BALLOON SINUS OSTIAL DILATION

Policy Number: 2016T0571C Effective Date: December 1, 2016

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Balloon sinus ostial dilation is medically necessary for treating chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) when all of the following are met:

• Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography (CT) scan. CT scan findings of chronic rhinosinusitis include one or more of the following:
  o Mucosal thickening,
  o Bony remodeling,
Bony thickening, or
- Obstruction of the ostiomeatal complex.
- Balloon sinus ostial dilation is limited to the frontal, maxillary or sphenoid sinuses.
- Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS).
- Balloon sinus ostial dilation is performed in persons older than 12 years of age whose symptoms persist despite medical therapy with one or more of the following:
  - Nasal lavage
  - Antibiotic therapy, if bacterial infection is suspected
  - Intranasal corticosteroids

**Balloon sinus ostial dilation is not medically necessary for treating nasal polyps or tumors.**
There is insufficient published clinical evidence to conclude that balloon sinus ostial dilation is safe and effective for treating nasal polyps or tumors.

**Balloon sinus ostial dilation is not medically necessary in children 12 years of age or younger.**
There is insufficient evidence to support the use of balloon sinus ostial dilation in the management of rhinosinusitis in children. Long-term, well-designed studies using appropriate controls are needed to determine the effectiveness of balloon sinus ostial dilation in this population.

**DEFINITIONS**

**Chronic Rhinosinusitis (CRS):** An inflammatory process that involves the paranasal sinuses and persists for longer than 12 weeks.

**Functional Endoscopic Sinus Surgery (FESS):** A minimally invasive, mucosal-sparing surgical technique utilized to treat medically refractory CRS with or without polyps or recurrent acute rhinosinusitis.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)</td>
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*CPT® is a registered trademark of the American Medical Association*

**DESCRIPTION OF SERVICES**

Patients who have persistent or chronic rhinosinusitis that has failed medical therapy may require surgery. Functional endoscopic sinus surgery (FESS) is an accepted procedure for chronic rhinosinusitis refractory to medical therapy. FESS is a minimally invasive technique in which the sinus air cells and ostia are opened and drained under direct visualization. Polyps and infected tissue can be removed at the same time (Stewart and Vaughn, 2010). Chronic rhinosinusitis is defined as rhinosinusitis lasting longer than 12 weeks (Rosenfeld et al., 2015; Peters et al., 2014).

Balloon sinus ostial dilation, also known as balloon dilation sinuplasty or balloon catheter sinusotomy, has been proposed as an alternative or an addition to traditional endoscopic sinus surgery. Several procedural approaches have been proposed for balloon sinus ostial dilation. The first type of approach is done through the nostrils by inserting a small balloon through a tube placed in the nasal cavity where the blocked sinus is located. Using fluoroscopic guidance, the balloon is gradually inflated to compress tissue and bone and widen the sinus. The balloon is then removed and an endoscope may be used to assess the width of the nasal passage. The second type of approach is the transantral approach which is done by creating a small entry point under the lip. The balloon catheter is then directly inserted into the target sinus. Potential advantages of sinus balloon catheterization include minimal mucosal damage, minimal
Levy et al. (2016) conducted a systematic review and meta-analysis to evaluate paranasal sinus balloon catheter dilation (BCD) in the treatment of chronic rhinosinusitis (CRS). Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines were utilized to identify English-language studies reporting patient outcomes following BCD for CRS. Primary outcomes included the impact of BCD on validated measures of quality of life and sinonasal opacification. The systematic review identified 17 studies for qualitative analysis. Studies generally included cases with limited disease based on radiographic opacification. Five studies contained extractable data for change in 20-Item Sinonasal Outcome Test (SNOT-20) 1 year following BCD, with significant improvement in self-reported quality of life. Five studies reported a significant change in paranasal sinus opacification following BCD. Two studies directly compared change in SNOT-20 between BCD and endoscopic sinus surgery, without demonstration of significant difference in outcome. Subgroup analysis found that change in SNOT-20 score was greater after BCD in the operating room than in the office. The authors concluded that current evidence supporting the role of BCD in CRS remains incomplete. According to the authors, long-term within-group improvements in quality-of-life and sinus opacification scores are demonstrated among a restricted adult population with CRS. The authors indicated that additional study is needed to further evaluate the role for BCD in specific settings and patient subgroups.

In a prospective, multicenter, randomized trial, Bikhazi et al. (2014) evaluated and compared 1-year outcomes from the REMODEL study between office balloon dilation and functional endoscopic sinus surgery (FESS). Adults with maxillary chronic rhinosinusitis (CRS), including those with anterior ethmoid disease, who failed medical management and were surgical candidates for FESS, underwent either standalone balloon dilation or FESS in a 1:1 randomization scheme and were followed through a minimum of 1 year. Sinonasal symptom improvement was assessed using the validated 20-item Sino-Nasal Outcome Test (SNOT-20) survey. Standardized effect sizes were computed to further assess clinical significance. Ostial patency rate, rhinosinusitis episode frequency, impact of sinus disease on activity and work productivity, and daily activity impairment due to chronic sinusitis were significantly improved in both groups. There were no complications and revision surgery rate was 2% in each arm through 1 year. The authors concluded that with 1-year follow-up, standalone balloon dilation is as effective as FESS in the treatment of CRS in patients with maxillary sinus disease with or without anterior ethmoid disease who failed medical therapy and met the criteria for medically necessary FESS.

Chandra et al. (2016) reported the final results from the REMODEL full-study cohorts and performed meta-analyses of standalone balloon sinus dilation studies to explore long-term outcomes in a large patient sample. Final outcomes from the REMODEL randomized trial, including a larger cohort of 135 patients treated with functional endoscopic sinus surgery (FESS) or in-office balloon dilation, were evaluated. One hundred thirty patients had 12-month data, 66 had 18-month data, and 25 had 24-month data. In addition, a meta-analysis evaluated outcomes from six studies including 358 standalone balloon dilation patients with up to 24 months follow-up. Outcomes out to 2 years from the REMODEL full-study cohort are consistent with 6-month and 12-month outcomes. In the meta-analysis of standalone balloon dilation studies, technical success was 97.5%, and mean 20-Item Sino-Nasal Outcomes Test scores are significantly and clinically improved at all time points. There are significant reductions in work/school days missed, homebound days, physician/nurse visits, acute infections, and antibiotic prescriptions. Mean recovery time is 1.4 days. Comparison of 12-month symptom improvements and revision rates between the REMODEL FESS arm (n = 59), REMODEL balloon dilation arm (n = 71), and pooled single-arm standalone balloon dilation studies (n = 243) demonstrated no statistical difference. The authors concluded that all outcomes are comparable between FESS and balloon dilation at all time points from 6 months to 24 months. Balloon dilation produces faster recovery, less postoperative pain, and fewer debridements than FESS. There is significant, durable benefit in a large series of 358 patients undergoing standalone balloon dilation.

Cutler et al. (2013) conducted a prospective randomized controlled study on patients with chronic rhinosinusitis (CRS) to test the hypotheses that symptom improvement after balloon dilation was non-inferior to functional endoscopic sinus surgery (FESS) and balloon dilation was superior to FESS for postoperative debridement. Adults with uncomplicated CRS of the maxillary sinuses with or without anterior ethmoid disease who met criteria for medically necessary FESS were randomized 1:1 to office balloon dilation or FESS and followed for 6 months. A minimum of 36

intraoperative bleeding, and minimal discomfort (Brown, 2006). Balloon sinus ostial dilation can be performed as a stand-alone procedure or with FESS. When performed with FESS, it may be referred to as a hybrid procedure.
patients per arm were required to test the hypotheses with 90% power. Symptom improvement using the validated 20-item Sino-Nasal Outcome Test (SNOT-20) survey, debridements, recovery outcomes, complications, and revision surgeries were compared between groups. Ninety-two patients (50 balloon dilation; 42 FESS) were treated. Mean SNOT-20 improvement was 1.67 ± 1.10 and 1.60 ± 0.96 in the balloon and FESS arms, respectively. Both groups showed clinically meaningful and statistically significant improvement and the balloon arm was non-inferior to FESS. The mean number of postprocedure debridement per patient was 0.1 ± 0.6 in the balloon arm versus 1.2 ± 1.0 in the FESS arm, with the balloon group showing superiority. Occurrence of postoperative nasal bleeding, duration of prescription pain medication use, recovery time, and short-term symptom improvement were all significantly better for balloon dilation versus FESS. No complications occurred in either group and one revision surgery was reported in each arm. The authors concluded that balloon dilation is non-inferior to FESS for symptom improvement and superior to FESS for postoperative debridement in patients with maxillary and anterior ethmoid disease. The authors stated that balloon dilation is an effective treatment in patients with uncomplicated CRS who meet the criteria for medically necessary FESS.

In a double-blind randomized controlled trial (Plaza et al., 2011), the efficacy and safety of balloon sinuplasty with the Relieva was compared with standard FESS with the Draf I procedure in 40 patients (median age 41.3 years) with chronic sinusitis of the frontal sinus in whom medical therapy had failed. All of the patients had nasal polyposis treated during surgery. The patients were randomly allocated in a 1:1 manner to balloon dilation of the affected frontal recess or to conventional frontal sinus drainage with a Draf I procedure. Both procedures were performed during FESS directed to the affected frontal sinus. The patients and the evaluating physician were blinded to the treatment arm. Before initiation of treatment, 6 patients dropped out or were excluded leaving 17 patients in each group. The patients were followed for 12 months. In both groups, a statistically significant reduction in the Lund-Mackay stage was obtained. Resolution of frontal sinus disease confirmed by computed tomographic scan seemed to be more common after balloon dilation, although this finding was not statistically significant. Permeability of the frontal recess was seen on endoscopy statistically more frequently after balloon treatment (73% versus 62.5%). Four patients needed revision surgery. No major complications were observed. The authors concluded that balloon dilation of the frontal recess is a relatively safe and effective tool in the management of chronic frontal rhinosinusitis after intensive medical treatment has failed.

In a prospective, nonrandomized controlled study, Ramadan and Terrell (2010) compared the efficacy and safety of Relieva balloon sinuplasty combined with adenoidectomy (n=30) with that of adenoidectomy alone (n=19) in 49 children (mean age 6.6 years, range 2-11) with chronic sinusitis that was refractory to medical therapy for ≥ 6 months. The patients were followed at regular intervals for up to 1 year. Twenty-four of the 30 (80%) patients in the Relieva + Adenoidectomy group showed symptom improvement at 1 year compared with 10 of 19 (52.6%) children in the Adenoidectomy Alone group. Two (6%) patients with hypoplastic sinuses failed balloon sinuplasty and required revision FESS. One patient was lost to follow-up, and another had no improvement in SN-5 scores. Three (15%) children who did not improve after adenoidectomy had balloon sinuplasty. Overall, the mean SN-5 score for all of the children decreased from a baseline value of 4.1 to 2.9 after surgery. In the Relieva + Adenoidectomy group, the mean SN-5 score decreased from 4.2 to 3.0 while in the Adenoidectomy Alone group, the score decreased from 3.8 to 2.9. A multivariate analysis that adjusted for age, sex, asthma, and CT score showed that the hybrid procedure was more efficacious than adenoidectomy alone. No major complications occurred in either treatment group. Further research with randomized controlled trials is needed to validate these findings.

Thottam et al. (2016) evaluated the 2-year post-operative outcomes of pediatric patients with chronic rhinosinusitis (CRS) treated with balloon catheter sinuplasty (BCS) and ethmoidectomy compared to functional endoscopic sinus surgery (FESS). Two-group, retrospective cohort study of 28 children with CRS was performed. Of these 28 participants, 15 were treated with traditional FESS (53.6 %) and 13 (46.4 %) underwent traditional ethmoidectomy with balloon sinuplasty. Pre-operative and 2-year postoperative total symptom scores and medications were compared. To examine the potential long-term differences in surgical outcomes and surgical procedure on symptom outcome, one-tailed Chi square analyses were employed. The mean age of the children examined was 9.3 and 61.9 % were male. Pre-operative symptomatology, medication and Lund Mackay scores were evaluated for both groups and no significant differences were identified. Overall, 73.3 % of children that underwent traditional FESS and 76.9 % of those who had BCS with ethmoidectomy reported significant long-term improvement in at least one of their pre-operative sinus complaints. According to the authors, this data suggests that both BCS with ethmoidectomy and traditional FESS are effective treatment options for uncomplicated CRS and result in long-term alleviation of core sinus complaints, as well as decreased sinus related medication use. The investigators indicated that larger prospective studies are needed to further evaluate these procedures.

In a prospective case-control study, Wang et al. (2015) evaluated the efficacy of sinus balloon catheter dilation (SBCD) on pediatric chronic rhinosinusitis (CRS). The study included a total of 79 patients, aged 7 to 12 years, with CRS resistant to medical therapy. Age, sex, and results of computed tomographic scan, SBCD (case group) or conservative treatment (control group), sinonasal-5 questionnaire (SN-5), and visual analog scale (VAS) were analyzed and compared. Data from 79 of 96 patients who had complete follow-up documents were statistically analyzed (42 boys;
In a prospective, multicenter study, Gould et al. (2014) assessed 1-year changes in sinonasal symptoms and health care use after office-based multisinus balloon dilation. Adults diagnosed with chronic or recurrent acute rhinosinusitis per the 2007 adult sinusitis guidelines were enrolled in this Institutional Review Board-approved study. Balloon dilation of the maxillary sinuses/ethmoid infundibula with or without frontal or sphenoid ostial dilation was performed in the physician’s office under local anesthesia. A total of 313 ostial dilations were attempted and 307 were successfully completed (98.1%) in 81 subjects. Mean procedure tolerance was 2.8 ± 2.2 (0 = no pain; 10 = severe pain). Clinically meaningful and statistically significant mean Sino-Nasal Outcome Test (SNOT-20) symptom improvement was observed at 1 and 6 months and sustained through 1 year. The Rhinosinusitis Symptom Inventory (RSI) treatment effect for all major rhinosinusitis symptoms was “large” and improvement in each was significant. Compared with the previous 1-year period, patients reported an average of 2.3 fewer acute sinus infections, 2.4 fewer antibiotic courses taken, and 3.0 fewer sinus-related physician visits after balloon dilation. No serious device or procedure-related adverse events occurred. One subject (1.3%) underwent revision surgery. The authors concluded that in-office, multi-sinus balloon dilation is safe, effective, and well tolerated. Patients reported significant reductions in both sinonasal symptoms and health care use after balloon dilation. Efficacy observed at 1 and 6 month follow-up was sustained through 1 year with a very low rate of revision surgery.

Karanfilov et al. (2013) conducted an Institutional Review Board (IRB)-approved, prospective, 14-center trial that included 203 patients requiring endoscopic sinus surgery (ESS) for medically refractory chronic sinusitis who underwent transnasal balloon sinus dilation (BSD) treatment in an office setting under local anesthesia. Safety, tolerability, technical success, clinical efficacy (20-item Sino-Nasal Outcome Test [SNOT-20]), and radiographic outcome (Lund-Mackay [LMK] score) of ESS with BSD in the office setting were assessed. Patients were followed at 2, 8, and 24 weeks. A total of 552 sinuses were dilated in 203 patients: 47.6% maxillaries, 45.5% frontals, and 6.9% sphenoids. Seventy-seven patients were revisions of prior ESS. The mean number of sinuses dilated per patient was 2.7. Technical dilation success was 93.3%, 90.5%, and 93.7% for maxillary, sphenoid, and frontal sinuses, respectively. SNOT-20 and LMK computed tomography (CT) scoring showed statistically significant improvement at 24 weeks and clinically significant improvement in quality of life. The procedure was reported as tolerable or highly tolerable by 82.3% of patients. There were 0.15 postoperative debridements per patient and the majority returned to normal activity within 48 hours. The authors concluded that performance of ESS with BSD in the office under local anesthesia is feasible, well-tolerated, safe, and effective. Twenty-four week follow-up demonstrates clinical and statistical improvement in patient quality of life and radiographic outcomes. Additional follow-up data were obtained by Sikand et al. (2015) who reported outcomes 1 year after office-based BSD. According to the authors, significant improvements in quality of life observed at 24 weeks were maintained 1 year post-surgery.

In a manufacturer-sponsored, multi-center review, Levine et al. (2008) (with declared affiliation) conducted a standardized retrospective chart review of 1,036 patients (3,276 sinuses) having functional endoscopic sinus surgery that included the use of balloon catheter instruments. All of the patients had a diagnosis of chronic sinusitis unresponsive to medical management and had undergone endoscopic sinus surgery. Sinus guide catheters, sinus guide wires, and sinus balloon catheters (from a single manufacturer, Acclarent) were used in the study. Patients were followed for an average of 40.2 weeks. Balloon catheters were used widely across the maxillary, frontal, and sphenoid sinuses. The revision rate was 1.3% of sinuses treated with balloon catheters. Of the patients treated with balloon catheters, 95.5% reported improvement of their sinonasal symptoms. In addition, 73.8% of patients were free of sinus infections in the follow-up period after treatment with balloon catheters. No major adverse events attributed to the balloon catheter were reported. The authors conclude that the use of balloon catheters to treat patients with chronic sinusitis appears to be relatively safe and effective.

Prince and Bhattacharyya (2016) conducted an analysis of adverse events related to balloon sinuplasty devices. The Open FDA program website of the FDA was queried for adverse events related to dilation of paranasal sinus ostia from January 2006 to December 2014. A total of 114 adverse events were identified, including patient injury (n=72), device malfunction (n=36), death (n=4), and unclassified (n=2). The most common injuries were orbital wall fractures (n=23), postseptal orbital injuries (n=22), preseptal orbital injuries (n=22), and skull base injuries (n=17). Two of the 4 deaths were attributed to the procedure: postoperative meningitis following a hybrid sinus procedure and surgeon error due to off-label use of device for frontal sinus trephination.

37 girls; mean [SD] age, 9.3 [1.7] years). Compared with the preoperative scores, the SN-5 and VAS scores in children with CRS who underwent SBCD with or without adenoidectomy were significantly lower at 3 months and at 1 year. Both SN-5 and VAS scores in the control group were significantly decreased at 3 months but not significantly changed at 12 months. The SN-5 and VAS scores in the SBCD group were significantly lower than those for controls at 3 months and at 1 year after surgery. By the 12-month SN-5 score evaluation, the rates of marked, moderate, and mild improvement were significantly better in the SBCD group (52% [22 of 42], 26% [11 of 42], and 14% [6 of 42], respectively) than in the control group (14% [5 of 37], 19% [7 of 37], and 11% [4 of 37], respectively). The authors concluded that the SBCD procedure is a safe and effective technique for pediatric CRS resistant to medical therapy. Further research with randomized controlled trials is needed to validate these findings.
In 2008, the National Institute for Health and Care Excellence (NICE) published guidance on balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. Evidence on the short-term efficacy of balloon catheter dilation was considered adequate without raising major safety concerns. NICE recommended that this procedure be performed by surgeons experienced in complex sinus surgery, and who have specific training in the procedure and the use of fluoroscopy. NICE advocated the publication of long-term outcomes to guide the future use of the technique. NICE noted that both patient selection and the selection of specific sinus(es) for treatment can be difficult (NICE, 2008).

**Professional Societies**

**American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)**

The AAO-HNS position statement, Dilation of Sinuses, Any Method (e.g., balloon) states the following (AAO-HNS, 2014a):

- Sinus ostial dilation (e.g., balloon ostial dilation) is an appropriate therapeutic option for selected patients with sinusitis. This approach 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.

In an AAO-HNS Statement on Reimbursement of Balloon Sinus Ostial Dilation, the AAO-HNS states that they support the use of a balloon as a tool in a standard approach to sinus ostial dilation along with other indicated endoscopic surgery. According to the AAO-HNS, surgical management for patients that have failed medical management has progressed from open surgical procedures to functional endoscopic sinus surgery (FESS) to balloon sinus ostial dilation (BSOD). The AAO-HNS states that sinus ostial dilation may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (e.g., microdebrider, forceps) (AAO-HNS, 2014b).

The AAO-HNS clinical pediatric chronic rhinosinusitis consensus statement concluded that “the effectiveness of balloon sinusplasty compared to traditional endoscopic sinus surgery for pediatric CRS cannot be determined based on current evidence” (Brietzke et al. 2014).

In a 2015 Clinical Practice Guideline (Update) for Adult Sinusitis, the AAO-HNS indicates that clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of chronic rhinosinusitis. Surgical management of CRS is not discussed “because of insufficient evidence (e.g., randomized controlled trials) for evidence-based recommendations” (Rosenfeld et al. 2015).

**American Rhinological Society (ARS)**

In a position statement released in 2015, the ARS states that sinus ostial dilation (e.g., balloon ostial dilation) is an appropriate therapeutic option for selected patients with sinusitis. This approach 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 (ARS, 2015).

**American Academy of Allergy Asthma and Immunology (AAAAI), the American College of Allergy Asthma and Immunology (ACAAI), and the Joint Council of Allergy Asthma and Immunology (JCAAI)**

In a practice parameter for the diagnosis and management of rhinosinusitis, the AAAAI, ACAAI, and JCAAI recommends that ostial dilation with a balloon should be considered in a small sub-segment of patients with medically unresponsive acute rhinosinusitis (ARS), primarily those with early or localized disease (strength of evidence D - directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence). According to the authors, there are different opinions regarding the extent of surgery that should be performed for chronic rhinosinusitis (CRS), ranging from a very minimal procedure or balloon dilatation of the affected ostia, to very complete opening of all the sinuses. The authors state that the standard teaching for the functional endoscopic approach is that the surgical procedure should extend beyond the margins of the ostiomeatal disease and the inflamed bony partitions should be removed. Although symptomatic improvement from balloon dilatation has been well documented, in general, patients selected for this approach have only minor disease, a significant proportion of which might be amenable to medical therapy alone. According to the authors, conclusions regarding long-term resolution of disease with minimal interventional approaches remain unproved. The authors state that it remains debatable whether balloon sinus ostial dilation is efficacious as an alternative to traditional functional endoscopic sinus surgery (FESS). In summary, balloon catheter technology has been shown as a safe method to dilate sinus ostia but no studies to date can conclude an advantage over FESS (Peters et al. 2014).

Regarding medical management for chronic rhinosinusitis, the AAAAI, ACAAI, and JCAAI indicate that the role of antibiotics in chronic rhinosinusitis CRS is controversial. For CRS associated with suspected bacterial infection, a longer duration of therapy beyond the usual 10 to 14 days is suggested; the choice of appropriate antibiotic therapy may need to consider the possible presence of anaerobic pathogens. Because CRS is an inflammatory disease, intranasal corticosteroids (INSs) are indicated for treatment. Other adjunctive therapy, such as intranasal...
antihistamines, decongestants, saline irrigation, mucolytics, and expectorants, might provide symptomatic benefit in select cases (Peters et al. 2014).

**American College of Radiology (ACR)**

The ACR Appropriateness Criteria for Sinonasal Disease states that computed tomography (CT) of the sinuses without contrast is the imaging method of choice in patients with recurrent acute sinusitis or chronic sinusitis, or to define sinus anatomy prior to surgery (ACR, 2012).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

The FDA classifies devices used for balloon catheter dilation for treating chronic sinusitis under product code LRC (instrument, ENT, manual surgical). This is a broad product code category that includes a variety of devices used in ear, nose, and throat surgeries (e.g., knives, hooks, injection systems, dilation devices). Additionally, this product code is 510(k)-exempt. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a “Device Listing” form; these records can be viewed in the Registration and Device Listing Database (search by product code, device, or manufacturer name). See the following website for more information: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). (Accessed August 24, 2016)

The Relieva Sinus Balloon Catheter® (Acclarent Inc.) is classified by the Center for Devices and Radiological Health (CDRH) as an ENT (ear-nose-throat) manual surgical instrument and regulated as a Class I device. Acclarent, Inc. received FDA approval for the Relieva Sinus Catheter® and the Relieva Sinus Guidewire® on August 18, 2006. This device is intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. Subsequent devices developed by Acclarent have also been granted 510(k) marketing clearance. These include the Relieva Spin Sinus Dilation System® approved in August 2011, and the Relieva Seeker Balloon Sinuplasty System® approved in November 2012. Balloon Sinuplasty™ is a trademarked term that describes the use of the Acclarent Relieva™ Sinus Balloon Catheter. See the following website for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061903.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061903.pdf). (Accessed August 24, 2016)

Entellus Medical, Inc. received FDA approval for the Entellus Medical RS-Series System™ on April 8, 2008. This device is intended to access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures. A modification was approved on June 27, 2008 to change the trade name to FinESS™ Sinus Treatment. See the following website for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf8/K081542.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/K081542.pdf). (Accessed August 24, 2016)

The XprESS Multi-sinus Dilation System was cleared by the FDA on November 20, 2015 for use to access and treat the maxillary ostia/ethmoid infundibula in patients aged ≥ 2 years and frontal ostia/recesses and sphenoid sinus ostia in patients aged ≥ 12 years using a transnasal approach. See the following for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf15/K152434.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/K152434.pdf). (Accessed September 19, 2016)


**Additional Products**


**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for balloon sinus ostial dilation used in the treatment of chronic rhinosinusitis. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed September 13, 2016)
REFERENCES

Academy of Otolaryngology Head and Neck Surgery (AAO-HNS). Dilation of sinususes, any method (e.g., balloon, etc.). 2014a.


**POLICY HISTORY/REVISION INFORMATION**

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<td>• Added reference link to policy titled Functional Endoscopic Sinus Surgery (FESS)</td>
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<td>• Updated definitions; added definition of “chronic rhinosinusitis (CRS)” and</td>
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<td>“functional endoscopic sinus surgery (FESS)”</td>
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<td>• Updated supporting information to reflect the most current description of</td>
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<td>services, clinical evidence, FDA information, and references</td>
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<td>• Archived previous policy version 2016T0571B</td>
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