



## FEP Medical Policy Manual

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

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**Effective Policy Date: July 1, 2020**

**Original Policy Date: June 2012**

#### **Related Policies:**

5.45.11 - Sinus Implants

7.01.158 - Balloon Dilation of the Eustachian Tube

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## 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 patients 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.

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## Medical Treatment

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics).<sup>1</sup>

## 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 uncinata 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 uncinata 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. <https://www.jnjmedicaldevices.com/en-US/product/relieva-spinplus-balloon-sinuplasty-system>

This evidence review is limited to BOD when used as a standalone procedure. BOD may also be used in combination with FESS.<sup>2,3</sup> 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.

## OBJECTIVE

The objective of this evidence review is to evaluate whether BOD improves the net health outcome for patients with CRS or RARS. This evidence review is limited to BOD when used as a standalone procedure.

## 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:

- Patient 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 two of the following, at least one of which is (a) or (b), present for at least 12 continuous weeks:

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- o a. Mucopurulent nasal drainage (anterior, posterior, or both);
- b. Nasal obstruction (congestion);
- c. Facial pain-pressure-fullness;
- d. Decreased sense of smell.

AND

- Optimal medical therapy has been attempted and failed, as indicated by all of the following:
  - o
    - Allergy evaluation, education, and optimal treatment when indicated;
    - Two 10-day courses of antibiotics, or one 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 should be documented by all of the following:

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

AND

- CT scan of the paranasal sinuses showing mucosal thickening of greater than 3mm, opacification, or air-fluid levels.

## 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.

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

- 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.

## 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.<sup>2</sup>

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

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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 dilation (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 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 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 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.

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## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

#### American Academy of Otolaryngology - Head and Neck Surgery et al

In 2018, the American Academy of Otolaryngology<97>Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses.<sup>17</sup> 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**.

##### 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 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 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..."<sup>18</sup>.

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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.<sup>1</sup>

## National Institute for Health and Care Excellence

In 2008, 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."<sup>19</sup>

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis<sup>20</sup>:

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.

## American Rhinologic Society

A position statement, revised in 2017, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected patients with chronic rhinosinusitis (CRS) ... who have failed appropriate medical therapy."<sup>21</sup>

## 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.

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

<b>Date</b>	<b>Action</b>	<b>Description</b>
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."

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