Medical Policy

Balloon Sinuplasty for Treatment of Chronic Sinusitis

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Policy Number: 582
BCBSA Reference Number: NA
NCD/LCD: N/A

Related Policies
None

Policy
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. Intraorbital 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**

Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<td>Medicare PPO BlueSM</td>
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**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**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa</td>
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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**

<table>
<thead>
<tr>
<th>ICD-10-CM-diagnosis codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>J32.0</td>
<td>Chronic maxillary sinusitis</td>
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<tr>
<td>J32.1</td>
<td>Chronic frontal sinusitis</td>
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<tr>
<td>J32.2</td>
<td>Chronic ethmoidal sinusitis</td>
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<tr>
<td>J32.3</td>
<td>Chronic sphenoidal sinusitis</td>
</tr>
<tr>
<td>J32.4</td>
<td>Chronic pansinusitis</td>
</tr>
<tr>
<td>J32.8</td>
<td>Other chronic sinusitis</td>
</tr>
<tr>
<td>J32.9</td>
<td>Chronic sinusitis, unspecified</td>
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</table>

**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. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms are variable because considerable variation exists in the location and shape of these sinus ostia.

Estimates are that approximately 30 million individuals in the United States suffer from chronic sinusitis. Most cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. FESS has become an important aspect for 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. Approximately 350,000 FESS procedures are done each year in the United States for chronic sinusitis.

A newer procedure, balloon ostial dilatation can be used as an alternative to FESS or as an adjunct to FESS for those with chronic sinusitis. The goal of this technique, when used as an alternative to FESS, is to achieve improved 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 uncinate process. An alternate 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 uncinate process.

To quantify the severity of chronic sinusitis and to assess treatment response, various outcomes measures can be used. The Lund-McKay scoring system utilizes radiologist-rated information derived from computed tomography scans regarding opacification of the sinus cavities. The Sino-Nasal Outcome Test is a validated questionnaire in 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.

Summary
Balloon ostial dilation (also known as balloon sinuplasty™) is proposed as an alternative to traditional endoscopic sinus surgery (ESS) for patients with chronic sinusitis 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).

The evidence related to the use of balloon ostial dilation, as a stand-alone procedure or an adjunct to FESS, has been reviewed in several systematic reviews, including a Cochrane review and a Blue Cross and Blue Shield Association TEC Assessment. These reviews have concluded that, although nonrandomized evidence suggests that balloon ostial dilation has similar outcomes to ESS, evidence from randomized trials is needed to demonstrate an improvement in outcomes for patients treated with balloon ostial dilation. Since the publication of the systematic reviews, an additional randomized controlled trial has been published, the REMODEL study. This study, which included 105 patients, reported short-term improvement in symptoms that are similar to those seen with FESS, and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. Limitations of the REMODEL study include the unblinded design, lack of blinded outcome assessment across the range of outcome measures, and differential dropout between groups. Other trials are either very small, or nonrandomized comparisons. Despite the mixed picture from current clinical literature, evidence suggests that balloon sinuplasty has similar outcomes to FESS, can be performed in the outpatient setting with fewer potential postoperative risks and has been adopted into clinical practice. Therefore, balloon sinuplasty may be considered medically necessary for chronic sinusitis. Evidence continues to be lacking regarding balloon sinuplasty for recurrent acute sinusitis.

Policy History

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<tr>
<th>Date</th>
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<tr>
<td>6/2017</td>
<td>Policy statements clarified from standalone balloon sinuplasty to office-based or outpatient hospital/ambulatory balloon sinuplasty. 6/1/2017.</td>
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<tr>
<td>10/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>1/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>2/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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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


Endnotes

1 Based on expert opinion