MASSACHUSETTS

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Medical Policy

Balloon Sinuplasty for Treatment of Chronic Sinusitis

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Policy Number: 582

BCBSA Reference Number: N/A
NCD/LCD: N/A

Related Policies

Steroid-Eluting Sinus Stents and Implants, #800

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Office-based or outpatient hospital/ambulatory balloon sinus ostial dilation (balloon sinuplasty) as an alternative to traditional endoscopic sinus surgery is **MEDICALLY NECESSARY** for the treatment of uncomplicated chronic sinusitis when all of the following criteria are met:

1. Balloon sinuplasty is limited to the frontal, maxillary and sphenoid sinuses, **AND**
2. Individual has documented chronic sinusitis (CRS) persisting for 12 weeks or longer which negatively impacts quality of life, **AND**
    a. Symptoms include (any 2 of the following):
        i. Headache
        ii. Rhinorrhea
        iii. Sinus pressure
        iv. Nasal blockage or congestion
3. There is CT and/or nasal endoscopic evidence of persistent sinus pathology (CRS) including one or more of the following:
    a. Mucosal thickening,
    b. Sinus opacification,
    c. Air-fluid levels,
    d. Ostial narrowing or obstruction,
    e. Infraorbital or supraorbital ethmoid cells narrowing the drainage pathway of the maxillary or frontal sinuses respectively, **AND**
4. There is failure of optimal medical therapy defined as the following:
    a. 2-4 weeks of appropriate antibiotics (preferably culture-directed), **AND**
    b. A course of topical nasal steroids
5. Allergic or immune etiologies of symptoms have been ruled out or treated appropriately.

Office-based or outpatient hospital/ambulatory balloon sinus ostial dilation (balloon sinuplasty) for all other indications is **INVESTIGATIONAL** including but limited to the following**:**

1. Recurrent acute sinusitis
2. Repeat balloon procedure in any of the sinuses
3. Nasal polyposis (Grade 2 or greater)
4. Samter's triad (aspirin sensitivity)
5. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e. including, but not limited to, sarcoidosis, granulomatosis with polyangiitis (PGA))
6. Severe sinusitis secondary to ciliary dysfunction, (i.e. including, but not limited to, cystic fibrosis, Kartagener's Syndrome)
7. Bony dysplasia (i.e. including but not limited to Paget's disease, fibrous dysplasia)
8. Extensive fungal sinusitis
9. Mucocele causing sinusitis
10. Suppurative or non-suppurative complications of sinusitis including extension to adjacent structures such as the orbit or central nervous system
11. Suspected or known sinonasal benign or malignant tumor (including but not limited to squamous cell, adenoid cystic or adenocarcinoma, inverted papilloma)
12. History of failed balloon procedure in the sinus to be treated
13. Isolated ethmoid sinus disease
14. Reduction of inferior nasal turbinate hypertrophy.

Note: A catheter-based inflatable device may be used as a tool during functional endoscopic sinus surgery, but it is not reimbursed separately.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required.**
Commercial PPO and Indemnity	Prior authorization is **not required.**
Medicare HMO Blue℠	Prior authorization is **not required.**
Medicare PPO Blue℠	Prior authorization is **not required.**

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Code

CPT codes:	Code Description

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)
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)

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified

Description

Rhinosinusitis

Rhinosinusitis can be classified according to the duration of symptoms. Acute rhinosinusitis lasts fewer than 4 weeks, while subacute sinusitis lasts between 4 and 12 weeks. Chronic rhinosinusitis (CRS) lasts more than 12 weeks. Recurrent acute rhinosinusitis (RARS) is defined as experiencing 4 or more episodes of acute rhinosinusitis per year, with each episode lasting at least 10 days and without persistent symptoms in between individual episodes.[1] Rhinosinusitis affects 1 in 8 adults and accounts for 20% of antibiotic prescriptions.[2] A longitudinal analysis of a medical claims database from 2003-2008 showed that 1 in 3,000 individuals had RARS, with 72% being female and an average age of 43.5 years. Individuals had an average of 5.6 healthcare visits and 9.4 prescriptions annually[3].

Chronic Rhinosinusitis

CRS is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults.[4] In adults, CRS is characterized by symptoms related to nasal and sinus obstruction and inflammation, including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

Three CRS subtypes exist and may have somewhat different treatment strategies: CRS without nasal polyposis; CRS with nasal polyposis; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This evidence review focuses on the more common subtypes: CRS with and without nasal polyposis. Both subtypes present with similar symptoms. However, CRS with nasal polyposis is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyposis is more likely to be associated with asthma and aspirin intolerance; this triad is referred to as Samter syndrome or aspirin-exacerbated respiratory disease.

Chronic rhinosinusitis is associated with impaired quality of life for affected patients, and with high direct and indirect costs for medical treatments and lost productivity. Most often, the negative health effects of CRS are related to the unpleasant symptoms associated with CRS, including nasal congestion, nasal

drainage, and facial pain or pressure. In rare cases, CRS can be associated with serious complications, including orbital cellulitis, osteomyelitis, or intracranial extension of infection.

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria.[5,6] On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in patients with and without CRS found a quantitative increase in bacterial and fungal RNA expression in patients with CRS, but no major differences in the types of microorganisms detected.[7] Bacterial biofilms have been identified in cases of CRS.[8]

Recurrent Acute Rhinosinusitis

RARS is defined as having four or more episodes of acute bacterial rhinosinusitis per year, with no symptoms between episodes. Diagnosis is primarily based on medical history and physical examination, following the guidelines of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS).[9] Because other diseases can present with similar symptoms, it is important to consider various differential diagnoses. Nasal endoscopy is recommended for severe, one-sided, or persistent cases without septal deviation. Routine radiological imaging is generally not necessary for uncomplicated RARS, but noncontrast CT scans are crucial for chronic cases, suspected anatomical problems, or when planning surgeries like balloon ostial dilation (BOD) or functional endoscopic sinus surgery (FESS). The outlook for RARS is usually positive, with most patients responding well to treatments such as topical nasal sprays and oral antibiotics. It is rare for patients to need hospitalization, surgery, or intravenous antibiotics for complications. BOD has been proposed as a viable treatment option to provide symptom relief and an improved quality of life.

Medical Therapy

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics).[2]

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, monoclonal antibodies, and/or antibiotic therapy.[10] Guidelines from the AAO-HNS (2015; affirmed in 2020 by the American Academy of Family Physicians) have recommended the use of saline nasal irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs).[11,2] There is a specific recommendaton against the use of topical and systemic antifungal therapies. The guidelines do not include a statement specifically addressing the use of systemic antibiotics for CRS; however, in the list of future research needs, the authors included: “Perform additional RCTs to clarify the impact of antibiotic therapy on CRS outcomes.”

In 2019, the U.S. Food and Drug Administration (FDA) approved the first treatment for CRS with nasal polyps - dupilumab (Dupixent®). Results from clinical trials revealed that patients who received dupilumab "had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group" and also "reported an increased ability to smell and required less nasal polyp surgery and oral steroids."[12] This was followed by the approval of omalizumab (Xolair®) in 2020 as add-on maintenance treatment for adults with nasal polyps with an inadequate response to nasal corticosteroids.[13]In 2021, mepolizumab (Nucala®) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps.[14]

The mainstay of treatment for RARS is medical management, which often involves a multifaceted therapeutic approach. Patients typically benefit from a range of treatments aimed at different aspects of RARS's complex pathophysiology. These may include topical intranasal therapies, antibiotics, decongestants, oral antihistamines, steroids, and leukotriene modifiers.

Functional Endoscopic Sinus Surgery
The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and preventing the effective delivery of local medical therapies. In addition, to varying degrees, surgical techniques involve the creation of open sinus cavities, usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

Techniques for FESS, in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. FESS has largely replaced various open techniques for CRS (eg, Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (eg, endonasal tumors). FESS encompasses a variety of degrees of sinus access and tissue removal and is described based on the sinuses accessed. This procedure can also be used to access the ethmoid sinuses, which may involve creation of drainage into the maxillary sinuses (maxillary antrostomy).

Balloon Ostial Dilation
BOD can be used as an alternative or as an adjunct to FESS for those with CRS or RARS. The goal of this technique, when used as an alternative to FESS, is to improve sinus drainage using a less invasive approach. 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. According to the manufacturer, the RELIEVA SPINPLUS® Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

This evidence review is limited to BOD when used as a standalone procedure. BOD may also be used in combination with FESS.[15,16.] When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. BOD may also be used on 1 sinus and FESS on another sinus in the same patient during the same operation.

Summary
Balloon ostial dilation (BOD, also known as balloon sinuplasty) is proposed as an alternative to functional endoscopic sinus surgery (FESS) for individuals with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (RARS) 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 FESS. This evidence review addresses BOD as a standalone procedure.

Summary of Evidence
For individuals with CRS who receive BOD as a stand-alone procedure, the evidence includes a systematic review, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A meta-analysis of three studies indicated a statistically significant yet not clinically significant preference for BOD over FESS in terms of patient-related quality of life. The REMODEL RCT confirmed that BOD was not inferior to FESS for treating chronic rhinosinusitis, with the effect's durability observed over 24 months. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in individuals who underwent BOD (n=2851) or FESS (n=11,955), the overall complication rate was 5% with BOD and 7% with FESS. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with RARS who receive BOD as a stand-alone procedure, the evidence includes a systematic review and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review on RARS management identified two (of 10) studies focused on BOD as a treatment modality. Although an improvement in quality of life was observed across both studies, the small sample sizes, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis. In the REMODEL RCT, 32% of participants (N=29) with RARS

were diagnosed. BOD was found to be non-inferior to FESS in terms of quality of life at both 6 and 12 months post-procedure. Another RCT, CABERNET, comparing BOD plus medical care to medical care alone in individuals with RARS (N=59), demonstrated significantly improved quality of life and fewer sinus infections after 6 months in the balloon dilation group. The current body of evidence is limited by small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
4/2025	Annual policy review. Policy updated with literature review through December 9, 2024; references added. Policy statements unchanged.
9/2024	Annual policy review. Description, summary and references reviewed. Policy statements unchanged.
4/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
9/2022	Policy criteria clarified. Reduction of inferior nasal turbinate hypertrophy added to list of investigational procedures. 9/1/2022.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2021	Policy criteria clarified to align with IFAR/EPOS guidelines for chronic rhinosinusitis. 10/1/2021.
5/2021	Policy updated with literature review through 2020; no references added.
4/2020	Policy updated with literature review through February 29, 2020; references added.
4/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
3/2018	BCBSMA Medical Policy Group - Allergy, ENT/Otolaryngology review. No changes to policy statements.
1/2018	Clarified coding information.
6/2017	Policy statements clarified from standalone balloon sinuplasty to office-based or outpatient hospital/ambulatory balloon sinuplasty. 6/1/2017.
5/2017	New medically necessary and investigational indications. Clarified coding information. Effective 5/1/2017.
10/2016	Annual policy review. New references added.
1/2016	Annual policy review. New references added.
11/2014	Annual policy review. Policy statement edited to remove trademarked name. Effective 12/1/2014.
2/2014	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/17/2011	New policy effective 6/17/2011 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion