MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Balloon Dilation of the Eustachian Tube**
Policy Number	**7.01.101**
Category	**Technology Assessment**
Original Effective Date	**08/15/19**
Committee Approval Date	**08/15/19, 9/17/20, 09/16/21, 09/15/22, 09/21/23**
Current Effective Date	**09/21/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, balloon dilation of the eustachian tube has not been medically proven to be effective and, therefore, is considered **investigational** in the treatment of chronic eustachian tube dysfunction (ETD).

POLICY GUIDELINES

In September 2016, the Acclarent AERA was granted Section510(k) classification by the Food and Drug Administration (FDA). The device is cleared for dilation of the ET in patients aged 22 years and older who have persistent ETD. In January 2018, the device received 510(k) clearance to treat patients ages 18 and older.

In December 2016, the XprESS ENT Dilation System was also cleared by the FDA through the Section 510(k) process. The FDA determined that the device was equivalent to existing devices used for ETD.

In August 2021, the NuVent Eustachian Tube Dilation Balloon (Medtronic) was cleared for marketing through the 501(k) process to treat persistent ETD in patients 18 years and older (K210841).

DESCRIPTION

Eustachian tube dysfunction (ETD) is a common healthcare problem, affecting both children and adults. Children are at greater risk because of immature immune systems, which are necessary to fight infections, and shorter eustachian tubes, which increases the chance of mucous and germ entrapment. In adults, ETD may occur more frequently in smokers, in obese individuals (who are more prone to develop fatty deposits around the tubes), and in individuals with allergies (which may cause increased mucus and congestion).

The eustachian tube (ET) is a tube that links the nasopharynx to the middle ear. In adults, the ET is approximately 35 millimeters (mm) in length. It functions in ventilating the middle ear space allowing for pressure equalization across the

tympanic membrane. The ET opens during yawning, swallowing, and sneezing which aids in clearing secretions, and protects the middle ear from infection and nasopharyngeal contents.

When the ET becomes blocked, usually due to inflammation, the pressure across the tympanic membrane is unable to equalize and contents are unable to clear leading to ETD. Inflammation in the ET is usually caused by rhinosinusitis and allergic rhinitis. Symptoms of ETD include a feeling of fullness in the ear, tinnitus, muffled hearing loss, and vertigo. Chronic ETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas.

Current medical management of ETD is dependent upon the underlying etiology. Decongestants and antihistamines can be used for rhinosinusitis to relieve inflammation and secretions. Nasal steroid sprays can also be used to aid in the relief of inflammation.

Patients who do not find relief with medical management may be treated with surgery. Available surgical interventions include myringotomy with tympanostomy tube placement, in which a small incision is made to the tympanic membrane and a small tube is placed, to allow for drainage of secretions.

Balloon dilation of the eustachian tube (BDET) is a novel procedure intended to improve the patency of the cartilaginous eustachian tube and ease the symptoms of ETD by expanding the ET. During the procedure, which is usually performed under general anesthesia, a saline-filled balloon catheter is inserted through the nose and into the ET with endoscopic guidance. Once the balloon is placed, it is inflated. Pressure is maintained for approximately two minutes, followed by deflation and removal. Expansion of the ET aims to allow for the drainage of secretions and equalization of pressure across the tympanic membrane, providing relief for those suffering from ETD.

RATIONALE

For individuals who have chronic obstruction ETD despite medical management and receive balloon dilation of the ET, the evidence includes RCTs, prospective observational studies, case series, and systematic reviews of these studies. To date, RCTs have only published 52-week outcome results. Without longitudinal data, it is unclear how many people will develop recurrent problems over longer observation periods.

Two six-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 individuals 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 individuals 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.

A randomized controlled trial was conducted by Poe et al. (2017) to assess the safety and efficacy of BDET. The sample size was 323 patients, with 162 in the investigational group and 80 in the control group; 81 patients were included as nonrandomized lead-in subjects. Patients included in the study were aged 22 years and older who had persistent ETD and who had failed medical management, which consisted of either a minimum of four weeks of continuous daily usage of any intranasal steroid spray or a minimum of one completed course of an oral steroid within 90 days of study enrollment. A positive diagnosis of persistent ETD was confirmed with both abnormal tympanometry and symptomatic dysfunction, as determined by the Eustachian Tube Dysfunction Questionnaire (ETDQ-7). BDET was performed in the operating room under general anesthesia. Each dilation was done at an inflation pressure of 10-12 atm, with a total time of two minutes. On the day of the procedure subjects in the investigational group began their triamcinolone acetonide nasal steroid spray regimen. Subjects in the control group began the same regimen on the day of randomization. Throughout the duration of study participation, subjects were permitted to continue any concomitant medications for their ETD or other medical conditions deemed clinically necessary, per the investigator's discretion. The primary effectiveness endpoint was normalization of tympanometry at six-week follow-up. At the six-week follow up period, 51.8% of the investigational group had a normal tympanogram versus 13.9% in the control group. At 24 weeks postoperatively, tympanogram normalization in the treatment group was 62.2%, however, the majority of the failed control group subjects had crossed over, so no statistical comparison could be made. Improvement in tympanometry was also associated with normalization of the ETDQ-7 at six-weeks. There were no serious adverse effects noted in the study, but two subjects did develop mild

symptoms of patulous ET, one of which resolved by the completion of the study. The authors concluded that the study shows BDET, with adjunctive medical management, is superior to medical management alone. Some limitations were identified; Patients were not blinded to their treatment, due to the nature of the study; in addition, the majority of patients in the control group (82%) did opt to crossover and receive BDET before their 12-week follow-up. As a result, six weeks post-randomization, the control group became relatively small and self-selecting in nature, likely biasing any statistical comparison between treatment groups.

Anand, et al. (2019) published a 52-week follow up to the same study. At 52 weeks, the overall results of tympanograms and ETDQ-7 questionnaires of subjects who received balloon dilation remained comparable to the results at the six-week follow-up period. Tympanograms were done at six weeks, 12 weeks, 24 weeks and 52 weeks. At six weeks, the tympanogram results were 51% normalized; at 52 weeks, 55.5% were normalized. There were many instances in which ears had normalized tympanograms, then reverted to non-normalized tympanograms, then normalized tympanograms again. In total, 63.6% of ears had normalized tympanograms at 52 weeks, either remaining normal throughout the study or converting to normal (failure then becoming normal or temporary failure but return to normal). The authors concluded that the beneficial effects of BDET with medical management at the 52-week follow-up demonstrate a durability that is clinically relevant.

A randomized controlled trial by Meyer et al. (2018) compared BDET to continued medical therapy for treating persistent ETD. Subjects were randomized in a 1:1 ratio to balloon dilation or control (medical management). Of the 60 patients in the study, 31 patients were randomized to the balloon dilation group, and 29 were randomized to the control group. Patients were required to follow-up at six-weeks, and then at three-, six-, and 12-months post-procedure. Patients included in the study were aged 18 years and older, who had been diagnosed with ETD for 12 months or greater, had three or more symptoms, and had failed medical therapy of intranasal steroids or oral steroids. After six weeks, subjects in the control group had the option to undergo the procedure if their symptoms persisted. Comparison between baseline and post treatment was evaluated using a seven-item eustachian tube dysfunction questionnaire (ETDQ-7). The study found that balloon dilation led to a significant reduction in overall ETDQ-7 scores, as well as statistically significant improvement in ETD symptoms and middle ear functional assessments. The authors concluded that BDET is a safe, effective, and durable treatment for ETD.

Froehlich et al. (2020) conducted a systematic review and meta-analysis of balloon dilation for ETD. Twelve studies were included in the meta-analysis, including 3 RCTs, 5 prospective observational studies, and 4 case series. One RCT (Liang et al 2016) that compared balloon dilation to tympanic paracentesis reported tympanometry and otoscopy scores but not symptoms. The other 2 RCTs compared balloon dilation plus medical management to medical management alone and used the ETDQ-7 to measure symptoms. Pooled analyses showed improvements in subjective and objective measures including ETDQ-7 scores, tympanograms, otoscopy exams, and ability to perform a Valsalva maneuver. Improvements appeared to be maintained in studies with longer-term follow up (3 to 12 months).

A meta-analysis by Huisman et al. (2018) was conducted to evaluate the success of BDET in reducing symptoms in adult patients with ETD. The search yielded 15 studies that met inclusion criteria for a total of 1,155 patients. Inclusion criteria involved studies that were BDET in adults with ETD. The studies evaluated improvement of ETD symptoms to measure effectiveness of treatments such as the Valsalva maneuver, otoscopy, tympanometry, and the ET score. Revisions due to failure of the first ET balloon dilation procedure were reported in three of the 15 studies, including 714 patients. Overall, the results from the studies included in the analysis found that all types of ETD showed an improvement in short-term follow-up, and the number of complications was relatively low. The authors recommended future research in randomized homogenous populations.

In 2019, the American Academy of Otolaryngology Head and Neck Surgery published a clinical consensus statement on BDET (Tucci et al). The target population was defined as adults ≥18 years who are candidates for BDET because of obstructive ETD in one or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded that although BDET is an option for treatment of obstructive ETD, further studies are needed to refine patient selection and outcome assessment.

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET (NICE, 2019). The guidance was based on a rapid review of the evidence and stated, "Evidence on the safety and efficacy of

balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." NICE standard arrangements recommendations mean that there is enough evidence for doctors to consider the procedure as an option. The guidance also noted the procedure was not effective in all patients, there was little evidence on the benefit of repeat procedures, and the procedure is only indicated for chronic ETD refractory to medical treatment.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
31231	Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)
69705 **(E/I)**	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral
69706 **(E/I)**	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral
69799	Unlisted procedure, middle ear
92511	Nasopharyngoscopy with endoscope (separate procedure)

HCPCS Codes

Code	Description
	none

ICD10 Codes

Code	Description
H68.001-H68.029	Eustachian salpingitis and obstruction (code range)
H69.80-H69.93	Other specified and unspecified disorders of Eustachian tube (code range)
H65.00-H65.93	Nonsuppurative otitis media (code range)
H66.001-H66.93	Suppurative and & unspecified otitis media (code range)
H67.1-H67.9	Otitis media in diseases classified elsewhere (code range)
H71.00-H71.93	Cholesteatoma of middle ear (code range)
H72.00-H72.93	Perforation of tympanic membrane (code range)
H81.01-H81.09	Meniere's disease (code range)
H81.311-H81.4	Peripheral and Central vertigo (code range)
H91.01-H91.93	Other and unspecified hearing loss (code range)
J30.0-J30.9	Vasomotor and allergic rhinitis (code range)
J31.0-J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis (code range)
J32.0-J32.9	Chronic sinusitis (code range)

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*Key Article

KEY WORDS

Balloon dilation, eustachian tube, Acclarent Aera, XprESS

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, balloon dilation of the eustachian tube is not addressed in National or Regional CMS coverage determinations or policies.