

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

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[Coding Implications](#)

[Revision Log](#)

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 for minimally invasive sinus surgery. Per the FDA, the Relieva Sinus Balloon Dilation Catheter is 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

- I. It is the policy of health plans affiliated with Centene Corporation® that balloon sinuplasty is **medically necessary** for individuals with chronic rhinosinusitis (CRS) 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. Documentation that the inflammation of the paranasal sinuses has persisted for 12 weeks or longer;
  - B. If > 18 years of age, meets both of the following (1 and 2):
    1. Has at least one of the following:
      - a. Anterior or posterior mucopurulent nasal discharge;
      - b. Nasal obstruction;
      - c. Facial-pain-pressure-fullness;
      - d. Decreased or lost sense of smell;
    2. Has at least one finding of chronic sinusitis by computed tomography (CT) scan (a or b):
      - a. Polyps in nasal cavity or the middle meatus, and/or opacification;
      - b. Radiographic imaging showing inflammation of the paranasal sinuses.
  - C. If ≤ 18 years of age, meets both of the following (1 and 2):
    1. Has at least two of the following:
      - a. Purulent rhinorrhea;
      - b. Nasal obstruction;
      - c. Facial pressure/pain;
      - d. Cough;
    2. Mucosal changes within the osteomeatal complex and/or sinuses, by CT scan;
  - D. 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. Antibiotic therapy guided by culture and sensitivity for ≥ 3 weeks;

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- b. Beta-lactamase resistant antibiotic for  $\geq 3$  weeks (e.g., amoxicillin [recommended], amoxicillin-clavulanate, trimethoprim-sulfisoxazole, cefuroxime).
  2. Intranasal corticosteroids for  $\geq 4$  weeks.

**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 surgery with significant osteoneogenesis.

### Background

Chronic rhinosinusitis (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. 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 (OMC) on nasal endoscopy or CT imaging. The goal of functional endoscopic sinus surgery or FESS 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 chronic sinusitis.

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 chronic sinusitis refractory to medical therapy is safe and efficacious. The data show that balloon sinuplasty can successfully dilate the sinus ostia and relieve symptoms of chronic sinusitis. 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<sup>16,18</sup>. Additionally, one study found that balloon sinuplasty led to improved outcomes after failure to respond adequately to adenoidectomy<sup>14</sup>.

*Guideline Recommendations*

Both the American Academy of Otolaryngology (AAO)-Head and Neck Surgery and the American Rhinologic Society (ARS) position statements on dilation of sinuses, any method (e.g., balloon, etc.), state “sinus ostial dilation (e.g., balloon ostial dilation) is an appropriate therapeutic option for selected patients with sinusitis. This approach may be used alone to dilate a 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.

**Coding Implications**

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<b>CPT® Codes</b>	<b>Description</b>
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)
31296	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)

<b>HCPCS Codes</b>	<b>Description</b>
N/A	

**ICD-10-CM Diagnosis Codes that Support Coverage Criteria**

<b>ICD-10-CM Code</b>	<b>Description</b>
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.3	Chronic sphenoidal sinusitis

ICD-10-CM Code	Description
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP307 Balloon Sinuplasty for Treatment of Chronic Sinusitis.	07/16	
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.	11/16	11/16

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#### **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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