FEP Medical Policy Manual

FEP 7.01.158 Balloon Dilation of the Eustachian Tube

Effective Policy Date: July 1, 2019

Original Policy Date: March 2018

Balloon Dilation of the Eustachian Tube

Description

Eustachian tube (ET) 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 dysfunction can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. 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.

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.

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**POLICY STATEMENT**

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

**BENEFIT APPLICATION**

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

**FDA REGULATORY STATUS**

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acclarent Aera Eustachian Tube Balloon D</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 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**

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

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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.

REFERENCES


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15. Satmis MC, van der Torn M. Balloon dilatation of the Eustachian tube in adult patients with chronic dilatory tube dysfunction: a retrospective cohort study. Eur Arch Otorhinolaryngol. Feb 2018;275(2):395-400. PMID 29285624


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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>March 2018</td>
<td>New Policy</td>
<td>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.</td>
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