

FEP 7.01.105 Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis

Effective Date: July 15, 2018

Related Policies:

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

Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis

Description

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).

FDA REGULATORY STATUS

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 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 (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.

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FDA product code: LRC.

OBJECTIVE

The objective of this evidence review is to evaluate whether balloon ostial dilation improves the net health outcome for patients with chronic rhinosinusitis.

POLICY STATEMENT

Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of chronic rhinosinusitis is considered **investigational**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available systematic reviews (including a Cochrane review and a TEC Assessment) have concluded that, although nonrandomized evidence has suggested balloon ostial dilation has similar outcomes to FESS, evidence from randomized trials is needed to demonstrate an improvement in outcomes for patients treated with balloon ostial dilation. Since the publication of those systematic reviews, an additional RCT (REMODEL) has been published. It assessed 105 patients, reporting short-term improvement in symptoms similar to those seen with FESS and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. Limitations of the REMODEL trial included its unblinded outcomes assessment and differential dropout between groups. Other trials have provided limited additional evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as an adjunct to FESS, the evidence includes 2 RCTs and single-arm series. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Neither available RCT reported significant clinically meaningful benefits associated with the addition of balloon ostial dilation to FESS. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

A 2008 guidance on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Care Excellence has stated: "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns."³³ In 2016, the Institute published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis³⁴:

- 1.1 "The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS).

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- 1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia.”

American Academy of Otolaryngology – Head and Neck Surgery

In 2017, the American Academy of Otolaryngology – Head and Neck Surgery updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: “Sinus ostial dilation ... is a therapeutic option for selected patient with chronic rhinosinusitis.... This approach may be used alone ... or in conjunction with other instruments....”³⁵

In 2015, the Academy’s Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.³⁶

American Rhinologic Society

A position statement, revised in 2017, from the American Rhinologic Society, stated that sinus ostial dilation is “a therapeutic option for selected patients with chronic rhinosinusitis (CRS) ... who have failed appropriate medical therapy.”³⁷

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
June 2012	New Policy	Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis is considered investigational .
March 2014	Update Policy	Policy updated with literature review. Policy title changed to balloon ostial dilation. Numerous references added and removed. No change to policy statement.
March 2015	Update Policy	Policy updated with literature review; References 6, 7, 21-25, and 30-31 added. Rationale section reorganized. Policy statement edited to remove trademarked name, but otherwise unchanged.
March 2017	Update Policy	Policy updated with literature review. References 1-3, 7, 18-19, 27, 33, 35 and 38 added. Rationale extensively revised. Policy statements unchanged. Policy statement unchanged, but "sinusitis" changed to "chronic rhinosinusitis" to be consistent with the title change to "Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis."
June 2018	Update Policy	Policy updated with literature review through December 11, 2017. No references added; updated references 25 and 37. No change to policy statement. Objective statement added: The objective of this evidence review is to evaluate whether balloon ostial dilation improves the net health outcome for patients with chronic rhinosinusitis.

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