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

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease, #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

Chronic and Recurrent Acute 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.

Recurrent acute rhinosinusitis (RARS) is defined as 4 or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes.

Medical Treatment

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics).[1]

Balloon Ostial Dilation

A newer procedure, balloon ostial dilatation 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 individual 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.https://www.jnjmedicaldevices.com/en-US/product/relieva-spinplus-balloon-sinuplasty-system

This evidence review is limited to BOD when used as a standalone procedure. BOD may also be used in combination with FESS.[2,3,] 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.

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 the effects 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 RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. In the REMODEL study of BOD compared to FESS, 32% of individuals were diagnosed with recurrent acute rhinosinusitis (N=29). Balloon ostial dilation was non-inferior to FESS on measures of quality of life at 6 months and 12 months post-procedure. One RCT comparing balloon ostial dilation plus medical care to medical care alone in individuals with RARS found significantly improved quality of life and lower mean number of sinus infections after 24 months in the balloon dilation group. A third RCT included a mix of individuals with chronic and RARS and found improved quality of life compared to FESS, but results were not reported separately by diagnosis. The body of evidence is limited by the small number of individuals studied, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures used. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
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. 9/1/22.
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

References

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Endnotes

[1] Based on expert opinion