

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



EFFECTIVE DATE: 03|03|2015
POLICY LAST UPDATED: 12|06|2016

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 uncinat 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 uncinat 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 transtrantral 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

31296

31297

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, January 2017

Provider Update, May 2015

Provider Update, June 2014

Provider Update, May 2013

Provider Update, June 2010

Provider Update, May 2011

Provider Update, April 2012

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 Dilatation 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

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary 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. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

