Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member’s plan contracts, state laws, and federal laws. Please reference the member’s plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Balloon Ostial Dilation

Summary

Oscar covers surgical treatment for chronic rhinosinusitis in patients who fail attempts at medical therapy such as antibiotics, intranasal steroids, systemic steroids, and/or saline irrigation. Traditional functional endoscopic sinus surgery (FESS) is a minimally invasive surgical technique that opens up and drains the sinus air cells and sinus passages under direct visualization.

Balloon ostial dilation (BOD), also known as balloon sinuplasty or balloon catheter sinusotomy, is a newer minimally invasive endoscopic technique that has been proposed as an alternative to or in addition to FESS for the surgical management of chronic rhinosinusitis. This technique involves using a balloon to dilate the sinus ostia to improve sinus drainage. Potential benefits of BOD include outflow tract enlargement with preservation of normal anatomy, excellent mucosal sparing, minimal intraoperative bleeding, and less discomfort than traditional sinus surgery. BOD is most frequently used in combination with FESS, which is also known as a “hybrid” technique.

Studies have confirmed the safety and efficacy of balloon ostial dilation in patients who have failed medical therapy. Balloon dilation also has some advantages when compared to FESS in terms of recovery time and degree of postoperative pain.
Definitions

“**Rhinosinusitis**” is defined as an inflammatory condition of one or more of the paranasal sinuses and nasal passages. Rhinosinusitis can be further classified based on acuity (acute vs. chronic), anatomical location (involvement of the maxillary, ethmoid, frontal, or sphenoid sinuses), and severity (uncomplicated vs. complicated).

“**Acute rhinosinusitis (ARS)**” is an inflammatory condition of one or more of the paranasal sinuses and nasal passages (“rhinosinusitis”) that lasts up to 4 weeks.

“**Chronic Rhinosinusitis (CRS)**” is an inflammatory condition of one or more of the paranasal sinuses and nasal passages (“rhinosinusitis”) that persists for 12 weeks or longer.

“**Functional Endoscopic Sinus Surgery (FESS)**” is a minimally invasive, mucosal-sparing surgical technique to improve the drainage pathways of the paranasal sinuses. It is performed with a telescope inserted into the nasal cavity to allow for direct visualization of sinus anatomy.

“**Hybrid Technique**” is the combination of traditional endoscopic sinus surgery and balloon ostial dilation techniques during a single procedure.

Clinical Indications and Coverage

**Chronic Rhinosinusitis**

Oscar considers balloon ostial dilation medically necessary when ALL of the following criteria are met:

1. Patient 13 years of age and older; **and**
2. Documented persistent chronic rhinosinusitis for at least 12 weeks; **and**
3. Documented failure of medical therapy despite treatment for at least 12 weeks with:
   a. At least one course of oral antibiotics; **and**
   b. A trial of at least **TWO** of the following topical intranasal therapies:
      i. Intranasal steroids; **or**
      ii. Saline irrigations; **or**
      iii. Antihistamine spray.
4. Confirmation of chronic rhinosinusitis by CT scan as demonstrated by the presence of at least **ONE** of the following:
   a. Mucosal thickening; **or**
   b. Bony remodeling or thickening; **or**
   c. Sinus opacification; **or**
   d. Obstruction of the ostiomeatal complex.
5. Dilation is limited to the maxillary, frontal, or sphenoid sinuses.

**Coverage Exclusions**

Oscar considers balloon ostial dilation experimental and investigational for all other conditions, including the treatment of nasal polyps, tumors and acute rhinosinusitis, as its safety and efficacy have not been clearly established in the published clinical literature.

Oscar considers balloon ostial dilation experimental and investigational in children 12 years of age and younger as there is insufficient evidence to determine its effectiveness in this population.

**Acute Rhinosinusitis**

There are several case reports in the literature (Roland et al. 2015; Zhao et al. 2016; Hopkins et al. 2009) and one small retrospective case series (Wittkopf et al. 2009) addressing the use of balloon dilation in cases of acute sinusitis, with or without associated complication. The results of these reports are interesting but do not provide objective data, statistics, or long-term follow up to allow a conclusion that is generalizable to the standard acute rhinosinusitis patient. Further studies that provide clinical data based on randomized trials comparing medical therapy to balloon ostial dilation for acute rhinosinusitis and traditional FESS to balloon dilation for complicated acute disease are needed to make any scientific conclusions.

**Chronic Rhinosinusitis in Patients 12 Years-of-Age and Younger**

A consensus statement from the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) on the use of balloon sinuplasty for the treatment of pediatric chronic rhinosinusitis concluded that the effectiveness cannot be determined based on current evidence. The current literature includes a nonrandomized prospective study (Ramadan et al. 2011), a retrospective case control study (Wang et al. 2015), a retrospective cohort study (Thottam et al. 2016), and several case reports that have suggested that balloon catheter sinuplasty is safe and might be as effective as FESS in children with chronic or acute rhinosinusitis, but larger, prospective, randomized control trials with long term follow up are needed to determine the true efficacy in this population.
Applicable Billing Codes (HCPCS & CPT Codes)

Codes covered if clinical criteria are met:

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<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa</td>
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<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)</td>
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<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)</td>
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<td>31298</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)</td>
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Codes not covered for indications listed in this Guideline:

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<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant</td>
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<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement</td>
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<tr>
<td>S1090</td>
<td>Mometasone furoate sinus implant, 370 micrograms</td>
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References


49. Thottam PJ, Haupert M, Saraiya S, Dworkin J, Sirigiri R, Belenky WM. Functional endoscopic sinus surgery (FESS) alone versus balloon catheter sinuplasty (BCS) and ethmoidectomy: a


Clinical Guideline Revision / History Information

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<th>Original: Review/Revise Dates</th>
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<tr>
<td>Reviewed/Revised:</td>
<td>1/18/2018</td>
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<td>Signed:</td>
<td>Sean Martin, MD</td>
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