

(Formerly Balloon Sinuplasty for Treatment of Chronic Sinusitis)

Medical Benefit		Effective Date: 04/01/14	Next Review Date: 01/15
Preauthorization	No	Review Dates: 07/07, 07/08, 11/08, 05/09, 01/10, 01/11, 01/12, 03/12, 01/13, 01/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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.

Background

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. 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 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. The procedure may be used when patients fail to respond to aggressive medical management. Approximately 350,000 procedures are done each year in the U.S. for chronic sinusitis. Estimates are that approximately 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.

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.

To quantify the severity of chronic sinusitis and to assess treatment response, various outcomes measures can be used. The Lund-McKay scoring system utilizes radiologist-rated information derived from computed

tomography (CT) scans regarding opacification of the sinus cavities. The Sino-Nasal Outcome Test (SNOT-20) is a validated questionnaire in which patients complete 20 symptom questions on a categorical scale (0=no bother to 5=worst symptoms can be). Average rankings can be reported over all 20 symptoms, as well as by four subclassified symptom domains.

Regulatory Status

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. 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. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices by Entellus Medical Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

Policy (Formerly Corporate Medical Guideline)

Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of medically refractory chronic sinusitis may be considered **medically necessary** as a minimally invasive alternative to endoscopic sinus surgery.

Benefit Application

When balloon sinuplasty is performed in conjunction with a medically necessary functional endoscopic sinus surgery (FESS) in the same sinus, balloon sinuplasty is considered to be **not medically necessary** as it would be an integral part of FESS and therefore not separately payable.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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

2. 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* 2013.
3. Kutluhan A, Salviz M, Bozdemir K et al. The effects of uncinectomy and natural ostial dilatation on maxillary sinus ventilation: a clinical experimental study. *Eur. Arch. Otorhinolaryngol.* 2011; 268(4):569-73.
4. 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* 2012; 32(5):314-9.
5. Bozdemir K, Kutluhan A, Cetin H et al. Comparison of outcomes of simple polypectomy plus balloon catheter dilatation versus functional endoscopic sinus surgery in nasal polyposis: a preliminary study. *Am J Rhinol Allergy* 2011; 25(3):198-200.
6. Ramadan HH, Terrell AM. Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinosinusitis. *Ann Otol Rhinol Laryngol* 2010; 119(9):578-82.
7. Friedman M, Schalch P, Lin HC et al. Functional endoscopic dilatation of the sinuses: patient satisfaction, postoperative pain, and cost. *Am J Rhinol* 2008; 22(2):204-9.
8. Koskinen A, Penttila M, Myller J et al. Endoscopic sinus surgery might reduce exacerbations and symptoms more than balloon sinuplasty. *Am J Rhinol Allergy* 2012; 26(6):e150-6.
9. Plaza G, Eisenberg G, Montojo J et al. Balloon dilation of the frontal recess: a randomized clinical trial. *Ann Otol Rhinol Laryngol* 2011; 120(8):511-8.
10. Plaza G. Personal Communication with primary author (G Plaza). April 12, 2012.
11. 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.
12. Batra PS, Ryan MW, Sindwani R et al. Balloon catheter technology in rhinology: Reviewing the Evidence. *Laryngoscope* 2011; 121(1):226-32.
13. Cutler J, Truitt T, Atkins J et al. First clinic experience: patient selection and outcomes for ostial dilation for chronic rhinosinusitis. *Int Forum Allergy Rhinol* 2011; 1(6):460-5.
14. Bolger WE, Vaughan WC. Catheter-based dilation of the sinus ostia: initial safety and feasibility analysis in a cadaver model. *Am J Rhinol* 2006; 20(3):290-4.
15. Kuhn FA, Church CA, Goldberg AN et al. Balloon catheter sinusotomy: one-year follow-up--outcomes and role in functional endoscopic sinus surgery. *Otolaryngol Head Neck Surg.* 2008; 139(3 Suppl 3):S27-37.
16. Weiss RL, Church CA, Kuhn FA et al. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. *Otolaryngol Head Neck Surg.* 2008; 139(3 Suppl 3):S38-46.
17. Stankiewicz J, Truitt T, Atkins J, Jr. One-year results: Transantral balloon dilation of the ethmoid infundibulum. *Ear Nose Throat J* 2010; 89(2):72-7.
18. Stankiewicz J, Truitt T, Atkins J et al. Two-year results: transantral balloon dilation of the ethmoid infundibulum. *Int Forum Allergy Rhinol* 2012; 2(3):199-206.
19. Levine HL, Sertich AP, 2nd, Hoisington DR et al. Multicenter registry of balloon catheter sinusotomy outcomes for 1,036 patients. *Ann Otol Rhinol Laryngol* 2008; 117(4):263-70.
20. Brown CL, Bolger WE. Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: a preliminary investigation. *Ann Otol Rhinol Laryngol* 2006; 115(4):293-9; discussion 300-1.

21. Ramadan HH. Safety and feasibility of balloon sinuplasty for treatment of chronic rhinosinusitis in children. *Ann Otol Rhinol Laryngol* 2009; 118(3):161-5.
22. Wittkopf ML, Becker SS, Duncavage JA et al. Balloon sinuplasty for the surgical management of immunocompromised and critically ill patients with acute rhinosinusitis. *Otolaryngol Head Neck Surg.* 2009; 140(4):596-8.
23. Tomazic PV, Stammberger H, Koele W et al. Ethmoid roof CSF-leak following frontal sinus balloon sinuplasty. *Rhinology* 2010; 48(2):247-50.
24. Chandra RK. Estimate of radiation dose to the lens in balloon sinuplasty. *Otolaryngol Head Neck Surg.* 2007; 137(6):953-5.
25. Vaughan WC. Review of balloon sinuplasty. *Curr Opin Otolaryngol Head Neck Surg* 2008; 16(1):2-9.
26. NICE. National Institute of Health and Clinical Excellence (NICE). Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. *Interventional Procedure Guidance 273.* September 2008. 2008; (November 30, 2010.).
27. AAOHNS. American Academy of Otolaryngology-Head and Neck Surgery. Statement on Balloon Dilation. Adopted June 28, 2010. 2010; (November 30, 2010.).
28. ARS. American Rhinologic Society (ARS) Revised Position Statement on Endoscopic Balloon Catheter Sinus Dilation Technology. 2010. Available online at: <http://www.american-rhinologic.org/patientadvocacy.balloon.phtml>. Last accessed November 2010.