

Balloon Dilation of the Eustachian Tube

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

The eustachian tube (ET) 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, and 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. Chronic ETDD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. 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. A eustachian tube balloon dilation system is a device which includes an inflatable balloon and flexible catheter

that dilates the cartilaginous portion of the eustachian tube, and is used to treat persistent eustachian tube dysfunction.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	<p><i>Medicare coverage guidance is not available for balloon dilation of the eustachian tube. Therefore, the health plan's medical policy is applicable.</i></p> <p>Balloon Dilation of the Eustachian Tube, Surgery, Policy No. 206 (see <i>"NOTE" below</i>)</p>

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

In December 2015, the AERA® (Acclarent) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II.^[9] 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.^[1]

In April 2017, the XprESS™ ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by FDA through the 510(k) process. 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.^[2]

Note, the fact a service or procedure has been issued a CPT/HCPCS code or “is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary.” (*Noridian LCD L35008*) The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

[Investigational \(Experimental\) Services and New and Emerging Medical Technologies and Procedures](#), Medicine, Policy No. M-149

REFERENCES

1. Food and Drug Administration. De Novo Classification Request For Acclarent Aera™ Eustachian Tube Balloon Dilation System. 2015. [cited 3/6/2018]; Available from: https://www.accessdata.fda.gov/cdrh_docs/reviews/den150056.pdf
2. The XprESS ENT Dilation System [cited 2/20/2018]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf16/k163509.pdf
3. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, [§30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services](#)

CODING

Codes	Number	Description
CPT	69799	Unlisted procedure, middle ear
HCPCS	C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.