Balloon Dilation of the Sinuses or Eustachian Tubes

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to the Oregon Administrative Rule (OAR) 410-120-1200 and 410-141-3820 to 3830 for coverage of Balloon Dilation of the Eustachian Tube (BDET).

Balloon Sinus Ostial Dilation: Guideline Note 35

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes: Balloon sinuplasty when performed in conjunction with functional endoscopic sinus surgery (FESS) or other more extensive sinus surgery of the same sinus, is considered an integral part of the procedure and is, therefore, not separately reimbursable.

Balloon Dilation of the Sinuses

I. Balloon sinus ostial dilation (balloon sinuplasty) with a catheter-based inflatable device, may be considered **medically necessary** in the out-patient setting when all of the following criteria (A.-D.) are met:
   A. Sinus dilation will be performed on the frontal, maxillary, and/or sphenoid sinuses; **and**
   B. Recurrent acute rhinosinusitis (RARS; with 4 or more episodes a year) or chronic rhinosinusitis (CRS; lasting 12 weeks or more) is documented in the clinical notes; **and**
   C. Documented failure of medical management (unless contraindicated) consisting of **all** of the following criteria (1.-3.):
      1. A minimum of 2 antibiotic courses have been completed (one course should be at least 21 days); **and**

2. A trial of oral steroids and nasal steroids has been completed (verification of oral steroid prescription may be requested by the Medical Director); **and**
3. A trial of nasal saline irrigation; **and**

D. Abnormal findings on computerized tomography (CT) scan read by an independent radiologist indicating **at least one** of the following conditions (1.-3.):
1. Opacification of sinus cavity; **or**
2. Air fluid levels; **or**
3. Mucosal thickening of at least 2mm.

II. Balloon sinus ostial dilation (balloon sinuplasty) with a catheter-based inflatable device is considered **not medically necessary** when criterion I. above is not met, including but not limited to the following:

A. In locations other than the frontal, maxillary, and/or sphenoid sinuses
B. Significant polyposis
C. Autoimmune disorders
D. Repeat balloon sinuplasty
E. Isolated ethmoid disease
F. Frontal or migraine headaches without evidence of significant sinus disease on imaging that meets criterion I. above.

Balloon Dilation of the Eustachian Tube(s)

III. Balloon dilation of the eustachian tube(s) may be considered **medically necessary** for the treatment of chronic obstructive eustachian tube dysfunction when all of the following criteria are met (A.-H.):

A. Patient is 18 years and older; **and**
B. Patent has chronic signs and symptoms of obstructive eustachian tube dysfunction that has significantly affected quality of life or functional health status for at least 12 months, including any of the following (1.-4.):
1. Aural fullness; **or**
2. Aural pressure; **or**
3. Otalgia; **or**
4. Hearing loss; **and**

C. Documentation shows that other causes of aural fullness have been ruled out (e.g. temporomandibular joint disorder, extrinsic obstruction of the eustachian tube, superior semicircular canal dehiscence); **and**
D. Symptoms are continuous rather than episodic (e.g. symptoms occurring only in response to barochallenge such as pressure changes while flying); **and**
E. Documentation shows that the patient's eustachian tube dysfunction is reversible, as demonstrated by any of the following (1.-3.):
1. The patient states that they are able to relieve the pressure by performing a Valsalva maneuver to "pop" their ears**; or**
2. Performing a Valsalva maneuver produces temporary improvement of the patient's tympanogram to Type A tympanogram**; or**

3. Performing a Valsalva maneuver causes the member's middle ear to aerate, which is indicated by the provider visualizing lateral movement of the tympanic membrane otoscopy**; and**

F. Documentation shows patient has undergone a comprehensive diagnostic assessment, including patient-reported questionnaires, history and physical exam, tympanometry if the tympanic membrane is intact, nasal endoscopy, and comprehensive audiometry, with both of the following findings (1.-2):
   1. Abnormal tympanogram (Type B or C) (see Policy Guidelines); **and**
   2. Abnormal tympanic membrane (e.g. retracted membrane, effusion, perforation or any other abnormality identified following otoscopy exam); **and**

G. If applicable, patient has failed to respond to appropriate medical management of co-occurring conditions including examples below (1.-2.):
   1. Allergic rhinitis, rhinosinusitis, including 4-6 weeks of a nasal steroid, if indicated; **or**
   2. Laryngopharyngeal reflux, with proton pump inhibitor or antacid treatment; **and**

H. If the patient has a history of tympanostomy tube placement, symptoms of obstructive eustachian tube dysfunction improved while tubes were patent.

*Eustachian tube balloon dilation in pediatric patients >8 y/o with chronic eustachian tube dysfunction that has been refractory to at least one surgical procedure may be considered medically necessary on an individual basis after case review.

IV. Balloon dilation of the eustachian tube(s) is considered **not medically necessary** criterion III. above is not met, including but not limited to the following contraindications:

A. Patient has patulous eustachian tube dysfunction
B. Patient has aural fullness but normal exam and tympanogram
C. Patient has extrinsic reversible or irreversible causes of eustachian tube dysfunction including but not limited to any of the following:
   1. Craniofacial syndromes, including cleft palate spectrum;
   2. Neoplasms causing extrinsic obstruction of the eustachian tube;
   3. History of radiation therapy to the nasopharynx;
   4. Enlarged adenoid pads;
   5. Nasopharyngeal mass;
   6. Neuromuscular disorders that lead to hypotonia/ineffective eustachian tube;
   7. Dynamic opening;
   8. Systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g. Samter's triad, Wegener's disease, mucosal pemphigus) that is ongoing/active (i.e. not in remission.

Link to Evidence Summary

POLICY CROSS REFERENCES

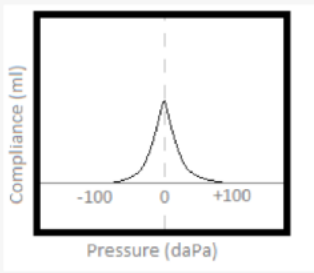
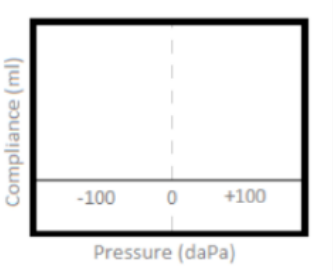
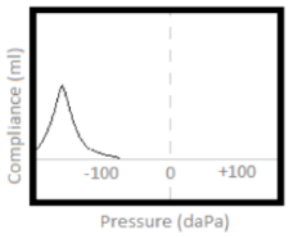
None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Tympanograms

Tympanogram tracings are classified as type A (normal), type B (flat, clearly abnormal), and type C (indicating a significantly negative pressure in the middle ear, possibly indicative of pathology).

Type	Image	Description
A		Type A tympanograms look like a cone, and indicate a normal middle ear system, free of fluid or physiological anomalies which would prevent the admittance of sound from the middle ear into the cochlea.
B		Type B tympanograms are a flat line, which is consistent with middle ear pathology, such as fluid or infection behind the ear drum.
C		Type C tympanograms are also shaped like a cone, but are shifted negatively on the graph. This indicates negative pressure in the middle ear space, often consistent with sinus or allergy congestion, or the end-stages of a cold or ear infection.

BACKGROUND

Acute, Chronic and Recurrent Rhinosinusitis (ARS/CRS/RARS)

According to the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF), rhinosinusitis is defined as, "as symptomatic inflammation of the paranasal sinuses and nasal cavity. The term rhinosinusitis is preferred because sinusitis is almost always accompanied by inflammation of the contiguous nasal mucosa."[1] Nearly 12% or 1 in every 8 adults are diagnosed with rhinosinusitis per year and it is the fifth leading cause of antibiotic treatment. There are various severities of rhinosinusitis as described by Hayes and the AAO-HNSF:

- Acute Rhinosinusitis (ARS): ARS is a clinical condition characterized by inflammation of the mucosa of the nose and paranasal sinuses with associated sudden onset of symptoms of purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both, of up to 4 weeks duration.
- Recurrent Acute Rhinosinusitis (RARS): RARS is characterized by 4 or more recurrent episodes of ARS with complete clearing of symptoms between episodes over a one year period.
- Chronic Rhinosinusitis CRS: CRS is a clinical disorder characterized by inflammation of the mucosa of the nose and paranasal sinuses with associated signs and symptoms of 12 week consecutive duration. CRS is characterized by 2 or more symptoms, one of which is nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip), with or without facial pain/pressure and reduction or loss of smell with endoscopic evidence of mucopurulence, edema, and/or polyps and/or CT presence of mucosal thickening or air-fluid levels in the sinuses.

CRS is diagnosed via symptom presentation (i.e., facial pain, reduction in smell, nasal obstruction, congestion, or discharge, etc.), and findings on CT or endoscopy to stage the extent of the disease. In addition, patients may undergo allergy testing, blood tests, and other diagnostics to rule out intranasal bacterial or fungal infections.

ARS/CRS/RARS Treatment

Treatment of ARS is limited to medical management due to the short duration of the condition. Surgical intervention is not recommended.[2]

According to Hayes, "(m)edical management of CRS includes intranasal and systemic antibiotics and steroids to reduce inflammation, nasal lavage and saline irrigation, mucolytics, decongestants, antihistamines, and leukotriene modifiers. Patients who have CRS that is persistent or recurring and fails to respond to medical management may require surgery. Functional endoscopic sinus surgery (FESS) is the standard procedure for refractory CRS in adult patients. FESS is a minimally invasive surgical procedure that is performed in an operating room and the patient is typically under general anesthesia. The surgery involves tissue and bone removal under direct visualization to access and drain the sinuses and to remove pathological tissue. The removal of tissue and bone is associated with bleeding, pain, and scarring and often requires postoperative debridements."[3]

According to UpToDate, "Multiple therapies are used in the management of CRS with or without nasal polyposis (NP), including saline washes and sprays, intranasal and systemic glucocorticoids, antibiotics, and antileukotriene agents."[4]

Balloon Sinuplasty

According to Hayes, "(b)alloon sinuplasty is a minimally invasive endoscopic technique that aims to dilate the sinus ostia in patients with CRS. A disposable catheter delivers a balloon, which, when inflated, compresses the tissue that is blocking the sinus ostia, thereby allowing drainage of the treated sinus and a resolution or reduction of symptoms."[3] The procedure is designed to preserve normal sinus tissue and anatomy and may be performed in either the operating room or in the office setting. The Hayes review noted that, ideally, balloon sinuplasty would be performed in the office setting to reduce the utilization of operating rooms and postanesthesia care units.

Per the American Academy of Otolaryngology, "(e)ndoscopic sinus surgery is …recommended only after it has been determined that medical management has been, or will be, unsuccessful. Surgery, medical management, and failure to intervene all have risks, including the possibility of postoperative bleeding, eye complication (visual impairment). Intracranial injury (brain damage or infection), leakage of cerebrospinal fluid, persistent or recurrent nasal obstruction due to failure to fully control polyps, and recurrent nasal or sinus infection. The risk of surgery should generally be less than that of untreated or under-treated sinus disease."[1]

Eustachian Tube Dysfunction (ETD)

Eustachian tube dysfunction, or ETD, occurs when the normal function of the eustachian tube – helping maintain pressure in the ear by periodically opening and closing – is impaired, leading to pressure, pain, impaired hearing, persistent ear infections, tinnitus, or other symptoms. ETD affects approximately 1% of adults.

According to a Hayes Technology Brief regarding ETD, "(e)ustachian tube dysfunction is the inability of the eustachian tube (ET) to ventilate the middle ear, drain secretions, or protect the middle ear from sounds or pathogens in the nasopharynx. The cartilaginous portion of the ET is the most likely source of pathology. ETD is associated with otologic and rhinology symptoms, including tinnitus (ringing in the ears), aural fullness, an inability to equilibrate middle ear pressure, a sensation of being underwater, impaired hearing, pain, and balance problems. Currently available treatments for ETD may be ineffective and do not correct the underlying obstructive nature of ETD."[5]

ETD Treatment

A eustachian tube balloon dilation system is a device that includes an inflatable balloon and flexible catheter that dilates the cartilaginous portion of the eustachian tube and is proposed to treat persistent eustachian tube dysfunction. According to the Hayes review, "(t)he Aera Eustachian Tube Balloon Dilation (ETBD) System is the first balloon device approved for ETD in the United States. The Aera device consists of a guidance catheter and a 16 × 6 millimeter (mm) balloon. The blunt-tipped guidance catheter is inserted through the nose and advanced to the ET. The balloon is then advanced through the guidance catheter to the isthmus of the ET, which is at the end of the cartilaginous tissue prior to the bony portion. When the endoscopic marker is visualized at the distal end of the guidance catheter, the balloon is inflated to 12 atmospheres for 2 minutes and then withdrawn."[6]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Sinus Balloon Catheters

Sinus balloon catheters have been FDA approved via the 510(k) Premarket Notification process for nearly 15 years. Approved indications include dilating the sinus ostia and paranasal spaces. The following list of approved systems are examples, and is not all inclusive. FDA product code: LRC.
Relieva Scout™ Multi-Sinus Dilation System (Acclarent, Inc.) (K153341)[7]
Indications for use: For patients aged 18 and older, the Relieva Scout™ Multi-Sinus Dilation System is intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces associated with the sphenoid, frontal, and maxillary sinus cavities for diagnostic and therapeutic procedures. In addition, the device is intended to illuminate within and transilluminate across nasal and sinus structures.

NuVent EM™ Balloon Sinus Dilation System (Medtronic Xomed, Inc.) (K152121)[8]
Indications for use: The EM Sinus Dilation System is intended for use in conjunction with the Medtronic Computer-Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. When used concomitantly, these systems may be used to:

- locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia; or
- locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses that is scarred, granulated or previously surgically altered to facilitate dilation of the sinus ostia.

XprESS® Multi-Sinus Dilation Tool (Entellus Medical, Inc.) (Entellus Medical Balloon Device) (K112506, K121174, K121943, K132440, K142252)[9]

Indications for use: To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

FinESS™ Sinus Treatment (Entellus Medical, Inc.) (K091681)[10]

Indications for use: To access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Singulair

In March 2020, the F.D.A issued a "boxed warning" regarding serious mental health side effects for the allergy drug montelukast (Singulair).[11] The warning advised that "the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medicines."

Eustachian Tube Dilation Systems

Several Eustachian Tube Balloon Dilation System have received clearance under the FDA 510(k) Premarket Notification process. For additional information, refer to the FDA's 510(k) Premarket Notification website (product code: PNZ).

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of balloon dilation of the sinuses or eustachian tubes. Below is a summary of the available evidence identified through September of 2024.

Chronic and Recurrent Rhinosinusitis (CRS/RARS) in Adults

Systematic Reviews

- In 2022, Hayes published an updated health technology assessment regarding the use of balloon sinuplasty (BS) to treat chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (RARS) in adult patients.[3] The narrative review provided a comprehensive update to the current evidence. The evidence base was comprised of 13 studies in 16 publications meeting inclusion criteria. Eleven of the studies were randomized controlled trials (RCTs); of the two nonrandomized studies, one prospective and one retrospective cohort study were each included. Primary outcomes included ostial patency (6 studies, 8 publications), validated measures of quality of life (QOL) and symptom severity (sinonasal outcome test [SNOT] scores, RSDI and CSS scores), and other measures of symptom severity and QOL (days until normal activity resumed, continued sinusitis events, revision rate). Studies were excluded if measurement did not include any of the relevant clinical outcomes, or if BS was applied in both treatment arms. As demonstrated in six RCT's amongst eight publications, ostial patency did not differ between FESS and BS majority of the time (four studies found no difference; one favored FESS over BS, and one favored BS over FESS). Studies reporting quality of life measures mostly did not find meaningful differences between BS and FESS.

  Overall, authors concluded that there is a moderate-quality body of evidence suggesting that BS as a stand-alone procedure or when combined with FESS (hybrid procedure) may have similar efficacy rates as FESS. (Hayes Rating, B) Rates of revision ranged 0% to 7.89% in BS, and 0% to 16.85% following FESS (five studies); BS was statistically significantly favored over FESS in one study. The authors stated that well-designed RCTs may change current conclusions given the risk of underpowered studies from past reports, and large heterogeneity in outcome measures.

- In 2016, ECRI published a systematic review of the evidence regarding standalone balloon sinus dilation for treating chronic rhinosinusitis in adults.[12] Overall the evidence regarding long-term impact on quality of life such as work activity, activity impairment, and the rhinosinusitis symptom inventory score was rated low. However, the ECRI report concluded that sinus symptoms did improve at 1 and 2 year follow-up and that balloon sinuplasty provided similar long-term results compared to FESS.

- In 2011, Ahmed and colleagues published a Cochrane systematic review which evaluated the efficacy of balloon dilation as a treatment for CRS.[13] Reviewers included randomized controlled trials with patients of any age with rhinosinusitis >12 weeks who failed a prolonged course of medical management. A single study (n=34) met inclusion criteria and compared balloon

dilatation of the frontal recess (plus conventional FESS of other involved sinuses) versus conventional FESS. At 12 months follow-up there were no statistically significant differences between groups. Patent frontal recesses were observed in 75% of patients in the balloon sinuplasty group and 63% in the FESS-only group. No major complications were reported. The authors concluded the evidence, at the time of the review, was insufficient to support the use of balloon dilation compared to standard surgical and medical management approaches for treating CRS.

Randomized Controlled Trials (RCT)

In 2013, Culter and colleagues published an RCT deemed to be the highest quality of those included in the 2016 update of the Hayes review above (REMODEL trail).[14] The trial compared balloon dilation to FESS to assess noninferiority in 92 adult patients with CRS. Inclusion criteria were:

- Patients who were diagnosed with recurrent or chronic rhinosinusitis,
- All patients had maxillary sinus disease, with or without anterior ethmoid disease,
- All patients met criteria for FESS for uncomplicated rhinosinusitis:
    - Failure of medical management
    - CT documentation of CRS or RARS

Patients were excluded from the study if any of the following were met:

- Patients with posterior ethmoid, sphenoid, or frontal rhinosinusitis requiring FESS or balloon dilation, as well as those with fungal sinusitis, severely deviated septum causing complete obstruction, or gross sinonasal polyposis were excluded.
- Patients who had previously undergone sinus surgery, those who underwent nasal surgery within 3 months before randomization, and anyone requiring concomitant sinonasal surgery at the time of the study procedure (e.g., septoplasty) were not eligible.
- Patients with ciliary dysfunction or Samter's triad along with individuals either undergoing chemotherapy in the head/neck region or who were pregnant were also excluded from study participation.

Primary endpoints were improvements in sinus symptom as assessed by a mean change in the SNOT score between baseline and 6 month follow-up. No differences were observed between groups and statistically significant improvements ($p<0.0001$) were observed in both arms. Strengths of this study included a large patient population which allowed for comparison of statistical differences between groups, randomized design and long-term follow-up.

Bizhazi et al. and Chandra et al. both reported on long term follow-up of the REMODEL study.[15,16] At one-year 96.7% (89/92) patients completed follow-up. Ostial patency was 96.7% and 98.7% after balloon dilation and FESS and both groups demonstrated significant reductions in rhinosinusitis episodes (4.2 for balloon dilation and 3.5 in the FESS group).

In 2016, Chandra reported the final results of the REMODEL study and also included a larger cohort population in a meta-analysis to evaluate long-term outcomes of treatment of stand-alone balloon sinuplasty compared to FESS.[16] The REMODEL study cohort included 135 patients with 12-24-month outcomes. In addition, 358 standalone balloon dilation patients with 24 month follow-up were included in the analysis. Final results were similar to those reported in the 6-month and 12-month outcomes of

the REMODEL study. A significant reduction was observed in work/school days missed, clinical visits, acute infections, and prescription antibiotic use. Authors concluded that balloon dilation was comparable in FESS in both short and long-term outcomes.

Chronic and Recurrent Rhinosinusitis (CRS/RARS) in Children

Systematic Reviews

In 2022, Hayes published a health technology assessment on balloon sinuplasty (BSP) alone or combined with an adjunct surgery for treatment of pediatric chronic rhinosinusitis (PCRS) in children and adolescents with intractable symptoms after optimal medical therapy.[17] The authors identified a total of 7 studies of BSP for treating patients with PCRS, one of which was an RCT (n=24; follow-up time: 6 months). The overall body of evidence was therefore considered to be of low quality. Sample sizes ranged from 24-96 patients; follow-up from 6 months to 2 years. Amongst 3 studies reporting adverse events, complication rate ranged from 2.4 to 10 percent. At 6 months, the RCT comparing BSP plus adenoidectomy plus irrigation (n=12) and adenoidectomy plus irrigation (n=12) found no statistically significant difference in quality of life (measured by SN-5 questionnaire) between the treatment groups. The Hayes report concluded with a C-rating: This Rating reflects a small, overall low-quality body of evidence suggesting that PCRS patients treated with BSP experience symptom relief and improved quality of life compared with pretreatment assessments. However, no firm conclusions regarding safety can be drawn because the evidence is very limited. There is insufficient evidence regarding the relative efficacy and safety of BSP with other treatments.

Nonrandomized Studies

Several additional clinical trials assessing the efficacy of balloon catheter sinuplasty for the treatment of CRS/RARS in children were identified.[18,19] Findings from these studies were limited by their small sample sizes and lack of long-term follow-up.

Eustachian Tube Dysfunction (ETD)

Systematic Reviews

- In 2024, Hayes published a health technology assessment for eustachian tube balloon dilation (ETBD) for the treatment of chronic eustachian tube dysfunction (ETD) in adults.[5] Searching the literature through 2021, Hayes identified 11 studies in 13 publications (n=53-2272 patients; n=70-3670 dilations) that evaluated ETBD for the treatment of chronic ETD. The evidence base comprises 4 randomized controlled trials, 1 retrospective comparative study and 5 pre/post studies. Follow-up ranged from post-operation to 3 years. Consolidated findings across the studies included for review indicated that ETBD is associated with improved patient outcomes, including better ET function and reduced symptom severity compared with pretreatment assessments and may be similar to or better for most outcomes for continued medical management, tympanic paracentesis or tympanoplasty. ETBD also appeared to be relatively safe with no major complications reported in the reviewed studies. Despite positive results, investigators concluded that the overall body of evidence for the use of ETBD for the treatment of chronic ETD refractory to medical management was “low quality.”

Limitations across the reviewed studies included small sample sizes, a lack of controls, lack of power analyses, retrospective design, lack of randomization and blinding, poor reporting of the data, inadequate follow up times to determine long-term outcomes, and non-contemporaneous comparison groups. Comparison of study results was also limited by variability in treatment protocols, including procedure protocols and outcome measures. Hayes ultimately assigned a "C" rating (potential but unproven benefit) for the use of ETBD for the treatment of ETD in adults that is refractory to medical management. Evidence was also insufficient to determine patient selection criteria given the variability of treatment parameters employed to date.

- In 2020, Froehlich et al. published a systematic review with meta-analysis examining the effectiveness of eustachian tube balloon dilation for the treatment of eustachian tube dysfunction.[20] The authors performed a literature search in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Thirty five studies were included in the systematic review, including 12 for meta-analysis. Amongst the 12 publications, 448 patients and 545 ears were included for quantitative analysis. Three RCT's were included, 5 prospective studies, and 4 retrospective case series. Collectively, the author's independently assessed the studies to have a high risk of bias in every category measured when evaluating study quality. Seven-item Eustachian Tube Dysfunction Questionnaire (ETDQ7) mean score at 6 weeks as compared to baseline, and at the long-term (3-12 months) time point as compared to 6 weeks were significantly decreased (-2.13; 95% CI: -3.02 to -1.24;) and not different (-0.09; 95% CI: -0.38 to 0.19), respectively. At the short-time point, 53.5% (95% CI: 47.0 to 59.8%) of baseline ETDQ7 scores > 2.1 normalized; the proportion of ETDQ7 scores that normalized at the long-term time point was not significantly different than the proportion at 6 weeks. Data for ETDQ7 were represented by three studies. Objective measures included tympanogram type (type A versus type B versus type C) represented from 12 studies; otoscopy exam findings, represented from 7 studies; and ability to perform the Valsalva maneuver, represented by seven studies. The authors reported improvements across all measures, though concluded that the number of studies available are still relatively low and the disease is highly subjective, thus requiring further study for definitive conclusions.

- In 2018, Wang et al. conducted a systematic review and meta-analysis to compare balloon dilation and laser eustachian tuboplasty in patients with eustachian tube dysfunction.[21] Independent reviewers identified relevant literature, assessed quality, and extracted data. The review identified no randomized controlled trials, two retrospective studies, and 11 prospective studies (n=1063; 942 treated with balloon dilation and 121 treated with laser tuboplasty). The primary outcomes of interest were eustachian tube score (ETS) and tympanometry and Valsalva maneuver results. In pooled analysis, balloon tuboplasty resulted in a significant improvement of ETS and a greater tympanometry improvement rate, compared to laser tuboplasty. Valsalva maneuver improvement rate was not different between the two groups. Although these results may indicate short-term efficacy of balloon dilation, the reliability of these results is uncertain due to low quality of the available evidence. The review included only a small number of nonrandomized studies, and all but two had very small sample sizes (n<100). Additionally, no studies had follow-up data beyond one year. The authors concluded that "because of the limited numbers of studies reporting data of the outcomes of interest, it remains unclear if one procedure provides greater benefits."

- In 2021, the ECRI Institute conducted a narrative evidence review to evaluate Acclarent Aera Eustachian Tube (ET) Balloon Dilation System for treating persistent eustachian tube dysfunction.[22] The evidence review identified one randomized controlled trial (RCT) (n=323) and three prospective case series (n=91). Results of the RCT indicated that the Aera ET balloon dilation added to medical management was better than medical management alone at 6-week follow-up. Tympanogram normalization was 51.8% in the ET balloon group and 13.9% in the medical management group (P <0.0001). "Normal levels of mucosal inflammation and the percentage of patients that could perform the Valsalva maneuver were also significantly higher in the treated group at six-week follow-up than in the control group (p <0.001)." The case series reported increases in quality of life, the number of patients able to perform the Valsalva maneuver, and the number of patients with normal tympanograms. The ECRI review concluded that while evidence supporting the procedure is "somewhat favorable," additional RCTs with longer-term follow-up are required to confirm the results of the RCT and to determine how ET balloon dilation compares with other treatments for refractory ET dysfunction.

Additional systematic reviews were identified which indicated there is insufficient evidence to assess the safety or efficacy of balloon dilation of the eustachian tubes as a treatment of any condition.[23-25]

Randomized Controlled Trials (RCTs)

No randomized controlled trials were identified evaluating balloon dilation of the eustachian tube for eustachian tube dysfunction that were not already included in analysis of the systematic reviews summarized above.

CLINICAL PRACTICE GUIDELINES

Acute, Chronic, or Recurrent Rhinosinusitis (ARS/CRS/RARS) in Adults

American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF)

- In 2015, the AAO-HNSF published an updated evidence-based guideline to address adult sinusitus.[26] The following recommendations were made regarding CRS:
  - The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography.
    - Strong recommendation based on cross-sectional studies with a preponderance of benefit over harm.
  - Clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS.
    - Recommendation based on a preponderance of benefit over harm.
- In 2010 (reviewed in 2021) the American Academy of Otolaryngology-Head and Neck Surgery and AAO-HNSF committees published a position statement regarding dilation of the sinuses.[27] The position statement was generated by committee members that may have included those on the board who approved the statement.

- "Sinus ostial dilation (e.g. balloon ostial dilation) is a therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate 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. This approach may be used alone to dilate an obstructed sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (eg, microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon."

American Rhinologic Society (ARS)

In 2023, the ARS published an updated identical position statement on ostial balloon dilation endorsed by both the American Rhinologic Society and the Academy of Otolaryngology - Head and Neck Surgery.[28]

Acute, Chronic, or Recurrent Rhinosinusitis (ARS/CRS/RARS) in Children

American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF)

In 2014, the AAO-HNSF published an expert opinion (consensus statement) regarding the use of balloon sinuplasty in pediatric patients.[29] The panel reached consensus in the opinion that there was insufficient current evidence to compare balloon sinuplasty to ESS for pediatric chronic rhinosinusitis.

Eustachian Tube Dysfunction (ETD)

The National Institute for Health and Care Excellence (NICE)

In 2019, NICE published an evidence-based clinical practice guideline regarding the use of balloon dilation of the eustachian tube in adults and children.[30] Despite a lack of long-term follow-up and definitive patient selection criteria, investigators stated that "evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit."[30]

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

In 2019, the AAO-HNS released a consensus statement on balloon dilation of eustachian tubes for the treatment of ETD.[31] On the basis of expert opinion and a review of the literature, authors concluded that balloon dilation of eustachian tubes is an option for treatment of selected patients with ETD who have failed medical management for identifiable treatable causes. Authors also noted, however, that there is "no published or widely accepted guidance for assessment of OETD, safety parameters of BDET, established risks and complications, or outcome assessment." Authors stated that "additional RCTs with longer follow-up are still necessary to establish a higher level of evidence for BDET efficacy" and that the panel ultimately could not reach consensus regarding the overall short-term or long-term effectiveness of BDET." [31]

EVIDENCE SUMMARY

Balloon Sinuplasty

The evidence for long term benefit of balloon sinuplasty compared to standard operative procedures, such as functional endoscopic sinus surgeries (FESS), have not been shown in large, well-designed studies; however, in small randomized trials balloon dilation appears to be equivalent to FESS and may be more cost effective. Therefore, balloon sinuplasty in adults may be medically necessary and covered when medical policy criteria are met. Evidence is insufficient, however, to support the use of balloon sinuplasty in children. Studies conducted to date are limited by small sample sizes, a lack of long-term follow-up and a lack of definitive patient selection criteria.

Balloon Dilation of the Eustachian Tube (BDET)

Low-quality but consistent evidence indicates that eustachian balloon dilation for the treatment of eustachian tube defects may be helpful in select patients. Overall, the evidence is limited in quantity and quality, but sufficiently establish the safety and efficacy of this procedure in targeted patient populations. In addition, clinical practice guidelines recommend BDET. Therefore, balloon dilation of the eustachian tube may be considered medically necessary.

BILLING GUIDELINES AND CODING

Balloon sinuplasty when performed in conjunction with FESS or other more extensive sinus surgery of the same sinus, is considered and integral part of the procedure and is, therefore, not separately reimbursable. This is not applicable to inferior turbinate resection as represented by the following CPTs: 30140, 31254, 30117, 31240. CPT's 31231 and 31237 have separate procedure designation, and may not be billed when performed with another procedure in an anatomically related region through the same incision, orifice, or surgical approach.

The following codes are not appropriate to bill for balloon sinuplasty:

- 31231- Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)
- 31294- Nasal/sinus endoscopy, surgical; with optic nerve decompression

Effective January 1, 2021, CPT codes 69705 and 69706 were implemented and should be used for balloon dilation of eustachian tube. Prior to January 1, 2021, there were no specific codes available for this service and unlisted code 69799 (Unlisted procedure, middle ear) was used.

CODES*		
CPT	31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
	31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)

	31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)
	31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, 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

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
11/2023	Annual review. Updated Billing guideline regarding termed code. Removal of unlisted code from code table. Formatting updates.
6/2024	Interim review. Removal of noncoverage criteria of fungal disease.
12/2024	Annual review. Removal of age criteria for sinus procedures. Note added to top of criteria.