Clinical Policy: Balloon Sinus Ostial Dilation for Treatment of Chronic Sinusitis
Reference Number: CP.MP.119
Last Review Date: 11/17

See Important Reminder at the end of this policy for important regulatory and legal information.

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. The Relieva Balloon Sinuplasty System by Acclarant Inc. received FDA approval in April of 2005. It is a set of single-use, endoscopic, catheter-based instruments intended to 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
1. It is the policy of health plans affiliated with Centene Corporation® 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. Has at least one of the following findings (a or b):
               a) Computed tomography (CT) scan showing either of the following:
                  1) Polyps in nasal cavity or the middle meatus, and/or sinus opacification;
                  2) Inflammation of the paranasal sinuses;
               b) Nasal endoscopy showing either of the following:
                  1) Purulent mucous or edema in the middle meatus or ethmoid region;
                  2) Polyps in the nasal cavity or middle meatus;
         b. If ≤ 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;

C. Allergic or immune etiologies of symptoms have been ruled out or treated appropriately.

II. It is the policy of health plans affiliated with Centene Corporation 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. Fiber optics can also be used to illuminate the sinus cavity, without radiation exposure. 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 Sinuplasty

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 adenoidectomy.14

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 rhinosinusitis (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 (eg, 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.

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 made a recommendation 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
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<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa</td>
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<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)</td>
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<tr>
<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)</td>
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<th>HCPCS Codes</th>
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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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<tr>
<th>ICD-10-CM Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J01.01</td>
<td>Acute recurrent maxillary sinusitis</td>
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<tr>
<td>J01.11</td>
<td>Acute recurrent frontal sinusitis</td>
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<tr>
<td>J01.31</td>
<td>Acute recurrent sphenoidal sinusitis</td>
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<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>J32.3</td>
<td>Chronic sphenoidal sinusitis</td>
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Reviews, Revisions, and Approvals

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<tr>
<th>Date</th>
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<tr>
<td>07/16</td>
<td>11/16</td>
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Differentiated criteria by age ≤ 18 and >18. For ≥ 18, replaced headache with lost or decreased smell per AAO guidelines. Edited objective findings (via CT) for > 18 to reflect AAO guidelines. Added criteria for pediatric CRS diagnosis. Added a required trial of intranasal corticosteroids per pediatric and adult AAO guidelines. Added supporting background information for pediatric indication. Removed nasal polyps from not medically necessary list.

Changed 2nd listing of CPT code 31296 to 31297 in order to correctly match the code description.
Reviews, Revisions, and Approvals

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<tr>
<td>Changed criteria to apply to RARS as well as CRS, and allowed endoscopic</td>
<td>11/17</td>
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<td>diagnosis of CRS/RARS. Modified AAO statement in background. Added that</td>
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<td>allergic or immune etiologies should be ruled out or treated appropriately.</td>
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<td>Included AAAI guideline statements in background. Updated ICD-10 CM codes</td>
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<td>to include acute recurrent sinusitis. Removed “other” and “unspecified”</td>
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<td>ICD-CM codes.</td>
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<td>Clarified in &gt; 18 CRS section that CT findings of opacification should be</td>
<td>04/18</td>
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<td>in the sinuses, and removed statement that CT findings should be</td>
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<td>radiographic.</td>
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References


**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at [http://www.cms.gov](http://www.cms.gov) for additional information.

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