

# Protocol

## Balloon Dilation of the Eustachian Tube

(701158)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/19	<b>Next Review Date:</b> 09/20
<b>Preauthorization</b>	No	<b>Review Dates:</b> 09/18, 09/19	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With chronic eustachian tube dilatory dysfunction despite medical management</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Balloon dilation of the eustachian tube</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Continued medical management</li><li>• Mechanical pressure equalization device</li><li>• Tympanostomy</li><li>• Eustachian tuboplasty other than balloon dilation</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Change in disease status</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>

### DESCRIPTION

Eustachian tube (ET) dysfunction occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure is frequently due to inflammation and can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo. Chronic dysfunction can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the ET is a procedure intended to improve the patency by inflating a balloon in the cartilaginous part of the ET to cause local dilation.

### SUMMARY OF EVIDENCE

For individuals who have chronic ET dilatory dysfunction despite medical management who receive balloon dilation of the ET, the evidence includes case series, systematic reviews of case series, a retrospective cohort study, and two randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The criteria for diagnosing ET dilatory dysfunction are not standardized. Several medical and surgical treatments are used for ET dilatory dysfunction, but there is limited evidence for available treatments. Most case series assessed provided follow-up of less than a year and all showed short-term improvement comparing symptoms before and after balloon dilation. The number of revision procedures required due to the failure of the first ET balloon dilation procedure was reported in three case series (n=714 patients); 122 revisions were reported. In one published RCT evaluating balloon dilation of the ET, patients were eligible if they reported persistent ET dilatory dysfunction symptoms as measured on the 7-item Eustachian Tube Dysfunction Questionnaire, a tool to assess symptoms, and had abnormal tympanometry. A greater proportion of patients in the balloon dilation group demonstrated tympanogram normalization (52%) compared

with the medical management group (14%) at six weeks and reported a reduction in symptoms at six weeks on the 7-item Eustachian Tube Dysfunction Questionnaire. The durability of effect at 24 weeks was demonstrated in a subset of patients. The rate of adverse events was low, and none of the serious adverse events were thought to be related to the device or procedure. The 52-week follow-up data have not been reported. The second RCT enrolled patients with moderate to severe ET dysfunction based on the 7-item Eustachian Tube Dysfunction Questionnaire but who were not required to have abnormal middle ear functional assessments. Symptom score change was the primary outcome and mean score decrease was greater in the balloon dilation group than the medical management group. In both RCTs, the initiation, concomitant or continued use of medical therapy of multiple drug classes was at the discretion of the investigators. The durability of effect, rates of re-operation or revisions, and safety data over the first year are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

Balloon dilation of the eustachian tube for treatment of patients with chronic eustachian tube dilatory dysfunction is considered **investigational**.

## BACKGROUND

### EUSTACHIAN TUBE FUNCTION

The ET connects the middle ear space to the nasopharynx. It is approximately 36 mm long in adults. The ET 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.<sup>1</sup> The tube opens during swallowing or yawning.

Eustachian tube dysfunction (ETD) occurs when the functional valve of the ET fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. ET dilatory dysfunction (ETDD) is most commonly caused by inflammation including rhinosinusitis and allergic rhinitis. ETDD can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo.<sup>2</sup> Chronic ETDD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas.

### Epidemiology of ETD

The epidemiology of ETD, including incidence and prevalence of the disorder and associated symptoms in the community, primary care, and referral populations, is not well-characterized. Data are also lacking to describe the natural history of the disorder and impact on patient functioning.

### Diagnosis and Outcome Measures

There are no comprehensive guidelines regarding the diagnosis of ETD. In response to a National Institute for Health Research Health Technology Assessment (2014) concluding that an important limitation with available evidence for treatments of ETD is a lack of consensus on the definition and diagnosis,<sup>3</sup> an international group of scientists and physicians with expertise in ET disorders developed consensus statements on ETD.<sup>1</sup> The meeting was funded by Acclarent, a manufacturer of a dilation technology. The following summarizes relevant 2015 consensus statements from the group.

- There is no universally accepted set of patient-reported symptom scores, functional tests, or scoring systems to diagnose ETD.
- Diagnosis of ETDD should consider patient-reported symptoms along with evidence of negative pressure in the middle ear assessed by clinical assessment.

- Transient ETD is ETD with symptoms and signs lasting less than three months while chronic ETD is ETD with symptoms and signs lasting for more than three months.
- Future clinical trials should include outcomes related to patient-reported symptoms, otoscopy, tympanometry, and pure-tone audiometry, and outcomes should be assessed at baseline, in the short-term (six weeks to three months) and the long-term (six to 12 months).
- The 7-item Eustachian Tube Dysfunction Questionnaire is the only patient-reported outcome scale to have undergone initial validation studies.

Tympanometry is a frequently used outcome measure in ETD. Tympanometry measures the mobility of the tympanic membrane and graphically displays results in tympanograms. Tympanograms are classified by the height and location of the tympanometric peak. They are classified into three general patterns: type A indicates normal middle ear and ET function; type B indicates poor tympanic membrane mobility (“flat” tympanogram), and type C indicates the presence of negative middle ear pressure.<sup>4</sup>

The 7-item Eustachian Tube Dysfunction Questionnaire is used to assess ETD-related symptoms such as pressure, pain, “clogged” ears, and muffled hearing over the previous month. The seven items are rated by patients on a 7-level scale from one (no problem) to seven (severe problem). The overall score is reported as a mean item score with a range from 1.0 to 7.0. The Eustachian Tube Dysfunction Questionnaire has been shown to be a valid and reliable symptom score for use in adults with ETD with an overall score of 2.1 or higher having high accuracy to detect the presence of ETD.<sup>5</sup>

Other important outcomes for evaluating a treatment for ETD are hearing outcomes, otitis media, clearance of middle ear effusion, tympanic membrane retraction, and quality of life. Another important consideration is the need for additional treatment, e.g., additional surgical procedures (including reintervention).

#### Treatment of ETDD

Medical management of ETDD is directed by the underlying etiology: treatment of viral or bacterial rhinosinusitis; systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; and treatment of mass lesions. Although topical nasal steroids are commonly used for ETDD, triamcinolone acetonide failed to show benefit in patients ages six and older presenting with otitis media with effusion and/or negative middle ear pressure in a randomized, placebo-controlled, double-blind trial published (2011).<sup>6</sup>

Patients who continue to have symptoms following medical management may be treated with surgery. Available surgical management includes myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. There is limited evidence and no randomized controlled trials supporting use of these surgical techniques.<sup>7</sup> Norman et al (2014) reported that eustachian tuboplasty (other than balloon dilation) has been evaluated in seven case series and was associated with improvement in symptoms in 36% to 92% of patients with low rates (13%-36%) of conversion to type A tympanogram (which is normal). Myringotomy and tympanostomy have been evaluated in two case series and were associated with symptom alleviation in a subgroup of patients.<sup>7</sup>

#### Balloon Dilatation of the ET

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous ET. During the procedure, a saline-filled balloon catheter is introduced into the ET through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for approximately two minutes after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.<sup>8,9</sup>

## 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 eustachian tube in patients ages 22 and older with persistent ETD.

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

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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