# **Medical Coverage Policy** | Balloon Dilation of the Eustachian Tube



**EFFECTIVE DATE:** 03 | 01 | 2021

**POLICY LAST REVIEWED:** 11 | 05 | 2025

#### **OVERVIEW**

Eustachian tube dysfunction occurs when the functional valve of the eustachian tube fails to open and/or close properly. Chronic dysfunction can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the eustachian tube is a procedure intended to improve the patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

#### **MEDICAL CRITERIA**

## Medicare Advantage Plans and Commercial Products

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

- 1. Adults (age 22 years and older) with symptoms of obstructive eustachian tube dysfunction (aural fullness\*, aural pressure, otalgia, and/or hearing loss) for 12 months or longer in one or both ears that significantly affects quality of life or functional health status; AND,
  - \*Aural fullness with abnormal exam and abnormal tympanogram
- 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 the following findings:
  - O Abnormal tympanogram (Type B or C)
  - O Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam); AND,
- 3. Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4-6 weeks of a nasal steroid spray, if indicated; AND,
- 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; AND,
- 5. If the individual had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent; AND,
- 6. The individual does not have patulous eustachian tube dysfunction or another contraindication to the procedure as noted below:
  - Contraindications are as follows:
    - Individuals with patulous eustachian tube dysfunction
      - 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 eustachian tube dysfunction 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)

- o Individuals with chronic and severe atelectatic ears; AND,
- 7. The individual's eustachian tube dysfunction has been shown to be reversible as defined below:
  - O The individual states that they are able to relieve the pressure by performing a Valsalva maneuver to "pop" their ears
  - O Performing a Valsalva maneuver produces temporary improvement of the individual's tympanogram to Type A tympanogram
  - 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; AND,
- 8. Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying); AND,
- 9. The individual has not had a previous BDET procedure

#### **PRIOR AUTHORIZATION**

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

#### **POLICY STATEMENT**

## Medicare Advantage Plans and Commercial Products

Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction may be considered medically necessary when the above medical criteria are met.

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

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

#### **COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage.

## **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 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 addresses BDET as a standalone procedure.

Multiple devices have been given a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA):

- Acclarent Aera Eustachian Tube Balloon Dilation System (Acclarent, Inc)
- Xpress ENT Dilation System (Entellus Medical, Inc)
- Nuvent Eustachian Tube Dilation Balloon (Medtronic Xomed, Inc)
- Audion Et Dilation System (Entellus Medical, Inc)
- Vensure Balloon Dilation System (Fiagon GmbH)

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.

#### **CODING**

#### Medicare Advantage Plans and Commercial Products

The following CPT code(s) are medically necessary for Medicare Advantage Plans and Commercial Products when the above medical criteria has been met:

69705 Nasopharyngoscopy, surgical with dilation of eustachian tube (i.e. balloon dilation); unilateral Nasopharyngoscopy, surgical with dilation of eustachian tube (i.e. balloon dilation); bilateral

#### **RELATED POLICIES**

Prior Authorization of Services, Treatments or Procedures

# **PUBLISHED**

Provider Update, January 2026 Provider Update, January/December 2024 Provider Update, February 2023

#### **REFERENCES**

- 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
- Tucci D, McCoul E, Rosenfeld R, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. American Academy of Otolaryngology

  Head and Neck Surgery Foundation 2019. April 15, 2019:1-12. 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, McRackan TR, Rizk HG, Meyer TA. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. Otolaryngol Head Neck Surg. 2020 Jun2:194599820924322. doi: 10.1177/0194599820924322. Online ahead of print. 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, Roberts WH, Stolovitzky JP et al. (2018) Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope 128 (5): 1200-1206. PMID: 28940574
- Meyer TA, O'Malley EM, Schlosser RJ, Soler ZM, Cai J et al. (2018) A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otol Neurotol 39 (7):894-902. PMID: 29912819
- 10. Anand V, Poe D, Dean M, Roberts W, Stolovitzky P et al. (2019) Balloon Dilation of the Eustachian Tube: 12-MonthFollow-up of the Randomized Controlled Trial Treatment Group. Otolaryngol Head Neck Surg 160 (4): 687-694.PMID: 30620688
- 11. Cutler JL, Meyer TA, Nguyen SA, O'Malley EM, Thackeray L et al. (2019) Long-term Outcomes of Balloon Dilation for Persistent Eustachian Tube Dysfunction. Otol Neurotol 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. https://www.nice.org.uk/guidance/ipg665. Accessed August 1, 2024.
- 13. National Institute for Health and Care Excellence. Interventional procedure overview of balloon dilation for chronic eustachian tube dysfunction. https://www.nice.org.uk/guidance/ipg665/documents/overview-2 December 2019. Accessed August 1, 2024.
- 14. Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, Dawson DE, Dykewicz MS, Hackell JM, Han JK, Ishman SL, Krouse HJ, Malekzadeh S, Mims JW, Omole FS, Reddy WD, Wallace DV, Walsh SA, Warren BE, Wilson MN, Nnacheta LC. Clinical practice guideline: allergic rhinitis. Otolaryngol Head Neck Surg. 2015 Feb;152(1 Suppl):S1-S43. [364 references] PMID: 25644617
- 15. Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW et al. (2011) Management of eustachian tube dysfunction with nasal steroid spray: a prospective, randomized, placebo-controlled trial. Arch Otolaryngol Head Neck Surg 137 (5): 449-455. PMID: 21576556
- Altman KW, Prufer N, Vaezi MF. A Review of Clinical Practice Guidelines for Reflux Disease: Toward Creating a Clinical Protocol for the Otolaryngologist. Laryngoscope, 121:717–723, 2011 PMID: 21298646
- 17. Ashry Y, Kawai K, Poe D. Utility of Adjunctive Procedures with Balloon Dilation of the Eustachian Tube. Laryngoscope Investig Otolaryngol. 2017 Nov 30;2(6):337-343 PMID: 29299505

- 18. Huisman JML, Verdam FJ, Stegeman I, de Ru JA (2018) Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. Laryngoscope 128 (1):237-247. PMID: 28799657
- 19. Kivekäs I, Chao WC, Faquin W, Hollowell M, Silvola J et al. (2015) Histopathology of balloon-dilation Eustachian tuboplasty. Laryngoscope 125 (2): 436-441. PMID: 25154612
- 20. Smith ME, Weir AE, Prior DCC, Cope W, Tysome JR, Sutcliffe M. The mechanism of balloon Eustachian tuboplasty: a biomechanical study. Med Biol Eng Comput. 2020 Apr;58(4):689-699. doi: 10.1007/s11517-020-02121-z. Epub 2020 Jan 17.PMID: 31953796
- 21. Luukkainen V, Kivekas I, Silvola J, Jero J, Sinkkonen ST (2018) Balloon Eustachian Tuboplasty: Systematic Reviewof Long-term Outcomes and Proposed Indications. J Int Adv Otol 14 (1): 112-126. PMID: 29764785
- 22. Luukkainen V, Vnencak M, Aarnisalo AA, Jero J, Sinkkonen ST (2018) Patient satisfaction in the long-term effects of Eustachian tube balloon dilation is encouraging. Acta Otolaryngol 138 (2): 122-127. PMID: 29017385
- 23. McCoul ED, Anand VK (2012) Eustachian tube balloon dilation surgery. Int Forum Allergy Rhinol 2 (3): 191-198.PMID: 22253073
- 24. Liang M, Xiong H, Cai Y, Chen Y, Zhang Z, Chen S, Xu Y, Ou Y, Yang H, Zheng Y. Effect of the Combination of Balloon Eustachian Tuboplasty and Tympanic Paracentesis on Intractable Chronic Otitis Media With Effusion. Am JOtolaryngol Sep-Oct 2016;37(5):442-6. doi: 10.1016/j.amjoto.2016.03.006. Epub 2016 Apr 2. PMID: 27221026
- 25. Shan A, Ward BK, Goman AM, Betz JF, Reed NS et al. (2019) Prevalence of Eustachian Tube Dysfunction in Adults in the United States. JAMA Otolaryngol Head Neck Surg PMID: 31369057
- 26. Kim AS, Betz JF, Goman AM, Poe DS, Reed NS, Ward BK, Nieman CL. JAMA Otolaryngol Head Neck Surg. Prevalence and Population Estimates of Obstructive Eustachian Tube Dysfunction in US Adolescents 2020 Jun4;e200962 doi: 10.1001/jamaoto.2020.0962. Online ahead of print. PMID: 32496532
- Vila PM, Thomas T, Liu C, Poe D, Shin JJ. The Burden and Epidemiology of Eustachian Tube Dysfunction in Adults. Otolaryngol Head Neck Surg. 2017 Feb;156(2):278-284. doi: 10.1177/0194599816683342. Epub 2017 Jan24. PMID: 28116997
- 28. Rosenfeld RM, Shin JJ, Schwartz SR, Coggins R, Gagnon L, Hackell JM, Hoelting D, Hunter LL, Kummer AW, Payne SC, Poe DS, Veling M, Vila PM, Walsh SA, Corrigan MD. Clinical Practice Guideline: Otitis Media with Effusion (Update). Otolaryngol Head Neck Surg. 2016 Feb;154(1 Suppl):S1-S41. doi: 10.1177/0194599815623467.PMID: 26832942
- 29. McMurran AEL, Hogg GE, Gordon S, Spielmann PM, Jones SE. Balloon Eustachian tuboplasty for Eustachian tube dysfunction: report of long-term outcomes in a UK population. J Laryngol Otol. 2020 Jan;134(1):34-40. doi:10.1017/S0022215119002548. Epub 2020 Jan 8. PMID: 31910908
- 30. Hwang SY, Kok S, Walton J. Balloon dilation for Eustachian tube dysfunction: systematic review. J Laryngol Otol.2016;130(suppl 4):S2-S6. PMID: 27488333
- 31. Ramakrishnan N, D'Souza R, Kadambi P. A systematic literature review of the safety and efficacy of eustachian balloon tuboplasty in patients with chronic eustachian tube dysfunction. Indian J Otolaryngol Head Neck Surg. 2019;71(3):406-412 PMID: 31559212
- 32. American Medical Association (Web Page) CPT® Editorial Summary of Panel Actions. Updated September 2019. Available online at: https://www.ama-assn.org/system/files/2019-11/september-2019-summary-panel-actions.pdf Accessed: June 24, 2020
- 33. Padia R, Hall D, Sjogren P, Narayanan P, Meier J. Sequelae of Tympanostomy Tubes in a Multihospital Health System. Otolaryngol Head Neck Surg 2018 May;158(5):930-933. doi: 10.1177/0194599817752633. Epub 2018 Jan16. PMID: 29336221
- 34. Poe DS, Abou-Halawa A, Abdel-Razek O. Analysis of the dysfunctional eustachian tube by video endoscopy. Otol Neurotol. 2001;22(5):590-5. PMID: 11568663
- 35. Luukkainen V, Kivekäs I, Hammarén-Malmi S, Rautiainen M, Pöyhönen L, Aarnisalo AA, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty under local anesthesia: Is it feasible? Laryngoscope. 2017 May;127(5):1021-1025.doi: 10.1002/lary.26488. Epub 2017 Feb 3. PMID: 28409844
- 36. Luukkainen V, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty under monitored anesthesia care with different balloon dilation devices: A pilot feasibility study with 18 patients. Clin Otolaryngol. 2019 Jan;44(1):87-90.doi: 10.1111/coa.13236. Epub 2018 Nov 4. PMID: 30281926

- 37. Dean M, Pynnonen MA. In-Office Balloon Dilation of the Eustachian Tube under Local Anesthesia. Otolaryngol Clin North Am. 2019 Jun;52(3):509-520. doi: 10.1016/j.otc.2019.02.005. Epub 2019 Mar 22. PMID: 30905561
- 38. Plaza G, Navarro JJ, Alfaro J, Sandoval M, Marco J. Consensus on treatment of obstructive Eustachian tube dysfunction with balloon Eustachian tuboplasty. Acta Otorrinolaringol Esp. 2020 May-Jun;71(3):181-189. English, Spanish. doi: 10.1016/j.otorri.2019.01.005. Epub 2019 May 24. PMID: 31133274.
- 39. Wang T, Lin C, shih T et al. Comparison of Balloon Dilation and Laser Eustachian Tuboplasty in Patients with Eustachian tube dysfunction: A Meta-analysis. Otolaryngol Head Neck Surg. 2018. 158: 617-626.
- 40. Yin G et al. Balloon dilation of eustachian tube combined with tympanostomy tube insertion and middle ear equalization therapy for recurrent secretory otitis media. J Otol. 2019, 14:101
- 41. Huhnd LE. et al. Balloon dilation of the eustachian tube in tympanic membrane retractions. Laryngorhinootologie. 2018. 97:688-93
- 42. Giunta A, Liberati L, Pellegrino C et al. Eustachian tube balloon dilation in treatment of equalization problems of freediving spearfisherman. Diving Hyperb Med. 2019. 49: 9-15;
- 43. Cheng T, Kaylie D. Recurrent and progressive facial Sbaroparesis on flying relieved by eustachian tube dilation. Ann Otol Rhinol Laryngol. 2019. 128: 778-781;
- 44. Utz, E, Wise S. Navy Diver with Recurrent Facial Nerve Baroparesis treated with Eustachian tube Balloon dilation. Laryngoscope. 2019. 129: E412-E414.)
- 45. Siow J, Tan J. Indications for Eustachian tube dilation. Curr Opin Otolaryngol Head Neck Surg. 2020. 28: 31-35)

## ----- CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

