

## ***Balloon Ostial Dilation for Treatment of Sinusitis***

**Effective:** November 1, 2023

**Next Review:** August 2024

**Last Review:** September 2023

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Balloon ostial dilation is proposed as a less invasive alternative to traditional endoscopic sinus surgery. In this procedure, a balloon catheter is placed in the opening of the sinus and inflated to widen the opening, allowing for better drainage of secretions.

### **MEDICAL POLICY CRITERIA**

- I. The use of a catheter-based inflatable device for the treatment of chronic sinusitis may be considered **medically necessary** when all of the following Criteria are met:
  - A. Patient has chronic sinusitis that interferes with lifestyle and has persisted for at least 12 weeks; and
  - B. Documentation of abnormal findings from diagnostic evaluation including at least one of the following:
    1. CT findings suggestive of obstruction or infection of the sinus including but not limited to air fluid levels, air bubbles, significant mucosal thickening of greater than 3 mm, pansinusitis, or diffuse opacification documented by a formal CT scan report from an independent radiologist; or
    2. Nasal endoscopy findings suggestive of significant sinus ostial obstruction disease; and

- C. Inadequate response to maximal medical therapy that included all of the following:
1. Saline nasal irrigations or saline nasal spray; and
  2. Two or more antibiotic courses or one prolonged course of at least 21 days; and
  3. A trial of nasal steroids.
- II. The use of a catheter-based inflatable device for the treatment of chronic sinusitis is considered **investigational** when Criterion I. is not met.
- III. The use of a catheter-based inflatable device for the treatment of recurrent acute rhinosinusitis may be considered **medically necessary** when all of the following Criteria are met:
- A. Four or more documented and treated episodes of acute rhinosinusitis over a period of 12 months; and
  - B. CT findings performed during the fourth episode should demonstrate obstruction or infection of the sinus including but not limited to air fluid levels, air bubbles, significant mucosal thickening of greater than 3 mm, pansinusitis, or diffuse opacification documented by a formal CT scan report from an independent radiologist.
- IV. The use of a catheter-based inflatable device for the treatment of recurrent acute rhinosinusitis is considered **investigational** when Criterion III. is not met.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Indication for the requested service
- If indication is chronic rhinosinusitis:
  - Documentation of chronic rhinosinusitis including length of time present and interference with lifestyle;
  - CT and/or nasal endoscopy report;
  - Failure of maximum medical therapy including saline nasal irrigations/nasal spray, two or more antibiotic courses or one minimum 21 day course, and nasal steroid trial.
- If indication is recurrent acute rhinosinusitis:
  - Documentation of four or more documented and treated episodes of acute rhinosinusitis over 12 months;
  - CT report.

## CROSS REFERENCES

1. [Implantable Sinus Devices for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinonasal Polyposis](#), Surgery, Policy No. 198
2. [Balloon Dilation of the Eustachian Tube](#), Surgery, Policy No. 206
3. [Cryoablation for Chronic Rhinitis](#), Surgery, Policy No. 224

## BACKGROUND

Balloon ostial dilation (BOD, also known as balloon sinuplasty, balloon catheter dilation, or sinus ostial dilation) for the treatment of sinusitis involves placement and inflation of a balloon catheter within an obstructed frontal, sphenoid, or maxillary sinus ostium. The balloon catheter is placed using transnasal endoscopy, or a transantral approach may be used for direct access to the maxillary sinus. Inflation of the balloon is intended to enlarge the sinus ostium by compressing mucosa and displacing local bony structures. This technique has been used as an alternative or adjunct to functional endoscopic sinus surgery (FESS) which involves surgical excision of the mucosa and bone. When performed in combination with FESS, it is sometimes referred to as a hybrid procedure.

### REGULATORY STATUS

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

In June 2008, the FinESS™ Sinus Treatment (Entellus Medical, Inc, Maple Grove, MN) device 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. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinuplasty devices by Entellus Medical, Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

In 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 (ArthroCare, San Antonio, TX), 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.

## EVIDENCE SUMMARY

To determine the benefits and harms of BOD as a stand-alone procedure for the treatment of

sinusitis, it must be compared with standard functional endoscopic sinus surgery (FESS) which involves excision of ostial tissues. Well-designed prospective comparative studies, preferably randomized controlled trials (RCTs), are needed to compare health outcomes between the two procedures and determine whether balloon dilation is as effective and durable as excision.

The most important clinical outcomes to compare for treatment of sinusitis are:

- Symptom relief
- Durability of any beneficial effects
- Adverse event rate and severity
- Rate and type of reoperations including repeat dilation procedures

The focus of this evidence review is on systematic reviews, randomized controlled trials, and nonrandomized comparative trials.

## **ADULT PATIENTS**

### **Systematic Reviews**

Sinha (2023) published a systematic review comparing BOD to FESS which included 18 studies and a subset of seven studies were used to conduct a meta-analysis.<sup>[1]</sup> The primary outcome was post-operative Sinonasal Outcome Test-20 scores and the pooled difference in means between BOD and FESS was 0.44, which was below the clinically meaningful difference of 0.8 set out in the study. The authors conclude that BOD is an appropriate choice and shows positive outcomes in patients with chronic rhinosinusitis while calling for additional high-quality studies comparing BOD to other treatment options.

Levy (2016) reported on a systematic review and meta-analysis of studies of paranasal BOD for chronic rhinosinusitis.<sup>[2]</sup> The review included 17 studies, only three of which were RCTs. Two of the RCTs reported on differences in the change in 20-Item Sinonasal Outcome Test (SNOT-20) scores between patients treated with BOD or FESS (n = 110; standard mean difference [SMD] -0.42, 95% CI -1.39 to 0.55,  $I^2=76%$ ).<sup>[3, 4]</sup> However, the reviewers found no significant differences in outcome in patients treated with BOD compared to those treated with conventional FESS (p=0.07). The reviewers did report improvements in SNOT-20 score and sinus opacification after BOD, but these conclusions were not drawn from comparative studies, but from five cohort studies.

A BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”.<sup>[5]</sup> This Assessment reviewed evidence from one RCT, three non-randomized comparative studies, and nine case series. The following conclusions were made concerning the adequacy of this evidence for determining the effect of balloon sinuplasty on health outcomes:

“The evidence is insufficient to determine the effect of the technology on health outcomes. One randomized clinical trial comparing balloon sinuplasty to FESS was inadequately powered and did not evaluate differences in outcomes between the two treatments. While most nonrandomized comparative studies of balloon sinuplasty and FESS show no difference in health outcomes between the two treatments, confounding factors may bias the comparison of the two treatments. Several case series show improvement in symptoms of rhinosinusitis over baseline measures, and such improvement appears durable up to 2 years. Case series do not allow conclusions

regarding the comparative efficacy of balloon sinuplasty to FESS.”

A 2011 Cochrane systematic review on balloon sinuplasty for chronic rhinosinusitis concentrated on RCTs.<sup>[6]</sup> One small RCT<sup>[7]</sup> met the inclusion criteria. Patients were randomized to a “hybrid approach” that included balloon sinuplasty of the affected frontal recess along with traditional FESS of other paranasal sinuses (n = 16), or to traditional FESS (n = 16). At 12-months follow-up, both groups reported improvements in symptoms, but there were no significant differences between the two groups. The authors of the Cochrane review rated this study as having a low risk for bias for most parameters, but a high risk for bias in reporting of the outcomes. Specifically, symptom scores were not presented systematically and details of statistical testing were not reported. The overall conclusion of this review was that there is no convincing evidence supporting the use of balloon sinuplasty in chronic rhinosinusitis (CRS).

Batra (2011) performed a comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology.<sup>[8]</sup> The authors noted significant study design flaws in the studies, including lack of comparator group in most, lack of randomization in the single comparative study, unclear selection criteria, and use of patient-reported symptom improvement.

The authors reached the following conclusions:

“The accrued data attests to its safety, whereas the largest published observational cohort studies have demonstrated the ability to achieve ostia patency for up to 2 years. However, because the selection criteria for these studies were not clearly defined, it is unclear if this data can be extrapolated to the general population with chronic rhinosinusitis (CRS). Is BCT superior or equivalent to the existing devices employed in FESS for the management of CRS? Will the use of BCT translate into improvements in patient outcomes, overall health, and/or quality of life? The many unsettled questions “will be best answered by prospective randomized trials that directly compare FESS to BCT, or directly compare medical to surgical treatment.”

## **Randomized Controlled Trials (RCTs)**

### The REMODEL Study

The REMODEL (Randomized Evaluation of Maxillary antrostomy versus Ostial Dilation Efficacy through Long-term follow-up) study was an industry-sponsored RCT that compared BOD as a stand-alone procedure with FESS.<sup>[4]</sup> A total of 105 patients with recurrent acute sinusitis or chronic sinusitis and failure of medical therapy were randomized to BOD or FESS. 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 prior to treatment, 11 in the FESS group (21%) and two in the BOD group (4%). The primary outcomes were the change in the SNOT-20 score at six-month follow-up, and the mean number of debridements performed postoperatively. Secondary outcomes included recovery time, complication rates, and rates of revision surgery. Both superiority and noninferiority analyses were performed on these outcomes.

A total of 91 patients were available at six-month follow-up. The improvement in the SNOT-20 score was  $1.67 \pm 1.10$  in the balloon dilation group and  $1.60 \pm 0.96$  in the FESS arm ( $p=0.001$

for noninferiority). Postoperative debridements were more common in the FESS group compared with balloon dilation ( $1.2 \pm 1.0$  vs.  $0.1 \pm 0.6$  in the FESS arm,  $p < 0.001$  for superiority). Patients in the balloon dilation arm returned to normal daily activities earlier (1.6 days vs. 4.8 days,  $p = 0.002$  for superiority), and required fewer days of prescription pain medications (0.9 days vs. 2.8 days,  $p = 0.002$  for superiority). There were no major complications in either group, and one patient in each group required revision surgery. This study was likely to have adequate power to detect group differences; however, there were some methodologic limitations. The study was unblinded and did not have blinded outcome assessment for the symptom-based outcomes or the secondary clinical outcomes. There was also evidence of differential dropout, with larger numbers of patients withdrawing from the FESS group following randomization (21% vs 4%).

Bikhazi (2014) reported one-year outcomes in the REMODEL study. A total of 92 patients (balloon dilation  $n = 50$ , FESS  $n = 42$ ) were treated and 89 (96.7%) completed one-year follow-up.<sup>[9]</sup> Both groups showed clinically meaningful and statistically significant ( $p < 0.0001$ ) improvement in mean overall SNOT-20 scores and in all four SNOT-20 subscales. Ostial patency was 96.7 and 98.7% after balloon dilation and FESS, respectively, and each group reported significant reductions ( $p < 0.0001$ ) in rhinosinusitis episodes (mean decrease 4.2 for balloon dilation and 3.5 for FESS) during the follow-up period of one year. Overall work productivity and daily activity impairment due to chronic sinusitis were significantly improved ( $p < 0.001$ ) in both groups. There were no complications, and the revision surgery rate was 2% in each arm through one year. The authors concluded that stand-alone balloon dilation was as effective as FESS in the treatment of CRS in patients with maxillary sinus disease, with or without anterior ethmoid disease, who failed medical therapy, and met the criteria for medically necessary FESS. The study included the use of self-reported quality of life questionnaires, which are subject to recall bias.

Chandra (2015) published final results of the REMODEL study<sup>[10]</sup>, which indicated that patients in the balloon sinus dilation groups experienced significantly faster recovery (1.7 vs. 5.0 days,  $p < 0.0001$ ), less nasal bleeding (32% vs. 56%;  $p = 0.009$ ), and less need for prescription pain medication (1.0 vs. 2.8 days,  $p < 0.0001$ ). Study authors also reported results of a meta-analysis of several stand-alone balloon sinus dilation studies. The meta-analysis was based on five studies that included non-randomized studies and two studies were reportedly unpublished. Based on results of the meta-analysis, FESS and balloon dilation were not significantly different for mean SNOT-20 symptom scores and revisions rates assessed at 12 months.

### Other Randomized Controlled Trials

Sikand (2019) published results from a trial where the primary outcome was the difference between arms in change in Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks.<sup>[11]</sup> The change in CSS was significantly greater in the BOD group compared to the control group (mean change 37.3 vs 21.8). Patients in the BOD group had a lower mean number of sinus infections through the 24-week followup period (0.2 vs 0.95). Durability of the outcome measure differences was demonstrated up to 48 weeks. After the 24-week followup period, 18 of 30 patients who were randomized to the control arm elected to receive BOD. Of those who crossed over at 24 weeks, none reported no change or worsening of symptoms, three reported improved symptoms but still used nasal sprays at high rates, four had improved symptoms to varying degrees but were not eliminated, and one reported a sinus infection just before their 24-week visit. There was one procedure-related serious adverse event in the BOD

group, two possibly procedure-related nonserious adverse events, and no device-related adverse events.

Bizaki (2014) reported results from an RCT that compared BOD to FESS among patients with symptomatic chronic or recurrent rhinosinusitis.<sup>[12]</sup> The trial enrolled 46 subjects, four of whom withdrew; the analysis included 42 patients (n = 21 in each group; statistical power calculations reported). Both groups demonstrated significant improvements in SNOT-22 scores from baseline to postprocedure. There were no differences in change in total SNOT-22 scores between groups at three months postprocedure. As a 2016 follow-up publication, trialists reported on nasal airway resistance and sinus symptoms between FESS- and BOD-treated groups.<sup>[13]</sup> For this analysis, 62 patients were included (32 from the FESS group, 30 from the balloon dilation group). Patients in the BOD group had significant improvements in nasal volume from pre- to postoperative measurements, but there were no significant differences between groups pre- or postoperatively in nasal volume.

Another RCT by Bizaki (2016) compared BOD to FESS, with a focus on mucociliary clearance.<sup>[14]</sup> It was conducted at the same institution as the previously reported Bizaki RCT; however, it was not specified whether it included the same patients. This trial enrolled 36 patients who were randomized to BOD (n=17) or FESS (n=19); seven patients dropped out (three in the FESS group, four in the balloon dilation group) and were not included in analyses. SNOT-22 scores improved in both groups from pre- to postoperative analyses. However, changes in total SNOT-22 scores did not differ significantly between groups. There was no significant change in mucociliary clearance before and after either treatment, nor was there a significant between-group difference in mucociliary clearance.

Marzetti (2014) reported results of a small RCT that compared BOD with an unspecified device (or devices) with FESS in the treatment of sinus headache.<sup>[15]</sup> The study included 83 patients with sinus headache, based on the American Academy of Otolaryngology-Head and Neck Surgery criteria, 44 of whom were randomized to conventional FESS and 35 to BOD. In the balloon dilation group, 23 patients were “only frontal sinus balloon” patients, in which balloon catheters were the only tools used for frontal sinus sinusotomy, and 12 were “hybrid,” in which balloon catheters and traditional endoscopic sinus surgery were used concurrently. It was not specified how patients were selected for these groups. FESS treatment was administered on participants in both groups, but specific data was not reported by study authors. At six months of follow up, scores on the SNOT-22 improved from 28.6 at baseline to 7.8 in the FESS group and 27.3 at baseline to 5.3 in the BOD group, with a statistically significant reduction in both groups ( $p < 0.001$ ). At six months of follow up, headache scores based on the visual analog score (VAS) improved from 6.5 to 5.4 in the FESS group and from 7.1 at baseline to 1.2 in the BOD group ( $p < 0.001$ ). Study authors did not report other patient-relevant outcomes, such as the number of headache days or use of pain medications following treatment. Limitations of this study included the small number of patients who received BOD, which limits the generalizability of study results, and the lack of blinding of both patients and clinical assessors. In addition, there were various concurrent surgical procedures conducted in both treatment and control groups, which made it difficult to properly assess the treatment effects of BOD.

Another small RCT published by Achar (2012) enrolled 24 patients with chronic sinusitis who had failed medical therapy and were scheduled for surgery.<sup>[3]</sup> Patients were randomized to balloon dilation or FESS and followed for a total of 24 weeks. The primary outcome measures were changes in the SNOT-20 score and the saccharine clearance time test. Both groups improved significantly on both outcome measures. The degree of improvement was greater for

the functional endoscopic dilatation sinus surgery group compared to the FESS group on both the SNOT-20 score ( $43.8 \pm 15.2$  vs.  $29.7 \pm 12.3$ ,  $p < 0.03$ ) and on the saccharine clearance score ( $7.5 \pm 5.1$  vs.  $3.5 \pm 4.3$ ,  $p = 0.03$ ). Adverse events were not reported.

A small RCT was published in 2011 that reported on physiologic outcomes.<sup>[16]</sup> Twenty patients were randomly assigned to removal of the uncinata process via FESS or balloon sinus ostial dilation as a stand-alone procedure. The main outcome measures were CO<sub>2</sub> concentration in the sinuses and maximum sinus pressure, both intended to be surrogate measures for sinus ventilation. The CO<sub>2</sub> concentration decreased in both study arms to a similar degree. The mean maxillary sinus pressure on inspiration decreased in the FESS group but did not change in the balloon sinus ostial dilation group.

Bozdemir (2011) published a small study of 10 patients with nasal polyposis, in which one side was treated with FESS and the other with balloon sinus ostial dilation.<sup>[17]</sup> All procedures were performed by the same surgeon, and polypectomy was performed prior to FESS or balloon sinus ostial dilation in all patients. Outcome measures included sinus patency, as measured by computed tomography (CT) scan (Lund-McKay classification) or repeat endoscopy (McKay grading). At 10 days following the procedure, there were improvements in both groups on measures of patency, but there were no differences between groups.

### **Nonrandomized Studies**

Gould (2014) assessed the one-year changes in sinonasal symptoms and health care use after office-based, multi-sinus balloon dilation in an industry-sponsored prospective, multicenter study.<sup>[18]</sup> A total of 313 ostial dilations were attempted and 307 were successfully completed (98.1%) in 81 subjects. Seventy-six of the 81 patients completed the one-year follow-up. Mean procedure tolerance was  $2.8 \pm 2.2$  (0 = no pain, 10 = severe pain). SNOT-20 symptom improvement was observed at one and six months and sustained through one year. The RSI questionnaire that rates five major and seven minor rhinosinusitis symptoms measured a treatment effect for all major rhinosinusitis symptoms. Compared with the previous one-year period, patients reported an average of 2.3 fewer acute sinus infections ( $p < 0.0001$ ), 2.4 fewer antibiotic courses taken ( $p < 0.0001$ ), and 3.0 fewer sinus-related physician visits ( $p < 0.0001$ ) after balloon dilation. No serious device or procedure-related adverse events occurred. One subject underwent revision surgery. The authors reported that patients reported significant reductions in both sinonasal symptoms and health care use after balloon dilation. Methodological limitations included the implementation of self-reported SNOT-20 and RSI questionnaires, which may lead to recall bias; lack of a comparison group, which precludes the ability to isolate any reported treatment effects; and the uncertain timing between the preoperative CT scan and failure of medical management.

Brodner (2013) reported a prospective, multi-center study to evaluate outcomes for the XprESS device for the treatment of the frontal recesses, maxillary ostia, and/or sphenoid sinus ostia in 175 adults who had previously been scheduled for conventional FESS.<sup>[19]</sup> The criteria for previously-scheduled conventional FESS are not specified. There were a mean 2.7 sinuses per patient treated; of the targeted sinuses, 479/497 (96.4%) were successfully accessed and treated. One-year follow up was planned in the first 50 subjects, who only underwent dilation of frontal recesses and sphenoid ostia; at one year, in the 41 subjects with one-year follow-up available, 76/83 (91.6%) of the ostia dilated with the study device were patent. At one year, in 44 subjects who completed follow-up, the average overall SNOT-20 score was 0.8 (vs 1.9 at baseline;  $p < 0.0001$  for change), which was considered a clinically meaningful improvement



(change  $\geq 0.8$ ).

Albritton (2012) reported results of a prospective, nonrandomized evaluation of the feasibility of in-office balloon sinus dilation with the Relieva device who were enrolled in the ORIOS trial.<sup>[20]</sup> The study included 37 subjects (59 sinuses) who had a diagnosis of chronic rhinosinusitis (>12 weeks of symptoms including but not restricted to nasal obstruction, sinus/ facial pressure, nasal discharge, and congestion) that was unresponsive to maximal medical management. Successful access and dilation of all targeted sinuses occurred in 33/37 subjects (89%). Follow up was available for 32 (86.5%), 31 (83.8%), 26 (70.2%), and 21 (56.8%) at 1-, 4-, 24-, and 52-weeks post-procedure, respectively. Symptoms were assessed based on the change in SNOT-20 score from baseline to follow up, with a mean reduction from baseline of -0.98 (95% CI -1.27 to -0.70), -1.32 (95% CI -1.65 to -1.00), -1.25 (95% CI -1.65 to -0.85), and -1.42 (95% CI -1.87 to -0.90) at 1-, 4-, 24-, and 52-weeks post-procedure, respectively. For the 29 subjects who had CT scans available at baseline and 24 weeks of follow up, Lund-Mackay score improved from 6.62 preprocedure to 2.79 postprocedure ( $p < 0.0001$ ).

In the ORIOS2 study, Karanfilov (2013) reported results of a prospective, nonrandomized, multicenter evaluation of office-based balloon sinus dilation with the Relieva device in 203 patients who required FESS for medically refractory chronic sinusitis.<sup>[21]</sup> Three cohorts were enrolled, a lead-in cohort which consisted of each investigator's first cases where all targeted sinuses were successfully dilated ( $n = 36$ ), a standard enrollment cohort which consisted of up to approximately 15 cases ( $n = 84$ ), and an extended enrollment cohort which included subjects after the first 15 cases ( $n = 83$ ). Dilation technically successful in 552 of 592 attempted sinuses (93.2%). Matched baseline and twenty-four week follow up was available for 112 patients, who demonstrated a mean improvement in SNOT-20 scores of -1.1 ( $p < 0.0001$ ). In the 110 patients with 24 week CT scans available, Lund-Mackay score improved by -4.3 compared with baseline ( $p < 0.0001$  for change).

Levine (2013) reported results of a prospective, nonrandomized, multicenter evaluation of office-based balloon sinus dilation with the FinESS device in 74 patients with chronic rhinosinusitis ( $n = 52$ ) or recurrent acute sinusitis ( $n = 17$ ).<sup>[22]</sup> Balloon dilation was successful in 69 patients, and analyses are reported per protocol. The overall technical success rate in patients was 91.9% (124 of 135 ostia) but it was not specified if this was in overall sample of 74 patients or in analysis sample of 69 patients. Mean SNOT-20 scores improved from a mean 2.3 at baseline to 1.1 at six months and 12 months in the 66 patients with follow up data available (mean change -1.2,  $p < 0.0001$ ). There were no significant differences in improvements reported between the chronic rhinosinusitis and recurrent acute sinusitis patients.

A number of additional nonrandomized studies have been identified, which do not allow conclusions concerning the impact of BSD on primary health outcomes compared with FESS. These studies have methodological limitations such as a limited number of patients,<sup>[20, 23]</sup> a heterogeneous study population,<sup>[24]</sup> no primary health outcomes reported,<sup>[25]</sup> limited follow-up,<sup>[20, 23, 24, 26]</sup> retrospective study design<sup>[26, 27, 28, 29]</sup>, or implementation of self-reported questionnaires.<sup>[18, 25, 27]</sup> The exception is a single-arm study by Tomazic (2013), in which the authors planned to evaluate a cohort of 200 patients with BOD or a hybrid procedure, but ended the study early after 45 patients after a high technical failure rate was noted, with 44/68 sinuses in a planned BOD group and 29/44 sinuses in a planned hybrid procedure group failing.<sup>[30]</sup>

Retrospective studies are limited by the accuracy of the medical records reviewed or the recall ability of patients when filling out a study questionnaire. In addition, there is no randomization or blinding in a retrospective study design and therefore it is difficult to control for bias and confounders.

## **PEDIATRIC PATIENTS**

### **Nonrandomized Studies**

Wang (2015) reported on a perspective nonrandomized controlled study of 79 pediatric patients (age 7-12) with chronic sinusitis resistant to medical therapy, including 42 patients treated with sinus balloon catheter dilation balloon (SBCD) and 37 control patients treated conservatively (including oral antibiotics, local nasal steroid spray, and nasal saline irrigation).<sup>[31]</sup> At one-year posttreatment, the SN-5 scores were significantly better in the SBCD group (22 patients [52%] had marked improvement, 11 [26%] had moderate improvement, and six [14%] had mild improvement) than in the control group (five [14%], seven [19%], and four [11%], respectively) ( $p < 0.05$  for all comparisons).

In a retrospective comparative study, Thottam (2012) evaluated the incremental value of Relieva balloon catheter sinuplasty when combined with FESS in 31 children (mean age 9.3 years) who had persistent chronic sinusitis despite standard maximal medical therapy.<sup>[32]</sup> The authors performed a blinded chart review of 15 children who underwent balloon catheter sinuplasty with ethmoidectomy and 16 children who underwent FESS. Thirteen children had prior adenoidectomy. A total symptom score was constructed for the number of complaints presurgery, postsurgery, and at the final postsurgical examination (> four months) including facial pain, sinus congestion, postnasal drip, rhinorrhea, headache, and low-grade fever. Success and improvement were defined as a decrease in the total complaint score of  $\geq 1$  point at the last visit, while total improvement was defined as total resolution of all complaints (i.e., symptom score of 0). Compared with baseline values, significant posttreatment reductions in overall sinusitis symptoms and needed interventions were observed in both treatment groups. In the Relieva balloon catheter sinuplasty group, 80% of the patients reported improvements in their overall sinus symptoms at an average of 37 weeks, versus 62.5% of the FESS patients. This difference between groups was not significant. No serious complications occurred.

In a prospective, nonrandomized controlled study, Ramadan (2010) compared the efficacy and safety of Relieva balloon sinuplasty combined with adenoidectomy ( $n=30$ ) with that of adenoidectomy alone ( $n = 19$ ) in 49 children (mean age 6.6 years, range 2-11) with chronic sinusitis that was refractory to medical therapy for at least six months.<sup>[33]</sup> The patients were followed at regular intervals for up to one year. Twenty-four of the 30 (80%) patients in the Relieva plus adenoidectomy group showed symptom improvement at one year compared with 10 of 19 (52.6%) children in the adenoidectomy alone group. Two (6%) patients with hypoplastic sinuses failed balloon sinuplasty and required revision FESS. One patient was lost to follow-up, and another had no improvement in SN-5 scores. Three (15%) children who did not improve after adenoidectomy had balloon sinuplasty. Overall, the mean SN-5 score for all participants decreased from a baseline value of 4.1 to 2.9 after surgery. In the Relieva plus adenoidectomy group, the mean SN-5 score decreased from 4.2 to 3.0, while in the adenoidectomy alone group, the score decreased from 3.8 to 2.9. No major complications occurred in either treatment group.

Prospective, multicenter single-arm studies have reported outcomes in pediatric patients with chronic sinusitis. In one study of 32 children, 24 had one-year follow-up data.<sup>[34]</sup> Of the 32

children enrolled, 24 were studied at one-year follow-up. Significant improvements in quality of life outcomes were reported using the SN-5 score ( $p < 0.0001$ ). Twelve (50%) children had a significant improvement of their SN-5 score, seven children (29%) had moderate improvement, two (8%) had mild improvement, one (4%) remained the same, and two children (8%) had worsening scores. A similar study with 50 participants and 157 total attempted dilations also reported significant improvement in SN-5 scores at six months ( $p < 0.0001$ ).<sup>[35]</sup> No adverse procedure-related events were reported in either study. However, these studies lacked a comparison group, limiting conclusions regarding the efficacy of the procedure.

## PRACTICE GUIDELINE SUMMARY

### AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY (AAO-HNS)

In 2018, the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses.<sup>[36]</sup> 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 following statements met consensus:

#### Patient Criteria:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT. (Strong consensus)
- Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- CT scanning of the sinuses is a requirement before balloon dilation can be performed. (Strong consensus)
- Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and CT evidence of ostial occlusion and mucosal thickening.

#### Perioperative Considerations:

- Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the FDA 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

## SUMMARY

There is enough research to show that balloon ostial dilation improves health outcomes for patients with sinusitis compared to functional endoscopic sinus surgery (FESS). In addition, there are clinical practice guidelines that address balloon ostial dilation for the treatment of sinusitis. Therefore, balloon ostial dilation as a treatment for sinusitis, either as a stand-alone procedure or in conjunction with FESS, may be considered medically necessary when policy criteria are met.

There is not enough research to show that balloon ostial dilation improves health outcomes for patients with chronic or acute sinusitis when policy criteria are not met. Therefore, balloon ostial dilation as a treatment for sinusitis, either as a stand-alone procedure or in conjunction with FESS, is considered investigational when policy criteria are not met.

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## CODES

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

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<b>Codes</b>	<b>Number</b>	<b>Description</b>
	31297	;sphenoid sinus ostium
	31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)
	31299	Unlisted procedure, accessory sinuses
HCPCS	C1726	Catheter, balloon dilatation, non-vascular

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**Date of Origin:** August 2006