0 to 55.0)
6 weeks % (95% CI)	53.5% (47.0, 59.8)	NR	71.2% (58.8 to 82.1)	58.9% (40.4 to 76.2)	53.0% (29.1 to 76.2)	53.8% (31.1 to 75.7)
Pooled Difference Pre-Post (95% CI):	NA	-2.13 (-3.02 to -1.24); p.0004	58.0% (52.0 to 63.3); p<.001	45.0% (39.9 to 49.8); p<.0001	NA	31.7% (22.5 to 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 ETD (Tables 5 to 7).[8,9,] Both compared BDET plus medical management to medical management alone for 6 weeks. Following the 6-week followup 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 a 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).

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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	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)[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 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 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)

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Study name (NCT Number)Publications	Countries Dates		Key Eligibility Criteria	Outcome Measures and Duration of Followup	Intervention	Comparator
			• 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 immuno-deficiency disease • Intolerance of medication for ETD • Prior intervention of eustachian tube			
XprESS Eustachian Tube Dilation StudyNCT02391584Meyer 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 • Have ear tubes in place or perforation of the tympanic membrane	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

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Study name (NCT Number)Publications	Countries Dates	Key Eligibility Criteria	Outcome Measures and Duration of Followup	Intervention	Comparator
		• Have evidence of internal carotid artery dehiscence • Be pregnant at the time of enrollment • Be currently participating in other drug or device studies			

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) [8];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)[9]						
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.

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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)[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 eustachian tube, both described as mild.
XprESS Eustachian Tube Dilation StudyNCT02391584Meyer 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 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)[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. Comparative 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.

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[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)[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] 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.

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

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 (BDET) for individuals with chronic obstructive eustachian tube dysfunction (ETD) 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,

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

A. Obstructive ETD for 3 months or longer in 1 or both ears that significantly affects quality of life or functional health status;
B. 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
C. Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated.

Further details from clinical input are included in the Appendix.

Practice Guidelines and Position Statements

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

American Academy of Otolaryngology-Head and Neck Surgery Foundation

In 2019, the American Academy of Otolaryngology published a clinical consensus statement on BDET.[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:

B. BDET is an option for treatment of patients with obstructive ETD.
C. The diagnosis of obstructive ETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy.
D. BDET is contraindicated for patients diagnosed as having a patulous ETD
E. 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.

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- The procedure is only indicated for chronic ETD refractory to medical treatment.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and 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			
NCT03886740	Tympanostomy Tubes Versus Eustachian Tube Dilation	32	Aug 2021 (status=unknown; last update Mar 2019)
NCT05719207	Efficacy of Balloon Dilation of the Eustachian Tube in Eustachian Tube Dilatory Dysfunction	76	Dec 2024
NCT05270031	Balloon Dilation of the Eustachian Tube	58	Feb 2026
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)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Appendix 1

Clinical Input
CI - Summary

CI - Objective
In 2020, clinical input was sought to help determine whether the use of balloon dilation of the eustachian tube for individuals with chronic eustachian tube dilatory 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.

Respondents
Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS)
- Dennis S. Poe, MD, PhD, Otolaryngology, Professor of Otolaryngology, Harvard Medical School and Boston Children's Hospital, identified by BCBSA**
- Anonymous, Otolaryngology/Neurotology, Associate Professor at an academic medical center, identified by BCBSA
- Anonymous, Neurotology, Associate Professor at an academic medical center, identified by BCBSA

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* Indicates that no response was provided regarding conflicts of interest related to the topic where clinical input is being sought.
** Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Appendix).

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by a specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a specialty society and/or physician member designated by a specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

Overview of Responses

Clinical Indication	Respondent	Identified by	Confidence Level That Clinical Use Expected to Provide Clinically Meaningful Improvement in Net Health Outcome (NO: High–Intermediate–Low; YES: Low–Intermediate–High)										Confidence Level that Clinical Use is Consistent with Generally Accepted Medical Practice (NO: High–Intermediate–Low; YES: Low–Intermediate–High)									
			Yes or No	5	4	3	2	1	1	2	3	4	5	Yes or No	5	4	3	2	1	1	2	3	4	5
Use of balloon dilation of the eustachian tube for individuals with chronic eustachian tube dilatory dysfunction despite medical management	AAO-HNS		Yes										■	Yes										■
	Dr. Poo **	BCBSA	Yes										■	Yes										■
	Anonymous	BCBSA	Yes								■			Yes								■		
	Anonymous	BCBSA	Yes								■			Yes								■		

AAO-HNS: American Academy of Otolaryngology - Head and Neck Surgery; BCBSA: Blue Cross Blue Shield Association
** Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Appendix).

Respondent Profile

Specialty Society

#	Name of Organization	Clinical Specialty
1	American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS)	Otolaryngology

Physician

#	Name	Degree	Institutional Affiliation	Clinical Specialty	Board Certification and Fellowship Training
Identified by BCBSA					
2	Dennis S. Poe	MD, PhD,	Professor of Otolaryngology, Harvard Medical School and Boston Children's Hospital	Otolaryngology	Board: Otolaryngology, Subspecialty Board: Neurotology, Fellowship: Neurotology
3	Anonymous	MD	Associate Professor at an academic medical center	Otolaryngology/Neurotology	Otolaryngology and Neurotology
4	Anonymous	MD. MBA. MPH	Associate Professor at an academic medical center	Neurotology	AbOto-HNS

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Respondent Conflict of Interest Disclosure

#	1) Research support related to the topic where clinical input is being sought		2) Positions, paid or unpaid, related to the topic where clinical input is being sought		3) Reportable, more than $1,000, health care–related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought		4) Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	
	YES/NO	Explanation	YES/NO	Explanation	YES/NO	Explanation	YES/NO	Explanation
1	No		No		No		No	
2	Yes	I was the PI for the FDA-mandated clinical trial of the balloon dilation technology in support of the application for FDA clearance. We received support for research administration and clinical care of the subjects. I did not receive any support for my time nor payment for clinic visits or surgery.	Yes	I am a consultant for Acclarent corp., one of the manufacturers of the balloon device. They reimburse me for my time and expenses, but I have no royalties from their products and no equity interest in the company.	Yes	I continue to serve as a consultant to Acclarent to further advance the technology for the treatment of Eustachian tube disorders	Yes	In my consultant role, my travel is reimbursed for me to participate in R&D and to teach programs to educate surgeons on Eustachian tube disorders and use of the balloon technology.
3	No		No		No		No	
4	No		No		No		No	

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response. NR = not reported

Detailed Responses

Question 1. We are seeking your opinion on whether using balloon dilation of the eustachian tube for individuals with chronic eustachian tube dilatory dysfunction despite medical management (see criteria below) provides a clinically meaningful improvement in net health outcome.
Patient selection criteria are further defined as:

- Eustachian tube dilatory dysfunction for 3 months or longer in one or both ears that significantly affects quality of life or functional health status; and
- Failure to respond to appropriate medical management of potential co-occurring conditions such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 12 weeks of a nasal steroid spray, unless contraindicated; and
- The patient has undergone a comprehensive diagnostic assessment; including tympanometry, nasopharyngoscopy, audiometry, and nasal endoscopy; and
- The patient has not been diagnosed as having patulous eustachian tube dysfunction.

Please respond based on the evidence and your clinical experience. Please address these points in your response:

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- Relevant clinical scenarios (e.g., a chain of evidence) where the technology is expected to provide a clinically meaningful improvement in net health outcome;
- Specific outcomes that are clinically meaningful;
- Are there any additional patient inclusion/exclusion criteria or clinical context important to consider in identifying individuals for this indication (e.g., atelectatic ears? osseous erosion? failure after ear tube insertion? documented conductive hearing loss? type B or C tympanogram in ear to be dilated? use in children and if so what age cut-off?);
- Supporting evidence from the authoritative scientific literature (please include PMID).

#	Rationale
1	The AAO-HNS believes nasal steroid sprays are indicated for the treatment of nasal congestion due to allergic rhinitis. Effects should occur within first 36 hours. It is not indicated, nor is it FDA approved, for the treatment of Obstructive Eustachian Tube dysfunction (OETD). Therefore, from AAO-HNS Clinical Practice Guideline (2015), "based on the above data, it is reasonable to assume that efficacy would be reached after 1 week of therapy at the most and, if none is observed, the treatment might be considered ineffective." (1) If OETD may be due at least in part from allergic rhinitis, 4 weeks duration should be sufficient to determine if the medication will be effective. Nasal steroid sprays have been shown to be ineffective in an RCT when used to treat OETD. (2) If rhinosinusitis is present, appropriate treatment may have included the use of prior antibiotics and sometimes surgery. If laryngopharyngeal reflux is present, antacids or proton pump inhibitors should demonstrate efficacy within a 4-week treatment course. (3) Indications for Balloon Dilation of the Eustachian tube (BDET) The AAO-HNS believes that the following would be appropriate: Balloon dilation of the eustachian tube (BDET) for treatment of adults (18 years of age and older) with chronic obstructive eustachian tube dysfunction may be considered MEDICALLY NECESSARY when ALL of the following criteria are met: • The patient has chronic signs and symptoms of eustachian tube obstruction including but not limited to: • Difficulty equilibrating pressure in ears when challenged with ambient barometric changes (baro-challenge), OR • Hearing loss or aural fullness that is relieved by auto-insufflation, OR • History of negative pressure in the middle ear, middle ear effusion, as defined as ≥ 3 months duration; AND • Failure to respond to appropriate medical management of co-occurring conditions such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4-6 weeks of a nasal steroid spray, unless contraindicated, AND • Objective pathological findings on dynamic endoscopic examination of the eustachian tube OR if no pathological findings visible, history and physical remain consistent with obstruction within the cartilaginous eustachian tube, AND • If the patient had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent. Trial of tympanostomy tubes are not required prior to BDET. These criteria are all consistent with the AAO-HNS 2019 Clinical Consensus Statement on Balloon Dilation of the Eustachian Tube. (4) In patients that meet the above criteria, BDET is not necessarily contra-indicated for the following conditions: • Adenoid tissue blocking the Eustachian tube orifice if it will be removed concurrently with BDET • Obstruction in the bony portion of the Eustachian tube when the nature or degree of obstruction is uncertain • Dehiscence of the internal carotid artery, if the dehiscence is a safe distance from the cartilaginous portion of the Eustachian tube • Fluctuating sensorineural hearing loss if it has been determined that BDET will not be expected to worsen the hearing loss. For instance, a tympanostomy tube in the tympanic membrane would vent any possible increase in middle ear pressure during the balloon inflation rendering the balloon dilation to be safe. • Intermittent or past history of patulous Eustachian tube

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#	Rationale

- Prior intervention of the Eustachian tube if lesions within the lumen of the Eustachian tube identified on nasal endoscopy appear appropriate for balloon dilation (e.g. scar bands, residual inflammation, cartilage hump protruding into the lumen that could be removed prior to BDET) (4,5)

BDET is considered investigational (excluded) in:

a. Craniofacial syndromes
b. Neoplasms causing extrinsic obstruction of the Eustachian tube
c. 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).
d. Pediatrics (< 18 years of age) in USA as BDET is not FDA-approved. (4)
e. Patients with aural fullness but normal exam and tympanogram
f. Adult Patients with chronic and severe atelectatic ears

Clinical Scenarios
The two most common clinical scenarios are described below:
1) An adult has developed persistent (3 or months) symptoms in one or both ears of aural fullness (blocked or pressure sensation), hearing loss, and difficulty clearing the ear(s), especially on flights or submerging in a pool. There may have been one or more episodes of ear infection (acute otitis media) or middle ear fluid (otitis media with effusion).
During the course of the ear complaint, the patient has been evaluated for possible underlying causes such as allergic rhinitis, rhinosinusitis or laryngopharyngeal reflux, which are the most common co-morbidities. If a co-morbidity has been identified, it has been treated appropriately for at least 4 weeks and has failed to show improvement in symptoms.
The patient may have been treated with a tympanostomy tube, one or more times. If a tube was placed, the patient's symptoms should have improved while it was patent, although complete resolution may not have occurred. In the event of tube extrusion, the patient's symptoms have recurred, and additional treatment is being considered.
The patient has not had complaints of persistent, chronic autophony of voice and breathing to suggest possible patulous Eustachian tube. There is difficulty or inability to clear their ear fullness sensation ("pop their ear") with autoinsufflation. One example of autoinsufflation is a modified Valsalva maneuver (nose and mouth closed, gently blowing nose to raise intranasal pressure and simultaneous swallow).

Examination:
Otoscopy shows retraction of the tympanic membrane with evidence of negative pressure within the middle ear. There may be a middle ear effusion, a retraction pocket that is fixed, atelectasis of a portion of the tympanic membrane, or even cholesteatoma. The presence of negative pressure may be confirmed by pneumatic insufflation.

Testing:
Audiogram shows a conductive hearing loss.
Tympanogram shows evidence of negative pressure (type B or C curves).

Nasal/nasopharyngeal endoscopy:
Endoscopy is done while the patient is at rest and when performing swallows and yawns (dynamic exam). In most cases, some pathology will be observed, usually inflammation. Examples of inflammatory changes can be edema, erythema, cobblestoning (lymphoid hyperplasia), hypertrophied tubal tonsil tissue, reduced opening of the lumen.
This patient meets the indications for either a tympanostomy tube (primary, repeat, or long-term tube depending on whether tubes have been used previously) or a balloon dilation of the Eustachian tube. As a tube does not treat the source of the Eustachian tube dysfunction, there may be a preference for BDET if symptoms have returned after previous tube placement. The risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tubes. (4)
2) An adult has developed persistent (3 or months) symptoms in one or both ears of aural fullness (blocked or pressure sensation), hearing loss and difficulty clearing the ear(s) that occurs consistently on flights, diving into a pool, high elevators or with other significant changes in ambient pressure (termed baro-challenge). There have not been any other ear problems, but the pain is significant when baro-challenged. Measures such as oral or nasal decongestants, nasal steroid sprays (only for allergic rhinitis patients) have not been helpful. (33-36)Examination:

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#	Rationale
	• Otoscopy may show a normal tympanic membrane without evidence of negative pressure within the middle ear as the patient is not presently baro-challenged. Testing: • Audiogram may be normal. • Tympanogram may be normal (type A curve) Nasal/nasopharyngeal endoscopy: • Endoscopy is done while the patient is at rest and when performing swallows and yawns (dynamic exam). In most cases, some pathology will be observed, usually inflammation, but it will be less prominent that in more severe cases of obstructive Eustachian tube dysfunction. Examples of inflammatory changes can be edema, erythema, cobblestoning (lymphoid hyperplasia), hypertrophied tubal tonsil tissue, reduced opening of the lumen. This patient meets the indications for either a tympanostomy tube or a balloon dilation of the Eustachian tube. Most patients will not want to have tube placed for the indication of relieving baro-challenge complaints for altitude changes or swimming and BDET may be the preferred option. (4)Specific outcomes that are clinically meaningful 1. Symptom improvement. Patient-Reported Outcomes Measures (PROM) symptom scores can be used to document improvement. The most commonly used instrument is the ETDQ-7 and it has been validated in numerous languages. A mean score of < 2.1 is considered normal. 2. Otoscopy shows improvement or relief of tympanic membrane retraction (when not fixed or adherent) and reduced negative pressure 3. Tympanometry B or C curves have improved to C or A curves 4. Audiometry shows improvement in conductive hearing loss (if hearing loss was present pre-treatment) 5. Ability to perform a Valsalva maneuver or modified Valsalva maneuver (gentle nose blow with simultaneous swallow) 6. Ability to tolerate baro-challenges has improved (4,6-9) Note that once a retraction pocket has become adherent ("fixed"), relief of negative pressure by BDET or a tube will not be expected to release the adhesions binding down the retraction. Progression of the pocket, erosion of ossicles or development of cholesteatoma may continue despite resolution of the Eustachian tube dysfunction that initiated the process, but correction of the dysfunction is important to limit progression and to prevent recurrence after surgical treatment of the retraction pocket or cholesteatoma. (5,6) Durability of results BDET has been shown to cause histological changes within the lumen of the Eustachian tube, including reduction in inflammation within the mucosa and elimination of the submucosal lymphoid hyperplasia. (10, 11) The pretreatment histopathology and post-operative changes are similar to findings with adenoidectomy. Therefore, permanent histological improvement would be expected, similar to adenoidectomy. However, if there is an on-going co-morbidity that may induce inflammation, adenoid tissue can regrow and the adenoid-like tissue within the lumen of the Eustachian tube could also regrow. Ongoing medical attention to possibly relevant co-morbidities may be important in durability of results, similar to adenoidectomy. (10) All of the studies to date with one year or longer duration of follow up have demonstrated that the results have been stable and durable. (8,9,12-15)
2	**Suggested edits to the indication and patient selection criteria:** Population for the indication: Preferred terminology by AAOHNS Clinical Consensus Statement is Obstructive Eustachian tube dysfunction as opposed to Patulous Eustachian tube dysfunction. **Suggested edits to the patient selection 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; 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; • The patient has undergone a comprehensive diagnostic assessment; including tympanometry if the tympanic membrane is intact, nasopharyngoscopy, audiometry, and nasal endoscopy; and • The patient has not been diagnosed as having chronic patulous eustachian tube dysfunction. **Rationale for above edits:** Nasal steroid sprays are indicated for the treatment of nasal congestion due to allergic rhinitis. Effects should occur within first 36 hours. It is not indicated, nor is it FDA approved for the treatment of Obstructive

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 # Rationale

Eustachian Tube dysfunction (OETD). Therefore, from AAOHNS CPG (2015), "based on the above data, it is reasonable to assume that efficacy would be reached after 1 week of therapy at the most and, if none is observed, the treatment might be considered ineffective." **(1)**
If OETD may be due at least in part from allergic rhinitis, 4 weeks duration should be sufficient to determine if the medication will be effective.
Nasal steroid sprays have been shown to be ineffective in an RCT when used to treat OETD. **(2)**
If rhinosinusitis is present, appropriate treatment may have included the use of prior antibiotics and sometimes surgery. If laryngopharyngeal reflux is present, antacids or proton pump inhibitors should demonstrate efficacy within a 4 week treatment course. **(3)**

Indications for Balloon Dilation of the Eustachian tube (BDET)

The Massachusetts Society of Otolaryngology and I worked with BCBS MA to draft the following indications in their policy # 018, BCBSA Reference no. 7.01.158, which was approved and went into effect on 5/1/2020. It states:
"Balloon dilation of the eustachian tube (BDET) for treatment of adults (18 years of age and older) with chronic obstructive eustachian tube dysfunction may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:

- The member has chronic signs and symptoms of eustachian tube obstruction including but not limited to:
- difficulty equilibrating pressure in ears when challenged with ambient barometric changes (baro-challenge), OR
- hearing loss or aural fullness that is relieved by auto-insufflation, OR
- history of negative pressure in the middle ear, middle ear effusion, as defined as ≥ 3 months duration; AND
- Failure to respond to appropriate medical management of co-occurring conditions such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4-6 weeks of a nasal steroid spray, unless contraindicated, AND
- Objective pathological findings on dynamic endoscopic examination of the eustachian tube OR if no pathological findings visible, history and physical remain consistent with obstruction within the cartilaginous eustachian tube, AND
- If the patient had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent. Trial of tympanostomy tubes are not required prior to BDET."

These criteria are all consistent with the AAOHNS Clinical Consensus Statement on Balloon Dilation of the Eustachian Tube. **(4)**
BDET is considered investigational (excluded) in:

a. Craniofacial syndromes
b. Neoplasms causing extrinsic obstruction of the Eustachian tube
c. 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).
d. Pediatrics (< 18 years of age) in USA as BDET is not FDA-approved. **(4)**

BDET may be indicated in selected patients for the following conditions:

- Adenoid tissue blocking the Eustachian tube orifice if it will be removed concurrently with BDET
- Obstruction in the bony portion of the Eustachian tube when the nature or degree of obstruction is uncertain
- Dehiscence of the internal carotid artery, if the dehiscence is a safe distance from the cartilaginous portion of the Eustachian tube
- Fluctuating sensorineural hearing loss if it has been determined that BDET will not be expected to worsen the hearing loss. For instance, a tympanostomy tube in the tympanic membrane would vent any possible increase in middle ear pressure during the balloon inflation rendering the balloon dilation to be safe.
- Intermittent or past history of patulous Eustachian tube
- Prior intervention of the Eustachian tube if lesions within the lumen of the Eustachian tube identified on nasal endoscopy appear appropriate for balloon dilation (e.g. scar bands, residual inflammation, cartilage hump protruding into the lumen that could be removed prior to BDET) **(4,5)**

Clinical Scenarios

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#	Rationale

The two most common clinical scenarios are described below:

Scenario 1

An adult has developed persistent (3 or more months) symptoms in one or both ears of aural fullness (blocked or pressure sensation), hearing loss and difficulty clearing the ear(s), especially on flights or submerging in a pool. There may have been one or more episodes of ear infection (acute otitis media) or middle ear fluid (otitis media with effusion).

During the course of the ear complaint, the patient has been evaluated for possible underlying causes such as allergic rhinitis, rhinosinusitis or laryngopharyngeal reflux, which are the most common co-morbidities. If a co-morbidity has been identified, it has been treated appropriately for at least 4 weeks and has failed to show improvement in symptoms.

The patient may have been treated with a tympanostomy tube, one or more times. If a tube was placed, the patient's symptoms should have improved while it was patent, although complete resolution may not have occurred. In the event of tube extrusion, the patient's symptoms have recurred and additional treatment is being considered.

The patient has not had complaints of persistent, chronic autophony of voice and breathing to suggest possible patulous Eustachian tube. There is difficulty or inability to clear their ear fullness sensation ("pop their ear") with autoinsufflation. One example of autoinsufflation is a modified Valsalva maneuver (nose and mouth closed, gently blowing nose to raise intranasal pressure and simultaneous swallow).

Examination:

- Otoscopy shows retraction of the tympanic membrane with evidence of negative pressure within the middle ear. There may be a middle ear effusion, retraction pocket that is fixed, atelectasis of a portion of the tympanic membrane, or even cholesteatoma. The presence of negative pressure may be confirmed by pneumatic insufflation

Testing:

- Audiogram shows a conductive hearing loss.
- Tympanogram shows evidence of negative pressure (type B or C curves)

Nasal/nasopharyngeal endoscopy

- Endoscopy is done while the patient is at rest and when performing swallows and yawns (dynamic exam). In most cases, some pathology will be observed, usually inflammation. Examples of inflammatory changes can be edema, erythema, cobblestoning (lymphoid hyperplasia), hypertrophied tubal tonsil tissue, reduced opening of the lumen.

This patient meets the indications for either a tympanostomy tube (primary, repeat or long-term tube depending on whether tubes have been used previously) or a balloon dilation of the Eustachian tube. As a tube does not treat the source of the Eustachian tube dysfunction, there may be a preference for BDET if symptoms have returned after previous tube placement. The risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tubes. **(4)**

Scenario 2

An adult has developed persistent (3 or more months) symptoms in one or both ears of aural fullness (blocked or pressure sensation), hearing loss and difficulty clearing the ear(s) that occurs consistently on flights, diving into a pool, high elevators or with other significant changes in ambient pressure (termed barochallenge). There have not been any other ear problems, but the pain is significant when barochallenged. Measures such as oral or nasal decongestants, nasal steroid sprays (only for allergic rhinitis patients) have not been helpful.

Examination:

- Otoscopy may show a normal tympanic membrane without evidence of negative pressure within the middle ear as the patient is not presently barochallenged.

Testing:

- Audiogram may be normal.
- Tympanogram may be normal (type A curve)

Nasal/nasopharyngeal endoscopy

- Endoscopy is done while the patient is at rest and when performing swallows and yawns (dynamic exam). In most cases, some pathology will be observed, usually inflammation, but it will be less prominent that in more severe cases of obstructive Eustachian tube dysfunction. Examples of inflammatory changes can be edema, erythema, cobblestoning (lymphoid hyperplasia), hypertrophied tubal tonsil tissue, reduced opening of the lumen.

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#	Rationale
	This patient meets the indications for either a tympanostomy tube or a balloon dilation of the Eustachian tube. Most patients will not want to have tube placed for the indication of relieving barochallenge complaints for altitude changes or swimming and BDET may be the preferred option. **(4)** **Specific outcomes that are clinically meaningful** 1. Otoscopy shows improvement or relief of tympanic membrane retraction (when not fixed or adherent and reduced negative pressure 2. Tympanometry B or C curves have improved to C or A curves 3. Audiometry shows improvement in conductive hearing loss (if hearing loss was present pre-treatment) 4. Symptom improvement. Patient-Reported Outcomes Measures (PROM) symptom scores can be used to document improvement. The most commonly used instrument is the ETDQ-7 and it has been validated in numerous languages. A mean score of < 2.1 is considered normal 5. Ability to perform a Valsalva maneuver or modified Valsalva maneuver (gentle nose blow with simultaneous swallow) 6. Ability to tolerate barochallenges has improved **(4,6-9)** Note that once a retraction pocket has become adherent ("fixed"), relief of negative pressure by BDET or a tube will not be expected to release the adhesions binding down the retraction. Progression of the pocket, erosion of ossicles or development of cholesteatoma may continue despite resolution of the Eustachian tube dysfunction that initiated the process, but correction of the dysfunction is important to limit progression and to prevent recurrence after surgical treatment of the retraction pocket or cholesteatoma. **(5,6)** **Durability of results** BDET has been shown to cause histological changes within the lumen of the Eustachian tube, including reduction in inflammation within the mucosa and elimination of the submucosal lymphoid hyperplasia. **(10, 11)** The pretreatment histopathology and post-operative changes are similar to findings with adenoidectomy. Therefore, permanent histological improvement would be expected, similar to adenoidectomy. However, if there is an on-going co-morbidity that may induce inflammation, adenoid tissue can regrow and the adenoid-like tissue within the lumen of the Eustachian tube could also regrow. Ongoing medical attention to possibly relevant co-morbidities may be important in durability of results, similar to adenoidectomy. **(10)** All of the studies to date with one year or longer duration of follow up have demonstrated that the results have been stable and durable. **(8,9,12-15)**
3	I view Eustachian tube balloon dilation as a moderately promising treatment for chronic hypoventilatory Eustachian tube dysfunction, although it remains to be determined which patients are most likely to benefit. As demonstrated by the two partially randomized prospective trials by Poe et al (PMID 30620688) and Meyer et al (PMID 29912819), 50-70% of treated patients appeared to achieve relatively durable improvements in tympanonometry (type B to C, type C to A , or type B to A), Eustachian tube dysfunction questionnaire results (ETDQ-7), and/or ability to valsalva the eadrum out. Although the results demonstrate a significant trend to improving Eustachian tube function, they hold the possibility that, when the procedure improves Eustachian tube function, it may help prevent otologic procedures that occur at the level of the tympanic membrane and mastoid which in turn may improve patient quality of life and decrease overall lifetime financial burden from medically necessary further otologic procedures. Meaningful outcomes of eustachian tube balloon dilation: 1. Symptomatic improvement, possibly based on improvement in ETDQ-7 2. Normalization or improvement of tympanogram 3. Improvement in conductive hearing loss 4. Ability to valsalva as needed, absent acute or subacute URI 5. Decreased need for tympanostomy tubes 6. Decreased need for future otologic procedures for chronic middle ear disorders (perforation, cholesteatoma, irreversible eardrum retraction) 7. Acceptable levels of complications: <1-5% risk of abnormally patulous eustachian tube, immeasurably low risk of carotid artery injury. For a patient to be considered a candidate for Eustachian tube balloon dilation, Eustachian tube hypoventilatory dysfunction should be demonstrated initially with history and symptomatology for at least 3 months, preferably 6 months, having failed medical therapy. Symptoms should include some of the following: 1. Ear fullness 2. Symptoms, longstanding, of recurrent barochallenge (difficulty clearing the ears with changes in ambient pressure) 3. Hearing loss 4. Otalgia

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#	Rationale

5. Tinnitus

For a patient to be considered a candidate for Eustachian tube balloon dilation, Eustachian tube hypoventilatory dysfunction should be demonstrated not only through history, but supported with objective findings:

1. Reversible tympanic membrane retraction. Such may be demonstrated with valsalva, politzer maneuver, or with examination under anesthesia with gases that may diffuse into and fill the middle ear space. For a tympanic membrane that is irreversibly retracted onto ossicles and/or the medial wall of the middle ear space, an attempt at eustachian tube balloon dilation without correction of the tympanic membrane adhesion is an intervention that would be performed too late.
2. Chronic tympanogram findings of at least 3 months duration (Type B or Type C).
3. Possibly a documented conductive hearing loss or conductive 'pad' separating the bone conduction audiogram from the air conduction audiogram. The distinction here is that patients with a conductive 'pad' may statistically have hearing within normal limits.
4. Nasopharyngoscopic findings of accessible Eustachian tube orifices absent potential extrinsic findings that may affect Eustachian tube function (e.g. Adenoid pad, nasopharyngeal mass).
5. Possibly CT scan of the sinuses or temporal bones which reveal complete bony covering over the internal carotid artery on the side(s) to undergo Eustachian tube balloon dilation.

Clinical scenarios where I feel that eustachian tube balloon dilation may be helpful:

- 1) Late adolescent or adult patients with symptoms and objective findings of acquired Eustachian tube dysfunction due to presumed inflammatory disorders (e.g. Allergic or chronic rhinitis, gastroesophageal reflux) where edema of the Eustachian tube lumen occurs secondarily from these disorders and medical therapy for the underlying disorder does not reverse Eustachian tube dysfunction. The presumed mechanism of Eustachian balloon dilation histologically is reduction of the lining thickness of the Eustachian tube lumen (PMID: 25154612) through fibrosis/scarification. Patients who have congenital or extrinsic causes of mechanical Eustachian tube dysfunction are NOT, in my opinion, candidates for Eustachian tube balloon dilation (e.g. choanal atresia, cleft palate spectrum, muscular hypotonia resulting in decrease 'force' of eustachian tube opening).
    - A corollary of this notion is that when Eustachian tube dysfunction occurs in the setting of potentially reversible extrinsic or inflammatory processes that may be treated through other surgical interventions (e.g. adenoidectomy for adenoid hypertrophy or sinus surgery for chronic rhinosinusitis), eustachian tube balloon dilation, I believe, should not be performed at the same time as these other procedures as the primary surgical intervention may lead to improvement of Eustachian tube ventilator function secondarily.
- 2) Late adolescent or adult patients with a history of chronic, repetitive barotrauma. For patients who are frequent air travelers, this indication may be a soft one as tympanostomy tube may be an easier and direct fix; however, deep-sea divers are not candidates for tympanostomy tubes and may benefit from Eustachian tube balloon dilation.

  Patients who are NOT candidates for eustachian tube balloon dilation:

1. Patients with extrinsic reversible or irreversible causes of Eustachian tube dysfunction (e.g.)
2. Enlarged adenoid pad
3. Nasopharyngeal mass
4. Radiation to the head and neck (relative contraindication; presumed scarring of nasopharynx or palatal musculature as cause)
5. Cleft palate spectrum
6. Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening
7. Patients who have lack of improvement or worsening of symptoms with tympanostomy tube or trial myringotomy; this suggests that eustachian tube dysfunction is not the correct diagnosis for the patient's symptoms.
8. Patients with unrepaired, irreversible retraction/adhesion of the eardrum to the ossicles and/or medial wall of the middle ear space, inclusive or ossicular erosion that has retracted tympanic membrane in contact to the erosive site(s)
9. Patients undergoing surgery for extrinsic disease that may secondarily improve Eustachian tube dysfunction (e.g. sinus or nasal surgery)

The notion of Eustachian tube balloon dilation in the pediatric population is a curious one. The majority of children who have Eustachian tube dysfunction improve by the age of 7 or 8. Also, there are particular concerns regarding sinonasal and skull development in the pediatric population. For this reason, without a great deal of evidence, I would suggest Eustachian tube balloon dilation in patients at least 14 years of age. I believe that Eustachian tube balloon dilation to be at least or more efficacious than "medical therapy" for

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#	Rationale
	Eustachian tube hypoventilatory dysfunction as there is no proven medical therapy for this disorder. Tympanostomy tube placement is the gold standard for true eustachian tube hypoventilatory dysfunction, but carries a not-insignificant risk of perforation and otorrhea. Additionally, tympanostomy tube placement does not address the underlying cause of middle ear hypoventilation and may be a repeat procedure for the life of the patient. Mechanical pressure equalization devices as well as other methods of eustachian tube dilation other than balloon treatment have much less supportive evidence regarding their utility and efficacy.
4	Based on current literature and FDA approval, relevant scenarios are adult patients (>17 yoa) who have chronic obstructive ETD that has not responded to medical management. Documentation of ETD complaints, history of barotrauma, serous otitis media, adhesive otitis, atelectatic middle ear and failure after tympanoplasty, past abnormal tympanograms (B or C), efforts at medical management, allergy management and GERD/LPR management as clinically appropriate should support the diagnosis of ETD and appropriateness of BDET (1, 2, clinical experience). As chronic obstructive ETD may fluctuate, isolated normal tympanogram(s) in an individual with document abnormal tympanograms and recurrent chronic symptoms should not be an exclusion. It should be noted that there is level I evidence that intranasal steroids are no more effective than placebo in the treatment of ETD (3,4), and that there is no FDA approved medication for chronic obstructive ETD (5). Past PE tube placement, atelectatic tympanic membranes, previous middle ear or mastoid surgery and/or incus erosion should not be considered and inclusion or exclusion requirement, but history of past PE tube placement, atelectatic tympanic membranes, previous middle ear or mastoid surgery and/or incus erosion does go towards establishing the chronic nature of the ETD. (Clinical experience) Patients who have a history of cleft palate, have undergone surgery for cleft palate, have a history of radiation therapy to the nasopharynx, or surgery to the nasopharynx (other than adenoidectomy, previous BDET) should not be considered for BDET (6-9). Specific meaningful outcomes are resolution of ETD as suggested by history and normalization tympanogram (primary) and improvement in hearing (secondary) (6-9). The available literature on pediatric BDET is very limited, and primarily from Europe (10,11), with reports of success in children as young as 18 months. BDET certainly has the potential to be an effective treatment for pediatric ETD, though this reviewer based on what is currently known this reviewer is unable to provide a minimal age based on the literature. In my conversations with other colleagues, most children are sufficient grown by 8 yoa to be considered anatomically appropriate for the current technology, but that is expert opinion/clinical experience at this time. 1. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. Otolaryngol Head Neck Surg. 2019;161(1):6-17. PMID: 31161864 doi:10.1177/0194599819848423 2. Plaza G, Navarro JJ, Alfaro J, Sandoval M, Marco J. Consensus on treatment of obstructive Eustachian tube dysfunction with balloon Eustachian tuboplasty. Acta Otorrinolaringol Esp. 2020 May-Jun;71(3):181-189. English, Spanish. doi: 10.1016/j.otorri.2019.01.005. Epub 2019 May 24. PMID: 31133274. 3. Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW, Orvidas LJ. Management of eustachian tube dysfunction with nasal steroid spray: A prospective, randomized, placebo-controlled trial. Arch Otolaryngol - Head Neck Surg. 2011;137(5):449-455. PMID: 21576556, doi:10.1001/archoto.2011.56 4. Wang DE, Lam DJ, Bellmunt AM, Rosenfeld RM, Ikeda AK, Shin JJ. Intranasal Steroid Use for Otitis Media with Effusion: Ongoing Opportunities for Quality Improvement. Otolaryngol - Head Neck Surg (United States). 2017;157(2):289-296. PMID: 28535109, doi:10.1177/0194599817703046 5. Adil E, Poe D. What is the full range of medical and surgical treatments available for patients with Eustachian tube dysfunction. Curr Opin Otolaryngol Head Neck Surg. 2014;22(1):8-15. PMID: 24275798 doi:10.1097/MOO.0000000000000020 6. Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope. 2018;128(5):1200-1206. PMID: 28940574 doi:10.1002/lary.26827 7. Anand V, Poe D, Dean M, et al. Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. Otolaryngol - Head Neck Surg (United States). 2019;160(4):687-694. PMID: 30620688 doi:10.1177/0194599818821938 8. Meyer TA, O'Malley EM, Schlosser RJ, et al. A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otol Neurotol. Aug 2018; 39(7): 894-902. PMID 29912819 9. Cutler JL, Meyer TA, Nguyen SA, et al. Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. Otol Neurotol. Dec 2019; 40(10): 1322-1325. PMID 31385858

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#	Rationale
	10. Tisch M, Maier H, Sudhoff H. Balloon dilation of the Eustachian tube: clinical experience in the management of 126 children. Acta Otorhinolaryngol Ital. 2017 Dec;37(6):509-512. doi: 10.14639/0392-100X-1690. PMID: 29327736; PMCID: PMC5782429. 11. Leichtle A, Hollfelder D, Wollenberg B, Bruchhage KL. Balloon Eustachian Tuboplasty in children. Eur Arch Otorhinolaryngol. 2017;274(6):2411-2419. PMID: 28283791 doi:10.1007/s00405-017-4517-8

NR = not reported

Question 2. Based on the evidence and your clinical experience for each of the clinical indications described in Question 1:

- Respond YES or NO for each clinical indication whether the intervention would be expected to provide a clinically meaningful improvement in net health outcome; AND
- Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
		1	2	3	4	5
1	Yes					X
2	Yes					X
3	Yes			X		
4	Yes			X		

NR = not reported

Question 3. Based on the evidence and your clinical experience for each of the clinical indications described in Question 1:

- Respond YES or NO for each clinical indication whether this intervention is consistent with generally accepted medical practice; AND
- Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
		1	2	3	4	5
1	Yes					X
2	Yes					X
3	Yes			X		
4	Yes			X		

NR = not reported

Question 4. Should balloon dilation of the eustachian tube only be done as a standalone procedure, or is it also appropriate to perform at the same time as a tympanoplasty or other middle ear surgery? Please describe such uses and supporting scientific citations (including the PMID).

#	Response
1	Balloon Dilation of the Eustachian tube can be done in conjunction with other procedures. Examples of adjunctive procedures that might commonly be performed would be: • Adenoidectomy • Intranasal surgery (e.g. Septoplasty, turbinate procedures or sinus surgery) • Surgery for Obstructive Sleep Apnea or Sleep Disturbed Breathing • Tympanostomy tubes Evidence suggests that some adjunctive procedures might reduce the inflammatory burden within the upper aero-digestive tract and might aid in outcomes and durability of BDET. (5,16,17) For tympanoplasty, mastoidectomy, or other ear surgery, this combination looks promising and, while there is a trend toward value in coupling these procedures reported in studies being conducted now, the evidence is not robust enough to confirm at this point.
2	Balloon Dilation of the Eustachian tube can be done in conjunction with other procedures. Examples of adjunctive procedures that might commonly be performed would be:

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#	Response
	Adenoidectomy Intranasal surgery (e.g. Septoplasty, turbinate procedures or sinus surgery) Surgery for Obstructive Sleep Apnea or Sleep Disturbed Breathing Tympanostomy tubes Tympanoplasty, mastoidectomy or other ear surgery Evidence suggests that some adjunctive procedures might reduce the inflammatory burden within the upper aero-digestive tract and might aid in outcomes and durability of BDET. References • Ashry Y, Kawai K, Poe D. Utility of Adjunctive Procedures with Balloon Dilation of the Eustachian Tube. Laryngoscope Investig Otolaryngol. 2017 Nov 30;2(6):337-343 PMID: 29299505 • McCoul ED, Anand VK (2012) Eustachian tube balloon dilation surgery. Int Forum Allergy Rhinol 2 (3): 191-198. PMID: 22253073 • Liang M, Xiong H, Cai Y, Chen Y, Zhang Z, Chen S, Xu Y, Ou Y, Yang H, Zheng Y. Effect of the Combination of Balloon Eustachian Tuboplasty and Tympanic Paracentesis on Intractable Chronic Otitis Media With Effusion. Am J Otolaryngol Sep-Oct 2016;37(5):442-6. doi: 10.1016/j.amjoto.2016.03.006. Epub 2016 Apr 2. PMID: 27221026
3	Eustachian tube balloon dilation may be performed as a standalone procedure or as an addition to otologic surgery: 1. As an adjunct to tympanoplasty in patients who have demonstrated poor long-term Eustachian tube dysfunction such as a. Ears that have perforated and have undergone at least 2 sets of tympanostomy tubes over the previous 2 years for recurrent or chronic serous otitis media. b. Cases of adhesive otitis media with conductive hearing loss or evidence of ossicular chain erosion (including cholesteatoma). c. 2nd look tympanoplasty or tympanoplasty with mastoidectomy with history of chronic Eustachian tube dysfunction or evidence of early retraction of a grafted eardrum. ▪ In cases of adhesive otitis media, concomitant Eustachian tube balloon dilation with cartilage tympanoplasty may significantly improves quality of life, Tinnitus handicap inventory, and ear stuffiness (PMID 30485447). An unmeasured endpoint is potential decrease in financial burden of repeat otologic surgery. 2. For patients who have undergone at least 2 sets of tympanostomy tubes symptoms and objective signs of chronic hypoventilatory Eustachian tube dysfunction, it may be worthwhile to perform ETBD while placing or replacing tympanostomy tubes to potentially decrease the potential need for future tube placement.
4	BDET may be performed concomitantly with myringotomy with or without tube placement, turbinectomy, adenoidectomy, and/or tympanoplasty with or without mastoidectomy when these other procedures are clinically indicated (1-5). 1. Ashry Y, Kawai K, Poe D. Utility of Adjunctive Procedures With Balloon Dilation of the Eustachian Tube. Laryngoscope Investig Otolaryngol. 2017;2(6):337-343. Published 2017 Nov 30. PMID: 29299505 doi:10.1002/lio2.110 2. Leichtle A, Hollfelder D, Wollenberg B, Bruchhage KL. Balloon Eustachian Tuboplasty in children. Eur Arch Otorhinolaryngol. 2017;274(6):2411-2419. PMID: 28283791 doi:10.1007/s00405-017-4517-8 3. Si Y, Chen Y, Xu G, Chen X, He W, Zhang Z. Cartilage tympanoplasty combined with eustachian tube balloon dilatation in the treatment of adhesive otitis media. Laryngoscope. 2019;129(6):1462-1467. PMID: 30485447 doi:10.1002/lary.27603 4. Li YQ, Chen YB, Yin GD, Zeng XL. Effect of balloon dilation eustachian tuboplasty combined with tympanic tube insertion in the treatment of chronic recurrent secretory otitis media. Eur Arch Otorhinolaryngol. 2019;276(10):2715-2720. PMID: 31197531 doi:10.1007/s00405-019-05512-7 5. Plaza G, Navarro JJ, Alfaro J, Sandoval M, Marco J. Consensus on treatment of obstructive Eustachian tube dysfunction with balloon Eustachian tuboplasty. Acta Otorrinolaringol Esp. 2020 May-Jun;71(3):181-189. English, Spanish. doi: 10.1016/j.otorri.2019.01.005. Epub 2019 May 24. PMID: 31133274.

Question 5. What is the appropriate duration of follow-up to assess outcomes after balloon dilation of the eustachian tube to establish a clinically meaningful improvement in net health outcome?

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#	Response
1	For general clinical practice, initial follow up examinations are typically done at 4 – 6 weeks to judge early efficacy (see Specific outcomes paragraph in responses to Q1). Nasal endoscopy to determine degree of inflammation and opening of the lumen of the Eustachian tube ("functional valve") with swallows and yawns may be done as an option. (4) If a patient is doing well, a subsequent visit would be scheduled for one year post-operatively. Subsequent visits are done on an as-needed basis. Clinical trials may be planned to have additional follow-up visits and testing as per specific protocols (e.g. 6 weeks, 24 weeks, 52 weeks, annual visits for long-term results).
2	For general clinical practice, initial follow up examinations are typically done at 4 – 6 weeks to judge early efficacy (see Specific outcomes paragraph in responses to Q1). Nasal endoscopy to determine degree of inflammation and opening of the lumen of the Eustachian tube ("functional valve") with swallows and yawns may be done as an option. (4) If a patient is doing well, a subsequent visit would be scheduled for one year post-operatively. Subsequent visits are done on an as-needed basis. Clinical trials may be planned to have additional follow-up visits and testing as per specific protocols (e.g. 6 weeks, 24 weeks, 52 weeks, annual visits for long-term results).
3	For lack of better evidence, following the timelines of the partially randomized controlled studies by Poe et al and Meyer et al, I would suggest monitoring for health outcomes from Eustachian tube balloon dilation for 2 years.
4	Based on our current understanding, follow up should be up to one year to appropriately establish a clinically meaningful improvement from after balloon dilation of the Eustachian tube (1-4) 1. Anand V, Poe D, Dean M, et al. Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. Otolaryngol - Head Neck Surg (United States). 2019;160(4):687-694. PMID: 30620688 doi:10.1177/0194599818821938 2. Meyer TA, O'Malley EM, Schlosser RJ, et al. A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otol Neurotol. Aug 2018; 39(7): 894-902. PMID 29912819 3. Cutler JL, Meyer TA, Nguyen SA, et al. Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. Otol Neurotol. Dec 2019; 40(10): 1322-1325. PMID 31385858 4. Plaza G, Navarro JJ, Alfaro J, Sandoval M, Marco J. Consensus on treatment of obstructive Eustachian tube dysfunction with balloon Eustachian tuboplasty. Acta Otorrinolaringol Esp. 2020 May-Jun;71(3):181-189. English, Spanish. doi: 10.1016/j.otorri.2019.01.005. Epub 2019 May 24. PMID: 31133274.

Question 6. Additional comments about the clinical context or specific clinical pathways for this topic and/or any relevant scientific citations (including the PMID) with evidence that demonstrates health outcomes you would like to highlight.

#	Additional Comments
1	Epidemiology of Eustachian Tube dysfunction on health outcomes. Epidemiology and impact on health have become better characterized. A review of NHaNES data for adults from USA revealed a prevalence of obstructive Eustachian tube dysfunction (ETD) in 4.6%, which was considerably higher than previous estimates with smaller datasets. The economic, social and medical burdens of the disease in adults have been studied. The natural history of persistent obstructive ETD may include the development of acute otitis media, chronic otitis media with effusion, conductive or sensorineural hearing loss, vertigo, baro-challenge pain, tympanic membrane perforation, progressive tympanic membrane retraction with development of pockets or cholesteatoma and repeated interventions such as myringotomy or placement of tympanostomy tubes. (18,19, 20) Comparators Mechanical pressure equalization devices are cited several times in the document, but there is no evidence for long-term success. They include a balloon that is inflated by blowing it up from the nose or an electric pump to insufflate the nasal cavity. These devices have been shown to have some short-term benefit (< 90 days), but compliance is challenging. (21) Comparison to placement of tympanostomy tubes A tympanostomy tube will provide ventilation to the middle ear and is expected to relieve negative pressure, including middle ear effusions if previously present. Although this has been the standard procedure for relief of obstructive ETD, it is only beneficial for the duration that the tube remains patent. Consequently, repeated placement of tubes is common in adults with chronic obstructive ETD. Complications from tympanostomy tubes are well known and include infection, otorrhea, tympanosclerosis, persistent

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#	Additional Comments
	perforation requiring tympanoplasty repair, surgical removal of tubes, ingrowth of skin to produce cholesteatoma and a need to observe water precautions among others. Longer duration of tubes or repeated tubes may be associated with a higher rate of complications. (25) In contrast, BDET is a less invasive intervention as it involves no cutting of tissues and no need for implants. Additionally, BDET is targeted to the pathology causing obstructive ETD, rather than providing a temporary bypassing of the problem as is done with a tympanostomy tube. BDET has similarities to adenoidectomy It is well known that adenoid hypertrophy may contribute to obstructive ETD if it interferes with the opening process of the Eustachian tube during swallows and yawns. (26) Histology has shown the presence of adenoid-like lymphocytic infiltrates and hyperplasia of lymphoid follicles within the lumen of the ET. (10) Obstructive ETD is commonly seen in association with adenoid hypertrophy (i.e. lymphoid hyperplasia) when the bulk of the adenoid compromises the opening process of the ET during swallows and yawns. Hypertrophied adenoid-like tissue around the opening of the ET (tubal tonsil tissue) may further contribute to compromise of the opening of the ET. Therefore, treatment of obstructive ETD should be directed to the causes identified and may involve adenoidectomy, reduction of tubal tonsil tissue, or BDET for adenoid-like disease/inflammation within the lumen of the ET. Any of these procedures may be done in isolation or in combination as indicated. (5) Histological study has shown that the tissues within the ET before and after balloon dilation resemble those seen with the adenoid, pre- and post-adenoidectomy. Durability of BDET would be expected to mirror the results of adenoidectomy in controlling hypertrophy. (5,10) Observational Study There are a number of studies with longer term follow up that show durability of benefits ranging from 12 – 60 months. (5,9,12-15,22) The 2nd paragraph discusses the revision cases done in three case series. Selecting 3 studies to add up a cumulative prevalence of revision surgery is not statistically appropriate as it skews the data. The revisions should be examined against the total denominator analyzed by the systematic review from which those cases were taken. Alternatively, a proper meta-analysis should be done if the goal is to accrue data from multiple studies. It is possible that these 3 hand-picked studies involved inexperienced surgeons, poor patient selection, or failure to maintain medical control of possible relevant co-morbidities. The systematic reviews have not shown a high incidence of revision surgery. (8,23,24)
2	The EVIDENCE SUMMARY for Balloon dilation of the Eustachian tube was reviewed. Comments were annotated in the Summary. Additional comments are presented here. Epidemiology of Eustachian Tube dysfunction Epidemiology and impact on health have become better characterized. A review of NHaNES data for adults from USA revealed a prevalence of obstructive Eustachian tube dysfunction (ETD) in 4.6%, which was considerably higher than previous estimates with smaller datasets. The economic, social and medical burdens of the disease in adults have been studied. The natural history of persistent obstructive ETD may include the development of acute otitis media, chronic otitis media with effusion, conductive or sensorineural hearing loss, vertigo, barochallenge pain, tympanic membrane perforation, progressive tympanic membrane retraction with development of pockets or cholesteatoma and repeated interventions such as myringotomy or placement of tympanostomy tubes. **(18,19, 20)** Comparators Mechanical pressure equalization devices are cited several times in the document, but there is no evidence for long-term success. They include a balloon that is inflated by blowing it up from the nose or an electric pump to insufflate the nasal cavity. These devices have been shown to have some short-term benefit (< 90 days), but compliance is challenging. **(21)** Review of Evidence needs update – see comments in the EVIDENCE SUMMARY draft Observational Study There are a number of studies with longer term follow up that show durability of benefits ranging from 12 – 60 months. **(5,9,12-15,22)** The 2nd paragraph discusses the revision cases done in three case series. Selecting 3 studies to add up a cumulative prevalence of revision surgery is not statistically appropriate as it skews the data. The revisions should be examined against the total denominator analyzed by the systematic review from which those cases were taken. Alternatively, a proper meta-analysis should be done if the goal is to accrue data from multiple studies. It is possible that these 3 hand-picked studies involved inexperienced surgeons, poor

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#	Additional Comments

patient selection, or failure to maintain medical control of possible relevant co-morbidities. The systematic reviews have not shown a high incidence of revision surgery. **(8,23,24)**

Supplemental information
Medicare National Coverage - Palmetto Region conducted a Local Coverage Determination (LCD) in 2019, performing a systematic review of the literature and a public commentary meeting was held on 10/07/2019. The proposal that would have denied coverage for BDET was retired on 02/13/2020 after the process was completed.
American Medical Association (AMA)
The AMA accepted the addition of two new Category 1 Current Procedural Terminology (CPT®) codes for BDET, effective January 1, 2021. **(25)**

Additional responses to Q6
Overview of indications for BDET
Chronic (≥ 3 months) obstructive Eustachian tube dysfunction as evidenced by at least one of the following:

- Barochallenge (difficulty equilibrating pressure in ears with large changes
- Hearing loss or aural fullness that is relieved by auto-insufflation
- History of negative pressure in the middle ear or middle ear effusion

Additionally, all of the following must be met:

- If a potentially causal co-morbidity is present (e.g. allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux), failure to respond to appropriate medical management (e.g. 4 week trial of nasal steroid spray for allergic rhinitis, 4 week trial of antacid or proton-pump inhibitor for reflux).
- Nasal endoscopy (dynamic – including swallows and yawns) has been performed. Findings may include pathological changes within the lumen of the Eustachian tube, but in the absence of findings, history and physical remain consistent with obstruction within the cartilaginous Eustachian tube
- If a tympanostomy tube was previously placed, it improved symptoms while patent. However, a trial of tubes is not a requirement.

Comparison to placement of tympanostomy tubes
A tympanostomy tube will provide ventilation to the middle ear and is expected to relieve negative pressure, including middle ear effusions if previously present. Although this has been the standard procedure for relief of obstructive ETD, it is only beneficial for the duration that the tube remains patent. Consequently, repeated placement of tubes is common in adults with chronic obstructive ETD. Complications from tympanostomy tubes are well known and include infection, otorrhea, tympanosclerosis, persistent perforation requiring tympanoplasty repair, surgical removal of tubes, ingrowth of skin to produce cholesteatoma and a need to observe water precautions among others. Longer duration of tubes or repeated tubes may be associated with a higher rate of complications. **(26)** In contrast, BDET is a less invasive intervention as it involves no cutting of tissues and no need for implants. Additionally, BDET is targeted to the pathology causing obstructive ETD, rather than providing a temporary bypassing of the problem as is done with a tympanostomy tube.

BDET has similarities to adenoidectomy
It is well known that adenoid hypertrophy may contribute to obstructive ETD if it interferes with the opening process of the Eustachian tube during swallows and yawns. **(27)** Histology has shown the presence of adenoid-like lymphocytic infiltrates and hyperplasia of lymphoid follicles within the lumen of the ET. **(10)** Obstructive ETD is commonly seen in association with adenoid hypertrophy (i.e.. lymphoid hyperplasia) when the bulk of the adenoid compromises the opening process of the ET during swallows and yawns. Hypertrophied adenoid-like tissue around the opening of the ET (tubal tonsil tissue) may further contribute to compromise of the opening of the ET. Therefore, treatment of obstructive ETD should be directed to the causes identified and may involve adenoidectomy, reduction of tubal tonsil tissue, or BDET for adenoid-like disease/inflammation within the lumen of the ET. Any of these procedures may be done in isolation or in combination as indicated. **(5)** Histological study has shown that the tissues within the ET before and after balloon dilation resemble those seen with the adenoid, pre- and post-adenoidectomy. Durability of BDET would be expected to mirror the results of adenoidectomy in controlling hypertrophy. **(5,10)**

Office setting procedure
BDET can be performed in either the operating room under general anesthesia or monitored sedation, or in

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#	Additional Comments
	an office setting with local anesthesia with proper patient selection. Although it is often compared to balloon sinuplasty, BDET has been found to be a technically more challenging procedure due in part to the location of the ET within the nasopharynx, posterior and lateral to the nasal cavity. Additionally, it has been shown to be more stimulating than sinuplasty, requiring careful and time-consuming protocols for administration of anesthetics and sedation for successful outcomes. **(28-30)** References see list in Question 7
3	Eustachian tube hypoventilatory dysfunction is a frustrating cause for the majority of middle ear inflammatory disease. If successfully treatable in a moderate percentage of patients, even in what the randomized controlled studies suggest (50-70%), then a large number of patients may avoid repeat costly otologic surgery for recidivistic middle ear disease as well as improved quality of life. Ideally, I would like to see a randomized controlled study, long term, that would demonstrate these measurable endpoints. Such a study, however, would take at least 5-10 years to complete and the participation of multiple institutions.
4	I believe I have adequately covered the issues in the previous and following sections.

NR = not reported

Question 7. Is there any evidence missing from the attached draft review of evidence that demonstrates clinically meaningful improvement in net health outcome?

#	YES / NO	Citations of Missing Evidence
1	Yes	**References :***** indicates reference not included in BCBSA Draft Evidence Opinion 1. *** Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, Dawson DE, Dykewicz MS, Hackell JM, Han JK, Ishman SL, Krouse HJ, Malekzadeh S, Mims JW, Omole FS, Reddy WD, Wallace DV, Walsh SA, Warren BE, Wilson MN, Nnacheta LC. Clinical practice guideline: allergic rhinitis. Otolaryngol Head Neck Surg. 2015 Feb;152(1 Suppl):S1-S43. [364 references] PMID: 25644617 2. Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW et al. (2011) Management of eustachian tube dysfunction with nasal steroid spray: a prospective, randomized, placebo-controlled trial. Arch Otolaryngol Head Neck Surg 137 (5): 449-455. PMID: 21576556 3. *** Altman KW, Prufer N, Vaezi MF. A Review of Clinical Practice Guidelines for Reflux Disease: Toward Creating a Clinical Protocol for the Otolaryngologist. Laryngoscope, 121:717–723, 2011 PMID: 21298646 4. Tucci D, McCoul E, Rosenfeld R, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. American Academy of Otolaryngology–Head and Neck Surgery Foundation 2019. April 15, 2019:1-12. PMID: 31161864 5. *** Ashry Y, Kawai K, Poe D. Utility of Adjunctive Procedures with Balloon Dilation of the Eustachian Tube. Laryngoscope Investig Otolaryngol. 2017 Nov 30;2(6):337-343 PMID: 29299505 6. Poe D, Anand V, Dean M, Roberts WH, Stolovitzky JP et al. (2018) Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope 128 (5): 1200-1206. PMID: 28940574 7. Meyer TA, O'Malley EM, Schlosser RJ, Soler ZM, Cai J et al. (2018) A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otol Neurotol 39 (7): 894-902. PMID: 29912819 8. Huisman JML, Verdam FJ, Stegeman I, de Ru JA (2018) Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. Laryngoscope 128 (1):237-247. PMID: 28799657 9. *** Froehlich MH, Le PT, Nguyen SA, McRackan TR, Rizk HG, Meyer TA. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. Otolaryngol Head Neck Surg. 2020 Jun 2:194599820924322. doi: 10.1177/0194599820924322. Online ahead of print. PMID: 32482125 10. *** Kivekäs I, Chao WC, Faquin W, Hollowell M, Silvola J et al. (2015) Histopathology of balloon-dilation Eustachian tuboplasty. Laryngoscope 125 (2): 436-441. PMID: 25154612 11. *** Smith ME, Weir AE, Prior DCC, Cope W, Tysome JR, Sutcliffe M. The mechanism of balloon Eustachian tuboplasty: a biomechanical study. Med Biol Eng Comput. 2020 Apr;58(4):689-699. doi: 10.1007/s11517-020-02121-z. Epub 2020 Jan 17.PMID: 31953796

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#	YES / NO	Citations of Missing Evidence
		12. Anand V, Poe D, Dean M, Roberts W, Stolovitzky P et al. (2019) Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. Otolaryngol Head Neck Surg 160 (4): 687-694. PMID: 30620688
		13. Cutler JL, Meyer TA, Nguyen SA, O'Malley EM, Thackeray L et al. (2019) Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. Otol Neurotol 40 (10): 1322-1325. PMID: 31385858
		14. Luukkainen V, Kivekas I, Silvola J, Jero J, Sinkkonen ST (2018) Balloon EustachianTuboplasty: Systematic Review of Long-term Outcomes and Proposed Indications. J Int Adv Otol 14 (1): 112-126. PMID: 29764785
		15. *** Luukkainen V, Vnencak M, Aarnisalo AA, Jero J, Sinkkonen ST (2018) Patient satisfaction in the long-term effects of Eustachian tube balloon dilation is encouraging. Acta Otolaryngol 138 (2): 122-127. PMID: 29017385
		16. *** McCoul ED, Anand VK (2012) Eustachian tube balloon dilation surgery. Int Forum Allergy Rhinol 2 (3): 191-198. PMID: 22253073
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		18. *** Shan A, Ward BK, Goman AM, Betz JF, Reed NS et al. (2019) Prevalence of Eustachian Tube Dysfunction in Adults in the United States. JAMA Otolaryngol Head Neck Surg PMID: 31369057
		19. *** Kim AS, Betz JF, Goman AM, Poe DS, Reed NS, Ward BK, Nieman CL. JAMA Otolaryngol Head Neck Surg. Prevalence and Population Estimates of Obstructive Eustachian Tube Dysfunction in US Adolescents 2020 Jun 4;e200962 doi: 10.1001/jamaoto.2020.0962. Online ahead of print. PMID: 32496532
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		21. *** Rosenfeld RM, Shin JJ, Schwartz SR, Coggins R, Gagnon L, Hackell JM, Hoelting D, Hunter LL, Kummer AW, Payne SC, Poe DS, Veling M, Vila PM, Walsh SA, Corrigan MD. Clinical Practice Guideline: Otitis Media with Effusion (Update). Otolaryngol Head Neck Surg. 2016 Feb;154(1 Suppl):S1-S41. doi: 10.1177/0194599815623467. PMID: 26832942
		22. *** McMurran AEL, Hogg GE, Gordon S, Spielmann PM, Jones SE. Balloon Eustachian tuboplasty for Eustachian tube dysfunction: report of long-term outcomes in a UK population. J Laryngol Otol. 2020 Jan;134(1):34-40. doi: 10.1017/S0022215119002548. Epub 2020 Jan 8. PMID: 31910908
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		24. *** Ramakrishnan N, D'Souza R, Kadambi P. A systematic literature review of the safety and efficacy of eustachian balloon tuboplasty in patients with chronic eustachian tube dysfunction. Indian J Otolaryngol Head Neck Surg. 2019;71(3):406-412 PMID: 31559212
		25. *** Padia R, Hall D, Sjogren P, Narayanan P, Meier J. Sequelae of Tympanostomy Tubes in a Multihospital Health System. Otolaryngol Head Neck Surg 2018 May;158(5):930-933. doi: 10.1177/0194599817752633. Epub 2018 Jan 16. PMID: 29336221
		26. *** Poe DS, Abou-Halawa A, Abdel-Razek O. Analysis of the dysfunctional eustachian tube by video endoscopy. Otol Neurotol. 2001;22(5):590-5. PMID: 11568663
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		29. *** Dean M, Pynnonen MA. In-Office Balloon Dilation of the Eustachian Tube under Local Anesthesia. Otolaryngol Clin North Am. 2019 Jun;52(3):509-520. doi: 10.1016/j.otc.2019.02.005. Epub 2019 Mar 22. PMID: 30905561

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#	YES / NO	Citations of Missing Evidence
		30. *** Wang T, Lin C, shih T et al. Comparison of Balloon Dilation and Laser Eustachian Tuboplasty in Patients with Eustachian tube dysfunction: A Meta-analysis. Otolaryngol Head Neck Surg. 2018. 158: 617-626. 31. *** Yin G et al. Balloon dilation of eustachian tube combined with tympanostomy tube insertion and middle ear equalization therapy for recurrent secretory otitis media. J Otol. 2019, 14:101 32. *** Huhnd LE. et al. Balloon dilation of the eustachian tube in tympanic membrane retractions. Laryngorhinootologie. 2018. 97:688-93 33. *** Giunta A, Liberati L, Pellegrino C et al. Eustachian tube balloon dilation in treatment of equalization problems of freediving spearfisherman. Diving Hyperb Med. 2019. 49: 9-15; 34. *** Cheng T, Kaylie D. Recurrent and progressive facial Sbaroparesis on flying relieved by eustachian tube dilation. Ann Otol Rhinol Laryngol. 2019. 128: 778-781; 35. *** Utz, E, Wise S. Navy Diver with Recurrent Facial Nerve Baroparesis treated with Eustachian tube Balloon dilation. Laryngoscope. 2019. 129: E412-E414.) 36. *** Siow J, Tan J. Indications for Eustachian tube dilation. Curr Opin Otolaryngol Head Neck Surg. 2020. 28: 31-35) The following are studies completed outside of the U.S. • Bast (2013), PMID: 24525675 • Bowles (2017), PMID: 27992946 • Dalchow (2016), PMID: 25786889 • Gurtler (2015), PMID: 25356762 • Satmis (2018), PMID: 29285624 • Schmitt (2018), PMID: 29289487 • Schröder (2015), PMID: 25867023 • Skevas (2018),PMID: 29143098 • Wanscher (2014), PMID: 24814593 • Williams (2016), PMID: 26869258 • Xiong (2016), PMID: 26954860
2	Yes	**References:** 1. Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, Dawson DE, Dykewicz MS, Hackell JM, Han JK, Ishman SL, Krouse HJ, Malekzadeh S, Mims JW, Omole FS, Reddy WD, Wallace DV, Walsh SA, Warren BE, Wilson MN, Nnacheta LC. Clinical practice guideline: allergic rhinitis. Otolaryngol Head Neck Surg. 2015 Feb;152(1 Suppl):S1-S43. [364 references] PMID: 25644617 2. Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW et al. (2011) Management of eustachian tube dysfunction with nasal steroid spray: a prospective, randomized, placebo-controlled trial. Arch Otolaryngol Head Neck Surg 137 (5): 449-455. PMID: 21576556 3. Altman KW, Prufer N, Vaezi MF. A Review of Clinical Practice Guidelines for Reflux Disease: Toward Creating a Clinical Protocol for the Otolaryngologist. Laryngoscope, 121:717–723, 2011 PMID: 21298646 4. Tucci D, McCoul E, Rosenfeld R, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. American Academy of Otolaryngology–Head and Neck Surgery Foundation 2019. April 15, 2019:1-12. PMID: 31161864 5. Ashry Y, Kawai K, Poe D. Utility of Adjunctive Procedures with Balloon Dilation of the Eustachian Tube. Laryngoscope Investig Otolaryngol. 2017 Nov 30;2(6):337-343 PMID: 29299505 6. Poe D, Anand V, Dean M, Roberts WH, Stolovitzky JP et al. (2018) Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope 128 (5): 1200-1206. PMID: 28940574 7. Meyer TA, O'Malley EM, Schlosser RJ, Soler ZM, Cai J et al. (2018) A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otol Neurotol 39 (7): 894-902. PMID: 29912819 8. Huisman JML, Verdam FJ, Stegeman I, de Ru JA (2018) Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. Laryngoscope 128 (1):237-247. PMID: 28799657

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		27. Poe DS, Abou-Halawa A, Abdel-Razek O. Analysis of the dysfunctional eustachian tube by video endoscopy. Otol Neurotol. 2001;22(5):590-5. PMID: 11568663 28. Luukkainen V, Kivekäs I, Hammarén-Malmi S, Rautiainen M, Pöyhönen L, Aarnisalo AA, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty under local anesthesia: Is it feasible? Laryngoscope. 2017 May;127(5):1021-1025. doi: 10.1002/lary.26488. Epub 2017 Feb 3. PMID: 28409844 29. Luukkainen V, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty under monitored anaesthesia care with different balloon dilation devices: A pilot feasibility study with 18 patients. Clin Otolaryngol. 2019 Jan;44(1):87-90. doi: 10.1111/coa.13236. Epub 2018 Nov 4. PMID: 30281926 30. Dean M, Pynnonen MA. In-Office Balloon Dilation of the Eustachian Tube under Local Anesthesia. Otolaryngol Clin North Am. 2019 Jun;52(3):509-520. doi: 10.1016/j.otc.2019.02.005. Epub 2019 Mar 22. PMID: 30905561
3	No	I do not believe the literature list provided is missing any major publications beyond what I have described in the above responses.
4	Yes	The following systematic review may help provide further evidence of clinically meaningful improvement from BDET. Plaza G, Navarro JJ, Alfaro J, Sandoval M, Marco J. Consensus on treatment of obstructive Eustachian tube dysfunction with balloon Eustachian tuboplasty. Acta Otorrinolaringol Esp. 2020 May-Jun;71(3):181-189. English, Spanish. doi: 10.1016/j.otorri.2019.01.005. Epub 2019 May 24. PMID: 31133274.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Reason for procedure/test/device
  - Pertinent past procedural and surgical history and results if applicable
  - Past and present diagnostic testing and results including tympanogram if applicable
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
  - Consultation and medical clearance report(s), when applicable
  - Radiology report(s) and interpretation (i.e., MRI, CT)
  - Laboratory results as applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.
The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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Effective Date	Action
04/01/2018	BCBSA Medical Policy adoption
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement.
01/01/2021	Coding Update
02/01/2021	Coding Update
04/01/2021	Annual review. Policy statement, guidelines and literature review updated.
11/01/2021	No change to policy statement. Literature review updated.
11/01/2022	Annual review. Policy statement, guidelines and literature review updated.
11/01/2023	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

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Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Balloon Dilation of the Eustachian Tube 7.01.158 **Policy Statement:** I. Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered **medically necessary** for **all** of the following: A. 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 1. Aural fullness and pressure must be present 2. 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 **all** of the following: a. Abnormal tympanogram (Type B or C) b. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam) 3. Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated. B. Documentation that 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 C. If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent D. The individual does not have patulous ETD or another contraindication to the procedure E. The individual's ETD has been shown to be reversible	**Balloon Dilation of the Eustachian Tube 7.01.158** **Policy Statement:** I. Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered **medically necessary** for **all** of the following: A. 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 1. Aural fullness and pressure must be present 2. 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 **all** of the following: a. Abnormal tympanogram (Type B or C) b. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam) 3. Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated B. Documentation that 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 C. If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent D. The individual does not have patulous ETD or another contraindication to the procedure E. The individual's ETD has been shown to be reversible

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POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
F. Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying) G. The individual has not had a previous BDET procedure II. Balloon dilation of the eustachian tube is considered **investigational** if the above criteria are not met.	F. Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying) G. The individual has not had a previous BDET procedure II. Balloon dilation of the eustachian tube is considered **investigational** if the above criteria are not met.

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