Name of Policy:  
Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Policy #: 225  
Category: Surgery  
Latest Review Date: August 2016  
Policy Grade: C

Background/Definitions:  
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
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 endoscopic sinus surgery (FESS).

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 are variable because considerable variation exists in the location and shape of these sinus ostia.

Estimates are that approximately 30 million individuals in the U.S. suffer from chronic sinusitis. The majority of cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. Functional endoscopic sinus surgery (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 U.S. for chronic sinusitis.

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 in the Evaluation of Chronic Rhinosinusitis
To quantify the severity of chronic sinusitis 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 uses radiologist-rated information derived from computed tomography (CT) scans regarding opacification of the sinus cavities, generating a score from 0-12.
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 in 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 is a variation of the SNOT-20 which includes 2 additional questions (“nasal obstruction” and “loss of smell and taste”). The minimal clinically-important difference (MCID) 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 Short Form Health Survey-36 (SF-36). The SF-36 consists of 8 scaled scores on various health domains, which are transformed into a 0-100 scale (100 corresponding to best health).

**Policy:**

**Effective for dates of service on or after April 22, 2014:**
Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

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**Effective for dates of service November 1, 2012 through April 21, 2014:**
Balloon catheter sinus dilation to treat chronic sinusitis (limited to the frontal, sphenoid, and maxillary sinuses) meets Blue Cross and Blue Shield of Alabama’s medical criteria when all the following criteria are met:

- Patient is 18 years of age or older; and
- Performed in the operating room setting; and
- The presence of two or more of the following signs or symptoms that persist for more than 12 weeks:
  - Anterior or posterior mucopurulent drainage; or
  - Nasal obstruction; or
  - Facial pain, pressure, or fullness; or
  - Decreased sense of smell; and
- Inflammation is documented by one of the following:
  - Purulent mucus or edema in the middle meatus or ethmoid regions; or
  - Polyps in the nasal cavity or middle meatus; or
  - Imaging that shows inflammation of the paranasal sinuses; and
- Patient has failed at least eight weeks appropriate medical treatment consisting of at least two different antibiotics with a trial of steroid spray, antihistamine spray and/or decongestant.

Repeat balloon catheter sinus dilation to treat chronic sinusitis meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients 18 years of age or older, performed in the operating room setting when all the following criteria are met:
• The presence of **two or more** of the following signs or symptoms that persist for **more than 12** weeks:
  o Anterior or posterior mucopurulent drainage; **or**
  o Nasal obstruction; **or**
  o Facial pain, pressure, or fullness; **or**
  o Decreased sense of smell; **and**

• Inflammation is documented by **one** of the following:
  o Purulent mucus or edema in the middle meatus or ethmoid regions; **or**
  o Polyps in the nasal cavity or middle meatus; **or**
  o Imaging that shows inflammation of the paranasal sinuses; **and**

• Patient has failed at least **eight** weeks appropriate medical treatment consisting of at least **two different antibiotics with a trial of steroid spray, antihistamine spray and/or decongestant.**

**Balloon catheter sinus dilation** performed in the **office setting does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational.**

**Balloon catheter sinus dilation** performed on **pediatric patients** (age 17 or less) **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational.**

If **tissue is removed during a balloon catheter sinus dilation procedure,** the procedure is considered to be a **functional endoscopic sinus surgery (FESS)** and the **balloon catheter sinus dilation** is considered a part of the FESS and **does not meet medical criteria for separate coverage.**

**Note**—**Balloon catheter sinus dilation may be performed on one sinus** and a FESS on a **different sinus in the same surgical setting.** In that case, if the **balloon catheter sinus dilation** meets medical criteria for coverage then both procedures are separately reimbursable.

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*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*
Key Points:
The most recent literature search was performed for the period through July 20, 2016. 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 since 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 are patient-reported symptoms and quality of life. Studies should pre-defined 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 non-RCTs, and a larger number of single-arm case series, the majority of which are retrospective. This evidence is reviewed below, with emphasis on the available controlled trials, in two categories: 1) balloon ostial dilation as a stand-alone procedure, and 2) balloon ostial dilation as an adjunct to FESS.

Systematic Reviews of Ostial Dilation as a Stand-Alone or Adjunct Procedure
A TEC Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”. This Assessment reviewed evidence from 1 RCT, 3 nonrandomized comparative studies, and 9 case series. The following conclusions were made concerning the adequacy of this evidence for determining the effect of balloon sinus ostial dilation on outcomes.

The Assessment concluded that the evidence is insufficient to determine the effect of the technology on health outcomes. One randomized clinical trial comparing balloon sinus ostial dilation to FESS was inadequately powered and did not evaluate differences in outcomes between the two treatments. While most nonrandomized comparative studies of balloon sinus ostial dilation and FESS show no difference in health outcomes between the 2 treatments, confounding factors may bias the comparison of the 2 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 sinus ostial dilation to FESS.
A Cochrane systematic review on balloon sinus ostial dilation for chronic rhinosinusitis was published in 2011. This review concentrated on RCTs, and included the Plaza et al RCT as the sole controlled trial that met their selection criteria. The authors rated this study as having a low risk for bias for most parameters, but a high risk for bias in reporting of the 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 chronic rhinosinusitis (CRS).

In 2015, Levy et al reported on a systematic review and meta-analysis of studies of paranasal balloon ostial dilation for chronic rhinosinusitis. The review included 17 studies, with 2 RCTs (Achar et al [2012], Bikhazi et al [2014], and Cutler et al [2013]). Two RCTs reported on differences in the change in SNOT-20 score between patients treated with balloon ostial dilation or FESS (n=110; standard mean difference [SMD] -0.42, 95% CI -1.39 to 0.55, I²=76%). There were improvements in SNOT-20 score and sinus opacification after balloon ostial dilation.

In 2011, Batra et al performed a comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology. This review concluded that prospective RCTs comparing FESS with balloon catheter technology are needed; however, it included observational cohort studies which provide relatively less evidence about the efficacy of balloon ostial dilation.

Controlled Trials of Balloon Ostial Dilation as a Stand-Alone Procedure versus FESS

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 prior to 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 non-inferiority 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 non-inferiority). 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<0.0001 for noninferiority). During one-year postprocedure, 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 post-procedure 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 or 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 are not reported for the additional 30 patients not described in the 2013 Cutler et al article. Balloon sinus dilation patients required 0.2 debridements per patient, compared with 1.0 per patient in the FESS group (P<0.0001). The mean change in SNOT-20 score from baseline to 12 month follow up was -1.59 (P<0.0001) and -1.60 (P<0.0001) 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% and 6.9% in the balloon sinus dilation and FESS groups, respectively. In addition to the longer-term results of the REMODEL trial, this article includes a meta-analysis including the REMODEL balloon dilation-treated patients and data from five manufacturer-sponsored trials, three of which had previously been reported in peer-reviewed form (BREATHE, Stankiewicz et al [2010] and Staniewicz et al [2012]; RELIEF, Levine et al [2013]; and XprESS Transnasal Maxillary Multi-Sinus, Gould et al [2014]). Across the six studies, 846 patients were treated with balloon sinus dilation, including 121 who were not described in prior publications. In a random-effects model, overall mean and subscale values for the SNOT-20 score improved compared with baseline at every follow-up time point.

Additional RCTs
Bizaki et al reported results from a small RCT that compared balloon ostial dilation with FESS among patients with symptomatic chronic or recurrent rhinosinusitis. The study enrolled 46 subjects, 4 of whom withdrew from the study; the analysis included 42 patients (n=21 in each group). Both groups demonstrated significant improvements in SNOT-22 scores from baseline to post-procedure. There were no differences in change in total SNOT-22 scores between the balloon sinus dilation and FESS groups at 3 months post-procedure. 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 and 30 from the balloon ostial dilation group). Patients in the balloon ostial dilation group had significant improvements in nasal volume from pre- to post-operative measurements, but there were no significant differences between groups pre- or postoperatively in nasal volume.

An additional publication by Bizaki et al reported on an RCT that compared balloon ostial dilation with FESS, with a focus on mucociliary clearance. It was conducted at the same institution as the previously-reported Bizaki et al RCTs; however, it is not specified that it was the same set of patients. This study enrolled 36 patients who were randomized to balloon ostial dilation (n=17) or FESS (n=19); however, 7 patients dropped out (n=3 in the FESS group and n=4 in the balloon ostial dilation group) and were not included in analyses. SNOT-22 scores
improved in both group from pre- to post-operative 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 both treatment, and no significant between-group difference in mucociliary clearance.

Marzetti et al reported results from a small RCT that compared balloon ostial dilation with an unspecified device (or devices) with FESS in the treatment of sinus headache. The study included 83 patients with sinus headache, based on American Academy of Otolaryngology-Head and Neck Surgery, 44 randomized to conventional 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 endoscopic sinus surgery were used concurrently. It is 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 visual analog score 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).

A small RCT from Turkey was published in 2011 that 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 to be surrogate measures for sinus ventilation. The CO2 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.

Another small RCT was published by Achar et al in 2012. This trial enrolled 24 patients with chronic sinusitis who had failed medical therapy and were scheduled for surgery. 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 (SCT) 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±15.2 vs 29.7±12.3, p<0.03) and on the SCT score (7.5±5.1 vs 3.5±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 one side was treated with FESS and the other with balloon sinus ostial dilation. 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-Mackay classification) or repeat endoscopy (Mackay 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, Comparative Studies
A large number of nonrandomized comparative studies have evaluated balloon ostial dilation. 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
There are a number of randomized trials comparing balloon ostial dilation as a stand-alone procedure, compared to FESS. These studies generally report that short-term outcomes of balloon ostial dilation are similar to those of FESS. Only one RCT, the REMODEL study (n=105 patients randomized), was likely to have adequate power to detect group differences. This study reported non-inferiority for the change in the SNOT-20 scores and superiority for balloon ostial dilation on postoperative recovery and pain medication use. The trial had some 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 chronic rhinosinusitis, but it is limited.

Controlled Trials of Balloon Ostial Dilation as an Adjunct to FESS versus 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 reported results of a single-blinded randomized trial of balloon dilation with the Ventera Sinus Dilation System as an adjunct to frontal sinusotomy (Draf 2a) in which each patient served as his or her own control. The Draf 2a procedure involves a more extensive drainage procedure with resection of the floor of the frontal sinus. Thirty patients with chronic rhinosinusitis were included and 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 post-procedure. 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. This study 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 were symptoms, the Rhinosinusitis Disability Index, CT results of sinus patency, and the permeability of the frontal recess, as assessed by office endoscopy. There was one dropout in each group, leaving a total of 16 patients per group for analysis. For both groups, there were improvements in symptoms and standardized rhinosinusitis scoring indices, but there were no differences between groups. There were also improvements in CT patency in both groups but no differences between groups. The outcome of endoscopic patency at 12 months was achieved by 73% of the balloon sinus ostial dilation patients versus 63% of the FESS patients. The published study contained contradictory
statements on whether this difference was statistically significant. Personal communication with the first author clarified that the difference reported in the results for endoscopic patency was not statistically significant. There were no major complications reported.

Section Summary: Balloon Ostial Dilation as an Adjunct to FESS versus FESS Alone
Two randomized controlled trials evaluating balloon ostial dilation as an adjunct to FESS were identified. Both studies suggest that the addition of balloon ostial dilation to traditional procedures can be done without adverse effects. One study 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 studies report no significant differences between the hybrid and standard approaches in terms of sinus ostia patency.

Some single-arm studies have reported follow up beyond 2 years for balloon ostial dilation and are described here.

Bolger and Vaughan reported on outcomes at 24 weeks from a prospective, multicenter study of balloon sinus ostial dilation of 115 patients. In this study, 115 patients, for whom endoscopic sinus surgery 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 of the 347 sinuses were evaluated (88%). While only five were nonpatent, the status of 18% was reported as indeterminate. Patients’ symptoms as measured by the SNOT-20 also improved posttreatment. The device malfunctioned in 12 of 358 cases (3.4%), the balloon ruptured in seven cases, and the catheter tip malfunctioned in 4 cases. The authors indicated that there were no serious adverse events.

Additional follow-up, up to 2 years, to this study has been published. These papers report on the 1 and 2-year follow-up on a subset of the 115 patients studied. In the 1-year follow-up, there were a total of 70 of 115 patients (61%) remaining 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 the 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 of 65 patients (9%).

A second prospective multicenter, single-arm study of balloon sinus ostial dilation in refractory rhinosinusitis was published by Stankiewicz et al in 2010. This study reported 1-year follow-up data of the Balloon Remodeling Antrostomy Therapy (BREATHE I) study. In this study, 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 quality-of-life measure utilizing the SNOT-20. Average overall symptom scores at baseline were 2.9±1.0. At 3, 6, and 12 months following the intervention, average overall symptom scores were 0.7±0.8, 0.8±0.9, and 0.8±0.9, respectively.

Two-year results of the BREATHE study were reported in 2012. At this time point, a total of 59 patients were treated with balloon sinus ostial dilation with a mean follow-up of 27±3.6 months. Mean SNOT-20 scores improved from 2.65±0.97 at baseline to 0.79±0.71 at the longest follow-
up. This report also included measures of functional impairment by 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 post-change was statistically significant (p<0.001). Similar improvements were reported on other parameters of the WLQ and WPAI scales.

Summary of Evidence
For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure includes the evidence includes systematic reviews, including a Cochrane review and a Blue Cross and Blue Shield Association TEC Assessment and 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 that balloon ostial dilation has similar outcomes to FESS. Since the publication of the systematic reviews, an additional RCT has been published (the REMODEL study). 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 the unblinded design, lack of blinded outcome assessment across the range of outcome measures, and differential dropout between groups. Other trials provide limited additional evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as an adjunct to FESS, the evidence includes 2 small RCTs. 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
National Institute for Health and Clinical 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 sinusitis 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.

American Academy of Otolaryngology – Head and Neck Surgery
In 2012, the American Academy of Otolaryngology– Head and Neck Surgery (AAO-HNS) Foundation offered a statement on balloon ostial dilation and reaffirmed their 2010 position statement which states: “sinus ostial dilation is an appropriate therapeutic option for selected patient with sinusitis. This approach may be used alone or in conjunction with other instruments…”

In 2014, the AAO-HNS Foundation issued updated clinical practice guidelines on adult sinusitis which do not discuss surgical therapy or the use of balloon sinuplasty.
American Rhinologic Society
In 2010, the American Rhinologic Society has offered a statement that endoscopic balloon catheter sinus dilation technology is acceptable and safe in the management of sinus disease.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:
Balloon sinuplasty, chronic sinusitis, Relieva™ Sinus Balloon Catheter, Acclarent, Entellus Medical RS Series System, Entellus Medical FinEss Sinus Treatment, endoscopic sinus surgery, balloon catheter sinus dilation, balloon sinus ostial dilation, Relieva Spin Sinus Dilation System®, Relieva Seeker Balloon Sinuplasty System®, ENTrigue® Sinus Dilation System, XprESS® Multi-Sinus Dilation Tool, Ventera™ Sinus Dilation System, NuVent™ EM Balloon Sinus Dilation System

Approved by Governing Bodies:
In March 2008, the device “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 granted 510(k) marketing clearance. 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 device, FinESS™ Sinus Treatment (Entellus Medical Inc, 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. 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, which has subsequently been acquired by ArthroCare, Corporation (Austin, TX), and the XprESS® Multi-Sinus Dilation Tool also received clearance in August, 2012.

In 2013, a sinus dilation system manufactured by 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 manufactured by ArthroCare Corporation (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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Current Coding:**
CPT Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa</td>
</tr>
<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)</td>
</tr>
<tr>
<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)</td>
</tr>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
</tr>
</tbody>
</table>

**References:**


61. Sedaghat AR, Cunningham MJ. Does balloon catheter sinuplasty have a role in the surgical management of pediatric sinus disease? Laryngoscope 2011; 121:2053-54.


**Policy History:**
Medical Policy Group, December 2006 (3)
Medical Review Committee, February 2007
Medical Policy Group, March 2007 (2)
Medical Review Committee May 2007
Medical Policy Administration Committee May 2007
Available for comment May 31-July 16, 2007
Medical Policy Group, July 2007 (2)
Medical Policy Administration Committee, July 2007
Medica Policy Group, March 2008 (2)
Medical Policy Group, September 2008 (2)
Medical Policy Group, October 2008 (2)
Medical Policy Group, January 2010 (2)
Medical Policy Group, November 2010: No policy changes
Medical Policy Group, November 2010: CPT Codes added
Medical Policy Group, March 2011 (2): Updated Code S2344
Medical Policy Panel, May 2011
Medical Policy Group, June 2011 (2): Key Points, Key Words, References updated
Medical Policy Group, October 2011 (2): Description, Key Points, References updated.
Medical Policy Panel, June 2012
Medical Policy Group, July 2012 (2): Policy updated for coverage for adults in the OR setting for patients with 12 weeks chronic sinusitis and refractive to 8 weeks medical treatment.

Medical Policy Administration Committee, August 2012
Available for comments, September 18 through October 31, 2012

TEC Assessment, November 2012

Medical Policy Group, February 2014 (2): Policy statement changed from covered to non-covered and investigational. Added statement to clarify if balloon sinus ostial dilation is performed in conjunction with cutting tools such as curettes and forceps, then the balloon dilation would be considered inclusive/incidental to the procedure and not separately payable.

Results of 2013 Blue Cross and Blue Shield Association clinical vetting added. Key Points, Key Words, Approved by Governing Bodies, References updated to support policy change.

Medical Policy Administration Committee, February 2014
Available for comment March 7 through April 21, 2014

Medical Policy Panel October 2014

Medical Policy Group, October 2014 (1): Update to Description of Procedure, Key Points, and References. Policy statement edited to remove trademarked name, no change in coverage criteria

Medical Policy Panel, October 2015

Medical Policy Group, December 2015 (6): Updates to Key Points, Key Words, Coding, Approved by Governing Bodies, and References; no change to policy statement.

Medical Policy Panel, August 2016

Medical Policy Group, August 2016 (6): Updates to Description, Key Points, Approved by Governing Bodies, Summary and References. No change to policy intent.

Medical Policy Group, February 2017 (6): Removed “If balloon sinus ostial dilation 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 and not separately payable.” from policy statement. No change to policy intent.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.