



Louisiana

Sinus Ostial Dilatation with Balloon Catheter for Rhinosinusitis

Policy # 00292

Original Effective Date: 04/13/2011

Current Effective Date: 06/20/2018

Returned to Active Status: 12/01/2015

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider sinus ostial dilatation with balloon catheter for the treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis to be **eligible for coverage**.

Patient Selection Criteria for chronic rhinosinusitis

Coverage eligibility will be met when the following criteria are present:

- Chronic rhinosinusitis in an adult which has persisted for a minimum of 12 weeks despite failure of aggressive medical therapy. This should include documentation of treatment with all of the following:
 - Saline nasal irrigations or saline nasal spray
 - Intranasal corticosteroids for at least 8 weeks
 - Two courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days
- Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography as evidenced by significant mucosal thickening of greater than 3 mm, opacification, or air-fluid levels documented by a formal CT scan report from an independent radiologist.

Patient Selection Criteria for recurrent acute rhinosinusitis

Coverage eligibility will be met when the following criteria are present:

- Four or more documented and treated episodes in a 12 month period; and
- CT imaging performed during the fourth episode should demonstrate pathology in the sinus to be dilated that meets the same CT imaging criteria (significant mucosal thickening of greater than 3 mm, opacification, or air-fluid levels documented by a formal CT scan report from an independent radiologist.)

When Services Are Considered Not Medically Necessary

The use of sinus ostial dilatation with balloon catheter when patient selection criteria are not met is considered to be **not medically necessary**.**

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers sinus ostial dilatation with balloon catheter for the treatment of nasal polyps or tumors to be **investigational**.*

Based on review of available data, the Company considers sinus ostial dilatation with balloon catheter for children ages 12 and under to be **investigational**.*

Background/Overview

The balloon ostial dilatation procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. It can be performed as a stand-alone procedure or as an adjunctive procedure to functional endoscopic sinus surgery (FESS).

Chronic rhinosinusitis (CRS) is characterized by purulent nasal discharge, usually without fever, that persists for weeks to months. Symptoms of congestion often accompany the nasal discharge. There also may be mild pain and/or headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms are variable because considerable variation exists in the location and shape of these sinus ostia.

Estimates are that approximately 30 million individuals in the United States suffer from chronic sinusitis. Most cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. Functional endoscopic sinus surgery has become an important aspect for surgical management of chronic sinusitis. For this procedure, a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. This procedure restores patency and allows air and mucous transport through the natural ostium. Approximately 350,000 FESS procedures are done each year in the United States for chronic sinusitis.

A newer procedure, balloon ostial dilatation can be used as an alternative to FESS or as an adjunct to FESS for those with chronic sinusitis. The goal of this technique, when used as an alternative to FESS, is to achieve improved sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. The procedure involves placing a guidewire in the sinus ostium, advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize patient movement.

The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinat process. An alternate approach to the maxillary ostia is through the sinus, via the canine fossa. A guidewire can be

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advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinate process.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In March 2008, the device “Relieva™ Sinus Balloon Catheter” (Acclarent, Menlo Park, CA) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been granted 510(k) marketing clearance. These include the Relieva Spin Sinus Dilation System® cleared in August 2011, and the Relieva Seeker Balloon Sinuplasty System® cleared in November 2012.

In June 2008, the device, FinESS™ Sinus Treatment (Entellus Medical Inc., Maple Grove, MN) was cleared for marketing by FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach. (FDA product code: EOB) The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices by Entellus Medical Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD) for balloon ostial dilation. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Balloon Ostial Dilation for Treatment of Chronic Sinusitis”, Policy 7.01.105, 02:2018.
2. Zinreich, James S. Imaging for Staging of Rhinosinusitis. *Ann Otol Rhinol Laryngol.* 2004; 113:19-23.
3. Langille, Morgan M.D. et al. Frontal sinus cells: Identification, prevalence, and association with frontal sinus mucosal thickening. *American Journal of Rhinology and Allergy.* 2012; 26:e107-e110.
4. Rak, Kevin M. et al. Paranasal Sinuses on MR Images of the Brain: Significance of Mucosal Thickening. *AJNR*:11 1990:1211-1214.
5. Piccirillo, Jay F. et al. Clinical Consensus Statement: Balloon Dilation of the Sinuses. *Clinical Consensus Statement. Otolaryngology-Head and Neck Surgery.* 2018 158(2) 203-214.

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04/07/2011 Medical Policy Committee review
 04/13/2011 Medical Policy Implementation Committee approval. New policy.
 02/15/2012 Policy Retired.
 09/03/2015 Medical Policy Committee review
 09/23/2015 Medical Policy Implementation Committee approval. Title change, patient selection criteria added. Policy rewritten. Policy returned to active status.
 02/04/2016 Medical Policy Committee review
 02/17/2016 Medical Policy Implementation Committee approval. Added the requirement of at least 2 weeks of antibiotics and significant mucosal thickening of at least 2 mm prior to approval. Also clarified age of children 12 years and under is considered to be investigational.
 06/02/2016 Medical Policy Committee review
 06/20/2016 Medical Policy Implementation Committee approval. Patient selection criteria revised to this:
 Coverage eligibility will be met when the following criteria are present:

- Chronic rhinosinusitis in an adult which has persisted for a minimum of 12 weeks despite failure of aggressive medical therapy. This should include documentation of treatment with all of the following:
 - o Saline nasal irrigations
 - o Intranasal corticosteroids for at least 8 weeks
 - o Two courses of antibiotics
- Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography as evidenced by significant mucosal thickening of 4 mm or greater, opacification or air-fluid levels as evidenced by a formal CT scan report from an independent radiologist.

09/08/2016 Medical Policy Committee review
 09/21/2016 Medical Policy Implementation Committee approval. Criteria revised to:
Patient Selection Criteria for chronic rhinosinusitis
 Coverage eligibility will be met when the following criteria are present:

- Chronic rhinosinusitis in an adult which has persisted for a minimum of 12 weeks despite failure of aggressive medical therapy. This should include documentation of treatment with all of the following:
 - o Saline nasal irrigations or saline nasal spray
 - o Intranasal corticosteroids for at least 8 weeks
 - o Two courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days
- Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography as evidenced by significant mucosal thickening of greater than 3 mm, opacification, or air-fluid levels documented by a formal CT scan report from an independent radiologist.
 Recurrent acute rhinosinusitis criteria added to the policy. "Chronic" removed from title.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
 06/01/2017 Medical Policy Committee review
 06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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06/07/2018 Medical Policy Committee review
 06/20/2018 Medical Policy Implementation Committee approval. No change to coverage.
 Next Scheduled Review Date: 06/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]†, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	31295, 31296, 31297, 31298, 31299
HCPCS	C1726
ICD-10 Diagnosis	C30.0, C31.0-C31.9, J32.0-J32.9, J33.0-J33.9, J34.0-J34.9, R09.81

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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