MEDICAL POLICY

Medical Policy Title	Balloon Sinus Ostial Dilation for Treatment of Chronic Rhinosinusitis (e.g., Balloon Sinuplasty)
Policy Number	7.01.85
Current Effective Date	August 21, 2025
Next Review Date	August 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Balloon sinus ostial dilation (also known as balloon sinuplasty) or any other catheter-based inflatable device, as a stand-alone procedure 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, posterior or both);
      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 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. Balloon sinus ostial dilation or any other catheter-based inflatable device is considered **investigational** for treating recurrent acute rhinosinusitis (RAS).

III. Self-expanding absorptive sinus ostial dilation (e.g., SinuSys Vent-OS) is considered **investigational** for all indications.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

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 or polypectomy.

DESCRIPTION

Rhinosinusitis may be classified by duration as acute rhinosinusitis (ARS) if less than a four-week duration or as chronic rhinosinusitis (CRS) if lasting more than 12 weeks, with or without acute exacerbations. 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 nasal obstruction (congestion); nasal mucopurulent drainage (anterior and/or posterior); facial pain, pressure, fullness; or decreased or loss of sense of smell; 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), and 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.

SUPPORTIVE LITERATURE

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 or those lost 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.

In 2025, Liang and colleagues published results of a meta-analysis aimed to evaluate the efficacy and safety of BOD compared to FESS in the treatment of CRS, to inform clinical decision-making. Two independent reviewers extracted data from 14 randomized controlled trials (RCTs) including patients diagnosed with CRS, with or without nasal polyposis and allergic rhinitis, who had not responded to drug therapy. The patients in the intervention group received BOD while the control group received FESS, and either Lund-Mackay or the sinonasal outcome test-20 (SNOT-20) score was reported. Other data included complications, operating time and revision surgery. The data represented a total of 1,060 patients with CRS, 531 of whom were treated with BOD versus 529 treated with FESS. Of the 24 studies, five RCTs reported Lund-Mackay score, of which there was no significant difference between the two groups. Eight RCTs reported a post-operative SNOT-20 score with the BOD group being significantly lower than the FESS group (p=.005). There was no significant difference noted in SNOT-20 scores reported at three, six, or 12 months. Three RCTs reported data on revision surgery,

which was not significantly different between the two groups. Postoperative complications, reported by four RCTs, did demonstrate that the BOD group had less incidence than the FESS group, which was significantly lower. Authors concluded that there were limitations to the analysis, including some RCTs with a high risk of bias, but that findings indicate BOD is an effective intervention for CRS and should be recommended. Additionally, that future studies should attempt to stratify randomization to control confounding factors such as the severity of sinusitis and presence or absence of nasal polyps.

BOD for Recurrent Acute Rhinosinusitis

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.

Self-Expanding Sinus Ostial Dilation

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 [AAO-HNS] and the American Rhinologic Society [ARS]).

PROFESSIONAL GUIDELINE(S)

In January 2023, the 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.

The AAO-HNS reached consensus and published a 2021 position statement stating 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 were 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).

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.

In May 2025, the AAO-HNS published a clinical practice guideline on the surgical management of chronic rhinosinusitis, summarized by Shin and colleagues. The recommendations were considered strong if the benefits of the approach clearly exceeded the harms, and that the quality of the supporting evidence is Grade A or B. The guideline made strong recommendations for the following considerations:

- “Before considering surgery, the surgeon should verify an existing diagnosis of chronic rhinosinusitis to ensure established diagnostic criteria (signs and symptoms) from clinical practice guidelines are met, and the surgeon should assess candidacy for sinus surgery based on symptoms, disease characteristics, quality of life, and prior medical or surgical therapy”

(Evidence Grade B);

- "The surgeon or their designee should not prescribe antibacterial therapy to an adult with chronic rhinosinusitis if significant or persistent purulent nasal discharge (anterior, posterior, or both) is absent on examination" (Evidence Grade B).

Recommendations with a lower quality of evidence rating B or C included the following:

- "The surgeon should not endorse or require a predefined, one-size-fits-all regimen or duration of medical therapy (e.g., antibiotics, steroids, antihistamines) as a prerequisite to sinus surgery for an adult with chronic rhinosinusitis;
- The surgeon should identify patients with chronic rhinosinusitis that would benefit most from surgery and are least likely to benefit from continued medical therapy alone, such as those with chronic rhinosinusitis subtypes that include, but are not limited to, chronic rhinosinusitis with polyps, polyps with bony erosion, eosinophilic mucin, or fungal balls;
- The surgeon or their designee should counsel patients before sinus surgery to establish realistic expectations, including the potential for chronicity or relapse, and the likelihood of long-term medical management, taking into account their chronic rhinosinusitis subtype;
- The surgeon should offer sinus surgery to an adult with chronic rhinosinusitis when the anticipated benefits exceed that of nonsurgical management alone, there is clarity regarding the anticipated outcomes, and the patient understands the expectation for long-term disease management following surgery;
- For an adult who is a candidate for sinus surgery, the surgeon or their designee should obtain a computed tomography (CT) scan with a fine-cut protocol, if not already available, to examine the paranasal sinuses for surgical planning;
- The surgeon should not plan the extent of sinus surgery (e.g., which specific sinuses to operate on) solely based on arbitrary criteria regarding a minimal level of mucosal thickening, sinus opacification, or outflow obstruction on a CT scan;
- The surgeon or their designee should educate an adult with chronic rhinosinusitis who is scheduled for sinus surgery regarding anticipated postoperative care, specifically pain control, debridement, medical management, activity restrictions, return to work, duration and frequency of follow-up visits, and the potential for recurrent disease or revision surgery;
- When the sinus involves polyps, osteitis, bony erosion, or fungal disease in an adult with chronic rhinosinusitis who is scheduled for sinus surgery, the surgeon should perform sinus surgery that includes full exposure of the sinus cavity (lumen) and removal of diseased tissue, not just balloon or manual ostial dilation, or refer the patient to a surgeon who can perform this extent of surgery;
- The surgeon or their designee should routinely follow up to assess and document outcomes of sinus surgery for chronic rhinosinusitis, between 3 and 12 months after the procedure, through history (symptom relief, quality of life, complications, adherence to therapy, need for rescue

medications, and ongoing care) and nasal endoscopy."

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates balloon sinus dilation devices as medical devices. All balloon sinus dilation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Jun 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Aug 21]

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.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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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SEARCH TERMS

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

04/21/11, 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, 08/21/25

Date	Summary of Changes
08/21/25	• Annual review. Policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
04/21/11	• Original effective date