MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Balloon Sinus Ostial Dilation for Treatment of Chronic Rhinosinusitis (e.g., Balloon Sinuplasty)**
Policy Number	**7.01.85**
Category	**Technology Assessment**
Original Effective Date	**04/21/11**
Committee Approval Date	**06/21/12, 05/23/13, 06/19/14, 06/18/15, 06/16/16, 06/15/17, 05/17/18, 05/16/19, 05/21/20, 05/20/21, 06/16/22, 08/17/23, 08/22/24**
Current Effective Date	**08/22/24**
Archived Date	**N/A**
Archived Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, balloon sinus ostial dilation (also known as balloon sinuplasty) or any other catheter-based inflatable device, as a stand-alone procedure, has been medically proven to be effective and, therefore, is considered **medically appropriate** for the treatment of chronic rhinosinusitis when **ALL** the following criteria have been met:

A. Documentation of **two (2) or more** of the following cardinal signs/symptoms of chronic rhinosinusitis (CRS) for more than three (3) months:
   1. Nasal obstruction (congestion);
   2. Nasal mucopurulent drainage (anterior and/or posterior);
   3. Facial pain, pressure, fullness; **or**
   4. Decreased or loss of sense of smell;

B. Documentation of failed medical therapy with **ALL** the following:
   1. Steroid nasal spray for at least 8-weeks;
   2. Saline nasal irrigation/lavage for at least 8-weeks;
   3. Antibiotics are only required when a bacterial infection is suspected; **and**
   4. Only for patients with documented chronic rhinosinusitis with nasal polyps (CRSwNP), at least one 10-day course of oral corticosteroids is required;

C. Objective evidence of chronic rhinosinusitis in following optimal medical therapy, documented by **one** of the following:
   1. Nasal endoscopy findings of purulent [not clear] mucus, or edema in the middle meatus or anterior ethmoid region; or polyps in the nasal cavity or in the middle meatus; **or**
   2. Sinus computerized tomography (CT) findings of air fluid levels, nasal polyps, opacification, **or** mucosal thickening greater than two (2) millimeters (also referred to as mild mucosal thickening).

II. Based upon our criteria and assessment of the peer-reviewed literature, balloon sinus ostial dilation or any other catheter-based inflatable device has not been medically proven to be effective and, therefore, is considered **investigational** for treating recurrent acute rhinosinusitis (RAS).

III. Based upon our criteria and the lack of peer-reviewed literature, self-expanding absorptive sinus ostial dilation (e.g., SinuSys Vent-OS) has not been medically proven to be effective and, therefore, is considered **investigational** for all indications.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Along with the four (4) cardinal symptoms of CRS, individuals may also experience non-specific symptoms (e.g., fatigue, cough, ear pain/pressure, halitosis, dental pain, nasal/throat irritation, or sleep disturbance).

II. If balloon sinuplasty is performed in conjunction with another sinus surgery in the same sinus, the balloon dilation is considered inclusive/incidental to the primary procedure, and, therefore, would not be reimbursed separately.

III. Balloon sinuplasty is limited to the frontal, maxillary, or sphenoid sinuses.

IV. Balloon sinuplasty can relieve symptoms for patients with CRSwNP; however, severe/gross polyposis may require biologic therapy and/or polypectomy.

DESCRIPTION

Rhinosinusitis may be classified by duration as acute rhinosinusitis (ARS) if less than a four (4) week duration or as chronic rhinosinusitis (CRS) if lasting more than 12 weeks, with or without acute exacerbations. Chronic rhinosinusitis (CRS) is an inflammatory condition of the paranasal sinuses and linings of the nasal passages that persists for at least 12 weeks. The four cardinal signs/symptoms are listed in Policy Statement I., with other symptoms being too non-specific for the diagnosis of CRS (e.g., cough, ear pain, headache, fatigue, or throat irritation). CRS can be divided into three subtypes: CRS without nasal polyposis (CRSsNP), CRS with nasal polyposis (CRSwNP), allergic fungal rhinosinusitis (AFRS). These four cardinal symptoms may be present with any subtype of disease and do not differentiate among the subtypes of CRS.

Balloon sinus ostial dilation (BOD, also known as balloon sinuplasty) is an alternative to functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis. The procedure can be performed as a stand-alone procedure or with FESS. When performed with FESS, it may be referred to as a hybrid procedure.

BOD involves placing a guidewire in the sinus ostium (confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity), advancing a balloon over the guidewire, and then stretching the sinus opening by inflating the balloon. The procedure aims to restore sinus drainage and function without damaging the sinus mucosa. Pressure caused by the inflated balloon restructures and widened the ostium by creating microfractures in the surrounding bone. General anesthesia may be needed to minimize patient movement; however, an increasing number of ENT doctors perform the procedure in the office under local anesthesia.

Self-expanding absorptive sinus ostial dilation has been proposed as an alternative to BOD. The self-expanding device is inserted into the sinus ostia to allow for a more gradual dilation through an osmotic process using the body's natural mucosal fluids to expand the insert before removal. Once inserted, the device absorbs moisture from the surrounding tissue and begins to expand, providing low-pressure, gradual dilation of the sinus ostia. Once the device has been given enough time to fully expand, it is removed. This type of device is proposed to maximize patient tolerability of the procedure.

RATIONALE

BOD For Chronic Rhinosinusitis

There is evidence that balloon sinuplasty can be performed successfully and safely in adult patients with chronic rhinosinusitis in both the outpatient setting and the provider office setting. Clinical studies identify improvement in symptoms similar to FESS, and potential advantages for balloon sinuplasty with respect to postoperative recovery time and pain medication. BOD is commonly used to open sinus ostia while preserving mucosa and minimizing trauma.

The largest randomized controlled trial (RCT) is the REMODEL (randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up) trial. REMODEL, an industry sponsored RCT that compared BOD as a stand-alone procedure with FESS, reported results at 6 and 12 months in two publications (Cutler et al., 2013; Bikhazi et al., 2014). Final results reported in Chandra et al. (2016), which included results up to 2 years post-procedure for subjects in the REMODEL trial, along with an additional 30 subjects treated with FESS or in-office balloon sinus dilation, for a reported total of 61 FESS patients and 74 BOD patients. Follow-up data were available for 130, 66, and 25 patients at 12, 18, and 24 months, respectively. Details about group-specific treatment received and loss to follow-up were not reported for the additional 30 patients not included in the REMODEL trial. The BOD group required 0.2 debridements per patient compared with 1.0 per patient in the FESS group (P <.001). Mean change in SNOT-20 score from baseline to 12-month follow-up was -1.59 (P <.001) and -1.60 (P <.001) for the BOD and FESS groups, respectively, which was considered clinically significant. These changes were maintained at 24 months. At 18 months, overall revision rates were 2.7% in the balloon dilation group and 6.9% in the FESS group. The authors concluded that all outcomes are comparable between FESS and balloon dilation at all time points from six months to 24 months. According to the authors, balloon dilation produces faster recovery, less postoperative pain, and fewer debridements than FESS.

<u>BOD For Recurrent Acute Rhinosinusitis</u>

There is insufficient evidence to determine that balloon ostial dilation (balloon sinuplasty) results in an improvement in the net health outcome for the treatment of recurrent acute rhinosinusitis.

Sikand et al. (2019) addressed the limited number of studies that have demonstrated symptomatic improvement for recurrent acute rhinosinusitis (RARS). This randomized sham-controlled study evaluated outcomes for balloon sinus dilation (BSD) with medical management (MM) (n = 29) as compared with MM only (n = 30) for patients diagnosed with RARS. Patients were followed through 48 weeks post-procedure, with the primary endpoint being the difference in the change in Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks between the 2 cohorts. The authors concluded that BSD plus MM proved superior to MM alone in enhancing QOL for RARS patients. According to the authors, BSD plus MM should be considered as a viable treatment option for properly diagnosed RARS patients. However, the authors reported the limited ability to perform meaningful comparisons between groups after 24-week follow-up due to 60% crossover in the MM arm, lack of an objective measure to assess staging of the disease, lack of properly validated instruments for RARS, high number of frontal sinuses performed, and conflicts of interest among the investigators.

<u>Self-Expanding Sinus Ostial Dilation</u>

Hathorn et al., (2014) conducted a pilot clinical trial to evaluate the new maxillary sinus ostium (MSO) self-dilation device (Vent-Os Sinus Dilation System, SinuSys Corporation, Palo Alto, CA). This nonrandomized, single-cohort, single-center, prospective study aimed to evaluate the safety and performance of the MSO self-dilation device. The study (n=12) included subjects with chronic rhinosinusitis and inserted 19 devices (10 [53%] right MSO and 9 [47%]) left MSO). The Vent-Os device was inserted and expanded by absorbing a small amount of fluid for a period of time, with 17 devices remaining in situ for the complete one hour. MSO patency was evaluated immediately after device removal (94% visibly patent) and at 1 week (80% patent), 1 month (87%), and 3 months (93% patent). No specific device related adverse events were reported throughout the trial or follow-up period.

The study had limitations (e.g., no assessment of patient reported outcomes and sample size), however, the authors concluded that the study was designed to only address feasibility and safety, and further studies are now required to compare the device with other techniques.

No further research findings have been published, and there is a lack of guidance documented within professional society guidelines, recommendations, or consensus statements (e.g., American Academy of Otolaryngology - Head and Neck Surgery and the American Rhinologic Society).

Professional Guidelines

In January 2023, the American Rhinologic Society (ARS) issued a position statement supporting the use of balloon sinus 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 is based on clinical consensus statements and primary research evidence. The 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. The ARS concluded this approach may be used alone or in conjunction with traditional endoscopic sinus surgery.

In 2018, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) development a clinical consensus statement for balloon dilation of the sinuses (Piccirillo et al., 2018). Based on a systematic review of the literature and expert consensus, the AAO-HNS reached consensus on statements for adults 18 years or older with chronic or recurrent rhinosinusitis (with or without nasal polyps, with or without prior sinus surgery), including:

- 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.

The AAO-HNS reached consensus that there is a role for sinus ostial dilation for the management of recurrent acute rhinosinusitis (RARS). Specifying that RARS should be defined not only by history of symptoms, but also by the presence of CT findings suggestive of inflammation or evidence of ostial blockage. However, after review of the available literature, no consensus could be reached that the procedure is effective in reducing the frequency of episodes or the number of antibiotic courses. Findings in the literature, from 2 observational studies without controls, show a reduction in the number of episodes of acute rhinosinusitis as well as the number of courses of antibiotics in the year following; however, the strength of the evidence was deemed inadequate for a strong supportive statement.

The AAO-HNS's most current clinical practice guidelines for adult sinusitis was published in 2015 (Rosenfeld et al.). The guideline provides the following definitions:

Chronic Rhinosinusitis

- 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 is documented by one or more of the following findings:
  - purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region;
  - polyps in nasal cavity or the middle meatus; or
  - radiographic imaging showing inflammation of the paranasal sinuses.

Recurrent Acute Rhinosinusitis

- four or more episodes per year of acute bacterial rhinosinusitis (ABRS) without signs or symptoms of rhinosinusitis between episodes;
- each episode of ABRS should meet diagnostic criteria of either:
  - symptoms or signs of acute rhinosinusitis fail to improve within 10 days or more beyond the onset of upper respiratory symptoms, or
  - symptoms or signs of acute rhinosinusitis worsen within 10 days after an initial improvement (double worsening).

Regulatory

In March 2008, the Relieva Sinus Balloon Catheter device (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been granted 510(k) marketing clearance.

These include the Relieva Spin Sinus Dilation System, cleared in August 2011, and the Relieva Seeker Balloon Sinuplasty System, cleared in November 2012. In June 2008, the FinESS Sinus Treatment (Entellus Medical, Inc., Maple Grove, MN) was cleared for marketing by the FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibula in adults using a transantral approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices by Entellus Medical, Inc. also received 510(k) approval in August 2012. These are the ENTrigue Sinus Dilation System and the XprESS Multi-Sinus Dilation Tool. In late 2013, the NuVent EM Balloon Sinus Dilation System (Medtronic) received FDA 510(k) clearance. It features a built-in electromagnetic surgical navigation technology.

In January 2014, the Vent-Os-Gentle Sinus Dilation System (SinuSys Corporation) received FDA clearance based on comparison to predicate devices. The Vent-Os System incorporates the Company's proprietary osmotic technology, which utilizes the body's natural mucosal fluids to expand the insert before removal. The Vent-Os System achieved post-procedural patency in 95 percent of the sinus ostia treated in a multi-center study and submitted as part of the developer's FDA application.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia
31299 (***E/I**)	Unlisted procedure, accessory sinuses (*****E/I when billing for self-expanding absorptive sinus ostial dilation)

HCPCS Codes

Code	Description
C1726	Catheter, balloon dilatation, nonvascular

ICD10 Codes

Code	Description
J32.0-J32.9	Chronic sinusitis (code range)

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*Key Article

KEY WORDS

Balloon sinuplasty, balloon dilation, catheter sinusotomy, chronic rhinosinusitis, recurrent acute rhinosinusitis

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, sinus ostial dilation/balloon sinuplasty is not addressed in National or Regional CMS coverage determinations or policies.