MP 7.01.158

Balloon Dilation of the Eustachian Tube

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Related Policies
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POLICY

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

POLICY GUIDELINES

There is a specific HCPCS code for this service, effective 07/01/17.

C9745: Nasal endoscopy, surgical; balloon dilation of Eustachian tube.

BENEFIT APPLICATION

BLUECARD/NATIONAL ACCOUNT ISSUES

State or federal mandates (e.g., Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

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.[1] 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.[2] 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,[3] an international group of scientists and physicians with expertise in ET disorders developed consensus statements on ETD.[1] 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 (6 weeks to 3 months) and the long-term (6-12 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.[4]

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 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 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.[5]

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, eg, 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).[6]

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.[7] 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 two case series and were associated with symptom alleviation in a subgroup of patients.[7]

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.[8,9]

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 D	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 novo510(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 and AERA® Eustachian Tube Balloon Dilation System.

RATIONALE

This evidence review was created in February 2018 with a search of the MEDLINE database through January 11, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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 randomized controlled trial (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

Clinical Context and Test Purpose

The purpose of balloon dilation of the Eustachian tube (ET) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as continued medical management, mechanical pressure equalization device, tympanostomy, and Eustachian tuboplasty other than balloon dilation in patients with chronic ETDD despite medical management.

The question addressed in this evidence review is: does balloon dilation of the Eustachian tube improve the net health outcome in patients with chronic (ETDD)?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with chronic ETDD despite medical management.

Interventions

The therapy being considered is balloon dilation of the Eustachian tube.

Comparators

Comparators of interest include continued medical management, mechanical pressure equalization device, tympanostomy, and Eustachian tuboplasty other than balloon dilation. Treatment for chronic ETDD includes decongestants, antihistamines, and in some cases steroid nasal sprays.

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity. The 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is a validated, standardized, 7-item patient-reported questionnaire to assess symptom severity associated with ETD. The seven questionnaire items cover the following ear symptoms: pressure, pain, feeling clogged, cold/sinusitis problems, crackling/popping, ringing, and muffled hearing. Each item is assessed on a scale of one (no problem) to seven (severe problem), and an overall score, which is the mean of the seven item scores, is calculated. Scores in the range of one to two indicate no to mild symptoms, three to five indicate moderate symptoms, and six to seven indicate severe symptoms. Patients may also undergo middle ear functional assessments such as tympanometry, otoscopy, and performance of the Valsalva maneuver.

Timing

The existing literature evaluating balloon dilation of the Eustachian tube as a treatment for chronic ETDD despite medical management has varying lengths of follow-up, ranging from 3, 6, 12, or 18 months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting

Patients with chronic ETDD despite medical management are managed by otolaryngologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

The evidence for balloon dilation for ETD consists of case series, systematic reviews of these case series, and two RCTs. Recent systematic reviews and meta-analyses are summarized in Tables 2 and 3. Huisman et al (2018)[10] provided pooled results while Hwang et al (2016)[11] provided qualitative summaries only. Most selected case series provided a 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 et al (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 2. Systematic Review Characteristics

Study	Dates	Included Studies	Participants	N (Range)	Design	Duration
Huisman (2018)[10]	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 (2016)[11]	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; mo: month(s).

Table 3. 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 (2018)[10]					
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-value)	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 (2016)[11]					
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

Poe et al (2017) published the results of an RCT that compared balloon dilation of the ET with ET balloon catheter (ETBC) plus medical management to medical management alone.[12] The balloon catheter used in the trial was a custom-designed ETBC (Acclarent). The RCT results are also described in the AERA (Acclarent) de novo summary from the Food and Drug Administration.[13] The RCT characteristics, key results, and evidence gaps are summarized in Tables 4 through 7.

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.[12] Each investigator was required to perform three 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 six-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.

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 had 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 six-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 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 prespecified 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 Food and Drug Administration 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 six 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 Food and Drug Administration summary.[13] 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 three 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 (four events in the balloon dilation of the Eustachian tube group, one event in the medical management group); all were thought to be unrelated to device, procedure, or medications.

Meyer et al (2018) published the results of a 1-year follow-up, inclusive, prospective, multi-center RCT of balloon dilation as a treatment for persistent ETD and compared the intervention to continued medical therapy (control).[14] Inclusion criteria required patients to be diagnosed with medically refractory, persistent ETD. Participants were randomly assigned (1:1) to intervention or control; however, control participants were offered the intervention after six weeks if their symptoms remained. The outcomes measured include primary efficacy endpoints using the ETDQ-7 scores and the rate of complications. The trial involved 60 randomized participants (31 intervention, 29 control). Mean standard deviation change in overall ETDQ-7 score at 6 weeks was 2.9 (1.4) for balloon dilation compared with 0.6 (1.0) for control: balloon dilation was superior to control ($p < 0.0001$). No complications were reported in either study arm. Among participants with abnormal baseline assessments, improvements in tympanogram type ($p < 0.006$) and tympanic membrane position ($p < 0.001$) were significantly better for balloon dilation than control. Improvements in the ETDQ-7 scores were maintained through 12 months after balloon dilation. Limitations of this RCT are its small sample size and the inability to blind the participants to their treatment.

Tables 4 and 5 summarize key characteristics and results for these two RCTs.

Table 4. Summary of Key RCT Characteristics: Balloon Dilation of Eustachian Tube

Description of Interventions						
Author; Study	Countries	Sites	Dates	Participants	Active	Comparator
Poe (2017)[12]; 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), ETDQ-72.1	· 162 patients (234 ears) · BDET plus MM	· 80 patients (117 ears) · MM alone
Meyer (2018)[14]; NCT02391584	U.S.	5	Aug 2015-Jun 2016	Age y, persistent ETDD, failed MM, ETDQ-73	· 31 patients BDET[1]	· 29 patients MM alone

BDET: balloon dilation of the Eustachian tube; ETDQ-7: Eustachian Tube Dysfunction Questionnaire; ETDD: Eustachian tube dilatory dysfunction; MM: medical management.

[1] patients were allowed to continue current medication regimen

Table 5. Summary of Key RCT Results: Balloon Dilation of Eustachian Tube (six Weeks)

Study	**Patients with Normalization of Tympanometry[1]** (% of patients)	**ETDQ-7 Symptom Scores <2.1[2]** (% of patients)	**Change in mean ETDQ-7 Score (SD)[3]**	**Change in Mucosal Inflammation Scores from BL**	**Increase in Ears with Positive Modified Valsalva Maneuver**	**SAEs**
Poe (2017)[12]						
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	NR
Meyer (2018)[14]						
N			28			
BDET with ETBC plus MM			-2.9 (1.4)			
N						
MM			27			
			-0.6 (1.0)			
p			<0.0001			

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.

[1.]Primary outcome for Poe
[2.]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.
[3]Primary outcome for Meyer

The purpose of gaps tables (see Tables 6 and 7) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 6. RCT Relevance Gaps

Study	Population	Intervention	Comparator	Outcomes	Follow-Up
Poe (2017)[12.]			1.MM not clearly described, nasal steroids and other medications initiated or continued other medications with clinical discretion	1. Limited information on harms provided in the primary publication vs. FDA dossier	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.
Meyer (2018)[14.]	1,3 Study enrollment criteria did not require abnormal middle ear functional assessments		1. MM not clearly described, nasal steroids and other medications initiated or continued other medications with clinical discretion	1. Primary outcome limited to ETDQ-7 symptom score	1.2 Comparative outcomes limited to 6 weeks
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	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

	subpopulation of intended use					

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

Table 7. RCT Study Design and Conduct Gaps

Study	Allocation	Blinding	Selective Reporting	Follow-Up	Power	Statistical
Poe (2017)[12]		1. Blinding of patients not possible; may bias patient-reported measures	2. The prespecified ETDQ secondary outcome was not reported	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. Treatment effects and CIs not reported.
Meyer (2018)[14]		1. Blinding of patients not possible; may bias patient-reported measures		5, 6. Analysis was not ITT; excluded patients who did not receive assigned treatment.		
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

CI: confidence interval; ETDQ: Eustachian Tube Dysfunction Questionnaire; ITT: intention to treat.

Observational Study

Satmis et al (2018) published a retrospective cohort study of 42 consecutive adult patients with chronic ETDD.[15] Patients in a tertiary referral hospital setting who received transnasal balloon dilation of the ET were evaluated. Objective outcome measures included the ETDQ-7 score, bone conduction threshold, and tympanic membrane and middle ear conditions, which were pre and postoperatively collected. Mean ETDQ-7 scores improved from 4.28 to 3.09 and from 4.10 to 2.96 postoperatively at 1 and 3 months respectively. There was a 62.0% improvement in the tympanic membrane and middle ear condition. No serious procedure-related complications were reported.

Section Summary: Balloon Dilation for ETD

Balloon dilation of the Eustachian tube has been evaluated in case series, systematic reviews of case series, a retrospective cohort study, and two published RCTs. Most 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 one published RCT, balloon dilation plus medical management was compared with medical management alone, with comparative data available at six 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%), the primary outcome, compared with the medical management group (14%) at 6 weeks and reported a reduction in symptoms at 6 weeks on a validated questionnaire, ETDQ-7. 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. In addition, the study was stopped at 6 weeks because 82% of the medical management arm crossed over to the balloon dilation intervention when it was allowed at this point in the study. 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, butlong-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. The second RCT enrolled patients with moderate to severe ETD based on the ETDQ-7 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.

Summary of Evidence

For individuals who have chronic ETDD 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 RCTs. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The criteria for diagnosing ETDD are not standardized. Several medical and surgical treatments are used for ETDD, 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 3 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 ETDD symptoms as measured on the ETDQ-7, 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-7. 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 ETD based on the ETDQ-7 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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2011) published guidance on balloon dilation of the Eustachian tube.[16.] The guidance stated:

"Current evidence on the efficacy and safety of balloon dilatation of the Eustachian tube is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research, which should address the efficacy of the procedure in the short and longer term, and also document safety outcomes."

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.

Ongoing and Unpublished Clinical Trials

A January 2019 search did not identify any ongoing or unpublished trials that might influence this review.

ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits ("EHBs"), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

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CODES

Codes	Number	Description
CPT		No specific CPT Code
HCPCS	C9745	Nasal endoscopy, surgical; balloon dilation of Eustachian tube

ICD-10-CM	H68.001-H68.029	Eustachian salpingitis code range
	H69.80-H69.93	Other specified and unspecified disorders of Eustachian tube code range
	H65.00-H65.93	Nonsuppurative otitis media code range
	H66.001-H66.93	Suppurative and & unspecified otitis media code range
	H67.1-H67.9	Otitis media in diseases classified elsewhere code range
	H71.00-H71.93	Cholesteatoma of middle ear code range
	H72.00-H72.93	Perforation of tympanic membrane code range
	H81.01-H81.09	Meniere's disease code range
	H81.311-H81.49	Peripheral and Central vertigo code range
	H91.01-H91.93	Other and unspecified hearing loss code range
	J30.0-J30.9	Vasomotor and Allergic rhinitis
	J31.0-J32.9	Chronic rhinitis and Sinusitis range
ICD-10-PCS	097F4ZZ	Dilation of Right Eustachian Tube, Percutaneous Endoscopic Approach
	097F8DZ	Dilation of Right Eustachian Tube with Intraluminal Device, Via Nat. or Artificial Opening Endoscopic
	097F8ZZ	Dilation of Right Eustachian Tube, Via Nat. or Artif Opening Endoscopic
	097G4ZZ	Dilation of Left Eustachian Tube, Percutaneous Endoscopic Approach
	097G8DZ	Dilation of Left Eustachian Tube with Intraluminal Device, Via Natural or Artificial Opening Endoscopic
	097G8ZZ	Dilation of Left Eustachian Tube, Via Natural or Artificial Opening Endoscopic
Type of Service	Surgical	
Place of Service	Office, Outpatient, Inpatient	

POLICY HISTORY

Date	Action	Description
02/26/18	New policy – Add to Surgery	Blue Cross of Idaho adopted policy, effective 05/30/2018. 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.
02/21/19	Replace policy	Blue Cross of Idaho adopted changes as noted, effective 02/21/2019. Policy updated with literature review through January 11, 2019. References 14-15 added. Policy statement unchanged.