Balloon Catheter Use for Sinus Ostial Dilation and Septoplasty

Medicare Advantage Medical Policy # MA-110
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Applies to all products administered or underwritten by the Health Plan, 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 Health Plan 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 without nasal polyps in an adult patient, which has persisted for a minimum of 12 weeks despite aggressive medical therapy. This should include documentation of treatment with all of the following:
    - Saline nasal irrigation for at least 8 consecutive weeks
    - Intranasal corticosteroids for at least 8 weeks
    - Two 10-day courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days; AND
- Chronic rhinosinusitis of the sinus to be dilated is confirmed with nasal endoscopy and computed tomography as evidenced by:
    - Purulent (not clear) mucus OR edema in the middle meatus, anterior ethmoid, or sphenoethmoid region; AND
    - 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 with interim symptom resolution; AND
- Nasal endoscopy performed during the fourth episode showing purulent (not clear) mucus OR edema in the middle meatus, anterior ethmoid, or sphenoethmoid region; 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 Investigational

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

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

Based on review of available data, the Health Plan 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 Health Plan considers dilation of sinus ostia using a device other than balloon catheter, including but not limited to reusable dilators (e.g. Simplicity®‡ Dilators), to be **investigational.***

Based on review of available data, the Health Plan considers the use of balloon catheter dilation for septoplasty to be **investigational.***

Policy Guidelines

Classification of rhinosinusitis is based upon symptom duration:

- Acute rhinosinusitis – Symptoms for less than 4 weeks
- Subacute rhinosinusitis – Symptoms for 4 to 12 weeks
- Chronic rhinosinusitis – Symptoms persist greater than 12 weeks
- Recurrent acute rhinosinusitis – Four or more documented and treated episodes of acute rhinosinusitis in a 12-month period, with interim symptom resolution

When indicated and appropriate, optimal medical therapy should include also:

- Allergy evaluation, education, and optimal treatment;
- Decongestants;
- Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants);
- Education on environmental irritants including tobacco smoke.

Balloon Ostial Dilation (BOD) used in combination with Functional Endoscopic Sinus Surgery (FESS)

- BOD when used as a tool during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the FESS procedure.

- When BOD is used as an adjunct to FESS (defined as FESS on one sinus and BOD on another sinus in the same patient during the same operation) medical necessity criteria for BOD apply to the sinus being considered for BOD.

According to the 2015 American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) guideline on adult sinusitis, abnormal findings on CT imaging may include moderate-to-severe mucosal thickening, opacification, or air-fluid levels. A subsequent consensus statement on balloon dilation of the sinuses published by the AAO-HNS in 2018 states: "The requirement of objective evidence of inflammation in addition to sinonasal symptoms suggestive of rhinosinusitis is consistent with AAO-HNSF diagnostic criteria for rhinosinusitis. However, evidence of inflammation or other findings on a CT scan was not deemed sufficient alone to make a patient a candidate for balloon dilation. The consensus that both symptoms and objective evidence of sinonasal disease are needed to deem a patient appropriate for a SOD [sinus ostial dilation] procedure is also reflected in many of the randomized clinical trials involving balloon dilation. The inclusion criteria for many of these trials require that the patient be deemed appropriate for conventional sinus surgery, which includes a trial of medical therapy and the presence of sinonasal symptoms in addition to objective evidence of sinus mucosal inflammation. On the surface, this statement may seem incompatible with the guidelines that mandate the presence of objective findings but do not specify which objective findings those are (i.e., polyps, purulence, or CT findings) for the diagnosis of CRS. However, the panel felt that the transition from diagnosis to management requires additional information. In that vein, a CT scan is necessary before proceeding with surgical management, and the findings of that CT scan would direct which sinuses were to be addressed. It was also agreed that an improved taxonomy for the classification of sinusitis would be helpful to improve the quality of clinical research."

For individuals undergoing evaluation for surgical management of chronic sinusitis (either dilation or standard functional endoscopic sinus surgery), the CT scan on which the surgical plan and evaluation are based is typically performed within 90 days of the planned procedure. CT scans beyond 90 days may be repeated, as both disease and anatomy may have changed. CT scans older than 90 days may rarely be used in adult individuals when the symptoms and/or condition have not changed since the CT scan was obtained.

When assessing for response to therapy and potential surgical candidacy for individuals with chronic rhinosinusitis, CT scanning is typically indicated approximately 1-2 weeks following completion of aggressive medical therapy. Imaging prior to this time may underrepresent patient response and overrepresent disease burden. However, in certain circumstances, such as in lack of response to treatment or uncertainty of diagnosis, imaging may be indicated earlier in the treatment course or even prior to the initiation of treatment.

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 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.
Recurrent acute rhinosinusitis (RARS) is defined as 4 or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes.

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics). Additionally, an anti-interleukin-5 (IL-5) monoclonal antibody (mAb), mepolizumab, received FDA-approval in July 2021 as an add-on maintenance treatment for chronic rhinosinusitis with nasal polyps. Previously in 2019, the FDA approved the interleukin-4 receptor alpha antagonist dupilumab as an add-on maintenance treatment in adults with inadequately controlled chronic rhinosinusitis with nasal polyps.

Balloon ostial dilatation can be used as an alternative or as an adjunct to FESS for those with CRS or RARS. The goal of this technique, when used as an alternative to FESS, is to improve sinus drainage using a less invasive approach. 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. According to the manufacturer, the RELIEVA SPINPLUS®‡ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

This evidence review is limited to BOD when used as a standalone procedure. BOD may also be used in combination with FESS. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. BOD may also be used on 1 sinus and FESS on another sinus in the same patient during the same operation.

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 individuals 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 uncinate process. An alternate approach to the maxillary ostia is through the sinus, via the canine fossa. A guidewire can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinate process.

Recently marketed reusable stainless steel dilators (e.g. Simplicity®‡ Dilators) may be comparable to balloon ostial dilators, however published evidence is insufficient at this time to support long-term efficacy and safety with their use, and confirm appropriate patient selection. In addition, there is not enough data comparing these reusable dilators to balloon dilation catheters cleared by FDA.

Septoplasty is traditionally performed in an endonasal fashion through an incision. In select cases septoplasty may be performed as an ‘‘open’’ or external approach to completely address a septal deviation, especially in circumstances where there is substantial caudal deviation or dorsal septal deviation or in cases where a large amount of cartilage must be removed, reshaped, and replaced. Endoscopic septoplasty has been shown to be equivalent to ‘‘open’’ septoplasty, as well as to demonstrate fewer complications and decreased operative time.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2008, the Relieva™‡ Sinus Balloon Catheter (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. 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 cleared by FDA through the 510(k) process. They include the Relieva Spin Sinus Dilation System®‡ (cleared in 2011) and the Relieva Seeker Balloon Sinuplasty System®‡ (cleared in 2012).

In 2008, the FinESS™‡ Sinus Treatment (Entellus Medical, 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, the ENTrigue®‡ Sinus Dilation System (ENTrigue Surgical, acquired by more recently by Smith & Nephew), and the XprESS™‡ Multi-Sinus Dilation Tool, also received 510(k) clearance in 2012.
In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™‡ EM Balloon Sinus Dilation System, was cleared for marketing by FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (Smith & Nephew), later named the Ventera™‡ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach. Ventera™‡Sinus Dilation System does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery.

Table 1 summarizes the currently FDA cleared balloon sinus dilation devices.

FDA product code: LRC.

Table 1. Balloon Ostial Dilation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	510(k) No.	Date Cleared	Indication
Relieva Ultirra Sinus Balloon Catheter	Acclarent, Inc.	K190525	05/03/2019	Sinus Ostia Dilation
Sinusway Dilation System	3NT Medical Ltd.	K181838	12/20/2018	Sinus Ostia Dilation
MESIRE - Balloon Sinus Dilatation System	Meril Life Sciences	K172737	12/12/2017	Sinus Ostia Dilation
Relieva UltirraNav Sinus Balloon Catheter	Acclarent Inc.	K161698	10/24/2016	Sinus Ostia Dilation
Vent-Os Sinus Dilation Family	Sinusys Corp.	K160770	6/29/2016	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K153341	2/12/2016	Sinus Ostia Dilation

XprESS Multi-Sinus Dilation System	Entellus Medical Inc.	K152434	11/20/2015	Sinus Ostia Dilation
DSS Sinusplasty Balloon Catheter	Intuit Medical Products LLC	K143738	8/27/2015	Sinus Ostia Dilation
Relieva SpinPlus Balloon Sinuplasty System	Acclarent Inc.	K143541	4/22/2015	Sinus Ostia Dilation
XprESS Multi-Sinus Dilation Tool	Entellus Medical Inc.	K142252	10/17/2014	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K140160	2/20/2014	Sinus Ostia Dilation

Simplicity®‡ Solid Dilators and Simplicity®‡ Suction Dilators were registered with the FDA in 2020. According to manufacturer's website, "Simplicity Dilators are made from medical grade stainless steel parts, which are easily cleaned and sterilized for multiple uses." "Simplicity Dilators do not require cutting of nasal bone or tissue nor any manipulation or inflation of extended devices. During sinus dilation, a Simplicity dilator is positioned and used to gently open the sinus passageways, facilitating drainage of the mucus buildup."

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Balloon ostial dilation (BOD, also known as balloon sinuplasty) is proposed as an alternative to functional endoscopic sinus surgery (FESS) for individuals with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (RARS) who fail medical management. The 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 FESS.

For individuals with CRS who receive BOD as a stand-alone procedure, the evidence includes a systematic review, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A meta-analysis of three studies indicated a statistically significant yet not clinically significant preference for BOD over FESS in terms of patient-related quality of life. The REMODEL RCT confirmed that BOD was not inferior to FESS for treating chronic rhinosinusitis, with the effect's durability observed over 24 months. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in individuals who underwent BOD

(n=2851) or FESS (n=11,955), the overall complication rate was 5% with BOD and 7% with FESS. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with RARS who receive BOD as a stand-alone procedure, the evidence includes a systematic review and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review on RARS management identified two (of 10) studies focused on BOD as a treatment modality. Although an improvement in quality of life was observed across both studies, the small sample sizes, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis. In the REMODEL RCT, 32% of participants (N=29) with RARS were diagnosed. BOD was found to be non-inferior to FESS in terms of quality of life at both 6- and 12-months post-procedure. Another RCT, CABERNET, comparing BOD plus medical care to medical care alone in individuals with RARS (N=59), demonstrated significantly improved quality of life and fewer sinus infections after 6 months in the balloon dilation group. The current body of evidence is limited by small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with septal deviation who receive ballon septoplasty, the evidence includes a case report. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A case report was published in Journal of Neurosurgical Case Lessons (September 2022) on use of balloon-assisted nasal access to augment endoscopic endonasal transsphenoidal approach (an illustrative case). Authors noted that long-term durability of balloon septoplasty is not relevant to surgical access to the sella and skull base region. Melroy et al. reported a complication rate of 0.0035% per sinus when reviewing orbital and cranial complications associated with balloon ostial dilation in the FDA database.

There is insufficient scientific evidence to support efficacy, safety, durability and improved net health outcomes with use of balloon septoplasty as compared to current standard medical and surgical care.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology – Head and Neck Surgery et al
In 2018, the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses. Participating subgroups included the Triologic Society, the American Rhinologic Society, the American Academy of Otolaryngic Allergy, and the American Academy of Allergy, Asthma & Immunology. The expert panel used Delphi method surveys to assess consensus on proposed statements. Statements achieving a mean score of 7.00 or higher and having no more than 1 outlier (2 or more LIkert points from the mean in either direction) met criteria for consensus. Strong consensus was defined as a mean Likert score of 8.00 or higher with no outliers. The following statements met consensus; statements reaching strong consensus are highlighted. The updated information to guideline statement can be found on the AAO-HNS website dated April 2021.

Patient Criteria:

- Balloon dilation is not appropriate for individuals who are without both sinonasal symptoms and positive findings on CT. (Strong consensus)
- Balloon dilation is not appropriate for the management of headache in individuals who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- Balloon dilation is not appropriate for the management of sleep apnea in individuals who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- CT scanning of the sinuses is a requirement before balloon dilation can be performed. (Strong consensus)
- Balloon dilation is not appropriate for individuals with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in individuals with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in individuals with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing individuals with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and CT evidence of ostial occlusion and mucosal thickening.

Perioperative Considerations:

- Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the FDA for reprocessing such devices and ensure that they are followed. (Strong consensus)
- Balloon dilation can be performed under any setting as long as proper precautions are taken and appropriate monitoring is performed.
- Balloon dilation can be performed under local anesthesia with or without sedation.

Outcome:

- Balloon dilation can improve short-term quality-of-life outcomes in individuals with limited CRS without polyposis.
- Balloon dilation can be effective in frontal sinusitis.

The AAO-HNS updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: "Sinus ostial dilation … is a therapeutic option for selected patient with chronic rhinosinusitis…. This approach may be used alone... or in conjunction with other instruments…."(Most recent revision with references added, 4/13/2021)

In 2015, the Academy's Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.

American Academy of Otolaryngology – Head and Neck Surgery et al
The 2015 Clinical Consensus Statement (Septoplasty with or without inferior turbinate reduction) defined nasal septoplasty as a surgical procedure designed to correct a deviated nasal septum for the purpose of improving nasal function, form, or both. For the surgical aspects of septoplasty, 3 statements reached consensus. Consensus was reached that an external rhinoplasty approach may be necessary in cases of severe septal deviation. The panel also reached consensus that septoplasty may be necessary as a surgical component in the repair of septal perforations. Last, the panel reached consensus that endoscopic visualization during septoplasty can assist the surgeon in correcting posterior septal deviations. There is no mention of balloon septoplasty in this consensus statement or other professional society guidelines.

National Institute for Health and Care Excellence
In 2008 (reaffirmed in 2012), a guidance on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Care Excellence (NICE) stated:

- "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns.
- This procedure should only be carried out by surgeons with experience of complex sinus surgery, and specific training in both the procedure and the use of fluoroscopy.
- Publication of long-term outcomes will be helpful in guiding the future use of this technique. NICE may review the procedure upon publication of further evidence."

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis:

1.1 "The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to FESS.

1.2 XprESS should be considered in individuals with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these individuals, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia."

The recommendation was based on the results of the REMODEL study: the committee "considered that the evidence from REMODEL demonstrated that balloon dilation (with either XprESS or FinESS) is clinically non-inferior to FESS in terms of alleviating symptoms in individuals with uncomplicated chronic sinusitis." Single-arm observational studies were of lower quality but were consistent with the findings of the REMODEL study. This guidance was reaffirmed in July 2020.

American Rhinologic Society
A position statement, revised in 2023, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected individuals with chronic rhinosinusitis (CRS) … who have failed appropriate medical therapy."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04645511	A Placebo Controlled Randomised Study of the Balloon Sinuplasty Efficiency in Chronic or Recurrent Maxillary Rhinosinusitis	120	Dec 2027

NCT: national clinical trial.

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Policy History

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Next Scheduled Review Date: 04/2026

Coding

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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, 30999
HCPCS	C1726
ICD-10 Diagnosis	All related diagnoses

*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. Food and Drug Administration (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 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.

**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent

professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.