MASSACHUSETTS

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Medical Policy

Balloon Dilation of the Eustachian Tube

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Policy Number: 018

BCBSA Reference Number: 7.01.158 (For Plans internal use only)
NCD/LCD: N/A

Related Policies

None

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

BDET as a Standalone Procedure

Balloon dilation of the eustachian tube (BDET) for treatment of adults (18 years of age and older) with chronic obstructive eustachian tube dysfunction may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

- The member has chronic signs and symptoms of eustachian tube obstruction including but not limited to:
  - difficulty equilibrating pressure in ears when challenged with ambient barometric changes (baro-challenge), OR
  - hearing loss or aural fullness that is temporarily relieved if the individual is capable of performing auto-insufflation OR
  - history of negative pressure in the middle ear, middle ear effusion, as defined as ≥ 3 months duration; AND
- Failure to respond to appropriate medical management of co-occurring conditions such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4-6 weeks of a nasal steroid spray, unless contraindicated, AND
- Objective pathological findings on dynamic endoscopic examination of the eustachian tube OR if no pathological findings visible, history and physical remain consistent with obstruction within the cartilaginous eustachian tube, AND
- If the individual had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent. Trial of tympanostomy tubes are not required prior to BDET.

BDET in Combination with Other Procedures[1]

Balloon dilation of the eustachian tube used in combination with other procedures may be considered **MEDICALLY NECESSARY** when one of the following criteria are met:

- Individuals undergoing 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.

BDET is considered **INVESTIGATIONAL** for all other indications.

Repeat BDET is considered **INVESTIGATIONAL**.

BDET is considered **INVESTIGATIONAL** when any of the following conditions are present:

- Adenoids that block the eustachian tube orifice as the sole cause of obstruction
- Obstruction in the bony portion of the eustachian tube
- History of carotid artery dehiscence
- Craniofacial syndrome
- Cystic fibrosis
- Acute perforation of the tympanic membrane
- History of persistent patulous eustachian tube
- Neoplasm causing extrinsic obstruction of the eustachian tube
- Prior intervention of eustachian tube
- Systemic mucosal or immunodeficiency disease
- History of radiation therapy to the nasopharynx
- Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening if it is determined to be the sole cause of the eustachian tube dysfunction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**
Commercial PPO and Indemnity	Prior authorization is **not required**
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, ~~and~~ Indemnity, Medicare HMO Blue, and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

Description

Eustachian Tube Function

The ET connects the middle ear space to the nasopharynx. It is approximately 36 mm long in adults. The ET 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.[1] The tube opens during swallowing or yawning.

Eustachian tube dysfunction (ETD) occurs when the functional valve of the ET fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. Obstructive ET dysfunction (OETD is most commonly caused by inflammation including rhinosinusitis and allergic rhinitis. OETD can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo.[2] Chronic OETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas.

Treatment of ETDD

Medical management of OETD is directed by the underlying etiology if one can be identified, such as treatment of chronic bacterial rhinosinusitis, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; and treatment of mass lesions. Although topical nasal steroids are commonly used for OETD, triamcinolone acetonide failed to show benefit in patients ages 6 and older presenting with otitis media with effusion and/or negative middle ear pressure in a randomized, placebo-controlled, double-blind trial published (2011).[6] Therefore, medical treatment in the absence of an identified underlying etiology is no longer recommended.

Patients who continue to have symptoms following medical management may be treated with surgery. Available surgical management includes myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. Norman et al (2014) reported that eustachian tuboplasty (other than balloon dilation) has been evaluated in 7 case series and was associated with improvement in symptoms in 36% to 92% of patients with low rates (13%-36%) of conversion to type A tympanogram (which is normal). Myringotomy and tympanostomy have been evaluated in two case series and were associated with symptom alleviation in a subgroup of patients.[7]

Balloon Dilatation of the ET

Balloon dilation is an intraluminal procedure intended to improve the patency of the cartilaginous ET. During the procedure, a saline-filled balloon catheter is introduced into the ET 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 may be performed either under general anesthesia or under local office anesthesia.[8,9]

The mechanism of action of the procedure is believed to be that the balloon crushes diseased epithelium and submucosal adenoid-like inflamed lymphoid follicular hyperplasia, allowing the tissues to heal with normal epithelium and elimination of the lymphoid follicles and inflammation.

Summary

Eustachian tube (ET) 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 dysfunction can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the ET is a procedure

intended to improve the patency by inflating a balloon in the cartilaginous part of the ET to cause local dilation.

For individuals who have chronic obstructive ET dysfunction despite medical management who receive balloon dilation of the ET, the evidence includes case series, systematic reviews of case series, a retrospective cohort study, and two randomized controlled trials (RCTs).

The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The criteria for diagnosing obstructive ET dysfunction are not standardized. Several medical and surgical treatments are used for obstructive ET dysfunction, but there is limited evidence for available treatments. Most case series assessed provided follow-up of less than a year and all showed short-term improvement comparing symptoms before and after balloon dilation. The number of revision procedures required due to the failure of the first ET balloon dilation procedure was reported in 3 case series (n=714 patients); 122 revisions were reported. In one published RCT evaluating balloon dilation of the ET, patients were eligible if they reported persistent obstructive ET dysfunction symptoms as measured on the 7-item Eustachian Tube Dysfunction Questionnaire, a tool to assess symptoms, and had abnormal tympanometry. A greater proportion of patients in the balloon dilation group demonstrated tympanogram normalization (52%) compared with the medical management group (14%) at 6 weeks and reported a reduction in symptoms at 6 weeks on the 7-item Eustachian Tube Dysfunction Questionnaire. The durability of effect at 24 weeks was demonstrated in a subset of patients. The rate of adverse events was low, and none of the serious adverse events were thought to be related to the device or procedure. The second RCT enrolled patients with moderate to severe ET dysfunction based on the 7-item Eustachian Tube Dysfunction Questionnaire but who were not required to have abnormal middle ear functional assessments. Symptom score change was the primary outcome and mean score decrease was greater in the balloon dilation group than the medical management group. In both RCTs, the initiation, concomitant or continued use of medical therapy of multiple drug classes was at the discretion of the investigators

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) created a panel of experts to review BDET, with participating subgroups including the American Academy of Otolaryngic Allergy, the American Neurotology Society, the American Otological society, the American Rhinologic Society and the Triological Society as well as committees within the AAO-HNS including the Board of Governors, the Rhinology and Paranasal Sinus Committee, the Physician Payment Policy Workgroup, the Hearing Committee, and the Medical Devices and Drugs Committee.

Based on consensus reached by the above panel, the diagnosis of OETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy. This process demonstrated that BDET is an option for treatment of patients with OETD. [17]

There is demonstrated superiority of balloon dilation of the Eustachian tube with balloon catheter combined with appropriate medical management as compared to medical management alone to treat obstructive eustachian tube dysfunction in adults.[12] The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History

Date	Action
9/2023	Annual policy review. Description and summary reviewed. References updated. Policy statements unchanged. 9/1/2023.
1/2023	Medicare information added.
11/2022	Minor refinements to policy statements; intent unchanged.
6/2022	Annual policy review. References added. Policy statements unchanged.
2/2021	New medically necessary and investigational indications described based on expert opinion. Effective 2/1/2021. Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
1/2021	Clarified coding information.

5/2020	New medical policy statements describing medically necessary and investigational indications. Effective 5/1/2020.
4/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
7/2018	New medical policy describing investigational indications. Effective 7/1/2018.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion