Balloon Sinus Ostial Dilation for Chronic Sinusitis

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Coverage Policy

Balloon sinus ostial dilation (balloon sinuplasty) is considered medically necessary in the sinus being considered for dilation (i.e., frontal, maxillary or sphenoid) for the treatment of chronic sinusitis when ALL of the following criteria are met:

- presence of two or more of the following signs/symptoms for more than three consecutive months:
  - nasal obstruction
  - anterior or posterior mucopurulent (foul) drainage
  - facial pain, pressure and/or fullness over the affected sinus
  - decreased sense of smell
- evidence of chronic rhinosinusitis on computerized tomography (CT) scan in each of the sinuses being considered for treatment including ANY of the following:
  - mucosal thickening >3 millimeters
  - air fluid levels
  - opacification
  - nasal polyposis
- failure, intolerance or contraindication of medical management for at least eight consecutive weeks including ALL of the following:
  - at least two different full courses of antibiotics
  - steroid nasal spray
  - antihistamine nasal spray and/or decongestant
• nasal saline irrigation

Balloon sinus ostial dilation (balloon sinuplasty) is considered experimental, investigational or unproven for all other indications.

Balloon sinus ostial dilation (balloon sinuplasty) when used as an adjunctive procedure during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the primary procedure and not separately reimbursable.

Overview

This Coverage Policy addresses balloon sinus ostial dilation, also called balloon sinuplasty, for the treatment of chronic sinusitis and other indications, including recurrent acute rhinosinusitis.

General Background

Rhinosinusitis, also referred to as sinusitis, is an inflammation of the mucous membrane of the paranasal sinuses and nasal cavity. It affects all age groups and can be caused by infection, airborne allergens (e.g., dust mites, mold, pollen) or autoimmune deficiencies. There are three classifications of rhinosinusitis. Acute rhinosinusitis (ARS) typically lasts four weeks or less. Subacute sinusitis lasts 4–12 weeks and chronic rhinosinusitis (CRS) lasts for more than 12 weeks, with or without exacerbation, and can continue for months or years. CRS leads to thickening of the paranasal sinuses due to constant inflammation. The condition can occur with or without nasal polyps. The four cardinal signs/symptoms of CRS are nasal obstruction; facial congestion, pressure, and or fullness; anterior and/or posterior mucopurulent drainage; and hyposmia (decreased ability to smell). CRS is associated with sinus edema and impaired mucociliary clearance (American Academy of Otolaryngology -Head and Neck Surgery [AAO-HNS], 2015; Parikh, et al., 2014; Ahmed, et al., 2011; Hopkins, et al., 2007).

The diagnosis of CRS is based on presenting signs and symptoms, clinical examination using anterior rhinoscopy or nasal endoscopy. Radiological evidence of CRs is plain films, computed tomography (CT) scan and in some cases MRI is also a part of the work-up for these patients. CT scan is the standard radiologic examination obtained when endoscopic sinus surgery is being considered. Radiological characteristics of sinusitis include air fluid levels, mucosal thickening greater than three millimeters, nasal polyposis, opacification, bony remodeling and thickening. CT also is used to determine the Lund-Mackey Score for assessing the severity of rhinosinusitis. This scale grades the right and left sides independently, looking at the maxillary, anterior ethmoids, posterior ethmoids, sphenoid, and frontal sinuses, as well as the ostiomeatal complex. Each sinus is scored a 0 (no abnormality), 1 (partial opacification), or 2 (total opacification), and the ostiomeatal complex is scored either a 0 or 2 (for presence or absence of disease). Each side is divided into six regions, corresponding to the location of specific sinuses. Ethmoid sinuses are divided into two regions, anterior and posterior, and the ostiomeatal complex is evaluated separately. Each sinus is scored as 0, 1, or 2, based on the severity of mucosal inflammation or fluid accumulation. Thus the score can range from 0, complete lucency of all 12 regions, to 24, complete opacity of all regions. Studies have reported an increased complication rate following surgery with increasing Lund-Mackay scores (Brook 2017; Vartanian, 2016; Ramanan, 2016; Brook, 2015; American Academy of Otolaryngology -Head and Neck Surgery [AAO-HNS], 2015; Parikh, et al., 2014; Noorian and Motaghi, 20120; Rege et al., 2012; Ahmed, et al., 2011; Huang et al., 2009; Hopkins, et al., 2007).

Because CRS is typically not cured, medical management is focused on minimizing mucosal inflammation and edema to prevent obstruction and minimize the incidence of infections and acute exacerbations. Medical treatment is typically tried for at least eight weeks and includes nasal saline irrigation, topical and systemic glucocorticoids, two or more antibiotics, and/or antileukotriene agents. When the patient becomes unresponsive to medical management, surgical intervention to clean and drain the sinuses may be indicated. In cases where obstruction of the nasal passages is present (e.g., polyps, deviated septum) surgery to correct the obstruction may be done (Brook; 2016; Brook, 2015; American Academy of Otolaryngology -Head and Neck Surgery [AAO-HNS], 2015; Parikh, et al., 2014.).
Functional endoscopic sinus surgery (FESS), also referred to as endoscopic sinus surgery (ESS), is the standard surgical procedure for CRS that is unresponsive to medical management. 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. FESS involves the insertion of an endoscopy into the nose for direct visual exam of the openings into the sinuses. Special instruments are used along with the endoscope to remove the blockages and improve breathing. Complications that can occur during ESS include: scarring and adhesions, intraoperative bleeding that can obscure surgical visualization, orbital injury, and accidental penetration of the brain (AAO-HNS, 2015; Parikh, et al., 2014; Brown, et al., 2006).

Balloon sinus ostial dilation, also known as balloon sinuplasty and balloon catheter sinusotomy, has become an accepted alternative procedure to functional endoscopic sinus surgery (FESS) for the treatment of CRS in a select subset of patients. Like FESS, balloon sinuplasty is intended to allow access to and ventilation of obstructed sinuses. The procedure is less invasive than FESS and proposed to have minimal bleeding, scarring and less postoperative pain. Risks of balloon sinuplasty include tissue and mucosal trauma, infection or possible optic injury. Basic equipment includes a sinus guidewire, a sinus delivery catheter; a sinus balloon and an inflation device. Guided by X-ray images or by a lighted fiberoptic tip, the catheter is threaded up to the opening of the blocked or poorly draining sinus and the guidewire is passed through the opening of the sinus. The guidewire is passed from the nasal cavity into the specific sinus being addressed and a balloon dilating catheter is passed over the wire to the narrowest part of the sinus drainage pathway. The balloon is then briefly inflated to a high pressure (up to 12 atmospheres). The pressure from the balloon widens the outflow tract of the sinus by fracturing bone and moving it outward along the mucous membrane without tissue removal. The balloon is then deflated and the catheter is removed (Hayes, 2017; Hepworth, 2016; American Rhinologic Society [ARS], 2015; Ahmed, et al., 2011).

When performed alone, balloon sinuplasty is an accepted procedure for a select subset of adult patients, age 18 years and older, with chronic rhinosinusitis (CRS). Appropriate surgical candidates have failed at least eight weeks of consecutive medical therapy including at least two antibiotics, steroid nasal spray, antihistamine nasal spray and/or decongestant and nasal saline washes. Computerized tomography (CT) scan should show air fluid levels, or opacification or nasal polys. When balloon sinuplasty is used as an adjunctive procedure with FESS it is considered an integral part of the procedure.

Balloon sinuplasty has been proposed for the treatment of other conditions including recurrent acute rhinosinusitis (RARS), headaches unrelated to CRS, nasal obstruction and obstructive sleep apnea (AAO-HNS, 2018). There is insufficient evidence in the peer-reviewed literature to support balloon sinuplasty for these other indications.

**U.S. Food and Drug Administration (FDA):**

Balloon Sinuplasty devices are approved by the FDA 510(k) process as Class I devices. One of the first balloon inflation devices approved was the Relieva Sinus Balloon Inflation Device (Acclarent, Inc., Menlo Park, CA) in 2005. The 2008 approved devices, Relieva Sinus Balloon Catheter and the Relieva Acella Sinus Balloon Catheter are also Class I devices. These devices are approved to “dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures”. The balloon may be inflated to dilate the frontal recess, frontal sinus ostia and spaces within the frontal sinus cavity. “For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures”. The DSS Balloon Catheter (Intuit Medical Products, LLC., Sugar Hill, GA) is also FDA approved for children aged 17 years and under.

The Acclarent Airway Balloon Catheter is a catheter with a high pressure balloon on the distal tip. The device is designed with a coaxial lumen for inflation and guidewire access, if required. There are two accessories for the Airway Balloon Catheter: the Inflation Device and the Relieva Vigor Guidewire. The most recent 510(k) device, the Acclarent Relieva SpinPlus Balloon Sinuplasty System, was approved in 2015 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”. These approved indications also include children aged 17 years and under. As a Class I, the device falls into a generic category and FDA clearance is not required before marketing the device in the US. The manufacturer is required to register their establishment with the FDA.
The XprESS Multi-Sinus Dilation System (Entellus Medical, Inc., Plymouth, MN) is a Class I device intended to “access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures”. The Dillard Sinuplasty Balloon Catheter (Intuit Medical Products, LLC, Sugar Hill, GA) (DSS Balloon Catheter) is intended “to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 years and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures”. The Sinus Dilation System with Cannulated Instrument, a modification to ENTrigue Sinus Dilation System, was FDA approved in 2013 for use in surgical procedures to access, examine or treat the nasal and paranasal tissues.

The Nuvent EM Sinus Dilation System (Medtronic XoMed, Inc., Jacksonville FL) is intended for use in conjunction with the Medtronic Computer-Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. This system combines electromagnetic (EM) “plug and play” tracking capability with the pathway expansion effects of balloon dilation technology and an inflator. Each of the three types of sinus seekers (frontal, maxillary and sphenoid) has a unique shape and angle that allows for entry into the sinus outflow tract. The inflator consists of a plunger, barrel and extension tube (FDA, 2013).

In contrast to the high pressure inflation systems, the Vent-Os™ Sinus Dilation System (SinuSys Corp., Palo Alto, CA), uses low-pressure, self-expanding technology and is proposed to gently and gradually open the maxillary ostia. The device was FDA approved in 2013 to dilate the maxillary sinus in adults for therapeutic and diagnostic procedures. The procedure is performed in the office (FDA, 2013; SinuSys Corp, 2016).

Literature Review – Chronic Rhinosinusitis
Randomized controlled trials have compared FESS to balloon sinuplasty of the frontal, maxillary or sphenoid sinuses for the treatment of CRS. The studies have small patient populations and short-term follow-up. However outcomes have shown that balloon sinuplasty is noninferior to FESS with shorter operative times, less bleeding and few to no reported complications (Chandra, et al., 2016; Bikhazi, et al., 2014; Marzetti, et al., 2014; Achar, et al., 2012; Plaza, et al., 2011) Balloon sinuplasty has evolved into an accepted alternative procedure for CRS.

Numerous case series have also been conducted to evaluate the safety and efficacy of balloon sinuplasty. Subjects were age 18 years and older, with CRS for more than 12 weeks that was unresponsive to medical management (e.g., antibiotic therapy, inhaled and/or systemic corticosteroids, decongestants, saline irrigations). Reported post-operative outcomes included: functional patency in 80.5%–97% of patients; statistically significant improvement in SNOT-20 scores; and CT Lund-Mackey scores and revision rates 3%–7.4%. The studies are limited by the small patient populations (n=37–115) and short-term follow-ups (e.g., 2–12 months) (Sikand, et al., 2015; Gould, et al. 2014; Levine, et al., 2013; Weiss, et al., 2008; Kuhn, et al., 2008; Bolger, et al, 2007). Published studies evaluating the outcomes of balloon sinuplasty in children are lacking (Ramadan, et al., 2010).

Brodner et al. (2013) conducted a prospective case series to evaluate the safety and efficacy of balloon sinuplasty dilation (BSD) (XprESS) in 175 patients and 497 sinuses (279 frontal, 138 sphenoid, 80 maxillary). Patients were age 18 years and older, scheduled for FESS prior to the study, and had a CT scan within 12 months of the surgery. At the one-year follow-up, 44 patients reported significant improvement in sinus symptoms (p<0.0001). At the one-year follow-up Ostial patency was maintained in 91.6% of sinuses and one revision surgery was required.

Karanfilov et al. (2012) conducted a prospective, multicenter, case series to evaluate the safety and efficacy of balloon sinuplasty dilation (BSD) in 203 subjects (552 sinuses). Patients, age 18 years and over, with CRS had failed the minimum maximal treatment protocol (i.e., more than 3–6 weeks of broad-spectrum or culture-directed antibiotics, intranasal steroid spray and/or oral steroids if polyps or severe inflammation were present; antihistamines and/or decongestants clinically indicated; and routine use of nasal saline irrigation during treatment course). CRS diagnosis was made according to the AAO-HNS CRS definition which includes ≥ 12 weeks of two or more major signs/symptoms and inflammation by purulent mucus/edema, presence of polyps, or radiographic imaging. The technical dilation success was 93.3% for maxillary sinuses, 90.5% for sphenoid and
93.7% for frontal. There was significant improvement in the Sino-Nasal Outcome Test (SNOT-20) and the Lund-Mackay CT scores (p<0.0001, each). Patients (82.3%) considered the procedure tolerable or highly tolerable.

**Literature Review – Other Indications**

There is insufficient evidence to support balloon sinuplasty for all other indications including the treatment of recurrent acute rhinosinusitis (RARS). Studies are primarily in the form of retrospective reviews or have evaluated balloon ostial dilation for the treatment of chronic sinusitis and included small numbers of patients with RARS (n=9–17) (Costa et al., 2015; Gould, et al., 2014; Levine et al., 2013). Data on the clinical effectiveness of balloon sinuplasty for RARS are limited.

**Professional Societies/Organizations**

**American Academy of Allergy, Asthma and Immunology (AAAAI):** In the practice parameter on rhinosinusitis, AAAAI defines CRS as persistent symptoms of rhinosinusitis for 12 weeks or longer. Signs and symptoms include purulent rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain or pressure, or headache and are associated with objective evidence of inflammation observed on nasal endoscopy and/or CT scan. CRS may occur with or without polyps. Sinus CT scan is the preferred imaging modality and the gold standard to clarify the extent of disease and specific location or locations of obstruction in acute or chronic sinus disease. CT scan is required before surgical intervention or if rhinosinusitis complications are suspected (Dass and Peters, 2016).

**American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS):** The AAO-HNS (2018) developed a clinical consensus statement on balloon dilation of the paranasal sinuses. The target population included adults ≥ age 18 years with chronic or recurrent rhinosinusitis (with or without nasal polyps, with or without prior sinus surgery) for whom sinus ostial dilation (SOD) was being recommended. SOD was defined as endoscopic use of a balloon device to enlarge or open the outflow tracts of the maxillary, frontal, or sphenoid sinuses, as a standalone procedure or with endoscopic surgery. The use of serial dilations over time in the same patient was not considered. According to AAO-HNS there has been an increasing rate of utilization of SOD without a reduction in the number of traditional functional endoscopic sinus surgeries being performed. Due to limited evidence to support a guideline, the topic of SOD was selected for clinical consensus statement (CCS) development. Based on a systematic review of the literature and expert consensus, the Society’s statements included the following:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT.
- 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.
- 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.
- CT scanning of the sinuses is a requirement before balloon dilation can be performed.
- 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 the CT evidence of ostial occlusion and mucosal thickening.
- 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.

In a 2017 position statement on dilation of the sinuses, AAO-HNS stated that sinus ostial dilation (e.g. balloon ostial dilation) is an appropriate therapeutic option for selected patients with chronic rhinosinusitis (CRS) and acute rhinosinusitis (RARS) who have failed medical therapy. The Society noted that sinus ostial dilation can be
used alone or in conjunction with other instruments. The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

The AAO-HNS (2015) clinical practice guideline on adult sinusitis defines chronic rhinosinusitis as twelve weeks or longer of two or more of the following signs and symptoms:

- mucopurulent drainage (anterior, posterior, or both)
- nasal obstruction (congestion),
- facial pain/pressure/fullness, or
- decreased sense of smell

AND inflammation as documented by one or more of the following:

- purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region,
- polyps in nasal cavity or the middle meatus, and/or
- radiographic imaging showing inflammation of the paranasal sinuses

The Society recommends that the clinician confirm the diagnosis of CRS with objective documentation of sinonasal inflammation using anterior rhinoscopy, nasal endoscopy, or computed tomography. The diagnosis CRS cannot be made based on signs and symptoms alone. CT of the paranasal sinuses should be obtained when endoscopic sinus surgery is considered or planned for patients with CRS.

American Rhinologic Society (ARS): In a position paper (2017), ARS stated that sinus ostial dilation is an appropriate therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by nasal endoscopy documenting sinonasal abnormality or mucosal thickening on computed tomography of the paranasal sinuses. This procedure may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (e. g., microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

Use Outside of the US

Acclarent Inc. received Conformité Européene (CE) marking approval of their first-generation balloon sinuplasty devices in February 2006. The XprESS multi-Sinus Dilation System received CE Marking in October 2010 (Hayes, 2016).

The National Institute for Health and Care Excellence (United Kingdom) (2008) guidance on balloon catheter dilation stated that the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis was supported by the evidence and raised no major safety concerns. The conclusion was based on case series, nonrandomized controlled trials and data registry (n=1036).

**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.

   2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

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<th>CPT® Codes</th>
<th>Description</th>
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<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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<tr>
<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>
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References


