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

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## Disclaimer

**Carefully check state regulations and/or the member contract.**
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## 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, when indicated; course(s) of antibiotics; decongestants when indicated; topical and/or systemic corticosteroids; saline nasal irrigation; treatment of rhinitis medicamentosa [rebound nasal congestion due to

extended use of topical decongestants], when present; 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. Computerized tomography (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 a Food and Drug Administration (FDA)-approved balloon ostial dilation device specified for children (age 17 and under) to treat the maxillary sinus space **may be considered medically necessary** as a minimally invasive alternative to functional endoscopic sinus surgery for medically refractory chronic sinusitis when:

- The individual has had at least 90 continuous days of two or more of the following symptoms:
  - Purulent rhinorrhea;
  - Nasal obstruction;
  - Facial pressure/pain; or
  - Cough; **AND**
- There is documented evidence of either:
  - Endoscopic signs of mucosal edema; or
  - Computed tomography (CT) scan showing mucosal changes within the osteomeatal complex and/or sinuses.

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 all other non-FDA approved indications.

## 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 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.

**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. (1) Rhinosinusitis affects 1 in 8 adults and accounts for 20% of antibiotic prescriptions. (2) 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. (3)

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. (4) 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 medical policy 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. (5, 6) 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. (7) Bacterial biofilms have been identified in cases of CRS. (8)

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). (1) 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 BOD or 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). (2)

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. (9) Guidelines from the AAO-HNS (2025) 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). (1) 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." (10) 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. (11) In 2021, mepolizumab (Nucala®) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps. (12)

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. (13)

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

Balloon ostial dilatation 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.

BOD may also be used in combination with FESS. (14, 15) 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**

**NOTE:** This section is to be used for informational purposes only. Food and Drug Administration (FDA) approval alone is not a basis for coverage.

In 2008, the Relieva® Sinus Balloon Catheter (Integra LifeSciences, formerly Acclarent Inc.), was cleared for marketing by the 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 (see Table 1 below).

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 (Smith & 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 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. (14)

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) Number | 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

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 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 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. (16)

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. (17) Although CT scans can provide an objective measure, often they do not correlate well with symptoms. (18)

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.

Systematic Review

Liang et al. (2025) conducted a meta-analysis comparing BOD and FESS for CRS. (19) 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. (20) 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% confidence intervals (CIs) between BOD and FESS groups, were fully reported by only two RCTs (Achar et al., 2012; Cutler et al., 2013) (21, 22) and one cohort study (Friedman et al., 2008). (23) 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 (24-27) 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) (19) | 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) (20) | 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; FESS: functional endoscopic sinus surgery; RCT: randomized controlled trial; N: sample size.

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

| **Study** | | | |
|---|---|---|---|
| **Liang et al. (2025) (19)** | **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) (20)** | **Quality of Life (SNOT-20): BOD vs FESS** | **Quality of Life (SNOT-20):** | |

| | | Improvement from baseline | |
|---|---|---|---|
| N analyzed | 186 | 463 | |
| Pooled effect (95% CI) | mean difference=0.435 (0.054 to 0.817)[a] | • 0.221 (-0.001 to 0.443)[b]<br>• 0.213 (0.00 to 0.426)[b]<br>• 0.203 (0.002 to 0.403)[b]<br>• 0.175 (0.008 to 0.343)[b] | |

BOD: balloon ostial dilation; CI: confidence interval; FESS: functional endoscopic sinus surgery; N: sample size; 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. (22, 28, 29) 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 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. 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. (22) 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. (28) 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). (29) 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. The studies were included in the Sinha et al. (2023) meta-analysis and are not further summarized.

**Table 4. REMODEL Trial of BOD compared to FESS in CRS: Characteristics**

| Study; Trial | Countries | Sites | Dates | Participants | Interventions | |
|---|---|---|---|---|---|---|
| | | | | | **Active** | **Comparator** |
| REMODEL (22, 28, 29) NCT01525849<br>• (6-month data)<br>• (12-month data)<br>• (24-month data) | U.S. | 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 | • BOD (office setting)<br>• N=74 | • FESS (operating room)<br>• N=61 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | 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; U.S.: United States.

**Table 5. REMODEL Trial of BOD Compared to FESS in CRS: Results**

| Study | Quality of Life | Symptoms | CT Scan Results | Adverse Events |
|---|---|---|---|---|
| Outcome measure<br><br>Number analyzed | Mean change from baseline in SNOT-20 score<br><br>N=91 at 6 months, 89 at 12 months | Time to return to normal daily activities | Overall Ostial Patency<br><br>N=89 patients, 169 ostia | |
| **REMODEL (22, 28, 29) NCT01525849**<br>(6-month data)<br>(12-month data)<br>(24-month data) | | | | |
| BOD | 6 months: 1.67 (1.10)<br><br>12 months: 1.64 (1.06)<br><br>24 months: -1.65 | 1.6 days | 6 months: NR<br><br>12 months: 96.7% (88/91) | No complications<br><br>28.0% nasal bleeding<br><br>1 (2.1%) revision surgery through 1 year |
| FESS | 6 months: 1.60 (0.96)<br><br>12 months: 1.65 (0.94)<br><br>24 months: -1.45 | 4.8 days | 6 months: NR<br><br>12 months: 98.7% (77/78) | No complications<br><br>54.8% nasal bleeding<br><br>1 (2.4%) revision surgery through 1 year |
| Between-group p-value | 6 months: *P* < 0.001<br><br>12 months): 0.01 (95% CI | 0.002 | 12 months: *P* = NS | Nasal bleeding: *P* =.011 |

| | | | | |
|---|---|---|---|---|
| | -0.43 to 0.44); BOD noninferior to FESS (*P* <.0001)<br><br>24 months: *P <.0001* | | | |

CI: confidence interval; CRS: chronic rhinosinusitis; CT: computed tomography; 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; NS: not significant.

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 (22, 28, 29) | 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. Clinically significant difference not prespecified; 6. Clinically 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 (22, 28, 29) | | 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. (30) 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 3 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 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 acute bacterial rhinosinusitis (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 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. (16)

The Chronic Sinusitis Survey (CSS) is a measure of symptoms and medication usage over an 8-week recall period. (31) 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.

The Rhinosinusitis Disability Index (RSDI) is a patient-reported questionnaire used to measure the impact of rhinosinusitis on a person's quality of life. (32, 33) 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.

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. (34) BOD was utilized as a treatment modality in two

studies: (35, 36) 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. (22, 28, 29) 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. (36) 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). (28) 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) (CABERNET), the primary outcome was the difference between arms in change in Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks. (36) 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 (22, 28, 29) NCT01525849 (6-month data) (12-month data) (24-month data) | U.S. | 10 | 2011-2014 | 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 | • BOD (office setting)<br>• N=16 | • FESS (operating room)<br>• N=13 |
| Sikand et al. (2019) (36) CABERNET NCT01714687 | U.S. | 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 | • BOD plus medical management<br>• N=29 | • Sham procedure plus medical manage-ment<br>• N=30 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | days beyond the onset of upper respiratory symptoms, or within 10 days after initial improvement (double worsening) | | |

BOD: balloon ostial dilation; FESS: functional endoscopic sinus surgery; 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; U.S.: United States.

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

| Study | Quality of Life | Acute Exacerbations | Adverse Events |
|---|---|---|---|
| **REMODEL (22, 28, 29) NCT01525849** | | | |
| Outcome measure<br>• Number analyzed | • Mean change from baseline in SNOT-20 score<br>• 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* <0.0001<br>• 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* <0.001) in both treatment arms and there was no difference (*P* = NS) in improvement between patients who | • 5.1 to 0.9<br>• *P* < 0.0001 | |

| | | | |
|---|---|---|---|
| | underwent balloon dilation or FESS."<br>• 24 months: NR separately for patients with RARS | | |
| FESS | • 6 months (RARS subgroup): -1.64 (±0.90); *P* <0.0001<br>• 24 months: NR separately for patients with RARS | • 4.5 to 0.8<br>• *P* < 0.0001 | |
| Between-group p-value | • 6 months: 0.838 | • 0.258 | |
| **Sikand et al. (2019) (36)**<br>**CABERNET NCT01714687** | | | |
| Outcome measure<br>• Number analyzed | • Mean change in CSS Score at 24 weeks<br>• N=59 | • Mean number of post-enrollment sinus infections, 24 weeks<br>• N=59 | • N=59 |
| BOD + medical management | • Total score: 37.3 (SD 24.4)<br>• Symptom subscore: 48.7 (SD 28.7)<br>• Medication subscore: 26.0 (SD 26.6) | 0.2 (0.4) | • 1 serious procedure-related adverse event (headache leading to hospital admission)<br>• No device-related adverse events<br>• Nonserious AEs: 58.6% |
| Sham + medical management | • Total score: 21.8 (29.0)<br>• Symptom subscore: 27.2 (40.1)<br>• Medication subscore: 16.4 (24.0) | • 0.9 (0.9) | • Nonserious AEs: 60.0% |
| Between-group p-value | • Total score: 0.0424<br>• Symptom subscore: 0.0484<br>• Medication subscore: 0.2607 | • 0.0015 | • Nonserious AEs: *P* = NS |

AEs: adverse events; CABERNET: Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients; CSS: Chronic Sinusitis Survey; 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; NS: not significant; 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 (22, 28, 29) | 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) (36) 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; CSS: Chronic Sinusitis Survey; 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. Clinically significant difference not prespecified; 6. Clinically 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 (22, 28, 29) | | 1, 2. Not blinded | | | Not powered to detect differences by RARS subgroup | |
| Sikand et al. (2019) (36) 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; 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.

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

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.

**Summary of Evidence**

For adult individuals with chronic rhinosinusitis (CRS) who receive balloon ostial dilation (BOD) as a stand-alone procedure, the evidence includes a systematic review, randomized controlled trials (RCTs), observational studies. Relevant outcomes are symptoms, change in disease status, quality of life, 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 quality of life. The REMODEL RCT confirmed that BOD was non-inferior to functional endoscopic sinus surgery (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 reported in individuals who underwent balloon dilation (n=2851), 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 outcomes.

For adult individuals with recurrent acute rhinosinusitis (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 the small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures. The evidence is insufficient 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. (37) 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) (38)

In 2025, the AAO-HNS updated its clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty. (1) However, surgical therapy is addressed in 2025 guidelines on chronic rhinosinusitis from AAO-HNS, but these guidelines do not address balloon sinuplasty. (39)

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." (40)

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis (41):

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.” (42)

American Academy of Otolaryngology Head and Neck Surgery Foundation

A clinical consensus statement for pediatric chronic rhinosinusitis (43) which is supported by the American Academy of Otolaryngology head and neck surgery foundation states: Chronic rhinosinusitis (PCRS) is defined as at least 90 continuous days of 2 or more symptoms of purulent rhinorrhea, nasal obstruction, facial pressure/pain, or cough and either endoscopic signs of mucosal edema, purulent drainage, or nasal polyposis and/or CT scan changes showing mucosal changes within the ostiomeatal complex and/or sinuses in a pediatric patient aged 18 years or younger.

**Ongoing and Unpublished Clinical Trials**

Some currently 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 (last update posted: Oct 2022) |

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®) ©2025 American Medical Association: Chicago, IL.

## References


1. Payne SC, McKenna M, Buckley J et al. Clinical Practice Guideline: Adult Sinusitis Update. Otolaryngol Head Neck Surg. Aug 2025; 173 Suppl 1:S1-S56. PMID 40742114
2. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. Apr 2015; 152(2 Suppl):S1-S39. PMID 25832968

3. Bhattacharyya N, Grebner J, Martinson NG. Recurrent acute rhinosinusitis: epidemiology and health care cost burden. Otolaryngol Head Neck Surg. Feb 2012; 146(2):307-312. PMID 22027867
4. Rudmik L, Soler ZM. Medical Therapies for Adult Chronic Sinusitis: A Systematic Review. JAMA. Sep 01 2015; 314(9):926-939. PMID 26325561
5. Finegold SM, Flynn MJ, Rose FV, et al. Bacteriologic findings associated with chronic bacterial maxillary sinusitis in adults. Clin Infect Dis. Aug 15 2002; 35(4):428-433. PMID 12145727
6. Brook I. Bacteriology of chronic maxillary sinusitis in adults. Ann Otol Rhinol Laryngol. Jun 1989; 98(6):426-428. PMID 2729825
7. Aurora R, Chatterjee D, Hentzleman J, et al. Contrasting the microbiomes from healthy volunteers and patients with chronic rhinosinusitis. JAMA Otolaryngol Head Neck Surg. Dec 2013; 139(12):1328-1338. PMID 24177790
8. Singhal D, Psaltis AJ, Foreman A, et al. The impact of biofilms on outcomes after endoscopic sinus surgery. Am J Rhinol Allergy. 2010; 24(3):169-174. PMID 20537281
9. Dautremont JF, Rudmik L. When are we operating for chronic rhinosinusitis? A systematic review of maximal medical therapy protocols prior to endoscopic sinus surgery. Int Forum Allergy Rhinol. Dec 2015; 5(12):1095-1103. PMID 26201538
10. Food and Drug Administration. Highlights of Prescribing Information: Dupixent (dupilumab) injection, for subcutaneous use. 2025. Available at: <https://www.dailymed.nlm.nih.gov> (accessed December 10, 2025).
11. Xolair prescribing information. South San Francisco, CA: Genentech, Inc.; 2025. Available at: <https://www.gene.com> (accessed December 11, 2025).
12. Nucala Prescribing Information. August 6, 2025. Available at: <https://www.dailymed.nlm.nih.gov> (accessed December 9, 2025).
13. Food and Drug Administration. Tezspire Prescribing Information. October 17, 2025. Available at: <https://www.accessdata.fda.gov> (accessed December 11, 2025).
14. Hathorn IF, Pace-Asciak P, Habib AR, et al. Randomized controlled trial: hybrid technique using balloon dilation of the frontal sinus drainage pathway. Int Forum Allergy Rhinol. Feb 2015; 5(2):167-173. PMID 25360863
15. Plaza G, Eisenberg G, Montojo J, et al. Balloon dilation of the frontal recess: a randomized clinical trial. Ann Otol Rhinol Laryngol. Aug 2011; 120(8):511-518. PMID 21922974
16. Bizaki AJ, Taulu R, Numminen J, et al. Quality of life after endoscopic sinus surgery or balloon sinuplasty: a randomized clinical study. Rhinology. Dec 2014; 52(4):300-305. PMID 25479206
17. Hopkins C, Browne JP, Slack R, et al. The Lund-Mackay staging system for chronic rhinosinusitis: how is it used and what does it predict? Otolaryngol Head Neck Surg. Oct 2007; 137(4):555-561. PMID 17903570
18. Gregurić T, Trkulja V, Baudoin T, et al. Association between computed tomography findings and clinical symptoms in chronic rhinosinusitis with and without nasal polyps. Eur Arch Otorhinolaryngol. May 2017; 274(5):2165-2173. PMID 28154930
19. Liang X, Lan H, Liang X, et al. Efficacy and safety of sinus balloon catheter dilation versus functional endoscopic sinus surgery in the treatment of chronic sinusitis: A meta-analysis. Medicine (Baltimore). Jun 13 2025; 104(24):e42841. PMID 40527772

20. Sinha P, Tharakan T, Payne S, et al. Balloon Sinus Dilation Versus Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis: Systematic Review and Meta-Analysis. Ann Otol Rhinol Laryngol. May 2023; 132(5):578-588. PMID 35703383
21. Achar P, Duvvi S, Kumar BN. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. Acta Otorhinolaryngol Ital. Oct 2012; 32(5):314-319. PMID 23326011
22. Cutler J, Bikhazi N, Light J, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial. Am J Rhinol Allergy. 2013; 27(5):416-422. PMID 23920419
23. Friedman M, Schalch P, Lin HC, et al. Functional endoscopic dilatation of the sinuses: patient satisfaction, postoperative pain, and cost. Am J Rhinol. 2008; 22(2):204-209. PMID 18416981
24. ElBadawey MR, Alwaa A, ElTaher M, et al. Quality of life benefit after endoscopic frontal sinus surgery. Am J Rhinol Allergy. 2014; 28(5):428-432. PMID 25198031
25. Marzetti A, Tedaldi M, Passali FM. The role of balloon sinuplasty in the treatment of sinus headache. Otolaryngol Pol. 2014; 68(1):15-19. PMID 24484944
26. Di Girolamo S, Mazzone S, Di Mauro R, et al. Surgical management of rhinosinusitis in onco-hematological patients. Clin Exp Otorhinolaryngol. Dec 2014; 7(4):302-306. PMID 25436050
27. Bizaki AJ, Numminen J, Taulu R, et al. Decrease of nasal airway resistance and alleviations of symptoms after balloon sinuplasty in patients with isolated chronic rhinosinusitis: a prospective, randomised clinical study. Clin Otolaryngol. Dec 2016; 41(6):673-680. PMID 26548697
28. Bikhazi N, Light J, Truitt T, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial with 1-year follow-up. Am J Rhinol Allergy. 2014; 28(4):323-329. PMID 24823902
29. Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. Jan 2016; 126(1):44-50. PMID 26228589
30. Chaaban MR, Rana N, Baillargeon J, et al. Outcomes and Complications of Balloon and Conventional Functional Endoscopic Sinus Surgery. Am J Rhinol Allergy. Sep 2018; 32(5):388-396. PMID 29947260
31. Gliklich RE, Metson R. Techniques for outcomes research in chronic sinusitis. Laryngoscope. Oct 2015; 125(10):2238-2241. PMID 26390386
32. Benninger MS, Senior BA. The development of the Rhinosinusitis Disability Index. Arch Otolaryngol Head Neck Surg. Nov 1997; 123(11):1175-1179. PMID 9366696
33. Senior BA, Glaze C, Benninger MS. Use of the Rhinosinusitis Disability Index (RSDI) in rhinologic disease. Am J Rhinol. 2001; 15(1):15-20. PMID 11258649
34. Saltagi MZ, Comer BT, Hughes S, et al. Management of Recurrent Acute Rhinosinusitis: A Systematic Review. Am J Rhinol Allergy. Nov 2021; 35(6):902-909. PMID 33622038
35. Levine SB, Truitt T, Schwartz M, et al. In-office stand-alone balloon dilation of maxillary sinus ostia and ethmoid infundibula in adults with chronic or recurrent acute rhinosinusitis: a prospective, multi-institutional study with-1-year follow-up. Ann Otol Rhinol Laryngol. Nov 2013; 122(11):665-671. PMID 24358625

36. Sikand A, Ehmer DR, Stolovitzky JP, et al. In-office balloon sinus dilation versus medical therapy for recurrent acute rhinosinusitis: a randomized, placebo-controlled study. Int Forum Allergy Rhinol. Feb 2019; 9(2):140-148. PMID 30452127
37. Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Sinuses. Otolaryngol Head Neck Surg. Feb 2018; 158(2):203-214. PMID 29389303
38. American Academy of Otolaryngology - Head and Neck Surgery. Position Statement: Dilation of sinuses, any method (e.g., balloon, etc.). 2021. Available at: <https://www.entnet.org> (accessed December 11, 2025).
39. Shin JJ, Wilson M, McKenna M, et al. Clinical Practice Guideline: Surgical Management of Chronic Rhinosinusitis. Otolaryngol Head Neck Surg. Jun 2025; 172 Suppl 2:S1-S47. PMID 40424072
40. National Institute of Health and Care Excellence (NICE). Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis [IPG273]. 2008. Available at: <https://www.nice.org.uk> (accessed December 11, 2025).
41. National Institute of Health and Care Excellence (NICE). XprESS multi sinus dilation system for treating chronic sinusitis [MTG30]. 2016. Available at: <https://www.nice.org.uk> (accessed December 10, 2025).
42. American Rhinologic Society (ARS). Ostial Balloon Dilation Position Statement. 2023. Available at: <https://www.american-rhinologic.org> (accessed December 11, 2025).
43. Brietzke SE, Shin JJ, Choi Sukgi et al. Clinical consensus statement: pediatric chronic rhinosinusitis. Otolaryngol Head and Neck Sur. Oct 2014; 151(4):542-553. PMID 25274375

## 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 |
|---|---|
| 09/15/2026 | Document updated. The following change was made to the Coverage: Incorporated information from “NOTE 1” into the criteria for Balloon Ostial Dilation in Children. Added references: 1, 13, 19, and 39. Some references updated, others removed. |
| 01/01/2026 | Document updated. The following change was made to the Coverage: Revised the experimental, investigational and/or unproven statement for balloon ostial dilation device specified for children (age 17 and under) by |

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| | removing: “for the treatment of medically refractory chronic sinusitis in all other sinus spaces except the maxillary sinus space” and replacing with “to include all other non-FDA approved indications”. Added references: 1, 3-11, 13, 20, 23-27, 32-35, and 42-44. |
| 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<br>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 |

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| | 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. |