Anthem

Clinical UM Guideline

Subject: Balloon Sinus Ostial Dilation
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Description

This document addresses the use of balloon sinus ostial dilation for surgery of the sinuses, including for the treatment of sinusitis. These procedures involve insertion of a balloon catheter device into a nasal sinus cavity to open blocked sinus ostia.

Note: Please see the following related documents for additional information:

- CG-SURG-18 Septoplasty
- CG-SURG-24 Functional Endoscopic Sinus Surgery (FESS)
- CG-SURG-57 Diagnostic Nasal Endoscopy
- CG-SURG-117 Balloon Dilation of the Eustachian Tubes
- MED.00091 Rhinophototherapy
- SURG.00089 Self-Expanding Absorptive Sinus Ostial Dilation
- SURG.00132 Drug-Eluting Devices for Maintaining Sinus Ostial Patency

Clinical Indications

Note: When Functional Endoscopic Sinus Surgery (FESS) is performed in conjunction with a procedure addressed in this policy, the criteria contained in CG-SURG-24 must be met for the FESS procedure.

Medically Necessary:

The use of balloon sinus ostial dilation is considered **medically necessary** when **all** of the following criteria have been met (A, B, C, and D):

A. Treatment is for uncomplicated sinusitis (for example, sinusitis confined to the paranasal sinuses without adjacent involvement of neurologic, soft tissue, or bony structures); **and**
B. Either of the following:
    1. Four or more documented episodes of acute rhinosinusitis (for example, less than 4 weeks duration) in 1 year; **or**
    2. Chronic sinusitis (for example, greater than 12 weeks duration);
    and
C. Maximal medical therapy has been attempted, as indicated by **all** of the following:
    1. Antibiotic therapy; **and**
    2. Trial of inhaled steroids; **and**
    3. Nasal lavage; **and**
    4. Allergy testing (if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy [for example, antihistamines or intranasal corticosteroids or leukotriene antagonists, etc.]);
    and
D. Abnormal findings from diagnostic work-up, as indicated by **any one** of the following:
    1. Computed tomography (CT) findings suggestive of obstruction or infection for example, but not limited to, air fluid levels, air bubbles, significant mucosal thickening, pansinusitis, or diffuse opacification; **or**
    2. Nasal endoscopy findings suggestive of significant disease; **or**
    3. Physical exam findings suggestive of chronic/recurrent disease (for example, mucopurulence, erythema, edema, inflammation).

Not Medically Necessary:

The use of balloon sinus ostial dilation is considered **not medically necessary** in all other circumstances not stated above, including the following:

A. The criteria above have not been met; **or**
B. The individual has been diagnosed with presence of sinonasal polyposis; **or**
C. The procedure is being used to treat the following conditions in the absence of CT-confirmed chronic sinusitis or recurrent acute sinusitis:
    1. Headache; **or**
    2. Sleep apnea.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium

31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia

HCPCS

	Note: this document applies to following HCPCS code only when the device is associated with a balloon ostial dilation procedure listed above
C1726	Catheter, balloon dilatation, non-vascular [when specified as a balloon sinus ostial dilation device]

ICD-10 Diagnosis

J01.01	Acute recurrent maxillary sinusitis
J01.11	Acute recurrent frontal sinusitis
J01.21	Acute recurrent ethmoidal sinusitis
J01.31	Acute recurrent sphenoidal sinusitis
J01.41	Acute recurrent pansinusitis
J01.81	Other acute recurrent sinusitis
J01.91	Acute recurrent sinusitis, unspecified
J32.0-J32.9	Chronic sinusitis

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses including, but not limited to the following:

ICD-10 Diagnosis

G43.001-G43.919	Migraine
G44.001-G44.89	Other headache syndromes
G47.00-G47.9	Sleep disorders
J33.1-J33.9	Nasal polyp
J34.1-J34.9	Other and unspecified disorders of nose and nasal sinuses
R51.0-R51.9	Headache

Discussion/General Information

Chronic sinusitis is defined as a prolonged or recurrent infection and inflammation of the nasal sinuses. Nasal sinuses are open spaces in the head connected by small passageways to the nasal passageways leading from the nose. Under normal conditions, air passes in and out of the sinuses and mucus and fluid drain from the sinuses into the nose.

Sinusitis occurs when there is infection or inflammation in one or more of the sinuses. Temporary or acute sinusitis is often associated with upper respiratory infections or irritation due to allergic reactions which cause temporary blockage of the passages leading from the sinuses. Blocked sinuses can accumulate nasal secretions and bacteria, leading to infection.

Chronic, long-term sinusitis may develop in people with chronic allergies, deviated nasal septum or other obstruction of the nose. Additionally, dental infections such as tooth abscesses may also spread into the sinus and infect it directly.

When sinusitis recurs frequently, or lasts for a prolonged period of time, it is classified as chronic. While acute sinusitis is usually caused by infection with a single type of bacteria or virus, chronic sinusitis is usually caused either by allergies or by infection with a mixture of different types of bacteria.

Chronic sinusitis may have less severe symptoms than acute sinusitis but can cause damage and destruction to the tissues of the sinuses. It may flare up spontaneously or may follow respiratory infections such as colds.

Treatment of chronic sinusitis usually involves the use of antibiotics if the infection is bacterial. Oral sinus decongestants are sometimes used as well. In more serious cases related to allergies, topical steroids in the form of nasal sprays may be helpful in controlling inflammation. Surgery to clean and drain the sinuses may be necessary to clear serious chronic infections. Finally, surgical repair of a deviated nasal septum or other nasal obstruction may prevent recurrence of chronic sinusitis.

Sinus surgery is commonly done with the use of thin fiberoptic tools that are passed through the nostrils. This method, referred to as endoscopic sinus surgery, allows visualization and manipulation of the surgical site without the need for surgical incisions in the mouth or face. Once the endoscopic tools are in place in the surgical site, small tools are used to obliterate the sinus tissue and bone to open the sinus passages.

A technique referred to as balloon sinus ostial dilation has been proposed as an alternative or addition to standard endoscopic surgery. This procedure proposes the use of a small balloon-like device instead of the other devices usually used. There are two different types of devices available on the market that dilate the sinuses. With one type of device, the balloon is placed in the blocked sinus passage under endoscopic guidance through the nostril. The other type is placed in the sinus through an incision made in the gums and maxillary bone under the front lip of the individual. In both cases, once the balloon is in place in the ostia of the targeted sinus, the balloon is inflated to push the sinus tissue and bone out of the way, creating a larger airway passage and allowing drainage of nasal secretions.

The U.S. Food and Drug Administration (FDA) has cleared several devices for the catheterization and balloon dilatation of the paranasal sinus ostia, a procedure known as balloon sinus ostial dilation, for the treatment of chronic sinusitis. These devices include the Acclarent Relieva™ Sinus Balloon Catheter (FDA clearance August, 2005 for transnasal use), the Entellus FinESS™ device (FDA clearance June, 2008 for transantral use), the Entellus XprESS® Multi-Sinus Dilation Tool (FDA clearance September, 2010 for transnasal use), the NuVEnt™ EM Sinus Dilation System (FDA clearance July, 2013 for transnasal use), and the Ventera® Sinus Dilation System (FDA clearance 2012 for transnasal use). In 2020, the Next Generation Balloon Dilation System (Acclarent, Inc., Irving, CA), an integrated balloon sinuplasty and eustachian tube dilation device, received 510(k) clearance. Balloon Sinuplasty™ is a trademarked term describing transnasal use of the Acclarent Relieva Sinus Balloon Catheter.

Specialty Society Recommendations

In 2017, the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) endorsed a position statement addressing the use of balloon dilatation. The statement says:

> Sinus 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 and evidence of 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 ([for example], microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

The AAO-HNS published a clinical consensus statement for balloon dilation of the sinuses (Piccirillo, 2018). This document published the following statement that reached consensus:

- 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.

In 2023 the American Rhinologic Society (ARS) published an updated position statement on ostial balloon dilation. This document reiterated the ARS's support for the use of sinus ostial dilation as a therapeutic option for selected individuals with CRS and RARS who have failed appropriate medical therapy.

Clinical Evidence

Initial studies in the literature was limited to small numbers with short-term follow-up (often less than 6 months). Chronic sinusitis is a complex and chronic illness which persists, often despite treatment, for years, and short term follow-up data does not allow conclusions as to whether a procedure benefits the individual treated. Where longer-term follow-up was reported, there was often a lack of concurrent comparison or other methodological concerns.

These early studies included the CLinical Evaluation to Confirm SAfety and Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR) Study (Bolger, 2007; Kuhn, 2008, and Weiss, 2008) which was a prospective multicenter case series study included 109 subjects with sinusitis treated with the Relieva device and followed for 6 months postoperatively. The authors reported a low revision rate and no serious complications. Self-reported data measured by the sino-nasal outcome test (SNOT-20) evaluation tool indicated significantly improved sinusitis symptoms, although only 77% (84/109) of subjects provided a complete set of data. Data presented evaluating the balloon-only group (n=49) vs. the combined approach group (n=57) found no significant differences between groups for symptom relief measures. At 1 year, endoscopy demonstrated that 85% of sinuses treated with Balloon Sinuplasty were still patent, 1% were not patent and 14% were indeterminate. Fourteen of the 26 subjects (53%) with indeterminate patency were found to have patent ostia on CT scans, for a clinical patency rate of 91.6%. At 2 years post-operation SNOT-20 scores were stable into year 2, which showed some durability of the benefits of the balloon procedure. However, methodological concerns, including small sample size, lack of a prospectively selected control group, no blinding, use of self-reported data, and significant loss to follow-up (23%), all negatively impacted the usefulness of this data.

The Balloon Remodeling Antrostomy Therapy [BREATHE I] study, on reported no serious adverse events or unexpected device effects. SNOT-20 scores were significantly improved and 95.8% of sinuses dilated continued to be patent at 3 months (Stankiewicz, 2009, 2010, 2011, and 2012). However, patency data was not reported at the 6-month follow-up visit. The Stankiewicz (2010) study reported the findings of the first 29 BREATHE I subjects to complete the 12-month trial period, all of whom had been successfully treated with the FinESS device alone. Significant improvements in SNOT-20 measures of rhinologic symptoms, ear and facial symptoms, sleep function and psychological issues were reported. Results on the Work Productivity and Activity Impairment (WPAI) and Work Limitations Questionnaire (WLQ) instruments, indicated significant improvements in all domains, including activity impairment, absenteeism, lost productivity, work output, and timeliness. At 2 years, the average symptom scores, as measured by the SNOT-20 tool, improved from 2.65 ± 0.97 at baseline to 0.79 ± 0.71 ($p<0.0001$). Gains seen on WPAI and WLQ instruments at 1 year continued to be significantly improved for all domains at 2 years. However, the BREATHE I study was an unblinded case series study with no control group for comparison and, only short-term patency data have been published. The lack of long-term patency data and the methodological flaws preclude generalization of the results.

Plaza (2011) published the results of a randomized controlled double-blind study involving subjects with frontal sinus disease who underwent either standard FESS with the Relieva device or combination FESS-balloon dilation. In addition to procedures to address sinus tract patency, participants also underwent septoplasty and/or partial middle turbinectomy, and polypectomy when indicated. The study began with a total of 40 subjects randomized, 20 to each group, but was completed with only 16 in each group (20% loss to follow-up). The study does not clearly describe how individuals were chosen for randomization or how individuals might have been eligible but not randomized. The main outcome measured was resolution of frontal sinus disease as shown by CT scan at 12 months. The authors reported that 80.76% of the operative balloon procedures were successfully conducted compared to 91.7% of control group procedures. No statistical significance data is available for this comparison. Significant improvement was noted in both groups in terms of Lund-Mackay score and Frontal sinus Lund-Mackay scores. Again, no statistical significance data is available between the two groups. Resolution of frontal sinus disease, as shown on CT scans, was 80.76% for the balloon group and 75% for the control group. This difference was not significantly different. However, the published report indicated in the abstract section that frontal sinus permeability was significantly better in the balloon group, and in the body of the results section they contradict this by stating that no significant difference was found. After initial publication, a letter to the editor was submitted making this point and, in response, the authors agreed and attributed the error to final editing (Lefevre, 2012; Plaza, 2012). This correction is important, as the erroneous statement in the Plaza abstract has been frequently cited as demonstrating the superiority of the balloon procedure. This study does not demonstrate that balloon sinus dilation is as good as standard FESS approaches, nor does it demonstrate that balloon sinus dilation is safer than existing techniques.

The ORIOS 2 study investigators also published results of a larger prospective case series study of 203 subjects (Karanfilov, 2012) who were separated into 3 cohorts treated with the Relieva device. As with the previously mentioned ORIOS study, SNOT-20 results indicated significant improvement at all time points (2 weeks, 8 weeks, 24 weeks; $p<0.001$). Lund-Mackay results were available for 110 subjects at 24 weeks, with improvements reported (6.9 ± 3.6 at baseline to 2.5 ± 3.0 at 24 weeks, $p<0.0001$). There were 6 revisions out of the total 203 subjects within the 24-week follow-up period (3.0%). The results of this study are promising, like those previously discussed. However, as with those studies, this study suffers from the same methodological flaws, lack of control group and randomization, subject selections bias, and short follow up period, thus long-term benefits are not demonstrated.

Other early studies have reported similarly beneficial outcomes, but were similarly limited by poor methodology (Albritton, 2012;

Brodner, 2013; Friedman, 2008; Heimgartner, 2011; Levine, 2008; Tomazic, 2013).

Cutler (2013) reported the results of the REMODEL study, a quasi-blinded non-inferiority RCT with 6 months follow-up. A total of 53 subjects were randomized to undergo FESS with maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy, and 52 subjects underwent balloon dilation of the maxillary sinus ostia and ethmoid infundibula only with either the XprESS or FinESS devices. Between randomization and the assigned procedures, 11 FESS subjects and 2 balloon subjects withdrew. One additional balloon subject was lost to follow-up after the procedure leaving 49 subjects in the balloon group and 42 in the FESS group. Uncinectomy was conducted on all FESS group subjects, with or without ethmoidectomy (n=42 with 80 maxillary uncinectomies; n=72 total and n=8 partial). Ethmoidectomy was conducted in 22 of the 42 FESS subjects. The authors reported that both groups had statistically and clinically significant improvements in the SNOT-20 scores at 6 months with no significant differences between groups, demonstrating non-inferiority ($p<0.0001$). Clinically significant was defined as SNOT-20 change of ≥ 0.8 units based on Piccirillo (2002). There was a significant difference between groups with regard to postoperative debridements, with 4 balloon subjects and 31 FESS subjects requiring debridements. The mean number of debridements in the FESS group was 1.2 ± 1.0 vs. 0.1 ± 0.6 in the balloon group ($p<0.0001$). Use of postoperative pain medications was less in the balloon group vs. the FESS group as well (0.9 vs. 2.8 days, $p<0.001$). No significant complications were reported for either group. While this study does provide information about postoperative debridement and pain management, the relatively short 6-months follow-up is not sufficient to address whether there are long-term benefits of the procedures performed.

Levine (2013) reported the results of a prospectively enrolled case series study of 74 individuals with CRS –or RARS –of the maxillary sinus or ethmoid infundibula who were treated with the FinESS device in the office setting after failure of medical management (antibiotics for at least 3 weeks and oral or intranasal steroids). Results were reported for 69 subjects (4% lost to follow-up) at 1 year. Overall technical success of ostia cannulation was 91.9%; and symptom scores measured by SNOT-20 ($p<0.0001$). Nasal steroid and antibiotic use decreased in both groups. Days of work missed, homebound days, the number of physician visits and acute infections were also significantly improved compared to baseline. Persistent mild numbness in the tissue around the canine fossa was reported in 5 (6.8%) subjects. The surgical revision rate was 5.8%, with 4 subjects continuing to have standard FESS due to persistent radiographic signs of maxillary and/or ethmoid sinus disease.

In the first report on the use of the Ventera Sinus Dilation System, Hathorn (2014) described a single-blind RCT involving frontal sinusotomy in 30 subjects. This paper does not describe how subjects were referred into the study, raising the possibility of referral bias. The authors do not describe the pretreatment condition or prior treatment of the subjects which limits generalizability. Randomization involved assignment of either the left or right sinus ostia to undergo treatment with standard FESS or a hybrid FESS-balloon procedure. The contralateral sinus underwent the other treatment option. The primary outcome measure was sinus ostial patency at 3 months by direct visualization. Although the methods section states that the clinician making the postoperative evaluations was not aware of group assignments, the discussion section states that the evaluation of patency was made by a single clinician who was also the surgeon. No significant differences were reported between groups with regard to ostial patency at the 5-week and 3-month time periods. The report claims that both operative times and blood loss were statistically better in the hybrid group; however, the mean values for each parameter were within the 95% confidence limits in each treatment arm. Primary data are not presented for validation of statistical significance. The clinical significance of these differences is questionable. The average operating time for the hybrid procedure is reported to be 243 seconds less than the FESS procedure. Average blood loss for the hybrid procedure was 58 cc vs. 91 cc for FESS. The blood loss difference calculation is confounded by the fact that the decision of which procedure to do first was not completely random. Blood loss for the second procedure may have included some continued oozing from the first treated side. The study randomized which side would receive the hybrid or FESS procedure. The intent was to always start with the left side, but in fact the surgeons would start on the least obstructed side. The authors do not include data to show how often FESS was the second procedure done. At 1-year postoperative follow-up, 22 of the original 30 subjects were available (73%), and patency was noted to be 100% for both groups (no difference between groups). No revision surgeries were reported. Of the 30 subjects, 12 (40%) were reported to have nasal polyps. A subgroup analysis found that there were no significant differences in ostial patency between subjects with and without polyps.

One-year follow-up data from the REMODEL study was published by Bikhazi in 2014. Complete data were available for 82 of the original 92 subjects (96.7%; n=48 balloon group, n=41 FESS group). The mean improvement in SNOT-20 scores at 1 year was -1.64 ± 1.06 in the balloon group and -1.65 ± 0.94 in the FESS arm ($p<0.001$ for both groups). The authors reported that no significant between-group differences were found on any of the four subscales on the SNOT-20 tool, demonstrating the non-inferiority of the stand-alone balloon procedure (p=NS [not significant] for all scales). Similarly, both groups demonstrated statistically significant improvements in rhinosinusitis symptoms ($p<0.001$) and no differences were found between groups (p=NS). A total of 47 balloon subjects (97.9%) and 41 FESS subjects (100%) had data available on maxillary ostial patency. Overall patency assessed by CT scanning was reported to be 96.7% in the balloon group and 98.7% in the FESS group (p=NS). Patency data from the ethmoid infundibula was not provided. The study also measured work productivity using the WPAI score. Subjects in each of the treatment arms saw statistically significant decreases in daily activity impairment, percent of impairment while working, and overall work impairment. There were no statistical differences between groups in WPAI measures. The authors further reported the 18-month follow-up results for the first 45 subjects treated in the REMODEL study. Of the initial 45 subjects, data was available for 43 (95.5%; n=22 balloon group, n=21 FESS group). It was reported that the previously reported improvements in the SNOT-20 tools were sustained ($p<0.0001$), and there continued to be no difference between groups (p=NS).

Chandra (2015) reported the final 2-year follow-up data for the 71 balloon group and 61 FESS group subjects (total n=135) included in the REMODEL study described above. Complete 24-month data was available for 20.3% (15/74) of balloon group subjects and 16.4% (10/61) of FESS subjects, for an overall loss to follow-up of 88.8%. In the subjects available at 24 months, the balloon group had significantly shorter recovery time (1.7 vs. 5.0 days, $p<0.001$), less nasal bleeding after discharge (32% vs. 56%, $p=0.009$), and shorter duration of post-operative pain medications use (1.0 vs. 2.8 days, $p<0.001$). The primary outcome of the number of post-operative debridements was significantly lower in the balloon group (0.2 vs. 1.0, $p<0.001$). Additional 1-year data was provided beyond that published by Bikhazi, indicating that there were no significant differences between groups in acute exacerbations of rhinosinusitis ($p=0.258$). The authors reported that the balloon procedure was non-inferior to FESS with regard to 2-year SNOT-20 scores ($p<0.001$). No significant differences between groups were reported with regard to overall revision rates or complication rates. As with the previously described studies, the results are promising. However, this trial had a very large loss to follow-up of almost 90% at 24 months. These results do not provide substantial or robust data sufficient to demonstrate the mid-term durability of balloon sinus ostial dilation.

The Chandra paper also included a meta-analysis of stand-alone balloon procedures. Data was presented from pooled case series studies as well as controlled studies. The analysis included data from six trials, all of which are addressed in this document, accounting for a total of 358 subjects. With the exception of the REMODEL study, all included trials were single arm studies with no comparator groups. The majority of the trials had a maximum follow-up of 12 months. Only the REMODEL trial had a longer follow-up. They reported good 12-month follow-up data, with 93% of subjects having data available. Technical success for the pooled data was 97.5%, and overall SNOT-20 mean change was significantly improved from baseline. The authors reported finding statistically significant improvements with regard to results from the Work Limitation Questionnaire (data from two studies, no p-value data provided) and as well as from the Rhinosinusitis Symptom Inventory (data from 160 subjects) ($p<0.001$). Subgroup analysis for

subjects with chronic rhinosinusitis (n=291) vs. recurrent acute rhinosinusitis (n=52) was conducted. No significant differences were reported, but both groups did demonstrate significant improvements on SNOT-20 scores (p<0.001). Similar findings were reported for subjects with and without ethmoid disease (p<0.001). As stated earlier, the lack of comparison groups, short follow-up, lack of blinding, and other methodological flaws impairs the value of this data.

Sikand and others reported the 1-year results of the ORIOS 2 study (2015), including data from 122 subjects who volunteered for extended follow-up (mean 1.4 years). The authors reported a mean SNOT-20 reduction of -1.1, which they state is both statistically (p<0.001) and clinically significant. Of the total subject population, 61 subjects had ethmoid disease. SNOT-20 scores did not differ significantly between the ethmoid and non-ethmoid groups at 1-year follow-up. A total of 7.3% (9/122) subjects underwent revision surgery due to recurrence, 8 of whom had ethmoid disease. Radiographic evaluation was conducted in 7 of the ethmoid subgroup subjects at 24 weeks, with 5 having residual ethmoid disease and 2 with none.

Levy and colleagues reported the results of a meta-analysis of 11 RCTs meeting their inclusions criteria (2016). They observed that potential conflicts of interest were identified in 10 of the 11 studies included in their analysis. The authors identified five studies containing extractable data regarding change in SNOT-20-scores 1 year following the balloon procedure, with significant improvement in self-reported quality of life (p=0.04). Additionally, another five studies were reported to have a significant change in paranasal sinus opacification following balloon ostial dilation (p<0.001). Only two studies were reported to have directly compared change in SNOT-20 between the balloon procedures and endoscopic sinus surgery. Neither demonstrated a significant difference in outcomes (p=0.07). Finally, a subgroup analysis was conducted that identified that the change in SNOT-20 score was greater after balloon procedures in the operating room than in the office (p=0.004). Overall, the authors concluded that the current evidence supporting the role of balloon sinus ostial dilation for chronic rhinosinusitis remains incomplete. Long-term within-group improvements in quality-of-life and sinus opacification scores are demonstrated among a restricted adult population with CRS, but additional study is needed to further evaluate the role for this technology in specific settings and participant subgroups.

In 2016, Payne and others published the results of a nonrandomized controlled trial involving 198 subjects with chronic rhinosinusitis. Subjects self-selected to receive continuing medical management (n=52) or treatment with balloon ostial dilation (n=146) and followed for 24 weeks post-procedure. The medical management arm did not have a proscribed regimen, which was left to the discretion of the treating physician. The balloon procedures were done either in the operating room (n=41) or in the office (n=105), again at the discretion of the treating physician. The authors reported that the study was stopped early following an interim analysis indicating the superiority of the balloon procedure. Technical success of the dilation procedure was reported to be 97.6%. At 24 weeks, improvements in SNOT-20, RSDI, and Chronic Sinusitis Survey (CSS) measures were all significantly better in the balloon group (p=0.002, p<0.001, and p=0.001, respectively). As with the other studies described above, the findings reported by Payne indicate significant benefit to the balloon procedure. However, it should be noted that these findings are impaired by the weak methodology utilized, including non-random assignment, no blinding, short follow-up times, and more.

Koskinen and others (2016) published the results of a retrospective-prospective, nonrandomized or blind controlled trial involving 208 subjects older than 13 years of age with bilateral maxillary sinus disease who underwent either FESS involving bilateral partial uncinectomy and middle meatal antrostomy (n=105) or balloon sinus dilation of the maxillary sinuses with the Relieva device (n=103). Subjects were identified through record review and contacted by phone at a mean of 6 years for FESS subjects and 6.4 years in the balloon group. The phone interview involved a questionnaire addressing the subject's medical history, smoking habits, occupational exposure, family history, number of sinusitis episodes in the past year, use of nasal steroids, and recent nasal lavage treatments. The FESS group was reported to begin the study with significantly lower Lund-Mackay scores on the right side. The authors reported that the number of episodes of acute sinusitis, thick nasal discharge and right sided nasal blockage were significantly improved in the FESS group vs. the balloon group. However, no differences were found in nasal symptom score (p>0.05). No significant differences between groups were reported with regard to maxillary lavage or antibiotic courses for acute sinusitis. The overall number of subject-reported episodes of acute sinusitis were significantly decreased in the FESS group (p<0.01). Revision procedures were conducted in 4 balloon group subjects and no FESS group subjects (p=0.048).

Chaaban and colleagues (2018) reported the results of a retrospective cohort study involving data from the Clinformatics Data Mart (CMD) database involving data from 16,040 subjects aged 7 to 65 year diagnosed with CRS and treated with FESS alone (n=11,955), balloon sinus dilation alone, (n=2,851) or hybrid FESS-balloon sinus dilation (n=1,234) procedures. Data from 2012-2014 were analyzed. They reported that during the first postoperative 6 months the balloon-only group had a complication rate of 5.26% vs. 7.35 for FESS-only group (no p-values provided). Revision rates for the same timeframe were 7.89% for the balloon-only group, 16.5% for the FESS–only group and 15.5% for the hybrid group (no p-values provided). The authors reported that FESS was associated with an almost 4-fold increase in risk of revision procedures (OR, 3.8). Complications included orbital complications (2.95% in the balloon-only group vs. 3.47% in the FESS-only group), bleeding (2.03% vs. 3.46%, respectively), and skull base/CNS complications (0.35% vs. 0.39%, respectively. Skull base injuries included pneumocephalus and CSF leaks. The rate of secondary procedure was 0.91% for balloon-only vs. 1.40% for FESS-only subjects. The authors concluded, despite the low overall risk, major complications do occur with balloon-only procedures, including cerebrospinal fluid leak, pneumocephalus, orbital complications, and severe bleeding.

Long term results from the Payne (2016) mentioned above were reported by Stolovitzky in 2018. At 52 weeks data were available for 122 (83.6%) of balloon group subjects and 27 (51.9%) of the control medical management group. Improvements in SNOT-20 symptom score, RSDI, and Chronic Sinusitis Survey (CSS) measures were all significantly better in the balloon group (p=0.023, p=0.003, and p=0.001, respectively). As with the other studies described above, the findings reported by Payne indicate significant benefit to the balloon procedure. However, as noted above these findings are impaired by the weak methodology utilized, as well as significant loss to follow-up in both the experimental and control groups.

Another study reported by Kutluhan and others (2020) described a split-face randomized controlled study involving 61 subjects with mild to severe CRS. Subjects with bilaterally consistent mild/mild (Lund-Mackay score ≤ 6) or severe/severe (Lund-Mackay score ≥7) RCS had each side randomly treated with Balloon-only of FESS-only procedures. Follow-up occurred between 13 and 17 months. The results indicated that overall, there were no significant differences in Lund-Mackay scores between the balloon and FESS groups (p=0.24). Similarly, no significant differences in Lund-Mackay scores were reported between treatment groups in subjects with mild CRS (p=0.63). For subjects with severe disease, Lund-Mackay scores were significant better in the FESS group (p=0.01). The authors concluded that for mild CRS, balloon and FESS procedures provide similar outcomes. However, as RCS severity increases the efficacy of balloon procedures decreases.

Balloon Sinus Ostial Dilation in Children

In 2014, Brietzke and others published a clinical consensus statement regarding the management and diagnosis of pediatric chronic rhinosinusitis (PCRS). The document included three statements, statements 28 through 30, specifically discussing balloon sinuplasty.

> Consensus was reached that there was insufficient current evidence to compare balloon sinuplasty to ESS for PCRS (statement 28). Not unexpectedly, the panel subsequently could not reach consensus regarding the effectiveness of balloon sinuplasty in treating PCRS although there was near consensus (mean Likert score = 6.56) regarding the safety of balloon

sinuplasty…

Soler (2017) reported the results of a prospective cohort study of 50 (157 sinuses) children (< 21 years of age) with medically refractory, CT-confirmed CRS treated with balloon sinus dilation with the XprESSS Multi-Sinus Dilation system. Subjects' parents were asked to complete the Sinus and Nasal Quality of Life Survey (SN-5) and SNOT-22 survey tools at 1, 3, and 6 months postoperatively. Overall follow-up was 99%. The SNOT-22 tool was only given to subjects greater than or equal to 12 years old. A total of 157 sinus dilations were attempted (98 maxillary, 30 frontal, and 29 sphenoid sinuses). The authors reported that all attempts (100%) were successful with no complications noted. Bilateral treatment was conducted in 92% of subjects. Concurrent procedures were conducted in 30 subjects, including adenoidectomy (n=21), inferior turbinate reduction (n=13), and ethmoidectomy (n=6). No serious adverse events or revision procedures were reported. Significant improvements were reported on the SN-5 tool for all subjects at 6 months vs. baseline ($p<0.0001$). A minimal clinically important difference (MCID) of 1.0 or more was reported in 92% of subjects. Subjects aged 2 to 12 years with balloon-only treatment demonstrated similar improvements between baseline and 6 months ($p<0.0001$). For subjects aged 12 to 21, SNOT-22 mean scores were also significantly improved at 6 months ($p<0.0001$). The authors concluded that, "Balloon sinus dilation is safe and appears effective for children with CRS aged 2 years and older."

Jia and colleagues (2020) reported the 3-year follow-up results of a prospective study of 30 (65 sinuses) children (6 to 15 years of age) with 3 to 6 months of failed medical management for CRS treated with balloon sinuplasty. Outcomes were measured using a VAS for subjective symptoms, assessment of quality of life using the SN-5 (< 12 years of age) or SNOT-22 (≥ 12 years of age), and CT findings graded using Lund-Mackay scoring system. If the SN-5 was used at baseline, it was used again at follow-up for consistency of measurement. Other data collected included reports on the use of nasal medications and irrigation, revision surgeries, assessment of adverse events, and a short survey assessing degree of satisfaction with the procedure. The VAS and SN-5 or SNOT-22 scores were all reported to be significantly lower ($p<0.001$) at 3-year follow-up. The authors reported that post-procedure Lund-Mackay scores were significantly lower ($p=0.028$) compared to baseline. Participants with a significant improvement in symptoms at the time of 3-year follow-up were not reexamined by CT. However, criteria for that determination were not provided. The most common post-procedural complication was nasal cavity adhesion. Three cases were identified at 15 to 30 days after surgery and two cases were identified at 3-years post-procedure. One participant had several complications that led to a revision surgery by FESS in the second year after the balloon procedure and was excluded from further follow-up. The authors also reported that most participants did not require post-procedure nasal medication for symptom management and that 29 of 30 participants were satisfied with the procedure. Some limitations of this study include a small sample size, non-randomized design, and lack of comparison group.

Conclusion

Overall, the number of studies addressing the use of sinus ostial dilation continues to grow. While the quality of the data remains low, there is growing consensus in the otolaryngological practice community that the use of balloon sinus ostial dilation provides significant benefits over FESS in terms of postoperative pain, blood loss and loss of work, while delivering similar health outcome benefits. While questions of long-term outcomes remain, the use of this procedure is reasonably safe and effective when used in appropriately selected populations. The use of this procedure for the treatment of individuals with polyposis, headaches, sleep apnea is as of yet unclear.

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Relieva Sinus Inflation Device
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Relieva Spin Sinus Dilation System®
Sinusitis
XprESS Multi-Sinus Dilation Tool

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting of the Clinical Indications section. Updated Description, References, and Websites sections.
Reviewed	05/12/2022	(MPTAC) review. Updated Discussion, References, and Websites sections.
Reviewed	05/13/2021	MPTAC review. Updated Description, Discussion, References, and Index sections. Reformatted Coding section.
	10/01/2020	Updated Coding section with ICD-10-CM diagnosis codes considered NMN; including 10/01/2020 coding updates R51.0-R51.9.
Reviewed	05/14/2020	MPTAC review. Updated Rationale and References sections.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; revised descriptors.
Reviewed	06/06/2019	MPTAC review. Updated Rationale and References sections.
Revised	07/26/2018	MPTAC review. Removed MN criteria text related to time limit for antibiotic therapy for uncomplicated sinusitis. Updated References sections.
New	03/22/2018	MPTAC review. Initial document development. Moved balloon ostial dilation related content from SURG.00089 Balloon and Self-Expanding Absorptive Sinus Ostial Dilation to new clinical utilization management guideline document.
