

BALLOON SINUS OSTIAL DILATION

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[Instructions for Use](#) ⓘ

Table of Contents	Page
COVERAGE RATIONALE	1
DOCUMENTATION REQUIREMENTS	1
DEFINITIONS	2
APPLICABLE CODES	2
DESCRIPTION OF SERVICES	3
CLINICAL EVIDENCE	3
U.S. FOOD AND DRUG ADMINISTRATION	9
CENTERS FOR MEDICARE AND MEDICAID SERVICES ..	10
REFERENCES	10
POLICY HISTORY/REVISION INFORMATION	12
INSTRUCTIONS FOR USE	12

Related Commercial Policy
• Functional Endoscopic Sinus Surgery (FESS)
Community Plan Policy
• Balloon Sinus Ostial Dilation
Medicare Advantage Coverage Summary
• Nasal and Sinus Procedures

COVERAGE RATIONALE

Balloon sinus ostial dilation is proven and medically necessary when either of the following conditions is present:

- Chronic Rhinosinusitis which has lasted longer than 12 weeks with **all** of the following:
 - Persistence of symptoms despite administration of full courses of **all** of the following treatments:
 - Antibiotic therapy, if bacterial infection is suspected,
 - Nasal lavage, and
 - Intranasal corticosteroids
 - Chronic Rhinosinusitis of the sinus to be dilated is confirmed on a computed tomography (CT) scan with findings of one or more of the following:
 - Mucosal thickening
 - Bony remodeling
 - Bony thickening
 - Obstruction of the ostiomeatal complex
 - Opacified sinus
 - 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)
- Recurrent Acute Rhinosinusitis with four or more episodes per year with distinct symptom free intervals between episodes and **all** of the following:
 - Sinonasal symptoms, and
 - CT evidence of ostial occlusion and/or mucosal thickening in the sinus to be dilated

Balloon sinus ostial dilation is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:

- Nasal polyps or tumors
- All other conditions that do not meet the [above criteria](#)

DOCUMENTATION REQUIREMENTS

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Balloon Sinus Ostial Dilation	
31295	Medical notes documenting all of the following:

CPT Codes*	Required Clinical Information
31296 31297 31298	<ul style="list-style-type: none"> • History of illness • Recent physical exam • One of the following: <ul style="list-style-type: none"> ○ Chronic Rhinosinusitis including all of the following: <ul style="list-style-type: none"> ▪ Treatment: <ul style="list-style-type: none"> - Duration of treatment/medical therapy, if applicable - Nasal lavage - Antibiotic therapy, if bacterial infection is suspected - Systemic and/or topical steroids - Topical and/or systemic decongestants - Treatment of concomitant allergic rhinitis ▪ CT scan findings of one of the following: <ul style="list-style-type: none"> - Mucosal thickening, - Bony remodeling, - Bony thickening, or - Obstruction of the ostiomeatal complex - Opacified sinus ▪ Evidence that the sinusitis involves frontal, maxillary, or sphenoid sinuses ▪ Planned procedure: Include if the procedure will be part of a functional endoscopic sinus surgery (FESS) ▪ Additional testing, if applicable: <ul style="list-style-type: none"> - Endoscopically obtained cultures - Allergy testing - Peripheral eosinophil count - Immunodeficiency evaluation ○ Recurrent Acute Rhinosinusitis with 4 or more episodes per year of acute rhinosinusitis with distinct symptom free intervals between episodes; each episode needs to be diagnosed by a clinician

*For code descriptions, see the [Applicable Codes](#) section.

DEFINITIONS

Acute Rhinosinusitis (ARS): ARS is a clinical condition characterized by inflammation of the mucosa of the nose and paranasal sinuses with associated sudden onset of symptoms of purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both of up to 4 weeks duration (American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Clinical indicators for endoscopic sinus surgery for adults. 2012, Updated 2015).

Chronic Rhinosinusitis (CRS): An inflammatory process that involves the paranasal sinuses and persists for longer than 12 weeks (Rosenfeld et al., 2015; Peters et al., 2014).

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.

Recurrent Acute Rhinosinusitis (RARS): RARS is defined as four episodes per year of acute rhinosinusitis with distinct symptom free intervals between episodes (Rosenfeld et al., 2015).

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.

CPT Code	Description
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)

CPT Code	Description
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)

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DESCRIPTION OF SERVICES

Individuals 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. 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 navigation or endoscopic visualization, 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 intraoperative bleeding, and minimal discomfort. 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.

CLINICAL EVIDENCE

REMODEL Trial

Three studies (Cutler et al., 2013, Bikhazi et al., 2014, Chandra et al., 2016) reported on the REMODEL trial, a prospective, multicentre, non-inferiority, parallel, randomised clinical trial. The REMODEL trial compared functional endoscopic sinus surgery (FESS) with balloon dilation systems in adult patients with uncomplicated chronic sinusitis or recurrent acute sinusitis associated with maxillary sinus disease with or without anterior ethmoid sinus disease.

Cutler et al. (2013) reported the first 6 month results of the REMODEL trial. Adults with an uncomplicated sinusitis diagnosis (chronic or recurrent acute) of the maxillary sinuses 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 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 an uncomplicated chronic rhinosinusitis (CRS) diagnosis who meet the criteria for medically necessary FESS. The authors also state that in patients with more advanced inflammatory or sinonasal disease pathology including severe polyposis, Samter's triad, fungal sinusitis, hyperplastic sinusitis, ciliary dysfunction, obstructive septal deviation, obstructive lesions, facial trauma, or cystic fibrosis, tissue resection continues to be the standard of care because tissue remodeling by balloon dilation has yet to be proven in these populations and further studies are needed.

Bikhazi et al. (2014) evaluated and compared 1-year outcomes from the REMODEL study. 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 using the validated Work Productivity and Activity Impairment survey, complications, and revision rate were also compared between the two groups. Ninety-two patients (50 balloon dilation; 42 FESS) were treated and 89 (96.7%) completed 1-year follow-up. Both groups showed clinically meaningful and statistically significant improvement in mean overall SNOT-20 scores and in all four SNOT-20

subscales. The 1-year mean change in SNOT-20 after balloon dilation (-1.64) was non-inferior to FESS. The standardized effect size was large, showing clinically significant improvement for both interventions. Ostial patency was 96.7 and 98.7% after balloon dilation and FESS, respectively, and each group reported significant reductions in rhinosinusitis episodes (mean decrease, 4.2 for balloon dilation and 3.5 for FESS). Overall 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 is 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 meta-analysis included a subgroup analysis for patients with chronic rhinosinusitis (n=191) versus recurrent acute rhinosinusitis (n=52). Both groups experienced statistically significant and clinically meaningful improvements in mean SNOT-20 scores, with no significant difference between groups. The authors concluded that all outcomes are comparable between FESS and balloon dilation at all time points from 6 months to 24 months. According to the authors, balloon dilation produces faster recovery, less postoperative pain, and fewer debridements than FESS.

Other Clinical Trials

In a randomized, controlled study Sikand et al. (2019) evaluated 24-week outcomes for balloon sinus dilation (BSD) performed in-office (IO) with medical management (MM) as compared with MM only for recurrent acute rhinosinusitis (RARS) patients. Adults diagnosed with RARS were randomized to groups with BSD plus MM (n = 29) or MM alone (n = 30). Patients who received MM alone also received a sham BSD-IO procedure to blind them to group assignment. Patients were followed to 48 weeks posttreatment. The primary outcome was the difference between arms in change in Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks. Change in patient-reported quality of life (QOL), as measured by the CSS total score from baseline to 24 weeks, was significantly greater in the BSD plus MM group compared with the MM-only group. The authors concluded that BSD plus MM proved superior to MM alone in enhancing QOL for RARS patients. According to the authors, BSD plus MM should be considered as a viable treatment option for properly diagnosed RARS patients.

Kutluhan et al. (2018) compared the technique of balloon sinoplasty with the classical functional endoscopic sinus surgery method by considering the severity of chronic sinusitis on the same patient. A total of 61 chronic sinusitis patients was included in the study. Paranasal sinus tomography of the patients was taken and according to the Lund-Mackay scoring, chronic sinusitis levels were determined. Cases were divided into two groups: Group 1 (severe chronic sinusitis group) and Group 2 (mild chronic sinusitis). There was no statistically significant difference in the results of comparison of sinuses which underwent balloon sinoplasty and classical functional endoscopic sinus surgery in Group 2 after Lund-Mackay scores. However in Group 1, the results of the comparison of postoperative Lund-Mackay scores of the balloon sinoplasty and the classical endoscopic operation were statistically significantly lower than those of the face half operated with the classical functional endoscopic sinus surgery. The authors concluded that the success of balloon sinoplasty in patients with mild sinusitis is the same as in classic functional endoscopic sinus surgery. However, as the severity of sinusitis increases, the efficacy of balloon sinoplasty decreases.

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.

Minni et al. (2018) conducted a multicenter prospective randomized study to assess the validity and safety of balloon catheter dilation (BCD) vs. endoscopic sinus surgery (ESS) in symptomatological chronic rhinosinusitis of the frontal sinus enrolling a population of 102 adult patients (64 men and 38 women; overall 148 frontal sinuses studied) with non-polypoid chronic rhinosinusitis (CRS). The radiological (Lund-McKay CT scoring modified by Zinreich) and symptomatological results (SNOT-20 questionnaire) were analyzed. The population affected was divided in two groups, one with light/mild frontal CRS and the other with moderate/severe frontal CRS, based on radiological findings at Lund-Mackay modified by Zinreich score. Every group was divided in two subgroups; one used BCD and the other used traditional ESS. The results showed a not statistically significant difference between BCD and conventional ESS of the frontal sinus in patients with light/mild CRS and in patients with moderate/severe CRS at Lund-Mackay modified by Zinreich score. The same not statistically significant difference was observed comparing the results of SNOT-20 questionnaire in the group of light/mild frontal chronic rhinosinusitis. A statistically significant better outcome of SNOT-20 score was noted in patients with moderate/severe chronic rhinosinusitis that underwent BCD of frontal sinus compared to ESS.

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, randomised, non-blinded, controlled trial, Bizaki et al. (2016) evaluated and compared the clinical outcome of balloon sinuplasty and uncinectomy for patients suffering from isolated chronic rhinosinusitis of the maxillary sinus. The study included adult patients with symptomatic isolated chronic or recurrent rhinosinusitis without severe findings in the sinuses, as documented in the sinus' Computer Tomography scan and clinical examination, were randomised into two groups: uncinectomy and balloon sinuplasty. The variables in the study are the Sinonasal Outcome Test-22 (SNOT 22), acoustic rhinometry and rhinomanometry. These parameters were analysed preoperatively and postoperatively (after 3 and 6 months). Both balloon sinuplasty and uncinectomy significantly improved almost all the parameters of SNOT22, with no significant difference being found between these two groups. Based on rhinomanometry results, airway resistance decreased after treatment. Regarding adverse effects, balloon sinuplasty was significantly associated with a lesser risk of synechia. The authors concluded that both balloon sinuplasty and uncinectomy improved the quality of life and decreased upper airway resistance of patients with mild, isolated chronic or recurrent rhinosinusitis.

Koskinen et al. (2016) compared the long-term efficacy and satisfaction in CRS patients who had undergone maxillary sinus operation with either balloon sinuplasty or endoscopic sinus surgery (ESS) technique. Study patients were recruited from 208 CRS-patients who underwent either ESS or balloon sinuplasty. Patients with nasal polyposis (gradus ≥ 2), previous sinonasal surgery, unilateral disease, or immune deficiency were excluded. Altogether 45 patients in the ESS group and 40 patients in the balloon group were included. Of these, 30 and 28, respectively, answered to a phone interview held on average 6 years after primary surgery. Symptom reduction and long-term satisfaction were evaluated by using symptom scores of 19 parameters altogether. Both groups experienced improvement in symptoms and were equally satisfied with the operation. The number of patient-reported acute exacerbations was higher among the balloon dilated patients. Also, the reduction of thick nasal discharge was less evident in the balloon sinuplasty group. Four patients in the balloon sinuplasty group underwent revision surgery. There were no revisions in the ESS group. According to the authors, this is the first controlled study of balloon sinuplasty's long-term efficacy with the follow-up time over 5 years. The authors stated that both techniques retained the efficacy and patient satisfaction on average 6 years after the surgery.

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 followup 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 postsurgery.

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.

In a prospective, multicenter, single-arm investigation, Soler et al. (2016) conducted a study of children (2 to 21 years old) with chronic rhinosinusitis (CRS) treated with balloon sinus dilation, who had failed medical management and followed them to 6 months postprocedure. Fifty children were treated at 4 centers; 33 participants were 2 to 12 years old, and 17 participants were >12 to 21 years. A total of 157 sinus dilations were attempted and all were successful with no complications. The results showed significant improvement in the Sinus and Nasal Quality of Life Survey (SN-5) was seen for all children between baseline and 6 months and 92% improved by a minimal clinically important difference (MCID) of 1.0 or more. Those children aged 2 to 12 years with standalone balloon dilation also showed significant SN-5 improvements between baseline and follow-up. Multivariate regression analysis showed no differences or associations of SN-5 improvement at 6 months with the presence of allergy, asthma, or concomitant procedures. For adolescents, overall 22-item Sino-Nasal Outcome Test (SNOT-22) mean scores were also significantly improved at 6 months. The authors concluded that the results of this study show balloon sinus dilation to be safe, and appears effective for children with CRS aged 2 years and older.

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.

Liu et al. (2017) performed a prospective study that included 30 children with chronic rhinosinusitis who failed medical therapy, who were scheduled for treatment by balloon sinuplasty of selected sinuses. Data were collected, including age, visual analog scale (VAS) score, computed tomography (CT) score, and nasal endoscopy findings. The procedure was successful in 61/65 sinuses (93.84%). Balloon sinuplasty improved sinus-related quality of life scores as well as CT and endoscopic findings for up to 1 year after operation. In this initial study, balloon sinuplasty showed a clinical curative effect in the treatment of children with refractory chronic rhinosinusitis, and was relatively safe. Structural abnormalities in sinus ostia and hypoplastic sinuses may not be amenable to balloon catheter sinuplasty.

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; 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.

In a prospective single-blinded randomized controlled trial, Laury et al. (2018) evaluated if balloon catheter dilation of sinus ostia affects the severity or frequency of headache among patients who have barometric pressure-related sinus headache. Subjects with a diagnosis of sinus pressure headache without evidence of mucosal thickening on computed tomography were included in the study. Subjects were blinded and randomized to undergo balloon dilation of affected sinus ostia (active treatment) or balloon dilation in the nasal cavity (placebo). Two balloon devices were utilized (Acclarent and Entellus) and outcomes compared. Subjects were followed with pre- and postprocedure SNOT-22 scores (Sinonasal Outcome Test-22), HIT-6 scores (Headache Impact Test-6), and medication utilization logs for 6 months. There was no statistically significant difference in SNOT-22 or HIT-6 scores between the arms at any time point. However, both arms experienced statistically and clinically significant decreases in SNOT-22 and HIT-6 scores from preprocedure to 6 months postprocedure. There was no statistically significant difference in SNOT-22 or HIT-6 score reductions between the Entellus and Acclarent devices. There was no statistically significant difference in medication utilization between the groups at any time point. The authors concluded that subjects with sinus pressure headache without evidence of mucosal thickening on computed tomography had no significant difference in outcomes between active treatment (balloon dilation of sinus ostia) and placebo (nasal dilation). The authors indicated that further study on the etiology and effective treatment of barometric pressure related sinus headache is needed.

Marzetti et al. (2017) evaluated if balloon sinuplasty could be an option in the treatment of rhinogenic headache due to a probable disventilation of frontal sinus recess. A total of 107 patients were included in the study with diagnosis of rhinogenic headache. The surgical group underwent bilateral balloon sinuplasty of the frontal sinus. The medical group underwent pharmacological treatment. Headaches characteristics were evaluated by a clinical personal diary. The severity was recorded by Visual Analog Scale 4 and 8 months after treatment. Ninety-eight out of 107 patients completed the protocol. In surgical group and in the medical group, the mean headache score improved at four and eight months follow up. The headache frequency attacks per month decrease from a preoperative frequency of 18 (± 4 SD) in the surgical group and 17 (± 3 SD) in the medical group to 3 (± 1 SD). However, in both groups despite the improvement observed at 4 months follow-up, the authors observed a further worsening of symptoms at 8 months follow-up. The authors concluded that balloon sinuplasty should be considered as an effective alternative option after an accurate selection of surgical candidates. The findings of this study need to be validated by well-designed controlled studies with larger sample sizes.

In 2016, the National Institute for Health and Care Excellence (NICE) published guidance on XprESS multi sinus dilation system for treating chronic sinusitis. NICE indicated that the case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis is supported by the evidence. According to NICE, XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia (NICE, 2016).

Professional Societies

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

AAO-HNS developed a clinical consensus statement on the use of sinus ostial dilation (SOD) of the paranasal sinuses (Piccirillo et al., 2018). Due to limited evidence to support a guideline, the topic of SOD was selected for clinical consensus statement (CCS) development. An expert panel of otolaryngologists was assembled to represent general otolaryngology and relevant subspecialty societies. A modified Delphi method was used to distill expert opinion into clinical statements that met a standardized definition of consensus. After three Delphi method surveys, 13 statements met the standardized definition of consensus while 45 statements did not. Strong consensus was obtained for not performing SOD in patients without sinonasal symptoms or positive findings on computed tomography (CT) in patients with symptoms only of headache or sleep apnea without criteria for sinusitis. In addition, strong consensus was met that CT scan of the sinuses was necessary before performing SOD. Consensus was reached that SOD is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease or for patients who are without both sinonasal symptoms and positive findings on CT. Additional statements that reached consensus include the following:

- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps
- 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

As noted in the second consensus statement above, recurrent acute rhinosinusitis (RARS) may be considered an appropriate indication for SOD. The authors indicated that several prospectively collected database studies for SOD (Gould et al., 2014; Levine et al., 2013) included patients diagnosed with recurrent acute rhinosinusitis. According to the AAO-HNS consensus statement, these studies report improved sinonasal symptoms with balloon dilation, but they are limited by possible selection bias.

The AAO-HNS position statement, *Dilation of Sinuses, Any Method* (e.g., balloon) states the following (AAO-HNS, 2016):

- Sinus ostial dilation (e.g., balloon ostial dilation) is a 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 approach may be used alone to dilate an obstructed 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.

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

In 2015, the AAO-HNS updated the Clinical Practice Guideline (Update) for Adult Sinusitis. The AAO-HNS update group recommended that clinicians should confirm a clinical diagnosis of chronic rhinosinusitis (CRS) with objective documentation of sinonasal inflammation, which may be accomplished using direct visualization (anterior rhinoscopy or nasal endoscopy) or computed tomography (CT). CT may demonstrate abnormal mucosa and opacified sinuses. An important role of CT imaging in CRS is to exclude aggressive infections or neoplastic disease that might mimic CRS or acute rhinosinusitis (ARS). The AAO-HNS update panel indicated 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 Rhinologic Society (ARS)

The ARS states that sinus ostial dilation (e.g., balloon ostial dilation) is a 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 approach may be used alone to dilate an obstructed 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, 2017). This ARS position statement does not contain referenced clinical evidence.

American Academy of Allergy Asthma and Immunology (AAAAI)/ American College of Allergy Asthma and Immunology (ACAAI)/ 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 dilatation 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 dilation 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 (INs) 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 noncontrast sinus computed tomography (CT) is indicated for evaluation of recurrent acute sinusitis (RARS) prior to surgical intervention or objective confirmation in cases of chronic recurrent rhinosinusitis. The documentation of sinonasal inflammation may also be accomplished with anterior rhinoscopy or nasal endoscopy. CT scanning provides the best preoperative information for endoscopic surgery, with excellent delineation of the complex ethmoidal anatomy, ostiomeatal unit, and anatomic variations, including the presence of sphenoidal (Onodi) air cells, which increase the risk of injury to the optic nerves or carotid arteries (ACR, 2017).

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/cfRL/rl.cfm>. (Accessed May 30, 2019)

To view all 510(k) substantial equivalence summaries for ENT manual surgical instruments, search [Product Code: LRC] at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed May 30, 2019)

Additional Products

Acclarent Relieva FLEX[®] Sinus Guide Catheter, Acclarent[®] Balloon Inflation Device, Entellus Medical RS-Series System[™], Entellus FinESS[™] Endoscope, Entellus FinESS Sinus Treatment Kit, Entellus XprESS[™] Pro Multi-Sinus Dilation System, Lenio[®]flex System for Sinus Ostia Dilation, Medtronic NuVent[™] EM Balloon Sinus Dilation System, Medtronic Fusion[®] ENT Navigation System, Relieva Luma Sentry[™] Sinus Illumination System and Accessories, Relieva SCOUT[™] Sinus Dilation System, Relieva Seeker[®] Balloon Sinuplasty System, Relieva SIDEKICK[™] Low Profile Handles, Relieva SIDEKICK Sinus Guide Catheter Handles, Relieva Solo Pro[™] Sinus Balloon Catheter, Sinus Balloon Catheter, Relieva Solo[™] Sinus Balloon Catheter, Relieva Ultirra[™] Sinus Balloon Catheter, Relieva VIGOR[®] Sinus Guidewire, Relieva VORTEX[®] 2 Sinus Irrigation Catheter, Relieva[®] Spin Balloon Sinuplasty System, SinuSys AerOs[™] Sinus Dilation System, SinuSys Vent-Os[™] Sinus Dilation System, VENTERA[®] Sinus Dilation System, XprESS[™] LoProfile Multi-Sinus Dilation System, XprESS Ultra Multi-Sinus Dilation System, XprESS Multi-sinus Dilation System.

Medicare does not have a National Coverage Determination (NCD) for balloon sinus ostial dilation. Local Coverage Determinations (LCDs) do not exist at this time.
(Accessed June 6, 2019)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2019	<p>Coverage Rationale</p> <ul style="list-style-type: none"> • Simplified content • Revised list of conditions for which balloon sinus ostial dilation is proven and medically necessary: <ul style="list-style-type: none"> <i>Chronic Rhinosinusitis</i> <ul style="list-style-type: none"> ○ Replaced criterion requiring “symptoms persist despite <i>medical therapy with one or more</i> of the following: nasal lavage, antibiotic therapy (if bacterial infection is suspected), <i>or</i> intranasal corticosteroids” with “persistence of symptoms despite <i>administration of full courses of all</i> of the following <i>treatments</i>: antibiotic therapy (if bacterial infection is suspected), nasal lavage, <i>and</i> intranasal corticosteroids” ○ Updated criterion addressing clinical diagnosis; added “opacified sinus” to the list of findings (one or more) to be confirmed by a computed tomography (CT) scan <i>Recurrent Acute Rhinosinusitis</i> <ul style="list-style-type: none"> ○ Clarified language addressing frequency of recurrence; replaced “four episodes per year with distinct symptom free intervals between episodes” with “four <i>or more</i> episodes per year with distinct symptom free intervals between episodes” <p>Documentation Requirements</p> <ul style="list-style-type: none"> • Updated documentation requirements for Chronic Rhinosinusitis and Recurrent Acute Rhinosinusitis <p>Supporting Information</p> <ul style="list-style-type: none"> • Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information • Archived previous policy version 2019T0571F

INSTRUCTIONS FOR USE

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