Medical Coverage Policy

Balloon Sinuplasty for Treatment of Chronic Sinusitis

☐ Device/Equipment ☐ Drug ☐ Medical ☒ Surgery ☐ Test ☐ Other

Effective Date:	3/2/2010	Policy Last Updated:	2/21/2012

☐ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☒ **Prospective review is not required.**

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 fiber-optic 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 United States for chronic sinusitis. Estimates are that about 30 million individuals in the United States suffer from chronic sinusitis.

Balloon sinuplasty is viewed 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.

The published scientific literature for this device/procedure is 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.

The role of balloon sinuplasty in patients 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. 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 not medically necessary.

Policy:

Balloon sinuplasty is considered not medically necessary due to the lack of published peer-review literature which supports the efficacy of the procedure.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage, subscriber agreement for services that are considered not medically necessary.

Codes:
The following codes are not medically necessary:
S2344 Nasal/sinus endoscopy, surgical; with enlargement of sinus ostium opening using inflatable device (i.e. balloon sinuplasty)

31295, 31296, 31297

NOTE:
- It is incorrect coding to use 31237, 31267, 31276, or 31288.
- Incidental removal of tissue does not constitute a separately reported procedure.

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services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.