Title: Balloon Sinuplasty for Treatment of Chronic Sinusitis

DESCRIPTION

Balloon ostial dilation (also known as balloon sinuplasty™) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic sinusitis who fail medical management. The procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. It can be performed as a stand-alone procedure or as an adjunctive procedure to 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 since 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™, is an alternative to endoscopic sinus surgery for those with chronic sinusitis. The goal of this technique is to allow improved sinus drainage using a less invasive approach. 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-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. Subsequent devices developed by Acclarent have also been granted 510(k) approval. These include the Relieva Spin Sinus Dilation System®, approved in August 2011, and the Relieva Seeker Balloon Sinuplasty System®, approved in November 2012.

In June 2008, the 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. Two other balloon sinuplasty devices by Entellus Medical, Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

**POLICY**

Use of a catheter-based inflatable device (balloon sinuplasty™) in the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to endoscopic sinus surgery.

**Policy Guidelines**

1. When a balloon sinuplasty is used as an adjunct in performance of a medically necessary functional endoscopic sinus surgery (FEES) in the treatment of chronic sinusitis, the use of the balloon catheter is considered included in the allowance for the FEES procedure. There is no additional reimbursement for use of the balloon catheter.
2. Beginning in 2011, there are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site.
3. If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the procedure might be coded using the CPT codes for nasal/sinus endoscopy with maxillary antrostomy (31256), nasal/sinus endoscopy with frontal sinus exploration (31276), or nasal/sinus endoscopy with sphenoidecomy (31287). In this instance, the balloon dilation would be considered inclusive/incidental to the procedure.
RATIONALE

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

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 sinuplasty.

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. This evidence is reviewed below, with emphasis on the available controlled trials.

A TEC Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”. (1) This Assessment reviewed evidence from one RCT, three non-randomized comparative studies, and nine case series. The following conclusions were made concerning the adequacy of this evidence for determining the effect of balloon sinuplasty on outcomes:

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

Controlled trials

A small double-blinded, RCT of balloon sinuplasty versus FESS was published by Plaza et al in 2011. (2) 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 (3) 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. (4) 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. (5) 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. (6) 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. (7) 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).

<table>
<thead>
<tr>
<th></th>
<th>Balloon sinuplasty</th>
<th>Endoscopic Surgery</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.80 ± 0.52</td>
<td>2.70 ± 0.85</td>
<td>NS</td>
</tr>
<tr>
<td>3-months postoperatively</td>
<td>0.78 ± 0.55</td>
<td>1.29 ± 0.87</td>
<td>0.006</td>
</tr>
</tbody>
</table>

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.

Another retrospective comparative study was published in 2012 by Koskinen et al. (8) This trial identified 208 patients who underwent either balloon sinuplasty 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 sinuplasty 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 sinuplasty group compared to the FESS group (4.37 vs. 3.22, p=0.04). Patients in the balloon sinuplasty 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 sinuplasty group showed superior outcomes compared to the FESS group.

**Systematic reviews**

A Cochrane systematic review on balloon sinuplasty for chronic rhinosinusitis was published in 2011. (9) 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. (10) 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. (11). 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. (12) 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. (13, 14) 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. (13) 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). (14) 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. (15) 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.

Two-year results of the BREATHE study were reported in 2012. (16) At this time point, a total of 59 patients were treated with balloon sinuplasty 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-/post- change was statistically significant (p<0.0001). 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 1,036 patients who received a balloon sinuplasty procedure at 27 sites from December 2005 to May 2007. (17) 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. (11, 18-20) 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. (21) 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. (22) 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. (23) 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.

**Ongoing Clinical Trials**

A search of ClinicalTrials.Gov using the term “balloon sinuplasty” returned 8 studies. One of these was an active RCT, and the remainder was either inactive or observational studies.

- **NCT01714687.** Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET). This is a randomized controlled trial 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 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.” (24) 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...” (25) 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. (26)

**CODING**

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

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa</td>
</tr>
<tr>
<td>31296</td>
<td>With dilation of frontal sinus ostium (eg, balloon dilation)</td>
</tr>
<tr>
<td>31297</td>
<td>With dilation of sphenoid sinus ostium (eg, balloon dilation)</td>
</tr>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
</tr>
<tr>
<td>C1726</td>
<td>Catheter, balloon dilation, nonvascular</td>
</tr>
</tbody>
</table>

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

**DIAGNOSIS**

473.0-473.9 Chronic sinusitis code range

**ICD-10 Diagnosis (Effective October 1, 2014)**

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

**REVISIONS**

| 02-16-2011       | Description Section updated.                                               |
|                  | Rationale Section updated.                                                |
|                  | References Section updated.                                               |
|                  | In Coding section:                                                        |
|                  | ▪ Added CPT codes: 31295, 31296, 31297.                                    |
| 08-01-2011       | In the Policy section:                                                    |
|                  | Liberalized the medical policy language from “Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of sinusitis is considered experimental / |
investigational.” to “Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to endoscopic sinus surgery.”

In the Rationale section:
- In the summary section, removed the second paragraph, “In addition, more information is needed to determine which patients and which sinuses might be treated with the balloon technique and which require standard approaches. Given the limitations of the available data, the uncertain impact on clinical outcomes and questions about which patients might be candidates for this procedure, this approach is considered investigational.”

Added Policy Guidelines section.

**09-21-2011**
- In the Policy Guidelines section:
  - Added the new Item #2, “Beginning in 2011, there are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site.” This statement was moved from the Coding section to the Policy Guidelines section.
  - Removed from the new Item #3, “Plans should be aware of this possibility.”

In the Coding section: removed S2344 (deleted 04/01/11).

**09-24-2012**
- Description section updated.
- Rationale section updated.
- Reference section updated.

**09-05-2013**
- Description section updated.
- Rationale section updated.
- In Coding section:
  - Added ICD-10 Diagnosis codes *(Effective October 1, 2014)*
- Reference section updated.

**REFERENCES**


Other References:
1. Blue Cross and Blue Shield of Kansas Otolaryngology Liaison Committee, August 2010.
2. Blue Cross and Blue Shield of Kansas Otolaryngology Liaison Committee, August 2011.