Balloon Dilation of the Eustachian Tube (BDET)
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Balloon Dilation of the Eustachian Tube (BDET)		
MNG #: 125	☒ CCA Senior Care Options (HMO D-SNP) (MA) ☒ CCA One Care (Medicare-Medicaid) (MA)	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Benefit Type: ☒ **Medicare** ☐ **Medicaid**	**Approval Date:** 9/12/2024	**Effective Date:** 11/18/2024; 1/1/2025
Last Revised Date: 1/22/2025	**Next Annual Review Date:** 9/12/2025	**Retire Date:**

OVERVIEW:

Obstructive eustachian tube dysfunction (OETD) is a common affliction wherein the eustachian tube does not open properly, causing a buildup of pressure and fluid in the middle ear. Generally accepted as the underlying cause for chronic ear diseases, such as chronic otitis media with effusion, OETD is associated with symptoms such as aural fullness, otalgia, inability to perform a Valsalva maneuver, and hearing loss. Nasal steroids, decongestants, and antihistamines to reduce symptoms is the commonly prescribed medical treatment for OETD, with little evidence of benefit. The development of endoscopic sinus surgery and the popularity of balloon sinuplasty led to the adoption of balloon dilation of the eustachian tube (BDET). By inserting and inflating a non-compressible balloon within the lumen of the ET and maintaining pressure for approximately two minutes, a single treatment can potentially lead to a sustained improvement of ET function. The U.S. Food and Drug Administration (FDA) has issued a Class II approval for two eustachian dilation balloons for OETD.

DEFINITIONS:

Audiometery - A series of tests that evaluate the ability to hear sounds.

Carotid-cochlear dehiscence (CCD) - An extremely rare condition involving the thinning of the bony canal separating the internal carotid artery from the cochlea.

Chronic Rhinosinusitis (CRS) - An inflammatory process that involves the paranasal sinuses and persists for ≥ 12 weeks.

Endolymphatic hydrops – An excessive build-up of endolymph fluid in the hearing and balance structures of the inner ear.

Otoscopy - A clinical procedure used to examine structures of the ear, particularly the external auditory canal, tympanic membrane, and middle ear.

Nasal endoscopy - A minimally invasive procedure that allows a doctor to examine the inside of the nasal cavity and openings to the sinus passages.

Tympanometery – A test that shows how well the middle ear is working.

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Valsalva Maneuver – Forceful attempt of expiration against a closed glottis.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Balloon dilation of the eustachian tube may be considered reasonable and medically necessary when ALL of the following criteria (1 through 8) are met:

1. Member has symptoms of obstructive ETD, which can include aural fullness, aural pressure, hearing loss, and otalgia.
2. Member has documented CRS that is refractory to medical treatment, including all of the following:
    - Nasal saline washes
    - Anti-inflammatory steroids
    - Antibiotics
    - Lifestyle modifications
3. Member has failed medical management for other identified and treatable causes of obstructive ETD, including either of the following:
    - Allergic rhinitis - Systemic decongestants, antihistamines, nasal steroid sprays, or sublingual immunotherapy; or
    - Laryngopharyngeal reflux - Behavioral modifications and/or proton pump inhibitors
4. Persistent eustachian tube dysfunction has been diagnosed by ruling out all of the following causes of aural fullness:
    - Patulous ETD; and
    - Temporomandibular joint disorders; and
    - Extrinsic obstruction of the ET; and
    - Superior semicircular canal dehiscence; and
    - Endolymphatic hydrops.
5. A comprehensive history and physical exam have been completed, including all of the following:
    - Otoscopy; and
    - Nasal endoscopy - Nasal endoscopy in patients who are candidates for BDET is necessary for assessing the ET lumen and assessing the feasibility of transnasal access to the nasopharynx. Nasal endoscopy is necessary to rule out extrinsic causes of ETD; and
    - Tympanometry; and
    - Audiometry.
6. Member is ≥ 18 years of age
7. FDA-approved balloon sinus ostial devices (e.g., catheter, inflation device, system) will be utilized according to FDA-approved indications and guidelines
8. Standard arrangements are in place for clinical governance, consent and audit.

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LIMITATIONS/EXCLUSIONS:

Balloon sinus ostial dilation is NOT considered reasonable and medically necessary for any of the following:

- Patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD; or
- Repeat BDET after a prior ineffective BDET; or
- Balloon sinus ostial dilation performed as a stand-alone procedure; or
- Nasal polyps or tumors.

Contraindications, including all of the following:

- Patients diagnosed as having a patulous ETD; and
- Use of a device without a depth marker that demarcates insertion into the cartilaginous eustachian tube when dehiscent carotid artery is identified on imaging; and
- The ACCLARENT AERA® Eustachian Tube Balloon Dilation System for use in a Eustachian tube with an identified ipsilateral carotid artery that is dehiscent into the ET lumen or history of ipsilateral patulous Eustachian tube; and
- Use of the XprESS device to treat patients with evidence of internal carotid artery dehiscence.

CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

CPT/HCPCS CODE	CODE DESCRIPTION
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage

Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists. Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

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This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

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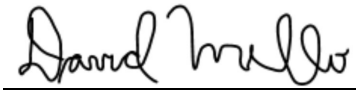
REVISION LOG:

REVISION DATE	DESCRIPTION
1/22/2025	Template update
1/21/2025	UMC Approval
1/13/2025	MPC Approval by email vote – to remove MAPD products from product grid
9/17/2024	UMC Approval
9/12/2024	New MNG

APPROVALS:

David Mello	Senior Medical Director Utilization Review and Medical Policy
CCA Senior Clinical Lead [Print]	**Title [Print]**
	1/13/2025
Signature	**Date**
Nazlim Hagmann, MD	Chief Medical Officer
CCA CMO or Designee [Print]	**Title [Print]**
	1/13/2025
Signature	**Date**