

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



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OVERVIEW

Balloon ostial dilation (also known as Balloon Sinuplasty™) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic sinusitis who fail medical management.

MEDICAL CRITERIA

Not applicable.

PRIOR AUTHORIZATION

Not applicable.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

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

Benefits may vary between groups/contracts. Please refer to the appropriate 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 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 are that approximately 30 million individuals in the U.S. suffer from chronic sinusitis. 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 chronic sinusitis.

A newer procedure, balloon ostial dilation, can be used as an alternative to FESS or as an adjunct to FESS for those with chronic sinusitis. 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 uncinata 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 uncinata 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. 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.

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

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, May 2015

Provider Update, June 2014

Provider Update, May 2013

Provider Update, June 2010

Provider Update, May 2011

Provider Update, April 2012

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