DRAFT Medical Coverage Policy | Balloon Dilation of the Eustachian Tube

EFFECTIVE DATE: 03|01|2021
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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

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 patient 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:
   - Abnormal tympanogram (Type B or C)
   - 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 patient had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent AND

6. The patient does not have patulous eustachian tube dysfunction or another contraindication to the procedure as noted below AND

   - Contraindications are as follows:
     - Patients 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.
     - Patients 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)
    - Patients with chronic and severe atelectatic ears

7. The patient's eustachian tube dysfunction has been shown to be reversible as defined below: AND

    - The patient states that they are able to relieve the pressure by performing a Valsalva maneuver to "pop" their ears
    - Performing a Valsalva maneuver produces temporary improvement of the patient'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

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 patient has not had a previous BDET procedure

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products.

POLICY STATEMENT

BlueCHiP for Medicare 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 medical criteria are met.

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

- Patients undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Patients with a middle ear effusion at the time of BDET 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 our without tympanostomy tube placement. This addresses BDET as a standalone procedure.

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) (class II, FDA product code: PNZ). The new classification applies to this device and substantially equivalent devices of this generic type. The AERA® is cleared for dilating the ET in patients ages 22 and older with persistent eustachian tube dysfunction (ETD).

In December 2016, the XprESS™ ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by the FDA through the 510(k) process (K163509). The FDA determined this device was substantially equivalent to existing devices for use in eustachian tube dysfunction (ETD). The predicate devices are XprESS™ Multi-Sinus Dilation System (K152434) and AERA® Eustachian Tube Balloon Dilation System.

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 followup. 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 the effects of the technology on the net health outcome.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are medically necessary when the criteria are met:

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

C9745 Nasal endoscopy, surgical; balloon dilation of Eustachian tube

RELATED POLICIES

None

PUBLISHED

Provider Update, January 2021
Provider Update, June 2019
Provider Update, Sep 2018

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