

Corporate Medical Policy

Balloon Sinuplasty for Treatment of Chronic Sinusitis

File Name: balloon_sinuplasty_for_treatment_of_chronic_sinusitis
Origination: 2/2010
Last CAP Review: 8/2011
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Last Review: 8/2011

Description of Procedure or Service

Balloon sinuplasty is proposed as an alternative to 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.

Chronic rhinosinusitis 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 option 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 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. 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.

In March 2008, the device “Relieva Sinus Balloon Catheter” (Acclarent, Menlo Park, CA) was cleared for marketing by the 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 transtrantral approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Related policy: Functional Endoscopic Sinus Surgery (FESS)

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

The use of a catheter-based inflatable device (balloon sinuplasty) is considered investigational in the treatment of sinusitis. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Balloon Sinuplasty for Treatment of Chronic Sinusitis is covered

Not applicable.

When Balloon Sinuplasty for Treatment of Chronic Sinusitis is not covered

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

Policy Guidelines

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. 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 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 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 31295, 31296, 31297

Beginning in 2011, there are specific CPT codes for Balloon Sinuplasty. These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site. Prior to 2011, this procedure might be coded as an unlisted sinus procedure, 31299, and could be

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submitted alone or along with other nasal/sinus endoscopy codes.

If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the procedure might be coded using the CPT codes 31256, 31276 or 31287. In this instance, the balloon dilation would be considered inclusive/incidental to the curette and/or forceps procedure.

See also policy titled, “Bundling Guidelines”

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.105, 9/11/08.

Senior Medical Director review - 12/21/2009.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.105, 12/10/09

National Institute of Health and Clinical Excellence (NICE). Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. *Interventional Procedure Guidance 273*. September 2008. Retrieved 7/6/11 from: <http://www.nice.org.uk/nicemedia/live/11899/42156/42156.pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.105, 5/12/2011

Policy Implementation/Update Information

- 2/2/2010 New policy issued. The use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of sinusitis is considered investigational. (pmo)
- 6/22/10 Policy Number(s) removed. (amw)
- 7/6/2010 Added reference to related policy “Functional Endoscopic Sinus Surgery (FESS).” Specialty Matched Consultant Advisory Panel review 5/24/10. No change to policy statement. (adn)
- 2/1/2011 Added CPT codes 31295, 31296, 31297. Information in the Billing/Coding section was deleted and replaced with the following: *Beginning in 2011, there are specific CPT codes for Balloon Sinuplasty. These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site. Prior to 2011, this procedure might be coded as an unlisted sinus procedure, 31299, and could be submitted alone or along with other nasal/sinus endoscopy codes. If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the procedure might be coded using the CPT codes 31256, 31276 or 31287. In this instance, the balloon dilation would be considered inclusive/incidental to the procedure.* (adn)
- 5/24/11 Coding update. Deleted S2344. (adn)
- 9/13/11 Description section updated. Policy Guidelines with rationale updated. No change in policy statement, remains Investigational. Specialty Matched Consultant Advisory Panel review 8/31/11. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.