

MEDICAL POLICY		Balloon Dilation of the Sinuses or Eustachian Tubes	
Effective Date: 1/1/2021		Section: SUR	Policy No: 136
 1/1/2021		Technology Assessment Committee Approved Date: 3/08; 6/09; 4/11; 5/13; 2/14; 11/14; 9/15; 5/16	
		Medical Policy Committee Approved Date: 2/11; 4/15; 7/17; 12/17; 3/18; 9/18; 12/19; 4/2020; 9/2020; 12/2020	
Medical Officer	Date		

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

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

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

Note: 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.

- I. Balloon sinus ostial dilation (balloon sinuplasty) with a catheter-based inflatable device, may be considered **medically necessary and covered** in the out-patient setting when all of the following criteria (A.-E.) are met:
 - A. The patient is 18 years of age or older; **and**
 - B. Sinus dilation will be performed on the frontal, maxillary, and/or sphenoid sinuses; **and**
 - C. 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**
 - D. 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**
- E. Abnormal findings on computerized tomography (CT) scan read by an independent radiologist indicating **at least one** of the following conditions:
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 and not covered** when criterion I. above is not met, including but not limited to:
- A. In locations other than the frontal, maxillary, and/or sphenoid sinuses
 - B. Significant polyposis
 - C. Autoimmune disorders
 - D. Repeat balloon sinuplasty
 - E. Sinusitis with fungal disease
 - F. Isolated ethmoid disease
 - G. In patients 17 years of age or younger
- III. Balloon dilation of the eustachian tube(s), with a catheter-based inflatable device is considered **investigational and is not covered** for the treatment of any condition, including but not limited to eustachian tube dysfunction.

BILLING GUIDELINES

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

Code C9745 may only be billed by a facility.

MEDICAL POLICY	Balloon Dilation of the Sinuses or Eustachian Tubes
-----------------------	--

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
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)
Not Covered	
C9745	TERMED 12/31/2020 Nasal endoscopy, surgical; balloon dilation of eustachian tube
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required .	
69799	Unlisted procedure, middle ear

DESCRIPTION

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.”⁵

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of sinus or eustachian tube dilation as a treatment for eustachian tube defects and recurrent or chronic rhinosinusitis. Below is a summary of the available evidence identified through November of 2020.

Chronic and Recurrent Rhinosinusitis (CRS/RARS)

Systematic Reviews

In 2019, 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, the 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.

Additionally, in 2019 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.⁶ 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.

In 2011, Ahmed and colleagues published a Cochrane systematic review which evaluated the efficacy of balloon dilation as a treatment for CRS.⁷ 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.

In 2007 (updated in 2016) ECRI published a systematic review of the evidence regarding standalone balloon sinus dilation for treating chronic rhinosinusitis in adults.⁸ 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.

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).⁹ 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.^{10,11} 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.¹¹ 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.

Eustachian Tube Dysfunction (ETD)Systematic Reviews

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.¹² 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.¹³ 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 2017 (updated 2018), the ECRI Institute conducted a narrative evidence review to evaluate Acclarent Aera Eustachian Tube (ET) Balloon Dilation System for treating persistent eustachian tube dysfunction.¹⁴ 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 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.

In July of 2017, Hayes published a narrative review of the evidence regarding the use of the Aera Eustachian Tube Balloon Dilation System (Acclarent Inc.), Balloon Sinuplasty System and Relieva Solo Balloon Catheter (Acclarent Inc.) for the treatment of ETD in adults (last reviewed in 2019).⁵ For the Aera ETBD System, a total of 5 studies were identified which included a range of 22-109 patients and 35-171 ears. The Hayes review indicated, “(o)verall, a very-low-quality body of evidence does not allow for definitive conclusions regarding the efficacy, effectiveness, or safety of ETBD with Acclarent systems. Study interventions were heterogeneous, with a majority of studies including concurrent sinonasal, otologic, or both procedures, limiting conclusions that can be drawn regarding the effectiveness of ETBD for chronic ETD. Study sample sizes were small, and study quality was poor. Without active comparators, the comparative effectiveness of the procedure cannot be determined. Follow-up was limited, which further complicated any determination regarding the durability of any benefit achieved. In general, complications were limited and rare. It appears as though benefit was achieved through ETBD with these systems; however, the lack of validated outcome measures evaluating patient-centered success do not allow for definitive conclusions.”

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.¹⁵⁻¹⁷

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)

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 sinusitis.¹⁸ 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 2017) the American Academy of Otolaryngology-Head and Neck Surgery and AAO-HNSF committees published a position statement regarding dilation of the sinuses.¹⁹ 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.”

In 2014 AAO-HNSF published an expert opinion (consensus statement) regarding the use of balloon sinuplasty in pediatric patients.²⁰ The panel reached consensus in the opinion that there was insufficient current evidence to compare balloon sinuplasty to ESS for pediatric chronic rhinosinusitis.

American Rhinologic Society (ARS)

The ARS published an identical position statement (2017) on ostial balloon dilation endorsed by both the American Rhinologic Society and the Academy of Otolaryngology - Head and Neck Surgery.²¹

Eustachian Tube Dysfunction (ETD)

The National Institute for Health and Care Excellence (NICE)

In 2011, NICE published an evidence-based clinical practice guideline regarding the use of balloon dilation of the eustachian tube which indicated the following:²²

“Current evidence on the efficacy and safety of balloon dilatation of the eustachian tube is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research, which should address the efficacy of the procedure in the short and longer term, and also document safety outcomes. Research studies should clearly describe which parts of the Eustachian tube are being treated and report subjective measurements of symptom improvement and objective measurements of Eustachian tube function.”

CENTERS FOR MEDICARE & MEDICAID (CMS)

As of November 5 2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addressed balloon dilation or the eustachian tubes or sinuses.

POLICY 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 may be medically necessary and covered when medical policy criteria are met.

Eustachian Tube Dysfunction (ETD)

There is insufficient evidence regarding the use of eustachian balloon dilation for the treatment of eustachian tube defects. Overall, the evidence is limited in quantity and quality and do not establish the safety or efficacy of this procedure in any patient population. In addition, no clinical practice guidelines were identified which recommend the use of tube dilation as a treatment of eustachian tube defects. Therefore, balloon dilation of the eustachian tube is considered investigational and is not covered for the treatment of any condition, including but not limited to eustachian tube dysfunction.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-day notice of policy changes that are restrictive in nature.

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 PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

Food & Drug Administration (FDA)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)²³

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)²⁴

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)²⁵

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)²⁶

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).²⁷ 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

The ACCLARENT AERA® Eustachian Tube Balloon Dilation System manufactured by Acclarent, Inc. received FDA 510(k) Premarket Approval in 2018 (K171761).²⁸ The device is classified as class II and is indicated for treatment of persistent eustachian tube dysfunction in adults 18 and older. FDA Product Code: PNZ.

REFERENCES

1. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): Adult Sinusitis Executive Summary. *Otolaryngol Head Neck Surg*. 2015;152(4):598-609. <https://www.ncbi.nlm.nih.gov/pubmed/25833927>
2. Scheid DC, Hamm RM. Acute bacterial rhinosinusitis in adults: part II. Treatment. *Am Fam Physician*. 2004;70(9):1697-1704. <https://www.ncbi.nlm.nih.gov/pubmed/15554487>
3. Hayes. Health Technology Assessment. Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Adult Patients. <https://evidence.hayesinc.com/report/dir.balloon3644>. Updated Sep 26, 2019. Accessed 11/05/2020.
4. UpToDate. Chronic rhinosinusitis: Management. Literature review current through: Oct 2020. | This topic last updated: Oct 30, 2020. <https://www.uptodate.com/contents/chronic-rhinosinusitis-management>. Accessed 11/05/2020.
5. Hayes. Acclarent Eustachian Tube Balloon Dilation For The Treatment Of Eustachian Tube Dysfunction In Adults. ARCHIVED Aug 12, 2020. Report outdated. <https://evidence.hayesinc.com/report/htb.eustachian3979>. Accessed 11/05/2020.
6. Hayes. Health Technology Assessment. Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Pediatric Patients. Oct 9, 2019. <https://evidence.hayesinc.com/report/dir.balloon4775>. Accessed 11/05/2020.
7. Ahmed J, Pal S, Hopkins C, Jayaraj S. Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. *Cochrane Database Syst Rev*. 2011(7):CD008515. <https://www.ncbi.nlm.nih.gov/pubmed/21735433>
8. ECRI Institute. Standalone Balloon Sinus Dilation for Treating Chronic Rhinosinusitis in Adults. Plymouth Meeting (PA): ECRI Institute; 2016 Jul 20. (Emerging Technology Report). <https://www.ecri.org/components/Target/Pages/9657.aspx>. Accessed 11/05/2020.
9. Cutler J, Bikhazi N, Light J, Truitt T, Schwartz M, Investigators RS. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial. *Am J Rhinol Allergy*. 2013;27(5):416-422. <https://www.ncbi.nlm.nih.gov/pubmed/23920419>
10. Bikhazi N, Light J, Truitt T, Schwartz M, Cutler J, Investigators RS. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial with 1-year follow-up. *Am J Rhinol Allergy*. 2014;28(4):323-329. <https://www.ncbi.nlm.nih.gov/pubmed/24823902>
11. Chandra RK, Kern RC, Cutler JL, Welch KC, Russell PT. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. *Laryngoscope*. 2016;126(1):44-50. <https://www.ncbi.nlm.nih.gov/pubmed/26228589>

12. Froehlich MH, Le PT, Nguyen SA, McRackan TR, Rizk HG, Meyer TA. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. *Otolaryngol Head Neck Surg.* 2020;163(5):870-882. <https://www.ncbi.nlm.nih.gov/pubmed/32482125>
13. Wang TC, Lin CD, Shih TC, et al. Comparison of Balloon Dilation and Laser Eustachian Tuboplasty in Patients with Eustachian Tube Dysfunction: A Meta-analysis. *Otolaryngol Head Neck Surg.* 2018;158(4):617-626. <https://www.ncbi.nlm.nih.gov/pubmed/29557245>
14. ECRI Institute. Acclarent Aera Eustachian Tube Balloon Dilation System (Acclarent, Inc.) for Treating Persistent Eustachian Tube Dysfunction. Plymouth Meeting (PA): ECRI Institute; 2018 Mar 06. (Custom Product Brief). <https://www.ecri.org/components/ProductBriefs/Pages/24861.aspx>. Accessed 11/05/2020.
15. Randrup TS, Ovesen T. Balloon eustachian tuboplasty: a systematic review. *Otolaryngol Head Neck Surg.* 2015;152(3):383-392. <https://www.ncbi.nlm.nih.gov/pubmed/25605694>
16. Huisman JML, Verdam FJ, Stegeman I, de Ru JA. Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. *Laryngoscope.* 2018;128(1):237-247. <https://www.ncbi.nlm.nih.gov/pubmed/28799657>
17. Hwang SY, Kok S, Walton J. Balloon dilation for eustachian tube dysfunction: systematic review. *J Laryngol Otol.* 2016;130 Suppl 4:S2-6. <https://www.ncbi.nlm.nih.gov/pubmed/27488333>
18. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg.* 2015;152(2 Suppl):S1-S39. <https://www.ncbi.nlm.nih.gov/pubmed/25832968>
19. American Academy of Otolaryngology—Head and Neck Surgery. Position Statement: Dilation of sinuses, any method (e.g., balloon, etc.). Adopted: 6/28/2010. Revisions Approved: 03/12/2017. <https://www.entnet.org/?q=node/542>. Accessed 11/05/2020.
20. Brietzke SE, Shin JJ, Choi S, et al. Clinical consensus statement: pediatric chronic rhinosinusitis. *Otolaryngol Head Neck Surg.* 2014;151(4):542-553. <https://www.ncbi.nlm.nih.gov/pubmed/25274375>
21. American Rhinologic Society. Ostial Balloon Dilation Position Statement. Revised 03/14/2017. https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=33:ostial-balloon-dilation-position-statement&catid=26:position-statements&Itemid=197. Accessed 11/05/2020.
22. National Institute for Health and Care Excellence. Balloon dilatation of the Eustachian tube. Published date: November 2011 <https://www.nice.org.uk/guidance/ipg409>. Accessed 11/05/2020.
23. Food and Drug Administration. 510(k) Premarket Notification approval. Relieva Scout™ Multi-Sinus Dilation System. Feb 12, 2016. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153341>. Accessed 11/05/2020.
24. Food and Drug Administration. 510(k) Premarket Notification approval. Nuvent EM Sinus Dilation System. Dec 1, 2015. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K152121>. Accessed 11/05/2020.
25. Food and Drug Administration. 510(k) Premarket Notification approval. XprESS Multi-Sinus Dilation Tool. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K112506>. Accessed 11/05/2020.

26. Food and Drug Administration. 510(k) Premarket Notification approval. FinESS™ Sinus Treatment. Jul 8, 2009.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K091681>. Accessed 11/05/2020.
27. U.S. Food and Drug Administration. FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis. 3-4-2020 FDA Drug Safety Communication. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug>. Accessed 11/05/2020.
28. Food and Drug Administration. 510(k) Premarket Notification approval. ACCLARENT AERA® Eustachian Tube Balloon Dilation System. Jan 16, 2018.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K171761>. Accessed 11/05/2020.