

MEDICAL POLICY

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

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| CLINICAL BENEFIT | <input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| Effective Date: | 2/1/2026 |

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

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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;

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- 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

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information 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>

DESCRIPTION/BACKGROUND

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

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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

| Device | Manufacturer | Date Cleared | 510(k) No. | Indication |
|--|------------------------|--------------|------------------|--------------------------|
| Acclarent Aera Eustachian Tube Balloon Dilation System | Acclarent, Inc. | 01/16/2018 | K171761; K230742 | Eustachian tube dilation |
| Xpress ENT Dilation System | Entellus Medical, Inc. | 04/05/2017 | K163509 | Eustachian tube dilation |
| Nuvent Eustachian Tube Dilation Balloon | Medtronic Xomed, Inc. | 08/16/2021 | K210841 | Eustachian tube dilation |

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| Audion Et Dilation System | Entellus Medical, Inc. | 04/12/2022 | K220027 | Eustachian tube dilation |
| Vensure Balloon Dilation System | Fiagon GmbH | 05/26/2023 | K230065 | Eustachian tube dilation |

Multiple devices have been given a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ) (Table 1).

RATIONALE

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.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

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CODING INFORMATION

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 | | | | | | | |
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| 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 |
| H69.93 | Unspecified Eustachian tube disorder, bilateral |

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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. |

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| | 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. |
| | 10/14/2025 Consensus Review. No change to policy statement. |

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