**Title:** Balloon Dilation of the Eustachian Tube

**Professional**
- Original Effective Date: June 3, 2021
- Revision Date(s): June 3, 2021
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- Original Effective Date: June 3, 2021
- Revision Date(s): June 3, 2021
- Current Effective Date: June 3, 2021

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<td>• Treatment-related morbidity</td>
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**DESCRIPTION**

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 eustachian tube dysfunction can lead to hearing loss, otitis media, tympanic membrane perforation, and
cholesteatomas. Balloon dilation of the eustachian tube 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 eustachian tube dilatory dysfunction.

**Background**

**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, eustachian tube dysfunction 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 eustachian tube dysfunction (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. Patients 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 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.\textsuperscript{4,5}.

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.

### REGULATORY STATUS

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
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<tbody>
<tr>
<td>Acclarent Aera Eustachian Tube Balloon Dilation System</td>
<td>Acclarent, Inc.</td>
<td>01/16/2018</td>
<td>K171761</td>
<td>Eustachian tube dilation</td>
</tr>
<tr>
<td>Xpress ENT Dilation System</td>
<td>Entellus Medical, Inc.</td>
<td>04/05/2017</td>
<td>K163509</td>
<td>Eustachian tube dilation</td>
</tr>
</tbody>
</table>

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 ET in patients ages 22 and older with persistent eustachian tube dysfunction (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 eustachian tube dysfunction (ETD). The predicate devices are XprESS™ Multi-Sinus Dilation System (K152434) and AERA® Eustachian Tube Balloon Dilation System.
POLICY

I. Balloon dilation of the eustachian tube for treatment of chronic obstructive eustachian tube dysfunction may be considered medical necessity under the following conditions:

A. Adults (age 22 years and older) with symptoms of obstructive eustachian tube dysfunction (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

1. Aural fullness and pressure must be present (see Policy Guidelines)

AND

2. The patient 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:
   a. Abnormal tympanogram (Type B or C)
   b. Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam)

AND

3. 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

B. 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

C. If the patient had a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction should have improved while tubes were patent

AND

D. The patient does not have patulous eustachian tube dysfunction or another contraindication to the procedure (see Policy Guidelines)

AND

E. The patient’s eustachian tube dysfunction has been shown to be reversible (see Policy Guidelines)

AND

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

AND

G. The patient has not had a previous BDET procedure

II. Balloon dilation of the eustachian tube is considered experimental / 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 patients will have aural fullness and aural pressure. Many patients will have otalgia, but hearing loss may not be present in all patients (e.g., patients with Type C tympanograms).

Contraindications to Balloon Dilation of the Eustachian Tube
• The following patients should not be considered for balloon dilation of the eustachian tube:
  o Patients with patulous eustachian tube dysfunction
    ▪ A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
  o Patients with extrinsic reversible or irreversible causes of eustachian tube dysfunction 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)
  o Patients with aural fullness but normal exam and tympanogram
  o Patients with chronic and severe atelectatic ears

Reversibility of Eustachian Tube Dysfunction
Reversibility of Eustachian Tube dysfunction can be demonstrated by several means, including any of the following:
• The patient 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 patient’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
• Patients undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
• Patients with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement
RATIONALE
This evidence review has been updated regularly with searches of the PubMed database. The most recent literature search was conducted through July 12, 2020.

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, 2 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 CHRONIC OBSTRUCTIVE EUSTACHIAN TUBE DYSFUNCTION
Clinical Context and Therapy Purpose
The purpose of balloon dilation of the eustachian tube is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with chronic obstructive eustachian tube dysfunction 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 obstructive eustachian tube dysfunction?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is individuals with chronic obstructive eustachian tube dysfunction despite medical management.

Eustachian tube (ET) dysfunction occurs when the functional valve of the ET fails to open and/or close properly, frequently due to inflammation. Symptoms may include ear fullness, recurrent barochallenge (difficulty clearing the ears with changes in ambient pressure), hearing loss, otalgia, and tinnitus.

Patients with chronic obstructive eustachian tube dysfunction are managed by otolaryngologists and primary care providers in an outpatient clinical setting.
**Interventions**
The therapy being considered is balloon dilation of the eustachian tube.

Balloon dilation of the ET is a procedure intended to improve the patency by inflating a balloon in the cartilaginous part of the ET 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.

**Comparators**
Medical management of eustachian tube dysfunction 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. Treating underlying conditions, if identified, may be useful in resolving ETD. Patients who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes, methods of eustachian tube dilation other than balloon dilation, or mechanical pressure equalization devices.

**Outcomes**
The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity. Specific outcome measures are described in Table 2. Initial follow up examinations are typically done at 4 to 6 weeks to judge early efficacy. Follow-up should be at least one year to appropriately establish a clinically meaningful improvement.

**Table 2. Outcome Assessment of Chronic Obstructive Eustachian Tube Dysfunction**

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Description</th>
<th>MCID, if known</th>
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</table>
| Eustachian Tube Dysfunction Questionnaire (ETDQ-7) | Validated, standardized, 7-item patient-reported questionnaire to assess symptom severity associated with eustachian tube dysfunction. Pressure, pain, feeling clogged, cold/sinusitis problems, crackling/popping, ringing, and muffled hearing. Patients rate the severity of seven symptoms on a scale ranging from 1 (no problem) to 7 (severe problem). Dividing the total score by seven yields the mean item score. A total score of $\geq 14.5$ and mean item score of $\geq 2.1$ indicate ETD scores in the range of 1-2 indicate no to mild symptoms, 3-5 moderate symptoms, and 6-7 severe symptoms. | 0.5 point improvement
Normalization is defined as a mean item score $<2.1$ or a total score $<14.5$ |
| Valsava maneuver | Patient breathes out while closing the nose and mouth to direct air to the ET and help them open. Modified: gentle nose blow with simultaneous swallow | Positive (ability to perform the maneuver when needed)
Negative (unable to perform the maneuver) |
### Outcome Measure | Description | MCID, if known
--- | --- | ---
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. 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. | Type A (normal)
Otoscopy findings | Visual examination of the tympanic membrane using an otoscope. Classifies tympanic membrane as abnormal (retracted membrane, effusion, perforation, or any other abnormality identified on exam) or normal | Normal tympanic membrane

ET: eustachian tube; ETD: eustachian tube dysfunction; MCID: minimal clinically important difference.

### Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.

### REVIEW OF EVIDENCE

#### Systematic Reviews
Froehlich et al (2020) conducted a systematic review and meta-analysis of balloon dilation for eustachian tube dysfunction (Tables 3 and 4). Twelve studies were included in the meta-analysis, including 3 RCTs, 5 prospective observational studies, and 4 case series. One RCT (Liang et al, 2016) that compared balloon dilation to tympanic paracentesis reported tympanometry and otoscopy scores but not symptoms. The other 2 RCTs compared balloon dilation plus medical management to medical management alone and used the ETDQ-7 to measure symptoms. Table 3 summarizes results at 6 weeks. Pooled analyses showed improvements in subjective and objective measures including ETDQ-7 scores, tympanograms, otoscopy exams, and ability to perform a Valsalva maneuver. Improvements appeared to be maintained in studies with longer-term follow up (3-12 months).

Several earlier systematic reviews of observational studies have been published. Case series included in these reviews consistently reported that patients experienced improvement when comparing symptoms before and after balloon dilation. The studies varied in the type of medical management used to treat eustachian tube dysfunction before and after balloon dilation.
Table 3. Systematic Review Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Search End Date</th>
<th>Included Studies</th>
<th>Participants</th>
<th>N (range)</th>
<th>Study Designs</th>
<th>Duration</th>
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</thead>
<tbody>
<tr>
<td>Froehlich et al (2020)5</td>
<td>January 2019</td>
<td>35 total, 12 included in quantitative meta-analysis</td>
<td>Adults with eustachian tube dysfunction</td>
<td>448 patients (2-202) 445 ears (2-234)</td>
<td>3 RCTs, 5 prospective observational, 4 case series</td>
<td>6 weeks-12 months</td>
</tr>
</tbody>
</table>

RCTs: randomized controlled trials

Table 4. Systematic Review Results

<table>
<thead>
<tr>
<th>Study</th>
<th>ETDQ-7 Normalization (Proportion with score &lt;2.1)</th>
<th>ETDQ-7 Mean Score</th>
<th>Valsalva Maneuver (Proportion able to perform)</th>
<th>Tympanometry Normalization (Proportion with Type A)1</th>
<th>Tympanometry Improvement (Proportion with change from Type B to Type A or from Type C to Type B)1</th>
<th>Otoscopy Findings (Proportion with a normal finding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N studies/patients Study designs</td>
<td>2/245 RCTs</td>
<td>3/2261 RCT, 1 prospective observational, 1 case series</td>
<td>6/436 ears RCTs</td>
<td>12/606 ears RCTs, prospective observational, case series</td>
<td>4/287 ears</td>
<td>7/252 ears</td>
</tr>
</tbody>
</table>

Baseline% (95% CI) | NA | NR | 13.2% (0.7-37.5%) | 13.9% (1.5-35.6) | NA | 22.1% (2.0-55.0) |

6 weeks % (95% CI) | 53.5% (47.0, 59.8) | NR | 71.2% (58.8% - 82.1%) | 58.9 (40.4-76.2) | 53.0% (29.1-76.2) | 53.8% (31.1-75.7) |

Pooled Difference Pre-Post (95% CI): | NA | -2.13 (-3.02, -1.24); P = .0004 | 58.0% (52.0%-63.2%); P < .0001 | 45.0% (39.9-49.8); P < .0001 | NA | 31.7% (22.5-40.4), P < .0001 | |

I² (p-value) | NR | 87% (.0004) | NR | NR | NR | NR |

1Type 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. CI: confidence interval; ETDQ-7: 7-item Eustachian Tube Dysfunction Questionnaire; N: sample size; NA: not applicable; NR: not reported; RCT: randomized controlled trial

Randomized Controlled Trials

Two randomized controlled trials have evaluated BDET for obstructive eustachian tube dysfunction (Tables 5-7).7,8 Both compared BDET plus medical management to medical management alone for 6 weeks. Following the 6-week follow-up period, patients who were
randomized to medical management alone could elect to receive BDET and were followed up to 52 weeks in an extension phase.

The balloon catheter used in Poe et al (2017) was a custom-designed eustachian tube balloon catheter (ETBC) (Acclarent). Eligible patients had persistent patient-reported symptoms of eustachian tube dysfunction (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 1 course of an oral steroid. Each investigator was required to perform 3 successful balloon dilation 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.

Anand et al (2019) reported 52-week data on 128 patients who received a ETBC, including those randomized to the intervention and those who crossed over following the 6-week randomized phase. Of 128 patients with normalized tympanogram at 6 weeks, 71 remained normalized at 52 weeks and 71 of 124 had normalized scores on the ETDQ. Some ears failed to normalize at earlier visits but converted at subsequent follow-up visits. Overall, 119 of 187 (63.6%) ears had type A tympanograms at 52 weeks, either remaining normal throughout the study or converting to normal. There were no device- or procedure-related serious adverse events during the 52-week follow-up period.

Meyer et al (2018) an RCT evaluating eustachian tube balloon dilation versus continued medical therapy for treating in 60 participants with persistent eustachian tube dysfunction. The primary efficacy outcomes were symptoms as measured by the ETDQ-7 score and the primary safety outcome was rate of complications. 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 medical management; balloon dilation was superior to medical management (p <.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. Cutler et al (2019) reported longer-term follow-up data from this trial. Of 58 patients from the original study who were eligible for the extension study, 47 were enrolled (81.0%) The mean follow-up time was 29.4 months post-procedure (range 18-42 months). Changes from baseline at the end of the longer-term follow-up period were similar to improvements observed at 1 year on outcome measures including the ETDQ-7, normalized tympanogram, ability to perform the Valsalva maneuver, and patients' satisfaction with the outcome of the procedure. One patient underwent a revision ET dilation after 362 days, performed concurrently with balloon dilation for recurrent sinus disease. No other surgeries or adverse events were reported.

Study limitations are summarized in Tables 8 and 9. Limitations included a lack of blinding, which could bias reports of patient-reported symptoms, and short (6-week) comparative follow-up period.
Table 5. Randomized Controlled Trials of Balloon Dilation of the Eustachian Tube: Study Characteristics

<table>
<thead>
<tr>
<th>Study name (NCT Number) Publications</th>
<th>Countries</th>
<th>Dates</th>
<th>Key Eligibility Criteria</th>
<th>Outcome Measures and Duration of Follow-up</th>
<th>Intervention</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150) Poe et al (2017)7; NCT02087150</td>
<td>U.S., 21 sites</td>
<td>2014-2016</td>
<td>Inclusion: 22 years or older, persistent ETD, failure of medical management, positive diagnosis of ETD Exclusion: Anatomy that requires an adjunctive surgical procedure Concomitant nasal or sinus procedures planned on the same day as surgical procedure Concomitant ear procedures planned on the same day as surgical procedure History of major surgery of the head or neck within four (4) months prior to surgery History of patulous ET History of fluctuating sensorineural hearing loss Active acute otitis media Tympanic membrane perforation</td>
<td>Primary: Tympanogram normalization (Type A) in all indicated ears at 6 weeks. Secondary: Improvement of 0.5 points on ETDQ-7 at 6 weeks. Exploratory: Tympanogram normalization (Type A) at 12, 24, and 52 weeks ETDQ-7 Improvement at 12, 24, 52 weeks Work and activity impairment at 6, 12, 24, 52 weeks</td>
<td>BDET plus medical management (daily nasal steroid spray for 6 weeks) 162 patients (234 ears)</td>
<td>Medical management alone (daily nasal steroid spray for 6 weeks) 80 patients (117 ears)</td>
</tr>
<tr>
<td>Study name (NCT Number) Publications</td>
<td>Countries</td>
<td>Dates</td>
<td>Key Eligibility Criteria</td>
<td>Outcome Measures and Duration of Follow-up</td>
<td>Intervention</td>
<td>Comparator</td>
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<tr>
<td>XprESS Eustachian Tube Dilation Study NCT02391584 Meyer et al (2018)&lt;sup&gt;8,10&lt;/sup&gt;</td>
<td>U.S., 5 sites</td>
<td>2015-2017</td>
<td>Inclusion: 18 years or older, diagnosed with symptoms of chronic eustachian tube dysfunction for at least 12 months, ETDQ-7 score ≥ 3.0, record of failed medical management</td>
<td>Primary: Mean change in overall ETDQ-7 at 6 weeks, complication rate through 6 months post-procedure Secondary: technical success rate, revision rate at 12 months, mean change in ETDQ-7 at 3 months</td>
<td>BDET • 31 patients</td>
<td>Continued medical management • 29 patients</td>
</tr>
<tr>
<td><strong>Key Eligibility Criteria</strong></td>
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<td></td>
<td>• Tympanosclerosis  • Acute upper respiratory infection  • Temporomandibular joint disorder  • Cleft palate  • Craniofacial syndrome  • Cystic fibrosis  • Ciliary dysmotility syndrome  • Systemic mucosal or immunodeficiency disease  • Intolerance of medication for ETD  • Prior intervention of Eustachian tube</td>
<td></td>
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<tr>
<td>Study name (NCT Number) Publications</td>
<td>Countries</td>
<td>Dates</td>
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<td>Intervention</td>
<td>Comparator</td>
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<tr>
<td>Balloon Dilation of the Eustachian Tube</td>
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<td>perforation of the tympanic membrane • Have evidence of internal carotid artery dehiscence • Be pregnant at the time of enrollment • Be currently participating in other drug or device studies</td>
<td>months, 6 months and 12 months</td>
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</table>

Table 6. Randomized Controlled Trials of Balloon Dilation of the Eustachian Tube: Results at 6 Weeks

<table>
<thead>
<tr>
<th>Study name (NCT Number) Publications</th>
<th>ETDQ-7 Normalization (Score &lt;2.1)</th>
<th>ETDQ-7 Mean Change</th>
<th>Valsalva Maneuver Positive</th>
<th>Normalized Tympanogram (Type A)</th>
<th>Otoscopy Results (Tympanic Membrane position normal)</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150)Poe et al (2017) 7;NCT02087150</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDET plus medical management</td>
<td>77/137 (56.2%)</td>
<td>32.8% increase in number of ears</td>
<td></td>
<td>72/139 (51.8%)</td>
<td></td>
<td>4 serious adverse events No device- or procedure-related serious adverse events</td>
</tr>
<tr>
<td>Medical management alone</td>
<td>6/71 (8.5%)</td>
<td>3.1% increase in</td>
<td>10/72 (13.9%)</td>
<td></td>
<td></td>
<td>1 serious adverse</td>
</tr>
</tbody>
</table>

BDET: balloon dilation of the eustachian tube; ETDQ-7: Eustachian Tube Dysfunction Questionnaire; ETD: eustachian tube dysfunction; NCT: National Clinical Trial.
### Table 7. Randomized Controlled Trials of Balloon Dilation of Eustachian Tube—Uncontrolled Extension Phase Results (52 weeks)

<table>
<thead>
<tr>
<th>Study name (NCT Number) Publications</th>
<th>ETDQ-7 Normalization (Score &lt;2.1) at 52 Weeks</th>
<th>ETDQ-7 Mean Change</th>
<th>Valsalva Maneuver Positive at 52 Weeks</th>
<th>Normalized Tympanogram (Type A) at 52 weeks</th>
<th>Otoscopy Results (Tympanic Membrane position normal)</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Study of Safety and Efficacy for the Eustachian Tube Balloon Catheter (NCT02087150)³</td>
<td>124</td>
<td>230 (Ears)</td>
<td>128 (187 ears)</td>
<td>219</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study name (NCT Number)</td>
<td>Publications</td>
<td>ETDQ-7 Normalization (Score &lt;2.1) at 52 Weeks</td>
<td>ETDQ-7 Mean Change</td>
<td>Valsalva Maneuver Positive at 52 Weeks</td>
<td>Normalized Tympanogram (Type A) at 52 weeks</td>
<td>Otoscopy Results (Tympanic Membrane position normal)</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------</td>
<td>-----------------------------------------------</td>
<td>--------------------</td>
<td>--------------------------------------</td>
<td>---------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>BDET plus medical management</td>
<td>71/124 (57.3%)</td>
<td>Ears: 185/230 (80.4%)</td>
<td>Patients: 71/128 (55.5%)</td>
<td>Ears: 119/187 (63.6%)</td>
<td>Not assessed</td>
<td>No device-or procedure-related serious adverse events; Two occurrences of patulous ET, both described as mild.</td>
</tr>
<tr>
<td>XprESS Eustachian Tube Dilation Study NCT02391584 Meyer et al (2018)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>49</td>
<td>47</td>
<td>80</td>
<td>49</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>BDET plus medical management</td>
<td>2.1 (SD reported in graph only)</td>
<td>31/47 (66.0%)</td>
<td>70/80 (87.5%)</td>
<td>42/49 (85.7%)</td>
<td>No complications</td>
<td></td>
</tr>
</tbody>
</table>

BDET: balloon dilation of the eustachian tube; ETDQ-7: Eustachian Tube Dysfunction Questionnaire; NCT: National Clinical Trial.

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poe et al (2017)</td>
<td></td>
<td></td>
<td>Limited information on harms provided in the primary publication vs. FDA dossier</td>
<td>Only 6 weeks of comparative data; longer follow-up of BDET to 52 weeks in subset of patients.</td>
<td></td>
</tr>
<tr>
<td>Meyer et al (2018)</td>
<td></td>
<td>Study enrollment criteria did not require abnormal middle ear functional assessments</td>
<td>Comparative outcomes limited to 6 weeks; longer follow-up of BDET in subset of patients.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 8. Randomized Controlled Trials: Study Relevance Limitations
<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key</td>
<td>Unintended use population unclear Clinical context for treatment is unclear Study population unclear Study population not representative of intended use Study population is subpopulation of intended use</td>
<td>Not clearly defined Version used unclear Delivery not similar intensity as intervention</td>
<td>Not clearly defined Not standard or optimal Delivery not similar intensity as intervention Not delivered effectively</td>
<td>Key health outcomes not addressed Physiologic measures, not validated surrogates Not CONSORT reporting of harms Not established and validated measurements Clinically significant difference not prespecified Clinically significant difference not supported</td>
<td>Not sufficient duration for benefits Not sufficient duration for harms</td>
</tr>
</tbody>
</table>

BDET: balloon dilation of the eustachian tube

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

### Table 9. Randomized Controlled Trials: Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poe et al (2017)&lt;sup&gt;7, 8&lt;/sup&gt;</td>
<td>Blinding of patients not possible; may bias patient-reported measures</td>
<td>1.</td>
<td>Treatment effects and CIs not reported.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meyer et al (2018)&lt;sup&gt;8&lt;/sup&gt;</td>
<td>Blinding of patients not possible; may bias patient-reported measures</td>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Key</td>
<td>Participants not randomly allocated Allocation not concealed Allocation concealment unclear Inadequate control for</td>
<td>Not blinded to treatment assignment Not blinded outcome assessment Outcome assessed by treating physician Not registered Evidence of selective reporting Evidence of selective publication</td>
<td>High loss to follow-up or missing data Inadequate handling of missing data High number of crossovers Inadequate handling of crossovers Power calculations not reported Power not calculated for primary outcome Power not based on clinically important difference</td>
<td></td>
<td>Test is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event Test is not appropriate for multiple observations per patient</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Allocation</td>
<td>Blinding</td>
<td>Selective Reporting</td>
<td>Follow-Up</td>
<td>Power</td>
<td>Statistical</td>
</tr>
<tr>
<td>-------</td>
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<td>-------------</td>
</tr>
<tr>
<td></td>
<td>selection bias</td>
<td></td>
<td>Inappropriate exclusions Not intent to treat analysis (per protocol for noninferiority trials)</td>
<td></td>
<td></td>
<td>Confidence intervals and/or p values not reported Comparative treatment effects not calculated</td>
</tr>
</tbody>
</table>

CI: confidence interval

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

**Summary of Evidence**

For individuals who have chronic obstructive eustachian tube dysfunction despite medical management who receive balloon dilation of the eustachian tube, the evidence includes 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 randomized controlled trials 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 follow-up. 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 the effects of the technology on the net health outcome.

**SUPPLEMENTAL INFORMATION**

**Clinical Input From Physician Specialty Societies And Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2020 Input

Clinical input was sought to help determine whether the use of balloon dilation of the eustachian tube for individuals with chronic obstructive eustachian tube dysfunction despite medical management would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 4 respondents, include 1 specialty society-level response including physicians with academic medical center affiliation; 3 physician-level responses affiliated with an academic medical center, identified by BCBSA.

For individuals who have obstructive eustachian tube dysfunction who receive balloon dilation of the eustachian tube, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients using the following criteria:
• Obstructive eustachian tube dysfunction for 3 months or longer in one or both ears that significantly affects quality of life or functional health status;
• The patient has undergone a comprehensive diagnostic assessment; including history and physical exam, tympanometry if the tympanic membrane is intact, nasopharyngoscopy, and comprehensive audiometry; 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.

Further details from clinical input are included in the Appendix.

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 balloon dilation of the eustachian tube (BDET). The target population was defined as adults ages 18 years or older who are candidates for BDET because of obstructive eustachian tube dysfunction (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. The guidance was based on a rapid review of the evidence, 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 eustachian tube dysfunction refractory to medical treatment.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 10.
Table 10. Unpublished Clinical Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04136977</td>
<td>XprESS Eustachian Tube Balloon Dilation Registry</td>
<td>300</td>
<td>Jul 2020</td>
</tr>
<tr>
<td>NCT03499015</td>
<td>Balloon Dilation of the Eustachian Tube in Children: a Randomized Side-controlled Clinical Trial</td>
<td>50</td>
<td>Oct 2020</td>
</tr>
<tr>
<td>NCT04055714</td>
<td>Feasibility of Balloon Dilation of the Eustachian Tubes for Dilatory Dysfunction Under Local Anesthesia</td>
<td>25</td>
<td>Oct 2021</td>
</tr>
<tr>
<td>NCT03886740</td>
<td>Tympanostomy Tubes Versus Eustachian Tube Dilation</td>
<td>32</td>
<td>Aug 2021</td>
</tr>
<tr>
<td>NCT03556215</td>
<td>Balloon Eustachian Tuboplasty in Treatment of Chronic Eustachian Tube Dysfunction</td>
<td>55</td>
<td>Nov 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the “Policy” section of this document.

CPT/HCPCS

- C9745  Nasal endoscopy, surgical; balloon dilation of eustachian tube
- 69705  Surgical nasopharyngoscopy with dilation of eustachian tube unilateral
- 69706  Surgical nasopharyngoscopy with dilation of eustachian tube bilateral
- 69799  Unlisted procedure, middle ear

ICD-10 Diagnoses codes

- H65.00  Acute Serous Otitis Media, Unspecified Ear
- H65.01  Acute Serous Otitis Media, Right Ear
- H65.02  Acute Serous Otitis Media, Left Ear
- H65.03  Acute Serous Otitis Media, Bilateral
- H65.04  Acute Serous Otitis Media, Recurrent, Right Ear
- H65.05  Acute Serous Otitis Media, Recurrent, Left Ear
- H65.06  Acute Serous Otitis Media, Recurrent, Bilateral
- H65.07  Acute Serous Otitis Media, Recurrent, Unspecified Ear
- H65.11  Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Right Ear
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H65.112</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Left Ear</td>
</tr>
<tr>
<td>H65.113</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Bilateral</td>
</tr>
<tr>
<td>H65.114</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Recurrent, Right Ear</td>
</tr>
<tr>
<td>H65.115</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Recurrent, Left Ear</td>
</tr>
<tr>
<td>H65.116</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Recurrent, Bilateral</td>
</tr>
<tr>
<td>H65.117</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Recurrent, Unspecified Ear</td>
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<tr>
<td>H65.119</td>
<td>Acute And Subacute Allergic Otitis Media (Mucoid) (Sanguinous) (Serous), Unspecified Ear</td>
</tr>
<tr>
<td>H65.191</td>
<td>Other Acute Nonsuppurative Otitis Media, Right Ear</td>
</tr>
<tr>
<td>H65.192</td>
<td>Other Acute Nonsuppurative Otitis Media, Left Ear</td>
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<td>H65.193</td>
<td>Other Acute Nonsuppurative Otitis Media, Bilateral</td>
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<td>H65.194</td>
<td>Other Acute Nonsuppurative Otitis Media, Recurrent, Right Ear</td>
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<td>H65.195</td>
<td>Other Acute Nonsuppurative Otitis Media, Recurrent, Left Ear</td>
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<td>H65.196</td>
<td>Other Acute Nonsuppurative Otitis Media, Recurrent, Bilateral</td>
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<tr>
<td>H65.197</td>
<td>Other Acute Nonsuppurative Otitis Media Recurrent, Unspecified Ear</td>
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<td>H65.199</td>
<td>Other Acute Nonsuppurative Otitis Media, Unspecified Ear</td>
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<td>H65.22</td>
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<td>H65.30</td>
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<td>Chronic Mucoid Otitis Media, Right Ear</td>
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<td>H65.32</td>
<td>Chronic Mucoid Otitis Media, Left Ear</td>
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<td>H65.33</td>
<td>Chronic Mucoid Otitis Media, Bilateral</td>
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<td>H65.411</td>
<td>Chronic Allergic Otitis Media, Right Ear</td>
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<td>H65.419</td>
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<td>Other Chronic Nonsuppurative Otitis Media, Bilateral</td>
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<td>H65.499</td>
<td>Other Chronic Nonsuppurative Otitis Media, Unspecified Ear</td>
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<td>H65.90</td>
<td>Unspecified Nonsuppurative Otitis Media, Unspecified Ear</td>
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<td>Unspecified Nonsuppurative Otitis Media, Right Ear</td>
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<td>Unspecified Nonsuppurative Otitis Media, Left Ear</td>
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<tr>
<td>H65.93</td>
<td>Unspecified Nonsuppurative Otitis Media, Bilateral</td>
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<tr>
<td>H66.001</td>
<td>Acute Suppurative Otitis Media Without Spontaneous Rupture Of Ear Drum, Right Ear</td>
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<td>H66.002</td>
<td>Acute Suppurative Otitis Media Without Spontaneous Rupture Of Ear Drum, Left Ear</td>
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<td>H66.003</td>
<td>Acute Suppurative Otitis Media Without Spontaneous Rupture Of Ear Drum, Bilateral</td>
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<td>H66.004</td>
<td>Acute Suppurative Otitis Media Without Spontaneous Rupture Of Ear Drum, Recurrent, Right Ear</td>
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<td>H66.005</td>
<td>Acute Suppurative Otitis Media Without Spontaneous Rupture Of Ear Drum, Recurrent, Left Ear</td>
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<td>Acute Suppurative Otitis Media Without Spontaneous Rupture Of Ear Drum, Unspecified Ear</td>
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<td>Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Right Ear</td>
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<td>H66.012</td>
<td>Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Left Ear</td>
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</table>
H66.013  Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Bilateral
H66.014  Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Recurrent, Right Ear
H66.015  Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Recurrent, Left Ear
H66.016  Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Recurrent, Bilateral
H66.017  Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Recurrent, Unspecified Ear
H66.019  Acute Suppurative Otitis Media With Spontaneous Rupture Of Ear Drum, Unspecified Ear
H66.10   Chronic Tubotympanic Suppurative Otitis Media, Unspecified
H66.11   Chronic Tubotympanic Suppurative Otitis Media, Right Ear
H66.12   Chronic Tubotympanic Suppurative Otitis Media, Left Ear
H66.13   Chronic Tubotympanic Suppurative Otitis Media, Bilateral
H66.20   Chronic Atticoantral Suppurative Otitis Media, Unspecified Ear
H66.21   Chronic Atticoantral Suppurative Otitis Media, Right Ear
H66.22   Chronic Atticoantral Suppurative Otitis Media, Left Ear
H66.23   Chronic Atticoantral Suppurative Otitis Media, Bilateral
H66.3X1  Other Chronic Suppurative Otitis Media, Right Ear
H66.3X2  Other Chronic Suppurative Otitis Media, Left Ear
H66.3X3  Other Chronic Suppurative Otitis Media, Bilateral
H66.3X9  Other Chronic Suppurative Otitis Media, Unspecified Ear
H66.40   Suppurative Otitis Media, Unspecified, Unspecified Ear
H66.41   Suppurative Otitis Media, Unspecified, Right Ear
H66.42   Suppurative Otitis Media, Unspecified, Left Ear
H66.43   Suppurative Otitis Media, Unspecified, Bilateral
H66.90   Otitis Media, Unspecified, Unspecified Ear
H66.91   Otitis Media, Unspecified, Right Ear
H66.92   Otitis Media, Unspecified, Left Ear
H66.93   Otitis Media, Unspecified, Bilateral
H67.1    Otitis Media In Diseases Classified Elsewhere, Right Ear
H67.2    Otitis Media In Diseases Classified Elsewhere, Left Ear
H67.3    Otitis Media In Diseases Classified Elsewhere, Bilateral
H67.9    Otitis Media In Diseases Classified Elsewhere, Unspecified Ear
H68.001  Unspecified Eustachian Salpingitis, Right Ear
H68.002  Unspecified Eustachian Salpingitis, Left Ear
H68.003  Unspecified Eustachian Salpingitis, Bilateral
H68.009  Unspecified Eustachian Salpingitis, Unspecified Ear
H68.011  Acute Eustachian Salpingitis, Right Ear
H68.012  Acute Eustachian Salpingitis, Left Ear
H68.013  Acute Eustachian Salpingitis, Bilateral
H68.019  Acute Eustachian Salpingitis, Unspecified Ear
H68.021  Chronic Eustachian Salpingitis, Right Ear
H68.022  Chronic Eustachian Salpingitis, Left Ear
H68.023  Chronic Eustachian Salpingitis, Bilateral
H68.029  Chronic Eustachian Salpingitis, Unspecified Ear
H69.80   Other Specified Disorders Of Eustachian Tube, Unspecified Ear
H69.81   Other Specified Disorders Of Eustachian Tube, Right Ear
H69.82   Other Specified Disorders Of Eustachian Tube, Left Ear
H69.83   Other Specified Disorders Of Eustachian Tube, Bilateral
H69.90   Unspecified Eustachian Tube Disorder, Unspecified Ear
H69.91   Unspecified Eustachian Tube Disorder, Right Ear
H69.92   Unspecified Eustachian Tube Disorder, Left Ear
H69.93  Unspecified Eustachian Tube Disorder, Bilateral
H71.00  Cholesteatoma Of Attic, Unspecified Ear
H71.01  Cholesteatoma Of Attic, Right Ear
H71.02  Cholesteatoma Of Attic, Left Ear
H71.03  Cholesteatoma Of Attic, Bilateral
H71.10  Cholesteatoma Of Tympanum, Unspecified Ear
H71.11  Cholesteatoma Of Tympanum, Right Ear
H71.12  Cholesteatoma Of Tympanum, Left Ear
H71.13  Cholesteatoma Of Tympanum, Bilateral
H71.20  Cholesteatoma Of Mastoid, Unspecified Ear
H71.21  Cholesteatoma Of Mastoid, Right Ear
H71.22  Cholesteatoma Of Mastoid, Left Ear
H71.23  Cholesteatoma Of Mastoid, Bilateral
H71.30  Diffuse Cholesteatosis, Unspecified Ear
H71.31  Diffuse Cholesteatosis, Right Ear
H71.32  Diffuse Cholesteatosis, Left Ear
H71.33  Diffuse Cholesteatosis, Bilateral
H71.90  Unspecified Cholesteatoma, Unspecified Ear
H71.91  Unspecified Cholesteatoma, Right Ear
H71.92  Unspecified Cholesteatoma, Left Ear
H71.93  Unspecified Cholesteatoma, Bilateral
H72.00  Central Perforation Of Tympanic Membrane, Unspecified Ear
H72.01  Central Perforation Of Tympanic Membrane, Right Ear
H72.02  Central Perforation Of Tympanic Membrane, Left Ear
H72.03  Central Perforation Of Tympanic Membrane, Bilateral
H72.10  Attic Perforation Of Tympanic Membrane, Unspecified Ear
H72.11  Attic Perforation Of Tympanic Membrane, Right Ear
H72.12  Attic Perforation Of Tympanic Membrane, Left Ear
H72.13  Attic Perforation Of Tympanic Membrane, Bilateral
H72.2X1 Other Marginal Perforations Of Tympanic Membrane, Right Ear
H72.2X2 Other Marginal Perforations Of Tympanic Membrane, Left Ear
H72.2X3 Other Marginal Perforations Of Tympanic Membrane, Bilateral
H72.2X9 Other Marginal Perforations Of Tympanic Membrane, Unspecified Ear
H72.811 Multiple Perforations Of Tympanic Membrane, Right Ear
H72.812 Multiple Perforations Of Tympanic Membrane, Left Ear
H72.813 Multiple Perforations Of Tympanic Membrane, Bilateral
H72.819 Multiple Perforations Of Tympanic Membrane, Unspecified Ear
H72.821 Total Perforations Of Tympanic Membrane, Right Ear
H72.822 Total Perforations Of Tympanic Membrane, Left Ear
H72.823 Total Perforations Of Tympanic Membrane, Bilateral
H72.829 Total Perforations Of Tympanic Membrane, Unspecified Ear
H72.90  Unspecified Perforation Of Tympanic Membrane, Unspecified Ear
H72.91  Unspecified Perforation Of Tympanic Membrane, Right Ear
H72.92  Unspecified Perforation Of Tympanic Membrane, Left Ear
H72.93  Unspecified Perforation Of Tympanic Membrane, Bilateral
H81.311 Aural Vertigo, Right Ear
H81.312 Aural Vertigo, Left Ear
H81.313 Aural Vertigo, Bilateral
H81.319 Aural Vertigo, Unspecified Ear
H81.391 Other Peripheral Vertigo, Right Ear
H81.392 Other Peripheral Vertigo, Left Ear
H81.393 Other Peripheral Vertigo, Bilateral
H81.399 Other Peripheral Vertigo, Unspecified Ear
H81.4 Vertigo Of Central Origin
H81.41 Vertigo Of Central Origin, Right Ear
H81.42 Vertigo Of Central Origin, Left Ear
H81.43 Vertigo Of Central Origin, Bilateral
H81.49 Vertigo Of Central Origin, Unspecified Ear
H90.0 Conductive Hearing Loss, Bilateral
H90.11 Conductive Hearing Loss, Unilateral, Right Ear, With Unrestricted Hearing On The Contralateral Side
H90.12 Conductive Hearing Loss, Unilateral, Left Ear, With Unrestricted Hearing On The Contralateral Side
H90.2 Conductive Hearing Loss, Unspecified
H90.3 Sensorineural Hearing Loss, Bilateral
H90.41 Sensorineural Hearing Loss, Unilateral, Right Ear, With Unrestricted Hearing On The Contralateral Side
H90.42 Sensorineural Hearing Loss, Unilateral, Left Ear, With Unrestricted Hearing On The Contralateral Side
H90.5 Unspecified Sensorineural Hearing Loss
H90.6 Mixed Conductive And Sensorineural Hearing Loss, Bilateral
H90.71 Mixed Conductive And Sensorineural Hearing Loss, Unilateral, Right Ear, With Unrestricted Hearing On The Contralateral Side
H90.72 Mixed Conductive And Sensorineural Hearing Loss, Unilateral, Left Ear, With Unrestricted Hearing On The Contralateral Side
H90.8 Mixed Conductive And Sensorineural Hearing Loss, Unspecified
H90.A11 Conductive Hearing Loss, Unilateral, Right Ear With Restricted Hearing On The Contralateral Side
H90.A12 Conductive Hearing Loss, Unilateral, Left Ear With Restricted Hearing On The Contralateral Side
H90.A21 Sensorineural Hearing Loss, Unilateral, Right Ear, With Restricted Hearing On The Contralateral Side
H90.A22 Sensorineural Hearing Loss, Unilateral, Left Ear, With Restricted Hearing On The Contralateral Side
H90.A31 Mixed Conductive And Sensorineural Hearing Loss, Unilateral, Right Ear With Restricted Hearing On The Contralateral Side
H90.A32 Mixed Conductive And Sensorineural Hearing Loss, Unilateral, Left Ear With Restricted Hearing On The Contralateral Side
H91.01 Ototoxic Hearing Loss, Right Ear
H91.02 Ototoxic Hearing Loss, Left Ear
H91.03 Ototoxic Hearing Loss, Bilateral
H91.09 Ototoxic Hearing Loss, Unspecified Ear
H91.10 Presbycusis, Unspecified Ear
H91.11 Presbycusis, Right Ear
H91.12 Presbycusis, Left Ear
H91.13 Presbycusis, Bilateral
H91.20 Sudden Idiopathic Hearing Loss, Unspecified Ear
H91.21 Sudden Idiopathic Hearing Loss, Right Ear
H91.22 Sudden Idiopathic Hearing Loss, Left Ear
H91.23 Sudden Idiopathic Hearing Loss, Bilateral
H91.3 Deaf Nonspeaking, Not Elsewhere Classified
H91.8X1 Other Specified Hearing Loss, Right Ear

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H91.8X2 Other Specified Hearing Loss, Left Ear
H91.8X3 Other Specified Hearing Loss, Bilateral
H91.8X9 Other Specified Hearing Loss, Unspecified Ear
H91.90 Unspecified Hearing Loss, Unspecified Ear
H91.91 Unspecified Hearing Loss, Right Ear
H91.92 Unspecified Hearing Loss, Left Ear
H91.93 Unspecified Hearing Loss, Bilateral
J30.0 Vasomotor Rhinitis
J30.1 Allergic Rhinitis Due To Pollen
J30.2 Other Seasonal Allergic Rhinitis
J30.5 Allergic Rhinitis Due To Food
J30.81 Allergic Rhinitis Due To Animal (Cat) (Dog) Hair And Dander
J30.89 Other Allergic Rhinitis
J30.9 Allergic Rhinitis, Unspecified
J31.0 Chronic Rhinitis
J31.1 Chronic Nasopharyngitis
J31.2 Chronic Pharyngitis

REVISIONS
06-03-2021 Policy added to the bcbsks.com web site.

REFERENCES
