Policy Number	**SUR706.019**
Policy Effective Date	**10/15/2024**
Policy End Date	**12/31/2025**

Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

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Related Policies (if applicable)
None

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Coverage

Balloon Ostial Dilation in Adults
Use of a catheter-based inflatable device (balloon ostial dilation) for the treatment of chronic rhinosinusitis in the sinus being considered for dilation **may be considered medically necessary** when the following criteria are present:

- Individual is 18 years of age or older; **AND**
- Chronic rhinosinusitis that negatively impacts quality of life, characterized by at least two of the following, at least one 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-fullness;
  d) Decreased sense of smell; **AND**
- Optimal medical therapy (e.g., allergy evaluation and treatment; course(s) of antibiotics; decongestants; topical and/or systemic corticosteroids; saline nasal irrigation; treatment of

rhinitis medicamentosa [rebound nasal congestion due to extended use of topical decongestants]; education on environmental irritants including tobacco smoke) has been attempted and failed; **AND**

- Clinical and radiographic documentation of persistent inflammation following optimal medical therapy documented by either of the following:
  1. Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoethmoid region; **OR**
  2. CT scan of the paranasal sinuses showing mucosal thickening, opacification, or air-fluid levels.

The use of balloon ostial dilation for the treatment of chronic rhinosinusitis **is considered experimental, investigational and/or unproven** when the above criteria are not met.

The use of balloon ostial dilation for the treatment of recurrent acute rhinosinusitis **is considered experimental, investigational and/or unproven.**

Balloon Ostial Dilation in Children
The use of an FDA-approved balloon ostial dilation device specified for children (age 17 and under) **may be considered medically necessary** as a minimally invasive alternative to functional endoscopic sinus surgery for medically refractory chronic sinusitis (See **NOTE 1**) when treating the maxillary sinus space.

The use of an FDA-approved balloon ostial dilation device specified for children (age 17 and under) **is considered experimental, investigational and/or unproven** as a minimally invasive alternative to functional endoscopic sinus surgery for the treatment of medically refractory chronic sinusitis in all other sinus spaces except the maxillary sinus space.

NOTE 1: Pediatric chronic rhinosinusitis is defined as: At least 90 continuous days of two or more of the following symptoms:

- Purulent rhinorrhea;
- Nasal obstruction;
- Facial pressure/pain; or
- Cough.

AND <u>either</u>:

a) Endoscopic signs of mucosal edema; OR
b) CT scan showing mucosal changes within the osteomeatal complex and/or sinuses in a pediatric patient.

Policy Guidelines

None.

Description

Balloon ostial dilation (BOD, also known as balloon sinuplasty) is proposed as an alternative to functional endoscopic sinus surgery (FESS) for individual 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.

Chronic and Recurrent Acute Rhinosinusitis

Chronic rhinosinusitis (CRS) is characterized by purulent nasal discharge, usually without fever, that persists for weeks to months. 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 the sinus ostia.

Recurrent acute rhinosinusitis (RARS) is defined as 4 or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes.

Medical Treatment

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics). (1) Additionally, an anti-interleukin-5 (IL-5) monoclonal antibody (mAb), mepolizumab, received FDA-approval in July 2021 as an add-on maintenance treatment for chronic rhinosinusitis with nasal polyps. (2) Previously in 2019, the FDA approved the interleukin-4 receptor alpha antagonist dupilumab as an add-on maintenance treatment in adults with inadequately controlled chronic rhinosinusitis with nasal polyps. (3)

Functional Endoscopic Sinus Surgery

FESS involves the insertion of an endoscope into the nose for a direct visual examination of the openings into the sinuses. Using the endoscope and a combination of surgical tools (e.g., curettes, forceps, powered micro-debriders, powered shavers, and/or sinus balloon catheters), surgeons enlarge the patient's sinus openings to clear passageways in order to restore normal sinus ventilation and drainage. The goal of surgery is to improve sinus ventilation and drainage by enlarging the openings of the sinuses, removing any polyps and correcting significant structural problems that may be hindering drainage.

The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinate process. An alternative approach to the maxillary ostia is through the sinus, via the canine fossa. A guidewire can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinate process.

Approximately 350,000 FESS procedures are done each year in the United States for CRS.

Balloon Ostial Dilation

Balloon ostial dilatation (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. (27)

BOD may also be used in combination with FESS. (4, 5) 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 one sinus and FESS on another sinus in the same patient during the same operation.

Regulatory Status

In 2008, the Relieva® Sinus Balloon Catheter (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been cleared by the FDA through the 510(k) process. They include the Relieva Spin Sinus Dilation System® (cleared in 2011) and the Relieva Seeker Balloon Sinuplasty System® (cleared in 2012).

In 2008, the FinESS™ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by the FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid 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 (ENTrigue Surgical, acquired by Smith & Nephew), and the XprESS™ Multi-Sinus Dilation Tool, 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 the 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. (4)

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 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 medical policy was created in 2021 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 29, 2024.

Medical policies 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 Patients with Chronic Rhinosinusitis

Clinical Context and TherapyPurpose

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 policy.

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.

Intervention

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, 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 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. (6)

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. (7) Although CT scans can provide an objective measure, often they do not correlate well with symptoms. (8)

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

<u>Study Selection Criteria</u>
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.

Systematic Review

Levy et al. (2016) conducted a systematic review and meta-analysis of BOD for CRS (Table 2). (9) Studies of BOD in combination with FESS were included if they reported data on subgroups of patients undergoing BOD as a standalone procedure. Reviewers included 17 studies; 11 of these provided data for meta-analysis. Two RCTs were included. The other studies were prospective or retrospective observational studies.

Results of the meta-analyses conducted by Levy et al. are summarized in Table 3. Change from baseline in quality of life, as measured by SNOT-20 scores was clinically and statistically significant in patients who received BOD. Secondary outcome measures of postoperative complications, debridements, and revision surgery were heterogeneously reported without the consistency or power needed to make statistically valid comparisons. The reviewers concluded that BOD for the treatment of CRS in the reported study population had positive impact on patient quality of life as assessed by a validated measurement. Improvements exceeded the threshold of 0.8 and could be considered clinically significant. The reviewers also concluded that additional information was needed to determine the role of BOD in specific patient populations such as those with moderate to advanced sinus disease, to compare the incidence of postoperative complications and debridements in patients who receive BOD compared with FESS, and additional study of patient outcomes following BOD in the operating room versus the office setting.

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

Study	Search Dates	Studies	Participants	N (Range)	Design	Duration
Levy et al. (2016) (9)	1996-2014	17 (11 provided data for meta-analysis)	Adults >18 years undergoing transnasal paranasal sinus BOD for CRS	1032 (6-328)	• RCT (n=2) • Prospective cohort (n=9) • Retrospective cohort (n=6)	Varied (<6 months to >1 year)

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	Quality of Life (SNOT-20)			CT Findings (Lund-McKay Score)	Recovery Time
Levy et al. (2016) (9)	Change from baseline ≤6 months	Change from baseline ≥1 year	BOD vs FESS	Improvement from baseline	• BOD vs FESS • Number days to return of regular activity

					following intervention
N analyzed	242	214	110	194	116
Pooled effect (95% CI)	1.45 (0.99, 1.91)	1.41 (1.07, 1.74)	-0.42 (-1.39, 1.55)	1.15 (0.87-1.43)	Weighted mean 1.72 days vs 4.84 days (P <.001)
I^2 (*P*-value)	78% (.001)	59% (.04)	76% (.04)	30% (.22)	NA

SNOT-20: Sino-Nasal Outcome Test-20; CT: computed tomography; BOD: balloon ostial dilation; FESS: functional endoscopic sinus surgery; N: sample size; CI: confidence interval

Randomized Controlled Trials

BOD as a standalone procedure for patients with CRS has been evaluated in 4 RCTs reported in 6 publications (Tables 2 and 3). Two studies were published after the systematic review conducted by Levy et al. (10, 11)

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. (10, 12, 13) This was an industry-sponsored RCT that compared BOD as a stand-alone procedure with FESS. A total of 105 patients with CRS or recurrent acute rhinosinusitis (RARS) and failure of medical therapy were randomized to BOD or FESS. Patients with gross sinonasal polyposis were excluded. BOD 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. (12) 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. (13) 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). (10) 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, three 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. (11) At three 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 BOD with FESS among patients with symptomatic chronic or recurrent acute rhinosinusitis. (6) 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 one 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 post-procedure. There were no differences in change in total SNOT-22 scores between groups at 3 months post-procedure.

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. (14) 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.

Table 4. RCTs of BOD compared to FESS in CRS: Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
REMODEL (10, 12, 13) 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
Minni et al. (2018) (11)	Italy	3	NR	102 adults (148 sinuses) with non-polypoid CRS according to European Position Paper on Rhinosinusitis (EPOS) (2012) criteria.	• BOD • N=69 sinuses	• FESS (DRAF I) • N=79 sinuses
Bizaki et al. (2014) (6)	Finland	1	NR	42 adults with CRS or RARS who fulfilled indications for surgical treatment. Patients with visible polyps in nasal direct endoscopy were excluded.	• BOD • N=21	• FESS • N=21
Achar et al. (2012) (14)	UK	2	NR	24 adults with CRS diagnosed as per EPOS guidelines who failed medical treatment (topical steroids for 12 weeks with or without antibiotics) and were proceeding to surgery. Patients	• BOD • N=12	• FESS • N=12

				with extensive nasal polyps were excluded.		

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; UK: United Kingdom; US: United States.

Table 5. RCTs of BOD Compared to FESS in CRS: 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 (10, 12, 13) 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: $P < 0.001$	0.002	12 months: P = NS	Nasal bleeding: P =.011

	12 months): 0.01 (95% CI -0.43 to 0.44); BOD noninferior to FESS (*P* <.0001) 24 months			
Minni et al. (2018) (11)				
Outcome measure Number analyzed	Mean decrease in SNOT-20 at 12 months mild: 105 sinuses severe: 33 sinuses		Mean decrease in Lund-McKay score at 12 months mild: 105 sinuses severe: 33 sinuses	102 patients
BOD	mild: 36.34 severe: 41.32		mild: 1.1 severe: 2.57	No major complications
FESS	mild: 38.0 severe: 36.57		mild: 1.03 severe: 2.29	No major complications
Between-group difference p-value	mild: *P* =.42 severe: *P* <.05		mild: *P* =.30 severe: *P* =.38	
Bizaki et al. (2014) (6)				
Outcome measure Number analyzed	Mean decrease in SNOT-22 from baseline to 3 months N=42		NR	N=42
BOD	21.47			No major complications 7 infection, 2 crusting, 2 synechia, 1 anosmia, 1 bleeding

FESS	20.95			No major complications 4 infection, 3 crusting, 6 synechia, 4 anosmia
Between-group difference p-value	*P* =.587			*P* >.05
Achar et al. (2012) (14)				
Outcome measure Number analyzed	Mean decrease in SNOT-22 from baseline to 6 months N=24	Mean time to get back to routine activities	NR	NR
BOD	43.83 (SD 15.17)	2.2 days		
FESS	29.66 (SD 12.33)	5.0 days		
Between-group difference p-value	*P* =.026	NR		

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 RCTs 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 patients added to the study for final results was unclear	1.Randomization of added patients occurred outside of key study			1. Differential loss post-randomization between study arms

Minni et al. (2018) (11)					
Achar et al. (2012) (14)					
Bikazi et al. (2014) (6)	3. Combined patients with CRS and RARS; results not reported separately by diagnosis				1, 2. three-month follow-up may be insufficient to assess benefits and harms

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 Complete-ness[d]	Power[e]	Statistical[f]
REMODEL		1, 2. Not blinded				
Minni et al. (2018) (11)	3. Method not described	1,2, 3. No information on blinding	1. Not registered		1. Power calculation not reported	Results reported by sinuses (N=148), not by patient (N=102)
Achar et al. (2012) (14)		1, 2. Not blinded	1. Not registered		1. Power calculation not reported; small sample	

					size (N=24)	
Bikazi et al. (2014) (6)	3. Method not described	1,2, 3. No information on blinding	1. Not registered		1. Power calculation not reported; small sample size (N=42)	

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 literature 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. (15) 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

Four RCTs have compared BOD to 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 Individuals with Recurrent Acute Rhinosinusitis

Clinical Context and Therapy Purpose

The purpose of 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 FESS.

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

Population

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. (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.

Intervention

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, 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. (16) 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.

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.

Randomized Controlled Trials

Two RCTs of BOD reported results separately for patients with RARS (Table 8). A third RCT, reported by Bizaki et al. (2014) compared BOD with FESS among patients with CRS or RARS, but results were not reported separately by diagnosis. (17) The study authors stated, "For this study, both CRS and RARS were considered to be one disease." This trial is discussed in the previous section on BOD for CRS.

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). (13) Data were not reported separately by diagnosis, but the publication states, "At 1 year, symptom improvement in each of the four 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. (18) 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 one 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), two possibly procedure-related nonserious adverse events, and no device-related adverse events.

Table 8. Summary of Key RCT Characteristics - Balloon Ostial Dilation for Recurrent Acute Rhinosinusitis

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
REMODEL (10, 12, 13) NCT01525849 (6-month data) (12-month data)	US	10	2011-2014	Adults with medically refractory chronic (68%) or recurrent acute (32%) rhinosinusitis	• BOD (office setting) • N=16	• FESS (operating room) • N=13

(24-month data)				according to AAO-HNS clinical practice guidelines; all met criteria for medically necessary FESS		
Sikand et al. (2019) (18) CABERNET NCT01714687	US	3	2013-2015	Adults with a diagnosis of recurrent acute rhinosinusitis, defined as having 4 or more episodes of acute bacterial rhinosinusitis 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=30	• Sham procedure plus medical manage-ment • N=29

AAO-HNS: American Academy of Otolaryngology – Head and Neck Surgery; CABERNET: Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients; RCT:

randomized controlled trial; REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up.

Table 9. Summary of Key RCT Results- Balloon Ostial Dilation for Recurrent Acute Rhinosinusitis

Study	Quality of Life	Acute Exacerbations	Adverse Events
REMODEL (10, 12, 13) NCT01525849			
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 four 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: 0.838	• .258	

Sikand et al. (2019) (18) **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
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

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; RCT: randomized controlled trial; BOD: balloon ostial dilation; FESS: functional endoscopic sinus surgery; NCT: National Clinical Trial; N: sample size; RARS: recurrent acute rhinosinusitis.

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 (10, 12, 13)	3. Some outcomes not reported separately by diagnosis of RARS	1.Randomization of added patients occurred outside of key study			1. Differential loss post-randomization between study arms
Sikand et al. (2019) (18) 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; RARS: recurrent acute rhinosinusitis; 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 Complete-ness[d]	Power[e]	Statistical[f]
REMODEL (10, 12, 13)		1, 2. Not blinded			Not powered to detect differences by RARS subgroup	
Sikand et al. (2019) (18) CABERNET		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; RARS: recurrent acute rhinosinusitis.
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

Two RCTs of BOD reported results separately for individuals with RARS; one (REMODEL) compared BOD to FESS in a subgroup of 29 patients, and the other (CABERNET) compared BOD to medical care in 59 patients. In the REMODEL study BOD was non-inferior to FESS on measures of quality of life at 6 months and 12 months post-procedure; 24-month results were not reported separately for patients with RARS. One RCT comparing BOD plus medical care to medical care alone in patients with RARS found significantly improved quality of life and lower mean number of sinus infections after 24 months in the balloon dilation group. A third RCT included a mix of patients with chronic and RARS and found improved quality of life compared to FESS, but results were not reported separately by diagnosis.

Balloon Ostial Dilation of Children with Chronic Rhinosinusitis

Thottam et al. (2012) reported on a two-group, retrospective cohort with blinded chart review comparison, to evaluate whether the addition of BCS (balloon catheter sinuplasty) would improve the treatment outcome in children with CRS compared to FESS (functional endoscopic sinus surgery). (24) Charts reviewed were of 15 pediatric patients who underwent BCS with ethmoidectomy and 16 who underwent FESS from 2008-2011 for treatment of CRS in a tertiary care, university affiliated pediatric institution. Pre-operative CT-scans as well as pre and post-operative sinus symptoms and medications were compared. The mean age of children at the time of the procedure was 9.3 (SD=4.19; range=3-17). Both groups had similar pre-surgical Lund-Mackay CT CRS scores (FESS: mean=9.33 and t=0.67; balloon: mean=10.58, t=0.68, and p=0.51). Analyses identified significant post-treatment reductions in overall symptoms and needed interventions in both treatment groups. Side-by-side post-operative comparison of patients who underwent balloon sinuplasty to FESS demonstrated statistically significant post-

operative difference between the two groups in antibiotic requirement, sinus congestion and headaches. Though not statistically significant, 62.5% of FESS patients and 80.0% of BCS patients ($\chi(2)=1.15$) reported improvement in their overall sinus symptoms post-operatively. The authors concluded that both BCS and FESS are suitable treatments for CRS in children. Both treatments significantly reduced CRS complaints post-operatively and had similar overall results. BCS patients required significantly fewer antibiotics post-operatively for CRS related disease when compared to FESS. Larger prospective studies with long-term data are needed to further evaluate.

Wang et al. (2015) reported on a prospective case-control study that was conducted from October 1, 2012 to May 31, 2013 in an academic tertiary referral hospital. (25) Participants included a total of 79 patients, aged 7 to 12 years, with CRS resistant to medical therapy to evaluate the efficacy of sinus balloon catheter dilation. Data from 79 of 96 patients who had complete follow-up documents were statistically analyzed (42 boys; 37 girls; mean [SD] age, 9.3 [1.7] years). Sinonasal-5 questionnaire (SN-5), and visual analog scale (VAS) were analyzed and compared. Compared with the preoperative scores, the SN-5 and VAS scores in children with CRS who underwent sinus balloon catheter dilation with or without adenoidectomy were significantly lower at 3 months (2.5 vs 4.3 for SN-5; $P < .001$; 3.1 vs 5.2 for VAS; $P < .001$) and at 1 year (2.9 vs 4.3 for SN-5; $P = .001$; 3.1 vs 5.2 for VAS; $P < .001$). Both SN-5 and VAS scores in the control group were significantly decreased at 3 months (3.1 vs 4.2 for SN-5; $P = .001$; 3.9 vs 5.1 for VAS; $P < .001$) but not significantly changed at 12 months (3.8 vs 4.2 for SN-5; $P = .01$; 4.9 vs 5.1 for VAS; $P = .54$). The SN-5 and VAS scores in the sinus balloon catheter dilation group were significantly lower than those for controls at 3 months (2.5 vs 3.1 for SN-5; $P = .003$; 3.1 vs 3.9 for VAS; $P = .01$) and at 1 year after surgery (2.9 vs 3.8 for SN-5; $P < .001$; 3.1 vs 4.9 for VAS; $P < .001$). By the 12-month SN-5 score evaluation, the rates of marked, moderate, and mild improvement were significantly better in the sinus balloon catheter dilation group (52% [22 of 42], 26% [11 of 42], and 14% [6 of 42], respectively) than in the control group (14% [5 of 37], 19% [7 of 37], and 11% [4 of 37], respectively) ($P < .05$ for all comparisons). Conclusions reached by the authors included that sinus balloon catheter dilation procedure is a safe and effective technique for pediatric CRS resistant to medical therapy.

Soler et al. (2017) evaluated the safety and effectiveness of balloon sinus dilation in children (2 to 21 years old) with CRS who had failed medical management in a prospective, multicenter, single-arm investigation (NCT02278484). (26) Fifty children were treated at 4 centers; 33 participants were 2 to 12 years old (mean ± standard deviation age: 6.6 ± 2.2 years) and 17 participants were >12 to 21 years (mean age: 15.7 ± 2.5 years) and were followed for 6 months post-procedure. A total of 157 sinus dilations were attempted (98 maxillary, 30 frontal, and 29 sphenoid sinuses) and all were successful with no complications. Significant improvement in the Sinus and Nasal Quality of Life Survey (SN-5) was seen for all children between baseline and 6 months (4.6 ± 1.2 vs 1.7 ± 0.8; $p < 0.0001$) and 92% improved by a minimal clinically important difference (MCID) of 1.0 or more. Those children aged 2 to 12 years with standalone balloon dilation also showed significant SN-5 improvements between baseline and follow-up (4.5 ± 1.0 vs 1.9 ± 0.8; $p < 0.0001$). Multivariate regression analysis showed no differences or associations of SN-5 improvement at 6 months with the presence of allergy, asthma, or concomitant

procedures. For adolescents, overall 22-item Sino-Nasal Outcome Test (SNOT-22) mean scores were also significantly improved at 6 months (42.2 ± 19.2 vs 10.4 ± 9.7; $p < 0.0001$). The authors concluded that balloon sinus dilation is safe and appears effective for children with CRS aged 2 years and older.

Mirza et al. (2020) performed a review to systematically assess the literature for studies demonstrating the effectiveness and safety of balloon catheter sinuplasty in pediatric CRS patients. (27) Observational- and interventional-based studies reporting efficacy and/or side effects of balloon catheter sinuplasty among pediatric populations were included. The duration of follow-ups ranged from 4 months to 5 years. Maxillary sinus, among all paranasal sinuses, was the predominant sinus being treated with balloon catheter sinuplasty in children. Efficacy was evaluated by clinically reliable measures including Sino-Nasal 5 (SN-5) QoL scale. Antibiotic usage and revision surgery were also evaluated. The reviewers' findings included: Out of 112 articles identified, 10 articles were included: two interventional controlled trials and eight observational studies. All studies evaluating QoL by SN-5 showed a remarkable reduction in SN-5 score postoperatively. Improvement in the computed tomography (CT) and endoscopic findings for up to 1 year after operation was reported. Furthermore, the majority of patients treated with balloon catheter sinuplasty did not receive any course of sinusitis-indicated antibiotics during long-term follow-up, and they had low surgical revision rates. Minor side effects were reported, most commonly synechia. The authors concluded that available evidence suggests that balloon catheter sinuplasty is safe and effective for the treatment of CRS in pediatric patients.

Section Summary: Balloon Ostial Dilation of Children with Chronic Rhinosinusitis

In one retrospective cohort with blinded chart review comparison, the addition of BCS (balloon catheter sinuplasty) treatment was evaluated to determine the treatment outcome in children with CRS compared to treatment with FESS. Authors noted that both BCS and FESS are suitable treatments for CRS in children, BCS patients required significantly fewer antibiotics post-operatively for CRS related disease when compared to FESS. In two prospective studies, a case-controlled study that evaluated SN-5 scores in pediatric patients who underwent sinus balloon catheter dilation compared to the control group that received conservative treatment, as well as in a multicenter, single-arm investigation, authors concluded that sinus balloon catheter dilation procedure is a safe and effective technique for pediatric CRS resistant to medical therapy. A systematic review of literature revealed that SN-5 showed a remarkable reduced score postoperatively, as well as improvement in the computed tomography (CT) and endoscopic findings for up to 1 year following balloon catheter sinuplasty was reported. Furthermore, the authors noted low surgical revision rates, and that the majority of patients treated with balloon catheter sinuplasty did not receive any course of sinusitis-indicated antibiotics during follow-up.

Summary of Evidence

For adult individuals with chronic rhinosinusitis (CRS) who receive balloon ostial dilation (BOD) as a stand-alone procedure, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are symptoms, change in

disease status, quality of life, and treatment-related morbidity. In the REMODEL RCT, BOD was non-inferior to functional endoscopic sinus surgery (FESS) for patients with chronic rhinosinusitis. Durability of effect was demonstrated in uncontrolled studies that followed individuals 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 individuals 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 that the technology results in an improvement in the net health outcomes.

For adult individuals with recurrent acute rhinosinusitis (RARS) who receive BOD as a stand-alone procedure, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. In the REMODEL study of BOD compared to FESS, 32% of individuals were diagnosed with RARS (N=29). BOD was non-inferior to FESS on measures of quality of life at 6 months and 12 months post-procedure. One RCT comparing BOD plus medical care to medical care alone in individuals with RARS found significantly improved quality of life and lower mean number of sinus infections after 24 months in the balloon dilation group. A third RCT included a mix of individuals with chronic and RARS and found improved quality of life compared to FESS, but results were not reported separately by diagnosis. The body of evidence is limited by the small number of individuals studied, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures used. The evidence is insufficient to determine the effects of the technology on health outcomes.

For pediatric individuals with CRS who receive BOD, the evidence includes a retrospective cohort with blinded chart review comparison, a prospective case-controlled study, a prospective multicenter, single-arm investigation, and a systematic review of literature. Although, the studies reviewed are small in number, and follow up length of times vary, improvement in overall sinus symptoms post-operatively was indicated by quality of life scores in the SN-5, VAS scores, and Sino-Nasal Outcome Test (SNOT-22). Other indicators evaluated included CT scans, medication use, revision rates and side effects from the procedure. The evidence is sufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Academy of Otolaryngology – Head and Neck Surgery et al.

In 2018, the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses. (19) 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 **bolded**. The updated information to guideline statement can be found on the AAO-HNS website dated April, 2021.

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 (American Academy of Otolaryngology—Head and Neck Surgery Foundation) 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 BOD, 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, April 13, 2021) (20)

In 2015, the Academy's Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty. (1)

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." (21)

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis (22):

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.

American Rhinologic Society

A position statement, revised in 2023, from the American Rhinologic Society, 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." (23)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04645511	A Placebo Controlled Randomised Study of the Balloon Sinuplasty Efficiency in Chronic or Recurrent Maxillary Rhinosinusitis	120	Dec 2027

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	31256, 31276, 31287, 31295, 31296, 31297, 31298, 31299
HCPCS Codes	C1726

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2024	Document updated with literature review. Coverage unchanged. Reference 3 added; others updated, none removed.
01/01/2024	Reviewed. No changes.
07/01/2022	Document updated with literature review. Coverage unchanged. Reference 2 and 27 added, other references removed.
11/15/2021	Document updated with literature review. The following changes were made to Coverage: 1) Removed without nasal polyps from the following statement: Chronic rhinosinusitis without nasal polyps that negatively impacts quality of life, characterized by at least two of the following, at least one of which is (a) or (b), present for at least 12 continuous weeks; under

	the Balloon Ostial Dilation in Adults section: 2) Removed (i.e., purulent drainage, or nasal polyposis) from NOTE 1. No references added or removed.
07/01/2021	Reviewed. No changes.
03/15/2021	New medical document originating from: SUR706.001 Nasal and Sinus Surgery. Use of a catheter-based inflatable device (balloon ostial dilation) for the treatment of chronic rhinosinusitis in the sinus being considered for dilation may be considered medically necessary when the following criteria are present: Patient is 18 years of age or older AND Chronic rhinosinusitis without nasal polyps that negatively impacts quality of life, characterized by at least two of the following, at least one 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-fullness; d. Decreased sense of smell.; AND Optimal medical therapy (e.g., allergy evaluation and treatment; course(s) of antibiotics; decongestants; topical and/or systemic corticosteroids; saline nasal irrigation; treatment of rhinitis medicamentosa [rebound nasal congestion due to extended use of topical decongestants]; education on environmental irritants including tobacco smoke) has been attempted and failed. AND Clinical and radiographic documentation of persistent inflammation following optimal medical therapy documented by either of the following: a. Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoethmoid region OR b. CT scan of the paranasal sinuses showing mucosal thickening, opacification, or air-fluid levels. The use of balloon ostial dilation for the treatment of chronic rhinosinusitis is considered experimental, investigational and/or unproven when the above criteria are not met. The use of balloon ostial dilation for the treatment of recurrent acute rhinosinusitis is considered experimental, investigational and/or unproven. The use of a FDA-approved balloon ostial dilation device specified for children (age 17 and under) may be considered medically necessary as a minimally invasive alternative to functional endoscopic sinus surgery for medically refractory chronic sinusitis when treating the maxillary sinus space. The use of a FDA-approved balloon ostial dilation device specified for children (age 17 and under) is considered experimental, investigational and/or unproven as a minimally invasive alternative to functional endoscopic sinus surgery for the treatment of medically refractory chronic sinusitis in all other sinus spaces except the maxillary sinus space. NOTE 1: Pediatric chronic rhinosinusitis is defined as: At least 90 continuous days of 2 or more of the following symptoms: Purulent rhinorrhea; Nasal obstruction; Facial pressure/pain; or Cough. AND either: a. Endoscopic signs of mucosal edema (i.e., purulent drainage, or nasal polyposis); OR b. CT scan showing mucosal changes within the ostiomeatal complex and/or sinuses in a pediatric patient.