Anthem

Clinical UM Guideline

Subject: Balloon Dilation of the Eustachian Tubes
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Description

This document addresses the use of balloon dilation of the Eustachian tubes (BDET), also known as balloon dilatation Eustachian tuboplasty. Balloon dilation of the Eustachian tubes is an endoscopic procedure that usually approaches the Eustachian tubes trans-nasally to expand and stretch the Eustachian tube using a balloon catheter. It is proposed to relieve chronic ear congestion and middle ear and mastoid infections.

Note: Please see the following related document(s):

- CG-SURG-46 Myringotomy and Tympanostomy Tube Insertion
- CG-SURG-73 Balloon Sinus Ostial Dilation

Clinical Indications

Medically Necessary:

A single treatment of unilateral or bilateral balloon dilation of the Eustachian tubes via nasal endoscopy is considered **medically necessary** when **all** the following criteria are met for the ear(s) to be treated (A, B, C, D, and E):

A. The individual is 18 years of age or older; **and**
B. The individual's history and physical exam include **all** the following (1, 2, 3, and 4):
    1. Eustachian tube dysfunction:
        i. Has been present for 3 months or more; **and**
        ii. Persists despite medical therapy of any associated conditions (if present) such as allergic rhinitis, rhinosinusitis, or laryngopharyngeal reflux; **and**
    2. Otoscopic examination shows either of the following (i or ii):
        i. Persistent otitis media with effusion; **or**
        ii. Tympanic membrane retraction; **and**
    3. Nasal endoscopic examination does not show physical obstruction of the Eustachian tube; **and**
    4. Either of the following (i or ii):
        i. Abnormal tympanogram tracings (Type B or C); **or**
        ii. Symptoms consistent with baro-challenge induced Eustachian tube dysfunction (that is: recurrent aural fullness, popping, or pain that reproducibly occurs with changes in pressure); **and**
C. If history includes placement of tympanostomy tube(s), demonstrated improvement of obstructive Eustachian tube symptoms while the tube(s) were in place; **and**
D. No history of previous balloon dilation of the Eustachian tubes; **and**
E. No contraindication for balloon dilation, for example:
    1. Carotid abnormalities in the skull base; **or**
    2. Nasopharyngeal or skull base neoplasm; **or**
    3. Patulous Eustachian tube.

Not Medically Necessary:

Balloon dilation of the Eustachian tubes is considered **not medically necessary** when the criteria above are not met, and for all other indications.

Repeat balloon dilation of the Eustachian tube is **not medically necessary** for all indications.

Trans-tympanic balloon dilatation of the Eustachian tube is **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services may be Medically Necessary when criteria are met:

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

ICD-10 Diagnosis	
H65.20-H65.499	Chronic nonsuppurative otitis media
H66.10-H66.3X9	Chronic suppurative otitis media
H66.90-H66.93	Otitis media, unspecified
H68.001-H68.029	Eustachian tube salpingitis
H68.101-H68.109	Unspecified obstruction of Eustachian tube
H69.80-H69.83	Other specified disorders of Eustachian tube
H69.90-H69.93	Unspecified Eustachian tube disorder

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for all other diagnoses not listed, or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

The diagnosis of Eustachian tube dysfunction is considered for individuals with symptoms due to difficulty in equalizing pressure between the middle ear and the environment. Typical symptoms include aural fullness, aural pressure, hearing loss, and ear pain. Eustachian tube dysfunction (ETD) occurs in 2 main forms: obstructive dysfunction and patulous dysfunction. Obstructive dysfunction can result from inflammation of nasopharyngeal mucosae due to infection, allergy, or laryngopharyngeal or gastroesophageal reflux. Less common causes of obstructive dysfunction include mechanical obstruction due to hypertrophy of the adenoids, nasopharyngeal tumors, or scarring or deformity due to trauma. Patulous dysfunction is less common than obstructive dysfunction. The term patulous describes a condition in which the Eustachian tube is chronically patent. Symptoms suggesting patulous dysfunction include loudly hearing one's own voice or an echo of one's own voice (autophony), audible respirations, pulsatile tinnitus, and/or aural fullness (Tucci, 2019). BDET is contraindicated for patulous Eustachian tube dysfunction (Tucci, 2019).

Based on estimates from surveys administered between 2001-2012 (Oehlandt, 2022; Shan, 2019), Eustachian tube dysfunction affects 4-5% of adults. Medical management is frequently used for treatment of associated conditions, but success rates are limited. Established surgical approaches include myringotomy (creating a hole in the eardrum) and tympanostomy (small tubes implanted through a hole in the ear drum). (Tucci, 2019).

In 2019, the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) published a set of consensus statements regarding the use of BDET (Tucci, 2019). The published consensus statements were reached through a Delphi survey method involving a panel representing a variety of medical specialty societies. The target population for the statements was defined as adults 18 years of age or older who had symptoms for 3 months or longer that significantly affects their quality of life or functional health status. The panel reached consensus on the following 18 statements regarding selection of patients for BDET:

1. A comprehensive history and physical exam, including otoscopy, are essential parts of the diagnostic evaluation of a candidate for BDET.
2. Nasal endoscopy is an essential part of the diagnostic evaluation prior to BDET.
3. BDET is contraindicated for patients diagnosed as having a patulous ETD.
4. Nasal endoscopy in patients who are candidates for BDET is necessary for assessing the ET lumen and assessing the feasibility of transnasal access to the nasopharynx.
5. A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
6. The benefit of repeat BDET after a prior ineffective BDET has not been determined.
7. Symptoms of obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia.
8. Tympanometry is an essential part of the diagnostic evaluation prior to BDET. 8.50 0
9. Establishing a diagnosis of obstructive ETD requires ruling out other causes of aural fullness such as patulous ETD, temporomandibular joint disorders, extrinsic obstruction of the ET, superior semicircular canal dehiscence, and endolymphatic hydrops.
10. Patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD.
11. Nasal endoscopy is necessary to rule out extrinsic causes of ETD.
12. Comprehensive audiometry is an essential part of the diagnostic evaluation prior to BDET.
13. BDET is appropriate in patients with obstructive ETD who have failed medical therapy for identified treatable causes.
14. Common causes of obstructive ETD that benefit from identification and management are allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.
15. Medical management of known pathology that could affect nasal or ET function is appropriate to perform prior to BDET.
16. Patients with a history of recurrent baro-challenge, defined as uncomfortable pressure in the ear upon exposure to ambient pressure changes that cannot be easily relieved, may improve following BDET.
17. There is no scientifically proven or standard medical therapy for ETD.
18. Pneumatic otoscopy can identify negative pressure in the middle ear space and can differentiate between adhesive and non-adhesive retractions of the tympanic membrane.

BDET is an endoscopic procedure proposed to relieve chronic ear congestion and middle ear and mastoid infections. In 2016, the US Food and Drug Administration (FDA) approved AERA® Eustachian Tube Balloon Dilation System for adults 22 years and older. The FDA approved the XprESS® ENT Dilation System in 2017 for adults 18 years and older. The Next Generation Balloon Dilation System was approved by the FDA in 2020 for use with adults 18 years and older. Each device uses an endoscopically directed balloon to dilate the Eustachian tube. During the procedure, an endoscopic balloon catheter is inserted trans-nasally to expand and stretch the Eustachian tube.

There have been several case studies and a handful of randomized controlled trials (RCTs) addressing BDET. In 2018, Poe and colleagues reported the results of a pivotal trial (AERA® Eustachian Tube Balloon Dilation System). This trial included 323 participants (462 ears) 22 years and older with persistent (12 weeks or more) Eustachian tube dilatory dysfunction that was refractory to medical management that included either a 4-week course of nasal steroids or a course of oral steroid therapy in the previous 12 months. A pool of 81 participants were treated as a lead-in population to acclimate the investigators to the study procedure. The remaining participants were randomized in a 2:1 manner to undergo treatment with BDET with concurrent medical management (n=162, with 100 [61.7%] completing study) or continued medical management (n=80, with 71 [88.8%] completing the study). The condition was confirmed by tympanometry, the Eustachian Tube Dysfunction Questionnaire-7 symptom scoring tool (ETDQ-7) and nasal endoscopy. Participants were allowed to continue concomitant use of other medications to treat sinus or nasal conditions when deemed to be medically necessary. Follow-up continued to 24 weeks. Continuation of medical therapy was at the discretion of the investigator. After 6 weeks, control participants were permitted to cross over to the BDET group and followed through 12 weeks. A majority of participants in the control arm completed the 6-week follow-up and then crossed over to the BDET group before the 12-week follow-up (82%, 59/71). At the 6-week follow-up, significantly more BDET group participants had normal tympanograms (51.8% vs. 13.9%, $p<0.0001$). ETDQ-7 improvement was significantly greater in the BDET group compared to controls at 6 weeks (56.2% vs. 8.5%, $p<0.001$). Worsening of tympanograms was noted in 4% of BDET participants and 5.7% of controls (no p-value provided). The number of participants with a positive modified Valsalva maneuver was better in the BDET group vs. controls at 6 weeks (32.8% vs. 3.1%). No device- or procedure-related serious adverse events were reported. At 24 weeks, tympanogram normalization was 62.2% in the BDET group. Only 9 of the original 81 control group members remained in the study at the 24 weeks follow-up and no comparison to the controls was possible at that time point. Only 100 of the 149 participants (67.1%) in the original BDET arm remained in the study at the 12-weeks follow-up. The high rate of attrition makes it possible that the outcomes for these missing group members, if known, could have affected the results of the study. Neither the participants nor their treating providers were blinded to the study's intervention. Medication use was permitted at the discretion of the treating provider. The study did not report or analyze

the medication use of study participants. Potential between-group differences in medication use introduces the possibility that performance bias confounded the results. Due to significant attrition in the control arm, this study was essentially uncontrolled after the 6-weeks follow-up. The 6-weeks outcomes did show significantly more tympanogram normalization in the BDET group. This improvement appeared to persist through the 24-weeks follow-up.

In 2019, Anand and colleagues published the results of a 52-week continuation of the Poe study detailed above. This trial included outcomes for 136 participants in the BDET group, 73 control participants, and 74 of the lead-in period participants. Out of the 73 control original participants, 70 (95.9%) received BDET after their 6-week follow-up. At 52 weeks, the authors reported that the number of BDET-group participants maintaining normalized tympanograms and normalized ETDQ-7 scores remained unchanged from the 6-week time point (tympanograms: 51.0% vs. 55.5%, ETDQ-7 scores: 57% vs. 63.6%). No device-related adverse events were reported. The authors acknowledge that, due to high attrition in the control group, no meaningful comparison between the BDET and control groups could be made after the 6-weeks follow-up. For this cohort of treated individuals, the study shows that the observed 6-weeks improvement in tympanograms and ETDQ-7 scores were sustained at the 52-week follow-up.

In 2016, Dalchow and colleagues reported the results of a prospective case series involving 202 participants (342 dilations). The authors computed a “tube score” consisting of the tympanogram type (A, B, or C) and the latency time for Eustachian tube opening during tubomanometry (R value). The R score indicates whether Eustachian tube opening is normal (R < 1), delayed (R > 1), or absent (R near 0). The tube score was used to evaluate pre- and postoperative tube function. All participants underwent follow-up with postoperative assessments at 1 month (n=175, 86.6%), 3 months (n=92, 45.5%), 9 months (n=29, 14.4%) and 12 months (n=19, 9.4%). The mean pre-treatment tube score was 2.23 ± 1.147 and was reported to have significantly improved to 2.68 ± 1.011 at 1 year (no p-value provided). Although these data show that BDET led to improvement of the R score at 1 month, the very high attrition rate confounds interpretation of results beyond that time.

In 2017, Skevas and colleagues published the results of a multi-center analysis assessing cervicofacial and mediastinal emphysema involving 3670 procedures in 2272 participants treated with BDET at four centers across Europe. The ages ranged from 2 to 83 years. Postoperative emphysema developed in 7 participants, limited to parotid region cheek and soft and hard palate. Another 3 developed emphysema of the soft tissues associated with pneumomediastinum. The overall complication rate involving pneumomediastinum was reported as 0.27%. None of the participants experienced serious clinical signs or symptoms beyond cutaneous crepitations. After treatment with antibiotic prophylaxis and abstinence from Valsalva maneuver all 10 participants achieved complete resolution and recovery of the emphysema within 2-6 postoperative days.

In 2018, Meyer and colleagues reported the results of a pivotal RCT (XprESS® ENT Dilation System) involving 60 participants 18 and older with persistent (diagnosed at least 12 months prior) Eustachian tube dysfunction undergoing treatment with either balloon dilation (n=31) or medical therapy (n=29). Eligible participants had all received treatment with either a 4-week course of nasal steroids or a course of oral steroid therapy in the previous 12 months. Participants were followed for 1 year, but control participants had the option to undergo balloon dilation after their 6-week follow-up if their symptoms persisted. This crossover occurred in 23 of the 29 control group participants (79.3 %). The 6 control group participants who continued medical management were no longer included in the study. The crossover cohort underwent balloon dilation treatment and continued through the remainder of the trial. This resulted in 49 total participants whose outcomes were reported at 12 months. No adverse events were reported in either group. At the 6-week follow-up, among participants with abnormal baseline assessments, there was significantly more improvement in the tympanogram type ($p<0.006$) and in tympanic membrane position ($p<0.001$) among the balloon dilation group participants compared to the control group participants. The mean overall EDTQ-7 score improvement at 6 weeks was -2.9 ± 1.4 for the balloon dilation group and -0.6 ± 1.0 for the control group. The authors reported that technical success was 100% (91 successful dilations/91 attempts). Most procedures (72%) were completed in the office under local anesthesia. Improvements in the ETDQ-7 scores were maintained through 12 months after balloon dilation. Although these 12-month results are encouraging, the elimination of the control group after the 6-week follow-up prevents comparison of long-term outcomes for BDET and medical treatment.

In 2019, Cutler and colleagues published the results of a follow-up study of the experimental arm of the trial reported by Meyer et al. in 2019. Out of the 49 participants completing the initial 12-month study, 47 were included in this follow-up study. The mean follow-up for all participants was 29.4 months (range 18-42 months). Overall, ETDQ-7 scores were significantly reduced from a mean of 4.5 at baseline to 2.0 at last measured timepoint ($p<0.0001$). Additionally, each individual component of the ETDQ-7 tool was likewise significantly improved ($p<0.0001$ for all). Only 1 participant underwent repeat dilation procedure concurrently with FESS for rhinosinusitis. The ability to clear the ears with the Valsalva maneuver increased from 28.3% to 73.9% ($p<0.0001$). Type A tympanograms also increased from 70% to 86.3% ($p=0.005$). In participants with abnormal middle ear assessments at baseline, tympanic membrane position was normalized in 76% ($p<0.0001$), Valsalva maneuver response was positive ($p<0.0001$), and normalization of tympanograms occurred in 62.5% ($p<0.001$). These results show that BDET is associated with significant long-term improvements in several patient-centered outcomes. As with the underlying Meyer study, the early elimination of the control group prevents comparison of these results with the outcomes for medical treatment.

In 2019, Si and colleagues conducted a double-blind RCT involving 120 participants aged 15-75 with adhesive otitis media (adOM) who were assigned to one of four groups: 1) conservative therapy, 2) BDET, 3) cartilage tympanoplasty, or 4) combined BDET and cartilage tympanoplasty. The authors did not describe prior treatments given to study participants. There were 30 participants in each group and the follow-up period was 2 years. All participants had baseline hearing loss. No significant pretreatment differences were noted between the tympanoplasty alone and combined groups. Both the tympanoplasty alone and combined groups had significant improvements in air-bone gap compared to controls ($p<0.1$), but no differences were found between these two groups. The BDET-alone group did not have a significant reduction in their mean air-bone gap. All three surgical groups had significant improvements in the Tinnitus Handicap Inventory (THI) compared to the control group ($p<0.05$). Results from the Chronic Otitis Media Outcome Score-15 (COMOT-15) indicated significant improvements in all surgical groups ($p<0.05$). Eustachian tube scores (ETS) improved in both the BDET-only and combined groups compared to controls and compared to tympanoplasty alone ($p<0.05$ for both). Two participants in the BDET-alone group reported patulous Eustachian tube post-operatively which resolved spontaneously within 1 year. This study showed that, for this group of individuals with adOM as compared to controls, BDET did not significantly improve hearing loss but was associated with greater improvement in Eustachian tube score, THI, visual analog score of ear stuffiness, and COMOT-15.

In 2020, Chen and colleagues reported the results of a retrospective non-randomized controlled trial involving 50 participants aged 4-14 years with otitis media with effusion. Participants who received myringotomy and tympanostomy tube placement in conjunction with Eustachian tube dilation (n=25) were compared those who received myringotomy and tympanostomy tube placement only (n=25). The method of selecting participants for the study was not explained. The authors did not specify what, if any, prior treatments were given to participants. Adenoidectomy was conducted in participants found to have adenoid hypertrophy (n=16 in the balloon group and n=17 in the control group). The authors reported a statistically significant difference in air-bone gap between the two groups at 18 months, with mean differences of the balloon group lower (about 4 dB HL) vs. the control group ($p=0.05$). At 18 months the cure rate was 76.1 % for the balloon group vs. 60.9% in the controls ($p=0.116$), and total effective rates were 93.5% and 89.1%, respectively ($p=0.71$). No serious adverse events or complications were reported. While significant improvements in air-bone gap measurements at 18 months were reported, differences in cure rate and total effective rates were not.

In 2020, Froehlich and colleagues published a systematic review and meta-analysis on the safety and efficacy of BDET in adults. The review included RCTs, prospective and retrospective studies. Twelve studies comprised of 448 participants met inclusion criteria for meta-analysis. At 6 weeks, mean ETDQ-7 scores decreased by 2.13 from (95% confidence interval [CI], -3.02 to -1.24; p<0.001) and 53.0% of study participants demonstrated improvement in tympanograms (p<0.001). At the longest follow-up (3-12 months), 50.5% of individuals had improved tympanograms from baseline (p<0.001); no significant difference was demonstrated in tympanogram results at 6 weeks compared to long term (p=0.535). The percent of normal otoscopy exams increased by 30.0% from baseline to 6 weeks (p<0.001) and further improved to 55.4% over the long-term (p<0.001). There was a 67.8% increase in the proportion of study participants able to perform a Valsalva maneuver in the long term compared to baseline (p<0.001). The authors concluded that Eustachian tube balloon dilation appears to be associated with improvement in subjective and objective outcomes and that this improvement appears stable at 3 to 12 months after dilation.

In 2021, Cheng and colleagues published results from a retrospective cohort of Australians who underwent BDET. Outcomes for 96 eustachian tube dilation operations performed on 62 study participants were reported. After a mean follow-up of 10 months, the cohort demonstrated a mean EDTQ-7 score improvement from 4.7 to 2.9 (p<0.01); improvement was achieved in 83.9% of individuals. Virtually 100% of the baro-challenge-induced subgroup achieved improvement in ETDQ-7 score and complete resolution of symptoms (ETDQ <2.1) was realized in 37.1% of the study cohort. No adverse safety events were reported.

In 2021, Toivonen and colleagues published results of a study to determine the safety and efficacy of BDET in children. The study involved 26 participants (46 Eustachian tubes). Participants ranged in age from 7 to 17 years. All participants underwent BDET. The study indicated that all participants also had adjunctive procedures at the time of BDET. The authors noted significant improvement in middle ear function following BDET. Tympanograms improved to type A in 50% at 6 months, 59% at 12 months, and 85% at 36 months. Mean scores of mucosal inflammation declined from 3.2 (± 0.6) preoperatively to 2.5 (± 0.7) at 6 months and 1.7 (± 0.6) at 36 months postoperatively.

In 2022, Aboueisha and colleagues published a systematic review and meta-analysis on the safety and efficacy of BDET in children and adolescents (18 and under). Seven articles fit comprised of 408 children met inclusion criteria. The mean age of study participants was 10 years old and the mean follow-up was 19.2 months. Following BDET, the percentage of abnormal tympanograms (Type B) decreased from 64.2% (95% CI, 53.3-73.8) to 16.1% (95% CI, 8.5-28.4) and air-bone gap decreased 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 following BDET was 5.1% (95% CI, 3.2-8.1), the majority of which were epistaxis; no major adverse events reported. Three of the studies included in the analysis compared BDET to Eustachian tube insertion; post-operative ABG decreased significantly more in the BDET group (mean difference -6.4 dB; 95% CI, -9.8, -3.1; p=0.002). Prospective randomized trials including children and adolescents are warranted.

In 2022, Yang and colleagues sought to retrospectively identify clinical predictors of treatment response to BDET based on ETDQ-7 scores in 113 individuals who underwent the procedure. After a mean follow-up period of 13 months, 77% experienced > 0.5 point improvement in the ETDQ-7; 37% of the participants' score normalized (ETDQ < 2.1). A higher pre-operative ETDQ-7 and history of chronic rhinosinusitis or chronic otitis media predicted were significantly associated with and increased odds of ETDQ-7 score improvement.

The RCTs, cohort studies, meta-analysis and expert consensus described above show that a single BDET can be associated with significant improvement in objective and subjective outcomes. There is insufficient evidence to assess the benefits of repeated BDET procedures or trans-tympanic BDET.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion and References sections.
New	02/16/2023	MPTAC review. Initial document development. Moved content of SURG.00151 to new clinical utilization management guideline document with the same title.
