

MEDICAL POLICY

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

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:	7/1/2026

POLICY

Balloon dilation of the eustachian tube (BDET) with a device cleared by the U.S. Food and Drug Administration (FDA) for treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered **medically necessary** when used according to FDA labeling and under the following conditions:

- Individuals with symptoms of obstructive ETD (aural fullness, aural pressure, otalgia, and/or hearing loss) for 3 months or longer in 1 or both ears that significantly affects quality of life or functional health status;
 - Aural fullness and pressure must be present (see Policy Guidelines).
- AND**
- The individual has undergone a comprehensive diagnostic assessment; including patient-reported questionnaires, history and physical exam, tympanometry if the tympanic membrane is intact, nasal endoscopy, and comprehensive audiometry, with the following findings:
 - Abnormal tympanogram (Type B or C);
 - Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam).
- AND**
- Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated.
- AND**
- 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 ruled out.
- AND**
- If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent.
- AND**
- The individual does not have patulous ETD or another contraindication to the procedure (see Policy Guidelines).
- AND**
- The individual's ETD has been shown to be reversible (see Policy Guidelines).
- AND**

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- Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying).
- AND**
- The individual has not had 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.

(For pediatric use (8-17 years of age) of balloon dilation of Eustachian tube see Policy Guidelines.)

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 eustachian tube dysfunction (ETD)
 - A diagnosis of patulous ETD 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;

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- 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.

Balloon Dilation of the Eustachian Tube Used in Pediatric Populations

- Individuals between the ages of 8 to 17 are eligible for treatment of persistent obstructive ETD refractory to standard surgical interventions with the Acclarent AERA Eustachian Tube Balloon Dilation System.
- Clinical input from 2 specialty societies provided the following feedback on contraindications for pediatric individuals:
 - Absolute Contraindications
 - Patulous eustachian tube dysfunction
 - Dehiscent carotid artery identified on imaging without appropriate device safeguards
 - Active acute infection of the nasopharynx or middle ear
 - Anatomic obstruction from non-adenoid nasopharyngeal masses requiring alternative management
 - Relative Contraindications
 - Age <8 years
 - Failure to confirm obstructive ETD with objective testing
 - Uncontrolled allergic rhinitis or gastroesophageal reflux
 - Craniofacial anomalies with possible abnormal eustachian tube anatomy
 - Coagulopathy or bleeding disorders
 - Trisomy 21
 - Chronic inflammatory diseases and immunodeficiency

Cross-Reference:

MP 1.119 Balloon Ostial Dilation for the Treatment of Chronic Rhinosinusitis and Recurrent Acute Rhinosinusitis

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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 dysfunction occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure is frequently due to inflammation and can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo. Chronic obstructive ETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the eustachian tube (BDET) is a procedure intended to improve patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

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 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 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.

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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.

In December 2023, the FDA expanded the indication for the Acclarent AERA Eustachian Tube Balloon Dilation System (K230742), authorizing its use in pediatric patients aged 8 to 17 years with persistent obstructive Eustachian tube dysfunction refractory to medical management.

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
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

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Multiple devices have been given a de novo 510(k) classification by the 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 permitted 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.

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:

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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
H69.93	Unspecified Eustachian tube disorder, bilateral

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POLICY HISTORY

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.
	10/14/2025 Consensus Review. No change to policy statement.
	03/06/2026 Consensus Review. No change to policy statement. Policy reformatted. Background updated. References added.

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