Molina Clinical Policy
Balloon Sinus Ostial Dilation (Balloon Sinuplasty)
Policy No. 408

Last Approval: 12/11/2024
Next Review Due By: December 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Rhinosinusitis, also known as sinusitis, is an inflammation of the paranasal sinuses and nasal mucosa in all age groups. It can be caused by infection, airborne allergens (such as dust mites, mold, pollen), or autoimmune deficiency. There are two main types of sinusitis: acute and chronic. Acute sinusitis is inflammation that lasts for less than 4 weeks. Subacute sinusitis lasts from 4 to 12 weeks, while chronic sinusitis lasts for more than 12 weeks.

Chronic rhinosinusitis (CRS) is an inflammatory condition involving the paranasal sinuses and the lining of the nasal passages, lasting 12 weeks or longer, despite attempts at medical management, and is associated with sinus edema and impaired mucociliary clearance. The diagnosis of chronic rhinosinusitis requires objective evidence of mucosal inflammation, with or without nasal polyps, based on clinical presentation and examination using anterior rhinoscopy, or nasal endoscopy. The four cardinal symptoms of chronic rhinosinusitis are: nasal obstruction, facial congestion, anterior and/or posterior mucopurulent drainage, and hyposmia (decreased ability to smell). The fourth cardinal symptom may be cough in pediatric patients. First-line treatment for chronic rhinosinusitis is usually conservative medical therapy to resolve the symptoms, such as oral antibiotics, saline nasal irrigation, topical and/or systemic decongestants, topical steroids in the form of nasal sprays for controlling inflammation and/or systemic steroids, and/or treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy. For patients who do not experience adequate relief with medical and pharmaceutical therapy, surgical interventions may be necessary. Radiologic imaging must be obtained, of which a CT scan is the gold standard, when surgery is being considered. The typical surgical treatment for chronic rhinosinusitis is functional endoscopic sinus surgery in which soft tissue and/or bone is removed to create openings from the sinuses into the nose. Surgical intervention may also be considered in the setting of recurrent acute rhinosinusitis, which is defined as 4 or more episodes of acute bacterial rhinosinusitis within a year, without persistent symptoms between episodes.

Balloon sinus ostial dilation (BSOD), also referred to as balloon dilation sinuplasty or balloon catheter sinusotomy, is a minimally invasive technique using an endoscopic, catheter-based system. The technology places a small, flexible, sinus balloon catheter into the nasal cavity which is guided to the blocked sinus. The balloon device is then inflated to gently restructure and widen the walls of the passageway while maintaining the integrity of the sinus lining. This assists with mucus drainage which effectively opens blocked sinus passageways and restores normal sinus drainage, after which the balloon is deflated and removed. BSOD is performed as a stand-alone procedure or in conjunction with a functional endoscopic sinus surgery procedure either in the inpatient or office setting; and may be considered an alternative to endoscopic sinus surgery for those with chronic rhinosinusitis or recurrent acute rhinosinusitis of the frontal, maxillary, or sphenoid sinuses.

Regulatory Status

Balloon Sinuplasty devices are approved by the FDA 510(k) Premarket Approval process as Class I devices under the product code LRC. 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). There are a multitude of FDA approved balloon sinuplasty devices on the market, such as Vensure Balloon Dilation System (K230065), BB 8 Sinus Dilation Kit (K230258), and Dillard Nasal Balloon Catheter (K181546).

COVERAGE POLICY

Balloon sinus ostial dilation (BSOD), performed as a stand-alone procedure, for the treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis in the frontal, maxillary or sphenoid sinus may be **considered medically necessary** when **ALL** the following criteria are met:

1. Diagnosis of chronic rhinosinusitis *without* nasal polyps

2. Documentation of **ONE** of the following:
   a. Chronic rhinosinusitis for at least 12 continuous weeks
   b. Recurrent acute rhinosinusitis of ≥4 episodes of acute bacterial rhinosinusitis in the past year without signs or symptoms of rhinosinusitis between episodes

3. Chronic rhinosinusitis confirmed on a computed tomography (CT) scan for *each* sinus to be dilated with supporting documentation of **ALL** the following criteria:
   a. CT images obtained after completion of medical management
   b. CT scan report documents the following:
      i. Sinus affected by chronic rhinosinusitis (right/left/both)
      ii. The extent of the disease including the percent of opacification OR the use of a scale such as the Modified Lund-Mackay Scoring System
   c. CT findings include **ONE** or more of the following:
      i. Bony remodeling
      ii. Bony thickening
      iii. Opacified sinus
      iv. Ostial obstruction (outflow tract obstruction) and mucosal thickening

4. Sinonasal symptoms present on the same side as CT scan findings of either: 1) **Chronic rhinosinusitis** characterized by at least **TWO** of the following for at least 12 continuous weeks, or 2) **Recurrent acute rhinosinusitis** of ≥ 4 episodes in the past year with distinct symptom-free intervals between episodes despite attempts at medical management:
   a. Anterior and/or posterior nasal mucopurulent drainage
   b. Nasal obstruction/blockage/congestion
   c. Facial pain, pressure, and/or fullness over the affected sinus
   d. Reduction or loss of smell

5. Medical management has been attempted, and unsuccessful, for *at least 8 consecutive weeks* with supporting documented of failure, intolerance, and/or contraindication to **ALL** the following:
   a. Antibiotics, when bacterial infection suspected: Two courses of antibiotics or one prolonged course of oral antibiotic of at least 21 days
   b. Topical and/or systemic corticosteroids
   c. Nasal saline lavage or irrigation
   d. Antihistamine nasal spray and/or decongestant (when indicated)
   e. Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants) if present
   f. Education on environmental irritants including tobacco smoke

6. The balloon sinuplasty procedure requested is intended for use in the treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis of the frontal, maxillary or sphenoid sinuses

Limitations and Exclusions

1. BSOD, when performed as a component of functional endoscopic sinus surgery in the same sinus cavity, is an integral part of the functional endoscopic sinus surgery procedure and is not separately reimbursable.

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. BSOD in the setting of, or for the treatment of **ANY** of the following:
    a. Chronic rhinosinusitis with nasal polyposis or tumors
    b. Chronic rhinosinusitis or recurrent acute rhinosinusitis patients without CT findings
    c. An asymptomatic patient
    d. Treatment of the following conditions in the absence of CT-confirmed chronic rhinosinusitis or recurrent acute rhinosinusitis:
        i. Headache without chronic rhinosinusitis or recurrent acute rhinosinusitis
        ii. Sleep apnea without chronic rhinosinusitis or recurrent acute rhinosinusitis
    e. Allergic fungal sinusitis
    f. Malignancy
    g. Prior skull-based dehiscence
    h. Samter's triad (aspirin sensitivity)
    i. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, Granulomatosis with polyangiitis)
    j. Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis
    k. Intolerance or contraindication to local and/or topical anesthetic
    l. History of failed balloon procedure in the sinus to be treated
    m. Isolated or advanced ethmoid sinus disease
    n. Mucous retention cysts/mucocele
    o. Significant neo-osteogenesis

2. Self-Expanding Absorptive Sinus Ostial Dilation
    Informational Note: 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)

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Three studies (Cutler et al., 2013, Bikhazi et al., 2014, Chandra at al., 2016) reported on the REMODEL trials results at 6, 12, and 24 months. REMODEL was an industry sponsored a prospective, multicenter, non-inferiority, parallel, RCT that compared balloon sinus ostial dilation (BSOD) as a stand-alone procedure with functional endoscopic sinus surgery (FESS) in adult patients with uncomplicated chronic rhinosinusitis or recurrent acute rhinosinusitis associated with maxillary sinus disease with or without anterior ethmoid sinus disease. A total of 105 patients with chronic rhinosinusitis or recurrent acute rhinosinusitis and failure of medical therapy were randomized to BSOD or FESS. Patients with gross sinonasal polyposis were excluded. BSOD was performed with the Entellus device, which is labeled for a transantral approach. FESS consisted of maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy. Thirteen patients withdrew consent before treatment (11 in the FESS group and 2 in the BSOD group). The primary outcomes were the change in the 20-item Sino-Nasal Outcome Test (SNOT-20) scores at 6-month follow-up and mean number of postoperative debridements. Secondary outcomes included recovery time, complication rates, and rates of revision surgery. Noninferiority analysis was performed for the primary outcome of change in symptom score and superiority analyses was performed on the debridement outcome.

Cutler et al. (2013) reported the first 6-month results of the REMODEL trial. Adults with an uncomplicated sinusitis diagnosis (chronic or recurrent acute) of the maxillary sinuses who met criteria for medically necessary FESS were randomized 1:1 to office balloon dilation or FESS and followed for 6 months. A minimum of 36 patients per arm were

required to test the hypotheses with 90% power. Symptom improvement using the validated SNOT-20 survey, debridements, recovery outcomes, complications, and revision surgeries were compared between groups. Ninety-two patients (50 BSOD; 42 FESS) were treated. Mean SNOT-20 improvement was 1.67 ± 1.10 and 1.60 ± 0.96 in the balloon and FESS arms, respectively. Both groups showed clinically meaningful and statistically significant improvement, and the balloon arm was non-inferior to FESS. Postoperative debridements were more likely in the FESS group with a mean per patient of 0.1 ± 0.6 in the balloon arm versus 1.2 ± 1.0 in the FESS arm, with the balloon group showing superiority. Patients in the balloon dilation group returned to normal daily activities faster (1.6 days vs 4.8 days) and required fewer days of prescription pain medications (0.9 days vs 2.8 days). There were no major complications in either group, and 1 patient in each group required revision surgery. Occurrence of postoperative nasal bleeding, duration of prescription pain medication use, recovery time, and short-term symptom improvement were all significantly better for BSOD versus FESS. The authors concluded that BSOD is non-inferior to FESS for symptom improvement and superior to FESS for postoperative debridement in patients with maxillary and anterior ethmoid disease. The authors stated that balloon dilation is an effective treatment in patients with an uncomplicated CRS diagnosis who meet the criteria for medically necessary FESS.

Bikhazi et al. (2014) evaluated and compared 1-year outcomes from the REMODEL study. Sinonasal symptom improvement was assessed using the validated SNOT-20 survey. Ostial patency rate, rhinosinusitis episode frequency, impact of sinus disease on activity and work productivity using the validated Work Productivity and Activity Impairment survey, complications, and revision rate were also compared between the two groups. Ninety-two patients (50 BOD; 42 FESS) were treated and 89 (96.7%) patients completed 1-year follow-up. Both groups showed clinical and statistically significant improvement in mean overall SNOT-20 scores and in all four SNOT-20 subscales. Improvement in the mean SNOT-20 score was 1.64 in the BSOD arm and 1.65 in the FESS arm. During the year post-procedure, both groups had fewer self-reported rhinosinusitis episodes (mean reduction in episodes, 4.2 in the balloon arm vs 3.5 in the FESS arm; P <.001). Overall work productivity and daily activity impairment due to chronic sinusitis were significantly improved in both groups. There were no serious complications and revision surgery rate was 2% in each arm through 1 year. The authors concluded that with 1-year follow-up, standalone BSOD is as effective as FESS in the treatment of CRS in patients with maxillary sinus disease with or without anterior ethmoid disease who failed medical therapy and met the criteria for medically necessary FESS.

Chandra et al. (2016) published the final results from the REMODEL full-study cohorts and meta-analyses of standalone BSOD studies to evaluate long-term outcomes in a large patient sample. This publication included results up to 2 years post-procedure for subjects in the REMODEL trial, along with an additional 30 subjects treated with FESS or in-office BSOD, for a reported total of 61 FESS patients and 74 BSOD patients. Follow-up data were available for 130, 66, and 25 patients at 12, 18, and 24 months, respectively. In addition, a meta-analysis evaluated outcomes from 6 studies including 358 standalone BSOD patients with up to 24 months follow-up. Outcomes out to 2 years from the REMODEL full-study cohort are consistent with 6-month and 12-month outcomes. In the meta-analysis of standalone BSOD studies, technical success is 97.5%, and mean SNOT scores are significantly and clinically improved at all time points. There are significant reductions in work/school days missed, homebound days, physician/nurse visits, acute infections, and antibiotic prescriptions. Mean recovery time is 1.4 days. Comparison of 12-month symptom improvements and revision rates between the REMODEL FESS arm (n = 59), REMODEL balloon arm (n = 71), and pooled single-arm standalone BSOD studies (n = 243) demonstrated no statistical difference. The meta-analysis included a subgroup analysis for patients with chronic rhinosinusitis (n=191) versus recurrent acute rhinosinusitis (n=52). Both groups experienced statistically significant and clinically meaningful improvements in mean SNOT-20 scores, with no significant difference between groups. The authors concluded that all outcomes are comparable between FESS and balloon dilation at all time points from 6 months to 24 months. According to the authors, BSOD produces faster recovery, less postoperative pain, and fewer debridements 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.

Systematic Reviews and Meta-Analyses

Sinha et al. (2023) conducted a systematic review and meta-analysis that evaluated the effectiveness of balloon sinus dilation (BSD) compared to functional endoscopic sinus surgery (FESS) and medical management for chronic rhinosinusitis (CRS). The review included randomized and observational studies involving adults aged 18 and over with chronic or recurrent sinusitis, focusing on BSD outcomes versus traditional FESS, no treatment, or medical

therapy. The primary outcome measured was the change in Sinonasal Outcome Test (SNOT)-20 scores. BSD was the sole intervention in 6 out of 9 randomized controlled trials (RCTs) and 2 out of 9 cohort studies, with the remaining studies incorporating additional procedures like septoplasty, turbinectomy, uncinectomy, and polypectomy. The inclusion criteria for the RCTs were based on the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) or AAO-HNS guidelines. The results revealed significant variability in several parameters, including eligibility criteria, types of interventions, treated sinuses, operative settings, anesthesia types, post-intervention care, and follow-up durations. No clinically significant differences were found in SNOT-20 outcomes between BSD and FESS. Due to these limitations, definitive conclusions on patient-related quality of life (QOL) comparisons between the two procedures could not be drawn. The authors recommended future research with more standardized inclusion criteria, outcome reporting, and long-term follow-up.

Saltagi et al. (2021) performed a systematic review of the literature on the management of recurrent acute rhinosinusitis. A total of 1022 titles/abstracts possibly related to recurrent acute rhinosinusitis were identified. Of these, 69 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 results were primarily based on symptomatic improvement, although some articles also reported post-treatment endoscopic and radiographic findings. Management options included medical therapy, BSOD, and ESS. Two included studies focused on BSOD, with level of evidence assessed at 3 and 4. Surgical patients (BSOD 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 which include considering surgery when patients experience 4 annual episodes (with at least 1 episode confirmed via CT or nasal endoscopy) and the patient has either failed a trial of topical nasal steroids or experienced recurrent acute rhinosinusitis-related productivity loss.

Mirza et al. (2020) conducted a systematic review and meta-analysis of the efficacy and safety of balloon catheter sinuplasty in pediatric chronic rhinosinusitis. Out of 112 articles identified, ten were included: 2 interventional controlled trials and 8 observational studies that evaluated the efficacy of balloon catheter sinuplasty for chronic rhinosinusitis. All studies evaluating quality of life by Sinus and Nasal Quality of Life Survey (SN-5) showed a remarkable reduction in SN-5 score postoperatively. Improvement in the CT and endoscopic findings for up to 1 year after operation was reported (Liu 2017). In addition, most patients treated with BSOD 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. Synechia was a common minor side effect noted. The evidence suggests that BSOD is safe and effective for the treatment of chronic rhinosinusitis in pediatric patients. The limitations include the small number of studies available and the unspecified number of patients under 7 years (although the age range was specified). Future RCTs with larger sample size and long-term follow-up are needed to determine the efficacy of balloon catheter sinuplasty in managing children with chronic rhinosinusitis.

Hayes Health Technology Assessment ([1-2] 2022)
A Hayes Health Technology Assessment, 'Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Adult Patients' concluded that there is sufficient evidence to support the use of balloon sinuplasty for treating chronic rhinosinusitis and recurrent acute rhinosinusitis without nasal polyps that is refractory to medical management. Patients who have concurrent cannot be treated with stand-alone BSOD.

A Hayes Health Technology Assessment for 'Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Pediatric Patients' assigned a C rating to this procedure in the pediatric population due to a small, low-quality body of evidence. The current evidence does suggest that the procedure is safe and pediatric patients with chronic rhinosinusitis have symptom relief and improved quality of life after balloon sinuplasty; however, no firm conclusions could be made regarding the safety and efficacy in children because of limited evidence.

National and Specialty Organizations

The **American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS)** (Piccirillo et al. 2018) developed a clinical consensus statement for balloon sinuplasty in adults with chronic sinusitis and recurrent acute rhinosinusitis stating the following:

- May improve short-term quality-of-life outcomes in patients with limited chronic sinusitis without polyposis, and may be effective in frontal sinusitis

- Can be performed
  - Alone or with traditional FESS
  - Under local anesthesia, with or without sedation
- CT imaging
  - CT scanning of the sinuses is a requirement before BSOD can be performed.
  - Objective evidence of inflammation on CT imaging is necessary, in addition to sinonasal symptoms for a patient to be deemed appropriate to undergo sinus ostial dilation.
- Indications and contraindications
  - BSOD may be appropriate:
    - As an adjunctive procedure to FESS in patients with chronic sinusitis *without* nasal polyps
    - For patients with persistent sinus disease who have had previous sinus surgery
  - BSOD is not appropriate for
    - Patients who are without both sinonasal symptoms and positive findings on CT
    - Patients with sinonasal symptoms who do not have evidence of sinonasal disease on CT
    - Management of headache or sleep apnea in patients who do not otherwise meet criteria for chronic sinusitis
- There can be a role for BSOD in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for BSOD in managing patients with recurrent acute rhinosinusitis.

The **American Academy of Allergy Asthma and Immunology (AAAAI), American College of Allergy Asthma and Immunology (ACAAI),** and the **Joint Council of Allergy Asthma and Immunology (JCAAI)** published a practice parameter for the diagnosis and management of rhinosinusitis, recommends that ostial dilatation with a balloon should be considered in a small sub-segment of patients with medically unresponsive acute rhinosinusitis, primarily those with early or localized disease (strength of evidence D: directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence). According to the authors Peters et al. (2014):

- There are different opinions regarding the extent of surgery that should be performed for chronic rhinosinusitis ranging from a very minimal procedure or balloon dilatation of the affected ostia to very complete opening of all the sinuses. The standard teaching for the FESS 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 BSOD 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.
- Conclusions regarding long-term resolution of disease with minimal interventional approaches remain unproved. The authors state that it remains debatable whether BSOD 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 chronic rhinosinusitis, the AAAA, ACAAI, and JCAAI indicate that the role of antibiotics in chronic rhinosinusitis is controversial. For chronic rhinosinusitis 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. Intranasal corticosteroids are indicated for treatment due to chronic rhinosinusitis being an inflammatory disease. Other adjunctive therapy, such as intranasal antihistamines, decongestants, saline irrigation, mucolytics, and expectorants, might provide symptomatic benefit in select cases.

The **American Rhinologic Society (ARS)** (2023) states that sinus ostial dilation (e.g., balloon ostial dilation) is a therapeutic option for selected patients with chronic rhinosinusitis and recurrent acute rhinosinusitis who have failed appropriate medical therapy. Clinical diagnosis should be based on symptoms of sinusitis and supported by objective evidence, including nasal endoscopy documenting sinonasal abnormality or mucosal thickening on computed tomography of the paranasal sinuses. This approach may be used alone or in conjunction with traditional endoscopic sinus surgery. Balloon dilation has been shown to have similar post-operative outcomes to functional endoscopic sinus surgery for selected patients. This position statement is endorsed by the AAO-HNS.

SUPPLEMENTAL INFORMATION

Measures and Scoring Systems

Modified Lund-Mackay Scoring System: A widely used method for radiologic staging of CRS (to quantify the severity based on CT scan findings). 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 Lund-Mackay staging system assigns a value of 0, 1, or 2 to each of the following sinuses: maxillary, anterior ethmoid, posterior ethmoid, frontal, and sphenoid. Each side is graded, and their sum is the total score out of maximum of 54 (Likness et al., 2014).

Sinus and Nasal Quality of Life Survey (SN-5): The only validated symptom questionnaire for children ages 2–12 and is completed by parents to evaluate the QOL of their children with CRS (Kay and Rosenfeld, 2003).

Sino-Nasal Outcome Test (SNOT): An approximation of CRS disease burden, defined as its impact on patient's functional status and disease-related QOL, is to use patient-reported outcome measures. This is the most widely used instrument, a collection of several validated instruments (SNOT-16, SNOT-20, SNOT-22) defined by the number of included items. All of the SNOT instruments are derived from the Rhino-Sinusitis Outcome Measure (RSOM-31) (Piccirillo et al. 1995). The scores of each question range from 0 to 5, according to the severity of the symptom, with 5 being the worst. Higher scores represent a lower health related quality of life. In addition, patients identify the five items that affect them the most. Typically, the impact of treatment is assessed with the SNOT absolute change score.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, trans-nasal 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

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C1726	Catheter, balloon dilatation, non-vascular [when specified as a balloon sinus ostial dilation device]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/11/2024	Policy reviewed, no changes to coverage criteria. Updated references and summary of medical evidence. IRO Peer Review October 28, 2024, by a practicing physician board-certified in Otolaryngology-Head and Neck Surgery, and Facial Plastic and Reconstructive Surgery.
12/13/2023	Policy reviewed, no changes to coverage criteria, updated references, and summary of medical evidence.
12/14/2022	Policy reviewed, no changes to coverage criteria, updated references, and summary of medical evidence.
12/08/2021	New Policy. IRO Peer Review on 11/30/21 by practicing board certified physician in otolaryngology and Head and Neck Surgery.

REFERENCES

1. American Rhinologic Society (ARS). Position statement: Criteria for sinus-ostial dilation. Published January 28, 2023. Accessed October 3, 2024.
2. Bikhazi N, Light J, Truitt T. REMODEL Study Investigators, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up. Am J Rhinol Allergy. 2014 Jul-Aug;28(4):323-9.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed October 23, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx
4. Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. 2016; 126(1):44-50.
5. Cutler J, Bikhazi N, Light J, Truitt T, Schwartz M. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial. Am J Rhinol Allergy. 2013;27(5):416-422.
6. [1]Hayes.,Balloon sinuplasty for treatment of chronic rhinosinusitis in adult patients. Health Technology Assessment. Published September 26, 2019. Updated September 30, 2022. Accessed October 2, 2024.
7. [2]Hayes. Balloon sinuplasty for treatment of chronic rhinosinusitis in pediatric patients. Health Technology Assessment. Published October 9, 2019. Updated December 9, 2022. Accessed October 2, 2024.
8. Mirza AA, Shawli HY, Alandejani TA, et al. Efficacy and safety of paranasal sinus balloon catheter dilation in pediatric chronic rhinosinusitis: A systematic review. J Otolaryngol Head Neck Surg. 2020 Sep 29;49(1):69.
9. Peters AT, Spector S, Hsu J, et al. Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology. Diagnosis and management of rhinosinusitis: A practice parameter update. Ann Allergy Asthma Immunol. 2014 Oct;113(4):347-85. doi: 10.1016/j.anai.2014.07.025. PMID: 25256029.
10. Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical consensus statement: Balloon dilation of the sinuses. Otolaryngol Head Neck Surg. 2018 Feb;158(2):203-214. doi: 10.1177/0194599817750086. PMID: 29389303.
11. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015 Apr;152(2 Suppl): S1-S39. doi: 10.1177/0194599815572097. PMID: 25832968.
12. Saltagi MZ, Comer BT, Hughes S, et al. Management of recurrent acute rhinosinusitis: A systematic review. Am J Rhinol Allergy. 2021 Feb 23:1945892421994999.
13. Sinha P, Tharakan T, Payne S, et al. Balloon Sinus Dilation Versus Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis: Systematic Review and Meta-Analysis. Ann Otol Rhinol Laryngol. 2023 May;132(5):578-588. doi: 10.1177/00034894221104939. Epub 2022 Jun 15. PMID: 35703383; PMCID: PMC10559877.
14. United States Food and Drug Administration (FDA). 510(k) Premarket Approval: Product Code LRC. Accessed October 23, 2024. https://www.accessdata.fda.gov.