BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Balloon Dilation of the Eustachian Tube

Policy #: 704
Latest Review Date: September 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after 10/1/2021:

Blue Advantage will treat **balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD)** as a **covered benefit** under the following conditions:

- Adults (age 18 years and older) with symptoms of obstructive ETD (aural fullness, aural pressure, otalgia, and/or hearing loss) for 12 months or longer in one 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 4-6 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 semi-circular canal dehiscence, and endolymphatic hydrops have been ruled out.

AND

- If the individual had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction 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

Blue Advantage will treat **balloon dilation of the eustachian tube** as a **non-covered benefit** and as **investigational** if the above criteria are not met.

Policy Guidelines:

Symptoms of obstructive ETD 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., individuals 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 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 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.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Eustachian Tube Function and Dysfunction

The eustachian tube connects the middle ear space to the nasopharynx. It 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. Normally, the tube is closed or collapsed and opens during swallowing, sneezing or yawning. Eustachian tube dysfunction occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. Symptoms of chronic obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia. In milder cases, ETD may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions.

Diagnosis

Because the symptoms of ETD are nonspecific, clinical practice guidelines emphasize the importance of ruling out other causes of ETD with a comprehensive diagnostic assessment that includes patient-report questionnaires, history and physical exam, tympanometry, nasal endoscopy, and audiometry to establish a diagnosis.

Medical and Surgical Management of Eustachian Tube Dysfunction

Medical management of ETD is directed by the underlying etiology. Treatment of identified underlying conditions, such as systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; or treatment of mass lesions, may be useful in resolving ETD.

Individuals who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the eustachian tube. There is limited evidence and no randomized controlled trials (RCTs) supporting use of these surgical techniques for this indication. Additionally, surgery may be associated with adverse events such as infection, perforation, and otorrhea. Tympanostomy tube placement may be a repeat procedure for the life of the patient, and the risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

Balloon Dilation of the Eustachian Tube

Balloon dilation of the eustachian tube is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube to cause local dilation. 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 2 minutes or less, after which

the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

Balloon dilation of the eustachian tube can be done as a standalone procedure or in conjunction with other procedures such as adenoidectomy, intranasal surgery (e.g., septoplasty, turbinate procedures or sinus surgery), surgery for obstructive sleep apnea or sleep disturbed breathing, and myringotomy with our without tympanostomy tube placement. This evidence review addresses BDET as a standalone procedure.

KEY POINTS:

The most recent literature search was conducted through August 1, 2024.

Summary of Evidence

For individuals who have chronic obstructive ETD despite medical management who receive BDET, 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 individual-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.

Practice Guidelines and Position Statements

American Academy of Otolaryngology-Head and Neck Surgery Foundation

In 2019, the American Academy of Otolaryngology published a clinical consensus statement on BDET. The target population was defined as adults ≥ 18 years who are candidates for BDET because of obstructive ETD in one or both ears for three 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. The guidance was based on a rapid review of the evidence, and stated, "Evidence on the safety and efficacy of BDET 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.

KEY WORDS:

Balloon dilation, eustachian tube, Acclarent AERA®, Acclarent AERA® Eustachian Tube Balloon Dilatation System, XprESS® ENT dilation system, Nuvent® Eustachian Tube Dilation Balloon, Audion ®Et Dilation System, Vensure® Balloon Dilation System

APPROVED BY GOVERNING BODIES:

Table 1. Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Acclarent Aera® Eustachian Tube Balloon Dilatation System	Acclarent, Inc.	01/16/2018	K171761, K230742	Eustachian tube dilation
XprESS® ENT dilation system	Entellus Medical Inc.	04/05/2017	K163509	Eustachian tube dilation
Nuvent® Eustachian Tube Dilation Balloon	Medtronic Xomed, Inc.	08/16/2021	K210841	Eustachian tube dilation
Audion ®Et Dilation System	Entellus Medical, Inc.	04/12/2022	K220027	Eustachian tube dilation

Vensure® Balloon Dilation System	Fiagon GmbH	05/26/2023	K230065	Eustachian tube dilation

Multiple devices have been given a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ) (Table 1).

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral

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POLICY HISTORY:

Adopted for Blue Advantage, February 2018
Available for comment February 21 through April 6, 2018
Medical Policy Group, February 2019
Medical Policy Group, November 2020: 2021 annual coding update. Added CPT codes 69705-69706 to the current coding section.
Medical Policy Group, August 2021
Medical Policy Group, September 2022
Medical Policy Group, September 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, September 2024
UM Committee, September 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.