Protocol

Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Medical Benefit		**Effective Date**: 04/01/15	**Next Review Date**: 11/17
Preauthorization	No	**Review Dates**: 07/07, 07/08, 11/08, 05/09, 01/10, 01/11, 01/12, 03/12, 01/13, 01/14, 11/14, 11/15, 11/16	

Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic rhinosinusitis	Interventions of interest are: • Balloon ostial dilation as a stand-alone procedure	Comparators of interest are: • Medical management • Functional endoscopic sinus surgery	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With chronic rhinosinusitis	Interventions of interest are: • Balloon ostial dilation as an adjunct to functional endoscopic sinus surgery	Comparators of interest are: • Functional endoscopic sinus surgery alone	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity

Description

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

Policy

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

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, although symptoms vary considerably because of variation in the location and shape of these sinus ostia.

Estimates suggest approximately 30 million individuals in the United States 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. 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 dilitation, 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 improve 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.

Outcomes in the Evaluation of CRS

To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used including patient-reported quality of life (QOL) measures, radiologic scores, and endoscopic grading.

The Lund-McKay scoring system utilizes radiologist-rated information derived from computed tomography (CT) scans regarding opacification of the sinus cavities, generating a score from 0-12.[1, 2]

Several disease-specific patient-reported QOL scores have been used. Commonly used is the Sino-Nasal Outcome Test (SNOT-20)which 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. The SNOT-22, variation of the SNOT-20, includes two additional questions (“nasal obstruction” and “loss of smell and taste”). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.[3]

Additionally, QOL may be reported based on overall health-related QOL scores, such as the 36-Item Short-Form Health Survey-36 (SF-36). The SF-36 includes eight scaled scores on various health domains, which are transformed into a 0-to-100 scale (100 corresponding to best health).

Regulatory Status

In March 2008, 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 cleared by FDA through the 510(k) process. 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 by Entellus Medical 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.

In 2013, a sinus dilation system manufactured by Medtronic Xomed (Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by the FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (ArthroCare, San Antonia, TX , a division of Smith and Nephew), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmold infundibula in adults using a transnasal approach.

FDA product code: LRC

Related Protocol

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery

---

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. 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
11. Batra PS, Ryan MW, Sindwani R, et al. Balloon catheter technology in rhinology: Reviewing the Evidence. Laryngoscope. Sep 7 2011; 121(1):226-232. PMID 20824793
12. Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. Jan 2016; 126(1):44-50. PMID 26228589
13. Stankiewicz J, Truitt T, Atkins J, Jr. One-year results: Transantral balloon dilation of the ethmoid infundibulum. Ear Nose Throat J. Feb 2010; 89(2):72-77. PMID 20155675
14. Stankiewicz J, Truitt T, Atkins J, et al. Two-year results: transantral balloon dilation of the ethmoid infundibulum. Int Forum Allergy Rhinol. May-Jun 2012; 2(3):199-206. PMID 22337530
15. Levine SB, Truitt T, Schwartz M, et al. In-office stand-alone balloon dilation of maxillary sinus ostia and ethmoid infundibula in adults with chronic or recurrent acute rhinosinusitis: a prospective, multi-institutional study with-1-year follow-up. Ann Otol Rhinol Laryngol. Nov 2013; 122(11):665-671. PMID 24358625
16. Gould J, Alexander I, Tomkin E, et al. In-office, multisinus balloon dilation: 1-Year outcomes from a prospective, multicenter, open label trial. Am J Rhinol Allergy. Mar-Apr 2014; 28(2):156-163. PMID 24598043
17. Bizaki AJ, Taulu R, Numminen J, et al. Quality of life after endoscopic sinus surgery or balloon sinuplasty: a randomized clinical study. Rhinology. Dec 2014; 52(4):300-305. PMID 25479206
18. Bizaki AJ, Numminen J, Taulu R, et al. Decrease of nasal airway resistance and alleviations of symptoms after balloon sinuplasty in patients with isolated chronic rhinosinusitis. A prospective, randomized clinical study. Clin Otolaryngol. Nov 9 2015. PMID 26548697
19. Bizaki AJ, Numminen J, Taulu R, et al. A controlled, randomized clinical study on the impact of treatment on antral mucociliary clearance: uncinectomy versus balloon sinuplasty. Ann Otol Rhinol Laryngol. May 2016; 125(5):408-414. PMID 26611244
20. Marzetti A, Tedaldi M, Passali FM. The role of balloon sinuplasty in the treatment of sinus headache. Otolaryngol Pol. Jan-Feb 2014; 68(1):15-19. PMID 24484944
21. 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. Apr 2011; 268(4):569-573. PMID 21110035

22. 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. May-Jun 2011; 25(3):198-200. PMID 21679533
23. Ramadan HH, Terrell AM. Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinosinusitis. Ann Otol Rhinol Laryngol. Sep 2010; 119(9):578-582. PMID 21033023
24. Wang F, Song Y, Zhang X, et al. Sinus balloon catheter dilation in pediatric chronic rhinosinusitis resistant to medical therapy. JAMA Otolaryngol Head Neck Surg. Jun 2015; 141(6):526-531. PMID 25835158
25. Friedman M, Schalch P, Lin HC, et al. Functional endoscopic dilatation of the sinuses: patient satisfaction, postoperative pain, and cost. Am J Rhinol. Mar-Apr 2008; 22(2):204-209. PMID 18416981
26. Koskinen A, Penttila M, Myller J, et al. Endoscopic sinus surgery might reduce exacerbations and symptoms more than balloon sinuplasty. Am J Rhinol Allergy. Nov-Dec 2012; 26(6):e150-156. PMID 23232189
27. Hathorn IF, Pace-Asciak P, Habib AR, et al. Randomized controlled trial: hybrid technique using balloon dilation of the frontal sinus drainage pathway. Int Forum Allergy Rhinol. Feb 2015; 5(2):167-173. PMID 25360863
28. Plaza G. Personal communication April 12, 2012.
29. Bolger WE, Vaughan WC. Catheter-based dilation of the sinus ostia: initial safety and feasibility analysis in a cadaver model. Am J Rhinol. May-Jun 2006; 20(3):290-294. PMID 16871931
30. 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. Sep 2008; 139(3 Suppl 3):S27-37. PMID 18707992
31. Weiss RL, Church CA, Kuhn FA, et al. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. Otolaryngol Head Neck Surg. Sep 2008; 139(3 Suppl 3):S38-46. PMID 18707993
32. National Institute of Health and Clinical Excellence (NICE). Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis [IPG421]. 2008; http://www.nice.org.uk/guidance/IPG273/chapter/1-Guidance. Accessed August 8, 2016.
33. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Dilation of sinuses, any method (e.g., balloon, etc.). Adopted June 28, 2010; reaffirmed December 8, 2012; Re-reviewed January 2, 2014. http: //www.entnet.org/content/position-statement-dilation-sinuses-any-method-eg-balloon-etc. Accessed August 8, 2016.
34. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. Apr 2015; 152(2 Suppl):S1-S39. PMID 25832968
35. American Rhinologic Society (ARS). Revised Position Statement on Endoscopic Balloon Catheter Sinus Dilation Technology; 2010 http://www.american-rhinologic.org/patientadvocacy.balloon.phtml. Accessed August 6, 2014.
36. Plaza G, Gusravo E, Montojo J et al. Balloon Dilation of the Frontal Recess: A Randomized Clinical Trial. Annals of Otology, Rhinology & Laryngology 2011; 120(8):511-518.