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Balloon Dilation of the Eustachian Tube

Audience
Providers, Members, Brokers, MHC

Purpose

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Definition

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

Policy/Procedure

1. Mountain Health Co-Op Health Plans covers balloon dilation of the eustachian tube (BDET) when medical necessity criteria are met.

2. Coverage Criteria for BDET for treatment of chronic obstructive Eustachian tube dysfunction may be considered medically necessary when ALL of the following criteria are met (2.1-2.7):
   - **2.1** Patient is 18 years and older;
   - **2.2** Patient has chronic signs and symptoms of obstructive eustachian tube dysfunction that impairs function and meets ALL of the following Criteria (i-iii):
     - **a)** Symptoms have occurred for at least 12 months, including but not limited to aural fullness, aural pressure, otalgia, or hearing loss;
     - **b)** 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 excluded by appropriate studies/imaging;
     - **c)** Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to baro-challenge such as pressure changes while flying);
   - **2.3** ETDQ-7* is greater than 2.1 (take the score and divide by 7) after medical management;
   - **2.4** The patient has undergone a comprehensive diagnostic assessment documenting ALL of the following findings:
     - **a.** Abnormal tympanogram (Type B or C)~, and
     - **b.** Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam).
   - **2.5** Failure to respond to appropriate medical management of co-occurring conditions, including six weeks of a nasal steroid spray, decongestants, and topical/systemic antihistamines. Co-occurring conditions include but are not limited to allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.
   - **2.6** If the patient had a history of tympanostomy tube placement, obstructive eustachian tube dysfunction symptoms should have improved while the tubes were patent.
   - **2.7** Patient does not have one of the following contraindications
     - **a)** Presence of patulous eustachian tube dysfunction (ETD)#
     - **b)** Individuals with aural fullness but normal exam and tympanogram
     - **c)** Individuals with aural fullness but normal exam and tympanogram
     - **d)** Individuals with extrinsic reversible or irreversible causes of ETD including but not limited to:
       - **i.** Craniofacial syndromes, including cleft palate spectrum;
       - **ii.** Neoplasms causing extrinsic obstruction of the eustachian tube;
       - **iii.** History of radiation therapy to the nasopharynx;
       - **iv.** Enlarged adenoid pads;
       - **v.** Nasopharyngeal mass;
       - **vi.** Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening;

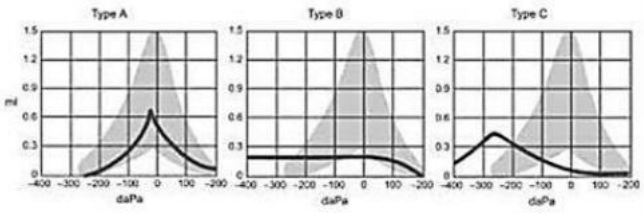
vii. Systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g., Samter's triad, Wegener's disease, mucosal pemphigus) that is ongoing/active (i.e., not in remission).

 # A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and aural fullness.

** The Eustachian Tube Dysfunction Questionnaire–7 (ETDQ-7)*

Over the past 1 month, how much has each of the following been a problem for you?	No Problem		Moderate Problem			Severe Problem	
1. Pressure in the ears?	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Crackling or popping sounds in the ears?	1	2	3	4	5	6	7
6. Ringing in the ears.	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled.	1	2	3	4	5	6	7

~ Tympanogram and categorized as Type A, B, or C. Type A refers to eardrum movement within normal limits. Type B indicates little or no eardrum movement, suggesting fluid in the middle ear space. A child with this type of tympanogram needs medical attention. Type C refers to a middle ear with negative pressure.



BDET is not covered and considered investigational for all other circumstances
Repeat BDET is considered investigational as current evidence is insufficient to determine efficacy and safety.

3. Clinical Rationale

3.1 The National Institute for Health and Care Excellence (NICE) published an updated guidance on Balloon Dilation of the Eustachian Tube (BDET) in 2019. 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 there is enough evidence for doctors to consider the procedure an option. The guidance also noted that the procedure was ineffective in all patients, and there was little evidence of the benefit of repeat procedures, along with the procedure they only indicated for chronic eustachian tube dysfunction (ETD) refractory to medical treatment.

3.2 The American Academy of Otolaryngology published a clinical consensus statement on BDET in 2019 (Tucci et al). The target population was defined as adults ages 18 years or older who are candidates for BDET because of obstructive ETD in 1 or both ears for three months or longer that significantly affects their quality of life or functional health status. The expert panel concluded that BDET is an option for the treatment of individuals with obstructive ETD. However, the diagnosis of obstructive ETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy. Furthermore, BDET is contraindicated for individuals diagnosed as having a patulous ETD, and additional studies will be needed to refine individual selection and outcome assessment. The authors stressed the importance of identifying other potentially treatable causes of ETD, including allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, and that medical management of these disorders is indicated before 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 the need for additional procedures.

3.3 Eustachian tube dysfunction (ETD) is a disorder for which symptoms are commonly treated with oral medications, nasal sprays, and placement of ear tubes. Recently, Eustachian tube balloon dilation has been proposed as a potential solution. Hwang et al., 2016 performed a systematic literature review. Abstracts were selected for relevance, and pooled data analysis and qualitative analysis were conducted. Nine prospective studies describing 713 Eustachian tube balloon dilations in 474 patients (aged 18 to 86 years) were identified. Follow-up duration ranged from 1.5 to 18 months. The ability to perform a Valsalva maneuver improved from 20 to 177 out of 245 ears following Eustachian tube balloon dilation, where data were reported in terms of patient numbers, from 15 to 189 out of 210 patients. Tympanograms were classified as type A in 7 out of 141 pre-operatively and 86 out of 141 years post-operatively. The authors concluded that prospective case series can confirm the safety of Eustachian tube balloon dilation. As a potential solution for chronic Eustachian tube dysfunction, further investigations are needed to establish higher evidence of efficacy.

3.4 Additional studies have attempted to determine the safety and effectiveness of Eustachian tube balloon dilation for treating Eustachian tube dysfunction. Studies include a 2015 retrospective cohort study by Gurtler et al., a 2015 retrospective analysis by Maier et al., a 2015 meta-analysis, and a systematic review by Randrup, Ovesen, et al. All studies concluded balloon tube dilation showed promise and appeared to have some efficacy level, but further study was necessary to identify long-term efficacy and define the definitive value of the procedure. Several of these studies concluded that additional randomized, controlled trials were required as much of the evidence is retrospective cohort reviews.

3.5 In a 2015 publication, the Food and Drug Administration (FDA) summarizes more adverse events. Two hundred ninety-nine patients treated with ETBC were included in the safety analysis (80 leading patients, 149 patients randomized to ETBC, and 70 patients randomized to medical management who received ETBC). There were 16 non-serious device or procedure-related adverse events in 13 patients, most commonly epistaxis and ETD. Two patients had three potentially device-related

adverse events: mucosal tear worsened ETD and conductive hearing loss. The potential device- or procedure-related adverse events were mild or moderate in severity and resolved without sequelae. Five serious adverse events were reported (4 events in the BDET group and one event in the medical management group); all were thought to be unrelated to the device, procedure, or medications.

3.6 More recent reviews include a systematic literature search by Huisman et al., 2018 and Hayes, 2017, and systematic reviews on the Bielefeld and the Acclarent Eustachian tube balloon dilation procedures. The Huisman review was based on title and abstracts and resulted in 36 articles included in the review. These articles were screened as full text, and 15 were eligible for critical appraisal. Data were extracted from selected studies and presented. A meta-analysis was conducted for four subgroups. 1,155 patients were treated with balloon dilation of the tuba auditiva. Outcome parameters were relief of symptoms, otoscopy, Valsalva maneuver or Toynbee test, audiometry, tympanometry, Eustachian tube dysfunction classification, and Eustachian tube score. All articles showed short-term improvement of original symptoms; some showed further improvement over time. Follow-up ranged from just after therapy to 50 months. Relatively mild and self-limiting complications were described in 36 patients. All current studies suggest that balloon dilation of the Eustachian tube can be a helpful treatment in patients with Eustachian tube dysfunction. However, placebo-controlled trials are still warranted.

3.7 The 2017 Hayes reviews similarly concluded that unanswered questions regarding the effectiveness of this therapy remain. In the case of the Bielefeld catheter system, the efficacy of ETBD does not allow for definitive conclusions due to a very low-quality body of evidence provided by one randomized controlled trial and several single-arm observational studies with substantial limitations. Similarly, the efficacy of ETBD in the Acclarent system did not allow for definitive conclusions either by small single-arm observational studies.

3.8 According to a 2018 systematic review (Luukkainen et al.), Balloon Eustachian tube dilation is a promising and novel treatment for patients with chronic Eustachian tube dysfunction resulting in chronic ear disease. The long-term follow-up studies were heterogeneous regarding the Eustachian tube dysfunction (ETD) definition, patient selection, follow-up duration, additional treatments, and outcome measures. The current but limited evidence suggests that BET is effective in the long term. However, more long-term studies with uniform criteria and outcome measures and placebo-controlled studies are needed. Currently, the data is limited by small prospective and extensive retrospective studies. Large prospective trials with higher evidence levels are required to show efficacy.

3.9 A 2020 systematic review identified 35 studies (Froehlich et al.). Twelve studies met inclusion for meta-analysis (448 patients). Mean ETDQ7 scores decreased by 2.13 from baseline to 6 weeks (95% CI, –3.02 to −1.24; $P < .001$). From baseline to 6 weeks, 53.0% of patients had improvement in tympanograms ($P < .001$). At the long-term point (3-12 months), 50.5% of patients had improved tympanograms from baseline ($P < .001$). There was no significant difference in the proportion of improved tympanograms at six weeks compared to the long term ($P = .535$). Normal otoscopy exams at baseline increased by 30.0% at six weeks ($P < .001$) and 55.4% in

the long term (P < .001). There was a 67.8% increase in the proportion of patients able to perform a Valsalva maneuver in the long term compared to baseline (P < .001). The author concluded that BDET appears to be associated with improved subjective and objective treatment outcome metrics. The improvement seems stable at 3 to 12 months after dilation. Patients with ETD are likely to benefit from balloon dilation, particularly those with medication-refractory disease. This study demonstrates that balloon eustachian tube dilation can be considered when all other treatments, including tympanostomy tube placement, have failed.

3.10 Countering some of the evidence conclusions, Hayes (2022) recently updated a review on Eustachian tube balloon dilation (ETBD) for the treatment of adults with chronic Eustachian tube dysfunction (ETD) refractory to medical management (MM). Eleven studies met the criteria: 4 RTCs, five pre/post studies, one case-control, and one retrospective comparative study. No significant safety concerns related to ETBD were found. The authors concluded that "the body of low-quality evidence suggests that patients with ETD treated with ETBD experience symptom relief and improved function compared with pretreatment assessments. In addition, ETBD appears to be comparable to or better than standard care; however, additional studies are needed to confirm these conclusions. The reviewed evidence also suggests that ETBD may be safe. However, this review identified only a few studies comparing ETBD with other treatments; therefore, no conclusions can be made regarding the relative efficacy and safety of ETBD with other treatments."

3.11 Also, in 2022, UpToDate revised their review on "Eustachian tube dysfunction" (Poe, Hanna, et al) and stated that the American Academy of Otolaryngology-Head and Neck Surgery Clinical Consensus Statement states that BDET is indicated for chronic obstructive eustachian tube (ET) dysfunction (i.e., ≥ three months) with type B (flat) or C (negative pressure) tympanogram. However, there is an exception if symptoms only occur under the baro-challenge since these patients may have normal tympanometry results on testing. These patients will typically have a history of significant pain with or sequelae from the baro-challenge. The authors noted that surgical intervention, which includes tympanostomy tubes and balloon dilation of the ET, is generally indicated when medical management of obstructive ET dysfunction is unsuccessful. However, and most importantly, if a patient has had a tympanostomy tube but it did not help relieve their symptoms, it is probable that there is a diagnosis other than obstructive ET dysfunction, and BDET is not indicated.

Applicable Coding

CPT Codes

69705	Nasopharyngoscopy, surgical, with dilation of the eustachian tube (i.e., balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of the eustachian tube (i.e., balloon dilation); bilateral

HCPCS Codes

No applicable codes

Vendors

- **Personify**
- **HPS**

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Review/Revision/Approval History	
Date	Description
06/2024	**New Policy**
3/9/2026	**Revised by Mountain Health CO-OP Policy Committee**

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