Priority Health

MEDICAL POLICY
No. 91596-R4

BALLOON SINUS OSTIAL DILATION FOR CHRONIC SINUTIS AND EUSTACHIAN TUBE DILATION

Effective Date: September 1, 2024	**Review Dates: 12/11, 12/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23, 2/24, 5/24, 5/25**
Date Of Origin: December 14, 2011	**Status: Current**

I. POLICY/CRITERIA

A. The use of balloon sinus ostial dilation, e.g., Balloon Sinuplasty™, for the treatment of chronic sinusitis is considered medically necessary when all of the following criteria are met:

1. Documentation of persistent rhinosinusitis for greater than three months; **AND**
2. Documented failure of medical therapy greater than three months in duration demonstrated by persistent upper respiratory symptoms despite therapy consisting of a minimum of two different antibiotics with a trial of steroid spray, antihistamine spray and/or decongestant; **AND**
3. Radiological evidence of at least ONE of the following:

    i. Air fluid levels; OR
    ii. Mucosal thickening > 2 mm; OR
    iii. Opacification; OR
    iv. Nasal polyposis

B. The use of devices (e.g., the Propel™ sinus implant, the Relieva Stratus™ MicroFlow spacer, and the Sinu-Foam™ spacer) for maintaining sinus ostial patency following balloon sinus ostial dilation and / or endoscopic sinus surgery is **experimental and investigational** because their effectiveness has not been established.

Balloon sinus ostial dilation used as an adjunct during functional endoscopic sinus surgery (FESS) is considered integral to the primary FESS procedure and not separately reimbursable.

C. Nasopharyngoscopy, surgical, with dilation of eustachian tube (Eustachian tube balloon dilation)

1. Medical Necessity Criteria:

    Unilateral or bilateral **Eustachian tube balloon dilation (ETBD)** is considered medically necessary once per lifetime for the treatment of

chronic obstructive Eustachian tube dysfunction when ALL of the following criteria are met:

- Age 18 years or older
- Any of the following symptoms continuously for at least six months:
    - aural fullness (clogged ear sensation)
    - aural pressure or otalgia
    - hearing loss
    - autophony

  Note: standardized patient reported questionnaire (ETDQ-7) recommended.

- History of chronic ear disease or intolerance to barometric changes greater than six months
- Tympanic membrane abnormality (i.e., retracted membrane, effusion) on exam
- Complete nasal endoscopy assessing the **Eustachian tube (ET)** lumen confirming transnasal access to the nasopharynx and eliminating extrinsic causes of **Eustachian tube dysfunction (ETD)**
- Failure, intolerance or contraindication to appropriate medical management of co-occurring conditions (rhinosinusitis, allergic rhinitis, laryngopharyngeal reflux)
- Tympanometry of intact tympanic membrane showing either:
    - Type A tympanogram (only provided that symptom relief occurred with prior myringotomy and tympanostomy tubes), OR
    - Type B or Type C tympanogram

- If history of prior tympanostomy tube placement, relief from classic Eustachian tube obstructive symptom must be demonstrated while tubes were patent

Eustachian tube balloon dilation (ETBD) is considered **experimental, investigational, or unproven** for all other indications.

2. Exclusions: The following patients should not be considered for balloon dilatation of the Eustachian Tube:

- Patulous ETD (demonstrated by autophony of voice, pulsatile tinnitus, and/or aural fullness, visible respiratory variation of tympanic membrane (TM))
- Reversible or irreversible causes of the eustachian tube dysfunction including but not limited to:
    - Neoplasm, enlarged adenoids, or nasopharyngeal mass resulting in extrinsic compression
    - Congenital Craniofacial syndromes (eg. cleft)
    - Chronic degenerative neuromuscular conditions resulting in adynamic eustachian tube
    - Active systemic mucosal or autoimmune inflammatory conditions affecting nasal mucosa
    - Tobacco use
- Superior semicircular canal dehiscence
- Previous balloon dilation procedure

Patients undergoing BDET **concurrent with sinus ostial dilation or myringotomy** should meet the same diagnostic criteria for BDET as those undergoing BDET alone.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***

- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Chronic sinusitis is defined as a prolonged or recurrent infection and inflammation of the nasal sinuses. Chronic, long-term sinusitis may develop in people with chronic allergies, deviated nasal septum or other obstruction of the nose. Additionally, dental infections such as tooth abscesses may also spread into the sinus and infect it directly.

A technique referred to as balloon sinus ostial dilation or Balloon Sinuplasty™ has been proposed as an alternative or in addition to standard endoscopic surgery. This procedure proposes the use of a small balloon-like device instead of the other devices usually used. There are two different devices available on the market that dilate the sinuses. With the first type of device, the balloon is placed in the blocked sinus passage under endoscopic guidance through the nostril. The second is placed in the sinus through an incision made in the gums and maxillary bone under the front lip of the individual. In both cases, once the balloon is in place in the ostia of the targeted sinus, the balloon is inflated to push the sinus tissue and bone out of the way, creating a larger airway passage and allowing drainage of nasal secretions.

Results of the available studies provide preliminary evidence that balloon sinus ostial dilation is relatively safe and efficacious for the treatment of chronic sinusitis that is refractory to medical therapy. Despite these promising early findings, the overall quality of the evidence is low since the majority of the available studies lack controls and adequate follow-up of the majority of the enrolled patients. The patient selection criteria for this therapy have not been well defined. Furthermore, many of the studies evaluated hybrid procedures, which creates difficulties in determining the specific role of balloon sinus ostial dilation in treatment outcomes. Additional studies are needed to confirm that balloon sinus ostial dilation is safer and more effective over the long term than FESS or

adenoidectomy, particularly well-designed trials that randomize patients to balloon sinus ostial dilation or to standard treatment for chronic sinusitis.

Eustachian tube dysfunction (ETD) is a physiological disorder of the **eustachian tube (ET)** that results in the inability to appropriately equalize pressure between the middle ear and the environment. Pressure equalization and ventilation of the middle ear is a primary function of the ET; other functions include mucociliary clearance of secretions from the middle ear and protection of the middle ear from pathogens, material, and sounds from the nasopharynx. ETD ranges from obstructive dysfunction, in which there is failure of the Eustachian tube (ET) to open and provide adequate ventilation to the middle ear, to patulous ETD in which there is failure of the ET to close. Patients may move back and forth on this spectrum, creating difficulties in diagnosis and appropriate treatment. The choice of management strategies for isolated Eustachian tube dysfunction should be directed at the underlying etiology, if known. The usual treatments for obstructive Eustachian tube dysfunction include medical management (decongestants, systemic and topical nasal steroids, or antihistamines) and pressure equalization methods (insufflation, tympanostomy, or balloon dilation of the eustachian tube. The Eustachian tube balloon dilation system is a device that includes a flexible catheter attached to an inflatable balloon. The system is intended for use in dilating the cartilaginous portion of the Eustachian tube to improve ET function.

Tympanometry measures the changes in the acoustic impedance of the middle ear system in response to changes in air pressure. As the pressure increases, the tympanic membrane is pushed medially; as negative pressure is placed, the tympanic membrane protrudes laterally. The point of maximum compliance of the middle ear is identified, indicating the status of air pressure in the middle ear.

Five types of tympanograms can be seen

- Type A – Normal middle ear pressure
- Type B – Little or no mobility, suggestive of fluid behind the tympanic membrane or perforation
- Type C – Negative pressure in the middle ear, suggestive of a retracted tympanic membrane
- Type A_S – A very stiff middle ear system that can be caused by myringosclerosis or otosclerosis
- Type A_D – The highly compliant tympanic membrane seen in ossicular chain discontinuity

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): The AAO-HNS (2019) developed a clinical consensus statement on balloon dilation of the Eustachian tube (ET). Eustachian tube balloon dilation was

defined as "inserting a catheter with a balloon temporarily into the cartilaginous portion of the ET and then inflating the balloon to alleviate obstructive ETD." Based on a systematic review of the literature and expert consensus, the Society's statements included the following:

- "A comprehensive history and physical exam, including otoscopy, are essential parts of the diagnostic evaluation of a candidate for BDET
- Patient-reported symptom scores are useful in assessing baseline ETD symptoms and treatment outcomes.
- Patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD.
- Nasal endoscopy is necessary to rule out extrinsic causes of ETD.
- Tympanometry and Comprehensive audiometry is an essential part of the diagnostic evaluation prior to BDET.
- BDET is contraindicated for patients diagnosed as having a patulous ETD (as suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness).
- The benefit of repeat BDET after a prior ineffective BDET has not been determined.
- BDET is an alternative to tympanostomy tube placement for obstructive ETD.

The seven-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is a disease-specific instrument to assess symptoms with respect to ETD.

IV. CODING INFORMATION

ICD-10 Codes that may apply:

J32.0 Chronic maxillary sinusitis
J32.1 Chronic frontal sinusitis
J32.2 Chronic ethmoidal sinusitis
J32.3 Chronic sphenoidal sinusitis
J32.4 Chronic pansinusitis
J32.8 Other chronic sinusitis
J32.9 Chronic sinusitis, unspecified

CPT/HCPCS Codes:

31295 Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
31296 Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)
31297 Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)
31298 Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)

69705 Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706 Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral
C2625 Stent, noncoronary, temporary, with delivery system *(Prior authorization required. Not Covered when used with Propel system)*
J7402 Mometasone furoate sinus implant, (Sinuva), 10 mcg *(covered only for Medicare. Prior authorization required)*

Not Covered:
S1091 Stent, noncoronary, temporary, with delivery system (Propel)

V. REFERENCES

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