BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.105 Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2012

Related Policies:

7.01.158 - Balloon Dilation of the Eustachian Tube

Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

Description

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. This evidence review addresses BOD as a standalone procedure.

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 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).[1,] 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.[2,]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.[3,]

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

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.[4,5,] 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.

OBJECTIVE

The objective of this evidence review is to evaluate whether BOD improves the net health outcome for individuals with CRS or RARS.

POLICY STATEMENT

Use of a catheter-based inflatable device (balloon ostial dilation) for the treatment of chronic 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 that negatively impacts quality of life, characterized by at least 2 of the following, at least 1 of which is (a) or (b), present for at least 12 continuous weeks:
    - 1. Mucopurulent nasal drainage (anterior, posterior, or both);
    - 2. Nasal obstruction (congestion);
    - 3. Facial pain-pressure-fullness;
    - 4. Decreased sense of smell.

AND

- Optimal medical therapy has been attempted and failed, as indicated by all of the following:
    - Allergy evaluation, education, and optimal treatment when indicated;
    - Two 10-day courses of antibiotics, or 1 prolonged course of at least 21 days duration;

- Decongestants when indicated;
- Topical and/or systemic corticosteroids for at least 8 weeks;
- Saline nasal irrigation for at least 8 consecutive weeks;
- Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present;
- Education on environmental irritants including tobacco smoke.

AND

- Clinical and radiographic documentation of persistent inflammation following optimal medical therapy (see Policy Guidelines).

The use of balloon ostial dilation for the treatment of chronic rhinosinusitis is considered **investigational** when the above criteria are not met.

The use of balloon ostial dilation for the treatment of recurrent acute rhinosinusitis is considered **investigational**.

POLICY GUIDELINES

Inflammation may be documented by all of the following:

- Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoethmoid region.

AND

- Abnormal CT scan of the paranasal sinuses.

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 (ie, 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."

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 1 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:

- U.S. Food and Drug Administration 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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.[4,]

Table 1 summarizes a selection of 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

RATIONALE

Summary of Evidence

For individuals with chronic rhinosinusitis (CRS) who receive balloon ostial dilatation (BOD) as a stand-alone procedure, the evidence includes randomized controlled trials (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 functional endoscopic sinus surgery (FESS) for individuals with chronic rhinosinusitis. Durability of effect was demonstrated in uncontrolled studies that followed individuals 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 individuals 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 that the technology results in an improvement in the net health outcome.

For individuals with recurrent acute rhinosinusitis (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 individuals 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 The randomized controlled trial (RCT) comparing balloon ostial dilation plus medical care to medical care alone in individuals 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 individuals 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 individuals studied, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures used. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.[19,] 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 **emphasized** below. 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 patients who are without both sinonasal symptoms and positive findings on CT. (Strong consensus)**
- **Balloon dilation is not appropriate for the management of headache in patients 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 patients 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 patients 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 patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients 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 U.S. Food and Drug Administration 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 patients 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)[20,]

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.[1,]

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."[21,]

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis[22,]:

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 functional endoscopic sinus surgery (FESS).

1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, 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 patients 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 patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy."[23,]

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.

REFERENCES

1. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. Apr 2015; 152(2 Suppl): S1-S39. PMID 25832968
2. Food and Drug Administration. Nucala Prescribing Information. July 29, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761122s006,125526s018lbl.pdf. Accessed January 23, 2024.
3. Food and Drug Administration. Highlights of Prescribing Information: Dupixent (dupilumab) injection, for subcutaneous use. 2024; https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761055s057lbl.pdf. Accessed January 22, 2024.
4. Hathorn IF, Pace-Asciak P, Habib AR, et al. Randomized controlled trial: hybrid technique using balloon dilation of the frontal sinus drainage pathway. Int Forum Allergy Rhinol. Feb 2015; 5(2): 167-73. PMID 25360863
5. Plaza G, Eisenberg G, Montojo J, et al. Balloon dilation of the frontal recess: a randomized clinical trial. Ann Otol Rhinol Laryngol. Aug 2011; 120(8): 511-8. PMID 21922974
6. Bizaki AJ, Taulu R, Numminen J, et al. Quality of life after endoscopic sinus surgery or balloon sinuplasty: a randomized clinical study. Rhinology. Dec 2014; 52(4): 300-5. PMID 25479206
7. Hopkins C, Browne JP, Slack R, et al. The Lund-Mackay staging system for chronic rhinosinusitis: how is it used and what does it predict?. Otolaryngol Head Neck Surg. Oct 2007; 137(4): 555-61. PMID 17903570
8. Gregurić T, Trkulja V, Baudoin T, et al. Association between computed tomography findings and clinical symptoms in chronic rhinosinusitis with and without nasal polyps. Eur Arch Otorhinolaryngol. May 2017; 274(5): 2165-2173. PMID 28154930
9. Levy JM, Marino MJ, McCoul ED. Paranasal Sinus Balloon Catheter Dilation for Treatment of Chronic Rhinosinusitis: A Systematic Review and Meta-analysis. Otolaryngol Head Neck Surg. Jan 2016; 154(1): 33-40. PMID 26519456
10. Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. Jan 2016; 126(1): 44-50. PMID 26228589
11. Minni A, Dragonetti A, Sciuto A, et al. Use of balloon catheter dilation vs. traditional endoscopic sinus surgery in management of light and severe chronic rhinosinusitis of the frontal sinus: a multicenter prospective randomized study. Eur Rev Med Pharmacol Sci. Jan 2018; 22(2): 285-293. PMID 29424885
12. Cutler J, Bikhazi N, Light J, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial. Am J Rhinol Allergy. 2013; 27(5): 416-22. PMID 23920419
13. Bikhazi N, Light J, Truitt T, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial with 1-year follow-up. Am J Rhinol Allergy. 2014; 28(4): 323-9. PMID 24823902
14. Achar P, Duvvi S, Kumar BN. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. Acta Otorhinolaryngol Ital. Oct 2012; 32(5): 314-9. PMID 23326011
15. Chaaban MR, Rana N, Baillargeon J, et al. Outcomes and Complications of Balloon and Conventional Functional Endoscopic Sinus Surgery. Am J Rhinol Allergy. Sep 2018; 32(5): 388-396. PMID 29947260
16. Gliklich RE, Metson R. Techniques for outcomes research in chronic sinusitis. Laryngoscope. Oct 2015; 125(10): 2238-41. PMID 26390386
17. Bizaki AJ, Numminen J, Taulu R, et al. A Controlled, Randomized Clinical Study on the Impact of Treatment on Antral Mucociliary Clearance: Uncinectomy Versus Balloon Sinuplasty. Ann Otol Rhinol Laryngol. May 2016; 125(5): 408-14. PMID 26611244
18. Sikand A, Ehmer DR, Stolovitzky JP, et al. In-office balloon sinus dilation versus medical therapy for recurrent acute rhinosinusitis: a randomized, placebo-controlled study. Int Forum Allergy Rhinol. Feb 2019; 9(2): 140-148. PMID 30452127
19. Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Sinuses. Otolaryngol Head Neck Surg. Feb 2018; 158(2): 203-214. PMID 29389303
20. American Academy of Otolaryngology - Head and Neck Surgery. Position Statement: Dilation of sinuses, any method (e.g., balloon, etc.). 2017; entnet.org/resource/position-statement-dilation-of-sinuses-any-method-e-g-balloon-etc/ Accessed January 22, 2024.
21. National Institute of Health and Care Excellence (NICE). Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis [IPG273]. 2008; https://www.nice.org.uk/guidance/ipg273. Accessed January 22, 2024.
22. National Institute of Health and Care Excellence (NICE). XprESS multi sinus dilation system for treating chronic sinusitis [MTG30]. 2016; https://www.nice.org.uk/guidance/mtg30. Accessed January 22, 2024.
23. American Rhinologic Society (ARS). Ostial Balloon Dilation Position Statement. 2023; https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=494:ostial-balloon-dilation-position-statement&catid=26:position-statements&Itemid=197. Accessed January 22, 2024.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	Use of a catheter-based inflatable device (balloon ostial dilatation) in the treatment of sinusitis is considered investigational.
March 2014	Replace policy	Policy updated with literature review; numerous references added and deleted. Policy title changed to balloon ostial dilation. Policy statement unchanged.
March 2015	Replace policy	Policy updated with literature review; reference 6, 7, 21-25, and 30-31 added. Rationale section reorganized. Policy statement edited to remove trademarked name, but otherwise unchanged.
March 2017	Replace policy	Policy updated with literature review; reference 1-3, 7, 18-19, 27, 33, 35 and 38 added. Rationale extensively revised. Policy statement unchanged but "sinusitis" changed to "chronic rhinosinusitis" to be consistent with the title change to "Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis".
June 2018	Replace policy	Policy updated with literature review through December 11, 2107. No references added; updated references 25 and 37. No change to policy statement. Objective statement added: "The objective of this evidence review is to evaluate whether balloon ostial dilation improves the net health outcome for patients with chronic rhinosinusitis".
June 2019	Replace policy	Policy updated with literature review through January 3, 2019; reference 17 added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through February 29, 2020; references added. Policy statement changed to medically necessary for chronic sinusitis under specified conditions. Added new indication and investigational statement for recurrent acute rhinosinusitis. Removed indication for balloon ostial dilation (BOD) as an adjunct to functional endoscopic sinus surgery (FESS); BOD when used as a tool during FESS in the same sinus cavity is considered to be an integral part of the FESS procedure. Title changed to "Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis."
June 2021	Replace policy	Policy updated with literature review through November 17, 2020; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through November 15, 2021; references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through November 14, 2022; no references added. Minor editorial changes to policy statements, intent unchanged.
June 2024	Replace policy	Policy updated with literature review through January 22, 2024; no references added. Policy statements unchanged. Minor editorial refinements to policy guidelines; intent unchanged.