MEDICAL POLICY

POLICY TITLE	**BALLOON OSTIAL DILATION FOR TREATMENT OF CHRONIC RHINOSINUSITIS AND RECURRENT ACUTE RHINOSINUSITIS (FORMERLY BALLOON OSTIAL DILATION FOR TREATMENT OF CHRONIC RHINOSINUSITIS)**
POLICY NUMBER	**MP-1.119**

Effective Date:	**9/1/2023**

I. POLICY

Use of a catheter-based inflatable device (balloon ostial dilation) for the treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis, in the sinus being considered for dilation, may be **medically necessary** when the following criteria are present:

- Individual is 18 years of age or older (see Policy Guidelines for younger ages); **and**
- Chronic rhinosinusitis without nasal polyps or recurrent acute rhinosinusitis that negatively impacts quality of life characterized by at least two of the following, at least one of which is the first two:
  - Mucopurulent nasal drainage (anterior, posterior, or both); **or**
  - Nasal obstruction (congestion); **or**
  - Facial pain-pressure-fullness; **or**
  - Decreased sense of smell; **or**
  - Cough (in pediatrics); **and**
- For individuals with chronic rhinosinusitis, symptoms have been present for at least 12 continuous weeks in the past 12 months; **or**
- For individuals with recurrent acute rhinosinusitis, there has been 4 or more episodes of acute bacterial rhinosinusitis in the last 12 months without signs or symptoms of rhinosinusitis between episodes; **and**
- Appropriate medical therapy has been attempted and failed, as indicated by all of the following in the past 12 months:
  - Allergy evaluation, education, and appropriate treatment when indicated; **and**
  - Antibiotics when indicated; **and**
  - Decongestants when indicated; **and**
  - Topical and/or systemic corticosteroids for at least 4 weeks, unless contraindicated; **and**
  - Saline nasal irrigation for at least 4 consecutive weeks; **and**

  - Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present; **and**
  - Education on environmental irritants including tobacco smoke; **and**
- Diagnosis of recurrent acute rhinosinusitis was obtained by symptomatology and computed tomography (CT) which shows evidence of ostial occlusion and mucosal thickening; **or**
- Diagnosis of chronic rhinosinusitis was obtained by symptomatology and one or more of the following objective findings:
  - Evidence of inflammation on nasal endoscopy or CT; **or**
  - Evidence of purulence coming from paranasal sinuses or ostiomeatal complex; **and**
  - If CT was not obtained for diagnosis, it has been obtained prior to surgery (see policy guidelines)

The use of balloon ostial dilation for the treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis is considered **investigational** when the above criteria are not met, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Per societal guidelines, CT scanning of the sinuses is a requirement before balloon dilation can be performed. In addition to demonstrating abnormal mucosa and opacified sinuses, the study will provide anatomic detail necessary to guide the surgery.

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 individual during the same operation) medical necessity criteria for BOD apply to the sinus being considered for BOD.

Considerations for the use of BOD in children under age 18 years include the following:

- The pediatric population would still be subject to all the criteria requirements as outlined in the policy statement.
- U.S. Food and Drug Administration (FDA) labeling for several 510(k) cleared devices includes use in children 17 years of age and under and is indicated to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

- A 2014 AAO-HNS Clinical Consensus Statement on Pediatric Chronic Rhinosinusitis had near consensus on the safety of BOD in children but did not reach a consensus on efficacy.
- American Academy of Pediatrics Clinical Practice Guidelines only address the diagnosis and treatment of acute bacterial rhinosinusitis.

Cross-reference:

MP 1.140 Steroid-Eluting Sinus Stents
MP 1.152 Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.
FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Chronic and Recurrent Acute Rhinosinusitis

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 a headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms vary considerably because of the location and shape of these sinus ostia.

Recurrent acute rhinosinusitis (RARS) is defined by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) as 4 or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes.

Medical Treatment

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.

Functional Endoscopic Sinus Surgery

FESS involves the insertion of an endoscope into the nose for a direct visual examination of the openings into the sinuses. Using the endoscope and a combination of surgical tools (e.g., curettes, forceps, powered micro-debriders, powered shavers, and/or sinus balloon catheters),

surgeons enlarge the patient's sinus openings to clear passageways in order to restore normal sinus ventilation and drainage. The goal of surgery is to improve sinus ventilation and drainage by enlarging the openings of the sinuses, removing any polyps, and correcting significant structural problems that may be hindering drainage.

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 alternative 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.

Approximately 350,000 FESS procedures are done each year in the United States for CRS.

Balloon Ostial Dilation

A newer procedure, 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 one sinus and FESS on another sinus in the same patient during the same operation.

Regulatory Status

In 2008, the Relieva™ Sinus Balloon Catheter (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (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 US Food and Drug Administration

Device	Manufacturer	510(k) No.	Date Cleared	Indication
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

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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

IV. RATIONALE

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Summary of Evidence

For individuals with CRS who receive BOD as a stand-alone procedure, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. In the REMODEL RCT, balloon ostial dilation was non-inferior to FESS for patients with chronic rhinosinusitis. Durability of effect was demonstrated in uncontrolled studies that followed patients who received balloon dilation for up to 24 months. Evidence from RCTs is supported by multiple observational studies and a systematic review showing improved quality of life following BOD. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events reported in patients who underwent balloon dilation (n=2851), FESS (n=11,955), or a hybrid procedure (n=1234), the overall complication rate was 7.35% with FESS and 5.26% with balloon dilation. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals with RARS who receive BOD as a stand-alone procedure, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. In the REMODEL study of BOD compared to FESS, 32% of patients were diagnosed with recurrent acute rhinosinusitis (N=29). Balloon ostial dilation was non-inferior to FESS on measures of quality of life at 6 months and 12 months post-procedure. One RCT comparing balloon ostial dilation plus medical care to medical care alone in patients with RARS found significantly improved quality of life and lower mean number of sinus infections after 24 months in the balloon dilation group. A third RCT included a mix of patients with chronic and RARS and found improved quality of life compared to FESS, but results were not reported separately by diagnosis. The body of evidence is limited by the small number of patients studied, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures used. The evidence is insufficient to determine the effects of the technology on health outcomes.

AAO-HNSF published a Clinical Consensus Statement titled “Balloon Dilation of the Sinuses” in 2018. RARS, when diagnosed per AAO-HNS guidelines, was considered an appropriate indication for sinus ostial dilation.

The international consensus statement on allergy and rhinology: rhinosinusitis 2021 states that patients with RARS may benefit both symptomatically and medically from endoscopic sinus surgery (ESS) or balloon sinus dilation (BSD) and recommends ESS or BSD for patients with RARS. Based on input from societal guidance, the evidence is sufficient to determine the effects of the technology on health outcomes

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice, and are subject to change. Treating providers are

solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Medically necessary when used to treat chronic rhinosinusitis or recurrent acute rhinosinusitis:

Procedure Codes								
31295	31296	31297	31298	31299	C1726			

ICD-10-CM Diagnosis Codes	Description
J01.01	Acute recurrent maxillary sinusitis
J01.11	Acute recurrent frontal sinusitis
J01.21	Acute recurrent ethmoidal sinusitis
J01.31	Acute recurrent sphenoidal sinusitis
J01.41	Acute recurrent pansinusitis
J01.81	Other acute recurrent sinusitis
J01.91	Acute recurrent sinusitis, unspecified
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.119	**CAC 5/25/10 New policy**.
	CAC 4/26/11 Consensus review. Adopt BCBSA language. No policy change.
	11/09/11 Administrative update. Change to policy statement for clarification.
	CAC 8/28/12 Consensus review. No changes to the policy statements, references updated. **7/9/12**- FEP variation revised to refer to the FEP medical policy manual. Codes reviewed 8/14/12 Code update 11/8/12
	1/1/14 Admin update. Added Rationale section for Medicare is silent project for codes 31295 and 31296**.**
	CAC 1/28/14 Minor review. Deleted the words "as an alternative to endoscopic sinus surgery" from the policy statement which now matches BCBSA. Title changed to Balloon Ostial Dilation for Treatment of Chronic Sinusitis (formerly Balloon Sinuplasty for Treatment of Chronic Sinusitis). Admin code review complete.

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	CAC 1/27/15 Consensus review. References and rationale updated. Policy statement edited to remove trademarked name, but otherwise unchanged. Coding reviewed
	CAC 1/26/16 Consensus review. No change to the policy statement. Reference and rationale update. Coding reviewed.
	11/10/16 Administrative update. Variation reformatting
	CAC 3/28/17 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	CAC 9/26/17 Consensus review. No change to policy statement. Title changed to "Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis." Coding reviewed.
	1/1/18 Administrative update. New code 31298 added; effective 1/1/18
	6/4/18 Consensus review. No change to policy statements. Rationale condensed to include summary only. References reviewed.
	4/17/19 Consensus review. No change to policy statements. References updated.
	4/14/2020 Consensus review. Policy statement unchanged. Background and references updated. Coding reviewed.
	7/17/2020 Minor review. Policy statement updated to include medically necessary indications for balloon ostial dilation. Policy guidelines added. Product variation, background, rationale, benefit variation, disclaimer, references, and coding updated.
	05/17/2021 Minor review. Policy Guidelines updated, added, "in the sinus (es) (to be) treated with BOD". References reviewed and updated. Product variations updated.
	03/31/2022 Consensus review. No change to policy statement. Policy Guidelines revised (removed table). Cross Referenced policies and FEP statement modified. Background and References updated.
	3/24/2023 Minor review. BOD for recurrent acute rhinosinusitis is now MN with specific criteria. Cough added as a symptom for the pediatric population. Antibiotics and decongestants are required "when indicated". Corticosteroids and saline nasal irrigation use changed from 8 weeks to 4 weeks. Removed requirement re: trial of discontinuation of meds that can cause nasal congestion. Diagnosis of CRS must include one or more of the objective findings listed. CT is required prior to surgery. Policy guidelines, background, rationale, and references updated. Removed procedure codes 31256, 31276, 31287. Added dx codes for recurrent acute rhinosinusitis.

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