Medical Coverage Policy | Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis

EFFECTIVE DATE: 03|03|2015
POLICY LAST UPDATED: 10|17|2017

OVERVIEW
Balloon ostial dilation (also known as balloon sinuplasty) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic rhinosinusitis who fail medical management.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis is considered not medically necessary due to the lack of published peer-review literature that supports the efficacy of the procedure.

COVERAGE
BlueCHiP for Medicare and Commercial Products
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
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 functional endoscopic sinus surgery (FESS).

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 because considerable variation exists in the location and shape of these sinus ostia.

Estimates suggest approximately 30 million individuals in the U.S. suffer from CRS. Most 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 CRS.

A newer procedure, balloon ostial dilation, can be used as an alternative to FESS or as an adjunct to FESS for those with CRS. The goal of this technique, when used as an alternative to FESS, is to achieve improved

sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. 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.

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) marketing clearance. These include the Relieva Spin Sinus Dilation System® cleared in August 2011, and the Relieva Seeker Balloon Sinuplasty System® cleared 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 (FDA product code: EOB). The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices, the ENTrigue® Sinus Dilation System (ENTrigue Surgical, subsequently acquired by ArthroCare, Austin, TX, acquired by Smith and Nephew, London, UK), and the XprESS™ Multi-Sinus Dilation Tool, also received 510(k) clearance in August 2012.

There is still insufficient evidence on the impact of balloon ostial dilation on health outcomes, therefore the service is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not medically necessary:

31295 Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal, or via canine fossa

31296 Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)

31297 Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)

NOTE:

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

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, December 2017
Provider Update, January 2017
Provider Update, May 2015
Provider Update, June 2014
Provider Update, May 2013

Provider Update, June 2010
Provider Update, May 2011

REFERENCES

1. Hopkins C, Browne JP, Slack R, et al. The Lund-Mackay staging system for chronic rhinosinusitis: how is it used and what does it predict? Otolaryngol Head Neck Surg. Oct 2007;137(4):555-561. PMID 17903570

2. Lund VJ, Kennedy DW. Staging for rhinosinusitis. Otolaryngol Head Neck Surg. Sep 1997;117(3 Pt 2):S35-40. PMID 9334786

3. Hopkins C, Gillett S, Slack R, et al. Psychometric validity of the 22-item Sinonasal Outcome Test. Clin Otolaryngol. Oct 2009;34(5):447-454. PMID 19793277

4. Blue Cross and Blue Shield Association Technology Evaluation Center Program. Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis. TEC Assessments 2012;27, Tab 9.

5. Ahmed J, Pal S, Hopkins C, et al. Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. Cochrane Database Syst Rev. 2011(7):CD008515. PMID 21735433

6. Plaza G, Eisenberg G, Montojo J, et al. Balloon dilation of the frontal recess: a randomized clinical trial. Ann Otol Rhinol Laryngol. Aug 2011;120(8):511-518. PMID 21922974

7. Levy JM, Marino MJ, McCoul ED. Paranasal sinus balloon catheter dilation for treatment of chronic rhinosinusitis: a systematic review and meta-analysis. Otolaryngol Head Neck Surg. Jan 2016;154(1):33-40. PMID 26519456

8. Achar P, Duvvi S, Kumar BN. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. Acta Otorhinolaryngol Ital. Oct 2012;32(5):314-319. PMID 23326011

9. Bikhazi N, Light J, Truitt T, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up. Am J Rhinol Allergy. Jul 2014;28(4):323-329. PMID 24823902

10. Cutler J, Bikhazi N, Light J, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial. Am J Rhinol Allergy. Sep-Oct 2013;27(5):416-422. PMID 23920419