Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices/Keystone First Community HealthChoices	**Submission Date**: 9/1/2024
Policy Number: ccp.1519	**Effective Date:** 9/2022 **Revision Date:** August 1, 2024
Policy Name: Balloon dilation of the Eustachian tube	

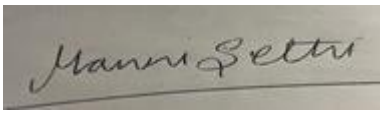
Type of Submission – Check all that apply:

- **New Policy**
- **X Revised Policy***
- **Annual Review – No Revisions**
- **Statewide PDL**

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

Please provide any clarifying information for the policy below:

See tracked changes below.

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

Keystone First
Community HealthChoices

Balloon dilation of the Eustachian tube

Clinical Policy ID: CCP.1519

Recent review date: 8/2024

Next review date: 12/2025

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

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Keystone First Community HealthChoices, 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. Keystone First Community HealthChoices' 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. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' 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, also called the pharyngotympanic or auditory tube, connects the middle ear space to the nasopharynx and regulates middle ear homeostasis. Its three main functions are to: ventilate the middle ear and equalize middle ear pressure; facilitate tube mucociliary transport for drainage; and protect the middle ear from loud sounds and pathogens (Hamrang-Yousefi, 2023).

Failure of the Eustachian tube to maintain any of these functions may result in acute or chronic symptoms of Eustachian tube dysfunction. Symptoms may include aural fullness, popping or cracking sounds, reduced hearing, tinnitus, autophony, otalgia, and imbalance. Left untreated, more serious complications may result in conductive hearing loss, otitis media, otitis media with effusion, cholesteatoma formation, and eardrum retraction, with subsequent progression toward speech and hearing problems, attentional disturbances, limited vocabulary, and sleep deprivation (Hamrang-Yousefi, 2023).

Eustachian tube dysfunction affects all ages. Approximately 1% of the adult population is diagnosed with the condition. It is more prevalent among children, particularly among preschool children who have immature Eustachian tube growth and in whom otitis media with effusion is a common sequela. Males are more likely to be diagnosed before the age of 20, while females are more likely to be diagnosed at older ages (Vila, 2017).

Diagnosis of Eustachian tube dysfunction can be complicated due to varied and nonspecific clinical presentations and underlying etiologies. It may present as baro-challenged induced (inhibiting regulation of middle ear pressure), patulous (failure of the tube to close at rest, resulting in continuous communication between the nasopharynx and the middle ear), or dilatory (involving inflammation and mucosal edema). In clinical practice, Eustachian tube dysfunction typically refers to ventilatory dysfunction defined by symptoms and signs of pressure dysregulation in the middle ear (Schilder, 2015).

Diagnosis is generally based on medical history and clinical examination to identify potential underlying causes. Objective means of assessment, including nasal endoscopy, otoscopy, tympanometry, and comprehensive audiometry, are essential. Validated patient questionnaires such as Eustachian Tube Dysfunction Patient Questionnaire (ETDQ-7) allow for evaluation of a wide array of symptoms (Hamrang-Yousefi, 2023).

Treatment is targeted toward the likely cause of dysfunction. Conservative management (e.g., lifestyle changes and pressure equalization methods) may benefit patients with certain etiologies. Topical or systemic medical treatment (e.g., anti-inflammatory agents, decongestants, and antihistamines) may be indicated if the etiology can be identified. Surgical interventions (e.g., adenoidectomy, myringostomy, and tympanostomy tube insertion) are usually reserved for persistent symptoms of obstructive Eustachian tube dysfunction. Newer minimally invasive surgical techniques include Eustachian tuboplasty with a laser or rotary cutting tool and balloon dilation (Llewellyn, 2014).

Balloon dilation of the Eustachian tube involves a balloon catheter inserted into the nose and threaded into the cartilaginous portion of the Eustachian tube. The balloon is inflated briefly with saline, deflated, and removed. The goal is to increase tubal patency and reduce or eliminate the inflammatory obstruction (Llewellyn, 2014).

The U.S. Food and Drug Administration (2023) has issued 510(k) approval to several devices for dilation of the cartilaginous portion of the Eustachian tube using a transnasal approach for treating persistent Eustachian tube dysfunction in patients age 18 years or older. No device has been approved for use in children.

Findings

Eustachian tube dysfunction is a complex and often ill-defined condition. An earlier systematic review confirmed that wide variation in diagnostic criteria used to define Eustachian tube dysfunction and measure treatment effects makes the safety and relative effectiveness of available treatments difficult to evaluate (Llewellyn, 2014).

To that end, the American Academy of Otolaryngology–Head and Neck Surgery Foundation® developed a clinical consensus statement using a modified Delphi method to provide guidance on the optimal patient selection criteria, perioperative considerations, and outcome measures for balloon dilation of the Eustachian tube. The consensus statement applies to adults 18 years or older with obstructive Eustachian tube dysfunction in one or both ears lasting three months or longer that significantly affects quality of life or functional health status. The committee emphasized using only devices approved for balloon dilation of the Eustachian tube to enhance safety (Tucci, 2019).

Topics for which consensus was reached include (Tucci, 2019):

- Balloon dilation of the Eustachian tube is appropriate for those who have failed medical therapy for identified treatable causes.

- Patients undergoing balloon Eustachian tube dilation concurrent with sinus ostial dilation should meet the diagnostic criteria for each procedure.
- Myringotomy with or without tympanostomy tube placement is not a mandatory prerequisite.
- Balloon dilation of the Eustachian tube is an alternative to tympanostomy tube placement for obstructive Eustachian tube dysfunction.
- Patients with a middle ear effusion at the time of balloon dilation may benefit from concurrent myringotomy with or without tympanostomy tube placement.
- Nasal endoscopy, otoscopy, tympanometry, and comprehensive audiometry are essential prior to the procedure.
- Validated patient-reported symptom scores and ability to perform a modified Valsalva maneuver are useful for assessing treatment outcomes for obstructive Eustachian tube dysfunction.
- The benefit of repeat balloon dilation of the Eustachian tube after a prior ineffective balloon dilation has not been determined.
- Contraindications to the procedure include patients with patulous Eustachian tube dysfunction, extrinsic obstruction of the Eustachian tube, active primary inflammatory disorders, temporomandibular disorders, superior semicircular canal dehiscence, and Meniere's disease.

The evidence base for children is limited to relatively few case series of adolescent enrollees primarily with persistent otitis media with effusion. Balloon dilation of the Eustachian tube was performed alone or with myringotomy with or without ventilation tube insertion. Preliminary evidence from two systematic reviews suggests balloon dilation improves symptoms, tympanometry, and air-bone gap measurement with no major complications (Aboueisha, 2022, n = 408; Saniasiaya, 2022, n = 284).

As a primary intervention, balloon dilation compared favorably to ventilation tube insertion with respect to air-bone gap (mean difference −6.4, 95% confidence interval -9.8 to − 3.1, $P < .001$) and failure rate (odds ratio 0.24, 95% confidence interval 0.10 to 0.44, $P = .013$). The pooled adverse event rate after balloon dilation was 5.1%. Most complications involved minor epistaxis, two cases of patulous Eustachian tubes, and no cases of serious injury (Aboueisha, 2022).

The evidence base for adults, described in the systematic reviews below, consists of three randomized controlled trials and several small prospective and retrospective case series. All studies had a high risk of bias, particularly selection bias, and study arms varied with respect to preoperative and postoperative treatment.

The strongest evidence comes from randomized controlled trials that enrolled patients age 18 or older with chronic, refractory unilateral or bilateral Eustachian tube dysfunction and in whom balloon dilation was performed alone, not concurrently with otologic and sinonasal procedures. A minority of patients had tympanostomy tubes or tympanic membrane perforation at the time of balloon dilation. Enrollees underwent a range of objective and subjective assessments before and after the procedure. Balloon dilation for persistent obstructive Eustachian tube dysfunction resulted in subjective and objective improvement of symptoms up to one year after the procedure. Most complications were minor and self-limiting, with local epistaxis being the most common.

A systematic review and meta-analysis of 11 low-quality studies (n = 81), including one study of laser Eustachian tuboplasty, found balloon dilation of the Eustachian tube appeared to improve the ability to Valsalva (mean 82.5%, 95% confidence interval 42% to 100%), return to work (79.1%, 57.9% to 94.1%), and any symptom (84.3%, 69.8% to 94.7%), along with significant improvements in ETDQ-7 scores ($P < .00001$) (Raymond, 2022).

A systematic review of 35 studies and a meta-analysis of 12 studies (n = 448) found balloon dilation of the Eustachian tube improved subjective and objective treatment outcomes from three to 12 months after the procedure. Statistically significant improvements from baseline to three to 12 months after dilation in ETDQ-7 scores, tympanograms, proportion of normal otoscopy exams, and ability to perform a Valsalva maneuver were reported ($P < .001$) (Froehlich, 2020).

Luukkainen (2018) summarized the long-term effects of balloon Eustachian tuboplasty to support recommendations by the Finnish Otosurgical Society. Results from five low-quality studies with at least 12 months follow-up reported Valsalva ability improved in 80% to 98%, overall subjective symptoms in 73% to 98%, and otoscopic findings in 90% of the enrollees. Lower improvements in tympanometry (24% to 54% of patients) and tubomanometry (28% to 43% of patients) were observed. Five additional studies with a shorter follow-up of six to 11 months reported findings consistent with the longer-term studies. The authors called for more controlled prospective studies with long-term (> 12 months) follow-up using more uniform outcome measures.

Results of a meta-analysis of 13 retrospective and prospective studies (n = 942 treated with balloon and 121 with laser tuboplasty) suggest balloon tuboplasty significantly improved the Eustachian tube score (pooled standardized mean difference 0.94; 95% confidence interval 0.23 to 1.66; *P* = .009) and tympanometry improvement rate (pooled event rate = 73% vs 13%; *P* = .001) compared with laser tuboplasty. There was no between-group difference in the Valsalva maneuver improvement rate (67% vs. 50%; *P* = .472) (Wang, 2018).

A systematic review of nine case series (n = 474) confirms the safety of balloon dilation of the Eustachian tube with follow-up durations of 1.5 to 18 months. Where reported, minor epistaxis, minor mucosal lacerations, self-resolving subcutaneous emphysema, acute otitis media, and C6–C7 contralateral radiculopathy were infrequent complications. Injury to an adjacent dehiscent carotid artery was not reported in any study but remains a theoretical concern (Hwang, 2016).

In 2023, we identified no newly published, relevant literature to add to the policy. No policy changes are warranted.

In 2024, we found systematic review examined six studies with (n = 193) patients that underwent balloon dilation of the eustachian tube under local anesthesia. The review found that balloon dilation of the eustachian tube under local anesthesia appears to be safe and effective for properly selected patients with obstructive eustachian tube dysfunction. Outcomes measured varied between studies but generally showed improvements in symptoms and objective measures like tympanometry. Minor complications were rare, and no major complications were reported. Patient satisfaction was high, with most patients willing to undergo the procedure again under local anesthesia if needed. The authors concluded that balloon dilation of the eustachian tube under local anesthesia is a feasible treatment option No policy changes warranted (Ungar, 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.