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

Policy #: 225  
Category: Surgery

Latest Review Date: February 2014  
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.

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. 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 sinuplasty™, 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.

To quantify the severity of chronic sinusitis and to assess treatment response, various outcomes measures can be used. The Lund-Mackay scoring system utilizes radiologist-rated information derived from computed tomography (CT) scans regarding opacification of the sinus cavities. The Sino-Nasal Outcome Test (SNOT-20) 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 four subclassified symptom domains.
Policy:
Effective for dates of service on or after April 22, 2014:
Use of a catheter-based inflatable device (balloon sinuplasty™) in the treatment of sinusitis does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

NOTE:
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.

Effective for dates of service on or after 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:
  - 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.

**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.

**Effective for dates of service July 17, 2007 through October 31, 2012:**
The use of a catheter-based inflatable device (balloon sinuplasty), in the treatment of chronic sinusitis does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

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 members' 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 of March 2012 through November 2013. 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.
Literature Review

Controlled trials are essential in determining the efficacy of this procedure in relation to alternatives. Medical therapy is effective in reducing symptoms for most patients, and surgical drainage is an invasive procedure with its own set of risks and benefits. Therefore, while single-arm series can give some information on success rates and adverse events, they are not sufficient to determine comparative efficacy of balloon sinus ostial dilation.

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.

A TEC Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”. This Assessment reviewed evidence from one RCT, three nonrandomized comparative studies, and nine 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 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 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 two years. Case series do not allow conclusions regarding the comparative efficacy of balloon sinus ostial dilation to FESS.

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

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 two in the balloon ostial dilation group (4%). The primary outcomes were the change in the Sino-Nasal Outcome Test (SNOT-20) score at six-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 six-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 one patient in each group required revision surgery.

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 ten 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 ten days following the procedure, there were improvements in both groups on measures of patency, but there were no differences between groups.

A nonrandomized comparison of balloon sinus ostial dilation with adenoidectomy in 49 children with chronic rhinosinusitis (CRS) who had failed medical management was published in 2010. Thirty of the children had balloon sinus ostial dilation and 19 had adenoidectomy. Outcomes at one year included change in the SN-5 scores and the need for revision surgery. There were significantly more patients in the balloon sinus ostial dilation group that had significant improvement in symptoms (24/30, 80%) compared to the adenoidectomy group (10/19, 53%; p<0.05). There was no difference in the need for revision surgery between the two groups.

In 2008, Friedman et al reported a retrospective chart review that compared results in 35 consecutive patients who received balloon sinus ostial dilation and 35 consecutive patients who received functional endoscopic surgery. During the time period under consideration, patients with Lund-Mackay scores of under 13 (scores can range from 0 to 24) without polyps had been given the choice of either procedure. Patients generally had a history of recurrent rhinosinusitis despite medical management, but there were no consistent eligibility criteria. Individuals who received a combination of the two procedures, or who were missing preoperative SNOT-20 scores, were excluded from the analysis. The SNOT-20 score three months after the operation was significantly higher (more symptoms) in the endoscopic surgery group (see Table 1).
### Table 1. SNOT-20 Scores

<table>
<thead>
<tr>
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<th>Balloon Sinus Ostial Dilation, mean (SD)</th>
<th>Endoscopic Surgery, mean (SD)</th>
<th>P value</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>2.80 (0.52)</td>
<td>2.70 (0.85)</td>
<td>NS</td>
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<tr>
<td>Three months postoperatively</td>
<td>0.78 (0.55)</td>
<td>1.29 (0.87)</td>
<td>0.006</td>
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Postoperative pain, as measured by the number of days patients used a narcotic, was significantly lower in the group of patients who underwent balloon sinus ostial dilation (0.8±0.7 days) compared to endoscopic sinus surgery (1.3±1.0; p=0.011). The patient satisfaction measure also favored the balloon sinus ostial dilation group. The primary complications reported were turbinate lateralization, or scarring, which occurred in eight patients who underwent balloon sinus ostial dilation and in three patients who had endoscopic surgery. One or more sinus infections occurred in six balloon sinus ostial dilation patients and nine endoscopic surgery patients during the three-month follow-up; one patient in the balloon sinus ostial dilation group required revision surgery due to persistent infection.

Another retrospective comparative study was published in 2012 by Koskinen et al. This trial identified 208 patients who underwent either balloon sinus ostial dilation or FESS. Of the 208 patients, 85 (41%) met inclusion criteria for the study and 53 (25%) responded to the mailed questionnaire. These 53 patients, 29 in the FESS group and 24 in the balloon sinus ostial dilation group, comprised the final study groups. The mailed questionnaires contained items on symptoms, exacerbations of chronic sinusitis, medication use, work exposure, and the Lund-Mackay score. The mean symptom score was worse in the balloon sinus ostial dilation group compared to the FESS group (4.37 vs 3.22, p=0.04). Patients in the balloon sinus ostial dilation group reported a greater number of exacerbations compared to the FESS group. The majority of other outcome measures were similar between groups, and there were no measures on which the balloon sinus ostial dilation group showed superior outcomes compared to the FESS group.

### Section Summary

There are a number of small randomized and nonrandomized comparative studies of 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. However, there remains a lack of high-quality evidence on the comparative efficacy of the two procedures. 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. It was unblinded and did not have blinded outcome assessment for the symptom-based outcomes or the secondary clinical outcomes. There was also some evidence of differential dropout, with larger numbers of patients withdrawing from the FESS group following randomization (21% vs 4%). The other trials were either very small RCTs, or nonrandomized comparative studies.
This evidence shows some support for balloon ostial dilation as an alternative to FESS in patients with CRS, but it is not definitive because of the small quantity of evidence and the limitations in the available trials. Further high-quality evidence is required to determine whether outcomes of balloon ostial dilation are equivalent to FESS.

**Controlled Trials of Balloon Ostial Dilation as an Adjunct to FESS versus FESS Alone**

A small 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 was 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.

**Systematic reviews**

A Cochrane systematic review on balloon sinus ostial dilation for CRS 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 CRS.

In 2010, Batra et al performed a comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology. Based on available evidence, they concluded:

“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 two 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.”
**Single-arm studies**

There are numerous single-arm series of balloon sinus ostial dilation. A representative sample of these studies, focusing on studies that are prospective, multicenter, large in number, or with extended follow-up, is presented below.

A prospective multicenter series of 71 subjects with CRS was published by Cutler et al. Successful dilatation was achieved in 129 of 132 (98%) of maxillary sinuses. Half of the procedures were performed in the operating room and half performed in the clinic setting. Tolerance of the procedure was good, with patients discharged within two hours after the procedure was completed. There were statistically significant improvements in symptoms at 3, 6, and 12 months postprocedure, with no difference in efficacy by site of procedure.

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 four cases. The authors indicated that there were no serious adverse events.

Additional follow-up, up to two years, to this study has been published. These papers report on the one- and two-year follow-up on a subset of the 115 patients studied. In the one-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 two-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 six 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 one-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. Additional subjects are continued to be enrolled, and follow-up data will continue to be collected at two years for the cohort.

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.

A large retrospective single-arm series published by Levine et al reported on results from a registry study of 1036 patients who received a balloon sinus ostial dilation procedure at 27 sites from December 2005 to May 2007. This registry was developed through retrospective chart review of consecutive cases at these institutions. All but two patients in this study had treatments while under general anesthesia. An average of 3.2 sinuses was treated per patient. Symptom improvement was reported at 95%. With average follow-up of 40 weeks, the revision rate was 1.3%

There are numerous other published single-arm studies. These are mostly small, retrospective, and from a single center. These studies generally report high rates of success, with continued patency at the longest follow-up and low rates of adverse events.

**Safety**

In 2010, Tomazic et al reported on a case of ethmoid roof cerebrospinal fluid leak following frontal balloon sinus ostial dilation that was not recognized until three weeks’ postprocedure. This is a known risk factor of any ethmoid manipulation, including endoscopic sinus surgery. The bony defect matched the tip of a standard sinus balloon catheter device. The patient underwent subsequent repair and is reportedly symptom-free. The authors commented that although relatively safe, complications can occur.

Chandra discussed questions about potential radiation damage to the lens (lenticular opacity) from the fluoroscopic guidance used to position the guide wire. By extrapolating information from other procedures, the authors suggested that the threshold for lenticular opacity would be attained in the left eye after approximately 29 minutes of fluoroscopy. In a recent review, Vaughan comments that in bilateral cases, less than five minutes of fluoroscopy is generally used. In that review, Vaughan also comments on the question of whether balloon sinus ostial dilation represents an exciting and minimally invasive set of devices or a premature attempt to transfer balloon dilation into the field of otolaryngology.

Posttreatment swelling and inflammation can occur following balloon sinus ostial dilation, as well as with endoscopic surgery, and this can lead to temporary sinus obstruction. The comparative rates of this complication with balloon sinus ostial dilation versus endoscopic surgery are not known. Also, the optimal treatment to reduce or prevent this side effect is uncertain. The most common treatment for postoperative swelling and obstruction are nasal packs and anti-inflammatory medications such as local or systemic steroids. Implantable spacers or stents are also available to maintain patency posttreatment. Repeat balloon sinus ostial dilation has also been used for this purpose, but no empiric evidence was identified in the literature on its use for this indication.
Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

In response to requests by the Blue Cross and Blue Shield Association, input was received from two physician specialty societies and two academic medical centers while this policy was under review in 2008. 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. Input from one 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 (e.g., CT scans) was on a limited number of patients. Input from two academic centers felt this treatment was not investigational but should be viewed as just another surgical tool for the treatment of chronic sinusitis. One comment received was that there are not adequate data in the peer-reviewed literature to sufficiently separate the benefits of balloon sinus ostial dilation from concurrent FESS. Another comment was that this may have a role in frontal and sphenoid sinus disease.

In response to requests, input was received from two physician specialty societies and six academic medical centers while this policy was under review in 2011. As noted above, 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. 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 to standard approaches. There were also comments about 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, since most studies used both techniques.

In response to requests, input was received from two specialty societies and six 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 CRS that might benefit from balloon ostial dilation. There was consensus that RCTs should be performed comparing balloon ostial dilation to standard care in order to determine efficacy.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov using the term “balloon sinuplasty” returned eight studies. One of these was an active RCT, and the remainder were either inactive or observational studies.

- NCT01714687. Comparison of Balloon Sinuplasty In-Office versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET)
This is an RCT comparing balloon sinuplasty to medical therapy in patients with recurrent acute rhinosinusitis. The outcome measures are changes in quality of life, medication usage, missed
days of work or school, medical visits due to sinusitis, number of sinus infections, and number of sinus procedures. The planned enrollment is 400 patients with an estimated completion date of October 2015.

Summary
Balloon sinus ostial dilation is a minimally invasive alternative to functional endoscopic sinus surgery (FESS), or can be used as an adjunct to endoscopic sinus surgery. There is evidence that this technique can be performed successfully and safely in patients with chronic rhinosinusitis. However, there is still insufficient evidence on the impact of balloon sinus ostial dilation on health outcomes. Small, randomized controlled trials, including the largest study (REMODEL) of 105 patients, report short-term improvement in symptoms that are similar to FESS, and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. These trials have limitations, which for 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 are either very small, or nonrandomized comparisons. The results of clinical vetting in 2013 (prior to publication of REMODEL study) were mixed, and did not show consistent support for the medical necessity of balloon dilation. Further high-quality trials are needed to determine the comparative efficacy of balloon ostial dilation and FESS.

In addition, more information is needed to determine which patients and which sinuses benefit from the balloon technique as an adjunct to traditional endoscopic sinus surgery, and which patients should get 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.

Practice Guidelines and Position Statements
National Institute for Health and Clinical Evidence (UK): “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.

In June 2010, the American Academy of Otolaryngology– Head and Neck Surgery offered a statement on balloon ostial dilation. They stated that “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…”

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.

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.

Proprietary Information of Blue Cross and Blue Shield of Alabama
Medical Policy #225
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 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.

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. Claims will be reviewed for medical necessity.
Pre-certification requirements: Not applicable

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>
</tbody>
</table>
References:
42. 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 Panel, November 2013
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

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.