Medical Coverage Policy

Effective Date.....4/15/2026
Next Review Date.....4/15/2027
Coverage Policy Number..... 0480

Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation

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Overview

This Coverage Policy addresses balloon sinus ostial dilation, also called balloon sinuplasty, for the treatment of chronic sinusitis and other indications, including recurrent acute rhinosinusitis. The Policy also addresses Eustachian tube dilation for all indications including Eustachian tube dysfunction.

Coverage Policy

Balloon Sinus Ostial Dilation

Balloon sinus ostial dilation (balloon sinuplasty) is considered medically necessary in each of the sinuses being considered for dilation (i.e., maxillary, frontal or sphenoid) for treatment of EITHER of the following conditions:

- Chronic rhinosinusitis when ALL of the following criteria are met:
  - presence of two or more of the following signs/symptoms for more than three consecutive months:
    - nasal obstruction
    - anterior or posterior mucopurulent (foul) drainage
    - facial pain, pressure and/or fullness over the affected sinus
    - decreased sense of smell
  - evidence of chronic rhinosinusitis on computerized tomography (CT) scan in each of the sinuses being considered for treatment including ANY of the following:
    - mucosal thickening
    - air fluid levels
    - opacification
    - nasal polyposis
  - failure, intolerance or contraindication of medical management when ALL the following have been tried, during at least eight (8) consecutive weeks:
    - antibiotic therapy
    - steroid spray
    - antihistamine nasal spray and/or decongestant
    - nasal saline irrigation
- Recurrent acute rhinosinusitis when ALL of the following criteria are met:
  - Four or more episodes per year of acute rhinosinusitis
  - Nasal endoscopy findings suggestive of significant disease (i.e., abnormal mucosal status, fluid, or infection)
  - CT scan evidence of ostial occlusion and mucosal thickening in each paranasal sinus being considered for treatment.
  - Sinonasal symptoms (e.g., pain, pressure, drainage, reduced sense of smell)

Balloon sinus ostial dilation (balloon sinuplasty) is considered not medically necessary for all other indications.

Balloon sinus ostial dilation (balloon sinuplasty) when used as an adjunctive procedure during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the primary procedure and not separately reimbursable.

Eustachian Tube Dilation

Adults
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
  - aural pressure
  - hearing loss
  - autophony
- history of chronic ear disease or intolerance to barometric changes greater than six months
- BOTH of the following prior to ETBD:
  - two abnormal tympanograms (Type B or C)
  - two abnormal tympanic membrane examinations (i.e., retracted membrane, effusion, perforation)
- failure, intolerance or contraindication to appropriate medical management including at least four weeks of a nasal topical spray
- if patient has a history of tympanostomy tube placement, symptoms of Eustachian tube obstruction improved while tubes were patent

Pediatrics
Unilateral or bilateral Eustachian tube balloon dilation (ETBD) using a U.S. Food and Drug Administration (FDA)-approved/cleared device is considered medically necessary in an individual 8 to 17 years of age when ALL of the following criteria are met:

- Objective signs of persistent Eustachian tube dysfunction (ETD) resulting in chronic otitis media with effusion as evidenced by:
  - middle ear effusion persisting for ≥3 months
  - tympanic membrane retraction with associated hearing loss
- refractory to at least one surgical intervention (e.g. tympanostomy tubes, adenoidectomy) for persistent Eustachian tube dysfunction

Eustachian tube balloon dilation (ETBD) is considered not medically necessary for all other indications.

Coding Information

Notes:
1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Balloon Sinus Ostial Dilation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia

Eustachian Tube Dilation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

General Background

Balloon Sinus Ostial Dilation

Rhinosinusitis, also referred to as sinusitis, is an inflammation of the mucous membrane of the paranasal sinuses and nasal cavity. It affects all age groups and can be caused by infection, airborne allergens (e.g., dust mites, mold, pollen) or autoimmune deficiencies. There are three classifications of rhinosinusitis. Acute rhinosinusitis (ARS) typically lasts four weeks or less. Subacute sinusitis lasts 4–12 weeks, and chronic rhinosinusitis (CRS) lasts for more than 12 weeks, with or without exacerbation, and can continue for months or years. CRS leads to thickening of the paranasal sinuses due to constant inflammation. The condition can occur with or without nasal polyps. Recurrent acute rhinosinusitis (RARS) is diagnosed when four or more episodes of acute rhinosinusitis occur in the past 12 months without signs or symptoms of rhinosinusitis between episodes. The four cardinal signs/symptoms of CRS and RARS are: nasal obstruction; facial congestion, pressure, and or fullness; anterior and/or posterior mucopurulent drainage; and hyposmia (decreased ability to smell). CRS and RARS are associated with sinus edema and impaired mucociliary clearance (American Academy of Otolaryngology-Head and Neck Surgery Foundation [AAO-HNSF], 2025; Parikh, et al., 2014; Hopkins, et al., 2007).

The diagnosis of CRS and RARS is based on presenting signs and symptoms, clinical examination using anterior rhinoscopy, or nasal endoscopy. Radiological evidence is plain films, computed tomography (CT) scan, and in some cases, MRI is a part of the work-up for these patients. CT

scan is the standard radiologic examination obtained when endoscopic sinus surgery is being considered. Radiological characteristics of sinusitis include air fluid levels, mucosal thickening greater than three millimeters, nasal polyposis, opacification, bony remodeling and thickening. CT is also used to determine the Lund-Mackey Score for assessing the severity of rhinosinusitis. This scale grades the right and left sides independently, looking at the maxillary, anterior ethmoids, posterior ethmoids, sphenoid, and frontal sinuses, as well as the ostiomeatal complex. Each sinus is scored a 0 (no abnormality), 1 (partial opacification), or 2 (total opacification), and the ostiomeatal complex is scored either a 0 or 2 (for presence or absence of disease). Each side is divided into six regions, corresponding to the location of specific sinuses. Ethmoid sinuses are divided into two regions, anterior and posterior, and the ostiomeatal complex is evaluated separately. Each sinus is scored as 0, 1, or 2 based on the severity of mucosal inflammation or fluid accumulation. Thus the score can range from 0, complete lucency of all 12 regions, to 24, complete opacity of all regions. Studies have reported an increased complication rate following surgery with increasing Lund-Mackay scores (Brook, 2025; Vartanian, 2023; Ramanan, 2021; AAO-HNSF, 2025; Parikh, et al., 2014; Hopkins, et al., 2007).

Because CRS is typically not cured, medical management is focused on minimizing mucosal inflammation and edema to prevent obstruction and minimize the incidence of infections and acute exacerbations. Medical treatment is typically tried for at least eight weeks and includes nasal saline irrigation, topical and systemic glucocorticoids, two or more antibiotics, and/or antileukotriene agents. When the patient becomes unresponsive to medical management, surgical intervention to clean and drain the sinuses may be indicated. In cases where obstruction of the nasal passages is present (e.g., polyps, deviated septum), surgery to correct the obstruction may be done (Brook, 2025; AAO-HNSF, 2025; Parikh, et al., 2014).

Functional endoscopic sinus surgery (FESS), also referred to as endoscopic sinus surgery (ESS), is the standard surgical procedure for CRS that is unresponsive to medical management. The goal of surgery is to improve sinus ventilation and drainage by enlarging the openings of the sinuses, removing any polyps and correcting significant structural problems that may be hindering drainage. FESS involves the insertion of an endoscopy into the nose for direct visual exam of the openings into the sinuses. Special instruments are used along with the endoscope to remove the blockages and improve breathing. Complications that can occur during ESS include: scarring and adhesions, intraoperative bleeding that can obscure surgical visualization, orbital injury, and accidental penetration of the brain (AAO-HNSF, 2025; Parikh, et al., 2014; Brown, et al., 2006).

Balloon sinus ostial dilation, also known as balloon sinuplasty and balloon catheter sinusotomy, has become an accepted alternative procedure to functional endoscopic sinus surgery (FESS) for the treatment of CRS and RARS in a select subset of patients. Like FESS, balloon sinuplasty is intended to allow access to and ventilation of obstructed sinuses. The procedure is less invasive than FESS and proposed to have decreased incidence of complications such as bleeding or adhesions. Risks of balloon sinuplasty include tissue and mucosal trauma, infection or possible optic injury. Basic equipment includes a sinus guidewire, a sinus delivery catheter, a sinus balloon and an inflation device. Guided by X-ray images or by a lighted fiberoptic tip, the catheter is threaded up to the opening of the blocked or poorly draining sinus and the guidewire is passed through the opening of the sinus. The guidewire is passed from the nasal cavity into the specific sinus being addressed and a balloon dilating catheter is passed over the wire to the narrowest part of the sinus drainage pathway. The balloon is then briefly inflated to a high pressure to dilate the sinus ostium and modify the sinus outflow tract without tissue excision. The balloon is then deflated, and the catheter is removed (Miglani et al., 2026; Liang et al., 2025; Rank & Holbrook, 2025; AAO-HNSF, 2018).

When performed alone, balloon sinuplasty is an accepted procedure for a select subset of adult patients, age 18 years and older, with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis

(RARS). Appropriate CRS surgical candidates have failed at least eight weeks of consecutive medical therapy including at least two antibiotics, steroid nasal spray, antihistamine nasal spray and/or decongestant and nasal saline washes. Computerized tomography (CT) scan should show air fluid levels, opacification or nasal polyps. RARS surgical candidates have had four or more episodes of acute rhinosinusitis per year with relief of symptoms between episodes. Nasal endoscopy results should include abnormal mucosal status, fluid or infection. Additionally, a CT scan should show ostial occlusion and mucosal thickening of the paranasal sinuses. When balloon sinuplasty is used as an adjunctive procedure with FESS it is considered an integral part of the procedure.

Balloon sinuplasty has been proposed for the treatment of other conditions including headaches unrelated to CRS, nasal obstruction and obstructive sleep apnea (AAO-HNSF, 2018). There is insufficient evidence in the peer-reviewed literature to support balloon sinuplasty for these indications.

U.S. Food and Drug Administration (FDA):
Balloon sinuplasty devices are regulated by the FDA as Class I medical devices and are subject to the 510(k) premarket notification pathway. These devices are indicated for transnasal dilation of sinus ostia to remodel sinus outflow tracts through controlled displacement of adjacent bone and paranasal sinus structures. FDA-cleared indications span pediatric through adult populations, with approved use beginning at age 2 years for maxillary sinus dilation and extending to adult use involving the maxillary, frontal, and sphenoid sinuses (FDA, 2026).

Device or Product	Identifier	Manufacturer
VenSure™ Balloon Dilation System	K230065	Fagron GmbH
SINUSPRIME Dilation System	K201398	Stryker Ent
Next Generation Balloon Dilation System	K201115	Acclarent, Inc.
Sinusway™ Dilation System	K181838	3NT Medical Ltd.
Vent-Os Sinus Dilation family	K160770	Sinusys Corporation
XprESS™ Multi-Sinus Dilation System	K152434	Entellus Medical, Inc.

*FDA product codes: LRC

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review – Chronic Rhinosinusitis
Randomized controlled trials have compared FESS to balloon sinuplasty of the frontal, maxillary or sphenoid sinuses for the treatment of CRS. The studies have small patient populations and short-term follow-up. However, outcomes have shown that balloon sinuplasty is noninferior to FESS with shorter operative times, less bleeding and few to no reported complications (Chandra, et al.,

2016; Bikhazi, et al., 2014; Marzetti, et al., 2014; Achar, et al., 2012; Plaza, et al., 2011). Balloon sinuplasty has evolved into an accepted alternative procedure for CRS.

Liang et al. (2025) conducted a systematic review and meta-analysis comparing the efficacy and safety of sinus balloon catheter dilation (SBCD) with functional endoscopic sinus surgery (FESS) for the treatment of chronic rhinosinusitis (CRS) in adults who were unresponsive to medical therapy. Fourteen randomized controlled trials were included, encompassing a total of 1060 participants with reported mean ages ranging from 30.4 to 47.9 years. Eligible studies enrolled patients diagnosed with CRS, with or without nasal polyposis or allergic rhinitis, who failed drug therapy, compared SBCD with FESS, and reported at least one of the following outcomes: Lund–Mackay score, Sino Nasal Outcome Test 20 (SNOT-20) score, complications, operating time, or revision surgery. Studies were excluded if they were nonrandomized designs, secondary publications, involved other disease states, included duplicate cohorts, or lacked available full text or extractable data. Across included trials, 531 participants underwent sinus balloon catheter dilation and 529 underwent functional endoscopic sinus surgery, with follow up durations ranging from 3 to 18 months and most studies reporting outcomes at 12 months. Five randomized controlled trials reported postoperative Lund–Mackay scores with no statistically significant differences between treatment groups. Eight trials reported postoperative SNOT-20 scores, demonstrating significantly lower scores in the SBCD group compared with FESS ($p=0.005$). Four trials evaluated postoperative complications, with a significantly lower overall complication rate observed in the SBCD group ($p<0.00001$), including significantly fewer adhesions ($p=0.001$). No significant differences were identified between groups for postoperative infection or bleeding. Revision surgery rates did not differ significantly between treatments. Two trials reported operating time, which was significantly shorter for SBCD compared with FESS ($p=0.001$). The authors identified several limitations, including a limited number of trials, relatively small overall sample size, incomplete reporting of outcome variability, limited availability of outcome data across studies, lack of adjustment for confounding variables, and methodological concerns such as unclear randomization procedures and lack of blinding. The authors concluded that SBCD is an effective and safe treatment option for chronic rhinosinusitis but emphasized the need for additional well designed randomized controlled trials to further confirm these findings.

Numerous case series have also been conducted to evaluate the safety and efficacy of balloon sinuplasty. Subjects were aged 18 years and older with CRS for more than 12 weeks that was unresponsive to medical management (e.g., antibiotic therapy, inhaled and/or systemic corticosteroids, decongestants, saline irrigations). Reported post-operative outcomes included: functional patency in 80.5%–97% of patients; statistically significant improvement in sino-nasal outcome (SNOT-20) scores; and CT Lund-Mackey scores and revision rates 3%–7.4%. The studies are limited by the small patient populations (n=37–115) and short-term follow-ups (e.g., 2–12 months) (Sikand, et al., 2015; Gould, et al., 2014; Levine, et al., 2013; Albritton, et al., 2012; Weiss, et al., 2008; Kuhn, et al., 2008). Published studies evaluating the outcomes of balloon sinuplasty in children are lacking (Ramadan, et al., 2010).

Brodner et al. (2013) conducted a prospective case series to evaluate the safety and efficacy of balloon sinuplasty dilation (BSD) (XprESS) in 175 patients and 497 sinuses (279 frontal, 138 sphenoid, 80 maxillary). Patients were 18 years and older, scheduled for FESS prior to the study, and had a CT scan within 12 months of the surgery. At the one-year follow-up, 44 patients reported significant improvement in sinus symptoms ($p<0.0001$). At the one-year follow-up, ostial patency was maintained in 91.6% of sinuses and one revision surgery was required.

Karanfilov et al. (2013) conducted a prospective, multicenter, case series to evaluate the safety and efficacy of balloon sinuplasty dilation (BSD) in 203 subjects (552 sinuses). Patients aged 18 years and over with CRS had failed the minimum maximal treatment protocol (i.e., more than 3–6 weeks of broad-spectrum or culture-directed antibiotics, intranasal steroid spray and/or oral

steroids if polyps or severe inflammation were present; antihistamines and/or decongestants clinically indicated; and routine use of nasal saline irrigation during treatment course). CRS diagnosis was made according to the AAO-HNS CRS definition which includes ≥ 12 weeks of two or more major signs/symptoms and inflammation by purulent mucus/edema, presence of polyps, or radiographic imaging. The technical dilation success was 93.3% for maxillary sinuses, 90.5% for sphenoid and 93.7% for frontal. There was significant improvement in the Sino-Nasal Outcome Test (SNOT-20) and the Lund-Mackay CT scores ($p<0.0001$, each). Patients (82.3%) considered the procedure tolerable or highly tolerable.

Literature Review – Recurrent Acute Rhinosinusitis
Saltagi et al. (2021) conducted a systematic review evaluating the effectiveness of medical therapy, balloon sinus dilation (BSD), and endoscopic sinus surgery (ESS) for the management of recurrent acute rhinosinusitis (RARS). Ten studies comprising a total of 890 participants (mean age 40.6 years) were included. Eligible studies consisted of randomized controlled trials, cohort studies, and case series published in English that specifically addressed RARS in adults and enrolled at least three participants, with clearly defined diagnostic criteria and measurable outcomes. Studies limited to single-episode acute rhinosinusitis or chronic rhinosinusitis were excluded. Across studies, outcomes were primarily assessed using sinonasal symptom rating scales, with some studies additionally reporting objective measures such as Lund–Kennedy endoscopic scores and computed tomography imaging findings before and after treatment. Follow-up durations ranged from 1 to 19 months. When outcomes were evaluated across studies, individuals undergoing surgical management (BSD or ESS) demonstrated a trend toward greater symptom improvement compared with those receiving medical therapy alone, as reflected by mean improvements in the Rhinosinusitis Disability Index (−30.94 vs −17.2) and the 22-item Sinonasal Outcome Test (−39.7 vs −24). Reported limitations included a small number of available studies, small sample sizes, variability in diagnostic criteria, inconsistent and heterogeneous outcome measures precluding meta-analysis, inconsistent reporting, and relatively short follow-up periods. The authors concluded that surgical intervention may be beneficial for individuals who do not respond to initial medical management; however, they emphasized the need for further research to establish standardized diagnostic criteria and evidence-based management approaches.

Sikand et al (2019) conducted a randomized, controlled trial comparing in-office balloon sinus dilation versus medical management for adults diagnosed with recurrent acute rhinosinusitis (RARS). Twenty-nine patients underwent balloon sinus dilation with medical management while 30 patients received medical management alone. Outcomes were measured at 24 weeks, and the patients were followed up to 48 weeks. Results included the patient-reported quality of life (QOL), as measured by the Chronic Sinusitis Survey (CSS) total score from baseline to 24 weeks, was significantly greater in the balloon sinus dilation plus medical management group compared with the medical management-only group (37.3 ± 24.4 [n = 26] vs 21.8 ± 29.0 [n = 27]; p = 0.0424).

Gould et al. (2014) conducted a prospective, multicenter study performing balloon dilation of the maxillary sinuses/ethmoid infundibula with or without frontal or sphenoid ostial dilation in the physician's office under local anesthesia for adults diagnosed with CRS or RARS. Three hundred seven sinuses among 81 subjects successfully completed ostial dilations. Clinically and statistically significant ($p<0.0001$) mean SNOT-20 symptom improvement was observed at one and six months and sustained through one year. The Rhinosinusitis Symptom Inventory (RSI) treatment effect for all major rhinosinusitis symptoms was "large" and improvement in each was significant ($p<0.0001$). Compared with the previous one year period, patients reported an average of 2.3 fewer acute sinus infections ($p<0.0001$), 2.4 fewer antibiotic courses taken ($p<0.0001$), and 3.0 fewer sinus-related physician visits ($p<0.0001$) after balloon dilation.

Levine et al. (2013) conducted a prospective, multi-institutional study that performed in-office balloon dilation of maxillary sinus ostia and ethmoid infundibula to treat both chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS). Seventy-four patients, all confirmed by computed tomography to have disease in the maxillary and anterior ethmoid sinuses, were followed for one year. The mean improvement on the SNOT-20 at one year was clinically and statistically significant ($p < 0.0001$), with no significant difference between the CRS and RARS patient outcomes. The treatment effect was the same in the CRS and RARS subgroups and was either "moderate" or "large" for ten of twelve symptoms. The mean numbers of antibiotic courses ($p \leq 0.001$), sinus-related physician visits ($p < 0.0001$) and number of acute sinus infections ($p < 0.001$) decreased significantly in both subgroups.

Professional Societies/Organizations

American Academy of Allergy, Asthma and Immunology (AAAAI): A joint task force published a practice parameter on the medical management of chronic rhinosinusitis with nasal polyposis (CRSwNP). They defined CRSwNP as an inflammatory disease of the nasal mucosa lasting at least twelve weeks. In people with CRSwNP, the guideline panel suggested intranasal corticosteroid (INCS) rather than no INCS (conditional recommendation). The small-to-moderate treatment effect and low certainty of evidence when all of the different INCS delivery methods were considered together for the two critical outcomes (disease-specific quality of life and nasal obstruction symptoms), balanced by the low burdens of medications, drove the conditional recommendation. The guideline indicated delivery method of the INCS as potentially important with stent, spray and EDS being the most beneficial. Clinical outcomes for sprays were found to improve symptoms, sense of smell and potentially reduce the need for rescue surgery. Adverse effects were no different than those observed with placebo. While there was moderate certainty of evidence for safety of INCS spray, there was low or very low certainty of evidence for the other delivery systems. The group concluded that more, larger, direct comparison RCTs of INCS treatments and comparison with other management options will lead to more definitive results. (Rank et al., 2023).

American Academy of Allergy, Asthma and Immunology (AAAAI): In the practice parameter on rhinosinusitis, AAAAI defines CRS as persistent symptoms of rhinosinusitis for 12 weeks or longer. Signs and symptoms include purulent rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain or pressure, or headache and are associated with objective evidence of inflammation observed on nasal endoscopy and/or CT scan. CRS may occur with or without polyps. Sinus CT scan is the preferred imaging modality and the gold standard to clarify the extent of disease and specific location or locations of obstruction in acute or chronic sinus disease. CT scan is required before surgical intervention or if rhinosinusitis complications are suspected (Dass and Peters, 2016).

American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF): The AAO-HNSF (2018) developed a clinical consensus statement on balloon dilation of the paranasal sinuses. The target population included adults ≥ age 18 years with chronic or recurrent rhinosinusitis (with or without nasal polyps, with or without prior sinus surgery) for whom sinus ostial dilation (SOD) was recommended. SOD was defined as endoscopic use of a balloon device to enlarge or open the outflow tracts of the maxillary, frontal, or sphenoid sinuses, as a standalone procedure or with endoscopic surgery. The use of serial dilations over time in the same patient was not considered. According to AAO-HNS, there has been an increasing rate of utilization of SOD without a reduction in the number of traditional functional endoscopic sinus surgeries being performed. Due to limited evidence to support a guideline, the topic of SOD was selected for clinical consensus statement (CCS) development. Based on a systematic review of the literature and expert consensus, the Society's statements included the following:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT.
- Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
- Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
- CT scanning of the sinuses is a requirement before balloon dilation can be performed.
- Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and the CT evidence of ostial occlusion and mucosal thickening.
- Balloon dilation can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.
- Balloon dilation can be effective in frontal sinusitis.

In a 2021 position statement on dilation of the sinuses, AAO-HNSF stated that sinus ostial dilation (e.g., balloon ostial dilation) is an appropriate therapeutic option for selected patients with chronic rhinosinusitis (CRS) and acute rhinosinusitis (RARS) who have failed medical therapy. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by nasal endoscopy documenting sinonasal abnormality or mucosal thickening on computed tomography of the paranasal sinuses. The Society noted that sinus ostial dilation can be used alone or in conjunction with other instruments. The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

The AAO-HNSF (2025) clinical practice guideline on adult sinusitis defines chronic rhinosinusitis (CRS) as twelve weeks or longer of two or more of the following signs and symptoms:

- mucopurulent drainage (anterior, posterior, or both),
- nasal obstruction (congestion),
- facial pain/pressure/fullness, or
- decreased sense of smell

AND inflammation as documented by one or more of the following:

- purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region,
- polyps in nasal cavity or the middle meatus, and/or
- radiographic imaging showing inflammation of the paranasal sinuses

Recurrent acute rhinosinusitis (RARS) is defined as four or more episodes per year of acute bacterial rhinosinusitis (ABRS) without signs or symptoms of rhinosinusitis between episodes. Each episode of ABRS must exhibit the following signs and symptoms:

- up to 4 weeks of purulent nasal drainage (anterior, posterior, or both) accompanied by nasal obstruction, facial pain-pressure-fullness, or both
- purulent nasal discharge that is cloudy or colored and may be reported by the patient or observed on physical examination
- nasal obstruction may be reported by the patient as nasal obstruction, congestion, blockage, or stuffiness, or may be diagnosed by physical examination
- facial pain-pressure-fullness may involve the anterior face, periorbital region, or manifest with headache that is localized or diffuse

Societal guideline recommendations include confirmation of CRS with objective documentation of sinonasal inflammation using anterior rhinoscopy, nasal endoscopy, or computed tomography. The diagnosis of CRS should not be made based on signs and symptoms alone. CT imaging of the paranasal sinuses is indicated when endoscopic sinus surgery is being considered or planned for patients with CRS or RARS. Clinicians should evaluate patients with CRS or RARS for comorbid conditions that may modify management and should confirm the presence or absence of nasal polyps in patients with CRS. Recommended strategies for symptomatic relief of CRS include saline nasal irrigation and topical intranasal corticosteroids. Antifungal therapy (topical or systemic) is not recommended for CRS, nor should biologic therapy be routinely prescribed for adults with CRS without nasal polyps. Antibiotic therapy is recommended as part of early conservative management; however, clinicians should not routinely prescribe antimicrobial therapy for adults with CRS in the absence of acute exacerbation.

American Rhinologic Society (ARS): In January 2023, the ARS issued a position statement in support of the use of sinus ostial dilation (e.g., balloon ostial dilation) as a therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy. Support of this treatment strategy is based on clinical consensus statements and primary research evidence. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by objective evidence (nasal endoscopy documenting sinonasal abnormality or mucosal thickening on CT scan of the paranasal sinuses) prior to considering the use of balloon sinus dilation. They concluded this approach may be used alone or in conjunction with traditional endoscopic sinus surgery.

Eustachian Tube Balloon Dilation

Eustachian tube balloon dilation (ETBD) is a minimally invasive procedure used to treat chronic Eustachian tube dysfunction (ETD), also referred to as Eustachian tube dilatory dysfunction (ETDD), which affects approximately 1% of the adult population. ETD occurs when the Eustachian tube (ET) fails to open or close appropriately, resulting in impaired middle ear ventilation and abnormal pressure regulation. Obstructive ETD is characterized by failure of the ET to open, whereas patulous ETD involves failure of the ET to close; some patients may alternate between these states, complicating diagnosis and management. The pathophysiology of obstructive ETD is primarily attributed to inflammation and structural remodeling within the cartilaginous portion of the ET lumen, leading to restricted airflow and impaired pressure equalization. Clinical manifestations may include aural pressure or fullness, sensation of a heavy ear, fluctuating hearing loss, popping, snapping, or buzzing sounds, and, in more severe cases, vertigo. If left untreated, ETD may contribute to complications such as conductive hearing loss, chronic otitis media, or cholesteatoma. Endoscopic evaluation of the pharyngeal opening of the ET may provide anatomic information; however, correlation with functional outcomes is limited. Initial management typically focuses on identification and treatment of contributing conditions and may include decongestants, oral and nasal steroids, antihistamines, pressure equalization methods, nasal irrigation, and antibiotics. These interventions primarily address symptoms rather than the underlying obstructive pathology of ETD (Poe & Corrales, 2024; Poe, et al., 2018; Schmitt, et al., 2018; Tisch, et al., 2017).

ETBD, also referred to as Eustachian tuboplasty, is intended to directly address the obstructive pathology within the Eustachian tube lumen. The procedure is performed via a transnasal endoscopic approach in which a balloon catheter is advanced into the cartilaginous segment of the ET and inflated for a brief, controlled period to dilate the narrowed lumen. Balloon dilation is hypothesized to improve ET function by reducing inflammation and promoting structural remodeling of the tubal mucosa. Proposed mechanisms include regeneration of normal ciliated pseudocolumnar epithelium, reduction of submucosal inflammatory infiltrates, elimination of lymphoid follicles, and replacement with a thin fibrotic layer. These histologic changes are similar to those observed following adenoidectomy and suggest that sustained improvement in ET

function may be more likely when contributing medical conditions, such as allergic rhinitis or chronic rhinosinusitis, are concurrently and effectively managed (Poe & Corrales, 2024).

Unilateral or bilateral Eustachian tube balloon dilation (ETBD) may be considered in adults aged 18 years or older with a diagnosis of chronic obstructive ETD and persistent symptoms lasting longer than three months. Evaluation for ETD may include clinical history, physical exam, tympanometry, audiometry, otoscopy, and nasal endoscopy or nasopharyngoscopy. Potential candidates for ETBD typically demonstrate objective evidence of obstructive ETD, such as a Type B tympanogram (a flat or unidentifiable peak suggesting middle ear effusion) or Type C tympanogram (a negative pressure or peak below 100 max pressure [daPa] suggesting ETD), or have abnormal tympanic membrane findings on examination. ETD and any co-occurring conditions such as allergic rhinitis, rhinosinusitis, middle ear effusion and laryngopharyngeal reflux are typically identified and appropriately managed prior to consideration of ETBD. Medical management may include systemic decongestants, antihistamines, nasal topical decongestants, or corticosteroid sprays. Tympanostomy tubes create a route for ventilation of the middle ear to help alleviate obstructive ETD symptoms but do not correct the underlying Eustachian tube pathology, and symptoms may recur following tube extrusion if ET dysfunction persists. In individuals with a prior history of tympanostomy tube placement, improvement of ETD symptoms while the tubes were patent supports the diagnosis of obstructive ETD (Poe & Corrales, 2024; Tucci, et al., 2019).

In pediatric populations, chronic obstructive ETD is commonly associated with otitis media with effusion (OME), defined as the presence of fluid in the middle ear without signs of acute infection. OME frequently follows episodes of acute otitis media but may also occur in young children due to ETD in the absence of a preceding infection. In most cases, OME is self-limited, and watchful waiting is the preferred management strategy. Exceptions include children with hearing loss, developmental delay, or underlying conditions such as cleft palate, in whom OME is more likely to persist and require intervention. Approximately 30–40% of children experience recurrent OME, and a subset develop chronic OME lasting three months or longer. Chronic OME is associated with fluctuating conductive hearing loss and, in rare cases, prolonged ETD may result in tympanic membrane retraction (atelectasis) with subsequent complications, including retraction pockets, ossicular erosion, chronic perforation, or cholesteatoma. Management goals include resolution of middle ear effusion and restoration of normal middle ear pressure and hearing. ETD treatment options include conservative management or surgical management including tympanostomy tube placement, with or without adenoidectomy. ETBD has been primarily studied in adults, with limited and emerging evidence in pediatric populations. Small observational studies suggest that, in carefully selected children with chronic obstructive ETD or OME refractory to standard surgical management, ETBD may be safe and moderately effective. However, despite increasing clinical use and encouraging early outcomes, the current evidence base remains limited, and additional prospective studies are needed to better define long-term outcomes and identify pediatric patients most likely to benefit (Marom et al., 2024; Merrill et al., 2023).

ETBD has emerged as an increasingly utilized alternative to tympanostomy tube placement for medically refractory obstructive ETD; however, published data on procedural complications remain limited. Reports have described the development of patulous ETD following ETBD. In a multicenter retrospective case series evaluating post-procedure patulous symptoms, Hubbell et al. reported patulous ETD in 6.8% of procedures and 9.3% of patients. Multivariable analysis identified age 18 years or younger, repeat balloon dilation, and severe preoperative ET inflammation as factors significantly associated with increased risk. Most cases were characterized as mild or intermittent, although persistent or delayed symptoms were observed in a subset of patients. The authors concluded that ETBD is generally well tolerated but may result in patulous ETD in select patients, underscoring the importance of careful patient selection and pre-procedural counseling (Hubbell et al., 2023).

ETBD has also been proposed for the treatment of other conditions including craniofacial syndromes, neoplasms causing obstruction of the Eustachian tube, systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx, and primary patulous ETD. At present, there is insufficient evidence in the published peer-reviewed literature to support the use of ETBD for these indications.

US Food and Drug Administration (FDA):
Eustachian tube balloon dilation (ETBD) devices are regulated by the FDA as Class II medical devices and are cleared through the 510(k) premarket notification pathway. ETBD devices are indicated to dilate the cartilaginous portion of the Eustachian tube using a transnasal approach for the treatment of persistent obstructive Eustachian tube dysfunction (ETD) in patients 18 years of age and older. A single device, the ACCLARENT AERA® Eustachian Tube Balloon Dilation System, has received FDA clearance for selected pediatric patients aged 8–17 years and is indicated for those with objective evidence of persistent obstructive ETD due to inflammatory pathology, resulting in chronic otitis media with effusion that is refractory to at least one prior surgical intervention. The device is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the ET lumen or history of ipsilateral patulous Eustachian tube (FDA, 2026).

Device or Product	Identifier	Manufacturer
Acclarent Aera™ Eustachian Tube Balloon Dilation System	K230742	Acclarent, Inc.
VenSure™ Balloon Dilation System	K230065	Fagron GmbH
TubaVent™ Balloon Dilatation System	K223542	Spiggle & Theis Medizintechnik
NuVent™ Eustachian Tube Dilation Balloon	K210841	Medtronic Xomed, Inc.
XprESS™ ENT Dilation System	K171761	Entellus Medical, Inc.

*FDA product codes: LRC, PGW, PNZ

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Adult ETBD Literature Review:
Overall, the evidence in the published peer-reviewed literature supports the safety and efficacy of Eustachian tube dilation in adults. Randomized controlled trials have compared ETBD to medical management alone (i.e., nasal topical steroids, auto inflation) and/or tympanoplasty alone for the treatment of obstructive ETD. Reported outcomes have shown that ETBD is noninferior to medical management and tympanoplasty with few to no reported complications. Follow-up times vary but are typically 12 months or more (Kjær et al., 2022; Si, et al., 2019; Poe, et al., 2018; Meyer, et al., 2018; Liang, et al., 2016). Studies have primarily been in the form of case series and retrospective reviews with small, heterogeneous patient populations; however, larger multicenter retrospective cohort studies have also demonstrated statistically significant improvements in patient-reported symptoms and objective middle-ear measures with follow-up extending up to 24 months (Sandoval et al., 2023; Huisman, et al., 2018; Luukkhainen, et al., 2018; Schröder, et al., 2015; Silvola, et al., 2014; McCoul and Anand, 2012).

Choi et al. (2021) conducted a prospective, multicenter, parallel group randomized controlled trial comparing navigation guided balloon Eustachian tuboplasty with medical management alone in participants with chronic Eustachian tube dilatory dysfunction. A total of 34 participants were enrolled and randomized to the balloon Eustachian tuboplasty group (n=17) or the medical

management group (n=17). Eligible participants were ≥19 years of age and had chronic Eustachian tube dysfunction defined by the presence of three or more symptoms (ear pain, ear pressure, tinnitus, cracking or popping in the ears, muffled hearing, or a sensation of ear fullness) lasting longer than 12 months, recurrent serous otitis media despite medical management, or adhesive otitis media despite medical management. Computed tomography confirmation of the absence of internal carotid artery dehiscence into the Eustachian tube lumen was required. Exclusion criteria included internal carotid artery dehiscence, patulous Eustachian tube dysfunction, tympanic membrane perforation or tympanostomy tube, Meniere's disease, chronic rhinosinusitis, anatomically difficult Eustachian tube access, recent major head or neck surgery, active otitis media, pregnancy or breastfeeding, significant hepatic or renal dysfunction, malignancy within the prior five years, or participation in another clinical trial within four weeks of screening. Participants in the balloon Eustachian tuboplasty group underwent navigation guided dilation under general anesthesia, while the control group received intranasal spray therapy and oral medications for six weeks. The primary outcome was change in the seven item Eustachian Tube Dysfunction Questionnaire score at six weeks compared with baseline. Secondary outcomes included changes in symptoms, questionnaire subscale scores, tympanometry type, pure tone audiometry, and the ability to perform a modified Valsalva maneuver. At six weeks, participants in the balloon Eustachian tuboplasty group demonstrated significantly greater symptom improvement compared with the medical management group ($p=0.001$), with a significant reduction in mean questionnaire scores from baseline ($p<0.001$); no significant improvement was observed in the control group. There was no statistically significant difference in tympanogram normalization between groups. The air–bone gap was significantly reduced in the balloon Eustachian tuboplasty group compared with controls at six weeks ($p=0.037$), and a higher proportion of participants achieved a positive modified Valsalva maneuver compared with baseline (31.6% vs 15.8%), with between group differences favoring balloon dilation ($p=0.014$). Study limitations included a small sample size, short term follow up, and loss of three participants prior to study completion.

Froehlich et al. (2020) conducted a systematic review and meta-analysis to examine the efficacy of Eustachian tube balloon dilation for Eustachian tube dysfunction. Twelve studies (n=448; 545 ears) including three randomized control trials, five prospective studies, and four case series met inclusion criteria. The inclusion criteria were adults diagnosed with ETD and one of the following outcome measures: ETDQ7 scores, tympanometry, otoscopy findings, and ability to perform Valsalva maneuver. From baseline to six weeks, ETDQ7 scores decreased by 2.13, 53.0% had improvement in tympanograms, and normal otoscopy exams increased by 30%. Baseline to long-term results (3-12 months) included 50.5% improved tympanograms, normal otoscopy exams increased by 55.4% and 67.8% increase in patients able to perform Valsalva maneuver. Author noted limitations included: possible theoretical publication bias due to only positive outcomes published in the individual studies; variations in surgical techniques including three different balloon dilation devices with different dilated diameters; some studies include patient populations with previous tympanostomy tubes or perforation at the time of balloon dilation.

Nibhanupudy et al. (2024) assessed topical intranasal corticosteroid efficacy in Eustachian tube dysfunction, and analyzed it's effect through tympanometric normalization. PubMed, EMBASE, Web of Science and Cochrane Library databases were searched. All RCTs assessing intranasal corticosteroids in adult or pediatric Eustachian tube dysfunction patients were included. Primary outcomes included changes in middle-ear fluid and negative middle-ear pressure severity (assessed through tympanometry and/or otoscopy), as well as Eustachian tube dysfunction symptomatology. Additional outcomes of interest included pure tone audiometry, adverse events, ability to delay procedural treatment, cost-effectiveness, quality of life (QoL) and nasopharyngoscopy, although analysis of these outcomes was not a requirement for study inclusion. Studies that were non-RCTs, non-English, still unpublished, or that focused on the incorrect patient population (e.g., patulous Eustachian tube dysfunction, acute otitis media,

rhinosinusitis) or incorrect intervention (e.g., orally administered corticosteroids) were excluded. A meta-analysis of proportions was used to evaluate tympanogram normalization. Of 330 results, eight randomized, controlled trials met inclusion criteria and underwent qualitative data synthesis and risk-of-bias analysis. Controls included placebo and/or no treatment in the selected studies. Meta-analysis of tympanometry data from four eligible trials (n = 512 ears) revealed no significant difference in tympanometric normalization between intranasal corticosteroids and control. The authors conclude that study results did not provide supportive evidence for the use of intranasal corticosteroids in Eustachian tube dysfunction. Neither intranasal corticosteroids nor control interventions were favored to a statistically significant degree when pooling tympanometric normalization rates from Eustachian tube dysfunction. Limitations included volume of data, heterogeneity, and mediocre study designs. These limitations emphasize the need for larger, higher quality, RCTs.

Wang et al. (2018) conducted a meta-analysis to examine balloon dilatation and laser tuboplasty for treatment of Eustachian tube dysfunction. Primary outcome measures for included studies were improvement of Eustachian tube score (ETS) and tympanometry and Valsalva maneuver results. Included were the results of two retrospective and eleven prospective studies which included both balloon tuboplasty and laser tuboplasty (n=13 studies; n=1063 patients; n=942 balloon tuboplasty; n=121 laser tuboplasty). Author concludes that balloon tuboplasty showed a statistically significant improvement of ETS overall (p=0.009). When compared with laser tuboplasty, balloon tuboplasty also showed a statistically significant improvement in tympanometry (p=0.001). Valsalva maneuver rate did not show a statistically significant difference between the procedures (p=0.472). Author noted limitations included heterogeneous outcome protocol between studies, sensitivity analysis indicated ETS results could have been overly influenced by two studies and no balloon tuboplasty studies reported ETS data which prevented comparison of two procedures.

Huisman et al. (2018) conducted a systematic review to evaluate effects of balloon dilation of the Eustachian tube in adult patients with Eustachian tube dysfunction. Inclusion criteria were balloon dilation of Eustachian tube (BDET) in adults with tube dysfunction. Eleven retrospective reviews and four case series (n=1155) met inclusion criteria. Outcome parameters included: relief of symptoms, otoscopy, Valsalva maneuver or Toynbee test, audiometry, tympanometry, Eustachian tube dysfunction classification, and Eustachian tube score. Patient populations were less than 70 with the exception of two studies (n-271; 622). Follow-ups primarily ranged from one week to 15 months. Several studies used BDET as an adjunct to other sinonasal and/or otologic procedures. All studies reported short-term improvement of original symptoms, and some showed further improvement over time. Meta-analysis was conducted in four subgroups: Valsalva maneuver, otoscopy, tympanometry, and Eustachian tube score. The Valsalva analysis (n=5 studies; 153 procedures) showed a significant decline of inability to perform the Valsalva maneuver after BDET (p=0.0002). A significant difference was seen in a decline in the inability to dilute the Eustachian tubes (p=0.0002) (n=9 studies; 255 procedures) and in the mean improvement in the ET score (p<0.00001). Six studies (n=166 procedures) showed a decline of otoscopic abnormal tympanic membranes after BDET, but the difference was not significant (p=0.26). Relatively mild and self-limiting complications were described in 36 patients. Most common events were a diffuse crush injury or local bleeding of the mucosa at the site of the Eustachian tube. The limitations of the study include the retrospective study design, small heterogenic patient populations, short-term follow-ups, heterogeneity of outcome measures, and high risk of bias.

A systematic review was conducted by Luukkainen et al. (2018) to identify studies reporting 12 months follow-up post BET. Five studies met the inclusion criterion (two prospective studies and three retrospective reviews). In the five individual studies, inclusion criteria varied and no two studies used the same outcome measures. No single outcome measure was used in all of the studies. Following BET, Valsalva maneuver improved in 80%–98% of patients, overall subjective

symptoms improved in 73%–98%, and otoscopic findings improved in 90% of the patients. Tympanometry and tubomanometry improved less, in 24%–54% and 28%–43% patients, respectively. Due to the limited number of studies, five additional studies with a 6–11 months follow-up were included and reported similar outcomes.

Poe et al. (2018) conducted a 2:1 ratio, randomized controlled trial (n=323 patients; 462 ears) to assess the safety and efficacy of balloon dilation of the Eustachian (BDET) using a custom-designed ET balloon catheter (ETBC) (Acclarent, Inc., Irvine, CA) in conjunction with medical management (MM) compared to MM alone in adult patients with drug-refractory Eustachian tube dilatory dysfunction (ETDD). Inclusion criteria were: 1) age ≥ 22 years; 2) persistent ETDD (defined by patient-reported symptoms and at least one of the protocol defined confirmatory indicators for 12 weeks or more prior to enrollment); 3) a positive diagnosis of persistent ETDD was confirmed with both abnormal tympanometry and symptomatic dysfunction per Eustachian Tube Dysfunction Questionnaire-7 Symptom (ETDQ-7) mean item score 2.1 after failed MM; 4) transnasal endoscopy of the ET was performed and the degree of mucosal inflammation scored with a validated scale, 5) absence of internal carotid artery (ICA) dehiscence on both sides per computed tomography (CT) scan, and 6) failed MM (i.e., four weeks intranasal steroid spray or minimum of one completed course of an oral steroid within 90 days prior to study enrollment). The primary outcome measure was normalization of tympanometry at the six-week follow-up. Secondary outcome was improvement in ETDQ-7, tympanograms and mucosal inflammation. Follow-ups occurred at 2, 6, 12, and 24 weeks. At six weeks follow-up, failed controlled group patients had the option of crossing over to BDET. A statistically significant improvement in tympanogram normalization at the 6-week follow-up was reported in 51.8% (72/139) of the study group compared to 13.9% (10/72) of control group ($p<0.0001$). At 24 weeks, tympanogram normalization was seen in 62.2% of BDET patients. Normalization of the ETDQ-7 scores at six weeks was observed in 56.2% (77/137) of the study group versus 8.5% (6/71) of controls ($p<0.001$). However, this difference was not maintained at the 12- and 24-week follow-ups. Significantly more normal levels of mucosal inflammation were seen in the study groups versus the control group at the six-week follow-up ($p<0.001$). The percentage of patients that could perform a positive modified Valsalva maneuver at 6-weeks was significantly higher in the study group ($p<0.001$). Limitations of the study include: the short-term follow-up (6 weeks for the two randomized groups); 59 control group patients (82%) crossed over to BEDT at the six-week follow-up period; and randomization was 2:1. According to the authors this is the first RCT investigating the safety and efficacy of BDET for ETDD compared to MM and they noted that MM has not been successful in treating ETDD. Anand et al. (2019) completed a follow up of this study focusing on twelve month outcomes of the Poe study. This was a prospective cohort from the previous multicenter randomized controlled trial. This study extends the follow up to fifty two weeks measuring ETDQ-7. The enrolled subjects (n=323) were randomized to BDET (n=149) and medical management (n=80) treatment groups. Primary endpoints and adverse events were described in original study. Results noted the subjects randomized to BDET and medical management remained comparable to those reported at six versus fifty two week follow-up: 73 of 143 (51.0%) versus 71 of 128 (55.5%); ETDQ-7, 79 of 142 (55.6%) versus 71 of 124 (57.3%). The overall number of ears with normalized tympanograms also remained comparable, with 117 of 204 (57%) versus 119 of 187 (63.6%).

Meyer et al. (2018) conducted a randomized controlled trial (n=60) to compare the safety and efficacy of Eustachian tube balloon dilation (n=31) versus continued medical therapy (n=29) (control) for treating persistent Eustachian tube dysfunction (ETD). Patients were included in the study if they were age ≥ 18 years, had a diagnosis of ETD for 12 months or longer with ≥ 3 ETD symptoms (ear pain, ear pressure, tinnitus, cracking or popping in ears, muffled hearing, feeling that ears were clogged) and had failed medical therapy. Failed medical therapy was defined as a minimum of either four weeks of daily intranasal steroid spray or one completed course of an oral steroid within 12 months before study enrollment. Patients were required to have an overall

Eustachian Tube Dysfunction Questionnaire (ETDQ-7) score of ≥ 3 (moderate to severe symptoms). The primary outcome measures were the comparison between randomization arms for the mean change in overall ETDQ-7 scores from baseline to six weeks and complications related to the device or procedure. Secondary outcomes included technical success, procedural details, and differences between treatment arms for changes from baseline in tympanic membrane position, Valsalva maneuver, and tympanogram type. All planned in-office procedures were completed in the office with dilation durations of 2 minutes per Eustachian tube and were performed under topical and local anesthetics. At the six-week follow-up the ETDQ-7 score was significantly more improved than the control group ($p<0.0001$). All dilation attempts were successful (91/91). For the patient with retracted tympanic membrane position measured at baseline (n=15), 66.7% of those undergoing ETD showed an improvement at six weeks ($p=0.002$) compared to no control patients (n=12). The comparison between the groups was significantly different in favor of the ETD group ($p<0.001$). Among the ears with type B or C tympanograms at baseline (n=14 ETD; n=10 control) there was a statistically significant improvement in favor of the ETD groups ($p=0.006$). There was no significant difference between the groups for those patients who had a negative Valsalva maneuver at baseline. At the six-week follow-up 23 patients crossed over to ETD and 49 patients completed the one-year follow-up. The mean overall ETDQ-7 score was significantly reduced from 4.6 at baseline to 2.1 ($p<0.0001$) 6 weeks following ETD maintained through the 12-month follow-up ($p<0.0001$). At 12 months, patients with normal tympanic membrane position, type A tympanograms, and ability to clear the ears with Valsalva maneuver was significantly improved compared to baseline. No complications were reported. During the study, two participants underwent additional ear surgeries for continuing or recurring symptoms. Five patients were lost to the six-week follow-up. Limitations of the study include the small patient population; short-term follow-up; inability to blind the patients to their treatment; secondary outcome data was not available on all patients; five patients were lost to the six-week follow-up; and 23 patients crossed over to ETD after six weeks. Cutler et al. (2019) completed a follow up of the Meyer study focusing on outcomes greater than 12-months (mean 29.4 months; range 18-42 months). This was a prospective cohort from the previous multicenter randomized controlled trial. Participants of the extension study had to have undergone balloon dilation and completed the 12-month follow-up from the original study. Forty-sever participants were enrolled and evaluated at six-month intervals with the ETDQ-7 and middle ear functional assessments. Results noted that 93.6% of the subjects reported a reduction of one or more of their overall ETDQ-7 score with a mean score of 4.5 at baseline to 2.0 at last follow-up; tympanic membrane position improved from 46.8% within normal limits at baseline to 85.1% at last follow-up; Valsalva maneuver improved from 28.3% to 73.9%; and type A tympanograms improved from 70% to 86.3% at the last follow-up.

Pediatric ETBD Literature Review:
Liu et al. (2025) conducted a retrospective pooled analysis to evaluate the safety and effectiveness of balloon dilation of the Eustachian tube in a pediatric population. The analysis included 219 participants (425 ears) aged 1–17 years (mean age 11.0 years), of whom 56.2% were diagnosed with chronic otitis media with effusion (COME) and 43.8% with recurrent acute otitis media (RAOM), with records analyzed across six institutions. Eligible participants had diagnoses of COME, defined as middle ear effusion present for more than 12 weeks; RAOM, defined as more than three episodes of acute otitis media within 6 months or four episodes within 12 months; or Eustachian tube dysfunction, with a history of at least one prior tympanostomy tube placement and recurrence of symptoms following tube extrusion. Individuals with craniofacial anomalies were excluded, as were records involving balloon dilation devices other than 6x16 mm size. Clinical outcomes were assessed using objective, standardized endpoints, including failure free survival (absence of further surgical intervention), tympanogram findings, and complication reporting. Follow up ranged from 0.1 to 10.1 years, with a mean duration of 3.4 years. Pre- and post procedure tympanogram data were available for 125 ears (29.4%) and demonstrated statistically significant improvements for both COME ($p<0.0001$) and RAOM ($p=0.0002$). Among individuals

with COME aged 0–17 years, type B tympanograms decreased from 69% to 9%, with improvement observed in 84% of ears; subgroup analyses showed decreases from 78% to 11% with 87% improvement in those aged 0–7 years and from 64% to 8% with 82% improvement in those aged 8–17 years. In the RAOM cohort, type B tympanograms decreased from 21% to 6% in those aged 0–17 years, with 83% improvement; from 10% to 0% with 100% improvement in those aged 0–7 years; and from 21% to 8% with 83.7% improvement in those aged 8–17 years. Failure free survival data were available for 124 participants (227 ears), with 193 of 227 ears (85.0%) remaining failure free after a mean follow up of 5.3 years. Complication data was available for all participants, with no major complications reported and mild complications occurring in 5.9%. In the COME cohort, no complications were reported in individuals aged 0–7 years; among those aged 8–17 years, reported events included transient epistaxis, transient self-resolving patulous Eustachian tube symptoms, transient hemotympanum, transient tinnitus, postoperative nausea, transient otalgia, transient migraine associated vertigo, and one aborted procedure due to severe septal deviation. Similarly, no complications were reported in the RAOM cohort aged 0–7 years, while individuals aged 8–17 years experienced transient self-resolving patulous Eustachian tube symptoms, epistaxis, and hemotympanum. Study limitations included the retrospective design, absence of a comparator group, and inability to isolate the effects of adjunctive procedures. The authors concluded that balloon dilation of the Eustachian tube demonstrated favorable safety, effectiveness, and durability in select pediatric participants.

Merrill et al., 2023, performed a literature review to assess current evidence for ETBD in pediatric patients. Studies relevant to ETBD in the pediatric population were identified by utilizing the PubMed MEDLINE database. The team reviewed one systematic review (Saniasiaya et al., 2022) and one systematic review with meta-analysis (Aboueisha et al., 2022) based on retrospective case series and a retrospective cohort study. These studies are reviewed in greater detail within this section of the coverage policy. The authors conclude that while ETBD appears safe and efficacious in children with refractory ETD, future prospective trials to confirm this conclusion are warranted.

Gurberg et al. (2023) reported the long-term safety and efficacy of this procedure in children with in a two-center retrospective matched cohort study. Balloon dilation of the Eustachian tube (BDET) has not been evaluated extensively in children outside of retrospective case series. The purpose of this study was to report the long-term safety and efficacy of this procedure in children with matched controls. Inclusion criteria included age< 18 years, indication for tympanostomy tube placement, middle ear fluid greater than three months duration or tympanic membrane retraction with accompanying hearing loss and failure on medical therapy. Exclusion criteria included conditions with increased susceptibility for otitis media with effusion and recurrent ear infections such as trisomy 21 and other syndromes, craniofacial anomalies, cleft palate, chronic inflammatory diseases, chronic ear disease (other than OME or AOM), and immunodeficiency. Children (age 14 months to 14 years) having undergone tympanostomy tube (TT) placement and adenoidectomy with recurrence of symptoms underwent BDET at an academic affiliated multi-specialty practice (n=20, 33 ears). Comparison was made with children receiving TT at a tertiary medical center, matching for number of prior TT, prior adenoidectomy, age, and sex. Outcome measures were risk of failure and the need for additional surgery. Kaplan-Meier survival plots were used to compare risk of failure. Patients undergoing BDET had normal post-operative tympanograms in 80% of cases. Mean follow up was 6.7 years with two patients failing in the BDET group and eight in the TT insertion group. Dilated patients had a significantly lower risk of failure than those who underwent TT insertion ($p = 0.03$). The probability of being failure free at six years was 88 % (95 % CI: 71, 95 %) in the BDET cohort and 53 % (95 % CI: 33, 70 %) in the TT insertion cohort. There were no complications. Although there were no significant adverse events, the authors noted the need for continued vigilance and careful technique to assure safety in this age group due to shorter ET with different angles compared to adults. This study was completed off-label with devices that were not approved, nor designed for pediatric BDET. The

authors state, "Great care is necessary to ensure that the balloon does not inadvertently pass into the bony ET, which would bring it into proximity with the internal carotid artery." The authors concluded BDET appeared to be safe and possibly superior to TT placement in children with refractory Eustachian tube dysfunction. Limitations of the study included the retrospective design (with all its inherent biases), small sample size, inclusion of three patients who could not be matched exactly for age, inclusion of concomitant procedures in the treatment group (FESS), and the fact that the two cohorts studied were from different geographic regions (Fort Worth, TX and Boston, MA) in the United States.

A systematic review and meta-analysis was conducted by Aboueisha et al. (2022) to determine the efficacy and safety of BDET amongst the pediatric population. A search, which returned seven studies (N=408) meeting criteria, was conducted using PubMed, Embase, Web of Science, Cochrane, Clinicaltrials.gov and CINAHL. Inclusion criteria consisted of children <18 years of age with an intervention of BDET either alone or in combination with a tympanostomy or myringoplasty. The patients possessed a mean age of 9.9 years old (95 % CI: 8.8 to 11.1) and had a mean follow-up of 19.2 months (95 % CI: 15 to 23). Outcomes of efficacy included audiometric findings and adverse events (AEs) were summarized for each study. Preoperatively Type B tympanogram was the most common presentation with an air bone gap (ABG) mean of 22.8 dB. Following BDET, the authors found Type B tympanograms had decreased [64.2% (95% CI: 53.3 to 73.8) to 16.1% (95% CI: 8.5 to 28.4)]. The pooled estimate of AEs after BDET was 5.1 % (95 % CI: 3.2 to 8.1), the majority being self-limited epistaxis with no major AEs reported. Three studies compared BDET to ventilation tube insertion and analysis of post-operative ABG showed a greater decrease in the BDET group (mean difference -6.4 dB; 95 % CI: -9.8 to -3.1; p=0.002). The authors concluded that although there are no prospective RCTs, BDET ± tympanostomy tube placement may produce outcomes that are comparable to tympanostomy tube placement in the treatment of OME in the pediatric population. Limitations included a small number of studies for analysis, lack of RCTs (majority of those included were retrospective), limited number of comparative studies, different indications for the use of BDET, and use of multiple types of balloons. Future RCTs in the pediatric population are needed to better determine the best candidates for BDET.

Saniasiaya et al. (2022) performed a sytematic review to determine the outcome of Eustachian tube balloon dilation (ETBD) in children as the procedure has recently shown promising results in recalcitrant Eustachian tube dysfunction in adults. A literature search from 1990 to 2020 of several databases over a 1-month period (January 2021) according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the Cochrane Handbook for Systematic Reviews for Interventions was completed. The primary outcome was defined as the success of the intervention determined by the resolution of symptoms; the secondary outcome was determined by the need for revision surgery and the presence of complications. Only seven articles were identified based on the selection criteria. The studies included consisted of six retrospective cohort case series and one cohort of matched controls. A total of 284 patients were included in this review, with a mean age of 7.8 years. A total of 463 balloon dilations were performed either bilaterally or unilaterally. The most common finding of ETD was middle ear effusion in five of the seven studies. Balloon dilation of Eustachian tube was second line treatment in six studies and first line treatment in one study. Improvement of symptoms was identified in all studies via various assessments performed. Revision surgery was performed in one study with no major complications reported. The authors concluded that balloon dilation of the Eustachian tube may be considered as an alternative procedure following failed standard treatment in children. The authors noted the quality of evidence was inadequate to recommend widespread use of the technique until better quality studies have been completed. They emphasized the need for randomized controlled trials (RCTs) with a large sample size to determine the efficacy of this procedure in children.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF): The AAO-HNSF (2019) developed a clinical consensus statement on balloon dilation of the Eustachian tube (ET). The target population included adults ≥ age 18 years with obstructive Eustachian tube dysfunction (ETD) in one or both years for greater than three months affecting quality of life or functional health status for whom balloon dilation of the Eustachian tube was being recommended. Patients with patulous ETD, extrinsic obstruction of the ET, or active primary inflammatory disorders were excluded. 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." Due to the knowledge gap regarding the role of balloon dilation of the Eustachian tube (BDET) in managing obstructive ETD and an increasing rate of utilization, but limited evidence to support a clinical practice guideline, the topic of BDET was selected for clinical consensus statement development. 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"
- Nasal endoscopy is an essential part of the diagnostic evaluation prior to BDET.
- BDET is contraindicated for patients diagnosed as having a patulous ETD.
- 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.
- A diagnosis of patulous ETD is 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.
- Symptoms of obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia.
- Tympanometry is an essential part of the diagnostic evaluation prior to BDET.
- Establishing a diagnosis of obstructive ETD requires ruling out other causes of aural fullness such as patulous ETD, temporomandibular joint disorders, extrinsic obstruction of the ET, superior semicircular canal dehiscence, and endolymphatic hydrops.
- 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.
- Comprehensive audiometry is an essential part of the diagnostic evaluation prior to BDET.
- BDET is appropriate in patients with obstructive ETD who have failed medical therapy for identified treatable causes.
- Common causes of obstructive ETD that benefit from identification and management are allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.
- Medical management of known pathology that could affect nasal or ET function is appropriate to perform prior to BDET.
- Patients with a history of recurrent barochallenge, defined as uncomfortable pressure in the ear upon exposure to ambient pressure changes that cannot be easily relieved, may improve following BDET.
- There is no scientifically proven or standard medical therapy for ETD.
- Pneumatic otoscopy can identify negative pressure in the middle ear space and can differentiate between adhesive and nonadhesive retractions of the tympanic membrane.
- Patients undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Potential risks of BDET that are relevant to patient counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.
- Myringotomy with or without tympanostomy tube placement is not a mandatory prerequisite to BDET.

- A dehiscent carotid artery identified on imaging is a contraindication to use of a device without a depth marker that demarcates insertion into the cartilaginous Eustachian tube.
- Patients with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement.
- BDET is an alternative to tympanostomy tube placement for obstructive ETD.
- Failure to relieve symptoms despite a functioning myringotomy or tympanostomy tube suggests a diagnosis other than obstructive ETD.
- Patient-reported symptom scores are useful in assessing baseline ETD symptoms and treatment outcomes.
- The ability to perform a modified Valsalva maneuver is appropriate for assessing outcome after BDET.
- Change in patient-reported symptom scores is appropriate for assessing outcome following BDET."

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): In July 2025, The AAO-HNS issued a position statement supporting Eustachian tube balloon dilation as an appropriate treatment option for selected pediatric patients with obstructive Eustachian tube dysfunction resulting in chronic otitis media that is refractory to standard surgical interventions, such as tympanostomy tube placement and adenoidectomy. The statement cites multiple studies demonstrating the safety and efficacy of Eustachian tube balloon dilation in the pediatric population, including improvements in hearing outcomes, tympanometric findings, quality of life measures, and a reduced likelihood of requiring additional surgical intervention. The statement noted the procedure may be performed safely as a stand-alone intervention or in combination with other otolaryngologic procedures. The Academy considers Eustachian tube balloon dilation to be a proven and effective therapeutic option in a select pediatric population, with treatment decisions determined by a qualified otolaryngology–head and neck surgeon. Preoperative computed tomography imaging is not routinely required unless deemed clinically indicated by the performing physician. Otolaryngologists are advised to use devices approved by the U.S. Food and Drug Administration for these indications and to adhere to all applicable regulatory requirements and device-specific guidelines.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Chronic rhinosinusitis (CRS), including recurrent acute rhinosinusitis, represents a substantial and persistent health burden in the United States. 2025 updates from the American Academy of Otolaryngology–Head and Neck Surgery Foundation indicate that approximately 12% of U.S. adults, or about 1 in 8, report having been diagnosed with rhinosinusitis, with prevalence increasing over recent decades. CRS accounts for millions of ambulatory care visits annually, and recent studies demonstrate a continued rise in physician office visits year after year, indicating that the overall burden of disease is not diminishing. On average, individuals with CRS experience 1 to 2 lost workdays per year and approximately 73 million days of restricted activity annually. Those with medically refractory CRS experience greater impairment, missing an average of 18

workdays per year, being absent from work because of sinusitis approximately 6.5% of the time, experiencing a 36% reduction in on-the-job effectiveness, and a 38% loss of productivity. Patients with CRS referred to otolaryngologists score significantly lower on measures of bodily pain and social functioning than patients with other chronic conditions, including angina, back pain, congestive heart failure, and chronic obstructive pulmonary disease, and have health utility scores that are worse than many of these conditions. Compared with individuals without CRS, patients with CRS have greater activity, work, and social limitations; however, treatment of CRS has been shown to improve health state utility values and substantially reduce fatigue and bodily pain, underscoring the significant impact of disease burden and symptom control on patient-reported outcomes (AAO-HNSF, 2025).

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Removed policy statement for prior evaluation with nasal endoscopy in adults undergoing Eustachian tube balloon dilation. • Added policy statements for pediatric Eustachian tube balloon dilation.	4/15/2026
Annual Review	• Revised policy statements for sinuplasty regarding mucosal thickening and antibiotics.	5/15/2025
Annual Review	• No changes to coverage.	4/15/2024