

Clinical Policy: Balloon Sinus Ostial Dilation for Treatment of Chronic Sinusitis

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Description

Sinuplasty, also known as balloon catheter sinusotomy and balloon sinus ostial dilation, is a minimally invasive technique intended to dilate the sinus ostia in patients with chronic sinusitis. Sinuplasty systems provide a means to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures to open passages and to restore normal drainage. Balloon sinuplasty is proposed to treat patients with chronic sinusitis who have exhausted less aggressive treatment options.

Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness® (PHW) that balloon sinuplasty is **medically necessary** in order to relieve obstruction of the maxillary, sphenoid, and frontal sinus ostia, either alone or in combination with standard endoscopic sinus surgery techniques, when all of the following are met:
 - A. Diagnosis of one of the following (1 or 2):
 1. Chronic rhinosinusitis (CRS) has persisted for ≥ 12 weeks and all of the following:
 - a. If > 18 years of age, meets both of the following (i and ii):
 - i. Has at least one of the following symptoms:
 - a) Anterior or posterior mucopurulent nasal discharge;
 - b) Nasal obstruction;
 - c) Facial pain/pressure/fullness;
 - d) Decreased or lost sense of smell;
 - ii. Computed tomography (CT) scan shows either of the following:
 - a) Polyps in nasal cavity or the middle meatus, and/or sinus opacification;
 - b) Inflammation of the paranasal sinuses;
 - b. If ≥ 2 years and ≤ 18 years of age, meets both of the following (i and ii):
 - i. Has at least two of the following symptoms:
 - a) Purulent rhinorrhea;
 - b) Nasal obstruction;
 - c) Facial pressure/pain;
 - d) Cough;
 - ii. Has at least one of the following findings:
 - a) Endoscopic signs of mucosal edema, purulent drainage, or nasal polyposis;
 - b) Mucosal changes within the ostiomeatal complex and/or sinuses, by CT scan;
 2. Recurrent acute rhinosinusitis (RARS), both of the following:
 - a. Documented ≥ 4 episodes of acute bacterial rhinosinusitis in the past year without signs or symptoms of rhinosinusitis between episodes;
 - b. Anterior or posterior purulent nasal discharge and at least one of the following:
 - i. Nasal obstruction;

- ii. Facial pain/pressure/fullness;
 - B. Continued symptoms after medical therapy consisting of both of the following (1 and 2):
 - 1. Antibiotic therapy meeting one of the following (a or b):
 - a. Therapy guided by culture and sensitivity for ≥ 3 weeks;
 - b. Beta-lactamase resistant antibiotic for ≥ 3 weeks (e.g., amoxicillin [recommended], amoxicillin-clavulanate, trimethoprim-sulfisoxazole, cefuroxime);
 - 2. Intranasal corticosteroids for ≥ 4 weeks; or contraindicated;
 - C. Allergic or immune etiologies of symptoms have been ruled out or treated appropriately. .
- I. It is the policy of PHW that balloon sinuplasty is **not medically necessary** in any of the following situations:
- A. For the treatment of ethmoid disease;
 - B. Extensive previous sinus surgery with significant osteoneogenesis.

Background

CRS is defined as an inflammatory condition involving the paranasal sinuses and linings of the nasal passages, which persists for 12 weeks or longer. Symptoms of CRS include anterior and/or posterior mucopurulent drainage, nasal obstruction, facial pain, pressure, and/or fullness and decreased sense of smell. RARS is defined as 4 or more episodes of ABRS within a year, without persistent symptoms between episodes. The goal of medical therapy (e.g., antibiotics, nasal irrigation, topical corticosteroids) is directed toward facilitating the drainage of sinus secretions and treatment to eradicate the offending pathogens. Surgical intervention may be indicated when the patient requires more than three courses of antibiotics for sinusitis within a 12-month period along with evidence of abnormalities of the sinuses or ostiomeatal complex on nasal endoscopy or CT imaging. The goal of functional endoscopic sinus surgery is to restore physiologic sinus ventilation and drainage, which allows for the gradual resolution of mucosal disease. Balloon dilation is a less invasive alternative to endoscopic sinus surgery in the management of CRS or RARS.

The goal of balloon sinuplasty is to restore normal sinus drainage by enlarging passages of the sinus ostia and spaces within the paranasal sinus cavities, without cutting bone or removing tissue. Per the manufacturer of the Relieva Sinus Balloon Dilation Catheter, the procedure is performed under fluoroscopic guidance using endoscopic technique, by an otolaryngologist trained in the use of the Balloon Sinuplasty System. The initial sinus access is achieved by the introduction of a guide catheter into the target sinus. A flexible guidewire is then introduced through the guide catheter and gently advanced into the target sinus. The balloon catheter tracks smoothly over the guide wire and positioned across the blocked ostium. After the position of the balloon catheter is confirmed, it is gradually inflated to gently restructure the blocked ostium. The system is removed leaving the ostium open and allowing the return of normal sinus drainage and function with little to no disruption to the mucosal lining. Balloon sinuplasty may be performed in conjunction with endoscopic sinus surgery and used as an assistive procedure for sinus tissue biopsy or culturing, sinus lavage, drainage, or antibiotic irrigation.

Studies evaluating balloon sinuplasty are limited and include a prospective randomized trial, cohort studies, case series, observational and retrospective studies. Most studies were small and long term studies are lacking. However, the available studies suggest that balloon sinuplasty for CRS or RARS refractory to medical therapy is safe and efficacious. The data show that balloon sinuplasty can successfully dilate the sinus ostia and relieve symptoms of CRS and RARS. In addition, the use of balloon sinuplasty is supported as a treatment option by the professional societies noted below.

There is limited evidence regarding balloon sinuplasty in the pediatric population. However, two small studies have found positive effects of balloon sinuplasty in pediatric patients with CRS failing to respond to medical therapy^{16,18}. Additionally, one study found that balloon sinuplasty led to improved outcomes after failure to respond adequately to adenoidectomy¹⁴.

Guideline Recommendations

American Academy of Otolaryngology (AAO)-Head and Neck Surgery and the American Rhinologic Society (ARS)

Both the AAO Head and the ARS position statements on dilation of sinuses, any method (e.g., balloon, etc.), state “sinus ostial dilation (e.g., balloon ostial dilation) is a therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinitis (RARS) who have failed appropriate medical therapy. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by nasal endoscopy documenting sinonasal abnormality or mucosal thickening on computed tomography of the paranasal sinuses. This approach may be used alone to dilate an obstructed sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (e.g., microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon. For pediatric patients, the AAO did not reach consensus on whether balloon sinuplasty should be recommended for the treatment of CRS; however, near consensus was reached regarding the safety of balloon sinuplasty.

The AAO released a 2018 Consensus Statement on Balloon Dilation of the sinuses in adult patients. They reached strong consensus that CT documentation of sinonasal disease is required before surgical management with balloon sinus ostial dilation. Furthermore, the AAO stated that balloon sinus dilation “can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.”

American Academy of Allergy Asthma and Immunology (AAAAI), the American College of Allergy Asthma and Immunology (ACAAI), and the Joint Council of Allergy Asthma and Immunology (JCAAI)

In 2014, the AAAI, ACAAI, and JCAAI recommended that balloon ostial dilation should be considered in a small subset of patients with medically unresponsive acute rhinosinusitis, primarily those with early or localized disease. They note that symptomatic improvement is primarily documented among patients with mild disease that could potentially be relieved with medical therapy alone. For CRS, the AAAI, ACAAI, and JCAAI list balloon sinus dilation as one of the most commonly used modalities for patients that have failed maximal medical therapy.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2018, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation; maxillary sinus ostium, transnasal or via canine fossa)
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia

HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
J01.01	Acute recurrent maxillary sinusitis
J01.11	Acute recurrent frontal sinusitis
J01.31	Acute recurrent sphenoidal sinusitis
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.3	Chronic sphenoidal sinusitis

Reviews, Revisions, and Approvals	Date	Approval Date
Changed 2 nd listing of CPT code 31296 to 31297 in order to correctly match the code description.	07/17	
Changed criteria to apply to RARS as well as CRS, and allowed endoscopic diagnosis of CRS/RARS. Modified AAO statement in background. Added that allergic or immune etiologies should be ruled out or treated appropriately. Included AAAI guideline statements in background. Updated ICD-10 CM codes to include acute recurrent sinusitis. Removed “other” and “unspecified” ICD-CM codes.	10/18	10/18

Reviews, Revisions, and Approvals	Date	Approval Date
Clarified in > 18 CRS section that CT findings of opacification should be in the sinuses, and removed statement that CT findings should be radiographic, Clarified in > 18 CRS section that CT findings of opacification should be in the sinuses, and removed statement that CT findings should be radiographic		
Removed option for adults to qualify for balloon sinus dilation by endoscopic findings, as CT findings are required before surgery in 2018 guidelines.	10/19	
Added CPT 31298	10/19	1/10/2020
Annual review completed. Added ≥ 2 years in the pediatric section. Description of CPT codes 31295, 31296, 31297, and 31298, revised for 2020. In I.B.2, gave an option for when corticosteroids are contraindicated. References reviewed and updated. Specialty review completed.	2/18/2021	
Policy is being retired effective on the Submission Date, with no replacement indicated.	4/29/2022	11/10/2022

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