07.01.31 Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

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Related Policies:

- 07.01.82 Steroid-Eluting Sinus Stents and Implants
- 07.01.83 Treatment of Nasal Valve Collapse

Summary

Description

Balloon ostial dilation (BOD, also known as balloon sinuplasty) is proposed as an alternative to functional endoscopic sinus surgery (FESS) for individuals 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. *This evidence review addresses BOD as a standalone procedure.*

Summary of Evidence

For individuals with CRS who receive BOD as a stand-alone procedure, the evidence includes systematic review, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, change in disease status, quality of life (QOL), and treatment-related morbidity. A meta-analysis of 14 RCTs found BOD patients had lower postoperative Sino-Nasal Outcome Test (SNOT-20) scores, shorter operating time, and lower postoperative complications compared with functional endoscopic sinus surgery (FESS). However, there was no difference between groups in revision surgery or Lund-Mackay scores. A meta-analysis of three studies indicated a statistically significant yet not clinically significant preference for BOD over FESS in terms of patient-related QOL. The REMODEL RCT confirmed that BOD was not inferior to FESS for treating chronic rhinosinusitis, with the effect's durability observed over 24 months. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in individuals who underwent BOD (n=2851) or FESS (n=11,955), the overall complication rate was 5% with BOD and 7% with FESS. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with RARS who receive BOD as a stand-alone procedure, the evidence includes a systematic review and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review on RARS management identified two (of 10) studies focused on BOD as a treatment modality. Although an improvement in quality of life was observed across both studies, the small sample sizes, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis. In the REMODEL RCT, 32% of participants (N=29) with RARS were diagnosed. BOD was found to be non-inferior to FESS in terms of quality of life at both 6 and 12 months post-procedure. Another RCT, CABERNET, comparing BOD plus medical care to medical care alone in individuals with RARS (N=59), demonstrated significantly improved quality of life and fewer sinus infections after 6 months in the balloon dilation group. The current body of evidence is limited by small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of this evidence review is to evaluate whether BOD improves the net health outcome for individuals with CRS or RARS.

PRIOR APPROVAL

Not applicable.

POLICY

Use of a catheter-based inflatable device (balloon ostial dilation) as a standalone procedure for the treatment of chronic rhinosinusitis (CRS) in the sinus being considered for dilation may be considered **medically necessary** when **ALL** the following criteria are met:

- Individual is 18 years of age or older (*See Policy Guidelines for younger ages*)
- Chronic rhinosinusitis (CRS) without nasal polyps that negatively impacts quality of life, characterized by at least 2 of the following signs or symptoms, and 1 of which is (a) or (b) present for at least 12 continuous weeks:
    a. Mucopurulent nasal drainage (anterior, posterior, or both)
    b. Nasal obstruction (congestion)
    c. Facial pain, pressure and/or fullness
    d. Decreased sense of smell
- Has tried and failed medical management as indicated by **ALL** the following:
    - Allergy evaluation, education and optimal treatment when indicated;
    - Decongestant when indicated;
    - Topical 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 duration;
    - 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:
    - Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoid ethmoid region; **and**
    - Abnormal CT scan of the paranasal sinuses (see Policy Guidelines).

Note: *for BOD used in combination with functional endoscopic sinus surgery (FESS):*

- *BOD when used as a tool during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the FESS procedure and not separately reimbursable.*
- *When BOD is used as an adjunct to FESS (defined as FESS on 1 sinus and BOD on another sinus in the same individual during the same operation) the above criteria for BOD apply to the sinus being considered for BOD.*

The use of balloon ostial dilation (BOD) for the treatment of chronic rhinosinusitis (CRS) is considered **investigational** when the above criteria are not met because the evidence is insufficient to determine that the technology results in an improvement in net health outcomes.

The use of balloon ostial dilation (BOD) for the treatment of recurrent acute rhinosinusitis (RARS) is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in net health outcomes.

POLICY GUIDELINES

Required Documentation

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

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

Abnormal CT-Scan

According to the 2015 American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) guideline on adult sinusitis, abnormal findings on CT imaging may include moderate-to-severe mucosal thickening, opacification, or air-fluid levels. A subsequent consensus statement on balloon dilation of the sinuses published by the AAO-HNS in 2018 states: "The requirement of objective evidence of inflammation in addition to sinonasal symptoms suggestive of rhinosinusitis is consistent with AAO-HNSF [AAO-HNS Foundation] diagnostic criteria for rhinosinusitis. However, evidence of inflammation or other findings on a CT scan was not deemed sufficient alone to make a patient a candidate for balloon dilation. The consensus that both symptoms and objective evidence of sinonasal disease are needed to deem a patient appropriate for a SOD [sinus ostial dilation] procedure is also reflected in many of the randomized clinical trials involving balloon dilation. The inclusion criteria for many of these trials require that the patient be deemed appropriate for conventional sinus surgery, which includes a trial of medical therapy and the presence of sinonasal symptoms in addition to objective evidence of sinus mucosal inflammation. On the surface, this statement may seem incompatible with the guidelines that mandate the presence of objective findings but do not specify which objective findings those are (i.e., polyps, purulence, or CT findings) for the diagnosis of CRS. However, the panel felt that the transition from diagnosis to management requires additional information. In that vein, a CT scan is necessary before proceeding with surgical management, and the findings of that CT scan would direct which sinuses were to be addressed. It was also agreed that an improved taxonomy for the classification of sinusitis would be helpful to improve the quality of clinical research."

Considerations for the use of BOD in Children under age 18 years Including the Following:

- U.S. Food and Drug Administration 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.
- A 2014 AAO-HNS Clinical Consensus Statement on Pediatric Chronic Rhinosinusitis had near consensus on the safety of BOD in children but did not reach a consensus on efficacy.
- American Academy of Pediatrics Clinical Practice Guidelines only address the diagnosis and treatment of acute bacterial rhinosinusitis.

Coding

See the Codes table for details.

BACKGROUND

Rhinosinusitis

Rhinosinusitis can be classified according to the duration of symptoms. Acute rhinosinusitis lasts fewer than 4 weeks, while subacute sinusitis lasts between 4 and 12 weeks. Chronic rhinosinusitis (CRS) lasts more than 12 weeks. Recurrent acute rhinosinusitis (RARS) is defined as experiencing 4 or more episodes of acute rhinosinusitis per year and without persistent symptoms in between individual episodes. Rhinosinusitis affects 1 in 8 adults and accounts for 20% of antibiotic prescriptions. A longitudinal analysis of a medical claims database from 2003-2008 showed that 1 in 3,000 individuals had RARS, with 72% being female and an average age of 43.5 years. Individuals had an average of 5.6 healthcare visits and 9.4 prescriptions annually.

Chronic Rhinosinusitis

CRS is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults. In adults, CRS is characterized by symptoms related to nasal and sinus obstruction and inflammation, including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

Three CRS subtypes exist and may have somewhat different treatment strategies: CRS without nasal polyposis; CRS with nasal polyposis; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This evidence review focuses on the more common subtypes: CRS with and without nasal polyposis. Both subtypes present with similar symptoms. However, CRS with nasal polyposis is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyposis is more likely to be associated with asthma and aspirin intolerance; this triad is referred to as Samter syndrome or aspirin-exacerbated respiratory disease.

Chronic rhinosinusitis is associated with impaired quality of life for affected patients, and with high direct and indirect costs for medical treatments and lost productivity. Most often, the negative health effects of CRS are related to the unpleasant symptoms associated with CRS, including nasal congestion, nasal drainage, and facial pain or pressure. In rare cases, CRS can be associated with serious complications, including orbital cellulitis, osteomyelitis, or intracranial extension of infection.

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria. On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in patients with and without CRS found a quantitative increase in bacterial and fungal RNA expression in patients with CRS, but no major differences in the types of microorganisms detected. Bacterial biofilms have been identified in cases of CRS.

Recurrent Acute Rhinosinusitis

RARS is defined as having four or more episodes of acute bacterial rhinosinusitis per year, with no symptoms between episodes. Diagnosis is primarily based on medical history and physical examination, following the guidelines of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Because other diseases can present with similar symptoms, it is important to consider various differential diagnoses. Nasal endoscopy is recommended for severe, one-sided, or persistent cases without septal deviation. Routine radiological imaging is generally not necessary for uncomplicated RARS, but noncontrast CT scans are crucial for chronic cases, suspected anatomical problems, or when planning surgeries like balloon ostial dilation (BOD) or functional endoscopic sinus surgery (FESS). The outlook for RARS is usually positive, with most patients responding well to treatments such as topical nasal sprays and oral antibiotics. It is rare for patients to need hospitalization, surgery, or intravenous antibiotics for complications. BOD has been proposed as a viable treatment option to provide symptom relief and an improved quality of life.

Medical Therapy

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

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, monoclonal antibodies, and/or antibiotic therapy. Guidelines from the AAO-HNS (2015) recommend the use of saline nasal irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs). There is a specific recommendation against the use of topical and systemic antifungal therapies. The guidelines recommend against routine use of antimicrobial therapy for CRS without exacerbation.

In 2019, the U.S. Food and Drug Administration (FDA) approved the first treatment for CRS with nasal polyps - dupilumab (Dupixent®). Results from clinical trials revealed that patients who received dupilumab "had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group" and also "reported an increased ability to smell and required less nasal polyp surgery and oral steroids." This was followed by the approval of omalizumab (Xolair®) in 2020 as add-on maintenance treatment for adults with nasal polyps with an inadequate response to nasal corticosteroids. In 2021, mepolizumab (Nucala®) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps. Tezepelumab was approved in 2025 as add-on maintenance treatment of adults and pediatric patients 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps.

The mainstay of treatment for RARS is medical management, which often involves a multifaceted therapeutic approach. Patients typically benefit from a range of treatments aimed at different aspects of RARS's complex pathophysiology. These may include topical intranasal therapies, antibiotics, decongestants, oral antihistamines, steroids, and leukotriene modifiers.

Functional Endoscopic Sinus Surgery

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and preventing the effective delivery of local medical therapies. In addition, to varying degrees, surgical techniques involve the creation of open sinus cavities, usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

Techniques for FESS, in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. FESS has largely replaced various open techniques for CRS (e.g., Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (e.g., endonasal tumors). FESS encompasses a variety of degrees of sinus access and tissue removal and is described based on the sinuses accessed. This procedure can also be used to access the ethmoid sinuses, which may involve creation of drainage into the maxillary sinuses (maxillary antrostomy).

Balloon Ostial Dilation

BOD can be used as an alternative or as an adjunct to 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 evidence review is limited to BOD when used 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.

Regulatory Status

In 2008, the Relieva™ Sinus Balloon Catheter (Integra LifeSciences, Formerly Acclarent Inc.) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. 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 cleared by FDA through the 510(k) process (see Table 1 below).

In 2008, the FinESS™ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach (FDA product code: EOB). The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices, the ENTrigue® Sinus Dilation System (Smith and Nephew, formerly ENTrigue Surgical), and the XprESS™ Multi-Sinus Dilation Tool (Stryker, formerly Entellus Medical), also received 510(k) clearance in 2012.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (Smith & Nephew), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses,

sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach. Ventera™ Sinus Dilation System does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery.

Table 1 summarizes a selection of FDA cleared balloon sinus dilation devices.

FDA product code: LRC.

Table 1. Balloon Ostial Dilation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	510(k) No.	Date Cleared	Indication
Relieva Ultirra Sinus Balloon Catheter	Acclarent, Inc.	K190525	05/03/2019	Sinus Ostia Dilation
Sinusway Dilation System	3NT Medical Ltd.	K181838	12/20/2018	Sinus Ostia Dilation
MESIRE - Balloon Sinus Dilatation System	Meril Life Sciences	K172737	12/12/2017	Sinus Ostia Dilation
Relieva SpinPlus Nav Balloon Sinuplasty System	Acclarent, Inc.	K171687	10/13/2017	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

RATIONALE

This evidence review was created in May 2006 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through March 2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to

function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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

Clinical Context and Therapy Purpose

The purpose of balloon ostial dilation (BOD) as a stand-alone procedure in individuals 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).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals 18 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.

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, QOL, 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 CRS are patient-reported symptoms and QOL. 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 QOL 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review

Liang et al (2025) conducted a meta-analysis comparing BOD and FESS for CRS. A total of 14 RCTs were included. Compared with FESS, BOD patients had lower postoperative SNOT-20 scores, shorter operating time, and lower postoperative complications. There was no difference between groups in revision surgery or Lund-Mackay scores. The characteristics and results are summarized in Tables 2 and 3, respectively.

Sinha et al. (2023) conducted a systematic review and meta-analysis to assess the efficacy of BOD in comparison to FESS or medical management for CRS. The qualitative review included 18 studies published up to July 2021, with seven of these included in the meta-analysis. Data necessary for the meta-analysis, specifically for differences in means with 95% CIs between BOD and FESS groups, were fully reported by only two RCTs (Achar et al., 2012; Cutler et al., 2013) and one cohort study (Friedman et al., 2008). A random-effects model meta-analysis of these three studies (n=186 patients; 97 BOD, 89 FESS) revealed a pooled mean difference of 0.435 (95% CI, 0.054 to 0.817), showing a statistically

significant preference for BOD over FESS, although it fell short of the clinically meaningful difference of 0.8 in mean SNOT-20 scores.

A sensitivity analysis was conducted on seven studies, incorporating four additional studies with imputed standard deviation (N=463; 204 BOD, 259 FESS). This analysis, performed for changes in mean scores from baseline across four different correlation coefficients (0.1, 0.3, 0.5, and 0.8), yielded pooled estimates of the difference in means (95% CI) as follows: 0.221 (-0.001 to 0.443), 0.213 (0.00 to 0.426), 0.203 (0.002 to 0.403), and 0.175 (0.008 to 0.343), respectively. Secondary outcomes, including but not limited to Lund-Mackay scores, postoperative sinus infections and olfactory function, were reported inconsistently and thus could not be analyzed. Both study groups exhibited low rates of complications and revision surgeries. Among the complications associated with BOD, reported more frequently in three studies, were synechiae, turbinate lateralization, and scarring. Findings from this systematic review indicate a statistically significant but not clinically significant greater increase in SNOT-20 scores following BOD in comparison to FESS. However, significant heterogeneity and inconsistency in the reporting of eligibility criteria, baseline characteristics, follow-up, and outcomes across studies prevent drawing definitive conclusions regarding patient-related quality of life between the two procedures.

Table 2. Systematic Review of Balloon Ostial Dilation for Chronic Rhinosinusitis-Characteristics

Study	Search Dates	Studies	Participants	N (Range)	Design	Duration
Liang et al (2025)	To October 7, 2024	14 RCTs	CRS patients who had not responded to drug therapy	1060 (24-148)	RCT	3 to 12 months
Sinha et al (2023)	2001-2021	18 (7 provided data for meta-analysis)	Adults >18 years with chronic or recurrent sinusitis that reported BOD outcomes and had traditional FESS, no treatment, or medical therapy as the comparator	737 (10-146)	RCT (n=9) Cohort (n=9)	Varied (3-months to >10 years)

BOD: balloon ostial dilation; CRS: chronic rhinosinusitis; RCT: randomized controlled trial; N: sample size

Table 3. Systematic Review of Balloon Ostial Dilation for Chronic Rhinosinusitis-Results

Study			
Liang et al (2025)	**Quality of Life (SNOT-20)**	**Revision Surgery**	**Complications**
N analyzed	593	234	284
SMD/OR (95% CI; p-value)	SMD: -0.25 (-0.42 to -0.07; p=.005)	OR: 0.51 (0.12 to 2.21; p=.37)	OR: 0.14 (0.08 to 0.26)
Sinha et al (2023)	Quality of Life (SNOT-20): BOD vs FESS	Quality of Life (SNOT-20): Improvement from baseline	
N analyzed	186	463	

Study			
Pooled effect (95% CI)	mean difference = 0.435 (0.054 to 0.817)[a]	• 0.221 (-0.001 to 0.443)[b] • 0.213 (0.00 to 0.426)[b] • 0.203 (0.002 to 0.403)[b] • 0.175 (0.008 to 0.343)[b]	

CI: confidence interval; BOD: balloon ostial dilation; FESS: functional endoscopic sinus surgery; OR: odds ratio; SMD: standardized mean difference; SNOT-20: Sino-Nasal Outcome Test-20.
[a] where 0.8 is the clinically meaningful difference in SNOT-20 scores; [b] based on Correlation Coefficient of 0.1, 0.3, 0.5 and 0.8, respectively.

Randomized Controlled Trials

BOD as a standalone procedure for patients with CRS has been assessed through multiple RCTs. The largest RCT is the REMODEL trial (Randomized Evaluation of Maxillary Antrostomy Versus Ostial Dilation Efficacy Through Long-Term Follow-Up). The trial's findings have been documented at 6, 12, and 24 months post-procedure across three separate publications. The above Sinha et al (2023) systematic review included the REMODEL trial results at 6 and 24 months, highlighting the procedure's efficacy and long-term outcomes.

REMODEL was the largest 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 debridements 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, and 1 patient in each group required revision surgery.

Bikhazi et al (2014) 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 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.

In addition to REMODEL, 3 smaller RCTs provide evidence on the comparison of BOD to FESS in patients with CRS. The studies were included in the Sinha et al (2023) meta-analysis, and are not further summarized.

Table 4. REMODEL Trial of Balloon Ostial Dilation Compared to Functional Endoscopic Sinus Surgery in Chronic Rhinosinusitis: Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
REMODEL • NCT01525849 • (6-month data) • (12-month data) • (24-month data)	US	10	2011-2014	135 adults with medically refractory chronic (68%) or recurrent acute (32%) rhinosinusitis according to AAO-HNS clinical practice guidelines; all met criteria for medically necessary FESS. Patients with nasal polyps were excluded.	• BOD (office setting) • N=74	• FESS (operating room) • N=61

REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up; RCT: randomized controlled trial; BOD: balloon ostial dilation; FESS: functional endoscopic sinus surgery; CRS: chronic rhinosinusitis; NCT: National Clinical Trial; AAO-HNS: American Academy of Otolaryngology – Head and Neck Surgery; N: sample size; RARS: recurrent acute rhinosinusitis

Table 5. REMODEL Trial of Balloon Ostial Dilation Compared to Functional Endoscopic Sinus Surgery in Chronic Rhinosinusitis: Results

Study	Quality of Life	Symptoms	CT Scan Results	Adverse Events
Outcome measure Number analyzed	Mean change from baseline in SNOT-20 score N=91 at 6 months, 89 at 12 months	Time to return to normal daily activities	Overall Ostial Patency N=89 patients, 169 ostia	
REMODEL				

Study	Quality of Life	Symptoms	CT Scan Results	Adverse Events
• NCT01525849 • (6-month data) • (12-month data) • (24-month data)				
BOD	6 months: 1.67 (1.10) 12 months: 1.64 (1.06) 24 months: -1.65	1.6 days	6 months: NR 12 months: 96.7% (88/91)	No complications 28.0% nasal bleeding 1 (2.1%) revision surgery through 1 year
FESS	6 months: 1.60 (0.96) 12 months:1.65 (0.94) 24 months: -1.45	4.8 days	6 months: NR 12 months: 98.7% (77/78)	No complications 54.8% nasal bleeding 1 (2.4%) revision surgery through 1 year
Between-group p-value	6 months: P < 0.001 12 months): 0.01 (95% CI -0.43 to 0.44); BOD noninferior to FESS (*P* <.0001) 24 months: P < .0001	0.002	12 months: *P* = NS	Nasal bleeding: *P* =.011

REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up; RCT: randomized controlled trial; BOD: balloon ostial dilation; FESS: functional endoscopic sinus surgery; SNOT-20: Sino-Nasal Outcome Test-20; NR: not reported

Tables 6 and 7 summarize the limitations of the REMODEL trial of BOD in individuals with CRS. A major limitation of these trials was a lack of blinding, combined with the use of subjective outcome measures, and small sample sizes. However, objective measures (CT findings), additional evidence from observational studies, and consistency and magnitude of effects across studies make these limitations less concerning.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
REMODEL	3. Source and characteristics of subjects added to the study for final results was unclear	1.Randomization of added subjects occurred outside of key study			1. Differential loss post-randomization between study arms

REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered

effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
REMODEL		1, 2. Not blinded				

REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Study of Adverse Events

A retrospective cohort study 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) between 2011 and 2014. The primary outcomes were surgical complication and revision rates within 6 months of the initial surgery. The overall complication rate was 7.35% with FESS and 5.26% with balloon dilation. The 6-month revision rates for balloon dilation, FESS, and hybrid surgeries were 7.89%, 16.85%, and 15.15%, respectively. Almost all revisions occurred with FESS regardless of primary procedure. However, differences in revision rates could have been due to differences in disease severity in patients who received FESS versus balloon dilation. Major complications included orbital complications, cerebrospinal fluid leak, severe epistaxis, and requirement for revision.

Section Summary: Balloon Ostial Dilation as a Stand-Alone Procedure for Individuals with Chronic Rhinosinusitis

Two meta-analyses have been conducted comparing BOD to FESS. A 2025 meta-analysis identified 14 RCTs and found BOD patients had lower postoperative SNOT-20 scores, shorter operating time, and lower postoperative complications. However, there was no difference between groups in revision surgery or Lund-Mackay scores. A 2023 meta-analysis of three studies indicated a statistically significant yet not clinically significant preference for BOD over FESS in terms of patient-related quality of life. The REMODEL RCT confirmed that BOD was not inferior to FESS for treating chronic rhinosinusitis, with the effect's durability observed over 24 months. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in individuals who underwent BOD (n=2851) or FESS (n=11,955), the overall complication rate was 5% with BOD and 7% with FESS.

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

Clinical Context and Therapy Purpose

The purpose of balloon ostial dilation (BOD) as a stand-alone procedure in individuals 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,

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals 18 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. Each episode of acute bacterial rhinosinusitis should meet the following diagnostic criteria:

- RARS 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 RARS 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 BOD as a stand-alone procedure. The procedure involves placing a balloon in the sinus ostium and inflating it to stretch the opening.

Comparators

Comparators of interest include medical management and FESS.

Outcomes

The general outcomes of interest are symptoms, change in disease status, QOL, 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 QOL. 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 QOL 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 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 sub scores 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.

The Rhinosinusitis Disability Index (RSDI) is a patient-reported questionnaire used to measure the impact of rhinosinusitis on a person's quality of life. The RSDI is a 30-item, Likert-scale survey consisting of three individual subscales that include the physical, functional, and emotional domains. Total scores range between 0–120. Higher RSDI total and domain scores imply a higher impact of disease.

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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Saltagi et al. (2021) conducted a systematic review on RARS management, analyzing ten studies published up to mid-2020 with a collective sample of 890 patients (mean age, 41 years) and follow-up periods from 1 to 19 months. BOD was utilized as a treatment modality in two studies: Levine et al. (2013) treated 16 RARS patients with BOD, observing a 1.2-point improvement in SNOT-20 scores over 12 months and five fewer missed workdays on average. Sikand et al. (2019) conducted a multi-center RCT (CABERNET) on 59 RARS patients and found that the BOD plus medical management group showed a significantly greater improvement in CSS total scores from baseline to 24 weeks compared to the medical

management-only group (37.3 ± 24.4 vs 21.8 ± 29.0; p=.04) (see below). The limited sample size, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis.

Randomized Controlled Trials

Two RCTs of BOD reported results separately for patients with RARS (REMODEL, CABERNET; Table 8).

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 are summarized in Table 9. 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 (2014). 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), (CABERNET), 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.

Table 8. Summary of Key Randomized Controlled Trial Characteristics – Balloon Ostial Dilation for Recurrent Acute Rhinosinusitis

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
REMODEL	US	10	2011-2014	Adults with medically refractory chronic	• BOD (office setting)	• FESS (operating room)

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
• NCT01525849 • (6 month data) • (12-month data) • (24-month data)				(68%) or recurrent acute (32%) rhinosinusitis according to AAO-HNS clinical practice guidelines; all met criteria for medically necessary FESS	• N=16	• N=13
Sikand et al (2019) • CABERNET • NCT01714687	US	3	2013-2015	Adults with a diagnosis of recurrent acute rhinosinustiis, defined as having 4 or more episodes of acute bacterial rhinosinusists within the previous 12 months, characterized by signs or symptoms of acute rhinosinusitis 10 or more days beyond the onset of upper respiratory symptoms, or within 10 days after initial improvement (double worsening)	• BOD plus medical management • N=29	• Sham procedure plus medical management • N=30

RCT: randomized controlled trial.

Table 9. Summary of Key Randomized Controlled Trial Results- Balloon Ostial Dilation for Recurrent Acute Rhinosinusitis

Study	Quality of Life	Acute Exacerbations	Adverse Events
REMODEL • NCT01525849			

Study	Quality of Life	Acute Exacerbations	Adverse Events
Outcome measure • Number analyzed	• Mean change from baseline in SNOT-20 score • N=29	Mean number per year, year before to year after treatment	NR separately for patients with RARS
BOD	• 6 months: (RARS subgroup): -1.57 (±1.08); *P* <.0001 • 12 months: Data not reported separately for patients with RARS. "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." • 24 months: NR separately for patients with RARS	• 5.1 to 0.9 • *P* < 0.0001	
FESS	• 6 months (RARS subgroup): -1.64 (±0.90); *P* <.0001 • 24 months: NR separately for patients with RARS	• 4.5 to 0.8 • *P* < 0.0001	
Between-group p-value	• 6 months:.838	• .258	
Sikand et al (2019) • CABERNET • NCT01714687			
Outcome measure • Number analyzed	• Mean change in CSS Score at 24 weeks • N=59	• Mean number of post-enrollment sinus infections, 24 weeks • N=59	• N=59

Study	Quality of Life	Acute Exacerbations	Adverse Events
BOD + medical management	• Total score: 37.3 (SD 24.4) • Symptom subscore: 48.7 (SD 28.7) • Medication subscore: 26.0 (SD 26.6)	• 0.2 (0.4)	• 1 serious procedure-related adverse event (headache leading to hospital admission) • No device-related adverse events • Nonserious AEs: 58.6%
Sham + medical management	• Total score: 21.8 (29.0) • Symptom subscore: 27.2 (40.1) • Medication subscore: 16.4 (24.0)	• 0.9 (0.9)	• Nonserious AEs: 60.0%
Between-group p-value	• Total score:.0424 • Symptom subscore:.0484 • Medication subscore:.2607	• .0015	• Nonserious AEs: *P* = NS

CI: confidence interval; HR: hazard ratio; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk.

Tables 10 and 11 summarize the limitations of the RCTs of BOD in individuals with RARS. Major limitations include no blinding of outcome assessors, a very small number of patients studied, and variation in the comparators and outcome measures used across the studies.

Table 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
REMODEL	3. Some outcomes not reported separately by diagnosis of RARS	1.Randomization of added subjects occurred outside of key study			1. Differential loss post-randomization between study arms
Sikand et al (2019) • CABERNET			Medical regimen not standardized (customized by the treating investigator)	5. Clinically significant difference on primary outcome (CSS) not specified	

CABERNET: Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients; REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not

representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
REMODEL		1, 2. Not blinded			Not powered to detect differences by RARS subgroup	
Sikand et al (2019) CABERNET		2. Patients, but not outcome assessors, blinded				4. Confidence intervals not reported

CABERNET: Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients; REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Balloon Ostial Dilation as a Standalone Procedure for Individuals with Recurrent Acute Rhinosinusitis

A systematic review on RARS management identified two (of 10) studies focused on BOD as a treatment modality. Although an improvement in quality of life was observed across both studies, the small sample sizes, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis. In the REMODEL RCT, 32% of participants (N=29) with RARS were diagnosed. BOD was found to be non-inferior to FESS in terms of quality of life at both 6 and 12 months post-procedure. Another RCT, CABERNET, comparing BOD plus medical care to medical care alone in individuals with RARS (N=59), demonstrated significantly improved quality of life and fewer sinus infections after 6 months in the balloon dilation group. The current body of evidence is limited by small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology – Head and Neck Surgery

In 2018, the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses. Participating subgroups included the Triologic Society, the American Rhinologic Society, the American Academy of Otolaryngic Allergy, and the American Academy of Allergy, Asthma & Immunology. The expert panel used Delphi method surveys to assess consensus on proposed statements. Statements achieving a mean score of 7.00 or higher and having no more than 1 outlier (2 or more LIkert points from the mean in either direction) met criteria for consensus. Strong consensus was defined as a mean Likert score of 8.00 or higher with no outliers. The following statements met consensus; statements reaching strong consensus are **emphasized** below**.**

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 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 any setting as long as proper precautions are taken and appropriate monitoring is performed.
- 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. The AAO-HNS updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: “Sinus ostial dilation … is a therapeutic option for selected patient with chronic rhinosinusitis…. This approach may be used alone... or in conjunction with other instruments….” (Most recent revision with references added, 4/13/2021)

In 2025, the AAO-HNS updated its clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty. However, surgical therapy is addressed in 2025 guidelines on chronic rhinosinusitis from AAO-HNS, but these guidelines do not address balloon sinuplasty.

American Rhinologic Society

A position paper (2023), from American Rhinologic Society (ARS) stated that sinus ostial dilation is “a therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy.”

National Institute for Health and Care Excellence

In 2008 (reaffirmed in 2012), a guidance on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Care Excellence (NICE) stated:

- "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns.
- This procedure should only be carried out by surgeons with experience of complex sinus surgery, and specific training in both the procedure and the use of fluoroscopy.
- Publication of long-term outcomes will be helpful in guiding the future use of this technique. NICE may review the procedure upon publication of further evidence."

In 2016, 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 anesthesia.”

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. This guidance was reaffirmed in July 2020.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
	31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)

Codes	Number	Description
	31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)
	31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)
	31299	Unlisted procedure, accessory sinuses (may be utilized for balloon ostial dilation [BOD])
HCPCS		
	C1726	Catheter, balloon dilatation, non-vascular (may be utilized for balloon ostial dilation [BOD])
Type of Service	Surgery	
Place of Service	Outpatient	

POLICY HISTORY

Date	Action	Action
April 2026	Annual Review	Policy Renewed
April 2025	Annual Review	Policy Renewed
April 2024	Annual Review	Policy Renewed
April 2023	Annual Review	Policy Revised
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

Date	Action	Action
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:

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Medical Policy Analyst
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