Corporate Medical Policy

Balloon Ostial Dilation (Balloon Sinuplasty)

File Name: balloon_ostial_dilation_balloon_sinuplasty
Origination: 5/2020
Last Review: 2/2024

Description of Procedure or Service

Chronic rhinosinusitis is a common condition that affects approximately 12% of the U.S. adult population and results in significant disease burden including the morbidity from symptoms and lost time from work and school. (Piccirillo, 2018) A course of conservative medical therapy is attempted initially to resolve the symptoms and may include antibiotics, nasal irrigation, decongestants, and steroids. In some cases, surgical drainage may be necessary, the most commonly used technique being functional endoscopic sinus surgery (FESS).

Balloon ostial dilation (BOD) may be considered an alternative to endoscopic sinus surgery for those with recurrent acute and chronic sinusitis of the frontal, maxillary, or sphenoid sinuses. The procedure involves placing a guidewire in the sinus ostium and advancing a balloon over the guidewire. The high-pressure balloon compresses the sinus mucosa and creates microfractures in the bone surrounding the sinus ostium or outflow tract, attempting to improve sinus drainage and ventilation. It may be performed as a standalone procedure or with endoscopic surgery.

Regulatory Status

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. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum 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 also received 510(k) approval in 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

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. Ventera™ Sinus Dilation System does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery.

Balloon Ostial Dilation (Balloon Sinuplasty)

The list below summarized the FDA cleared balloon sinus dilation devices:

- Relieva Ultirra Sinus Ballon Catheter (Acclarent, Inc)
- Sinusway Dilation System (3NT Medical Ltd.)
- MESIRE-Balloon Suns Dilatation System (Meril Life Sciences)
- Relieva UltirraNavSinus Balloon Catheter (Acclarent, Inc.)
- Vent-Os Sinus Dilation Family (Sinusys Corp.)
- Relieva Scout Multi-Sinus Dilation System (Acclarent, Inc.)
- XprESS Multi-Sinus Dilation System (Entellus Medical, Inc.)
- DSS Sinusplasty Balloon Catheter (Inuit Medical Products LLC)
- Relieva SpinPlus Balloon Sinuplasty System (Acclarent, Inc.)

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Related Policies
Surgical Treatment of Sinus Disease

Policy

BCBSNC will provide coverage for balloon ostial dilation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Balloon Ostial Dilation is covered

Balloon ostial dilation of the frontal, maxillary or sphenoid sinuses (balloon sinuplasty) is considered **medically necessary** for the treatment of uncomplicated sinusitis without nasal polyposis when **ALL** the following criteria are met:

1. Either four or more documented episodes of acute rhinosinusitis in one year, or chronic sinusitis (greater than 12 weeks duration), **AND**
2. Optimal medical therapy has been attempted and failed, **AND**
3. A CT scan has been performed and shows air fluid levels or opacification to support the diagnosis of sinusitis in each sinus to be dilated. (see Policy Guidelines).

When Balloon Ostial Dilation is not covered

Balloon ostial dilation is considered **investigational** when the criteria above are not met, to include each individual sinus that is evaluated for ostial dilation.

Balloon ostial dilation is considered **investigational** in the following situations:

1. The management of headache in individuals who do not otherwise meet criteria for recurrent acute or chronic sinusitis
2. The management of sleep apnea in individuals who do not otherwise meet the criteria for recurrent acute or chronic sinusitis
3. Samter's triad (aspirin sensitivity)

4. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e. including, but not limited to, sarcoidosis, Granulomatosis with polyangiitis (GPA)
5. Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis
6. Contraindication to, or inability to tolerate local and/or topical anesthetic
7. History of failed balloon procedure in the sinus to be treated
8. Sinusitis with extensive fungal disease
9. Isolated ethmoid sinus disease
10. Mucous retention cysts/mucocele
11. Significant neo-osteogenesis

Policy Guidelines

Prior to BOD, a CT scan must be performed to document air fluid levels or opacification for each sinus to be dilated. If an in-office CT scan is performed by the ENT surgeon, an interpretation of the CT scan by an independent radiologist, with documentation of inflammation of each sinus to be dilated, may be required. The Plan may require submission of, or access to, the CT images for review.

In 2018, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) published a Clinical Consensus Statement (CCS): Balloon Dilation of the Sinuses.

The CCS was developed in part to address the lack of formally agreed upon criteria for appropriate use of BOD after an observed wide variation in national practice patterns and use of BOD for indications for which there was no evidence of efficacy. (Piccirillo, 2018)

Consensus was reached on statements that include the following:

- CT scanning of the sinuses is a requirement before ostial dilation can be performed.
- BOD is not appropriate for individuals who are without both sinonasal symptoms and positive findings on CT.
- BOD is not appropriate for individuals with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Objective evidence of inflammation on CT imaging is necessary, in addition to sinonasal symptoms for an individual to be deemed appropriate to undergo sinus ostial dilation.

BOD may be performed either as a stand-alone procedure or as an adjunct to FESS. When BOD is used with FESS in the same sinus cavity, it is considered an integral part of the primary procedure and not separately reimbursable.

Balloon ostial dilation as a standalone procedure in an ambulatory setting must be performed by a board eligible/board certified otolaryngologist who has admitting privileges at a local hospital.

Optimal medical treatment

Balloon ostial dilation should be reserved for use in individuals in whom optimal medical treatment has failed. The majority of individuals with sinusitis do not require surgery, as their sinus symptoms can usually be successfully treated medically, including antibiotic therapy and other medications, treatment of allergy, and environmental control.

Optimal medical treatment consists of the following:

1. Oral antibiotics of 2 weeks duration for individuals with chronic rhinosinusitis if evidence of bacterial infection on endoscopy
2. Oral antibiotics with multiple 1-2 week courses for individuals with recurrent acute rhinosinusitis

3. Intranasal steroids for at least one month
4. Systemic steroids (at the discretion of the physician)
5. Saline irrigations (optional)
6. Topical and/or systemic decongestants (optional, if not contraindicated)
7. Treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy (at the discretion of the physician)

Note: Imaging studies should generally be obtained after maximal medical therapy.

For individuals with CRS who receive BOD as a stand-alone procedure, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. In the REMODEL RCT, balloon ostial dilation was non-inferior to FESS for individuals with chronic rhinosinusitis. Durability of effect was demonstrated in uncontrolled studies that followed individuals who received balloon dilation for up to 24 months. Evidence from RCTs is supported by multiple observational studies and a systematic review showing improved quality of life following BOD. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events reported in individuals who underwent balloon dilation (n=2851), FESS (n=11,955), or a hybrid procedure (n=1234), the overall complication rate was 7.35% with FESS and 5.26% with balloon dilation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 31295, 31296, 31297, 31298

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Bikhazi N, Light J, Truitt T, et.al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up. Am J Rhinol Allergy 2014; 28(4): 323-329.

Chandra RK, Kern RC, Cutler JL, Welch KC, Russell PT. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. 2016 Jan;126(1):44-50.

Gould J, Alexander I, Tomkin E, Brodner D. In-office, multisinus balloon dilation: 1-Year outcomes from a prospective, multicenter, open label trial. Am J Rhinol Allergy 2014; 28(2): 156-163.

Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Sinuses. Otolaryngol Head Neck Surg. 2018 Feb;158(2):203-214.

(A full-length copy of the CCS can be found at: https://journals.sagepub.com/doi/full/10.1177/0194599817750086?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed)

Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. Apr 2015;152(2 Suppl):S1-S39. PMID 25832968

Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. Apr 2015;152(2 Suppl):S1-S39. PMID 25832968

Medical Director review 8/2020

Specialty Matched Consultant Advisory Panel – 2/2021

Medical Director review 5/2021

Specialty Matched Consultant Advisory Panel – 2/2022

Medical Director review 2/2022

Medical Director review 3/2022

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Hathorn IF, Pace-Asciak P, Habib AR, et al. Randomized controlled trial: hybrid technique using balloon dilation of the frontal sinus drainage pathway. Int Forum Allergy Rhinol. Feb 2015; 5(2): 167-73. PMID25360863

Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. Jan 2016; 126(1): 44-50. PMID26228589

Medical Director review 2/2024

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Policy Implementation/Update Information

5/12/20	New policy developed. Balloon ostial dilation is considered medically necessary with criteria. Policy noticed 5/12/2020 for policy effective date 7/14/2020. (HB)
8/25/20	Medical Director review. Added mucocele to when not covered section. Updated Wegener's granulomatosis to more current name of Granulomatosis with polyangiitis (GPA). (sk)
12/14/21	Specialty Matched Consultant Advisory Panel review 2/17/2021. Medical Director review. Removed "mucosal thickening of at least 3 mm" from When Covered section. Added "The Plan may require submission of, or access to, the CT images for review" to Policy Guidelines. (sk)
3/8/22	Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)

3/31/22 Medical Director review. Added “air fluid levels or opacification to support the diagnosis of sinusitis” to criteria 3 of the When Covered statement. Added “air fluid levels or opacification for” to the first Policy Guidelines sentence. Notification given March 31, 2022 for policy effective date May 31, 2022. (sk)

3/7/23 Specialty Matched Consultant Advisory Panel review 2/15/2023. (sk)

3/20/24 Regulatory Status, Policy Guidelines, and References sections updated. No change to policy intent. Medical Director review 2/2024. Specialty Matched Consultant Advisory Panel review 2/2024. (ldh)