

MEDICAL POLICY



SUBJECT: SINUS OSTIAL DILATION FOR TREATMENT OF CHRONIC SINUSITIS (e.g., BALLOON SINUPLASTY) POLICY NUMBER: 7.01.85 CATEGORY: Technology Assessment	EFFECTIVE DATE: 04/21/11 REVISED DATE: 06/21/12, 05/23/13, 06/19/14, 06/18/15, 06/16/16, 06/15/17, 05/17/18 PAGE: 1 OF: 5
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, balloon sinuplasty or any other catheter-based inflatable device, as a stand-alone procedure has been medically proven to be effective and is considered **medically appropriate** for the treatment of chronic sinusitis when ALL the following criteria have been met:

- I. Documentation of persistent sinusitis for greater than three months; AND
- II. Failure of medical therapy greater than three months (e.g., antibiotics, steroid nasal spray, antihistamines); AND
- III. Radiologic evidence of chronic sinusitis by either air fluid levels, mucosal thickening greater than two mm, or opacification.

POLICY GUIDELINES:

If balloon sinuplasty is performed in conjunction with another sinus surgery in the same sinus, the balloon dilation would be considered inclusive/incidental to the primary procedure, and therefore, would not be allowed separate reimbursement.

DESCRIPTION:

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. In some cases of chronic sinusitis, surgical drainage may be necessary. Functional endoscopic sinus surgery (FESS, used when patients fail to respond to aggressive medical management, 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.

A new procedure, balloon sinuplasty, has been proposed as an alternative to endoscopic sinus surgery for those with chronic sinusitis. The procedure involves placing a guidewire in the sinus ostium (confirmed with fluoroscopy, or with direct transillumination of the targeted sinus cavity), advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. Balloon sinuplasty aims to restore sinus drainage and function without damaging the sinus mucosa. Pressure caused by the inflated balloon restructures and widens the ostium by creating microfractures in the surrounding bone. General anesthesia is usually needed for this procedure to minimize patient movement. However, an increasing number of ENT doctors perform the procedure in the office, under local anesthesia.

Newer devices have been developed that do not utilize balloon dilation, but allow for a more gradual dilation through an osmotic process using the body's natural mucosal fluids to expand the insert before removal. This technique is referred to as self-expanding absorptive sinus ostial dilation. This procedure involves the intranasal insertion of a plug-like device into the sinus ostia. Once inserted, the device absorbs moisture from the surrounding tissue and begins to expand, providing low-pressure, gradual dilation of the sinus ostia. Once the device has been given enough time to fully expand, it is removed. This type of device is proposed to maximize patient tolerability of the procedure.

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RATIONALE:

In March 2008, the device “Relieva Sinus Balloon Catheter” (Acclarent, Menlo Park, CA) was cleared for marketing by the 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. The indication noted is to access and treat the maxillary ostia/ethmoid infundibula in adults using a transantral approach. 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 Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool. The NuVent EM Balloon Sinus Dilation System (Medtronic) received FDA 510(k) clearance in late 2013. It features a built-in electromagnetic surgical navigation technology.

The Vent-Os-Gentle Sinus Dilation System (SinuSys Corporation) received FDA clearance in January 2014. Unlike balloon dilation devices that use rapid, high-pressure inflation, the Vent-Os sinus dilation system is a small, low-pressure, self-expanding insert designed to gently and gradually open the maxillary ostia. The Vent-Os System incorporates the Company’s proprietary osmotic technology, which utilizes the body’s natural mucosal fluids to expand the insert before removal. The FDA approval for the Vent-Os System was based on comparison to predicate devices. The Vent-Os System achieved post-procedural patency in 95 percent of the sinus ostia treated in a multi-center study and submitted as part of the Company’s FDA application; five percent of the treated ostia could not be visualized. In the study, the Vent-Os device was inserted into the maxillary sinus opening at the beginning of the procedure and removed after 60 minutes. No adverse events occurred during insertion or removal of the device. Three-month follow-up was completed in 33 patients (55 ostia), with 93 percent of the treated ostia remaining patent and seven percent that could not be visualized. No ostia were reported to be occluded. Fifteen percent of patients in the study were treated in an office setting after pre-procedural injection of anesthesia; no additional anesthesia or medication was required for these patients for the duration of the procedure. This is in contrast to balloon dilation devices, which often require administration of anxiolytics, analgesics and/or additional local injections of anesthetics during the procedure to increase patient tolerability. The remaining patients were treated in the operating room adjunctive to functional endoscopic sinus surgery (FESS).

While longer-term clinical outcomes are still required, there is short-term evidence that this technique can be performed successfully and safely in adult patients with chronic rhinosinusitis. Small, randomized controlled trials, including the largest study (REMODEL) of 105 patients, report short-term improvement in symptoms that are similar to FESS, and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
	31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)

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31297 Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)

31298 Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)

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HCPCS: C1726 Catheter, balloon dilatation, non-vascular

ICD10: J32.0-J32.9 Chronic sinusitis (code range)

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*key article

KEY WORDS:

Balloon sinuplasty, balloon dilation, catheter sinusotomy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, sinus ostial dilation/balloon sinuplasty is not addressed in National or Regional CMS coverage determinations or policies.