

## Corporate Medical Policy

### Balloon Dilation of the Eustachian Tube

**File Name:** balloon\_dilation\_of\_the\_eustachian\_tube  
**Origination:** 3/2018  
**Last CAP Review:** 2/2019  
**Next CAP Review:** 2/2020  
**Last Review:** 2/2019

#### Description of Procedure or Service

---

##### **Eustachian Tube Function**

The eustachian tube (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. 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. Chronic ETDD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas.

##### **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.

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.

##### **Balloon Dilation of the ET**

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube. 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 approximately 2 minutes after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

##### **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). 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.

# Balloon Dilation of the Eustachian Tube

In December 2016, the XprESS™ ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by FDA through the 510(k) process. 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.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

---

**Balloon dilation of the eustachian tube for treatment of patients with chronic eustachian tube dilatory dysfunction is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

---

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Balloon Dilation of the Eustachian Tube is covered

---

Not applicable.

## When Balloon Dilation of the Eustachian Tube is not covered

---

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

## Policy Guidelines

---

For individuals who have chronic eustachian tube dilatory dysfunction despite medical management who receive balloon dilation of the eustachian tube, the evidence includes case series, systematic reviews of case series, a retrospective cohort study, and two randomized controlled trials. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The criteria for diagnosing eustachian tube dilatory dysfunction are not standardized. Several medical and surgical treatments are used for eustachian tube dilatory dysfunction, but there is limited evidence for available treatments. Most case series assessed herein 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 eustachian tube balloon dilation procedure was reported in 3 case series (n=714 patients); 122 revisions were reported. In one published randomized controlled trial evaluating balloon dilation of the eustachian tube, patients were eligible if they reported persistent eustachian tube 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 6 weeks and reported a reduction in symptoms at 6 weeks on the 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

# Balloon Dilation of the Eustachian Tube

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 reoperation 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.

## **Billing/Coding/Physician Documentation Information**

---

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 69799, C9745*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

---

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.158, 2/8/2018

Specialty Matched Consultant Advisory Panel 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.158, 2/14/2019

## **Policy Implementation/Update Information**

---

3/9/18 New policy developed. Balloon dilation of the eustachian tube for treatment of patients with chronic eustachian tube dilatory dysfunction is considered investigational. (sk)

3/29/18 Code 69799 added to Billing/Coding section. (sk)

3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)

4/16/19 Reference added. Policy Guidelines updated. (sk)

---

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.