Balloon dilation of the Eustachian tube

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Policy contains: Balloon dilation; Eustachian tube; Eustachian tube dysfunction.

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Coverage policy

Transnasal balloon dilation of the Eustachian tube is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (Tucci, 2019):

- Only a U.S. Food and Drug Administration device approved for balloon dilation of the Eustachian tube is used.
- The member is 18 years or older.
- The member is diagnosed with obstructive Eustachian tube dysfunction in one or both ears lasting for three months or longer that presents as either of the following:
    - Obstructive Eustachian tube dysfunction in isolation.
    - After failed medical therapy, if a treatable cause has been identified (e.g., allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux).

- Otoscopy, nasal endoscopy, comprehensive audiometry, and tympanometry are required prior to the procedure.
- The diagnosis has a significant effect on quality of life or functional health status.
- There is no contraindication to the procedure.

Transnasal balloon dilation of the Eustachian tube is clinically proven and, therefore, may be medically necessary in members ages 8 through 17 years when all of the following criteria are met (American Academy of Otolaryngology-Head and Neck Surgery, 2025):

- A device cleared by the U.S. Food and Drug Administration for the member's age and indication is used according to its labeling.
- The member has objectively documented obstructive Eustachian tube dysfunction resulting in persistent chronic otitis media with effusion.
- The condition is refractory to standard surgical intervention, including at least one prior tympanostomy tube intervention and evaluation or treatment of adenoid disease when clinically indicated.
- The procedure is recommended and performed by a qualified otolaryngologist-head and neck surgeon.
- There is no contraindication to the procedure.

Concurrent balloon dilation of the Eustachian tube with sinus ostial dilation is clinically proven and, therefore, may be medically necessary when the diagnostic criteria for each procedure are met (Tucci, 2019).

Concurrent balloon dilation of the Eustachian tube with myringotomy with or without tympanostomy tube placement is clinically proven and, therefore, may be medically necessary when performed for treatment of middle ear effusion (Tucci, 2019).

Limitations

All other uses of balloon dilation of the Eustachian tube are investigational/not clinically proven and, therefore, not medically necessary, including but not limited to (Tucci, 2019):

- As a repeat procedure.
- Concurrent with tympanoplasty.
- Using a trans-tympanic approach.
- In members younger than age 8 years and in members ages 8 through 17 years who do not meet the pediatric criteria above.

Contraindications to balloon dilation of the Eustachian tube include, but are not limited to (Tucci, 2019):

- Prior myringostomy and/or tympanoplasty without improvement in symptoms.
- Patulous Eustachian tube dysfunction.
- Extrinsic obstruction of the Eustachian tube.
- Active primary inflammatory disorders.
- Temporomandibular disorders.
- Superior semicircular canal dehiscence.
- Meniere’s disease.

- Dehiscent carotid artery on imaging without using a depth marker that demarcates insertion into the cartilaginous Eustachian tube.

Alternative covered services

- Medical therapy for the underlying etiology.
- Adenoidectomy.
- Myringostomy.
- Tympanostomy tube insertion.

Background

The Eustachian tube connects the middle ear with the nasopharynx and maintains middle-ear ventilation, facilitates mucociliary clearance, and shields the tympanic cavity from pathogens and barometric stress (Hamrang-Yousefi, 2023). Impairment of any of these functions produces obstructive dysfunction manifested by aural fullness, fluctuating hearing, tinnitus, ear pain, or imbalance, and chronic disease can advance to otitis media, tympanic-membrane retraction, or cholesteatoma (Hamrang-Yousefi, 2023). A consensus panel on definition and diagnosis emphasises complete history, nasal endoscopy, otoscopy, tympanometry, comprehensive audiometry, the seven-item Eustachian Tube Dysfunction Questionnaire, and assessment of the ability to perform a pressure-equalising manoeuvre to confirm ventilatory failure and quantify symptom burden (Schilder, 2015).

Conservative treatment addresses reversible causes through lifestyle measures, topical or systemic anti-inflammatory drugs, and ventilation-tube placement. Balloon dilation introduces a saline-inflated catheter into the cartilaginous segment, briefly widens the lumen, and removes the catheter without mucosal resection, thereby preserving native tissue (Llewellyn, 2014). Several balloon devices have been cleared by the United States Food and Drug Administration for use in adults. In December 2023, the agency expanded clearance for the Acclarent AERA Eustachian Tube Balloon Dilation System to include pediatric patients aged 8 to 17 years (United States Food and Drug Administration, 2025; 2023).

Findings

Guidelines

A 2019 clinical-consensus statement from the American Academy of Otolaryngology–Head and Neck Surgery supports balloon dilation for adults whose obstructive dysfunction persists for at least three months after unsuccessful medical therapy and produces a measurable impact on quality of life (Tucci, 2019). It requires objective confirmation with nasal endoscopy, otoscopy, tympanometry, audiometry, and a validated symptom score; permits concurrent sinus ostial surgery or myringotomy; and lists absolute contraindications that include patulous dysfunction, extrinsic mass effect, active inflammatory disorders, temporomandibular conditions, superior semicircular canal dehiscence, and Ménière disease. Evidence remains insufficient to recommend routine repeat dilation.

An American Academy of Otolaryngology-Head and Neck Surgery position statement considers Eustachian tube balloon dilation an appropriate option for selected pediatric patients with obstructive Eustachian tube dysfunction resulting in chronic otitis media that is refractory to standard surgical interventions, including tympanostomy tube placement and adenoidectomy. The statement recommends use of an FDA-cleared device according to its labeling and treatment by a qualified otolaryngologist-head and neck surgeon (American Academy of Otolaryngology-Head and Neck Surgery, 2025).

Systematic reviews

Adults

A 2024 review of eleven observational cohorts reported consistent symptom relief and conversion of abnormal tympanograms to normal type A patterns after balloon dilation, while emphasizing heterogeneity and low methodological quality (Alghamdi, 2024). A 2025 Cochrane analysis synthesized nine randomized trials with 684 participants and found that balloon dilation probably improves symptom scores (mean difference −1.66 on the seven-item questionnaire, 95 % CI −2.16 to −1.16) and tympanogram class up to three months compared with medical therapy or observation; uncertainty rises sharply beyond three months (Swords, 2025).

A systematic review of 14 studies reported improvement in otoscopic findings, Valsalva maneuver performance, tympanometry, and Eustachian Tube Dysfunction Questionnaire-7 scores after balloon dilation. Pure-tone audiometry generally did not improve, several studies had risk-of-bias concerns, publication bias was detected, and follow-up did not extend beyond 52 weeks (Gołota, 2025).

A meta-analysis of six randomized or prospective studies involving 309 patients found a mean reduction of 2.03 points in Eustachian Tube Dysfunction Questionnaire-7 scores through six to 12 months after balloon dilation. Heterogeneity was high, and the analysis primarily compared patients before and after treatment rather than balloon dilation with a concurrent control. Studies of balloon dilation under local anesthesia reported high completion and similar symptom and tympanometry outcomes to general anesthesia, but direct comparative evidence was limited and subject to patient-selection bias (Khan, 2026).

A meta-analysis of randomized trials found that balloon dilation increased the likelihood of achieving a Type A tympanogram compared with control treatment (relative risk 4.68, 95% confidence interval 2.88 to 7.51). When balloon dilation was performed with cartilage tympanoplasty, air-bone-gap closure improved by 3.82 dB at three months and 4.06 dB at six months. The authors characterized the hearing improvement as statistically significant but not clinically perceptible (Raj, 2026).

Children

Aboueisha pooled seven single-arm cohorts (n = 408) and demonstrated symptom resolution, tympanogram normalization, and a mean air-bone-gap improvement of −6.4 dB (95 % CI −9.8 to −3.1 dB; P < .001) compared with ventilation-tube insertion, alongside a five-percent minor-complication rate dominated by transient epistaxis (Aboueisha, 2022). Saniasiaya aggregated seven further cohorts (n = 284) and confirmed parallel gains in otomicroscopy, audiometry, and tympanometry with few adverse events (Saniasiaya, 2022). In 2024, Ramagiri combined 11 observational studies (n = 589) and reported significant postoperative gains in otomicroscopy, tympanometry, and air-bone gap with a minor-complication rate of 3.6 % despite the absence of randomized comparisons (Ramagiri, 2024).

A meta-analysis of eight retrospective cohorts involving 652 children and 1,214 ears reported tympanogram improvement in 64% of cases (95% confidence interval 50% to 78%; I2 = 90.7%) and a pooled failure rate of 13%. Reported complications were minor and self-limited. The evidence was limited by retrospective designs, absent control groups, inconsistent outcome definitions, and substantial heterogeneity (Zujaj, 2026).

A meta-analysis of 20 observational studies involving 1,175 children and 1,868 ears found improvement from baseline in air-bone gap, Eustachian Tube Score, Valsalva maneuver, and selected tympanometric outcomes. Comparative analyses found no significant difference between balloon dilation and controls for air-bone gap at six or 12 months or for efficacy or cure (odds ratio 1.08, 95% confidence interval 0.31 to 3.73). The pooled complication rate was 3%, with essentially all reported events classified as minor. No eligible randomized pediatric trial was identified (Saade, 2026).

The pediatric reviews contain overlapping primary cohorts and should not be interpreted as independent replications. Favorable uncontrolled improvement rates do not establish that balloon dilation is superior to standard management because outcomes may also be affected by natural Eustachian tube maturation, prior treatment, concurrent procedures, and regression to the mean (Zujaj, 2026; Saade, 2026).

Adult procedural refinement was assessed by Ungar, who reviewed 193 balloon dilations performed under local anesthesia and found symptom, tympanometry, and patient-satisfaction outcomes comparable to general anesthesia with negligible major morbidity (Ungar, 2024).

A systematic review of four adult cohort studies involving 294 ears compared Eustachian tuboplasty plus tympanostomy tube insertion with tympanostomy tube insertion alone. Symptom recurrence was lower with combined treatment (9.9% versus 24.9%; relative risk 0.35, 95% confidence interval 0.17 to 0.70), but heterogeneity was substantial. One study used radiofrequency ablation rather than balloon dilation, one involved post-radiation otitis media with effusion, most outcomes were analyzed by ear rather than patient, and the air-bone-gap result became nonsignificant after outlier removal. Additional controlled studies are needed to establish superiority confidently (Geneau, 2026).

Meta-analyses

Froehlich combined twelve studies (n = 448) and observed significant improvements from baseline to three-to-twelve-month follow-up in symptom scores, tympanograms, otoscopy findings, and the pressure-equalizing maneuver (all P < .001) (Froehlich, 2020). Wang compared 942 balloon procedures with 121 laser interventions and reported a larger standardized mean improvement in composite Eustachian-tube scores (0.94; 95 % CI 0.23 to 1.66; P = .009) and a higher tympanogram normalization rate (73 % versus 13 %; P = .001), whereas the pressure-equalizing maneuver showed no significant difference (Wang, 2018). For barometric challenge dysfunction, Raymond synthesized 81 participants and noted symptom resolution in 84% and return to work in 79%, although heterogeneity remained high (Raymond, 2022). A Finnish review of five studies with ≥12-month follow-up recorded durable improvements in pressure-equalizing ability for 80 % – 98 % and symptom relief for 73 % – 98 %, while tympanogram normalization ranged from 24 % to 54 % (Luukkainen, 2018).

Other evidence

Randomized data, although limited, reinforce the short-term benefit and safety. A pivotal multicenter trial of 222 ears reported tympanogram normalization in 52 % of balloon-treated ears versus 14 % of medically managed controls at six weeks, with superiority maintained at 24 weeks and no device-related serious events (data reported within Froehlich, 2020). Safety findings align with a 2016 review of nine case series (n = 474) that recorded minor epistaxis in 1 % – 6 %, small mucosal lacerations in up to 3 %, transient subcutaneous emphysema in <1 %, and rare cervical radiculopathy; no carotid injury was reported, though caution is advised when a dehiscent artery is present (Hwang, 2016). The 2014 Health Technology Assessment remains foundational, cataloguing alternative interventions and advocating for controlled trials with standardized outcome measures and follow-up beyond one year (Llewellyn, 2014). Across the additional reviews, reported adverse events were uncommon and usually minor; however, sample size, inconsistent adverse-event definitions, observational designs, and incomplete follow-up limit estimation of rare harms (Gołota, 2025; Khan, 2026; Zujaj, 2026; Saade, 2026).

Interpretation is limited by overlapping patient cohorts across publications and reviews, variable definitions of obstructive Eustachian tube dysfunction and treatment success, high statistical and clinical heterogeneity, reliance on uncontrolled pre-post comparisons, subjective outcome measures, follow-up generally limited to one year, concurrent procedures that prevent attribution of benefit to balloon dilation, and analyses that do not consistently account for correlation between two ears in the same patient. Pediatric studies are additionally

confounded by natural anatomical and functional maturation of the Eustachian tube. These limitations reduce certainty regarding comparative effectiveness, durability, and rare adverse events (Gołota, 2025; Khan, 2026; Raj, 2026; Geneau, 2026; Zujaj, 2026; Saade, 2026).

In 2026 we added a pediatric specialty-society position statement supporting balloon dilation for carefully selected patients with refractory obstructive Eustachian tube dysfunction (American Academy of Otolaryngology-Head and Neck Surgery, 2025) and six systematic reviews and meta-analyses evaluating adult and pediatric clinical outcomes, comparative effectiveness, anesthesia approach, and safety while highlighting substantial heterogeneity and limitations in the evidence base (Gołota, 2025; Khan, 2026; Raj, 2026; Geneau, 2026; Zujaj, 2026; Saade, 2026).

References

On July 9, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Eustachian tube (MeSH),” “dilatation (MeSH),” “Eustachian tube,” “Eustachian tuboplasty,” and “Eustachian tube dysfunction.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

8/2022: initial review date and clinical policy effective date: 9/2022

8/2023: Policy references updated.

8/2024: Policy references updated.

8/2025: Policy references updated.

9/2026: Policy references updated.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1519.This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
69705	Nasopharyngoscopy, surgical, with dilation of Eustachian tube (i.e., balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of Eustachian tube (i.e., balloon dilation); bilateral