Clinical Policy: Balloon Sinus Ostial Dilation for Treatment of Chronic Sinusitis
Reference Number: CP.MP.119
Effective Date: 11/16
Last Review Date: 11/16

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 after medical therapy meeting one of the following (a or b):
         a. Antibiotic 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.

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. Additionally, one study found that balloon sinuplasty led to improved outcomes after failure to respond adequately to adenoidectomy.

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
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 2015, 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.

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)</td>
</tr>
<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J32.0</td>
<td>Chronic maxillary sinusitis</td>
</tr>
<tr>
<td>J32.1</td>
<td>Chronic frontal sinusitis</td>
</tr>
<tr>
<td>J32.3</td>
<td>Chronic sphenoidal sinusitis</td>
</tr>
</tbody>
</table>
ICD-10-CM Code | Description
--- | ---
J32.8 | Other chronic sinusitis
J32.9 | Chronic sinusitis, unspecified

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/16</td>
<td>07/16</td>
</tr>
<tr>
<td>11/16</td>
<td>11/16</td>
</tr>
</tbody>
</table>


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.

References
2. American Academy of Otolaryngology-Head and Neck Surgery. Position statement on dilation of sinuses, any method (e.g., balloon, etc.). Last updated 1/2014. Available at: http://www.entnet.org/content/position-statement-dilation-sinuses-any-method-eg-balloon-etc


**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.

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.
CLINICAL POLICY
Balloon Sinuplasty

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, 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.