Balloon Sinus Ostial Dilation (for Tennessee Only)

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Instructions for Use

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Related Policies

- Functional Endoscopic Sinus Surgery (FESS) (for Tennessee Only)
- Rhinoplasty and Other Nasal Procedures (for Tennessee Only)

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

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

- Chronic Rhinosinusitis which has **all** of the following:
  - Lasted longer than 12 weeks
  - Persistence of symptoms despite medical management with administration of full courses of **all** of the following treatments:
    - Intranasal corticosteroids (and/or oral corticosteroids when appropriate); and
    - Antibiotic therapy if bacterial infection is suspected; and
    - Nasal lavage/irrigation if appropriate
  - Confirmation of Chronic Rhinosinusitis on a Recent Computed Tomography (CT) Scan for each sinus to be dilated meeting **all** of the following criteria:
    - CT images are obtained after completion of medical management; and
    - Documentation of which sinus has the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and
    - CT findings include one or more of the following:
      - Bony remodeling
      - Bony thickening
      - Opacified sinus
      - Ostial obstruction (outflow tract obstruction) and mucosal thickening
  - Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis
  - The balloon sinus ostial dilation limited to the frontal, maxillary, or sphenoid sinuses
  - The balloon sinus ostial dilation performed as either a stand-alone procedure or part of Functional Endoscopic Sinus Surgery (FESS)

- Recurrent Acute Rhinosinusitis with **all** of the following:
  - Four or more episodes per year with distinct symptom free intervals between episodes; and
  - Recent Computed Tomography (CT) Scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated; and
  - Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis

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

- Nasal polyps or tumors
- Cases of CRS or RARS that do not meet the criteria above

Self-expanding absorptive sinus ostial dilation is unproven and not medically necessary for evaluating or treating sinusitis and all other conditions due to insufficient evidence of efficacy.

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: Endoscopic Sinus Surgery, Adult. 2012, Updated 2021).

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 (Homsi and Gaffey, 2022).

Modified Lund-Mackay Scoring System: A tool used to quantify the severity of Chronic Rhinosinusitis based on computed tomography (CT) scan findings. The Lund-Mackay System was modified by Zinreich by increasing the scale from 0 to 5. In the modified Lund-Mackay System, each sinus is assigned a score based on the percentage of opacification from mucosal thickening as follows: 0 = 0%, 1 = 1% to 25%, 2 = 26% to 50%, 3 = 51% to 75%, 4 = 76% to 99%, and 5 = 100% or completely occluded. The ostiomeatal complex is given a score of 0 to 2, depending on whether it is completely patent, partially obstructed, or completely obstructed. Each side is graded, and their sum is the total score out of maximum of 54 (Likness et al., 2014).

Recent Computed Tomography (CT) Scan: For the purpose of this policy, a CT scan is considered recent when performed within 12 months of the planned procedure.

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 federal, state, or contractual requirements 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 Guidelines may apply.

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

CPT Code	Description
31296	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia
31299	Unlisted procedure, accessory sinuses

Description of Services

Individuals who have persistent or Chronic Rhinosinusitis that has failed medical therapy may require surgery. Chronic Rhinosinusitis is defined as rhinosinusitis lasting longer than 12 weeks (Rosenfeld et al., 2015; Peters et al., 2014). 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.

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 ostium or outflow tract. 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.

Self-expanding absorptive sinus ostial dilation has been proposed as an alternative to standard balloon sinus ostial dilation. The self-expanding device is inserted into the sinus ostia and starts absorbing moisture and begins to expand providing gradual dilation of the sinus ostia. When the device is fully expanded, it is removed. The SinuSys Vent-OS Sinus Dilation System is a self-expanding device that has been cleared by the FDA. These devices are being studied to determine their safety and effectiveness.

Clinical Evidence

In a 2022 systematic review and meta-analysis, Sinha et al. compared the outcomes of balloon sinus dilation (BSD) to functional endoscopic sinus surgery (FESS) or medical management for chronic rhinosinusitis (CRS). Randomized or observational studies that included adults aged 18 and over with chronic or recurrent sinusitis that reported BSD outcomes and had traditional FESS, no treatment, or medical therapy as the comparator were included. Change in Sinonasal Outcome Test (SNOT)-20 score was the most common primary outcome. BSD alone was the intervention in 6 of 9 RCTs (including the Plaza 2011, Cutler 2013 and Bizaki 2016 studies previously included in this policy), and of 2 of 9 cohort studies (including the Koskinen 2016 study previously included in this policy), with the remainder consisting of BSD with additional procedures such as septoplasty, turbinectomy, uncinectomy and polypectomy. Inclusion criterion in the RCTs consisted of European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS or AAO-HNS guidelines). The results showed there was significant heterogeneity of many parameters, including eligibility criteria, type of intervention, which sinuses were treated, operative setting, type of anesthesia and result, post intervention care and follow up duration reported. No clinically significant difference was noted by the authors in SNOT-20 outcomes between BSD and FESS. These limitations preclude definitive conclusions on patient-related quality of life (QOL) comparison between the 2 procedures. The authors recommended future research that includes more standardized inclusion criteria and reporting outcomes as well as long term follow up.

Saltagi et al. (2021) performed a systematic review reviewing the literature on the management of recurrent acute rhinosinusitis (RARS). A total of 1022 titles/abstracts possibly related to RARS were identified. Of these, sixty-nine full texts were selected for review, and 10 met inclusion criteria (five with level 4 evidence, four with level 3 evidence, one with level 2 evidence). The studies included a total of 890 patients (Age range 5.8 to 53.5 years), with follow up ranging from 1 to 19 months. The focus or

end results were primarily based on symptomatic improvement, although some articles also reported post-treatment endoscopic and radiographic findings. Management options included medical therapy (intranasal steroids, antibiotics, nasal saline irrigations, N-acetylcysteine, allergy treatment, and decongestants), BSD, and endoscopic sinus surgery (ESS). Two included studies focused on BSD, with level of evidence assessed at 3 and 4. Surgical patients (BSD and ESS) had a trend towards greater symptom control than medically treated patients, but meta-analysis was not possible. Although there are study limitations, the author's note that until better evidence can be obtained, current recommendations are based on expert opinion. Recommendations include considering surgery when patients experience four annual episodes (with at least one episode confirmed via computed tomography or nasal endoscopy) and the patient has either failed a trial of topical nasal steroids or experienced RARS-related productivity loss (Sikand et al. 2018 included in this review).

In a single-center, retrospective analysis of 110 patients who underwent balloon sinuplasty for chronic rhinosinusitis (CRS), Castro et al. (2021) evaluated 4-year outcomes and effectiveness and determined that balloon sinuplasty appears to be safe and effective with great long-term outcomes. The authors divided the patients into two subgroups, CRS with nasal polyps (CRSwNP; n = 28) or without nasal polyps (CRSsNP; n = 82) and evaluated their sinus findings based on their results from the Sino-Nasal Outcome Test (SNOT-22), endoscopic examination using the Modified Lund Kennedy score (MLK) and their CT scan of paranasal sinuses (CT-PNS) with evaluation through Lund Mackay scores (LM). The first follow up was obtained at 2 years then at 4 years after balloon sinuplasty. The authors determined that the data demonstrated a significant improvement in CRS symptoms after balloon dilation when measured through SNOT-22 from baseline and at all time points and that the improvements were maintained over at least a 4-year time period regardless of the presence of nasal polyposis. They stated that these results were objectively confirmed through the significant reduction of the endoscopic MLK and LM CT scores. Study limitations noted by the authors include the absence of a control group, the retrospective nature, and the significant loss to follow up of 55 patients which could bias the outcomes. The authors concluded that balloon sinus dilation can be a safe alternative to conventional FESS with significant improvement in CRS symptoms that are maintained over the long term.

Mirza et al. (2020) performed a systematic review and meta-analysis of the efficacy and safety of balloon catheter sinuplasty (BCS) in pediatric CRS. Out of 112 articles identified, 10 articles were included: two interventional controlled trials and eight observational studies that evaluated the efficacy of BCS for CRS. All studies evaluating QoL by SN-5 showed a remarkable reduction in SN-5 score postoperatively. Improvement in the computed tomography (CT) and endoscopic findings for up to 1 year after operation was reported. (Liu 2017). Additionally, the majority of patients treated with BCS did not receive any course of sinusitis-indicated antibiotics during long-term follow-up, they had low surgical revision rates and overall improvement in quality of life. Minor side effects were described, most commonly synechia. The studies evidence suggests that BCS is safe and effective for the treatment of CRS in pediatric patients. The limited number of studies available was a limitation. While the age range was identified, the number of patients under 7 years was not known. Future randomized controlled studies with large sample size and long-term follow-up are needed. Such studies can further determine the efficacy of BCS in managing children with CRS (Liu et al. 2017 and Soler et al. 2017 are included in this review).

Liu et al. (2020 and Liu, et al. 2017) performed a prospective study that included 30 children with CRS who had insufficient benefits from medical therapy (such as oral antibiotics, topical steroids, saline nasal irrigation, and/or allergy management) for at least 3–6 months and received balloon sinuplasty of selected sinuses. Specific inclusion criteria were, among other: symptomatic inflammatory condition of the mucosa of nose and paranasal sinuses for more than 12 weeks; a positive computed tomography (CT) scan; medical management at least 3–6 months that failed. Data was collected, including age, visual analog scale (VAS) score, CT score, and nasal endoscopy findings. In the initial study, 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. The initial study, balloon sinuplasty showed a clinical curative effect in the treatment of children with refractory CRS and was relatively safe. The authors noted that structural abnormalities in sinus ostia and hypoplastic sinuses may not be amenable to BCS. In the 3-year follow-up, most study participants did not require nose-related medications or auxiliary therapies, and were free of symptoms, or the symptoms did not affect their daily activities. Of the 30 children there were no complications of facial pain, teeth numbness, facial deformity, and dysosmia. The clinical symptoms and quality of lives of all 29 children were improved during the 3-year follow up. The VAS scores after 2 years ranged from 0.0 to 5.0 and 3-year ranged from 0.0 to 9.0. VAS scores were significantly lower at 2-year ($p < 0.001$) and 3-year ($p < 0.001$) after surgery. The quality of life of the patients was evaluated by a questionnaire (SN-5 for < 12 years old; SNOT-22 for ≥ 12 years old). The questionnaire scores 2-years ranged from 0.0 to 7.0, 3-years between 0.0 and 10.0. A statistically significant ($p < 0.001$) score decrease was obtained by the questionnaire between preoperative and 2-year, 3-year post-surgery. These findings suggested that the symptoms, including nasal obstruction and rhinorrhea, were clearly improved, and lasted for 3-years after the surgery,

suggesting long-term efficacies of balloon sinuplasty in children. The findings are limited by lack of comparison group undergoing a different intervention.

A Hayes Health Technology Assessment (HTA) for balloon sinuplasty for treatment of CRS in adults concluded that an overall moderate-quality body of evidence (11 RCTs, 1 prospective cohort and 1 retrospective cohort) suggests that balloon sinuplasty (BS) as a stand-alone procedure or as a hybrid procedure combined with FESS leads to significant improvements and achieves similar efficacy rates as FESS with comparable complication rates. There is little evidence to suggest that BS procedures are superior to FESS, nor have definitive patient selection criteria been established (Hayes, September 2019, updated September 2022).

A Hayes Health Technology Assessment (HTA) for balloon sinuplasty for the treatment of CRS in children and adolescents identified 7 studies of balloon sinuplasty (BSP) for treating pediatric CRS (PCRS) that was refractory to prolonged medical management and, in some cases, to adenoidectomy. The evidence base included 1 RCT, 2 prospective comparative cohort studies, 1 retrospective chart review and 3 pre/post studies. The HTA indicated that there is a small, low-quality body of evidence that suggests that PCRS patients treated with balloon sinuplasty have symptom relief and improved quality of life after balloon sinuplasty. No firm conclusions could be made regarding the safety of balloon sinuplasty in children because of limited evidence (Hayes, October 2019, updated December 2022).

In a randomized, controlled study Sikand et al. (2018) evaluated 24-week outcomes for BSD performed in-office (IO) with medical management (MM) as compared with MM only for patients with RARS. 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. Inclusion criteria comprised having 4 or more episodes of acute bacterial rhinosinusitis within the previous 12 months and evidence of sinus or ostiomeatal complex disease during an acute episode from a CT scan. 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 (37.3 ±24.4 [n = 26] vs 21.8 ±29.0 [n = 27]; p = 0.04). 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.

Ni et al. (2018) conducted a systematic review and meta-analysis on studies using the Sinus and Nasal Quality of Life Survey (SN-5) which is a validated symptom questionnaire in pediatric CRS. A total of 10 studies, consisting of 13 separate treatment arms of either medical therapy, adenoidectomy, BCS, or FESS were included in the review. The investigators limited inclusion of studies to pre/post studies that reported changes in SN-5 scores. Despite the multiple interventions under consideration in this meta-analysis, no treatment comparisons were conducted. Five of the 10 studies that met inclusion criteria for the meta-analysis reported SN-5 improvement following treatment with BCS. In the BCS-stratified meta-analysis of these 5 articles that included 172 total patients, the mean SN-5 score decreased by 1.97 points (95% CI, −2.76 to −1.18), which the authors report as a statistically significant improvement ($p < 0.00001$). These findings are however limited by lack of direct comparison group in 4 out of the 5 studies of BCS (Soler, et al. 2017 and Wang, et al. 2015 are included in this review).

Kutluhan et al. (2018) compared the technique of balloon sinuplasty with the classical FESS method by considering the severity of chronic sinusitis on the same patient. A total of 61 patients with chronic sinusitis 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 sinuplasty and classical FESS in Group 2 after Lund-Mackay scores. However in Group 1, the results of the comparison of postoperative Lund-Mackay scores of the balloon sinuplasty 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 sinuplasty 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 sinuplasty decreases. The study is limited by lack of randomization between treatment approaches and a sample size that may have been too small to detect clinically significant differences.

Minni et al. (2018) conducted a multicenter prospective randomized study to assess the validity and safety of balloon catheter dilation (BCD) vs. ESS in CRS of the frontal sinus enrolling a population of 102 adult patients (64 men and 38 women; overall 148 frontal sinuses studied) with non-polypoid CRS. All patients had been subjected to medical therapy (antibiotics,

corticosteroids, and nasal irrigations with saline solution) for at least two months and had not shown improved evaluation criteria. The radiological (Lund-McKay CT scoring modified by Zinreich) and symptomatologic 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 significative 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 significative difference was observed comparing the results of SNOT-20 questionnaire in the group of light/mild frontal CRS. A statistically significant better outcome of SNOT-20 score was noted in patients with moderate/severe CRS that underwent BCD of frontal sinus compared to ESS. The study is however limited by a sample size that may have been too small to detect clinically significant group differences.

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 post-procedure 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 pre-procedure to 6 months post procedure. 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 dysventilation of frontal sinus recess. A total of 107 patients without signs of inflammatory disease 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 the 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. The study is limited by lack of randomization or sham procedure.

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 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 patients with standalone balloon dilation with up to 24 months follow-up. Outcomes out to 2 years from the REMODEL full-study cohort are consistent with 6-month and 12-month outcomes. In the meta-analysis of standalone balloon dilation studies, technical success was 97.5%, and mean 20-item Sino-Nasal Outcomes Test scores were significantly and clinically improved at all time points. There were significant reductions in work/school days missed, homebound days, physician/nurse visits, acute infections, and antibiotic prescriptions. Mean recovery time was 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 CRS (n = 191) versus RARS (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 debridement than FESS. (Cutler et al. 2013 and Bikhazi et al. 2014 are included in this report). This study is limited by the large loss-to-follow-up, which may have been differential and introduced biases in the findings, as well as a sample size that may have been too small to detect clinically significant differences between groups.

Levy et al. (2016) conducted a systematic review and meta-analysis to evaluate paranasal sinus balloon catheter dilation (BCD) in the treatment of 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 ESS, 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 (Friedman 2008 and Gould 2014 are included in this study).

In a prospective, multicenter, single-arm investigation, Soler et al. (2016) conducted a study of children (2 to 21 years old) with CRS treated with balloon sinus dilation, who had failed medical management and followed them to 6 months post procedure. 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. The findings are however limited by a lack of comparison group.

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

Modified Lund-Mackay Scoring System

In a prospective multicenter study, Likness et al. (2014) evaluated CT scans of CRS patients using a novel objective 3D computerized system and compared results with a novel 2D computerized analysis of a single coronal slice through the ostiomeatal complex (OMC) and subjective methods including Lund-Mackay and Zinreich's modified Lund-Mackay. Forty-six adults with a diagnosis of CRS underwent CT examination and received an intramuscular triamcinolone injection, dosage weight dependent, followed by CT scan 4 to 5 weeks later. Scans were evaluated with all 4 scoring methods over 5 months. The Lin's concordance class correlation (CCC) of the OMC method revealed the best correlation to the 3D volumetric computerized values (0.915), followed by the Zinreich (0.904) and Lund-Mackay methods (0.824). Posttreatment results demonstrated that both the OMC (0.824) and Zinreich's (0.778) methods had strong agreement with the 3D volumetric methods and were very sensitive to change, whereas the Lund-Mackay (0.545) had only moderate agreement. The authors concluded that

computerized CT analysis provides the most comprehensive, objective, and reproducible method of measuring disease severity and is very sensitive to change induced by treatment intervention. The authors stated that a 2D coronal image through the OMC provides a valid, user-friendly method of assessing CRS and is representative of CRS severity in all sinuses. According to the authors, Zinreich's subjective method correlated well overall, but the Lund-Mackay method lagged behind in disease representation and sensitivity to change.

Clinical Practice Guidelines

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

AAO-HNS developed an expert consensus statement on the use of sinus ostial dilation (SOD) of the paranasal sinuses (AAO-HNS, 2018). 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 the following:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT
- Balloon dilation is not appropriate for the management of headache or sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis

Additional statements that reached consensus include the following:

- 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 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
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery

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, 2021):

- 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 expert 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. It also states that adenoidectomy is an effective first-line surgical procedure for children aged 13 years and older with CRS (AAO-HNS, 2014).

In the 2021 clinical indicators for pediatric endoscopic sinus surgery, the AAO-HNS states that adenoidectomy should be strongly considered a minimum of three months prior to performing pediatric sinus surgery when there is failure of medical management for CRS or recurrent ARS.

In 2015, the AAO-HNS updated the 2007 Clinical Practice Guideline 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).

The AAO-HNS clinical indicators for endoscopic sinus surgery for adults indicates that imaging studies should generally be obtained after optimal medical therapy (AAO-HNS, 2012; Updated 2021).

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, 2023). Support of this treatment strategy is based on clinical consensus statements and primary research evidence and the use of balloon sinus dilation should remain an option for surgical treatment of paranasal sinus disease.

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 2014 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 categories 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 boney 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.

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

American College of Radiology (ACR)

The ACR Appropriateness Criteria for Sinonasal Disease (ACR 2021) indicates the following:

- Non-contrast 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
- Most cases of uncomplicated acute and subacute rhinosinusitis are diagnosed clinically and should not require any imaging procedure
- 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 sphenoethmoidal (Onodi) air cells, which increase the risk of injury to the optic nerves or carotid arteries

European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA)

The 2020 EUOFOREA evidence based position paper states that when patients present early, balloon sinuplasty may have a role in milder cases of CRS. The EUFOREA also confers support of NICE guideline on the use of the XprESS system.

National Institute for Health and Care Excellence (NICE)

In 2016, the National Institute for Health and Care Excellence (NICE) published guidance on the 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 anesthesia (NICE, 2016).

Self-Expanding Absorptive Sinus Ostial Dilation

The evidence is insufficient to support the use of self-expanding absorptive sinus ostial dilation devices. Studies with control groups are needed to demonstrate the efficacy of these devices.

Hathorn et al. (2014) conducted a pilot study to determine the safety and performance of a maxillary sinus ostium (MSO) self-dilation device. Twelve CRS patients presenting with maxillary sinus inflammation requiring FESS were enrolled. The device was inserted into the MSO at the start of surgery and removed after 60 minutes. Endoscopic evaluation for patency was performed immediately after removal, and at 1 week, 1 month, and 3 months. Adverse events were recorded intraoperatively and at each subsequent visit. The device was successfully inserted in 100% of cases attempted (19/19 MSOs, 12 patients). Seventeen (89%) devices remained in the MSO for 60 minutes and dilated to a mean diameter of 4.8 ±0.5 mm. One patient was withdrawn from the study. No adverse events occurred during insertion or removal of the device. At 3 months postinsertion 14 of 15 MSO dilated (93%) were confirmed patent. The investigators concluded that the placement of an osmotic self-dilating expansion device in human MSO is safe, achievable, and effective at dilating the ostia. This study is limited by a small sample size and lack of a comparison group.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm. (Accessed April 3, 2023)

In 2013, the FDA granted 510k clearance to the SinuSys Vent-OS Sinus Dilation System for dilation of the maxillary sinus ostia and associated spaces in adults. Refer to the following for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K133016.pdf. (Accessed April 3, 2023)

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 April 3, 2023)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2023	**Related Policies** • Added reference link to the Medical Policy titled *Rhinoplasty and Other Nasal Procedures (for Tennessee Only)*

Date	Summary of Changes
	Coverage Rationale • Revised list of unproven and not medically necessary indications for balloon sinus ostial dilation; replaced "*all other indications* that do not meet the criteria [listed in the policy]" with "*cases of Chronic Rhinosinusitis (CRS) or Recurrent Acute Rhinosinusitis (RARS)* that do not meet the criteria [listed in the policy **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS138TN.M

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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