MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Sinus Ostial Dilation for Treatment of Chronic Sinusitis (i.e., Balloon Sinuplasty/Balloon Ostial Dilation)**
Policy Number	**7.01.85**
Category	**Technology Assessment**
Original Effective Date	**04/21/11**
Committee Approval Date	**06/21/12, 05/23/13, 06/19/14, 06/18/15, 06/16/16, 06/15/17, 05/17/18, 05/16/19, 05/21/20, 05/20/21, 06/16/22**
Current Effective Date	**06/16/22**
Archived Date	**N/A**
Archived Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, balloon sinuplasty (also known as balloon ostial dilation) or any other catheter-based inflatable device, as a stand-alone procedure, has been medically proven to be effective and, therefore, 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 for 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 millimeters **(**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 reimbursed separately.

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 of 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.

Balloon sinuplasty (balloon ostial dilation is 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 sinus 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 rather 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.

RATIONALE

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 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. In late 2013, the NuVent EM Balloon Sinus Dilation System (Medtronic) received FDA 510(k) clearance. 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 developer'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 occluded ostia were reported. 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).

Chandra *et al*. (2016) reported the final results from the REMODEL full-study cohorts and performed meta-analyses of standalone balloon sinus dilation studies to explore long-term outcomes in a large patient sample. Final outcomes from the REMODEL randomized trial, including a larger cohort of 135 patients treated with functional endoscopic sinus surgery

(FESS) or in-office balloon dilation, were evaluated. One hundred thirty patients had 12-month data, 66 had 18-month data, and 25 had 24-month data. In addition, a meta-analysis evaluated outcomes from six studies that included 358 standalone balloon dilation patients with up to 24 months' follow-up. Outcomes out to two years from the REMODEL full-study cohort are consistent with six-month and 12-month outcomes. In the meta-analysis of standalone balloon dilation studies, technical success is 97.5%, and mean 20-item Sino-Nasal Outcomes Test scores are significantly and clinically improved at all time points. There are significant reductions in work/school days missed, homebound days, physician/nurse visits, acute infections, and antibiotic prescriptions. Mean recovery time is 1.4 days. Comparison of 12-month symptom improvements and revision rates between the REMODEL FESS arm (n = 59), REMODEL balloon dilation arm (n = 71), and pooled single-arm standalone balloon dilation studies (n = 243) demonstrated no statistical difference. The meta-analysis included a subgroup analysis for patients with chronic rhinosinusitis (n=191) versus recurrent acute rhinosinusitis (n=52). Both groups experienced statistically significant and clinically meaningful improvements in mean SNOT-20 scores, with no significant difference between groups. The authors concluded that all outcomes are comparable between FESS and balloon dilation at all time points from six months to 24 months. According to the authors, balloon dilation produces faster recovery, less postoperative pain, and fewer debridements than FESS.

There is evidence that balloon sinuplasty can be performed successfully and safely in adult patients with chronic rhinosinusitis in both the outpatient setting and the provider office setting. Clinical studies identify improvement in symptoms that are similar to FESS, and potential advantages for balloon sinuplasty with respect to on postoperative recovery time and pain medication use.

CODES

- *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.*

CPT Codes

Code	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia

HCPCS Codes

Code	Description
C1726	Catheter, balloon dilatation, nonvascular

ICD10 Codes

Code	Description
J32.0-J32.9	Chronic sinusitis (code range)

REFERENCES

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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.