Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

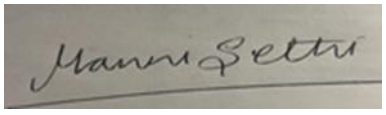
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 9/1/2025
Policy Number: CCP.1519	Effective Date: 9/1/2022 Revision Date: 8/1/2025
Policy Name: Balloon dilation of the Eustachian tube	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Balloon dilation of the Eustachian tube

Clinical Policy ID: CCP.1519

Recent review date: 8/2025

Next review date: 12/2026

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

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania on a case by case basis when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.

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.

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 18 years of age.

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–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.

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).

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).

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).

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).

In 2025, we condensed the background and findings sections and we identified four new studies relevant to balloon dilation of the Eustachian tube: a systematic review of adult outcomes (Alghamdi, 2024), a Cochrane meta-analysis of randomized trials (Swords, 2025), a systematic review and meta-analysis of pediatric cases (Ramagiri, 2024).

References

On July 9, 2024, 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.