Corporate Medical Policy

Balloon Dilation of the Eustachian Tube

File Name: balloon_dilation_of_the_eustachian_tube
Origination: 3/2018
Last Review: 2/2024

Description of Procedure or Service

Eustachian Tube Function and Dysfunction
The eustachian tube (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. 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 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.

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 ETD
Medical management of ETD is directed by the underlying etiology: treatment of identified underlying conditions; systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; and treatment of mass lesions.

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. 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 supporting use of these surgical techniques.

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

Regulatory Status

In September 2016, the AERA® (Acclarent) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA). 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 FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in eustachian tube dysfunction. The predicate devices are XprESS™ Multi-Sinus Dilation System and AERA® Eustachian Tube Balloon Dilation System.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Balloon Dilation of the Eustachian Tube when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Balloon Dilation of the Eustachian Tube is covered

Balloon dilation of the eustachian tube (BDET) for the treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered medically necessary in adults (age 18 years and older) when **all of the following** criteria have been met:

1. Symptoms of obstructive ETD in one or both ears that significantly affects quality of life or functional health status, including **all of the following**:
    a. Aural fullness
    b. Aural pressure
    c. Symptoms have been present for 12 months or longer
    d. Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying)
2. 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 **any of the following** findings:
    a. Abnormal tympanogram (Type B or C), or
    b. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam)
3. 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
4. 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
5. The individual's ETD has been shown to be reversible as demonstrated by **any of the following**:
    a. The individual states that they are able to relieve the pressure by performing a Valsalva maneuver to “pop” their ears
    b. Performing a Valsalva maneuver produces temporary improvement of the individual's tympanogram to Type A tympanogram

   c. Performing a Valsalva maneuver causes the member's middle ear to aerate, which is indicated by the provider visualizing lateral movement of the tympanic membrane on otoscopy
6. The individual **has not had** a previous BDET procedure in the same ear for which surgery is being proposed.
7. The individual **does not have** patulous ETD or another contraindication to the procedure to BDET (see Note 1 below)

***Note 1: **Contraindications to BDET may include any of the following**: Individuals with chronic and severe atelectatic ears; Individuals with a history of myringotomy with tympanostomy tube placements where the symptoms of obstructive ETD did not improve while the tubes were patent; Individuals with aural fullness but normal exam and tympanogram; 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).

When Balloon Dilation of the Eustachian Tube is not covered

1. Balloon dilation of the eustachian tube (BDET) is considered **investigational** if the above criteria are not met.
2. Repeat BDET on the same ear is considered **investigational**.
3. Trans-tympanic BDET is **investigational** for all indications.

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).

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.

For individuals who have chronic obstructive ETD despite medical management who receive BDET, the evidence includes randomized controlled trials (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 RCTs 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *69705, 69706*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.158, 2/8/2018

Specialty Matched Consultant Advisory Panel 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.158, 2/14/2019

Specialty Matched Consultant Advisory Panel 2/2020

Specialty Matched Consultant Advisory Panel 2/2021

Specialty Matched Consultant Advisory Panel 2/2022

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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

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

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

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Specialty Matched Consultant Advisory Panel 2/2024

Medical Director Review 2/2024

Policy Implementation/Update Information

3/9/18 New policy developed. Balloon dilation of the eustachian tube for treatment of patients with chronic eustachian tube dilatory dysfunction is considered investigational. (sk)

3/29/18 Code 69799 added to Billing/Coding section. (sk)

3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)

4/16/19 Reference added. Policy Guidelines updated. (sk)

6/30/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)

12/31/20 Added new codes 69705 and 69706 to Billing/Coding section for effective date 1/1/2021. Noted code C9745 deleted 12/31/2020. (sk)

7/13/21 Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)

3/8/22 Code 69799 deleted. Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)

5/30/23 Specialty Matched Consultant Advisory Panel review 2/15/2023. (sk)

4/01/24 Policy statement revised as follows: "BCBSNC will provide coverage for Balloon Dilation of the Eustachian Tube when it is determined to be medically necessary because the medical criteria and guidelines shown below are met." When Covered section revised with medically necessary criteria for BDET. When Not Covered section revised to include when BDET is investigational and not covered. Updated Description, Policy Guidelines, and References. Medical Director review 2/2024. Specialty Matched Consultant Advisory Panel review 2/2024. (ldh)