Balloon Sinuplasty for Treatment of Chronic Sinusitis

**Title:** Balloon Sinuplasty for Treatment of Chronic Sinusitis

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DESCRIPTION
Balloon ostial dilation (also known as balloon sinuplasty) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic sinusitis 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 functional endoscopic sinus surgery (FESS).

OBJECTIVE
The objective of this policy is to evaluate whether balloon ostial dilation improves health outcomes for patients with chronic rhinosinusitis.

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

Estimates are that approximately 30 million individuals in the United States suffer from chronic sinusitis. Most cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. FESS has become an important aspect for surgical management of chronic sinusitis, although evidence from randomized controlled trials (RCTs) is limited. For this procedure, a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. This procedure restores patency and allows air and mucous transport through the natural ostium. Approximately 350,000 FESS procedures are done each year in the United States for chronic sinusitis.

Treatment
A newer procedure, balloon ostial dilatation can be used as an alternative to FESS or as an adjunct to FESS for those with chronic sinusitis. The goal of this technique, when used as an alternative to FESS, is to achieve improved sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. 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.

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

**Outcomes**
To quantify the severity of chronic rhinosinusitis and to assess treatment response, various outcomes measures can be used, including patient-reported quality of life (QOL) measures, radiologic scores, and endoscopic grading.

The Lund-McKay scoring system utilizes radiologist-rated information derived from computed tomography scans regarding opacification of the sinus cavities, generating a score from 0 to 12.  

Several disease-specific patient-reported QOL scores have been used. Commonly used is the 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 SNOT-22, variation of the SNOT-20, includes 2 additional questions ("nasal obstruction" and "loss of smell and taste"). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.  

Additionally, QOL may be reported based on overall health-related QOL scores, such as the 36-Item Short-Form Health Survey-36 (SF-36). The SF-36 includes 8 scaled scores on various health domains, which are transformed into a 0-to-100 scale (100 corresponding to best health).

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

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

FDA product code: LRC
**POLICY**

A. Balloon sinus ostial dilation is considered **medically necessary** for treating rhinosinusitis lasting longer than 12 weeks or 4 or more documented episodes of acute rhinosinusitis (in one year) when all of the following are met:

1. Confirmation with computed tomography (CT) scan and/or nasal endoscopy of findings of rhinosinusitis that includes one or more of the following:
   a) Nasal endoscopy showing purulent discharge or persistent inflammatory sinus pathology, **OR**
   b) CT evidence of mucosal thickening, bony remodeling, bony thickening, or obstruction of the ostiomeatal complex; **AND**

2. Balloon sinus ostial dilation is limited to the frontal, maxillary or sphenoid sinuses; **AND**

3. Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS); **AND**

4. Balloon sinus ostial dilation is performed on patients whose symptoms persist despite maximal medical therapy (see Policy Guidelines).

B. Balloon ostial dilation is considered **not medically necessary** in the following situations:

1. Nasal polyposis (Grade 2 or greater);

2. Samter's triad (aspirin sensitivity);

3. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, Wegener's granulomatosis);

4. Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis;

5. Contraindication to, or inability to tolerate local and/or topical anesthetic;

6. History of failed balloon procedure in the sinus to be treated;

7. Sinusitis with extensive fungal disease;

8. Isolated ethmoid sinus disease;

C. Balloon sinus ostial dilation for treatment of chronic sinusitis is considered experimental / investigational for any other indication.

Policy Guidelines
1. There are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site.

2. When a balloon sinuplasty is used as an adjunct in performance of a medically necessary functional endoscopic sinus surgery (FESS) in the treatment of chronic sinusitis, the use of the balloon catheter is considered included in the allowance for the FESS procedure. There is no additional reimbursement for use of the balloon catheter.

3. If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the procedure might be coded using the CPT codes for nasal/sinus endoscopy with maxillary antrostomy (31256), nasal/sinus endoscopy with frontal sinus exploration (31276), or nasal/sinus endoscopy with sphenoidectomy (31287). In this instance, the balloon dilation would be considered inclusive/incidental to the procedure.

4. Maximal medical therapy:
   a) Oral antibiotics of 2-4 weeks' duration for patients with CRS (chronic rhinosinusitis) (culture-directed if possible).
   b) Oral antibiotics with multiple 1-3 week courses for patients with RARS (recurrent acute rhinosinusitis).
   c) Systemic or topical steroids (discretion of physician).
   d) Saline irrigation (optional).
   e) Topical and/or systemic decongestants (optional).

RATIONALE
This policy was created in 2006 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period through January 8, 2017. The following is a summary of the key literature evidence to date.

Balloon sinus ostial dilation can be performed as a stand-alone procedure or as an adjunct to functional endoscopic sinus surgery (FESS). When performed in combination with FESS, it is sometimes referred to as a hybrid procedure because there are elements of both balloon sinus ostial dilation and FESS.

Controlled trials are essential in determining the efficacy of this procedure in relation to alternatives. The natural history of the disorder includes resolution with medical therapy or no therapy in a large proportion of patients. Medical therapy is effective in reducing symptoms for most patients, and because surgical treatment is an invasive procedure with its own set of risks, it is appropriate to seek demonstration of improved outcomes with surgical therapy in direct comparison with medical therapy controls. Therefore, this review is limited to randomized controlled trials (RCTs) and systematic reviews of RCTs or studies that report on long-term follow-up.
The primary outcome measures relevant for the treatment of chronic rhinosinusitis (CRS) are patient-reported symptoms and quality of life. Studies should predefine responder criteria for whatever outcome measures are used and assess between-group differences in the proportion of patients considered responders. 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.

The literature consists of a few small randomized controlled trials (RCTs), a small number of nonrandomized controlled trials, and a larger number of single-arm case series, most of which are retrospective. This evidence is reviewed next, with emphasis on the available controlled trials, in 2 categories: (1) balloon ostial dilation as a stand-alone procedure and (2) balloon ostial dilation as an adjunct to FESS. The following is a summary of the key literature evidence to date.

**Systematic Reviews of Balloon Ostial Dilation as a Stand-Alone or Adjunct Procedure**

**Systematic Reviews**

A 2012 TEC Assessment on balloon ostial dilation for treatment of CRS reviewed evidence from 1 RCT, 3 nonrandomized comparative studies, and 9 case series. The TEC Assessment concluded that the evidence was insufficient to determine the effect of the technology on health outcomes. One RCT comparing balloon sinus ostial dilation with FESS was inadequately powered and did not evaluate differences in outcomes between the 2 treatments. While most nonrandomized comparative studies of balloon sinus ostial dilation and FESS showed no difference in health outcomes between the 2 treatments, confounding factors may have biased the comparisons. Several case series showed improvement in symptoms of rhinosinusitis over baseline measures, and such improvement appeared durable up to 2 years. Case series did not allow conclusions on the comparative efficacy of balloon sinus ostial dilation to FESS.

A 2011 Cochrane systematic reviewed the literature on balloon sinus ostial dilation for CRS. This review concentrated on RCTs, and included the Plaza et al RCT as the sole controlled trial that met selection criteria. The reviewers rated this study as having a low risk for bias for most parameters, but a high risk for bias in reporting outcomes. They noted that symptom scores were not presented systematically and that 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 sinus ostial dilation in CRS.

In 2016, Levy et al reported on a systematic review and meta-analysis of studies of paranasal balloon ostial dilation for CRS. The review included 17 studies, with 3 RCTs (Achar et al [2012], Bikhazi et al [2014], Cutler et al [2013]). Two RCTs reported on change score differences for the Sino-Nasal Outcome Test–20 (SNOT-20) between patients treated with balloon ostial dilation and with FESS (n=110; standard mean difference, -0.42; 95% confidence interval [CI], -1.39 to 0.55; I^2=76%). There were improvements in SNOT-20 scores and sinus opacification after balloon ostial dilation.

In 2011, Batra et al performed a comprehensive review of the literature on balloon catheter technology in rhinology. The review included observational cohort studies that provided relatively less evidence about the efficacy of balloon ostial dilation. The reviewers concluded that prospective RCTs comparing FESS with balloon catheter technology are needed.

**Balloon Ostial Dilation as a Stand-Alone Procedure vs FESS Alone**

**Randomized Controlled Trials**
REMODEL Trial
The REMODEL study was an industry-sponsored study RCT that compared balloon ostial dilation as a stand-alone procedure with FESS. A total of 105 patients with recurrent acute sinusitis or chronic sinusitis and failure of medical therapy were randomized to balloon ostial dilation or FESS. 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 in the FESS group (21%) and 2 in the balloon ostial dilation group (4%). The primary outcomes were the change in the Sino-Nasal Outcome Test (SNOT-20) score at 6-month follow-up, and the mean number of débridements 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 6-month follow-up. The improvement in the SNOT-20 score was 1.67±1.10 in the balloon dilation group and 1.60±0.96 in the FESS arm (p=0.001 for noninferiority). Postoperative débridements were more common in the FESS group compared with balloon dilation (1.2±1.0 vs 0.1±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 1 patient in each group required revision surgery.

Bikhazi et al reported 1-year follow-up from the REMODEL study in 2014. A total of 89 subjects (96.7%) were available for follow up to 1 year. The improvement in the SNOT-20 score was 1.64 in the balloon dilation arm and 1.65 in the FESS arm (p<0.001 for noninferiority). During 1-year post procedure, both the balloon dilation and FESS groups had fewer self-reported rhinosinusitis episodes (reduction in 4.2 episodes in the balloon arm and reduction in 3.5 episodes in the FESS; p=NS).

In 2016, Chandra et al reported results up to 2 years postprocedure for subjects in the REMODEL study, along with an additional 30 subjects treated with either FESS or in-office balloon sinus dilation, for a total of 61 FESS patients and 74 balloon sinus dilation 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 described in the 2013 Cutler article. Balloon sinus dilation patients required 0.2 débridements per patient compared with 1.0 per patient in the FESS group (p<0.001). Mean change in SNOT-20 score from baseline to 12-month follow-up was -1.59 (p<0.001) and -1.60 (p<0.001) for the balloon sinus dilation 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 sinus dilation group and 6.9% in the FESS group. In addition to the longer term results of the REMODEL trial, this article includes a meta-analysis of the REMODEL balloon dilation-treated patients and data from 5 manufacturer-sponsored trials, 3 of which had previously been reported in peer-reviewed form (BREATHE: Stankiewicz et al [2010], Stankiewicz et al [2012]; RELIEF: Levine et al [2013]; XprESS Transnasal Maxillary Multi-Sinus: Gould et al [2014]). Across the 6 studies, 846 patients were treated with balloon sinus dilation, including 121 not described in prior publications. In a random-effects model, overall mean and subscale values for SNOT-20 scores improved compared with baseline at every follow-up time point.
Additional RCTs
Bizaki et al reported results from an RCT that compared balloon ostial dilation to FESS among patients with symptomatic chronic or recurrent rhinosinusitis. The study enrolled 46 subjects, 4 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 the balloon sinus dilation and FESS groups at 3 months postprocedure. As a follow-up publication, Bizaki et al reported on nasal airway resistance and sinus symptoms between FESS- and balloon ostial dilation–treated groups. For this analysis, 62 patients were included (32 from the FESS group, 30 from the balloon ostial dilation group). Patients in the balloon ostial dilation 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 et al compared balloon ostial dilation to FESS, with a focus on mucociliary clearance. It was conducted at the same institution as the previously reported Bizaki RCTs; however, the RCT did not specify whether it was the same set of patients. This trial enrolled 36 patients who were randomized to balloon ostial dilation (n=17) or FESS (n=19); 7 patients dropped out (3 in the FESS group, 4 in the balloon ostial dilation group) and were not included in analyses. SNOT-22 scores improved in both group from pre- to postoperative analyses. However, change in total SNOT-22 score 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 et al reported results from a small RCT that compared balloon ostial dilation using an unspecified device (or devices) to FESS in the treatment of sinus headache. The trial included 83 patients with sinus headache, based on American Academy of Otolaryngology–Head and Neck Surgery definitions, 44 randomized to conventional endoscopic sinus surgery (ESS) and 35 to balloon ostial dilation. 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 ESS were used concurrently. It was not specified how patients were selected for these groups. At 6-month follow-up, scores on the SNOT-22 improved from 28.6 at baseline to 7.8 in the ESS group and from 27.3 at baseline to 5.3 in the balloon ostial dilation group, with a statistically significant reduction in both groups (p<0.001). At 6-month follow-up, headache scores based on a visual analog scale (VAS) improved from 6.5 at baseline to 5.4 in the ESS group and from 7.1 at baseline to 1.2 in the balloon ostial dilation group (p<0.001).

An RCT from Turkey, published in 2011, reported on physiologic outcomes. Twenty patients were randomly assigned to removal of the uncinate process via FESS or balloon sinus ostial dilation as a stand-alone procedure. The main outcome measures were CO₂ concentration in the sinuses and maximum sinus pressure, both intended as surrogate measures for sinus ventilation. The CO₂ concentration decreased in both study arms to a similar degree. The maximum sinus pressure decreased in the FESS group but did not change in the balloon sinus ostial dilation group.

Another RCT was published by Achar et al in 2012. It enrolled 24 patients with CRS who had failed medical therapy and were scheduled for surgery. Patients were randomized to balloon dilation or FESS and followed for 24 weeks. The primary outcome measures were changes in the SNOT-20 score and clearance time using the saccharin test. Both groups improved significantly on both outcome measures. The degree of improvement was greater for the balloon dilatation group.
than the FESS group on both the SNOT-20 score (43.8 [SD=15.2] vs 29.7 [SD=12.3], p<0.03) and on the saccharin test score (7.5 [SD=5.1] vs 3.5 [SD=4.3], p=0.03). Adverse events were not reported.

Bozdemir et al published a small study of 10 patients with nasal polyposis, in which 1 nasal passage was treated with FESS and the other with balloon sinus ostial dilation.22 All procedures were performed by the same surgeon, and polypectomy was performed before FESS or balloon sinus ostial dilation in all patients. Outcome measures included sinus patency, as measured by computed tomography (CT) scan (Lund-Mackay classification) or repeat endoscopy (Mackay grading). At 10 days postprocedure, there were improvements in both groups on measures of patency, but there were no differences between groups.

Nonrandomized Comparative Studies

A large number of nonrandomized comparative studies have evaluated balloon ostial dilation.23-27 Given the availability of RCT evidence, these studies do not provide significant additional evidence about the efficacy of balloon ostial dilation.

Section Summary: Balloon Ostial Dilation as a Stand-Alone Procedure Versus FESS Alone

There are a number of randomized trials comparing balloon ostial dilation as a stand-alone procedure to FESS. These trials have generally reported that short-term outcomes of balloon ostial dilation are similar to those of FESS. Only 1 RCT, the REMODEL study (105 patients randomized), was likely to have adequate power to detect group differences. It reported noninferiority for the change in the SNOT-20 scores and superiority for balloon ostial dilation on postoperative recovery and pain medication use. The trial had methodologic limitations, including lack of blinded outcome assessment and differential dropout. This evidence shows some support for balloon ostial dilation as an alternative to FESS in patients with CRS, but it is limited.

Balloon Ostial Dilation as an Adjunct to FESS vs FESS Alone

Two RCTs were identified that evaluate the incremental benefit of the addition of balloon ostial dilation to FESS compared with FESS alone.

Hathorn et al (2015) reported results of a single-blinded, randomized trial of balloon dilation with the Ventera Sinus Dilation System as an adjunct to frontal sinusotomy (Draf IIA) in which each patient served as his or her own control.28 The Draf IIA procedure involves a more extensive drainage procedure with resection of the floor of the frontal sinus. Thirty patients with CRS were randomized to right or left balloon sinus dilation in conjunction with frontal sinusotomy. Both groups had high (30/30) rates of sinus ostia patency at 3 months postprocedure. Several procedure-related factors differed between groups: the hybrid (balloon sinuplasty) procedures were significantly shorter (655 seconds vs 898 seconds; 95% CI for difference, 30.9 to 454.4 seconds; p=0.03) and associated with less estimated blood loss (53 mL vs 91 mL; 95% CI for difference, 8.8 to 57.5 mL; p=0.008).

A double-blinded RCT of balloon sinus ostial dilation as an adjunct to FESS versus FESS alone was published by Plaza et al in 2011.6 This trial enrolled 34 patients with CRS who were refractory to intensive medical management. Patients were randomized to a “hybrid approach” that included balloon sinus ostial dilation of the affected frontal recess along with traditional FESS of other paranasal sinuses, or to traditional FESS with the Draf I procedure. In both groups, an anterior ethmoidectomy was performed. A posterior ethmoidectomy and/or sphenoidotomy were performed as required by intraoperative assessment in both groups. Outcome measures at 12-month follow-
up included symptoms, the Rhinosinusitis Disability Index, CT results of sinus patency, and the permeability of the frontal recess, as assessed by office endoscopy. There was 1 dropout in each group, leaving 16 patients per group for analysis. For both groups, there were improvements in symptoms, standardized rhinosinusitis scoring indices, and CT patency, but no differences between groups. Rates for the 12-month outcome of endoscopic patency were 73% in balloon sinus ostial dilation patients and 63% in FESS patients. The published study contained contradictory statements on whether this difference was statistically significant. The lead author of this study clarified that the difference reported in the results for endoscopic patency was not statistically significant (G. Plaza, personal communication, April 2012). There were no major complications reported.

Section Summary: Balloon Ostial Dilation as an Adjunct to FESS vs FESS Alone
Two RCTs evaluating balloon ostial dilation as an adjunct to FESS were identified. Both suggested that the addition of balloon ostial dilation to traditional procedures can be done without adverse effects. One trial reported improved procedure times and less blood loss with balloon ostial dilation, although it is not clear whether the procedure time and blood loss were evaluated by a blinded observer. Both trials reported no significant differences between the hybrid and standard approaches in terms of sinus ostia patency.

Balloon Ostial Dilation as a Stand-Alone or Adjunct Procedure
Single-Arm Studies
Some single-arm studies have reported follow-up beyond 2 years for balloon ostial dilation and are described here. Bolger and Vaughan (2007) reported on outcomes at 24 weeks from a prospective, multicenter study of balloon sinus ostial dilation. In this study, 115 patients, for whom FESS was recommended, received treatment with the balloon catheter. Sinusotomy was attempted in 358 sinuses, and cannulation was successful in 347. Ostia patency rates were assessed at weeks 1, 12, and 24; at 24 weeks, 304 (88%) of the 347 sinuses were evaluated. While only 5 were nonpatent, the status of 18% was reported as indeterminate. Patients’ symptoms as measured by SNOT-20 scores also improved posttreatment. The device malfunctioned in 12 (3.4%) of 358 cases, the balloon ruptured in 7 cases, and the catheter tip malfunctioned in 4 cases. The authors indicated that there were no serious adverse events.

Additional follow-up to 2 years has been reported for a subset of the 115 patients in the previous study. At the 1-year follow-up, 70 (61%) of the 115 patients remained in the study. Of the 66 patients who had follow-up nasal endoscopy, 85% of sinus ostia were patent; however, by adding results of CT scans showing improvement, 92% were judged to have functional patency. The report on clinical symptoms with 2-year follow-up involved a similar subset of patients (N=65). In this longer term study, in which 34 patients had only balloon treatment, 85% of patients had improved symptoms. Revision treatment was required in 3.6% of sinuses involving 6 (9%) of 65 patients.

A second prospective multicenter, single-arm study of balloon sinus ostial dilation in refractory rhinosinusitis was published by Stankiewicz et al in 2010. They reported 1-year follow-up data of the Balloon Remodeling Antrostomy Therapy (BREATHE I) study. In it, 30 patients received balloon dilation of the ethmoid infundibulum using the FinESS system, a transantral dilation approach via the canine fossa. The primary outcome measure was patient-reported QOL measured using the SNOT-20. Average overall symptom score at baseline was 2.9. At 3, 6, and 12 months postintervention, average overall symptom scores were 0.7, 0.8, and 0.8, respectively.
Two-year results from the BREATHE study were reported in 2012. At that time, 59 patients were treated with balloon sinus ostial dilation, with a mean follow-up of 27 months. Mean SNOT-20 scores (SD) improved from 2.65 at baseline to 0.79 at the longest follow-up. This report also discussed measures of functional impairment using the Work Limitation Questionnaire (WLQ) and the Work Productivity and Activity Impairment Questionnaire (WPAI). Mean scores on the WLQ for overall productivity loss decreased from 8% at baseline to 2.5% at longest follow-up (estimates from graphical representation), and this pre- and postchange was statistically significant (p<0.001). Similar improvements were reported on other parameters of the WLQ and WPAI.

Series with shorter follow-up have also been published. For example, Soler et al (2016) reported results of a single-arm study evaluating stand-alone balloon sinus dilation for CRS in children ages 2 to 21 years. At 6-month follow-up, results of the Sinus and Nasal Quality of Life Survey were significantly improved compared with baseline (p<0.001).

SUMMARY OF EVIDENCE

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure, the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available systematic reviews have concluded that, although nonrandomized evidence suggests balloon ostial dilation has similar outcomes to functional endoscopic sinus surgery (FESS), evidence from randomized trials is needed to demonstrate an improvement in outcomes for patients treated with balloon ostial dilation. Since publication of the systematic reviews, an additional RCT (the REMODEL study) has been published. It included 105 patients, reporting short-term improvement in symptoms that are similar to those seen with FESS, and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. Limitations of the REMODEL study include an unblinded design, lack of blinded outcome assessment across the range of outcome measures, and differential dropout between groups. Other trials have provided limited additional evidence.

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as an adjunct to FESS, the evidence includes 2 small RCTs and single-arm series. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The 2 available RCTs did not report significant clinically meaningful benefits associated with the addition of FESS.

CLINICAL INPUT RECEIVED THROUGH PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2013 Input

In response to requests, input was received from 2 specialty societies and 6 academic medical centers while this policy was under review in 2013. The overall input was mixed on whether balloon ostial dilation should be medically necessary, either as a stand-alone procedure or as an adjunct to FESS. There was no consensus on subpopulations of patients with chronic rhinosinusitis who might benefit from balloon ostial dilation. There was consensus that RCTs should be performed comparing balloon ostial dilation with standard care in order to determine efficacy.
2011 Input
In response to requests, input was received from 2 physician specialty societies and 6 academic medical centers while this policy was under review in 2011. Input was mixed. A number of reviewers agreed that this technique was investigational. These reviewers commented about the need for additional trials to compare outcomes with standard approaches. Comments were made on the lack of selection criteria for use of the balloon catheter. Reviewers also noted that the current studies do not permit separating the results for use of the balloon from concurrent FESS, because most studies used both techniques.

2008 Input
In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2008. Input from 1 specialty society did not specifically address the clinical aspects of this technique but made comments related to coding. Another specialty society noted concerns due to lack of controlled studies and also commented that the long-term objective follow-up (eg, computed tomography scans) was on a limited number of patients. Input from 2 academic centers indicated this treatment was not investigational but should be viewed as just another surgical tool for the treatment of chronic sinusitis.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute for Health and Care Excellence
A 2008 practice guideline on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Clinical Evidence (UK) states: "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusis is adequate and raises no major safety concerns. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit." In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis:

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

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

American Academy of Otolaryngology – Head and Neck Surgery
In July 2016, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) Foundation updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: "Sinus ostial dilation ... is a therapeutic option for selected patient with chronic rhinosinusitis.... This approach may be used alone ... or in conjunction with other instruments...." In 2015, the AAO-HNS Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.

American Rhinologic Society
A position statement, revised in 2015, from the American Rhinologic Society, stated that sinus ostial dilation is “an appropriate therapeutic option for selected patients with sinusitis.”
U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01714687*</td>
<td>Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET)</td>
<td>400</td>
<td>Apr 2016 (ongoing)</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01990820</td>
<td>Study for the Management of Pediatric Chronic Rhinosinusitis With or Without Balloon Sinuplasty</td>
<td>48</td>
<td>Mar 2016 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

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

Prior to 2011, and perhaps in the future, this procedure might be coded as an unlisted sinus procedure (31299). It could be submitted alone or along with other nasal/sinus endoscopy codes.

ICD-9 Diagnoses

- 473.0-473.9 Chronic sinusitis code range

ICD-10 Diagnoses (Effective October 1, 2015)

- J32.0 Chronic maxillary sinusitis
- J32.1 Chronic frontal sinusitis
- J32.2 Chronic ethmoidal sinusitis
- J32.3 Chronic sphenoidal sinusitis
- J32.4 Chronic pansinusitis
- J32.8 Other chronic sinusitis
## REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>02-16-2011</td>
<td>Description Section updated. Rationale Section updated. References Section updated. In Coding section: ▪ Added CPT codes: 31295, 31296, 31297.</td>
</tr>
<tr>
<td>08-01-2011</td>
<td>In the Policy section: Liberalized the medical policy language from “Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of sinusitis is considered experimental / investigational.” to “Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to endoscopic sinus surgery.” In the Rationale section: ▪ In the summary section, removed the second paragraph,” In addition, more information is needed to determine which patients and which sinuses might be treated with the balloon technique and which require standard approaches. Given the limitations of the available data, the uncertain impact on clinical outcomes and questions about which patients might be candidates for this procedure, this approach is considered investigational.” Added Policy Guidelines section.</td>
</tr>
<tr>
<td>09-21-2011</td>
<td>In the Policy Guidelines section: ▪ Added the new Item #2, “Beginning in 2011, there are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site.” This statement was moved from the Coding section to the Policy Guidelines section. ▪ Removed from the new Item #3, “Plans should be aware of this possibility.” In the Coding section: removed S2344 (deleted 04/01/11).</td>
</tr>
<tr>
<td>09-24-2012</td>
<td>Description section updated. Rationale section updated. Reference section updated.</td>
</tr>
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</table>
| 11-11-2016 | Updated Description section. In Policy section: ▪ Removed "Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to endoscopic sinus surgery." ▪ Replaced with the following: "A. Balloon sinus ostial dilation is considered medically necessary for treating rhinosinusitis lasting longer than 12 weeks or 4 or more documented episodes of acute rhinosinusitis (in one year) when all of the following are met: 1. Confirmation with computed tomography (CT) scan and/or nasal endoscopy of findings of rhinosinusitis that includes one or more of the following: a) Nasal endoscopy showing purulent discharge or persistent inflammatory sinus pathology, OR b) CT evidence of mucosal thickening, bony remodeling, bony thickening, or obstruction of the ostiomeatal complex; AND 2. Balloon sinus ostial dilation is limited to the frontal, maxillary or sphenoid sinuses; AND 3. Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS); AND 4. Balloon sinus ostial dilation is performed on patients whose symptoms persist despite maximal medical therapy (see Policy Guidelines). B. Balloon ostial dilation is considered not medically necessary in the following situations: 1. Nasal polyposis (Grade 2 or greater). 2. Samter's triad (aspirin sensitivity). 3. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, Wegener's granulomatosis). 4. Severe sinusitis secondary to ciliary
Balloon Sinuplasty for Treatment of Chronic Sinusitis

5. Contraindication to, or inability to tolerate local and/or topical anesthetic.

6. History of failed balloon procedure in the sinus to be treated.

7. Sinusitis with extensive fungal disease.

8. Isolated ethmoid sinus disease.


C. Balloon sinus ostial dilation for treatment of chronic sinusitis is considered experimental / investigational for all other indications.

In Policy Guidelines:

- In Item 1, removed, "Beginning in 2011, t" and added "T" to read "There are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site."

- Added Item 4, "Maximal medical therapy: a) Oral antibiotics of 2-4 weeks' duration for patients with CRS (chronic rhinosinusitis) (culture-directed if possible. b) Oral antibiotics with multiple 1-3 week courses for patients with RARS (recurrent acute rhinosinusitis). c) Systemic or topical steroids (discretion of physician). d) Saline irritation (optional). e) Topical and/or systemic decongestants (optional).

Updated Rationale section.
Updated References section.

REFERENCES


Balloon Sinuplasty for Treatment of Chronic Sinusitis


**Other References:**