Medical Coverage Policy | Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis – EFFECTIVE 1.1.2019

EFFECTIVE DATE: 01|01|2019
POLICY LAST UPDATED: 08|21|2018

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. 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).

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
CHRONIC RHINOSINUSITIS
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 a headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms vary considerably because of the location and shape of these sinus ostia.

Treatment
Estimates have suggested 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. Functional endoscopic sinus surgery (FESS) has become an important aspect for surgical management of chronic sinusitis, although evidence from randomized controlled trials is limited. 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 dilatation can be used as an alternative 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 alternative 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 2008, the 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. 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. They include the Relieva Spin Sinus Dilation System® (cleared in 2011) and the Relieva Seeker Balloon Sinuplasty System® (cleared in 2012).

In 2008, the FinESS™ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by 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, acquired by more recently by Smith & Nephew), and the XprESS™ Multi-Sinus Dilation Tool, also received 510(k) clearance in 2012.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or imageguided 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 (Smith & 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.

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure, or as an adjunct to FESS, the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

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)

31298 Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation) (New code effective 1/1/2018)

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, November 2018
Provider Update, December 2017
Provider Update, January 2017
Provider Update, May 2015
Provider Update, June 2014

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