Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

(Formerly Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 02/01/21</th>
<th>Next Review Date: 11/21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 07/07, 07/08, 11/08, 05/09, 01/10, 01/11, 01/12, 03/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19, 11/20</td>
</tr>
</tbody>
</table>

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOLS
Balloon Dilation of the Eustachian Tube
Steroid-Eluting Sinus Stents

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: With chronic rhinosinusitis</td>
<td>Interventions of interest are: Balloon ostial dilation as a stand-alone procedure</td>
<td>Comparators of interest are: Medical management, Functional endoscopic sinus surgery</td>
<td>Relevant outcomes include: Symptoms, Change in disease status, Quality of life, Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: With recurrent acute rhinosinusitis</td>
<td>Interventions of interest are: Balloon ostial dilation as a stand-alone procedure</td>
<td>Comparators of interest are: Medical management, Functional endoscopic sinus surgery</td>
<td>Relevant outcomes include: Symptoms, Change in disease status, Quality of life, Treatment-related morbidity</td>
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DESCRIPTION
Balloon ostial dilation (also known as balloon sinuplasty) is proposed as an alternative to traditional endoscopic sinus surgery (ESS) for patients with chronic rhinosinusitis (CRS) 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 functional endoscopic sinus surgery (FESS). This protocol addresses BOD as a standalone procedure.

SUMMARY OF EVIDENCE
For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure, the
Protocol: Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

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evidence includes systematic reviews and RCTs. 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=2,851), FESS (n=11,955), or a hybrid procedure (n=1,234), 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.

POLICY
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:
  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;
  o Two 10-day courses of antibiotics, or one prolonged course of at least 21 days duration;
  o Decongestants when indicated;
  o Topical and/or systemic corticosteroids for at least eight weeks;
  o Saline nasal irrigation for at least eight consecutive weeks;
  o Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present;
  o 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 investigation-al.

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 sphenoidethmoid 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.

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.

BACKGROUND

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 four 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
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 microdebriders, 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. [https://www.jnjmedicaldevices.com/en-US/product/relieva-spinplus-balloon-sinuplasty-system](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. 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.

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>510(k) No.</th>
<th>Date Cleared</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>ME SIRE - Balloon Sinus Dilatation System</td>
<td>Merit Life Sciences</td>
<td>K172737</td>
<td>12/12/2017</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>Relieva SpinPlus Nav Balloon Sinuplasty System</td>
<td>Acclarent Inc.</td>
<td>K171687</td>
<td>9/5/2017</td>
<td>Sinus Ostia Dilation</td>
</tr>
<tr>
<td>XprESS ENT Dilation System</td>
<td>Entellus Medical Inc.</td>
<td>K163509</td>
<td>4/5/2017</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>Relieva UltirraNav Sinus Balloon Catheter</td>
<td>Acclarent Inc.</td>
<td>K161698</td>
<td>10/24/2016</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>Vent-Os Sinus Dilation Family</td>
<td>Sinusys Corp.</td>
<td>K160770</td>
<td>6/29/2016</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>Relieva Scout Multi-Sinus Dilation System</td>
<td>Acclarent Inc.</td>
<td>K153341</td>
<td>2/12/2016</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>XprESS Multi-Sinus Dilation System</td>
<td>Entellus Medical Inc.</td>
<td>K152434</td>
<td>11/20/2015</td>
<td>Sinus Ostia Dilation</td>
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<td>DSS Sinusplasty Balloon Catheter</td>
<td>Intuit Medical Products LLC</td>
<td>K143738</td>
<td>8/27/2015</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>Relieva SpinPlus Balloon Sinuplasty System</td>
<td>Acclarent Inc.</td>
<td>K143541</td>
<td>4/22/2015</td>
<td>Sinus Ostia Dilation</td>
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<tr>
<td>XprESS Multi-Sinus Dilation Tool</td>
<td>Entellus Medical Inc.</td>
<td>K142252</td>
<td>10/17/2014</td>
<td>Sinus Ostia Dilation</td>
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<td>Relieva Scout Multi-Sinus Dilation System</td>
<td>Acclarent Inc.</td>
<td>K140160</td>
<td>2/20/2014</td>
<td>Sinus Ostia Dilation</td>
</tr>
</tbody>
</table>

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.