Balloon Ostial Dilation (BOD)/Balloon Sinuplasty for the Treatment of Chronic and Recurrent Rhinosinusitis as a Stand-Alone Procedure or as an Adjunctive Procedure to Functional Endoscopic Sinus Surgery (FESS)

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DESCRIPTION

Balloon ostial dilation (BOD, also known as balloon sinuplasty) is proposed as an alternative to functional endoscopic sinus surgery (FESS) for patients with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (RARS) who fail medical management. The procedure involves placing a balloon in the sinus ostium and inflating

the balloon to stretch the opening. It can be performed as a stand-alone procedure or as an adjunctive procedure to FESS.

Recurrent Acute Rhinosinusitis (RARS): Is defined as 4 or more episodes a year f acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes.

Chronic Rhinosinusitis (CRS): Is characterized by purulent nasal discharge, usually without fever, that persists for persists for longer than 12 weeks. Symptoms of congestion often accompany the nasal discharge. There also may be mild pain and/or a headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms vary considerably because of the location and shape of these sinus ostia.

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics).

Balloon Ostial Dilation (BOD)
A newer procedure, balloon ostial dilatation (balloon sinuplasty) can be used as an alternative or as an adjunct to functional endoscopic sinus surgery (FESS) for those with CRS or RARS. The goal of this technique, when used as an alternative to FESS, is to improve sinus drainage using a less invasive approach. The procedure involves placing a guidewire in the sinus ostium, advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize patient movement. According to the manufacturer, the RELIEVA SPINPLUS® Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

This medical policy addresses BOD as a standalone procedure. BOD may also be used in combination with FESS. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. BOD may also be used on 1 sinus and FESS on another sinus in the same patient during the same operation.

In a typical FESS (functional endoscopic sinus surgery), the physician first identifies the middle turbinate and removes the uncinate process to expose the ethmoid bulla. The anterior ethmoid air cells are opened, leaving the bone covered with mucosa. This allows for better ventilation of the anterior ethmoid sinuses. The maxillary ostium is examined and, if it is obstructed, a middle meatal antrostomy is performed. This minimal surgery is often sufficient to improve the function of the osteomeatal complex, which improves the ventilation of the maxillary, ethmoid, and frontal sinuses.

Balloon sinuplasty is frequently used **within** the FESS procedure as a tool to open the sinuses, enabling the surgeon better access with the endoscope. Balloon sinuplasty as part of sinus surgery is considered a tool and therefore inherent to the procedure and not available for separate reimbursement.

Balloon Ostial Dilation as a Stand-Alone Procedure for Patients with Chronic Rhinosinusitis

Clinical Context and Test Purpose
The purpose of balloon ostial dilation (BOD) as a stand-alone procedure in patients with chronic rhinosinusitis (CRS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management and functional endoscopic sinus surgery (FESS).

Populations
The relevant population of interest is individuals 17 years of age and older with CRS, defined as an inflammatory condition involving the paranasal sinuses and linings of the nasal passages characterized by purulent nasal discharge, nasal obstruction, facial pain or pressure, and reduction in sense of smell, usually without fever, that persists for 12 weeks or longer.

Interventions
The treatment being considered is BOD (also known as balloon sinuplasty). The procedure involves placing a balloon in the sinus ostium and inflating it to stretch the opening.
BOD can be performed in the operating room or in an office setting under local anesthesia.

Comparators
Comparators of interest include medical management (steroids, antibiotics, or decongestants) and FESS.

Outcomes
The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity.

To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used, including radiologic scores, endoscopic grading, and patient-reported quality of life measures. The primary outcome measures relevant for the treatment of chronic rhinosinusitis (CRS) are patient-reported symptoms and quality of life. Examiner evaluation of the nasal and sinus appearance and polyp size may provide some information about treatment outcomes, but these evaluations are limited by the lack of universally accepted standards.

Disease-specific patient-reported quality of life scores include the commonly used Sino-Nasal Outcome Test-20 (SNOT-20), which is a validated questionnaire for which patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The possible range of SNOT-20 scores is 0 to 5, with a higher score indicating a greater rhinosinusitis-related health burden. The impact of treatment is measured by calculating the difference between SNOT-20 scores before and after treatment. A SNOT-20 change score of 0.8 or greater is believed to be clinically meaningful. The SNOT-22, a variation of the SNOT-20, includes 2 additional questions (on "nasal obstruction" and "loss of smell and taste"). The minimally important difference in SNOT-22 is considered to be 8.9 points.

The Lund-Mackay scoring system uses radiologist-rated information derived from computed tomography scans to assess opacification of the sinus cavities, generating a score from 0 to 24. Although CT scans can provide an objective measure, often they do not correlate well with symptoms.
Six months to 1 year of follow-up is considered necessary to demonstrate efficacy.

BOD as a standalone procedure for patients with CRS has been evaluated in randomized controlled trials (RCTs) and systematic reviews.

The largest RCT is the REMODEL (randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up) trial. REMODEL results at 6, 12, and 24 months have been reported in 3 publications. This was an industry sponsored RCT that compared BOD as a stand-alone procedure with FESS. A total of 105 patients with CRS or RARS and failure of medical therapy were randomized to BOD or FESS. Patients with gross sinonasal polyposis were excluded. Balloon ostial dilation was performed with the Entellus device, which is labeled for a transantral approach. FESS consisted of maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy. Thirteen patients withdrew consent before treatment, 11 (21%) in the FESS group and 2 (4%) in the BOD group. The primary outcomes were the change in SNOT-20 scores at 6-month follow-up and mean number of postoperative debridements. Secondary outcomes included recovery time, complication rates, and rates of revision surgery. Noninferiority analysis was performed for the primary outcome of change in symptom score and superiority analyses was performed on the debridement outcome.

Ninety-one patients who were enrolled in REMODEL were available at 6-month follow-up. The improvement in the mean SNOT-20 score was 1.67 (1.10) in the balloon dilation group and 1.60 (0.96) in the FESS arm (P =.001) for noninferiority. Postoperative debridement's were more likely in the FESS group with a mean of 1.2 (1.0) compared to a mean of 0.1(0.6) in the balloon dilation group (P <.001) for superiority in the balloon arm). Patients in the BOD arm returned to normal daily activities faster (1.6 days vs 4.8 days, P =.002 for superiority) and required fewer days of prescription pain medications (0.9 days vs 2.8 days, P =.002 for superiority) with balloon dilation. There were no major complications in either group, or 1 patient in each group required revision surgery.

In 2017, Bikhazi et. al. reported 1-year follow-up from the REMODEL trial. Eighty-nine (96.7%) subjects were available at 1 year. Improvement in the mean SNOT-20 score was 1.64 in the balloon dilation arm and 1.65 in the FESS arm (*P* <.001 for noninferiority). During the year post procedure, both groups had fewer self-reported rhinosinusitis episodes (mean reduction in episodes, 4.2 in the balloon arm vs 3.5 in the FESS arm; *P* <.001).

Final REMODEL results were reported in Chandra et al (2016). This publication 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 debridement's 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.

In addition to REMODEL, 3 smaller RCTs provide evidence on the comparison of BOD to FESS in patients with CRS.

Minni et, al. (2018) published a prospective, randomized study comparing BOD and traditional endoscopic sinus surgery (ESS) for CRS of the frontal sinuses.[9,] At 3 Italian hospitals, 102 individuals (148 sinuses) were enrolled with mild involvement of the frontal sinus, the average post-procedure SNOT-20 scores for the BOD and ESS groups were 24.6 and 27.54 (*P* =.42), respectively; for patients with moderate/severe involvement, the scores were 23.47 and 30.71 (*P* <.05), respectively. Post-procedure Lund-Mackay scores were 0.58 (BOD) and 0.54 (ESS; *P* =.30) in the mild group and 0.53 (BOD) and 0.78 (ESS; *P* =.38) in the moderate/severe group.

Bizaki et al (2014) reported on results from a RCT that compared balloon ostial dilation with FESS among patients with symptomatic chronic or recurrent acute rhinosinusitis. Results were not reported separately for patients with CRS and RARS, and the study authors stated, "For this study, both CRS and RARS were considered to be 1 disease." The trial enrolled 46 subjects, 4 of whom withdrew; the analysis included 42 patients (n=21 in each group; statistical power calculations not reported). Both treatment groups demonstrated significant improvements in SNOT-22 scores from baseline to postprocedure. There were no differences in change in total SNOT-22 scores between groups at 3 months postprocedure.

Achar et al (2012) was an open-label pilot study of 24 patients with CRS who had failed medical therapy and were scheduled for surgery. Patients were randomized to BOD or to FESS and followed for 24 weeks. The primary outcome measures were changes in

SNOT-20 scores and clearance time using the saccharin test. Both groups improved significantly on both measures. The degree of improvement was greater for the balloon dilatation group than for the FESS group on both the SNOT-20 score (43.8 vs 29.7, *P* <.03) Patients who received BOD were able to return to normal activities sooner than those who received FESS (2.2 days vs 5.0 days; *P* NR). Adverse events were not reported.

Section Summary

Randomized controlled trials (RCTs) have compared balloon ostial dilation (BOD) to functional endoscopic sinus surgery (FESS) for patients with CRS. The best evidence is from the REMODEL trial, which showed statistically and clinically significant improvements in quality of life for up to 24 months, as measured by the validated SNOT-20 scale. REMODEL results are supported by smaller RCTs, multiple comparative observational studies, and a systematic review showing improvements in quality of life, CT outcomes, and shorter recovery time with BOD than FESS. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in patients who underwent BOD (n=2851 or FESS (n-11,955), the overall complication rate 5.26% with BOD and 7.35% with FESS.

Balloon Ostial Dilation as a Stand-Alone Procedure for Patients with Recurrent Acute Rhinosinusitis

Clinical Context and Test Purpose

The purpose of balloon ostial dilation (BOD) as a stand-alone procedure in patients with recurrent acute rhinosinusitis (RARS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management and functional endoscopic sinus surgery (FESS),

Populations

The relevant population of interest is individuals 17 years of age and older with RARS. The American Academy of Otolaryngology-Head and Neck Surgery defines RARS as 4 or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes.[1,] Each episode of acute bacterial rhinosinusitis should meet the following diagnostic criteria:

- Acute rhinosinusitis that is caused by, or is presumed to be caused by, bacterial infection. A clinician should diagnose ABRS when: 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)
- Confirming a true bacterial episode of rhinosinusitis is desirable, but not essential, for substantiating an underlying diagnosis of RARS

Interventions

The therapy being considered is balloon ostial dilation (BOD) as a stand-alone procedure. The procedure involves placing a balloon in the sinus ostium and inflating it to stretch the opening.

Balloon ostial dilation can be performed in the operating room or in an office setting under local anesthesia.

Comparators

Comparators of interest include medical management and functional endoscopic sinus surgery (FESS).

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity.

To quantify the severity of RARS and to assess treatment response, various outcomes measures can be used, including radiologic scores, endoscopic grading, and patient-reported quality of life measures. The primary outcome measures relevant for the treatment of RARS are patient-reported symptoms and quality of life. Examiner evaluation of the nasal and sinus appearance and polyp size may provide some information about treatment outcomes, but these evaluations are limited by the lack of universally accepted standards.

Disease-specific patient-reported quality of life scores include the commonly used Sino-Nasal Outcome Test-20 (SNOT-20), which is a validated questionnaire for which patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The possible range of SNOT-20 scores is 0 to 5, with a higher score indicating a greater rhinosinusitis-related health burden. The impact of treatment is measured by calculating the difference between SNOT-20 scores before and after treatment. A SNOT-20 change score of 0.8 or greater is believed to be clinically meaningful.

The Chronic Sinusitis Survey (CSS) is a measure of symptoms and medication usage over an 8-week recall period. The CSS includes 3 questions regarding symptoms and 3 regarding medication usage, yielding a total score as well as symptom and medication subscores evaluated as secondary endpoints. CSS total score ranges from 0 to 100 in which a low CSS score represents greater symptoms and/or medication usage. The minimally clinically significant difference on the CSS has not been established.

A decrease in the number of acute infections occurring over a specified time period is used as an outcome measure in some studies.

Six months to 1 year of follow-up is considered necessary to demonstrate efficacy.

Two randomized controlled trials (RCTs) of balloon ostial dilation (BOD) reported results separately for patients with RARS. A third RCT, reported by Bizaki et. al. (2014) compared BOD with functional endoscopic sinus surgery (FESS) among patients with CRS or RARS, but results were not reported separately by diagnosis. The study authors stated, "For this study, both CRS and RARS were considered to be 1 disease."

In the REMODEL trial, 32% (N=29) of the patients enrolled had a diagnosis of RARS. The CABERNET (Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients) trial compared BOD plus medical therapy to medical therapy alone in 59 patients with RARS. Both trials used the AAO-HNS diagnosis of RARS to select eligible patients: 4 or more episodes of acute rhinosinusitis in the past 12 months. In CABERNET, evidence of sinus or osteomeatal complex disease during an acute episode from a CT scan was also required for enrollment. In REMODEL, all patients met criteria for medically necessary FESS, but explicit CT requirements for patients with RARS were not specified.

Results of the RCTs of patients with RARS, among the 29 patients diagnosed with RARS in the REMODEL trial, there was a significant improvement in quality of life for those who received either BOD or FESS, and the difference between treatment arms was not significant (*P* =.838). Twelve-month results from REMODEL were reported in Bikhazi et. al. Data were not reported separately by diagnosis, but the publication states, "At 1 year, symptom improvement in each of the 4 subgroups [including based on diagnosis] remained statistically significant (*P* <.001) in both treatment arms and there was no difference (*P* = NS) in improvement between patients who underwent balloon dilation or FESS." REMODEL results were not reported separately by diagnosis for secondary outcomes, or for the primary outcome (SNOT-20) at 24 months.

In Sikand et al (2019), the primary outcome was the difference between arms in change in Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks. The change in CSS was significantly greater in the BOD group compared to the control group (mean change 37.3 vs 21.8; *P* =.0424). The study authors did not specify whether this was considered clinically significant. Patients in the BOD group had a lower mean number of sinus infections through the 24-week follow-up period (0.2 vs 0.9; *P* =.0015). Durability of the outcome measure differences was demonstrated up to 48 weeks. After the 24-week follow-up period, 18 of 30 patients who were randomized to the control arm elected to receive BOD. Of those who crossed over at 24 weeks, 0 reported no change or worsening of symptoms, 3 reported improved symptoms but still used nasal sprays at high rates, 4 had improved symptoms to varying degrees but were not eliminated, and 1 reported a sinus infection just before their 24-week visit. There was 1 procedure-related serious adverse event in the BOD group (the patient sought treatment for a headache in the emergency department the evening after the procedure), 2 possibly procedure-related nonserious adverse events, and no device-related adverse events.

Section Summary

The randomized controlled trials (RCTs) regarding balloon ostial dilation (BOD) for patients with RARS, results were not reported separately by diagnosis and the body of

evidence is limited by the small number of patients studied, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures used.

Summary of Evidence
For individuals with chronic rhinosinusitis (CRS) who receive balloon ostial dilation (BOD) as a stand-alone procedure, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. In the REMODEL RCT, balloon ostial dilation (BOD) was non-inferior to functional endoscopic sinus surgery (FESS) for patients with chronic rhinosinusitis (CRS). Durability of effect was demonstrated in uncontrolled studies that followed patients who received balloon dilation for up to 24 months. Evidence from RCTs is supported by multiple observational studies and a systematic review showing improved quality of life following BOD. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events reported in patients who underwent balloon dilation (n=2851), FESS (n=11,955), or a hybrid procedure (n=1234), the overall complication rate was 7.35% with FESS and 5.26% with balloon dilation. The evidence is sufficient to determine the effects that the technology results in an improvement in the net health outcome.

For individuals with recurrent acute rhinosinusitis (RARS) who receive balloon ostial dilation (BOD) as a stand-alone procedure, the evidence includes randomized controlled trails (RCTs). Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The body of evidence is limited by the small number of patients studied, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures used. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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

Patient Criteria

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT. (Strong consensus)
- 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. (Strong consensus)
- 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. (Strong consensus)
- CT scanning of the sinuses is a requirement before balloon dilation can be performed. (Strong consensus)
- 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.

Perioperative Considerations

- Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the U.S. Food and Drug Administration for reprocessing such devices and ensure that they are followed. (Strong consensus)
- Balloon dilation can be performed under local anesthesia with or without sedation.

Outcome

- 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.

A 2014 AAO-HNS Clinical Consensus Statement on Pediatric Chronic Rhinosinusitis had near consensus on the safety of balloon ostial dilation in children but did not reach a consensus on efficacy.

American Academy of Pediatrics

American Academy of Pediatrics Clinical Practice Guidelines only address the diagnosis and treatment of acute bacterial rhinosinusitis.

American Rhinologic Society (ARS)

In a position paper (2017), ARS stated that sinus ostial dilation is an appropriate therapeutic option for selected patients with chronic rhinosinusitis (CRS) 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 procedure may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (e. g., microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

National Institute for Health and Care Excellence
In 2016, the National Institute for Health and Care Excellence (NICE) published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis:

1.1 "The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS).

1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia."

The recommendation was based on the results of the REMODEL study: the committee "considered that the evidence from REMODEL demonstrated that balloon dilation (with either XprESS or FinESS) is clinically non-inferior to FESS in terms of alleviating symptoms in patients with uncomplicated chronic sinusitis." Single-arm observational studies were of lower quality but were consistent with the findings of the REMODEL study.

Regulatory Status
The U.S. FDA labeling for several 510(k) cleared devices includes use in children 17 years of age and under and is indicated to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

Balloon Ostial Dilation Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	510(k) No.	Date Cleared	Indication
MESIRE - Balloon Sinus Dilatation System	Meril Life Sciences	K172737	12/12/2017	Sinus Ostia Dilation
Relieva UltirraNav Sinus Balloon Catheter	Acclarent Inc.	K161698	10/24/2016	Sinus Ostia Dilation
Vent-Os Sinus Dilation Family	Sinusys Corp.	K160770	6/29/2016	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K153341	2/12/2016	Sinus Ostia Dilation

XprESS Multi-Sinus Dilation System	Entellus Medical Inc.	K152434	11/20/2015	Sinus Ostia Dilation
DSS Sinusplasty Balloon Catheter	Intuit Medical Products LLC	K143738	8/27/2015	Sinus Ostia Dilation
Relieva SpinPlus Balloon Sinuplasty System	Acclarent Inc.	K143541	4/22/2015	Sinus Ostia Dilation
XprESS Multi-Sinus Dilation Tool	Entellus Medical Inc.	K142252	10/17/2014	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K140160	2/20/2014	Sinus Ostia Dilation

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies

- 07.01.82 Steroid-Eluting Sinus Stents and Implants
- 07.01.83 Nasal Implants for Nasal Vestibular Lateral Wall Stenosis or Collapse

Balloon Ostial Dilation (BOD)/Balloon Sinuplasty

Balloon ostial dilation (BOD)/balloon sinuplasty of the frontal, maxillary, or sphenoid sinuses may be considered **medically necessary** when **ALL** the following criteria are met:

- Individual is 18 years of age or older; **and**
- Diagnosed with Chronic rhinosinusitis (CRS) without nasal polyps, and present for at least 12 continuous weeks duration; **and**
- At least two of the following signs or symptoms, and 1 of which is (a) or (b):
    a. Mucopurulent nasal drainage (anterior, posterior, or both)
    b. Nasal obstruction (congestion)
    c. Facial pain, pressure and/or fullness over the affected sinus
    d. Decreased sense of smell; **and**
- Has tried and failed medical management as indicated by **ALL** the following
    - Allergy evaluation, education and optimal treatment when indicated; **and**
    - Decongestant (oral or nasal) when indicated;
    - Intranasal and/or systemic corticosteroids for a minimum of 8 weeks;
    - Saline nasal irrigation or nasal saline spray for at least 8 consecutive weeks;
    - Two 10-day courses of antibiotics or one prolonged course of antibiotics for at least 21- days;

    - Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants) when present; **OR**
    - Documented intolerance, contraindication, or hypersensitivity to intranasal corticosteroids, antihistamine nasal spray/decongestants and antibiotics; **and**
- Clinical and radiographic documentation of persistent inflammation following medical management as evidenced by **ALL** the following:
    - CT imaging of the paranasal sinuses showing mucosal thickening >3 mm; **and**
    - Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoid ethmoid region.

Note: *For Balloon Ostial Dilation (BOD)/Balloon Sinuplasty when utilized in combination with Functional Endoscopic Sinus Surgery (FESS), see below criteria statements.*

Balloon Ostial Dilation (BOD)/balloon sinuplasty is **investigational** when the above criteria are not met and for all other indications including but limited to the following, because the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- Recurrent acute rhinosinusitis (RARS)
- Repeat balloon procedure in any of the sinuses to be treated
- Nasal polyposis as a stand-alone treatment
- Samter's triad (chronic condition defined by asthma, sinus inflammation with recurring nasal polyps' aspirin sensitivity)
- Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, granulomatosis with polyangiitis (PGA))
- Severe sinusitis secondary to ciliary dysfunction, (i.e., including, but not limited to, cystic fibrosis, Kartagener's Syndrome)
- Bony dysplasia (i.e., including but not limited to Paget's disease, fibrous dysplasia)
- Extensive fungal sinusitis
- Mucocele causing sinusitis
- Suppurative or non-suppurative complications of sinusitis including extension to adjacent structures such as the orbit or central nervous system
- Suspected or known benign or malignant sinonasal tumors (including but not limited to squamous cell, adenoid cystic or adenocarcinoma, inverted papilloma)
- History of failed balloon procedure in the sinus to be treated
- Isolated ethmoid sinus disease.

Balloon Ostial Dilation (BOD)/Balloon Sinuplasty when utilized in combination with Functional Endoscopic Sinus Surgery (FESS)

Balloon Ostial Dilation (BOD) (balloon sinuplasty) may be performed as a stand-alone procedure or as a tool during functional endoscopic sinus surgery (FESS). When balloon ostial dilation (BOD) (balloon sinuplasty) is used with functional endoscopic sinus

surgery (FESS) in the same sinus cavity, it is considered to be an integral part of the primary procedure (FESS procedure) and not separately reimbursable.

Balloon Ostial Dilation (BOD) (balloon sinuplasty) may be utilized as an adjunct to functional endoscopic sinus surgery (FESS), defined as functional endoscopic sinus surgery (FESS) on one sinus and balloon ostial dilation (BOD) (balloon sinuplasty) on another sinus in the same patient during the same operation, and the medical necessity criteria above for balloon ostial dilation (BOD) (balloon sinuplasty) will apply to the sinus being considered for balloon ostial dilation BOD (balloon sinuplasty).

Policy Guidelines

Required Documentation
Documentation supporting the medical necessity criteria described in the policy must be included and submitted:

- Clinical notes describing the following:
    - Signs/symptoms of chronic or acute rhinosinusitis including duration of symptoms; **and**
    - Work up that has excluded other etiologies for sinus symptoms; **and**
    - Specific treatments, including duration and results.
- Reports of the sinus computerized tomography (CT) imaging and nasal endoscopy performed after all maximum medical therapy.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 31295 Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
- 31296 Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
- 31297 Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
- 31298 Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia
- 31299 Unlisted procedure, accessory sinuses
- C1726 Catheter, balloon dilatation, nonvascular

SELECTED REFERENCES

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POLICY HISTORY

Date	Reason	Action
October 2022	Annual Review	Policy Revised
October 2021	Annual Review	Policy Revised
October 2020	Annual Review	Policy Revised
June 2020	Annual Review	Policy Revised
October 2019	Annual Review	Policy Revised
October 2018	Annual Review	Policy Revised
April 2018	Interim Review	Policy Revised
October 2017	Annual Review	Policy Renewed
October 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
December 2014	Annual Review	Policy Revised
April 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Renewed
January 2013	Annual Review	Policy Renewed
January 2012	Annual Review	Policy Renewed
January 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
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