MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Balloon Dilation of the Eustachian Tube**
Policy Number	**7.01.101**
Category	**Technology Assessment**
Effective Date	**08/15/19**
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

Based upon our criteria and assessment of peer-reviewed literature, balloon dilation of the Eustachian tube has not been proven medically effective and is considered **investigational** in the treatment of chronic Eustachian tube dysfunction.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Eustachian tube dysfunction (ETD) is a common healthcare problem, affecting children and adults with children being at greater risk because of immature immune systems 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 35mm in length and 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 as well as it 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 are also 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, 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 tubes is a novel procedure intended to ease the symptoms of ETD by expanding the ET. The procedure is performed under general anesthesia during which a saline-filled balloon catheter is inserted through the nose and into the ET with endoscopic guidance. Once the balloon is in place it is inflated, and pressure is maintained for approximately two (2) minutes, followed by deflation and removal. Expansion of the ET aims to allow for the drainage of secretions and pressure equalizing across the tympanic membrane providing relief for those suffering from ETD. At this

time there are two (2) FDA approved devices for use in balloon dilation of the Eustachian tube, the Acclarent Aera® (Johnson & Johnson) and the XprESS™ (Stryker).

RATIONALE

In September 2016 the Acclarent AERA® was granted 510(k) classification by the U.S. Food and Drug Administration (FDA), the device is cleared for dilation the eustachian tube in patients ages 22 years and older with persistent eustachian tube dysfunction (ETD). In December 2016 the XprESS™ ENT Dilation System was cleared by the FDA through the 510(k) process. The FDA determined that the device was equivalent to existing devices used for ETD.

A meta-analysis by Huisman et al. (2018) was conducted to evaluate the success of balloon dilation of the eustachian tube in reducing symptoms in adult patients with eustachian tube dysfunction. The search yielded 15 studies that met inclusion criteria for a total of 1,155 patients. Inclusion criteria involved studies that were balloon dilation of the eustachian tube in adults with ETD. The studies measured improvement of ETD symptoms to measure effectiveness of treatment, including use of the Valsalva maneuver, otoscopy, tympanometry and the eustachian tube score. Revisions due to failure of the first ET balloon dilation procedure were reported in 3 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 recommend future research in randomized homogenous populations.

A randomized controlled trial was conducted by Poe, et al. (2018) to assess the safety and efficacy of balloon dilation of the Eustachian tube (ET). The sample size was 323 patients, 162 in the investigational group and 80 in the control group and 81 patients were included as nonrandomized lead-in subjects. Patients included in the study were 22 years and older with persistent ET dysfunction who had failed medical management consisting of either a minimum of 4 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). Balloon dilation of the ET 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 (2) 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 ETDD or other medical conditions deemed clinically necessary, per the investigator's discretion. The primary effectiveness endpoint was normalization of tympanometry at 6-week follow-up. At the 6-week follow up period 51.8% of the investigational group had a normal tympanogram vs. 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 6-weeks. There were no serious adverse effects noted in the study, but two (2) subjects did develop mild symptoms of patulous ET, one (1) of which resolved by the completion of the study. The authors conclude that the study shows balloon dilation of the ET with adjunctive medical management is superior to medical management alone. There were no adverse events in the study. Some limitations identified were that patients were not blinded to their treatment due to the nature of the study, also the majority of patients in the control group (82%) did opt to crossover and receive BDET before their 12-week follow-up, therefore, 6 weeks post-randomization, the control group became relatively small and self-selecting in nature, likely biasing any statistical comparison between treatment groups.

Poe, 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 6-week follow-up period. Tympanograms were done at 6-weeks, 12-weeks, 24-weeks and 52-weeks. At 6-weeks the tympanogram results were 51% normalized and at 52-weeks, 55.5% were normalized.. There were many instances where ears had normalized tympanograms which then reverted to nonnormalized tympanograms and finally back to normalized 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 conclude that

at the 52-week follow-up of this study the beneficial effects of balloon dilation of the Eustachian tube with medical management demonstrate a durability that is clinically relevant.

A randomized controlled trial by Meyer et al. (2018) compared eustachian tube balloon dilation versus continued medical therapy for treating persistent eustachian tube dysfunction. Subjects were randomized in a 1:1 ratio to balloon dilation or control, or medical management. Thirty-one patients were randomized to the balloon dilation group and 29 were randomized to the control group for a total of 60 patients. Patients were required to follow-up at 6-weeks, and 3-, 6-, and 12-month post-procedure. Patients included in the study were 18-years and older, diagnosed with ETD for 12-months or greater, with three (3) or more symptoms, and failed medical therapy of intranasal steroids or oral steroids. After 6-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 7-item eustachian tube dysfunction questionnaire (ETDQ). The study found balloon dilation lead to a significant reduction in overall ETDQ scores, and statistically significant improvement in eustachian tube dysfunction symptoms and middle ear functional assessments. The authors concluded that eustachian tube dilation is a safe, effective, and durable treatment for ETD.

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.*

CPT Codes

Code	Description
31231	Nasal endoscopy, diagnostic, unilateral or bilateral
68816	Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation
69799	Unlisted procedure, middle ear
92511	Nasopharyngoscopy with endoscope

HCPCS Codes

Code	Description
C9745 **(E/I)**	Nasal endoscopy, surgical; balloon dilation of eustachian tube

ICD10 Codes

Code	Description
H68.001-H68.029	Eustachian salpingitis 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-H81.49	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
J31.0-J32.9	Chronic rhinitis and Sinusitis range

REFERENCES

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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.