Oscar Clinical Guideline: Balloon Ostial Dilation (CG018, Ver. 9)

Balloon Ostial Dilation

Summary

The Plan considers surgical treatment for chronic rhinosinusitis medically necessary 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 may be used as a standalone procedure, but it 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.
- "Recurrent acute rhinosinusitis (RARS)" is defined as at least 4 episodes of acute rhinosinusitis in a 1 year period. Patients are asymptomatic between episodes. Even though the summed duration of all episodes may be greater than 12 weeks, this is differentiated from chronic rhinosinusitis in that each single episode is still less than 4 weeks long.
- "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 surgical technique to improve the drainage pathways of the paranasal sinuses. It is performed with an endoscope 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

Chronic Rhinosinusitis

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

1. Patient 18 years of age and older; *and*
2. Documented persistent chronic rhinosinusitis for at least 12 weeks with two or more of the following signs or symptoms:
    a. Mucopurulent drainage (not clear drainage); *and/or*
    b. Nasal obstruction (congestion); *and/or*
    c. Facial pain, pressure, or fullness (differentiated from headaches); *and/or*
    d. Decreased sense of smell; *and*
3. Documented failure of medical therapy despite treatment with:
    a. A trial of at least TWO different oral antibiotics (e.g., amoxicillin-clavulanate, cefpodoxime, clindamycin, doxycycline, levofloxacin, metronidazole, etc.) unless there is a specific contraindication,severe adverse reaction, or cause of rhinosinusitis is a viral illness; *and*
    b. A trial of at least TWO of the following topical intranasal therapies for a minimum of 4+ weeks each:
        i. Intranasal steroids; *or*
        ii. Saline irrigations; *or*
        iii. Antihistamine spray.

4. Allergic rhinitis has been adequately ruled out or treated appropriately with medications and/or documented lifestyle changes; *and*
5. Confirmation of chronic rhinosinusitis by CT scan radiology report 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.
6. Dilation is limited to the maxillary, frontal, or sphenoid sinuses; *and*
7. If a balloon ostial dilation is performed in conjunction with a functional endoscopic sinus surgery (FESS) in the same sinus cavity for a member without nasal polyps, it must meet above Chronic Rhinosinusitis criteria and MCG (A-0185) Functional Endoscopic Sinus Surgery (FESS) criteria.

Recurrent Acute Rhinosinusitis

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

1. Patient 18 years of age and older; *and*
2. Documented recurrent acute rhinosinusitis of at least 4 episodes in a 12 month rolling period with asymptomatic periods in between episodes; *and*
3. Documented recurrence of symptoms despite optimal prior medical therapy with:
    a. Oral antibiotic therapy (e.g., amoxicillin, amoxicillin-clavulanate, etc.) unless specific contraindication, or severe adverse reaction, or cause of rhinosinusitis is viral illness; *and*
    b. A trial of at least TWO of the following topical intranasal therapies for a minimum of 4+ weeks each:
        i. Intranasal steroids; *or*
        ii. Saline irrigations; *or*
        iii. Antihistamine spray.
4. Allergic rhinitis has been adequately ruled out or treated appropriately with medications and/or documented lifestyle changes; *and*
5. Confirmation of acute rhinosinusitis that would be reasonably expected to improve after surgical treatment, based on CT imaging radiology report results during an acute episode; *and*
6. Dilation is limited to the maxillary, frontal, or sphenoid sinuses; *and*
7. If a balloon ostial dilation is performed in conjunction with a functional endoscopic sinus surgery (FESS) in the same sinus cavity for a member without nasal polyps, it must meet above Recurrent Acute Rhinosinusitis criteria and MCG (A-0185) Functional Endoscopic Sinus Surgery (FESS) criteria.

Experimental or Investigational / Not Medically Necessary

The Plan considers balloon ostial dilation experimental and investigational for all other conditions, including but not limited to those listed here, as its safety and efficacy have not been clearly established in the published clinical literature:

- Nasal polyps
- Tumors
- Acute rhinosinusitis
- Aspirin sensitivity
- Sinusitis secondary to autoimmune or connective tissue disorders
- Sinusitis secondary to ciliary dysfunction (e.g., cystic fibrosis)
- Isolated ethmoid sinus disease
- Sleep apnea without chronic sinusitis symptoms and imaging findings
- Headache without chronic sinusitis symptoms and imaging findings

The Plan considers balloon ostial dilation experimental and investigational in children 17 years of age and younger as there is insufficient evidence to determine its effectiveness in this population.

The Plan considers the use of self-expanding absorptive sinus ostial dilation devices experimental and investigational as the safety and efficacy have not been clearly established in the published clinical literature

Balloon sinus ostial dilation used adjunctively during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered integral to the primary procedure and not separately reimbursable. Similarly, when balloon dilation and sinus tissue removal are performed as part of the same surgery, only one code will be considered reimbursable.

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 17 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 considered medically necessary if clinical criteria are met:

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

Codes not considered medically necessary for indications listed in this Guideline:

CPT/HCPCS codes not considered medically necessary:	
Code	*Description*
31299	Unlisted procedure, accessory sinuses
J7401	Mometasone furoate sinus implant, (Sinuva), 10 mcg

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