# FEP Medical Policy Manual

## FEP 7.01.158 Balloon Dilation of the Eustachian Tube

**Effective Policy Date: January 1, 2023**

**Original Policy Date: March 2018**

**Related Policies:**

7.01.105 - Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

## Balloon Dilation of the Eustachian Tube

### Description

## Description

Eustachian tube dysfunction (ETD) 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 obstructive ETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the eustachian tube (BDET) is a procedure intended to improve patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

## OBJECTIVE

The objective of this evidence review is to determine whether balloon dilation of the eustachian tube improves the net health outcome in patients with chronic obstructive eustachian tube dysfunction.

# POLICY STATEMENT

Balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered **medically necessary** under the following conditions:

- Adults (age 22 years and older) with symptoms of obstructive ETD (aural fullness, aural pressure, otalgia, and/or hearing loss) for 12 months or longer in 1 or both ears that significantly affects quality of life or functional health status;
    - Aural fullness and pressure must be present (see Policy Guidelines).

AND

- The individual 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

- Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated.

AND

- 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

- If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent.

AND

- The individual does not have patulous ETD or another contraindication to the procedure (see Policy Guidelines).

AND

- The individual's ETD has been shown to be reversible (see Policy Guidelines).

AND

- Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying).

AND

- The individual has not had a previous BDET procedure.

Balloon dilation of the eustachian tube is considered **investigational** if the above criteria are not met.

# POLICY GUIDELINES

Symptoms of obstructive eustachian tube dysfunction may include aural fullness, aural pressure, otalgia, and hearing loss. Nearly all individuals will have aural fullness and aural pressure. Many individuals will have otalgia, but hearing loss may not be present in all individuals (e.g., patients with Type C tympanograms).

## Contraindications to Balloon Dilation of the Eustachian Tube

- The following individuals should not be considered for balloon dilation of the eustachian tube:
    - Individuals with patulous eustachian tube dysfunction (ETD).
        - A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
    - Individuals with extrinsic reversible or irreversible causes of ETD 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).
    - Individuals with aural fullness but normal exam and tympanogram.
    - Individuals with chronic and severe atelectatic ears.

## Reversibility of Eustachian Tube Dysfunction

Reversibility of ETD can be demonstrated by several means, including any of the following:

- The individual 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 individual'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.

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

- Individuals undergoing balloon dilation of the eustachian tube (BDET) concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Individuals with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement.

# BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

# FDA REGULATORY STATUS

**Table 1. Devices Cleared by the U.S. Food and Drug Administration**

| Device | Manufacturer | Date Cleared | 510(k) No. | Indication |
|---|---|---|---|---|
| Acclarent Aera Eustachian Tube Balloon Dilation System | Acclarent, Inc. | 01/16/2018 | K171761 | Eustachian tube dilation |
| Xpress ENT Dilation System | Entellus Medical, Inc. | 04/05/2017 | K163509 | Eustachian tube dilation |

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 the FDA through the 510(k) process (K163509). The FDA determined this device was substantially equivalent to existing devices for use in ETD. The predicate devices are XprESS™ Multi-Sinus Dilation System (K152434) and AERA Eustachian Tube Balloon Dilation System.

# RATIONALE

## Summary of Evidence

For individuals who have chronic obstructive eustachian tube dysfunction (ETD) despite medical management who receive balloon dilation of the eustachian tube, the evidence includes randomized controlled trials (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 RCTs 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 that the technology results in an improvement in the net health outcome.

# SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## American Academy of Otolaryngology-Head and Neck Surgery Foundation

In 2019, the American Academy of Otolaryngology published a clinical consensus statement on BDET.[2,] The target population was defined as adults ≥18 years who are candidates for BDET because of obstructive ETD in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded:

- BDET is an option for treatment of patients with obstructive ETD.
- The diagnosis of obstructive ETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy.
- BDET is contraindicated for patients diagnosed as having a patulous ETD
- Further study will be needed to refine patient selection and outcome assessment.

The authors emphasized the importance of identifying other potentially treatable causes of ETD, including allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, and noted that medical management of these disorders is indicated prior to offering BDET. They also noted that potential risks of BDET that are relevant to patient counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.

## National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET.[11,] The guidance was based on a rapid review of the evidence,[12,] 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, and there was little evidence on the benefit of repeat procedures.
- The procedure is only indicated for chronic ETD refractory to medical treatment.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

# REFERENCES


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12. National Institute for Health and Care Excellence. Interventional procedure overview of balloon dilation for chronic eustachian tube dysfunction. https://www.nice.org.uk/guidance/ipg665/documents/overview-2 December 2019. Accessed August 3, 2021.

## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| March 2018 | New Policy | Policy created with literature review through October 16, 2017. Balloon dilation of the Eustachian tube for treatment of patients with chronic Eustachian tube dilatory dysfunction is considered investigational. |
| June 2019 | Replace policy | Policy updated with literature review through January 11, 2019. references 14-15 added. Policy statement unchanged. |
| December 2020 | Replace policy | Policy updated with literature review through July 12, 2020. references added. Policy statement changed: Balloon dilation of the eustachian tube for treatment of patients with chronic obstructive eustachian tube dysfunction may be considered medically necessary under specified conditions. |
| December 2021 | Replace policy | Policy updated with literature review through August 3, 2021; no references added. Policy statement unchanged. |
| December 2022 | Replace policy | Policy updated with literature review through June 20, 2022; no references added. Minor refinements to policy statements; intent unchanged. |