



MASSACHUSETTS

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Medical Policy

Balloon Sinuplasty for Treatment of Chronic Sinusitis

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)
- [Endnotes](#)

Policy Number: 582

BCBSA Reference Number: NA

NCD/LCD: N/A

Related Policies

- Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease, [#800](#)

Policy¹

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM 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. Patient has documented chronic sinusitis (CRS) persisting for 12 weeks or longer which negatively impacts quality of life, AND
 - a. Symptoms include
 - i. Headache
 - ii. Rhinorrhea
 - iii. Sinus pressure
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.

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 BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	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
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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

Chronic Rhinosinusitis

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 a headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms vary considerably because of the location and shape of these sinus ostia.

Treatment

Estimates have suggested approximately 30 million individuals in the United States suffer from CRS. Most cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. Functional endoscopic sinus surgery (FESS) has become an important aspect for surgical management of chronic sinusitis, although evidence from randomized controlled trials is limited. 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. Approximately 350,000 FESS procedures are done each year in the United States for CRS.

A newer procedure, balloon ostial dilatation can be used as an alternative or as an adjunct to FESS for those with CRS. The goal of this technique, when used as an alternative to FESS, is to improve sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. 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.

The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinat process. An alternative approach to the maxillary ostia is through the sinus, via the canine fossa. A guidewire

can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinat process.

Outcomes

To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used, including radiologic scores, endoscopic grading, and patient-reported quality of life (QOL) measures.

The Lund-Mackay scoring system uses radiologist-rated information derived from computed tomography scans to assess opacification of the sinus cavities, generating a score from 0 to 12.^{1,2}

Disease-specific patient-reported QOL scores include the commonly used Sino-Nasal Outcome Test-20 (SNOT-20), which is a validated questionnaire for which patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The SNOT-22, a variation of the SNOT-20, includes 2 additional questions (on “nasal obstruction” and “loss of smell and taste”). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.³ Additionally, QOL has been reported using overall health-related QOL scores, such as the 36-Item Short-Form Health Survey. That tool includes 8 scaled scores on various health domains, which are transformed into a 0-to-100 scale (100 corresponding to best health).

Summary

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).

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) 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, the REMODEL RCT has been published. It assessed 105 patients, reporting comparable symptom improvement from 6 months through 18 months in patients with chronic maxillary sinusitis who received balloon ostial dilation or FESS. Lower rates of postoperative debridement to remove clots and scar tissue were found in the balloon treated patients. Balloon ostial dilation can be performed with local anesthesia in the office setting. 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.

Policy History

Date	Action
4/2019	BCBSA National medical 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	New references added from BCBSA National medical policy.
1/2016	New references added from BCBSA National medical policy.
11/2014	BCBSA National medical policy review. Policy statement edited to remove trademarked name. Effective 12/1/2014.
2/2014	New references added from BCBSA National medical policy.
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