Sinus Surgeries and Interventions

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➲ Instructions for Use

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Application

UnitedHealthcare Commercial
This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange
This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

Balloon sinus ostial dilation and/or Functional Endoscopic Sinus Surgery (FESS) are proven and medically necessary when one or more of the following conditions are present:

- Chronic Rhinosinusitis (CRS) which has **all** of the following:
  - Lasted longer than 12 weeks
  - Persistence of symptoms despite recent 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 treated meeting **all** of the following criteria:
    - CT images are obtained after completion of medical management described above; 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
  - For balloon sinus ostial dilation only, the dilation is limited to the frontal, maxillary, or sphenoid sinuses

- Recurrent Acute Rhinosinusitis (RARS) with **all** of the following:
  - Four or more episodes per year with distinct symptom free intervals between episodes; and
  - Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis; and
  - Recent Computed Tomography (CT) Scan evidence of **one** of the following:
    - For balloon sinus ostial dilation, ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated
    - For FESS:
      - For the maxillary, frontal, or sphenoid sinuses, both of the following are present:
        - Ostial obstruction (outflow tract obstruction) in the sinus to be treated
        - Mucosal thickening in the sinus to be treated
      - For the ethmoid sinus, mucosal thickening is present

Functional Endoscopic Sinus Surgery (FESS) is also proven and medically necessary when any of the following conditions are confirmed on CT:
- Complications of sinusitis such as abscess
- Symptomatic concha bullosa
- Symptomatic mucocele
- Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps refer to the criteria above)
- Sinonasal tumor

Balloon sinus ostial dilation is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:
- Sinonasal polyps or tumors
- Cases of CRS or RARS that do not meet the criteria above

Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically necessary for cases of CRS or RARS that do not meet the criteria above due to insufficient evidence of efficacy.

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.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

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 with two or more of the following signs and symptoms:
- Mucopurulent drainage (anterior, posterior, or both);
- Nasal obstruction (congestion);
- Facial pain-pressure-fullness; or
- Decreased sense of smell

Diagnosing CRS requires that inflammation be documented (polyps, edema, or purulent mucus) in addition to persistent symptoms. Inflammation is documented by one or more of the following findings:
- Purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region;
- Polyps in the nasal cavity or the middle meatus; and/or
- Radiographic imaging showing inflammation of the paranasal sinuses (Rosenfeld et al., 2015; Peters et al., 2014)

Draf Classification System for Endoscopic Frontal Sinus Drainage: A classification system to describe degrees of endoscopic surgical interventions used in the management of frontal sinus disorders based on the sinuses accessed (Al Komser et al., 2013).

Type	Description
Draf I	A simple drainage of the cells of the frontal recess without altering the frontal sinus ostium; also known as an anterior ethmoidectomy
Draf IIa	Extended drainage with resection of the sinus floor from the lamina papyracea to the middle turbinate for the removal of agger nasi and frontal recess cells; also known as a frontal sinusotomy
Draf IIb	Extended drainage with more extensive resection of the frontal sinus floor from the lamina papyracea to the nasal septum; also known as drilling of the frontal sinus or unilateral frontal sinus drillout
Draf III	Removal of all of the frontal sinus floor, intersinus septum, the frontal beak and the superior septum; also known as an endoscopic modified Lothrop procedure or a bilateral frontal sinus drillout

Functional Endoscopic Sinus Surgery (FESS): A minimally invasive, mucosal-sparing surgical technique utilized to treat medically refractory CRS with or without polyps or RARS (Homsi and Gaffey, 2022).

Modified Lund-Mackay Scoring System: A tool used to quantify the severity of CRS based on 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 or more episodes per year of acute bacterial rhinosinusitis (ABRS) with distinct symptom free intervals between episodes. Each episode of ABRS should meet the following diagnostic criteria:

- Acute Rhinosinusitis that is caused by, or presumed to be caused by, bacterial infection;
- Symptoms or signs of Acute Rhinosinusitis fail to improve within 10 days or more beyond the onset of upper respiratory symptoms; or
- Symptoms or signs of Acute Rhinosinusitis worsens within 10 days after an initial improvement (double worsening)

Confirming a true bacterial episode of rhinosinusitis is preferred for substantiating an underlying diagnosis of RARS. When ABRS is not confirmed through laboratory analysis, examination of the member during an episode of ABRS (among the 4 episodes occurring per year) is needed to substantiate the diagnosis (Rosenfeld et al., 2015).

Rhinitis Medicamentosa (RM): A condition of rebound nasal congestion brought on by extended use of topical decongestants (e.g., oxymetazoline, phenylephrine, xylometazoline, and naphazoline nasal sprays) that constrict blood vessels in the lining of the nose. It classifies as a subset of drug-induced rhinitis (Wahid, 2022).

Applicable Codes

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

CPT Code	Description
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection
31253	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed
31254	Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)
31255	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)

CPT Code	Description
31256	Nasal/sinus endoscopy, surgical, with maxillary antrostomy
31257	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy
31259	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus
31267	Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed
31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy;
31288	Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus
31295	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
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 (CRS) that has failed medical therapy may require surgery. CRS 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 CRS 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.

FESS is a set of minimally invasive surgical techniques which allow direct visual examination and opening of the sinuses sometimes used for the treatment of CRS or RARS which have not responded to medical treatment. FESS has also been used to treat other conditions such as complications of sinusitis abscess, concha bullosa, mucocele, polyposis with obstructive symptoms or sinonasal tumor. Compared to other surgeries, the use of FESS allows for a much less invasive and traumatic procedure, resulting in shorter surgery and healing times, less postoperative discomfort, and fewer surgical complications.

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 2023 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, and of 2 of 9 cohort studies 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. This study included the Plaza 2011, Cutler, 2013, Bizaki 2016, and Koskinene 2016 studies previously summarized in this policy.

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 CT 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)

Kutluhan et al. (2018) compared the technique of balloon sinuplasty with the classical FESS method by considering the severity of CRS on the same patient. A total of 61 patients with CRS was included in the study. Paranasal sinus tomography of the patients was taken and according to the Lund-Mackay scoring, CRS levels were determined. Cases were divided into two groups: Group 1 (severe CRS group) and Group 2 (mild CRS). 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 FESS. The authors concluded that the success of balloon sinuplasty in patients with mild sinusitis is the same as in classic FESS. 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.

Chandra et al. (2016) reported the final results from the REMODEL full-study cohorts and performed meta-analyses of standalone BSD 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.

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.

Balloon Sinus Ostial Dilation

Han et al. (2023) conducted a prospective, non-randomized, single-arm, multi-center study to assess the safety and efficacy of the NuVent™ EM Balloon Sinus Dilation System. The study included 50 adults ≥ 18 years of age (58% female, mean age 58.0 years, 88% Caucasian, 98% non-Hispanic) who had CRS that was unresponsive to medical therapy, and who had undergone previous sinus surgery. Indications for surgery included scarring (38/51, 74.5 %), polyps (30/51, 58.8 %), adhesions (20/51, 39.2 %), missing or altered structures (18/51, 35.3 %), and granulations (7/51, 13.7 %) in at least one sinus cavity. A total of 121 sinuses (77 frontal, 34 sphenoid, and 10 maxillary sinuses) were treated in the study participants at one of six clinical sites in the United States. The authors reported that the device performed as expected in 100% of the treated sinuses and that the surgeon was able to both navigate and dilate the desired sinus ostia in 100% of the cases. Forty-seven of the study participants underwent a follow-up endoscopy at 14 days (+2/−5 days) post-treatment during their follow-up appointment (three subjects completed the 14-day follow-up via phone call) to assess for any post operative adverse events (AEs). The authors reported that there were ten mild AEs; however, none of the AEs were directly attributed to the device. Limitations of the study included the small sample size, the short follow-up period, the use of other surgical devices in conjunction with the NuVent system, and the homogeneity of the study population in relation to race. The authors concluded that the targeted frontal, maxillary or sphenoid sinus ostium were safely dilated in every patient with no AEs directly attributed to the device.

In a single-center, retrospective analysis of 110 patients who underwent balloon sinuplasty for 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 BSD 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 using the Sinus and Nasal Quality of Life Survey (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 QOL. 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 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 QOL 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 QOLs 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 QOL 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 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 balloon sinuplasty 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 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 QOL 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 post-treatment. 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 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 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.)

In a prospective single-blinded randomized controlled trial (RCT), Laury et al. (2018) evaluated if BCD 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 CT 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, 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 CT 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 the VAS at four and eight 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.

Levy et al. (2016) conducted a systematic review and meta-analysis to evaluate paranasal sinus BCD in the treatment of CRS. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 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 QOL 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 the SNOT-20 test one year following BCD, with significant improvement in self-reported QOL. 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 BSD, 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 SN-5 survey 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 SNOT-22 mean scores were also significantly improved at 6 months. The authors concluded that the results of this study show BSD 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.

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 CRS or RARS.

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 CRS without nasal polyps.
- There is a role for BSD in managing patients with RARS 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.

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 RARS. 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 CRS and 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 CT 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 CRS expert consensus statement concluded that the effectiveness of balloon sinuplasty compared to traditional ESS 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 ESS, 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 CRS with objective documentation of sinonasal inflammation, which may be accomplished using direct visualization (anterior rhinoscopy or nasal endoscopy) or 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 CRS. Surgical management of CRS is not discussed "because of insufficient evidence (e.g., RCTs) for evidence-based recommendations" (Rosenfeld et al. 2015).

The AAO-HNS clinical indicators for ESS 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 CRS) and 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 CT 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 BSD 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 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 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 CRS, the AAAA, ACAAI, and JCAAI indicate that the role of antibiotics in 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 CT is indicated for evaluation of 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, NICE published guidance on the XprESS multi sinus dilation system for treating CRS. NICE indicated that the case for adopting the XprESS multi-sinus dilation system for treating uncomplicated CRS is supported by the evidence. According to NICE, XprESS should be considered in patients with uncomplicated CRS 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).

Functional Endoscopic Sinus Surgery (FESS)

In their systematic review and meta-analysis, Fu et al. (2023) sought to determine the mean change in patients' scores on the SNOT-22 test before and after ESS for CRS to evaluate whether ESS improves the QOL in patients with CRS. The study included 15 multi-national, prospective cohort studies with an average follow-up of 25.5 months. The authors reported that all studies demonstrated a statistically significant difference in mean SNOT-22 scores between baseline and post-op time periods ranging from 5.1 to 55.4, and that the mean SNOT-22 changed significantly across all studies by 26.02 with nine studies having a mean change $\geq$ 26.02 and six studies having a mean change $\leq$ 26.02. The authors also reported that the risk of bias assessment showed that eight of the studies had a low risk of bias, four had a moderate risk of bias, and three had a high risk of bias. According to the stepwise multivariate analysis conducted by the authors, studies with higher average age and average pre-op SNOT-22 scores had greater changes in SNOT-22 scores following ESS, while the studies with longer average follow-up had less significant changes in SNOT-22 scores post-ESS. Limitations of the study included the scarcity of studies available for inclusion, the heterogeneity of the study designs with varied inclusion criteria and duration of follow-up, the use of aggregated data rather than individual participant data, the variability of the delineation of primary outcomes, and the inclusion of studies only written in English. The authors concluded that ESS leads to enhanced QOL outcomes, and that improvement is influenced by the initial SNOT-22 score, the average age of the patients, and the duration of the follow-up period.

Lourijsen et al. (2022) conducted an open-label, multi-center RCT to assess the efficacy of ESS plus medical therapy versus medical therapy alone in patients with CRSwNP. Their study included 238 participants with 142 men (61%) with a mean age of 50.4 years who were randomly assigned to either an ESS plus medical therapy group (n = 121) or to a medical therapy only group (n = 117). Adults with CRSwNP and an indication for ESS (failure of appropriate medical treatment) were randomly assigned to receive either the ESS plus medical therapy group or to the medical therapy only group. ESS was performed according to local practice with anterior ethmoidectomy mandatory. CT-sinus Lund-Mackay score was collected at baseline and follow-up. Concurrent medical therapy was prescribed at the patient's otorhinolaryngologist's discretion and consisted of, but was not limited to, nasal corticosteroids, nasal lavage, systemic corticosteroids, or systemic antibiotics. The primary outcome was disease-specific health-related quality of life (HRQoL) at 12 months of follow up, measured with the SNOT-22 test. The study showed that the mean SNOT-22 score in the ESS plus medical therapy group was 27.9 at 12 months and was 31.1 in the medical therapy group; adjusted mean difference of –4·9 (95% CI –9·4 to –0·4). The authors concluded that ESS plus medical therapy is more efficacious than medical therapy alone in patients with CRSwNP even though the minimal clinically important difference was not met in their study. They recommended additional studies with longer-term follow-up to determine whether the effect persists over time.

Authors Alekseenko and Karpischenko (2020) performed a prospective RCT along with a comparative analysis of outcomes in pediatric patients (n = 64) who underwent external sinus surgery with an open approach versus a FESS approach. Examinations of all patients were performed pre-operatively and at six-months post-operatively. The examinations performed were QOL, SNOT-20 questionnaire, an endoscopic examination of nasal mucosa using Lund-Kennedy scoring and a CT of the sinuses using Lund-Mackay scoring. The cohorts were divided into two groups, 30 pediatric patients underwent external sinus surgery and the other 34 underwent FESS. Pre-operative SNOT-20 scores external 46.1 ±8.6 versus FESS 35.0 ±6.8; Lund-Kennedy scores for external (rt) 4.57 ±1.87 and (lt) 4.67 ±2.07 versus FESS (rt) 4.50 ±1.44 and (lt) 4.29 ±1.55; Lund-Mackay scores for external 10.47 ± 3.88 versus FESS 9.56 ±5.61. Post-operative SNOT-20 scores for external 38.6 ±8.9 and FESS 22.0 ±2.5; Lund-Kennedy scores for external (rt) 4.57 ±1.94 and (lt) 4.50 ±2.10 versus FESS (rt) 1.71 ±1.68 and (lt) 1.38 ±1.48; Lund-Mackay scores for external 6.57 ±3.52 versus FESS 3.17 ±2.89. Postoperative total score outcomes for Lund-Mackay sinus opacification in pediatric patients that underwent external sinus surgery and FESS were reduced by 38, 67% as compared to the preoperative values. The authors concluded FESS significantly decreased surgery duration by 15% as compared to external sinus surgery (98.16 ±20.28 vs.83.08 ±29.89 min; p = 0.024). Both groups that underwent external sinus surgery and FESS resulted in a

significant improvement in total Lund-Kennedy, Lund-Mackay, and SNOT-20 scores, but it was more profound in the FESS group and appears to be more effective and safer in children with CRS.

Singh et al. (2020) conducted a prospective, single institution study of 30 patients with CRS that failed maximum medical treatment and underwent FESS. All the patients with CRS had undergone medical management with antibiotics, nasal decongestants and steroids for 4-8 weeks. Each patient had a CT of the paranasal sinuses prior to FESS provides an objective means of evaluation supporting the clinical findings and scoring using the Lund Mackay CT classification system. There was a total mean Lund Mackay CT preoperative score of 13.16 ±4.5. Using the scoring the patients were divided into two groups. Group A had a Lund Mackay score ≤ 13.1 and Group B ≥ 13.1. A statistically significant improvement in symptoms with good long-term prognosis was recorded in Group-B only. The authors concluded that using a CT scan with Lund Mackay scoring with patients that have a minimum score of 13.1 or greater is a good long-term predictor for determining the efficacy of FESS for the treatment of CRS.

Zhang et al. (2020) conducted a five-year prospective, cohort study of 81 patients who had CRSwNP and asthma. The aim of the study was to compare the long-term clinical outcomes of surgical interventions such as FESS, Radical Endoscopic Sinus Surgery (RESS) and RESS + Draf 3 in these patients. The study used data from January 1, 2010, and October 31, 2013, that included patients with bilateral CRSwNP scheduled to undergo ESS. The CRSwNP diagnosis was confirmed based on criteria of the European Position Paper on Rhinosinusitis and Nasal Polyps guidelines (EPOS). The asthma diagnosis was confirmed by a Pulmonologist according to Global Initiative for Asthma (GINA) guidelines. The 81 patients were randomized to undergo a FESS, RESS or RESS + Draf 3 surgery. The randomization was 1:1:1 that was completely computer generated. After surgery patient each patient underwent a 10-day course of antibiotics and a three-week tapering of oral methylprednisolone. Post-operative data was gathered at one, three- and five-year intervals. The patients were monitored for polyp recurrence; the polyp score was graded for each nasal cavity on a scale of 0–3 for each side, and the bilateral polyp grade of (maximum, 6); symptom scoring was according to the Lund–Kennedy with assessment of edema, nasal discharge, scarring, and crusting; endoscopic results were postoperative and measured by CT of paranasal sinuses, a baseline was performed in all patients preoperatively and were scored using the Lund-Mackay system; Sinus-specific quality of life (QoL) was assessed using the SNOT-22 test CRSwNP was graded using the EPOS 2012 guidelines; and clinical control of asthma was evaluated by pulmonary function testing using the percentage forced expiratory volume in 1 second (FEV1%) assessed by spirometer and a FEV1% of < 80% was graded as abnormal. The authors concluded that FESS had a higher short-term recurrence rate than RESS and RESS + Draf3 for patients with CRSwNP and asthma. Both RESS and RESS + Draf3 demonstrated a lower revision rate than FESS in the long-term. Patients with CRSwNP and asthma had poorer outcomes and higher recurrence rate after FESS for patients with CRSwNP and asthma. It is recommended for further studies, larger cohorts, longer follow-up duration and stricter standardization of medications used.

Smith et al. (2019) conducted an observational case series of 59 adult patients with CRS electing ESS. Long-term, disease-specific QOL outcomes, health utility values (HUV), revision surgery rate, development of asthma, and patient expectations/satisfaction with outcomes of ESS were examined using descriptive statistics and simple fixed-effects linear modeling. Fifty-nine adult patients were followed for an average of 10.9 years. Mean QOL significantly improved between baseline and 6 months and remained durable to 10 years. HUV improved to normal. A 17% revision surgery rate within the 10-year follow-up period was observed with a 25% revision rate in CRSwNP. New-onset asthma after ESS occurred at a rate of 0.8%/year. Patient satisfaction with ESS outcomes was generally high. The authors concluded that the ten-year prospective outcomes of ESS for CRS demonstrate that the initial clinically significant improvements in QOL seen 6 months postoperatively are durable over the long term.

Ni et al. (2018) conducted a systematic review and meta-analysis on studies using the 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, balloon catheter sinuplasty (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. Two of the 10 studies that met inclusion criteria for the meta-analysis reported SN-5 improvement following treatment with FESS. In the FESS-stratified meta-analysis of these 2 studies that included 22 total patients, the mean SN-5 score decreased by 1.83 points ((95% CI, 1.47 to 2.19), which the authors report as a statistically significant improvement ($p < 0.00001$).

The National Cancer Database was queried for cases of sinonasal squamous cell carcinoma (SNSCC) without cervical or distant metastases that were treated surgically between 2010 and 2014. They were divided into 2 groups based on surgical approach: open or endoscopic. Cox proportional hazard analysis was performed. Propensity score matching (PSM) was used to mimic an RCT. A total of 1,483 patients were identified: 353 (23.8%) received endoscopic and 1130 (76.2%) received open surgery. Age, gender, race, geographic region, tumor size, surgical margins, postoperative chemoradiation, and 30-day readmissions did not vary significantly between the 2 groups. Open surgery was more

common in academic centers (62.8% vs 54.2%; p = 0.004), less common for tumors of the ethmoid and sphenoid sinus (p < 0.0001), less common for stage IVB tumors, and associated with longer hospital stay. Five-year overall survival (5Y-OS) was not significantly different between the 2 approaches (p = 0.953; open: 5Y-OS, 56.5%; 95% confidence interval, 51.3% to 61.6%; endoscopic: 5Y-OS, 46.0%; 95% confidence interval, 33.2% to 58.8%). In the PSM cohort of 652 patients, there was also no significant difference in overall survival (p = 0.850). The investigators concluded that endoscopic surgery is an effective alternative to open surgery, even after accounting for confounding factors that may favor its use over the open approach (Kılıç et al., 2018).

Kim and Kwon (2017) conducted a meta-analysis to evaluate recurrence of sinonasal inverted papilloma (IP) based on the type of surgical approach. Fourteen retrospective cohort studies involving a total of 696 endoscopic approaches and 444 non-endoscopic approaches were included in the review. The pooled risk ratio (RR) for IP recurrence (endoscopic vs. external approach) was 0.56 [95% CI: 0.36-0.85, I2 = 48.3%]. The investigators concluded that surgical management of IP via an endoscopic approach reduces the risk of recurrence compared to an external approach. Although further data are needed, early- stage IP requires endoscopic or endoscopic-assisted surgery to reduce the risk of tumor recurrence.

In a systematic review and meta-analysis, Patel et al. (2017) examined the literature regarding management of CRS patient's refractory to appropriate medical therapy (AMT). Adult patients with CRS who received AMT and then underwent either medical or surgical therapy in moderate to high level prospective studies were included. Six observational or before/after studies were included in the systematic review with 5 included in the meta-analysis. On meta-analysis, for patients with CRS refractory to AMT, ESS significantly improves objective endoscopic scoring outcomes vs continued medical therapy alone. In patients with refractory CRS who had significant reductions in baseline QOL, ESS resulted in significant improvements. Continued medical therapy appeared to maintain outcomes in patients with less severe baseline QOL. Unpooled analysis demonstrated improvement in health utility and olfaction following ESS compared to continued medical therapy alone, in medically refractory CRS.

Wood et al. (2017) conducted a prospective case series to assess treatment outcomes of CRS patients undergoing FESS and post-operative medical treatment over a prolonged follow-up period. The study included 200 non-consecutive patients in the tertiary referral practice of a single surgeon. Symptoms were scored by patients pre-operatively and over a minimum follow-up period of 12 months. The median pre-operative symptom score was 16 (out of a maximum of 25). Symptom scores reduced to a median of 7 after 12 months of follow up. The median symptom score improved for all symptoms and across all patient subgroups. The authors concluded that extensive FESS offers significant and durable symptom improvement in patients with CRS refractory to medical treatment and that prolonged medical therapy is recommended after FESS. The findings are however limited by lack of comparison group undergoing a different treatment approach.

Djukic et al. (2015) evaluated the clinical outcomes and QOL in patients with nasal polyposis (NP) after FESS. The prospective study included 85 consecutive adult patients (≥ 18 years) with NP who were operated on using FESS after failure of the medical treatment and in certain cases of surgical treatment. The objective finding was presented as endoscopic and CT score. The intensity of each symptom, the values of symptom scores (major, minor and total), the values of dimension scales and summary scales of the QOL, as well as the values of endoscopic score through three periods of time (pre-surgery, 6 and 12 months after the surgery) were analyzed. Following FESS, mean intensity values of all individual symptoms and symptom scores were significantly lower and the values of all dimension scales and summary scales of QOL were significantly higher (p < 0.05). There was no statistically significant difference in symptom intensity and QOL after 6 and 12 months of surgical treatment (p > 0.05). Endoscopic score was on average significantly lower after 6 and 12 months of FESS (p < 0.05), but the mean score value after 12 months of operation was significantly higher in relation to that after 6 months of surgery (p < 0.05). Nevertheless, the recurrence of NP was observed in 28 patients (32.9 %) in the follow-up period. In conclusion, FESS in patients with NP resulted in significant improvement of symptom intensity, QOL and endoscopic score. While the intensity of symptoms and QOL showed a tendency to maintain between 6 and 12 months after surgery, endoscopic score showed a tendency of exacerbation in the same period. The findings were limited by lack of comparison group.

In a systematic review, Vlastarakos et al. (2013) evaluated the quality of evidence in the use of FESS for the treatment of CRS in children, regarding the respective changes in their QOL and the outcome that follows the operation. Fifteen studies were systematically analyzed. Four represented Level II, 5 Level III, and 6 Level IV evidence. The total number of treated patients was 1301. Thirteen research groups reported that pediatric FESS was an effective treatment for CRS; the respective positive outcome ranged between 71 and 100% of operated children. Five studies concluded that this treatment modality was associated with significant improvement in the children's postoperative QOL. Systemic diseases and environmental factors may have unfavorable prognostic effects; cystic fibrosis was associated with at least 50% recurrence rate. The rate of major complications following pediatric FESS was 0.6%, and the respective rate of minor complications was 2%. The authors concluded that surgical management with FESS in children with CRS is effective

when optimal medical treatment proves unsuccessful (grade B strength of recommendation) and was associated with improvement in the children's QOL (grade B strength of recommendation). FESS also improved the sinusitis-associated symptoms and QOL in children with cystic fibrosis (grade C strength of recommendation). According to the authors, most complications of pediatric FESS reported in the literature were minor and associated with difficulties in the postoperative assessment and care of pediatric patients.

Scangas et al. (2013) conducted a retrospective case series at a university tertiary referral center to characterize the natural history, clinical characteristics, management principles, and outcomes of paranasal sinus mucoceles. A chart review was performed on 102 patients with a total of 133 paranasal sinus mucoceles. Patients were diagnosed with a mucocele on average 5.3 years following prior FESS, 17.7 years following prior paranasal sinus trauma, and 18.1 years following prior open sinus surgery. The most common presenting symptoms were headache (42.1%) and maxillofacial pressure (28.6%). The most common sites were the frontal, frontoethmoidal, and ethmoid sinuses. Fifty-seven mucoceles (44.9%) had intraorbital extension, intracranial extension, or both. Out of 133 mucoceles, 114 underwent ESS without complication. The authors concluded that the endoscopic approach could be safely used for the management of mucoceles.

Higgins et al. (2011) conducted a systematic review with a pooled-data analysis to compare outcomes of endoscopic versus craniofacial resection of sinonasal malignancies. The review included 15 case series with individual data on 226 patients. The 5Y-OS rate for the sample was 56.5%. Because of the paucity of data with endoscopic resection of high-stage malignancies, the outcome results were highly variable, and no useful comparison could be made. Among low-stage malignancies (T1-2 or Kadish A-B), the endoscopic and open approaches demonstrated no statistically significant difference in outcome results. The 5Y-OS was 87.4% in the endoscopic group versus 76.8% for open approaches; disease-specific survival was 94.7% versus 87.7%; and locoregional control rate was 89.5% versus 77.2%. The authors concluded that transnasal endoscopic resection appears to be a reasonable alternative to craniofacial resection in the management of low stage sinonasal malignancies.

Toros et al. (2007) compared the outcomes of ESS in patients with CRSsNP and those with nasal polyps (NP). The investigators also determined the correlation between preoperative CT findings and postoperative endoscopy and symptom score improvement. Data were collected from two groups of patients diagnosed as CRSwNP and CRSsNP that underwent FESS with a 1-year postoperative follow up. Preoperative symptoms, CT scores, and endoscopic scores were recorded. Assessment of symptoms was performed subjectively using VAS. CT scan findings were scored using the Lund-Mackay system. The correlations between the CT score, endoscopic scores and VAS scores were calculated. There was a statistically significant correlation between the preoperative CT, symptom, and endoscopic scores. Postoperative symptom and endoscopic scores also showed a significant correlation. Total CT scores of the CRSsNP group were significantly lower than the scores of the NP group. Also, preoperative endoscopy and symptom scores were statistically lower in CRSsNP group compared to NP group. Endoscopy total scores and symptom total scores of both groups were significantly decreased at postoperative 12th month. Statistically significant difference was observed between the preoperative and postoperative symptom and endoscopy scores. The patients with polyps had higher symptom scores and worse objective findings compared to the patients with CRSsNP. In all patients' groups, objective and subjective scores seemed to correlate well preoperatively and postoperatively. These data suggest that ESS provides significant symptomatic relief and endoscopic healing in patients with CRSsNP and NP.

Maru and Gupta (1999) conducted a study of 150 patients with chronic sinusitis, who underwent CT scan of the paranasal sinuses prior to FESS. The CT scans were evaluated to detect the incidence of concha bullosa and its types, the significance of concha bullosa in the formation of ostiomeatal complex disease and the relation between type of concha bullosa and ostiomeatal complex disease. All patients underwent FESS. According to the investigators, FESS is the technique of choice for management of inflammatory disease of middle meatus and concha bullosa so as to restore the normal function of the middle turbinate.

Clinical Practice Guidelines

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

In a 2015 Clinical Practice Guideline (update) for Adult Sinusitis, the AAO-HNS indicates that clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS. CT of the paranasal sinuses should be obtained when ESS is considered or planned in patients with CRS or RARS. In addition to demonstrating abnormal mucosa and opacified sinuses, CT will provide the anatomic detail necessary to guide the surgery. Surgical management of CRS is not discussed "because of insufficient evidence (e.g., RCTs) for evidence-based recommendations" (Rosenfeld et al. 2015).

The AAO-HNS clinical indicators for ESS for adults states that the indications for ESS include a history of one of more of the following:

- CRS with or without nasal polyps with persistent symptoms and objective evidence of disease by endoscopic and/or CT imaging that is refractory to medical treatment.
- Allergic fungal rhinosinusitis.
- Unilateral paranasal sinus opacification, symptomatic or asymptomatic, consistent with CRS with or without nasal polyps, fungus ball, or benign neoplasm (i.e., inverted papilloma).
- Complications of sinusitis, including extension to adjacent structures such as orbit or skull base.
- Sinonasal polyposis with nasal airway obstruction or suboptimal asthma control.
- Mucocele.
- RARS.

The AAO-HNS clinical indicators for ESS also indicate that imaging studies should generally be obtained after optimal medical therapy (American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Clinical indicators: Endoscopic sinus surgery, adult 2012, Updated 2021).

The AAO-HNS clinical pediatric CRS expert consensus statement concluded that the effectiveness of balloon sinuplasty compared to traditional ESS 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 ESS, 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 RARS.

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 AAAA, ACAAI, and JCAAI recommends that although medical therapy is the mainstay of disease management, FESS should be considered when medical therapy fails. According to the AAAA, ACAAI, and JCAAI, indications for surgical intervention include the following:

- When nasal polyps obstruct sinus drainage and persist despite appropriate medical treatment.
- When there is recurrent or persistent infectious rhinosinusitis despite adequate trials of medical management that at least includes topical nasal steroids and nasal irrigations.
- For biopsy of sinonasal tissue to rule out granulomatous disease, neoplasm, ciliary dyskinesia, or fungal infections.
- When maxillary antral puncture is required (as for culture-directed therapy).
- When anatomic defects obstruct the sinus outflow tract, particularly the ostiomeatal complex (and adenoidal tissues in children).
- For rhinosinusitis with threatened complications (such as threat of brain abscess, meningitis, cavernous sinus thrombosis, or frontal bone osteomyelitis).

Regarding medical management for CRS, the AAAA, ACAAI, and JCAAI indicate that the role of antibiotics in 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 2017, revised 2021) indicates the following):

- Most cases of uncomplicated acute and subacute rhinosinusitis are diagnosed clinically and should not require any imaging procedure.
- CT of the sinuses without contrast is the imaging method of choice in patients with RARS or CRS, or to define sinus anatomy prior to surgery.
- Immunocompromised patients are at high risk for invasive fungal sinusitis.
- In patients with suspected sinonasal mass or suspected orbital and/or intracranial complication of sinusitis, MRI and CT are complementary studies.

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

The 2020 EUOFOREA evidence-based position paper makes the following recommendations regarding ESS surgery for CRS:

- A CT scan showing evidence of disease is mandatory.
- For adult patients with uncomplicated CRSsNP, ESS could be appropriately offered when:
  - The CT Lund-Mackay score is >/= 1.
  - A minimum trial of at least eight weeks' duration of a topical intranasal corticosteroid plus either a short-course of a broad spectrum/culture-directed systemic antibiotic or the use of a prolonged course of systemic low dose anti-inflammatory antibiotic with a post-treatment total SNOT-22 score >/= 20.

The International Consensus Statement on Allergy and Rhinology: Rhinosinusitis 2021 (ICAR-RS)

The 2021 ICAR-RS executive summary provides a compilation of evidenced-based recommendations for medical and surgical treatments for CRS, CRSwNP acute rhinosinusitis (ARS) and RARS (Orlandi et al. 2021). The summary states that ESS is recommended for rhinologic diseases that demonstrate a "failure of maximal medical therapy" (MMT). Criteria used to confirm MMT and eligibility for ESS, but not limited to:

- Presence of two specific cardinal symptoms for ≥ 12 weeks which may vary for the following conditions CRS, CRSwNP, ARS or RARS.
- SNOT-22 test preoperative score ≥ 20.
- Sinus inflammation and/or purulence on nasal endoscopy.
- Sinus inflammation on CT.

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.

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 CRS 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 March 27, 2024)

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 March 27, 2024)

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 March 27, 2024)

FESS is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Template Update** • Created shared policy version to support application to UnitedHealthcare West plan membership **Supporting Information** • Archived previous policy versions 2024T0571P and MMG143.N

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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