

Medical Policy



An Independent Licensee of the
Blue Cross and Blue Shield Association

Title: **Balloon Sinuplasty for Treatment of Chronic Sinusitis**

Professional

Original Effective Date: November 10, 2006

Revision Date(s): December 15, 2008

Current Effective Date: December 15, 2008

Institutional

Original Effective Date: January 14, 2009

Revision Date(s):

Current Effective Date: January 14, 2009

DESCRIPTION

Chronic sinusitis 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.

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. About 350,000 procedures are done each year in the U.S. for chronic sinusitis. Estimates are that about 30 million individuals in the U.S. suffer from chronic 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 balloon in the sinus ostium and then stretching the opening by inflating the balloon. General anesthesia may be needed for this procedure to minimize patient movement. This technique is said to allow improved sinus drainage.

Of note, surgical interventions are generally not necessary in patients with acute sinusitis.

The balloon sinuplasty device manufactured by Acclarent has received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance by being considered equivalent to an existing device. A number of physicians have been trained in using this device. There are reports of clinical trials being underway.

POLICY

Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of sinusitis is considered **investigational**.

RATIONALE

The published scientific literature for this device/procedure is very limited. The device received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance (1) by being considered equivalent to existing devices. No clinical outcomes data were found in reviewing the FDA clearance summary.

One preliminary study of the procedure has been published. (2) In this study, 18 sinus ostial regions were successfully dilated using this technique, including 10 maxillary, 5 sphenoid, and 3 frontal recesses. No adverse events were noted. Mucosal trauma and bleeding were reported to be less than with conventional endoscopic techniques. Clinical outcomes were not reported.

In addition, no published data were found concerning the durability of the treatment. 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.

2007 Update

A literature search was conducted using MEDLINE in July 2007. Bolger and colleagues reported on outcomes at 24 weeks from a multicenter study of balloon sinuplasty of 115 patients. (3) 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. Successful sinusotomy was performed in 143 maxillary ostia, 75 sphenoid ostia, and 124 frontal recesses. The average number of sinuses treated per patient with the balloon device was 3.1. In 52% of the patients (57 of 109 who were followed up in the study), traditional endoscopic surgery was used on some sinuses and balloon sinuplasty was used on at least 1 sinus. 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 indeterminate. Indeterminate was used if the ostium could not be viewed with rigid endoscopy or if the patient did not tolerate a complete endoscopic examination. 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 there were no serious adverse events. Patients' symptoms as measured by the Sino-Nasal Outcome Test (SNOT 20) also improved post-treatment.

In a commentary on balloon sinuplasty, Lanza and Kennedy present a number of questions regarding this procedure. (4) 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.

The role of this technique in those with chronic sinus disease remains uncertain. Prospective comparative studies are needed to determine the outcomes for this treatment with standard medical and surgical treatment. At the present time, it is uncertain how this procedure that provides ventilation to the sinuses compares to other treatments. Thus, this approach remains investigational.

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.

CPT/HCPCS

| | |
|-------|--|
| 31299 | Unlisted procedure, accessory sinuses |
| C1726 | Catheter, balloon dilatation, nonvascular |
| S2344 | Nasal/sinus endoscopy, surgical; with enlargement of sinus ostium opening using inflatable device (i.e., balloon sinuplasty) |

There is no CPT code that specifically describes the use of this balloon device. Thus, this procedure should be coded as an unlisted sinus procedure (31299). It could be submitted alone or along with other nasal/sinus endoscopy codes.

DIAGNOSIS

| | |
|--------|------------------------------|
| 473.0- | Chronic sinusitis code range |
| 473.9 | |

REFERENCES

1. <http://www.fda.gov/cdrh/pdf5/k052198>.
2. Brown DL, Bolger WE. Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: a preliminary investigation. *Ann Otol Rhinol Laryngol* 2006; 115(4):293-301.
3. Bolger WE, Brown CL, Church CA et al. Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. *Otolaryngol Head Neck Surg* 2007; 137(1):10-20.
4. Lanza DC, Kennedy DW. Balloon sinuplasty: not ready for prime time. *Ann Otol Rhinol Laryngol* 2006; 115(10):789-90.
5. American Academy of Otolaryngology – Head and Neck Surgery, Sinus Balloon Catheterization Position Statement. www.entnet.org/Practice/policySinusBalloonCatheterization.cfm Accessed October 22, 2008.