

FEP 7.01.158 Balloon Dilation of the Eustachian Tube

Effective Date: April 15, 2018

Related Policies: None

Balloon Dilation of the Eustachian Tube

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 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 the patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube. 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 approximately 2 minutes after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.^{8,9}

FDA REGULATORY STATUS

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 FDA through the 510(k) process (K163509). FDA determined that this device was substantially equivalent to existing devices for use in eustachian tube dysfunction. The predicate devices are XprESS™ Multi-Sinus Dilation System and AERA® Eustachian Tube Balloon Dilation System.

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).

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RATIONALE

Summary of Evidence

For individuals who have chronic ET dilatory dysfunction despite medical management who receive balloon dilation of the ET, the evidence includes case series, systematic reviews of case series, and an RCT. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The criteria for diagnosing ET dilatory dysfunction are not standardized. Several medical and surgical treatments are used for ET dilatory dysfunction, but there is limited evidence for available treatments. Most case series assessed herein provided follow-up of less than a year and all showed short-term improvement comparing symptoms before and after balloon dilation. The number of revision procedures required due to the failure of the first ET balloon dilation procedure was reported in 3 case series (n=714 patients); 122 revisions were reported. In the published RCT evaluating balloon dilation of the ET, patients were eligible if they reported persistent ET dilatory dysfunction symptoms as measured on the 7-item ETDQ, a tool to assess symptoms, and had abnormal tympanometry. A greater proportion of patients in the balloon dilation group demonstrated tympanogram normalization (52%) compared with the medical management group (14%) at 6 weeks and reported a reduction in symptoms at 6 weeks on the ETDQ. The durability of effect at 24 weeks was demonstrated in a subset of patients. The rate of adverse events was low, and none of the serious adverse events were thought to be related to the device or procedure. The 52-week follow-up data have not been reported. The durability of effect, rates of reoperation or revisions, and safety data over the first year are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2011, the National Institute for Health and Care Excellence published guidance on balloon dilation of the eustachian tube.¹⁵ 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
March 2018	New Policy	Policy created with literature review through October 16, 2017. Balloon dilation of the Eustachian tube for treatment of patients with chronic Eustachian tube dilatary dysfunction is considered investigational.

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