Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/12**
(See policy history boxes for previous effective dates)

Title: Balloon Sinuplasty for Treatment of Chronic Sinusitis

Description / Background

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. Considerable variation exists in the location and shape of these sinus ostia.

In some cases of chronic sinusitis, surgical drainage may be necessary. 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. The procedure may be used when patients fail to respond to aggressive medical management. Approximately 350,000 procedures are done each year in the U.S. for chronic sinusitis. Estimates are that approximately 30 million individuals in the U.S. suffer from chronic sinusitis. Of note, surgical interventions are generally not necessary in patients with acute sinusitis.

A new procedure, balloon sinuplasty, is being discussed as an alternative to endoscopic sinus surgery for those with chronic sinusitis. 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. This technique is said to allow improved sinus drainage.

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.

Various systems have been used to quantify the severity of chronic sinusitis. The Lund-McKay 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 4 subclassified symptom domains.

Regulatory Status:

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. The FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children.

In June 2008, the device, FinESS Sinus Treatment (Entellus Medical, Inc, Maple Grove, MN) was cleared for marketing by the FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Medical Policy Statement

Balloon sinuplasty for treatment of chronic sinusitis is experimental and investigational. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

31295 31296 31297

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 of March 2011 through March 2012. The following is a summary of the key literature evidence to date:
Balloon sinuplasty 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, since there are elements of both balloon sinuplasty and FESS. The majority of evidence, including the single randomized controlled trial (RCT) and the largest case series, used balloon sinuplasty as part of a hybrid procedure.

Literature Review
The literature consists of a very small number of controlled trials, and a larger number of single arm case series, the majority of which are retrospective. Controlled trials are essential in determining the efficacy of this procedure in relation to alternatives. Single arm series can give some information on success rates and adverse events but offer little relevant evidence on comparative efficacy of balloon sinuplasty.

Controlled trials
A small double-blinded, RCT of balloon sinuplasty versus FESS was published by Plaza et al in 2011. (1) This study enrolled 34 patients with chronic rhinosinusitis who were refractory to intensive medical management. Patients were randomized to a “hybrid approach” that included balloon sinuplasty 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 months of follow-up included were symptoms, the rhinosinusitis disability index, computed tomography (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 sinuplasty 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 (2) clarified that the difference reported in the results for endoscopic patency was not statistically significant. There were no major complications reported.

A small RCT from Turkey was published in 2011 that reported on physiologic outcomes. (3) Twenty patients were randomly assigned to removal of the uncinate process via FESS or balloon sinuplasty 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 maximum sinus pressure decreased in the ESS group but did not change in the balloon sinuplasty group.

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 sinuplasty. (4) All procedures were performed by the same surgeon, and polypectomy was performed prior to FESS or balloon sinuplasty in all patients. Outcome measures included sinus patency as measured by CT scanning (Lund-McKay classification) or repeat endoscopy (McKay grading). At 10 days following the procedure, there were improvements in both groups on measures of patency, but there were no differences between groups.

A non-randomized comparison of balloon sinuplasty with adenoidectomy in 49 children with chronic rhinosinusitis who had failed medical management was published in 2010. (5) Thirty of the children had balloon sinuplasty 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 sinuplasty 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 2 groups.

In 2008, Friedman and colleagues reported a retrospective chart review that compared results in 35 consecutive patients who received balloon sinuplasty and 35 consecutive patients who received functional endoscopic surgery. (6) During the time period under consideration, patients with Lund-McKay 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 2 procedures, or who were missing preoperative Sino-Nasal Outcome Test (SNOT-20) scores, were excluded from the analysis. The SNOT-20 score 3 months after the operation was significantly higher (more symptoms) in the endoscopic surgery group (see table, below).

SNOT-20 Scores (mean ± standard deviation [SD])

	Balloon sinuplasty	Endoscopic surgery	p-value
Baseline	2.80 + 0.52	2.70 + 0.85	NS
3-months postoperatively	0.78 + 0.55	1.29 + 0.87	0.006

Postoperative pain, as measured by the number of days patients used a narcotic, was significantly lower in the group of patients who underwent balloon sinuplasty (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 sinuplasty group. The primary complications reported were turbinate lateralization, or scarring, which occurred in 8 patients who underwent balloon sinuplasty and in 3 patients who had endoscopic surgery. One or more sinus infections occurred in 6 balloon sinuplasty patients and 9 endoscopic surgery patients during the 3-month follow-up; 1 patient in the balloon sinuplasty group required revision surgery due to persistent infection.

Systematic reviews

A Cochrane systematic review on balloon sinuplasty for chronic rhinosinusitis was published in 2011. (7) This review concentrated on RCTs, and included the Plaza et al. RCT (1) 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 sinuplasty in chronic rhinosinusitis (CRS).

In 2010, Batra and colleagues performed a comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology. (8) 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 2 years. However, because the selection criteria for these studies were not clearly defined, it is unclear if this data can be extrapolated to the general population with chronic rhinosinusitis (CRS). Is BCT superior or equivalent to the existing devices employed in FESS for the management of CRS? Will the use of BCT translate into improvements in patient outcomes, overall health, and/or quality of life? The many unsettled questions will be best answered by prospective randomized trials that directly compare FESS to BCT, or directly compare medical to surgical treatment."

Single-arm studies
There are numerous single-arm series of balloon sinuplasty. 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 chronic rhinosinusitis was published by Cutler et al. (9). Successful dilatation was achieved in 129/132 (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 2 hours after the procedure was completed. There were statistically significant improvements in symptoms at 3, 6, and 12 months post-procedure, 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 sinuplasty of 115 patients. (10) 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 5 were non-patent, the status of 18% was reported as indeterminate. Patients' symptoms as measured by the Sino-Nasal Outcome Test (SNOT-20) also improved post-treatment. The device malfunctioned in 12 of 358 cases (3.4%), 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, up to 2 years, to this study has been published. (11, 12) 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 70/115 patients (61%) remaining in the study. (11) 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). (12) 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 sinuplasty 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. (13) The primary outcome measure was patient-reported quality-of-life measure utilizing the SNOT-20. Average overall symptoms 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 2 years for the cohort.

A large retrospective single-arm series published by Levine et al. reported on results from a registry study of 1,036 patients who received a balloon sinuplasty procedure at 27 sites from December 2005 to May 2007. (14) This registry was developed through retrospective chart review of consecutive cases at these institutions. All but 2 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. (9, 15-17) 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 and colleagues reported on a case of ethmoid roof cerebrospinal fluid (CSF)-leak following frontal balloon sinuplasty that was not recognized until 3 weeks' postprocedure. (18) 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. (19) 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 5 minutes of fluoroscopy is generally used. (20) In that review, Vaughan also comments on the question of whether sinuplasty represents an exciting and minimally invasive set of devices or a premature attempt to transfer balloon dilation into the field of otolaryngology.

Post-treatment swelling and inflammation can occur following balloon sinuplasty, as well as with endoscopic surgery, and this can lead to temporary sinus obstruction. The comparative rates of this complication with sinuplasty versus endoscopic surgery are not known. Also, the optimal treatment to reduce or prevent this side effect is uncertain. The most common treatment for post-operative 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 post-treatment. Repeat balloon sinuplasty 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, input was received from 2 physician specialty societies and 2 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 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 (e.g., CT scans) was on a limited number of patients. Input from 2 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 sinuplasty from concurrent functional endoscopic sinus surgery (FESS). Another comment was that this may have a role in frontal and sphenoid sinus disease.

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. 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.

Summary

Balloon sinuplasty is being investigated as a minimally invasive alternative to functional endoscopic sinus surgery, or 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 sinuplasty on health outcomes. Small randomized, controlled trials do not report significant improvements on clinically relevant outcome measures. A large number of non-comparative single-arm series report high success rates, but are not sufficient to determine comparative efficacy with alternative treatments. Prospective comparative studies with larger patient populations are needed to determine the clinical outcomes for this treatment compared with standard surgical or medical approaches. This information is important to determine symptom improvement, as well as the durability of the procedure and the need for subsequent revision.

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." (21) 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…" (22)

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. (23)

Government Regulations

National:

There is no national Medicare policy addressing this specific service.

Local:

There is currently no local Medicare policy addressing this specific service.

Michigan Department of Community Health:

There is currently no policy relating to this procedure. Medicaid would review on an individual basis.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/14/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/07	3/20/07	3/1/07	Joint policy established
3/1/09	12/9/08	12/21/08	Routine maintenance
7/1/11	4/19/11	5/3/11	Routine maintenance, code update, added new CPT codes 31295-31297; S2344 deleted
9/1/12	6/12/12	6/19/12	Routine maintenance; reformatted to mirror BCBSA policy

Next Review Date: 2nd Qtr, 2013

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BALLOON SINUPLASTY FOR THE TREATMENT OF CHRONIC SINUSITIS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	Not covered.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service. Not covered.
Blue Cross Complete of Michigan	Not covered.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.