Regence

**Medical Policy Manual** Surgery, Policy No. 206

# *Balloon Dilation of the Eustachian Tube*

**Effective**: November 1, 2026

**Next Review:** March 2027
**Last Review:** October 2026

**IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

## DESCRIPTION

Balloon dilation of the Eustachian tube is a tuboplasty procedure intended to improve the patency of the cartilaginous Eustachian tube. During the procedure, a saline-filled balloon catheter is introduced into the Eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for approximately two minutes after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

## MEDICAL POLICY CRITERIA

**Note:** Clinical documentation to support criteria is required (See Required Documentation).

### Medically Necessary

I. Balloon dilation of the eustachian tube for treatment of chronic obstructive eustachian tube dysfunction may be considered **medically necessary** when all of the following Criteria are met (A. – I.):

A. Age consistent with the device specific FDA approval; and

B. The individual does not have patulous eustachian tube dysfunction or another contraindication (See Policy Guidelines); and

C. Symptoms have occurred for at least 12 months including but not limited to aural fullness, aural pressure, otalgia, or hearing loss; and

D. The individual does not have other causes of aural fullness such as temporomandibular joint disorders, extrinsic obstruction of the eustachian tube, superior semicircular canal dehiscence, and endolymphatic hydrops; and

E. Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to baro-challenge such as pressure changes while flying); and

F. The individual has undergone a comprehensive diagnostic assessment documenting all of the following findings:

1. Abnormal tympanogram (Type B or C); and
2. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam); and

G. Failure to respond to appropriate medical management of co-occurring conditions, including 4-6 weeks of a nasal steroid spray if indicated. Co-occurring conditions include but are not limited to allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux; and

H. Either of the following is met:

1. No history of tympanostomy tube placement; or
2. History of tympanostomy tube placement with improved symptoms of obstructive eustachian tube dysfunction while tubes were patent; and

I. Either of the following is met:

1. The individual is younger than 18 years old and is refractory to at least one surgical intervention (e.g., tympanoplasty tubes); or
2. The individual is age 18 years or older.

### Not Medically Necessary

II. Balloon dilation of the eustachian tube is considered **not medically necessary** when Criterion I. is not met.

### Investigational

III. Balloon dilation of the eustachian tube is considered **investigational** for repeat balloon dilation of the eustachian tube and all other indications.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

**Contraindications to Balloon Dilation of the Eustachian Tube**

The following individuals should not be considered for balloon dilation of the eustachian tube:

- Individual with patulous eustachian tube dysfunction
    - A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
- Individual with extrinsic reversible or irreversible causes of eustachian tube dysfunction including but not limited to:
    - craniofacial syndromes, including cleft palate spectrum
    - neoplasms causing extrinsic obstruction of the eustachian tube
    - history of radiation therapy to the nasopharynx
    - enlarged adenoid pads
    - nasopharyngeal mass
    - neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening
    - systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g. Samter's triad, Wegener's disease, mucosal pemphigus) that is ongoing/active (i.e. not in remission)
- Individuals with aural fullness but normal exam and tympanogram
- Individuals with chronic and severe atelectatic ears

## REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes including length of time signs and specific symptoms of obstructive eustachian tube dysfunction have been present and have impaired function.
- Indication for the requested service.
- Documentation patulous eustachian tube dysfunction and other contraindications to the procedure have been ruled out.
- Diagnostic findings documenting abnormal tympanogram and an abnormal tympanic membrane.
- Documentation of failure of medical management for any co-occurring conditions and specify length of time it was trialed.
- If there is a history of tympanostomy tube placement, provide documentation that symptoms of obstructive eustachian tube dysfunction improved while tubes were patent.

## CROSS REFERENCES

1. Balloon Ostial Dilation for Treatment of Sinusitis, Surgery, Policy No. 153

## BACKGROUND

### EUSTACHIAN TUBE FUNCTION

The Eustachian tube (ET) connects the middle ear space to the nasopharynx. It is approximately 36 mm long in adults. The ET ventilates the middle ear space to equalize pressure across the tympanic membrane, clears mucociliary secretions, and protects the middle ear from infection and reflux of nasopharyngeal contents.[1] The tube opens during swallowing or yawning.

Eustachian tube dysfunction (ETD) occurs when the functional valve of the ET fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. ET dilatory dysfunction (ETDD) is most commonly caused by inflammation including rhinosinusitis and allergic rhinitis. ETDD can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo.[2] Chronic ETDD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas.

## EPIDEMIOLOGY OF ETD

The epidemiology of ETD, including incidence and prevalence of the disorder and associated symptoms in the community, primary care, and referral populations, is not well-characterized. Data are also lacking to describe the natural history of the disorder and impact on individual functioning.

## DIAGNOSIS AND OUTCOME MEASURES

There are no comprehensive guidelines regarding the diagnosis of ETD. Schilder (2015) published a consensus statement from an international group of scientists and physicians with expertise in Eustachian tube disorders, prompted by a Health Technology Assessment from the UK National Institute of Health and Research stating that an important limitation with available evidence for treatments of ETD is a lack of consensus on the definition and diagnosis.[1] The meeting was funded by Acclarent, a manufacturer of a dilation technology. The following summarize relevant 2015 consensus statements from the group.

- There is no universally accepted set of individual-reported symptom scores, functional tests, or scoring systems to diagnose ETD.
- Diagnosis of ETDD should consider individual-reported symptoms along with evidence of negative pressure in the middle ear assessed by clinical assessment.
- Transient ETD is ETD with symptoms and signs lasting less than 3 months while chronic ETD is ETD with symptoms and signs lasting for more than 3 months.
- Future clinical trials should include outcomes related to individual-reported symptoms, otoscopy, tympanometry, and pure-tone audiometry, and outcomes should be assessed at baseline, in the short term (6 weeks to 3 months) and in the long term (6-12 months).
- The 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is the only individual-reported outcome scale to have undergone initial validation studies.

Tympanometry is a frequently used outcome measure in ETD. 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. They are classified into three general patterns: 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.[3]

The ETDQ-7 is used to assess ETD-related symptoms such as pressure, pain, “clogged” ears, and muffled hearing over the previous month. The 7 items are rated by individuals on a 7-level scale from 1 (no problem) to 7 (severe problem). The overall score is reported as a mean item score with a range from 1.0 to 7.0. ETDQ-7 has been shown to be a valid and reliable

symptom score for use in adults with ETD with overall score of 2.1 or higher having high accuracy to detect the presence of ETD.[4]

Other important outcomes for evaluating a treatment for ETD are hearing outcomes, otitis media, clearance of middle ear effusion, tympanic membrane retraction, and quality of life. Another important consideration is the need for additional treatment, e.g., additional surgical procedures (including reintervention).

### TREATMENT OF ETDD

Medical management of ETDD 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. Although topical nasal steroids are commonly used for ETDD, triamcinolone acetonide failed to show benefit in individuals ages six and older presenting with otitis media with effusion and/or negative middle ear pressure in a randomized, placebo-controlled, double-blind trial published in 2011.[5]

Individuals who continue to have symptoms following medical management may be treated with surgery. Available surgical management includes myringotomy with placement of tympanostomy tubes or eustachian tuboplasty. There is limited evidence supporting use of these surgical techniques.[6] Norman (2014) reported that eustachian tuboplasty (other than balloon dilation) has been evaluated in seven case series and was associated with improvement in symptoms in 36% to 92% of individuals with low rates (13%-36%) of conversion to type A tympanogram (which is normal). Myringotomy and tympanostomy have been evaluated in two case series and were associated with symptom alleviation in a subgroup of individuals.[6]

### REGULATORY STATUS

In December 2015, 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).[7] The new classification applies to this device and substantially equivalent devices of this generic type. The device was cleared for marketing by FDA through the 510(k) process (K163509) in January 2018 for individuals ages 22 and older. In December of 2023, the AERA® received additional FDA approval for use in pediatrics ages 8 and older.

In April 2017, the XprESS™ ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by FDA through the 510(k) process (K163509).[8] FDA determined that this device was substantially equivalent to existing devices for use in Eustachian tube dysfunction. The predicate devices are XprESS™ Multi-Sinus Dilation System and AERA® Eustachian Tube Balloon Dilation System.

## EVIDENCE SUMMARY

### SCIENTIFIC EVIDENCE

Evaluating the safety and effectiveness of balloon dilation of the Eustachian tube requires randomized comparisons with standard treatments. These comparisons are necessary to determine whether the benefits of balloon dilation of the Eustachian tube outweigh any risks and whether they offer advantages over conventional methods with respect to increasing quality of life and decreasing long-term morbidity and mortality, or secondary outcomes such

as improved Eustachian tube function. The evidence summary below is focused on systematic reviews and randomized controlled trials (RCTs).

**Systematic Reviews**

A 2025 Cochrane Review (Swords, 2025) identified nine clinical trials involving 684 participants across three comparison groups: Balloon Eustachian Tuboplasty (BET) versus non-surgical treatment (five trials, 422 participants),[9] BET versus sham surgery (one trial, 17 participants), and BET versus alternative surgical procedures (four trials, 275 participants). All studies had some risk of bias concerns. When comparing BET to non-surgical treatments in the short term (up to three months), low-certainty evidence suggests BET may decrease individual-reported Eustachian Tube Dysfunction (ETD) symptoms, with a mean difference in ETDQ-7 scores of -1.66 (95% CI -2.16 to -1.16; $I^2$ = 63%; 4 RCTs, 362 participants). Very low-certainty evidence indicates BET may improve objective ETD measures, with tympanometry improvements showing a risk ratio of 2.51 (95% CI 1.82 to 3.48; $I^2$ = 0%; 3 RCTs, 369 participants).

For longer-term outcomes (three to 12 months), the evidence remains highly uncertain regarding whether BET reduces ETDQ-7 scores (MD -0.55, -1.31 to 0.21; 1 RCT, 24 participants) or improves objective measures like tympanometry (RR 2.54, 95% CI 0.91 to 7.12). Evidence quality was downgraded due to bias risk, imprecision, indirectness, or combinations thereof.In the comparison of BET to sham surgery, very low-certainty evidence showed uncertain improvement in individual-reported symptoms at both short-term (ETDQ-7 change: MD -0.54, 95% CI -2.55 to 1.47; 1 RCT, 17 participants) and longer-term follow-up (MD 0.16, 95% CI -0.75 to 1.07; 1 RCT, 17 participants). This evidence was downgraded for indirectness and significant imprecision. The authors concluded that BET appears to offer meaningful symptom relief ETD when compared to either conservative management or placebo procedures (sham surgery) within the first three months of treatment and that research priorities should include investigating the durability of treatment effects over extended timeframes and documenting the frequency and severity of complications or adverse outcomes in everyday clinical settings outside of controlled research environments.

Aboueisha (2022) conducted a systematic review of balloon dilation for eustachian tube (BDET) dysfunction in pediatric populations which included seven studies and 408 participants with a mean age of 9.9 years.[10] The primary outcomes of interest were changes in tympanograms and air-bone gap. Type B tympanograms decreased after BDET from 64.2% (95%CI 53.3, 73.8) to 16.1% (95%CI 8.5, 28.4). Air-bone gap (ABG) decreased after BDET from a mean of 25.3 dB (95%CI 18.9, 31.6) to 10.2 dB (95%CI 8.9, 11.5). The pooled estimate of adverse events after BDET was 5.1% (95%CI 3.2, 8.1), the majority being self-limited epistaxis with no major adverse events reported. This review is limited by the lack of high quality studies including randomized, comparative trials. Additional comparative trials are needed to establish the efficacy of BDET in pediatric populations.

Froehlich (2020) conducted a systematic review and meta-analysis of balloon dilation for eustachian tube dysfunction.[11] Twelve studies were included in the meta-analysis, including three RCTs, five prospective observational studies, and four case series. One RCT (Liang 2016) that compared balloon dilation to tympanic paracentesis reported tympanometry and otoscopy scores but not symptoms. The other two RCTs compared balloon dilation plus medical management to medical management alone and used the ETDQ-7 to measure symptoms. Pooled analyses showed improvements in subjective and objective measures

including ETDQ-7 scores, tympanograms, otoscopy exams, and ability to perform a Valsalva maneuver. Improvements appeared to be maintained in studies with longer-term follow up (3-12 months). Case series included in these reviews consistently reported that individuals experienced improvement when comparing symptoms before and after balloon dilation. The studies varied in the type of medical management used to treat eustachian tube dysfunction before and after balloon dilation.

The results of two additional systematic reviews and meta-analyses for adults with ETD who were treated with balloon dilation are discussed here. Huisman (2018)[12] provided pooled results for 15 case series (n=1,155) while Hwang (2016)[13] provided qualitative summaries only, for nine case series (n=474). Most selected case series provided follow-up of less than a year. All case series reported that individuals experienced improvement when comparing symptoms before and after balloon dilation. The selected studies differed with respect to other treatments for ETD used before and after balloon dilation. In Huisman (2018), revisions due to failure of the first ET balloon dilation procedure were reported in three of the 15 studies (n=714); 122 revisions were reported. Huisman (2018) also reported studies had methodological limitations including risk of bias and high heterogeneity and that high quality RCTs are needed.

Jufas (2016) published a SR that evaluated balloon dilation, with a transtympanic approach for Eustachian tube dysfunction (ETD).[14] Three limited case series were included. The authors concluded there was a high risk of bias and safety and efficacy outcomes were conflicting.

Randrup (2015) published a SR evaluating balloon eustachian tuboplasty for ETD.[15] The authors evaluated nine case series and health outcomes for 443 individuals. All case series were poor quality and had a high risk of bias.

**Randomized Controlled Trials**

Gey (2025) published a randomized controlled trial including 76 participants (68 included in analysis) with 34 in the tympanoplasty group and 34 in the tympanoplasty plus balloon dilation group.[16] In the initial year following the procedure, the mean Eustachian Tube Score (ETS) improvement was comparable between individuals who received tympanoplasty alone (1.62 [95% CI, 0.66-2.59]) and those who underwent tympanoplasty combined with Eustachian Tube Balloon Dilation (ETBD) (1.41 [95% CI, 0.43-2.39]), with a minimal difference of 0.21 (95% CI, -1.17 to 1.59). This finding eliminates the possibility of a significant clinical difference of 3 points or greater in ETS between the two approaches.

At the one-year mark post-procedure, hearing function as measured by Air-Bone Gap (ABG) showed improvement in both groups: the tympanoplasty-only group saw a reduction from 26.1 dB to 19.0 dB hearing loss, while the combined tympanoplasty plus ETBD group improved from 30.1 dB to 20.1 dB hearing loss. The comparative change in ABG between the two groups was -2.8 dB (95% CI, -9.1 dB to 3.5 dB). Similarly, the difference in Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) score changes between the groups was negligible at -0.2 (95% CI, -3.4 to 3.1).

Joo (2025) published a randomized controlled trial with 16 participants (121 ears) between January 2021 and June 2023.[17] Participants were equally divided into two treatment groups: one receiving Balloon Eustachian Tuboplasty (BET) with Medical Management (MM), and the other receiving MM alone (consisting of fluticasone furoate nasal steroid spray). The main short-term outcome measured was normalization of the Valsalva maneuver at 8 weeks post-

treatment. Additional outcomes included improvements in Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) scores and reduction in air-bone gap (ABG), also assessed at the 8-week mark. Both groups were monitored for adverse events throughout the follow-up period.

Of the 116 study participants (121 ears total), 60 individuals (62 ears) underwent BET treatment combined with MM, while 56 individuals (59 ears) received only MM. The groups showed no significant differences in demographic information, baseline characteristics, initial ETDQ-7 scores, bone conduction thresholds, or ABG measurements. After treatment, 46.8% (29 out of 62 ears) in the BET group successfully performed the Valsalva maneuver, compared to only 15.3% (9 out of 59 ears) in the MM-only group ($p<0.001$). Subjective symptom improvement was more pronounced in the BET group, with ETDQ-7 scores decreasing by 6.2±9.4 points versus 2.6±8.6 points in the MM-only group ($p=0.028$). Similarly, ABG reduction was greater in the BET group (-5.8±11.4 dB) than in the MM-only group (-1.2±10.5 dB) ($p=0.023$). Throughout the 8-week follow-up period, neither group experienced serious procedure-related or device-related adverse events.

Krogshede (2022) published a randomized controlled trial with six months of follow up evaluating 24 individuals.[18] Of the 13 subjects randomized to the treatment group, nine showed normalization from retraction or serous otitis media in addition to showing improved tympanometry. There were no differences in audiometric findings or in Eustachian Tube Dysfunction Questionnaire-7 scores between the two groups. The authors concluded that the treatment is safe and effective for adult individuals with mild chronic Eustachian tube dysfunction.

Meyer (2018) published the results of a one-year-follow-up-inclusive, prospective, multi-center RCT of balloon dilation as a treatment for persistent eustachian tube dysfunction (ETD) and compared the intervention to continued medical therapy (control).[19] Inclusion criteria required individuals be diagnosed with medically refractory, persistent ETD. Participants were randomly assigned (1:1) to intervention or control; however, control participants were offered the intervention after six weeks if their symptoms remained. The outcomes measured include primary efficacy endpoint using Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores and the rate of complications. The trial involved 60 randomized participants (31 intervention, 29 control). Mean (SD) change in overall ETDQ-7 score at six weeks was 2.9 (1.4) for balloon dilation compared with 0.6 (1.0) for control: balloon dilation was superior to control ($p<0.0001$). No complications were reported in either study arm. Among participants with abnormal baseline assessments, improvements in tympanogram type ($p < 0.006$) and tympanic membrane position ($p<0.001$) were significantly better for balloon dilation than control. Improvements in the ETDQ-7 scores were maintained through 12 months after balloon dilation. Limitations of this RCT are its small sample size and the inability to blind the participants to their treatment.

Cutler (2019) reported longer-term follow-up data on a subset of individuals from the treatment arm of the RCT reported by Meyer.[20] Of 58 individuals from the original study who were eligible for the extension study, 47 were enrolled in the follow up study. The mean follow-up time was 29.4 months post-procedure. Changes from baseline at the end of the longer-term follow-up period were similar to improvements observed at one year on outcome measures including the ETDQ-7, normalized tympanogram, ability to perform the Valsalva maneuver, and individual satisfaction. One individual underwent a revision ET dilation after 362 days, performed concurrently with balloon dilation for recurrent sinus disease. No other surgeries or adverse events were reported.

Poe (2017) published a randomized trial (n=323) comparing balloon dilation of the eustachian tube (BDET) with ET balloon catheter (ETBC) plus medical management versus medical management alone. Participants were 22 years or older, had persistent individual-reported symptoms of ETD (ETDQ-7; mean item score, ≥2.1), abnormal tympanometry (type B or type C), and failed medical management including either a minimum of four weeks of daily use of any intranasal steroid spray or a minimum of one course of an oral steroid.[21] The balloon catheter used in the trial was a custom-designed ET balloon catheter (Acclarent). The RCT results are also described in the AERA (Acclarent) de novo summary from the Food and Drug Administration.[7]

The investigators in this study were required to perform three successful ETBC procedures in nonrandomized “lead-in” individuals who were then followed for durability and safety outcomes. Randomization and analyses were performed at the person-level regardless of whether the individual 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 individuals, both ears had to be rated as normalized for that individual to be considered normalized for the primary outcome. Individuals completed follow-up visits at 2, 6, 12, 24, and 52 weeks but data from the 52-week visit have not been reported. Individuals in the medical management arm were allowed to receive BDET after the six-week visit. Trial enrollment was stopped early after the second preplanned look when the prespecified O’Brien-Fleming stopping boundary for the primary outcome was crossed.

At baseline, the mean ETDQ-7 score was 4.7, 43% of individuals had allergic rhinitis, and 61% of individuals had at least one prior ear tube surgery. By the second interim analysis, 162 individuals had been assigned to ETBC and 141 were included in analysis; 80 had been assigned to medical management and 72 were included in analysis. Individuals were included in analysis if they received the study treatment for which they were randomized and had 6-week follow-up data. Approximately 52% of ETBC individuals experienced tympanogram normalization at 6 weeks compared with 14% of medical management individuals (p<.001). The publication reported that sensitivity analysis was performed to test the robustness of results for the impact of missing data in the analysis cohort versus an intention-to-treat cohort, but the method of sensitivity analyses was not described. It was noted that there was a significant treatment by site interaction. Two sites had a higher percentage of tympanogram normalization for MM subjects than for ETBC subjects while the remaining sites had higher normalization for ETBC. The pre-specified secondary efficacy outcome (percentage with minimal clinically important difference change of 0.5 points on ETDQ-7) was not reported in the publication but was reported in the FDA summary. The minimal clinically important difference change in ETDQ-7 scores was observed for 91% of ETBC individuals at 6 weeks compared with 45% of medical management individuals (p not reported). Fifty-six percent of ETBC individuals had an ETDQ-7 mean item score of less than 2.1 at six weeks compared with about 9% of medical management individuals (p<0.001). See the summary of results in table 1 below.

Comparative analyses were not possible after six weeks because 82% of medical management individuals elected to ETBC after 6 weeks. Durability of the effect is supported by analysis of tympanogram normalization in 170 individuals with week 24 data (98 randomized to ETBC and 74 from the lead-in); 62% of those randomized to ETBC and 58% of lead-in individuals demonstrated tympanogram normalization at 24 weeks. Data from 52 weeks have not been reported.

This trial had methodological limitations, including the inability to blind individuals, the exclusion of individuals who did not received the assigned treatment, and the premature ending of the study. In addition, there were relevance gaps that prevented the RCT from providing enough evidence to guide treatment for ETDD. These included but are not limited to:

- Individuals continued nasal steroids and other medications prescribed prior to the study
- Hearing outcomes were not reported
- Short-term follow-up prevented evaluation of long-term outcomes.

**Table 1. Summary of Key RCT Results**

| Study (Year) | Normalization of Tympanometry (% of individuals) | ETDQ-7 Symptom Scores <2.1 (% of individuals)[a] | Change in Mean ETDQ-7 Score (SD) | Change in Mucosal Inflammation | Positive modified Valsalva Maneuver (% ears) | SAEs (no. of events) |
|---|---|---|---|---|---|---|
| **Poe (2017)[21]** | | | | | | |
| N | 211 | 208 | | NR | NR | NR |
| BDET plus MM | 52% | 56% | | +22% | 33% | 4 |
| MM | 14% | 9% | | -5% | 3% | 1 |
| Tx effect | RR=NR | RR=NR | | NR | NR | NR |
| p | <0.001 | <0.001 | | | | |
| **Meyer (2018)[19]** | | | | | | |
| N | | | 28 | | | |
| BDET plus MM | | | -2.9 (1.4) | | | |
| N | | | 27 | | | |
| MM | | | -0.6 (1.0) | | | |
| p | | | <0.0001 | | | |

BDET: balloon dilation of the Eustachian tube; BL: baseline; ETDQ-7: 7-item Eustachian Tube Dysfunction Questionnaire; MM: medical management; NR: not reported; RR: relative risk; SAE: serious adverse event; Tx: treatment.
[a] The prespecified secondary outcome was the proportion of subjects achieving an improvement of at least a minimal clinically important difference of 0.5 points; it was not reported.

Adverse events were only briefly described in the publication but are more fully described in the Food and Drug Administration summary.[7] Two-hundred ninety-nine individuals who were treated with ETBC were included in the safety analysis (80 lead-in individuals, 149 individuals randomized ETBC, 70 individuals randomized to medical management who received ETBC). There were 16 nonserious device or procedure-related adverse events in 13 individuals—most commonly, epistaxis and ETD. Two individuals had three potentially device-related adverse events: mucosal tear, worsened ETD, and conductive hearing loss. The potentially device- or procedure-related adverse events were mild or moderate in severity and resolved without sequelae. Five serious adverse events were reported (four events in the BDET group, one event in the MM group); all were thought to be unrelated to device, procedure, or medication.

A 12-month follow-up on the treatment group was published by Anand (2019), which reported that the overall number of individual with normalized tympanograms and ETDQ-7 scores at one year were comparable to those reported after six weeks (71/128 vs. 73/143 and 71/124 vs. 79/142, respectively).[22] Results in the control group were not assessed.

### Nonrandomized Studies

Gurberg (2024) published a retrospective matched cohort study evaluating the long-term efficacy of tube dilation in pediatrics.[23] Thirty-three Eustachian tubes were dilated in 20

individuals, aged 14 months-14 years. All individuals had previously undergone tympanostomy tube (TT) insertion and adenoidectomy. Individuals undergoing BDET had normal post-operative tympanograms in 80 % of cases. Mean follow up was 6.7 years with 2 individuals failing in the BDET group and 8 in the TT insertion group. Dilated individuals had a significantly lower risk of failure than those who underwent TT insertion (adjusted HR: 0.18; 95 % CI: 0.04, 0.81; p = 0.03). The probability of being failure free at six years was 88 % (95 % CI: 71, 95 %) in the BDET cohort and 53 % (95 % CI: 33, 70 %) in the TT insertion cohort. There were no complications.This study is limited due to being a retrospective review, no comparators groups to standard of care, outcomes only related to risk of failure and need for additional surgery, and small sample sizes.

A retrospective chart review was published by Gurtler (2024) with a cohort of 19 individuals with 24 ears dilated (in 5 individuals subsequently after successful first intervention) and grouped as A (17) without and B (7) with additional tympanostomy tube insertion.[24] Most children suffered from either chronic otitis media with effusion or chronic perforation (12, 63%), the remainder comprising recurrent otitis media, adhesive otitis media and chronic eustachian tube dysfunction with barotrauma. Mean duration of symptoms were 7/8.2 years and mean follow-up 13.7/11.1 months. Eighty percent of individuals reported a subjective benefit. Accordingly, the *R*-value, Eustachian Tube Score (ETS), and ETS-7 were significantly ($P < .05$) improved. Tympanometry, hearing loss (CPT-AMA) and air bone gap showed a positive trend, but the result was not significant. Tympanic retraction remained largely the same; a spontaneous closure of a chronic tympanic perforation was seen in 1 of 3 cases. This study is limited due to being a retrospective chart review, no comparators groups to standard of care, small sample size, and no long term follow up.

Satmis (2018) published a retrospective cohort study of 42 consecutive adult individuals with chronic dilatory eustachian tube dysfunction. Individuals in a tertiary referral hospital setting who received transnasal balloon dilation of the Eustachian tube were evaluated. Objective outcome measures included the ETDQ-7 score, bone conduction threshold, and tympanic membrane and middle ear conditions, which were pre and postoperatively collected. Mean ETDQ-7 scores improved from 4.28 to 3.09 and from 4.10 to 2.96 postoperatively at one and three months, respectively. There was a 62.0% improvement in tympanic membrane and middle ear condition. No serious procedure related complications were reported.

## PRACTICE GUIDELINE SUMMARY

### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)

In 2019, The National Institute for Health and Care Excellence (NICE) published updated guidance on balloon dilation of the eustachian tube.[25] The guidance was based on a rapid review of the evidence and stated: "Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." 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 individuals, and there was little evidence on the benefit of repeat procedures.
- The procedure is only indicated for chronic eustachian tube dysfunction refractory to medical treatment.

**AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY FOUNDATION**

In 2019, The American Academy of Otolaryngology published a clinical consensus statement on balloon dilation of the eustachian tube.[26] The target population was defined as adults ages 18 years or older who are candidates for BDET because of obstructive eustachian tube dysfunction (ETD) in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded:

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

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

A clinical consensus statement by the American Academy of Otolaryngology-Head and Neck Surgery was published in July 2025 on eustachian tube balloon dilation in the pediatric population.[27] The consensus statement concluded that eustachian tube balloon dilatation as appropriate treatment for pediatric individuals with obstructive eustachian tube dysfunction resulting in chronic otitis media which is refractory to standard surgical interventions and considers ETBD as a proven and effective therapeutic option.

## SUMMARY

### Medically Necessary

There is enough research to show that balloon dilation of the Eustachian tube improves health outcomes in individuals with chronic signs and symptoms under certain circumstances. Additionally, clinical practice guidelines recommend the use of balloon dilation of the Eustachian tube for select individuals. Therefore, the use of balloon dilation of the Eustachian tube may be considered medically necessary for the treatment of Eustachian tube dysfunction when policy criteria are met.

### Not Medically Necessary

Due to not showing positive health outcomes for individuals who do meet individual selection criteria, the use of balloon dilation for the treatment of Eustachian tube dysfunction is considered not medically necessary when policy criteria are not met.

### Investigational

There is not enough research to show that balloon dilation of the Eustachian tube improves health outcomes for people with any other indication or for repeat balloon dilation

procedures. Therefore, balloon dilation of the Eustachian tube is considered investigational for the treatment for any other indication or repeat balloon dilation procedures.

## REFERENCES


1. Schilder AG, Bhutta MF, Butler CC, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. *Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery.* 2015;40(5):407-11. PMID: 26347263
2. Seibert JW, Danner CJ. Eustachian tube function and the middle ear. *Otolaryngol Clin North Am.* 2006;39:1221-35. PMID: 17097443
3. Katz J. *Handbook of Clinical Audiology. 5th ed.* Baltimore: Lippincott Williams & Wilkins, 2002, pp.
4. McCoul ED, Anand VK, Christos PJ. Validating the clinical assessment of eustachian tube dysfunction: The Eustachian Tube Dysfunction Questionnaire (ETDQ-7). *The Laryngoscope.* 2012;122(5):1137-41. PMID: 22374681
5. Gluth MB, McDonald DR, Weaver AL, et al. Management of eustachian tube dysfunction with nasal steroid spray: a prospective, randomized, placebo-controlled trial. *Arch Otolaryngol Head Neck Surg.* 2011;137:449-55. PMID: 21576556
6. Norman G, Llewellyn A, Harden M, et al. Systematic review of the limited evidence base for treatments of Eustachian tube dysfunction: a health technology assessment. *Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery.* 2014;39(1):6-21. PMID: 24438176
7. FDA. Food and Drug Administration. De Novo Classification Request For Acclarent Aera™ Eustachian Tube Balloon Dilation System. 2015. [cited 5/9/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/reviews/den150056.pdf.
8. (FDA) FaDA. The XprESS ENT Dilation System [cited 5/9/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf16/k163509.pdf.
9. Swords C, Smith ME, Patel A, et al. Balloon dilatation of the Eustachian tube for obstructive Eustachian tube dysfunction in adults. *Cochrane Database Syst Rev.* 2025;2(2):Cd013429. PMID: 40008607
10. Aboueisha MA, Attia AS, McCoul ED, et al. Efficacy and safety of balloon dilation of eustachian tube in children: Systematic review and meta-analysis. *Int J Pediatr Otorhinolaryngol.* 2022;154:111048. PMID: 35085875
11. Froehlich MH, Le PT, Nguyen SA, et al. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery.* 2020;163(5):870-82. PMID: 32482125
12. Huisman JML, Verdam FJ, Stegeman I, et al. Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. *The Laryngoscope.* 2018;128(1):237-47. PMID: 28799657
13. Hwang SY, Kok S, Walton J. Balloon dilation for eustachian tube dysfunction: systematic review. *J Laryngol Otol.* 2016;130 Suppl 4:S2-6. PMID: 27488333
14. Jufas N, Patel N. Transtympanic balloon dilatation of the eustachian tube: systematic review. *J Laryngol Otol.* 2016;130:425-30. PMID: 26965576

15. Randrup TS, Ovesen T. Balloon eustachian tuboplasty: a systematic review. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery.* 2015;152:383-92. PMID: 25605694
16. Gey A, Honeder C, Reiber J, et al. Tympanoplasty With Eustachian Tube Balloon Dilation for Chronic Inflammatory Middle Ear Disease: A Randomized Clinical Trial. *JAMA Otolaryngol Head Neck Surg.* 2025. PMID: 40372749
17. Joo HA, Park SM, Kim Y, et al. Balloon eustachian tuboplasty in chronic suppurative otitis media and dilatory eustachian tube dysfunction: a randomized controlled trial. *Clin Exp Otorhinolaryngol.* 2025. PMID: 39901665
18. Kjær Krogshede S, Kirchmann M, Peter Schjellerup Jørkov A, et al. Balloon Dilation of the Eustachian Tube: A Randomized Controlled Trial with 6 Months Follow-Up. *J Int Adv Otol.* 2022;18(6):501-06. PMID: 36349672
19. 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. *Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology.* 2018;39(7):894-902. PMID: 29912819
20. Cutler JL, Meyer TA, Nguyen SA, et al. Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. *Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology.* 2019;40(10):1322-25. PMID: 31385858
21. Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. *The Laryngoscope.* 2017. PMID: 28940574
22. 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. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery.* 2019;160(4):687-94. PMID: 30620688
23. Gurberg J, Dean M, Kawai K, et al. Long-term efficacy of balloon dilation of the pediatric Eustachian tube: A six-year matched cohort study. *Am J Otolaryngol.* 2024;45(3):104208. PMID: 38154198
24. Gürtler N, Honegger F. Eustachian Tube Balloon Dilation in Children: Short- and Long-Term Outcome. *Ann Otol Rhinol Laryngol.* 2024;133(4):369-74. PMID: 38197378
25. Excellence NIfHaC. Balloon Dilation for Chronic Eustachian Tube Dysfunction. [cited 5/9/2026]. 'Available from:' https://www.nice.org.uk/guidance/ipg665.
26. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery.* 2019;161(1):6-17. PMID: 31161864
27. Surgery AAoO-HaN. Eustachian Tube Balloon Dilation in the Pediatric Population. 2025. PMID:

## CODES

| Codes | Number | Description |
|---|---|---|
| CPT | 69705 | Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral |
| | 69706 | Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral |

| Codes | Number | Description |
|---|---|---|
| | 69799 | Unlisted procedure, middle ear |
| HCPCS | None | |

***Date of Origin:*** *June 2017*