MEDICAL POLICY

POLICY TITLE	**BALLOON DILATION OF THE EUSTACHIAN TUBE**
POLICY NUMBER	**MP 1.157**

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2025**

I. POLICY

Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction may be considered **medically necessary** when **ALL** of the following criteria are met:

- The individual is an adult (age 18 years and older)
- The eustachian tube dysfunction has been present for 3 months or longer (in one or both ears) and includes ALL of the following:
  - Aural fullness
  - Aural pressure
  - Significant, documented negative effects on quality of life and/or functional health status
- Comprehensive diagnostic assessment yields the findings of BOTH:
  - Abnormal tympanogram (Type B or C); AND
  - Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam)
- Lack of improvement despite appropriate medical management (including nasal steroids, when indicated) of commonly occurring co-morbidities:
  - Allergic rhinitis
  - Rhinosinusitis
  - Laryngopharyngeal reflux
- Documented absence of other causes of aural fullness:
  - Temporomandibular joint disorders
  - Extrinsic obstruction of the eustachian tube
  - Superior semi-circular canal dehiscence
  - Endolymphatic hydrops
- Improvement in symptoms of obstructive eustachian tube dysfunction if tympanostomy tubes were placed and patent

- Lack of patulous eustachian tube dysfunction or other contraindications to the BDET procedure
- Documented reversibility of the individual's eustachian tube dysfunction
- Continuous, not episodic symptoms (e.g., symptoms not occurring only in response to barochallenge such as pressure changes while flying)
- No history of a previous BDET procedure

Balloon dilation of the eustachian tube is considered **investigational** if the above criteria are not met. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Symptoms of obstructive eustachian tube dysfunction may include aural fullness, aural pressure, otalgia, and hearing loss. Nearly all individuals will have aural fullness and aural pressure. Many individuals will have otalgia, but hearing loss may not be present in all individuals (e.g., patients with Type C tympanograms).

Contraindications to Balloon Dilation of the Eustachian Tube

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

- Individuals with patulous (ETD), which is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
- Individuals with extrinsic reversible or irreversible causes of ETD including but not limited to:
  - craniofacial syndromes, including cleft palate spectrum;
  - 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.

Reversibility of Eustachian Tube Dysfunction

Reversibility of ETD can be demonstrated by several means, including any of the following:

- The individual states that they are able to relieve the pressure by performing a Valsalva maneuver to "pop" their ears;
- Performing a Valsalva maneuver produces temporary improvement of the individual's tympanogram to Type A tympanogram;
- Performing a Valsalva maneuver causes the individual's middle ear to aerate, which is indicated by the provider visualizing lateral movement of the tympanic membrane on otoscopy.

Balloon Dilation of the Eustachian Tube Used in Combination with Other Procedures

- Individuals undergoing balloon dilation of the eustachian tube (BDET) concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Individuals with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement.

Cross-reference:
MP 1.119 Balloon Ostial Dilation for the Treatment of Chronic Rhinosinusitis and Recurrent Acute Rhinosinusitis

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Eustachian Tube Function and Dysfunction

The eustachian tube connects the middle ear space to the nasopharynx. It ventilates the middle ear space to equalize pressure across the tympanic membrane, clears mucociliary secretions, and protects the middle ear from infection and reflux of nasopharyngeal contents. Normally, the tube is closed or collapsed and opens during swallowing, sneezing, or yawning. Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. Symptoms of chronic obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia. In milder cases, eustachian tube dysfunction may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions.

Diagnosis

Because the symptoms of ETD are nonspecific, clinical practice guidelines emphasize the importance of ruling out other causes of ETD with a comprehensive diagnostic assessment that includes patient-report questionnaires, history and physical exam, tympanometry, nasal endoscopy, and audiometry to establish a diagnosis.

Medical and Surgical Management of Eustachian Tube Dysfunction

Medical management of eustachian tube dysfunction (ETD) is directed by the underlying etiology. Treatment of identified underlying conditions, such as systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; or treatment of mass lesions, may be useful in resolving ETD.

Patients who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the eustachian tube. There is limited evidence and no randomized controlled trials (RCTs) supporting use of these surgical techniques for this indication. Additionally, surgery may be associated with adverse events such as infection, perforation, and otorrhea. Tympanostomy tube placement may be a repeat procedure for the life of the patient, and the risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

Balloon Dilation of the Eustachian Tube

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for 2 minutes or less, after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

Balloon dilation of the eustachian tube can be done as a standalone procedure or in conjunction with other procedures such as adenoidectomy, intranasal surgery (e.g., septoplasty, turbinate procedures, or sinus surgery), surgery for obstructive sleep apnea or sleep disturbed breathing, and myringotomy with or without tympanostomy tube placement. This evidence review addresses balloon dilation of the eustachian tube as a stand-alone procedure.

Regulatory Status

Table 1. Devices Cleared by the U.S. Food and Drug Administration

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

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

IV. RATIONALE

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For individuals who have chronic obstructive eustachian tube dysfunction despite medical management who receive balloon dilation of the eustachian tube, the evidence includes RCTs, prospective observational studies, case series, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Two 6-week randomized controlled trials found more improvement with balloon dilation plus medical management than medical management alone on patient-reported symptoms, ability to perform a Valsalva maneuver, proportion of patients with normalized tympanograms, and otoscopy findings. Durability of these effects was demonstrated at 52 weeks in the uncontrolled extension phase of both RCTs. No serious device- or procedure-related adverse events were reported through 52 weeks of follow up. Multiple observational studies and case series have reported that patients experienced improvement when comparing symptoms before and after balloon dilation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical

policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
69705	69706						

ICD-10-CM Diagnosis Code	Description
H68.001	Unspecified Eustachian salpingitis, right ear
H68.002	Unspecified Eustachian salpingitis, left ear
H68.003	Unspecified Eustachian salpingitis, bilateral
H68.009	Unspecified Eustachian salpingitis, unspecified ear
H68.021	Chronic Eustachian salpingitis, right ear
H68.022	Chronic Eustachian salpingitis, left ear
H68.023	Chronic Eustachian salpingitis, bilateral
H68.029	Chronic Eustachian salpingitis, unspecified ear
H68.121	Intrinsic cartilaginous obstruction of Eustachian tube, right ear
H68.122	Intrinsic cartilaginous obstruction of Eustachian tube, left ear
H68.123	Intrinsic cartilaginous obstruction of Eustachian tube, bilateral
H68.129	Intrinsic cartilaginous obstruction of Eustachian tube, unspecified ear
H69.80	Other specified disorders of Eustachian tube, unspecified ear
H69.81	Other specified disorders of Eustachian tube, right ear
H69.82	Other specified disorders of Eustachian tube, left ear
H69.83	Other specified disorders of Eustachian tube, bilateral
H69.90	Unspecified Eustachian tube disorder, unspecified ear
H69.91	Unspecified Eustachian tube disorder, right ear
H69.92	Unspecified Eustachian tube disorder, left ear

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ICD-10-CM Diagnosis Code	Description
H69.93	Unspecified Eustachian tube disorder, bilateral

IX. REFERENCES

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1. *Schilder AG, Bhutta MF, Butler CC, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. Clin Otolaryngol. Oct 2015; 40(5): 407-11. PMID 26347263*
2. *Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. Otolaryngol Head Neck Surg. Jul 2019; 161(1): 6-17. PMID 31161864*
3. *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. Clin Otolaryngol. Feb 2014; 39(1): 6-21. PMID 24438176*
4. *Poe DS, Hanna BM. Balloon dilation of the cartilaginous portion of the eustachian tube: initial safety and feasibility analysis in a cadaver model. Am J Otolaryngol. Mar-Apr 2011; 32(2): 115-23. PMID 20392533*
5. *Schroder S, Lehmann M, Ebmeyer J, et al. Balloon Eustachian tuboplasty: a retrospective cohort study. Clin Otolaryngol. Dec 2015; 40(6): 629-38. PMID 25867023*
6. *Froehlich MH, Le PT, Nguyen SA, et al. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. Otolaryngol Head Neck Surg. Nov 2020; 163(5): 870-882. PMID 32482125*
7. *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. Mar 2022; 154: 111048. PMID 35085875*
8. *Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope. May 2018; 128(5): 1200-1206. PMID 28940574*
9. *Meyer TA, O'Malley EM, Schlosser RJ, et al. A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otol Neurotol. Aug 2018; 39(7): 894-902. PMID 29912819*
10. *Anand V, Poe D, Dean M, et al. Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. Otolaryngol Head Neck Surg. Apr 2019; 160(4): 687-694. PMID 30620688*
11. *Cutler JL, Meyer TA, Nguyen SA, et al. Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. Otol Neurotol. Dec 2019; 40(10): 1322-1325. PMID 31385858*
12. *National Institute for Health and Care Excellence. Balloon dilation for chronic eustachian tube dysfunction. Interventional procedures guidance [IPG665]. December 2019.*
13. *National Institute for Health and Care Excellence. Interventional procedure overview of balloon dilation for chronic eustachian tube dysfunction.*

14. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.158. Balloon Dilation of the Eustachian Tube. October 2024

X. POLICY HISTORY

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MP 1.157	**11/06/2020 New Policy**. Full BCBSA Adoption.
	10/18/2021 Minor Review. Changed age criteria from 22 to 18 and modified chronic condition from 12 months to 3 months. Reformatted policy statement. FEP, Background, Rationale, and references updated. Updated ICD-10 table.
	11/08/2022 Consensus Review. Updated policy guidelines, background, and references. No changes to coding.
	11/03/2023 Consensus Review. Updated policy guidelines, regulatory status, and references. No changes to coding.
	10/15/2024 Consensus Review. Updated background and references. No changes to coding.

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