Balloon Dilation of the Eustachian Tube

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers balloon dilation of the eustachian tube (ET) for treatment of patients with chronic ET dilatory dysfunction to be **investigational.***

Background/Overview

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. 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. Eustachian tube 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.

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, an international group of scientists and physicians with expertise in ET disorders developed consensus statements on ETD. 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 3 months while chronic ETD is ETD with symptoms and signs lasting for more than 3 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 (6 weeks to 3 months) and the long-term (6-12 months).
- The 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) 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 3 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.

The ETDQ-7 is used to assess ETD-related symptoms such as pressure, pain, "clogged" ears, and muffled hearing over the previous month. The 7 items are rated by patients on a 7-level scale from 1 (no problem) to 7 (severe problem). The overall score is reported as a mean item score with a range from 1.0 to 7.0. The ETDQ has been shown to be a valid and reliable symptom score for use in adults with ETD with overall score of 2.1 or higher having high accuracy to detect the presence of ETD.

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 6 and older presenting with otitis media with effusion and/or negative middle ear pressure in a randomized, placebo-controlled, double-blind trial published (2011).

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 (RCTs) supporting use of these surgical techniques. Norman et al (2014) reported that eustachian tuboplasty (other than balloon dilation) has been evaluated in 7 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 2 case series and were associated with symptom alleviation in a subgroup of patients.

Balloon Dilation of the Eustachian Tube

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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 2 minutes after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In September 2016, the AERA®‡ (Acclarent) was granted a de novo 510(k) classification by the U.S. 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 ET 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 ETD. The predicate devices are XprESS™‡ Multi-Sinus Dilation System and AERA Eustachian Tube Balloon Dilation System.

Centers for Medicare and Medicaid Services (CMS)
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.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The RCT is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

BALLOON DILATION FOR EUSTACHIAN TUBE DYSFUNCTION

Systematic Reviews

The evidence for balloon dilation for ETD consists of case series, systematic reviews of these case series, and a 2017 RCT. Recent systematic reviews and meta-analyses are summarized in Tables 1 and 2. Huisman et al (2018) provided pooled results while Hwang et al (2016) provided qualitative summaries only. Most selected case series provided follow-up of less than a year. One series with 78 patients had a mean of 12 months of follow-up, and another with 37 patients had a mean of 18 months of follow-up. All case series reported that patients experienced improvement when comparing symptoms before and after balloon dilation. The selected studies differed concerning other treatments for ETD used before and after balloon dilation. In Huisman (2017), revisions due to failure of the first ET balloon dilation procedure were reported in 3 of the 15 studies (n=714 patients); 122 revisions were reported.

Table 1. Systematic Review Characteristics

Study	Dates	Included Studies	Participants	N (Range)	Design	Duration
Huisman et al (2018)	Through May 2016	15	Adults with ETD treated with balloon dilation	1155 (4-622)	Case series	11 studies <6 mo; 5 studies ≥6 mo
Hwang et al (2016)	1950 to Oct 2015	9	Adults with ETD treated with balloon dilation	474 (7-320)	Case series	Mean follow-up, 1.5-18 mo

ETD: eustachian tube dysfunction.

Table 2. Systematic Review Results

Study	Eustachian Tube Score (Difference, Pre-Post)	Valsalva Maneuver[a]	Abnormal Tympanic Membrane[b]	Abnormal Tympanogram (Type B or C)[c]	Quality of Life (SNOT-22)
Huisman et al (2018)					
Total N, studies/patients	3/82	5 /123	6 /144	9 /200	NR
Pooled effect (95% CI)	MD=3.94 (2.60 to 5.27)	RR=0.13 (0.04 to 0.38)	RR=0.38 (0.07 to 2.05)	RR=0.47 (0.32 to 0.70)	
I^2 (p)	66% (p=0.05)	78% (p=0.001)	99% (p<0.001)	84% (p<0.001)	
Range of N	8-40	4-40	11-40	4-40	
Range of effect sizes	MD: 3.10-6.40	RR: 0.03-0.50	RR: 0.01-1.00	RR: 07-0.73	
Hwang et al (2016)					
Range of N[d]	NR	7-210	NR	7-44	35
Summary		Ability to perform improved from 15 (7%) preop to 189 (90%) postop out of 210 patients		135 (95%) ears preop and 55 (39%) postop	SNOT-22 preop mean score improved from 51.4 to 30 at 6 mo

CI: confidence interval; MD: mean difference: postop: postoperative; preop: preoperative; RR: relative risk; SNOT-22: Sino-Nasal Outcome Test.

[a] The lower the score, the higher the number of patients who can successfully perform a Valsalva maneuver.

[b] Per otoscopy.
[c] Per tympanometry.
[d] Number of patients.

Randomized Controlled Trials

One 2017 published RCT (n-323) has compared balloon dilation of the ET with eustachian tube balloon catheter (ETBC) plus medical management vs medical management alone. The balloon catheter used in the trial was a custom-designed ET balloon catheter (Acclarent). The RCT results are also described in the AERA (Acclarent) de novo summary from the FDA. The RCT characteristics, key results, and evidence gaps are summarized in Tables 3 through 6. A second RCT (NCT02391584) was described in a single paragraph in the XprESS device 510(k) FDA summary. However, the results have not been published, and the information provided is not sufficient for evaluation.

Eligible patients in Poe et al (2017) had persistent patient-reported symptoms of ETD ([ETDQ-7]; mean item score, ≥2.1) and abnormal tympanometry (type B or type C), and failed medical management including either a minimum of 4 weeks of daily use of an intranasal steroid spray or a minimum of one course of an oral steroid. Each investigator was required to perform 3 successful ETBC procedures in nonrandomized "lead-in" patients who were then followed for durability and safety outcomes. Randomization and analyses were performed at the person-level whether or not the patient had unilateral or bilateral ETD. The primary efficacy outcome (normalization of tympanometry) was assessed by both site investigators and a blinded, independent evaluator; discrepancies were resolved by a second independent evaluator. For bilaterally treated patients, both ears had to be rated as normalized for that patient to be considered normalized for the primary outcome. Patients completed follow-up visits at 2, 6, 12, 24, and 52 weeks but data from the 52-week visit have not been reported. Patients in the medical management arm were allowed to receive balloon dilation of the ET after the 6-week visit. Trial enrollment was stopped early after the second preplanned look when the prespecified O'Brien-Fleming stopping boundary for the primary outcome was crossed.

Table 3. Summary of Key RCT Characteristics

					Description of Interventions	
Author; Study	**Countries**	**Sites**	**Dates**	**Participants**	**Active**	**Comparator**
Poe et al (2017); NCT02087150	U.S.	21	Mar 2014-Apr 2016	Age, 22+ y (mean, 56 y); persistent ETDD; failed MM; abnormal tympanometry (type B or type C)	• 162 patients (234 ears) • BDET with balloon catheter plus MM	• 80 patients (117 ears) • MM alone

BDET: balloon dilation of the eustachian tube; ETDD: eustachian tube dilatory dysfunction; MM: medical management.

Table 4. Summary of Key RCT Results

Study	Normalization of Tympanometry (% of patients)	ETDQ-7 Symptom Scores <2.1 (% of patients)[a]	Difference from BL in % Patients With Normal Mucosal	Positive modified Valsalva Maneuver (% ears)	SAEs (no. of events)

			Inflammation		
Poe et al (2017)					
Time point, wk	6	6	6	6	
N	211	208	NR	NR	NR
BDET with ETBC plus MM	52%	56%	+22%	33%	4
MM	14%	9%	-5%	3%	1
Tx effect (95% CI)	RR=NR	RR=NR	NR	NR	NR
p	<0.001	<0.001			
NNT (95% CI)	NR	NR	NR	NR	NR

BDET: balloon dilation of the eustachian tube; BL: baseline; CI: confidence interval; ETBC: eustachian tube balloon catheter; ETDD: eustachian tube dilatory dysfunction; ETDQ-7: 7-item Eustachian Tube Dysfunction Questionnaire; MM: medical management; NNT: number needed to treat; NR: not reported; RR: relative risk; SAE: serious adverse event; Tx: treatment.
[a] The prespecified secondary outcome was the proportion of subjects achieving an improvement of at least a minimal clinically important difference of 0.5 points; it was not reported.

At baseline, the mean ETDQ-7 score was 4.7, 43% of patients had allergic rhinitis, and 61% of patients had at least 1 prior ear tube surgery. By the second interim analysis, 162 patients had been assigned to ETBC and 141 were included in the analysis; 80 been assigned to medical management and 72 were included in the analysis. Patients were included in the analysis if they received the study treatment for which they were randomized and had 6-week follow-up data. Approximately 52% of ETBC patients experienced tympanogram normalization at 6 weeks compared with 14% of medical management patients (p<0.001). The publication reported that sensitivity analysis was performed to test the robustness of results for the impact of missing data in the analysis cohort vs an intention-to-treat cohort but the method of sensitivity analyses was not described. It was noted that there was a significant treatment by site interaction. Two sites had a higher percentage of tympanogram normalization for medical management subjects than for ETBC subjects while the remaining sites had higher normalization for ETBC. The pre-specified secondary efficacy outcome (percentage with minimal clinically important difference change of 0.5 points on ETDQ-7) was not reported in the publication but was reported in the FDA summary. The minimal clinically important difference change in ETDQ-7 scores was observed for 91% of ETBC patients at 6 weeks compared with 45% of medical management patients (p not reported). Fifty-six percent of ETBC patients had an ETDQ-7 mean item score of less than 2.1 at 6 weeks compared with about 9% of medical management patients (p<0.001).

Comparative analyses were not possible after 6 weeks because 82% of medical management patients elected to ETBC after 6 weeks. The durability of the effect is supported by analysis of tympanogram normalization in 170 patients with week 24 data (98 randomized to ETBC and 74 from the lead-in); 62% of those randomized to ETBC and 58% of lead-in patients demonstrated tympanogram normalization at 24 weeks. Data from 52 weeks have not been reported.

Adverse events were only briefly described in the publication but are more fully described in the FDA summary. Two-hundred ninety-nine patients who were treated with ETBC were included in the safety analysis (80 lead-in patients, 149 patients randomized ETBC, 70 patients randomized to medical

management who received ETBC). There were 16 nonserious device or procedure-related adverse events in 13 patients—most commonly, epistaxis and ETD. Two patients had 3 potentially device-related adverse events: mucosal tear worsened ETD, and conductive hearing loss. The potential device- or procedure-related adverse events were mild or moderate in severity and resolved without sequelae. Five serious adverse events were reported (4 events in the BDET group, 1 event in the medical management group); all were thought to be unrelated to device, procedure, or medications.

Table 5. RCT Relevance Gaps

Study	Population	Intervention	Comparator	Outcomes	Follow-Up
Poe et al (2017)			1. MM not clearly described, nasal steroids initiated and other medications already in use were permitted to continue	1. Hearing outcomes not reported 2. Little information on harms provided in the primary publication. More information is available in the FDA summary	1, 2. Only 6 wk of comparative data; longer follow-up of BDET to 24 wk in subset of patients. 52-wk data not reported. Long-term data on durability, safety, and repeat procedures needed.
Key	1. Intended use population unclear 2. Clinical context for treatment is unclear 3. Study population unclear 4. Study population not representative of intended use 5. Study population is subpopulation of intended use	1. Not clearly defined 2. Version used unclear 3. Delivery not similar intensity as comparator	1. Not clearly defined 2. Not standard or optimal 3. Delivery not similar intensity as intervention 4. Not delivered effectively	1. Key health outcomes not addressed 2. Physiologic measures, not validated surrogates 3. Not CONSORT reporting of harms 4. Not established and validated measurements 5. Clinically significant difference not prespecified 6. Clinically significant difference not supported	1. Not sufficient duration for benefits 2. Not sufficient duration for harms

BDET: Balloon dilation of the eustachian tube; FDA: Food and Drug Administration; MM: medical management.

Table 6. RCT Study Design and Conduct Gaps

Study	Allocation	Blinding	Selective Reporting	Follow-Up	Power	Statistical
Poe et al (2017)	3. Not described	1. Blinding of patients not possible; may bias patient-reported measures	2. The prespecified ETDQ secondary outcome was not reported in main paper; it was "not highly sensitive"	5, 6. Analysis was not ITT; excluded patients who did not receive assigned treatment. Due to early stopping, only a subset of patients had 6-wk follow-up		3, 4. Treatment effects and CIs not reported.

Key						
	1. Participants not randomly allocated 2. Allocation not concealed 3. Allocation concealment unclear 4. Inadequate control for selection bias	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician	1. Not registered 2. Evidence of selective reporting 3. Evidence of selective publication	1. High loss to follow up or missing data 2. Inadequate handling of missing data 3. High number of crossovers 4. Inadequate handling of crossovers 5. Inappropriate exclusions 6. Not intent to treat analysis (per protocol for noninferiority trials)	1. Power calculations not reported 2. Power not calculated for primary outcome 3. Power not based on clinically important difference	1. Test is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event 2. Test is not appropriate for multiple observations per patient 3. Confidence intervals and/or p values not reported 4. Comparative treatment effects not calculated

Section Summary: Balloon Dilation for Eustachian Tube Dysfunction

Although several medical and surgical treatments are used for ETD, none has strong evidence demonstrating effectiveness. Balloon dilation of the ET has been evaluated in case series, systematic reviews of case series, and a published RCT. Most assessed case series provided follow-up of less than a year and all showed short-term improvement comparing symptoms before and after balloon dilation. The number of revisions needed due to the failure of the initial ET balloon dilation procedure was reported in 3 case series (n=714 patients); 122 revisions were reported. In the published RCT, balloon dilation plus medical management was compared with medical management alone, with comparative data available at 6 weeks of follow-up. The trial was stopped early due to the significant benefit of the balloon dilation compared with medical management at the second preplanned analysis. A greater proportion 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 a validated questionnaire (ETDQ). The tympanogram outcome was assessed by blinded evaluation, but the symptom scores were patient-reported, and patients were not blinded (ie, there was no sham procedure); therefore, results could have been biased. Hearing outcomes were not reported. Intention-to-treat analyses were not shown, but a sensitivity analysis showing the robustness of the results to missing data was reportedly performed. There was variability in the treatment effect as 2 (of 21) sites did not show benefit for balloon dilation, which the investigators suggested could have been due to the device and procedural learning curve of the study staff or problems with protocol compliance. The rate of adverse events was low, and none of the serious adverse events was thought to be related to the device or procedure. The trial was designed to follow patients for 52 weeks, but long-term data have not yet been reported. The durability of effect, rates of reoperation or revisions, and safety data over the first year are needed.

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, and an RCT. 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 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 ET balloon dilation procedure was reported in 3 case series (n=714 patients); 122 revisions were reported. In the 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 ETDQ, 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 ETDQ. 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 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.

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Coding

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Code Type	Code
CPT	30999, 31299, 42950, 42999, 69799
HCPCS	C9745
ICD-10 Diagnosis	All related diagnoses

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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means

of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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