

Protocol

Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis

(Formerly Balloon Ostial Dilation for Treatment of Chronic Sinusitis)

Medical Benefit		Effective Date: 04/01/15	Next Review Date: 11/18
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, 11/17	

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: <ul style="list-style-type: none">• With chronic rhinosinusitis	Interventions of interest are: <ul style="list-style-type: none">• Balloon ostial dilation as a stand-alone procedure	Comparators of interest are: <ul style="list-style-type: none">• Medical management• Functional endoscopic sinus surgery	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Change in disease status• Quality of life• Treatment-related morbidity
Individuals: <ul style="list-style-type: none">• With chronic rhinosinusitis	Interventions of interest are: <ul style="list-style-type: none">• Balloon ostial dilation as an adjunct to functional endoscopic sinus surgery	Comparators of interest are: <ul style="list-style-type: none">• Functional endoscopic sinus surgery alone	Relevant outcomes include: <ul style="list-style-type: none">• 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 United States 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 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 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.

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 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 and more recently by Smith and Nephew), 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 Antonio, 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/ethmoid infundibula in adults using a transnasal approach.

FDA product code: LRC

Related Protocol

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

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.

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