ARBenefits	Medical Policy
ARBenefits Approval: 09/14/2011	Title: Balloon Sinuplasty
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Code(s):

31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)
C1726	Catheter, balloon dilatation, nonvascular
C1727	Catheter, balloon tissue dissector, nonvascular (insertable)

Administered by: QualChoice®

Public Statement:

In some cases of chronic sinusitis, surgical drainage may be necessary. Endoscopic sinus surgery 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 restores patency and allows mucous transport through the natural ostium. The procedure may be used when patients fail to respond to aggressive medical management.

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.

There is still little scientific data comparing the use of balloon sinuplasty with standard treatments. This procedure is therefore still considered by ARBenefits to be investigational and is not covered.

Medical Policy Statement:

The use of a balloon sinuplasty device for treatment of sinusitis is considered investigational and is not covered.

Background:

The role of this procedure, if any, in patients with sinus disease awaits further study. Prospective controlled studies that include relevant outcomes and durability of treatment are needed that compare this technique to both surgical and medical alternatives for patients with chronic sinusitis.

In a commentary on balloon sinuplasty, the authors present a number of questions regarding this procedure (Lanza 2006). They indicate that it is not to be used in chronic sinusitis when polypoid disease is present and note that this situation represents the majority of cases where endoscopic sinus surgery is indicated. They also indicate that while research supports the importance of tissue removal during sinus surgery, balloon sinuplasty does not lead to tissue removal. They also comment that the future role for this procedure is yet to be determined.

Levine reported on results from a registry study of 1,036 patients who received this procedure at 27 sites from December 2005 to May 2007 (Levine et al, 2008). 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%.

In 2008, 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 5 minutes of fluoroscopy is generally used (Vaughn 2008). In that review, Vaughan also comments on the question whether sinuplasty represents an exciting and minimally invasive set of devices or a premature attempt to transfer dilation into otolaryngology.

Additional follow-up, up to 2 years, to the study reported by Bolger and coworkers has been published (Kuhn et al, 2008) (Weiss et al, 2008). 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, two investigators could not participate in the analysis – one investigator moved and the other could not reapply to his institutional review board (IRB) for the 1-year follow-up study. This left a cohort of 86 patients, 16 of whom were lost to follow-up. Fifty-six of

these 70 patients had follow-up computed tomography (CT) scans, but 3 were not included due to revision procedures. Of the 53 patients, 23 underwent “balloon-only” treatments, while 30 were “hybrid” patients who underwent both balloon and traditional endoscopic procedures. 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) (Weiss et al, 2008). 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%).

In summary, while more data are becoming available, the role of this technique in those with chronic sinus disease remains uncertain. The published literature consists of non-comparative results on only a small number of patients. Prospective comparative studies with larger patient populations are needed to determine the outcomes for this treatment compared with standard surgical 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 (which sinuses) might be treated with the balloon technique and which require the more standard approaches. (Ethmoid sinuses are not currently treated with this technique.) It is also noted that the limited data for this procedure is just for patients who are considered candidates for sinus surgery and who do not have significant nasal polyps.

In 2010, Stankiewicz and colleagues reported one-year follow-up data of the Balloon REmodeling Antrostomy THErapy (BREATHE I) study. This multi-center, single-arm study has enrolled 30 patients to receive balloon dilation of the ethmoid infundibulum using the FinESS system, a transantral dilation approached via the canine fossa (Stankiewicz, 2010). Patients were included if they had radiographic evidence of maxillary mucosal thickening despite maximal medical therapy; they were excluded if they had mucosal thickening in other areas or required additional sinus surgery. Primary outcome measure was patient-reported quality of life measure utilizing the SNOT-20. Compliance with all follow-up visits was 29 of 30 subjects (97%). 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. The authors note the small sample size and lack of comparator groups as limitations of the study. Additional subjects are being enrolled and follow-up data will continue to be collected at 2 years for the cohort.

Tomazic and colleagues reported on a case of ethmoid roof CSF-leak following frontal balloon sinuplasty that was not recognized until 3 weeks post procedure (Tomazic, 2010). 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.

A comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology was published by Batra and colleagues (Batra, 2010). 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? [W]ill 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.”

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.

There is evidence that balloon sinuplasty is relatively safe. However, there is still insufficient evidence on the impact of balloon sinuplasty on health outcomes. Longer term outcome data are becoming available, and balloon sinuplasty is being investigated as a minimally invasive alternative to functional endoscopic sinus surgery. Prospective comparative studies with larger patient populations are still needed to determine the outcomes for this treatment compared with standard surgical or medical approaches.

Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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