

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

Reference Number: CP.MP.119

Last Review Date: 09/18

[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 or 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

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  $\geq 12$  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  $\leq 18$  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  $\geq 4$  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;

## CLINICAL POLICY

### Balloon Sinuplasty

- 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  $\geq 3$  weeks;
      - 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;
  - 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 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.

## CLINICAL POLICY

### Balloon Sinuplasty

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.<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*

##### *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.

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 AAAAI, 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 AAAAI, ACAAI, and JCAAI list balloon sinus dilation as one of the most commonly used modalities for patients that have failed maximal medical therapy.

## CLINICAL POLICY

### Balloon Sinuplasty

#### 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 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)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)

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
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

Reviews, Revisions, and Approvals	Date	Approval Date
Changed 2 <sup>nd</sup> listing of CPT code 31296 to 31297 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.	11/17	11/17
Clarified in > 18 CRS section that CT findings of opacification should be in the sinuses, and removed statement that CT findings should be radiographic.	04/18	
Removed option for adults to qualify for balloon sinus dilation by endoscopic findings, as CT findings are required before surgery in 2018 guidelines.	08/18	09/18
Added CPT 31298	07/19	

**References**

1. Abreu CB, Balsalobre L, Pascoto GR, et al. Effectiveness of balloon sinuplasty in patients with chronic rhinosinusitis without polyposis. *Braz J Otorhinolaryngol*. 2014 Nov-Dec;80(6):470-5.
2. American Academy of Otolaryngology-Head and Neck Surgery. Position statement on Dilation of sinuses, any method (e.g., balloon, etc.). Last updated March 2017. Available at: <http://www.entnet.org/content/position-statement-dilation-sinuses-any-method-eg-balloon-etc>
3. American Rhinologic Society (ARS). Ostial Balloon Dilation Position Statement. Revised March 2017. Available at: [http://www.american-rhinologic.org/position\\_balloon\\_dilation](http://www.american-rhinologic.org/position_balloon_dilation)
4. Bizaki AJ, Taulu R, Numminen J, Rautiainen M. Quality of life after endoscopic sinus surgery or balloon sinuplasty: a randomized clinical study. *Rhinology*. 2014 Dec;52(4):300-5.
5. Bolger WE, Brown CL, Church CA, et al.: Safety & Outcomes of Balloon Catheter Sinusotomy: A Multicenter 24 week Analysis in 115 Patients (The CLEAR Study). *Otolaryngology-Head & Neck Surgery*. 2007 Jul;137(1):10-20.
6. Brietzke SE, Shin JJ, Choi S et al. Clinical consensus statement: pediatric chronic rhinosinusitis by the American Academy of Otolaryngology- Head and Neck Surgery Foundation. *Otolaryngology– Head and Neck Surgery*. 2014, Vol. 151(4) 542–553
7. Brown CL, Bolger WE. Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: a preliminary investigation. *Ann Otol Rhinol Laryngol*. 2006 Apr;115(4):293-9;
8. ElBadawey MR, Alwaa A, ElTaher M, Carrie S. Quality of life benefit after endoscopic frontal sinus surgery. *Am J Rhinol Allergy*. 2014 Sep-Oct;28(5):428-32.
9. Hamilos DL. Chronic rhinosinusitis: Management. UpToDate. Corren J, Deschler DG (Eds.). Waltham, MA. Feb. 5, 2018. Accessed Aug. 28, 2018.
10. Hayes Medical Technology Directory. Balloon sinuplasty for Treatment of Chronic Rhinosinusitis. Published Sep. 15, 2016. Annual review Aug. 29, 2017. Accessed Sep. 4, 2018.

11. Kim E, Cutler JL. Balloon Dilatation of the Paranasal Sinuses: A Tool in Sinus Surgery. *Otolaryngologic Clinics of North America* - Volume 42, Issue 5 (Oct. 2009).
12. Koskinen A, Myller J, Mattila P, et al. Long-term follow-up after ESS and balloon sinuplasty: Comparison of symptom reduction and patient satisfaction. *Acta Otolaryngol.* 2016 May;136(5):532-6.
13. Liu J, Zhao Z, Chen Y, et al. Clinical curative effect and safety of balloon sinuplasty in children with chronic rhinosinusitis. *Int J Pediatr Otorhinolaryngol.* 2017 Sep;100:204-210. doi: 10.1016/j.ijporl.2017.06.026.
14. Orlandi RR, Kingdom TT, Hwang PH, et al. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis. *Int Forum Allergy Rhinol.* 2016 Feb; 6 Suppl 1: S22-209.
15. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol.* 2014 Oct;113(4):347-85.
16. Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Sinuses. *Otolaryngol Head Neck Surg.* 2018 Feb;158(2):203-214. doi: 10.1177/0194599817750086.
17. Ramadan HH. Safety and feasibility of balloon sinuplasty for treatment of chronic rhinosinusitis in children. *Ann Otol Rhinol Laryngol*, 01-MAR-2009; 118(3): 161-5.
18. Ramadan HH, Terrell AM. Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinosinusitis. *Ann Otol Rhinol Laryngol.* 2010; 119:578-582.
19. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical Practice Guideline (Update): Adult Sinusitis by the American Academy of Otolaryngology- Head and Neck Surgery Foundation. *Otolaryngology– Head and Neck Surgery.* 2015 152(2S) S1-S39.
20. Setzen G, Ferguson BJ, Han JK, et al. Clinical Consensus Statement: Appropriate Use of Computed Tomography for Paranasal Sinus Disease by the American Academy of Otolaryngology- Head and Neck Surgery Foundation. *Otolaryngology– Head and Neck Surgery.* 2012 Nov;147(5):808-16.
21. Soler ZM, Rosenbloom JS, Skarada D, et al. Prospective, multicenter evaluation of balloon sinus dilation for treatment of pediatric chronic rhinosinusitis. *Int Forum Allergy Rhinol.* 2017 Mar;7(3):221-229. doi: 10.1002/alr.21889. Epub 2016 Nov 26.
22. Thottam PJ, Metz CM, Kieu MC, et al. Functional Endoscopic Sinus Surgery Versus Balloon Sinuplasty with Ethmoidectomy: A 2-year Analysis in Pediatric Chronic Rhinosinusitis. *Indian J Otolaryngol Head Neck Surg.* 2016 Sep;68(3):300-6.
23. Tomazic PV, Stammberger H, Braun H, et al. Feasibility of balloon sinuplasty in patients with chronic rhinosinusitis: the Graz experience. *Rhinology.* 2013 Jun;51(2):120-7.
24. Wang F, Song Y, Zhang X, Tan G. Sinus balloon catheter dilation in pediatric chronic rhinosinusitis resistant to medical therapy. *JAMA Otolaryngol Head Neck Surg.* 2015 Jun;141(6):526-31

**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

## CLINICAL POLICY

### Balloon Sinuplasty

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs,

## **CLINICAL POLICY**

### **Balloon Sinuplasty**

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> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.