Balloon Dilation of the Eustachian Tube

Policy MP-005

Origination Date: 06/25/2018

Reviewed/Revised Date: 03/20/2024

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Current Effective Date: 05/20/2024

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

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.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans covers balloon dilation of the eustachian tube (BDET) when medical necessity criteria are met.

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 (A-G):

A. Patient is 18 years and older;

B. Patient has chronic signs and symptoms of obstructive eustachian tube dysfunction that impairs function and meets ALL of the following Criteria (i-iii):

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

ii. 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;

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

C. ETDQ-7* is greater than 2.1 (take the score and divide by 7) after a minimum 6 weeks of medical management;

D. The patient has undergone a comprehensive diagnostic assessment documenting ALL of the following findings:

i. Abnormal tympanogram (Type B or C)~, and

ii. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam).

E. Failure to respond to appropriate medical management of co-occurring conditions, including 6 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.

F. If the patient had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent.

G. Patient does not have one of the following contraindications

i. Presence of patulous eustachian tube dysfunction (ETD)#

ii. Individuals with aural fullness but normal exam and tympanogram

iii. Individuals with chronic and severe atelectatic ears

iv. Chronic tympanic membrane perforation

v. TMJ Disorder

vi. Individuals with extrinsic reversible or irreversible causes of ETD including but not limited to:

a. Craniofacial syndromes, including cleft palate spectrum;

b. Neoplasms causing extrinsic obstruction of the eustachian tube;

c. History of radiation therapy to the nasopharynx;

d. Enlarged adenoid pads;

e. Nasopharyngeal mass;

f. Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening;

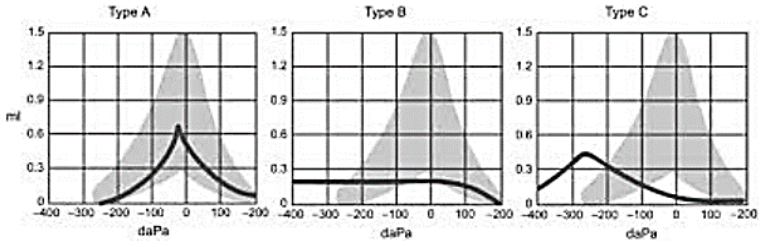
g. Systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g. Samter's triad, Wegener's disease, mucosal pemphigus) that is ongoing/active (i.e. not in remission).

[#] A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or 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 either a 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.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

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 that there is enough evidence for doctors to consider the procedure as an option. The guidance also noted that the procedure was not effective in all patients, and there was little evidence on the benefit of repeat procedures. Along with the procedure only indicated for chronic eustachian tube dysfunction (ETD) refractory to medical treatment.

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 3 months or longer that significantly affects their quality of life or functional health status. The expert panel concluded that BDET is an option for 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 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.

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 was conducted. A total of 9 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. Ability to perform a Valsalva maneuver improved from 20 to 177 out of 245 ears following Eustachian tube balloon dilation and, 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 ears pre-operatively and in 86 out of 141 ears 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 a higher level of evidence of efficacy.

Additional studies have attempted to determine the safety and effectiveness of Eustachian tube balloon dilation for treatment of 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 systematic review by Randrup, Ovesen et al. All studies concluded balloon tube dilation showed promise and appeared to have some level of efficacy but felt further study 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 necessary as much of the evidence is retrospective cohort reviews.

In 2015 publication, the Food and Drug Administration (FDA) summarizes more adverse events. Two-hundred ninety-nine patients who were treated with ETBC were included in the safety analysis (80 lead-in patients, 149 patients randomized ETBC, 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 3 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, 1 event in the medical management group); all were thought to be unrelated to device, procedure, or medications.

More recent reviews include a systematic literature search by Huisman, et al, 2018 and Hayes, 2017, systematic reviews on both 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, 15 of them were eligible for critical appraisal. Data were extracted from selected studies and presented. A meta-analysis was conducted for four subgroups. A total of 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.

The 2017 Hayes reviews similarly concluded there remained unanswered questions regarding the effectiveness of this therapy. 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 a number of 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.

According to a 2018 systematic review (Luukkainen et. al) Balloon Eustachian tube dilation is a promising and novel treatment for patients who have 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 as well as placebo-controlled studies are needed. At this time, the data is limited by small prospective studies and large retrospective studies. Large prospective trials with higher level of evidence are needed to show efficacy.

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 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 proportion of patients able to perform a Valsalva maneuver in the long term compared to baseline (P < .001). The author's concluded that BDET appears to be associated with improvement in subjective and objective treatment outcome metrics. The improvement appears 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.

Countering some of the evidence conclusions, Hayes (2022) recently updated a review on Eustachian tube balloon dilation (ETBD) for treatment of adults with chronic Eustachian tube dysfunction (ETD) refractory to medical management (MM). A total of eleven studies met criteria, 4 RTCs, 5 pre/post studies, 1 case-control and 1 retrospective comparative study. No major 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 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."

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., ≥3 months) with type B (flat) or C (negative pressure) tympanograms. However, there is an exception if symptoms only occur under 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 baro-challenge. The authors noted surgical intervention is generally indicated when medical management of obstructive ET dysfunction is unsuccessful which includes tympanostomy tubes and balloon dilation of the ET. 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 eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

HCPCS Codes

No applicable codes

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explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

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