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

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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 (Orlandi et al., 2016). The diagnosis of CRS requires objective evidence of mucosal inflammation. CRS may occur with or without nasal polyps. The four cardinal symptoms of CRS are: nasal obstruction; facial congestion, pressure, and or fullness; anterior and/or posterior mucopurulent drainage; and hyposmia (decreased ability to smell). The fourth cardinal symptom may be cough in pediatric patients. CRS is associated with sinus edema and impaired mucociliary clearance (AAO-HNS, 2015; Parikh, et al., 2014; Ahmed, et al., 2011). RARS is defined as 4 or more episodes of acute bacterial rhinosinusitis within a year, without persistent symptoms between episodes. First-line treatment for CRS is usually conservative medical therapy to resolve the symptoms and consists of the following: 1) oral antibiotics, 2) saline nasal irrigation, 3) topical and/or systemic decongestants (if not contraindicated), 4) topical steroids in the form of nasal sprays for controlling inflammation and/or systemic steroids, or 5) 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. The typical surgical treatment for CRS is functional endoscopic sinus surgery (FESS) in which soft tissue and/or bone is removed to create openings from the sinuses into the nose. The diagnosis of CRS is based on presenting signs and symptoms, clinical examination using anterior rhinoscopy, or nasal endoscopy. CT scan is the standard radiologic examination obtained when ESS is being considered.

Balloon sinus ostial dilation (BSOD or BOD), also referred to as known as balloon dilation sinuplasty or balloon catheter sinusotomy, is a minimally invasive technique using an endoscopic, catheter-based system. The FDA-cleared technology uses a small, flexible, sinus balloon catheter placed into the nasal cavity and guided to the blocked sinus. The balloon device is inflated and gently restructures and widens the walls of the passageway while maintaining the integrity of the sinus lining. This assists with mucus drainage which opens blocked sinus passageways, restoring normal sinus drainage. The balloon is then deflated, and the device is removed. BSOD is performed as a stand-alone procedure or in conjunction with a FESS procedure. BSOD has been proposed as an alternative or addition to standard endoscopic surgery, usually reserved for patients in whom optimal medical treatment has failed. The procedure may be considered an alternative to endoscopic sinus surgery (ESS) for those with CRS or RARS of the frontal, maxillary, or sphenoid sinuses. BSOD may be performed either in an operating room or office setting. The choice of setting is based upon many factors; however, more extensive, or complicated procedures will be performed in an operating room. The procedure does not involve surgical removal of tissue and can be performed in the office setting under local anesthesia (Hamilos & Holbrook, 2021). In the office setting, the BSOD may be combined with conventional ESS techniques, or as a standalone procedure.

Regulatory Status

Balloon Sinuplasty devices are approved by the FDA 510(k) process as Class I devices. The Food and Drug Administration (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). All manufacturers are required to register their establishment and device in the Establishment Registration & Device Listing database. Refer to 'Supplemental Information' section for a listing of devices (may not be all-inclusive).

COVERAGE POLICY

BSOD for the treatment of CRS in the frontal, maxillary or sphenoid sinus may be considered medically necessary when **ALL** the following criteria are met:

1. Diagnosis of CRS *without* nasal polyps

AND

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

AND

3. CRS confirmed on a computed tomography (CT) scan for *each* sinus to be dilated **and** documentation of **ALL** the following criteria:
   a. CT images obtained after completion of medical management; **and**
   b. CT scan report documents the following:
      - Sinus affected by CRS (right/left/both), **and**
      - The extent of the disease including the percent of opacification OR the use of a scale such as the Modified Lund-Mackay Scoring System.

   AND
   c. CT findings include **ONE** or more of the following:
      - Bony remodeling
      - Bony thickening
      - Opacified sinus
      - Ostial obstruction (outflow tract obstruction) and mucosal thickening.

AND

4. Sinonasal symptoms present on the same side as CT scan findings of either: 1) **CRS** characterized by at least **TWO** of the following for at least 12 continuous weeks, or 2) **RARS** 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.

AND

5. Medical management has been attempted for *at least 8 consecutive weeks* and documented by failure, intolerance 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; **and**
   b. Topical and/or systemic corticosteroids; **and**
   c. Nasal saline lavage or irrigation; **and**

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.

AND

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

AND

7. BSOD is performed either as a stand-alone procedure or as part of FESS:
   a. BSOD when performed as a stand-alone procedure will be authorized when medically necessary (meeting **ALL** the above criteria and the limitations and exclusions below), **OR**
   b. BSOD when performed as a component of FESS in the same sinus cavity. This is an integral part of the FESS procedure and is not separately reimbursable.

CONTINUATION OF THERAPY
Not applicable with this procedure.

LIMITATIONS AND EXCLUSIONS
BSOD is limited to the frontal, maxillary or sphenoid sinuses; AND is performed either as a stand-alone procedure or as part of FESS:

1. When performed as a stand-alone procedure, balloon sinuplasty will be covered when it is medically necessary and meets the above criteria and following limitations.
2. BSOD, when performed as a component of FESS in the same sinus cavity, is an integral part of the FESS procedure and is not separately reimbursable.

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

1. Any indications other than those listed above, including:
   - Nasal polyps (CRS with nasal polyposis) or tumors
   - CRS or RARS patients without CT findings or an asymptomatic patient
   - Treatment of the following conditions in the absence of CT-confirmed CRS or RARS::
     - Headache without CRS or RARS
     - Sleep apnea without CRS or RARS
   - Allergic fungal sinusitis
   - Malignancy
   - Prior skull-based dehiscence
   - Samter's triad (aspirin sensitivity)
   - Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, Granulomatosis with polyangiitis)
   - Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis
   - Intolerance or contraindication to local and/or topical anesthetic
   - History of failed balloon procedure in the sinus to be treated
   - Isolated or advanced ethmoid sinus disease
   - Mucous retention cysts/mucocele
   - 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

The consensus on the use of BSOD in the otolaryngological practice community as an accepted alternative to FESS for CRS continues to increase as the procedure is determined to be reasonably safe and efficacious when used in appropriately selected populations. Randomized controlled trials (RCTs) compared the effects of FESS with frontal, maxillary, or sphenoid sinus balloon sinuplasty in the treatment of CRS. The evidence base comprised 11 RCTs in 13 publications (Plaza et al., 2011; Achar et al., 2012; Cutler et al., 2013; Bikhazi et al., 2014; Bizaki et al., 2014; Marzetti et al., 2014; Hathorn et al., 2015; Bizaki et al., 2016a; Bizaki et al., 2016b; Chandra et al., 2016; Kutluhan et al., 2018; Minni et al., 2018; Sikand et al., 2019). The limitations of the studies included the small number small and short duration in follow-up time. However, outcomes show that balloon sinuplasty is noninferior to FESS with shorter operative times, less bleeding and few reported complications.

The REMODEL trial, a prospective, multicenter, non-inferiority, parallel, RCT compared FESS with balloon dilation systems in adult patients with uncomplicated CRS or RARS associated with maxillary sinus disease with or without anterior ethmoid sinus disease. Three studies (Cutler et al., 2013, Bikhazi et al., 2014, Chandra at al., 2016) reported on REMODEL results at 6, 12, and 24 months. REMODEL was an industry sponsored RCT that compared BOD as a stand-alone procedure with FESS. A total of 105 patients with CRS or RARS and failure of medical therapy were randomized to BOD or FESS. Patients with gross sinonasal polyposis were excluded. BOD 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 BOD 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 BOD; 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 BOD versus FESS. The authors concluded that BOD 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 BOD 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 BOD 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.

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 were reported by Chandra et al. (2016). 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 BOD, for a reported total of 61 FESS patients and 74 BOD 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 BOD 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 BOD 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 BOD 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, BOD 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.

In addition to REMODEL, three smaller RCTs provide evidence on the comparison of BOD to FESS in patients with CRS (Achar et al., 2012; Bikhazi et al., 2014; Minni et al., 2018).

Systematic Reviews/Meta-Analyses

Saltagi et al. (2021) performed a systematic review of the literature on the management of RARS. A total of 1022 titles/abstracts possibly related to RARS 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 BSD, 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 RARS-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 CRS. 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 CRS. 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, the majority of 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 CRS 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 CRS.

Levy et al. (2016) conducted a systematic review and meta-analysis to evaluate the quality of life and sinus opacification following sinus balloon catheter dilation for CRS. Experimental and cohort studies in adults were eligible for inclusion. A total of 17 studies were eligible for systematic review and 11 studies were eligible for data extraction and meta-analysis. The authors reported the results of a meta-analysis of 11 RCTs that met their inclusions criteria. Potential conflicts of interest were identified in 10 of the 11 studies included in their analysis and 5 studies contained extractable data regarding change in SNOT 22-scores 1 year following the balloon procedure, with significant improvement in self-reported quality of life. Additionally, another 5 studies were reported to have a significant change in paranasal sinus opacification following BSOD. Only 2 studies were reported to have directly compared change in SNOT-20 between the balloon procedures and ESS. Neither demonstrated a significant difference in outcomes. Finally, a subgroup analysis was conducted that identified that the change in SNOT-20 score was greater after balloon procedures in the operating room than in the office. Overall, the authors concluded that the current evidence supporting the role of BSOD for CRS remains incomplete. Long-term within-group improvements in quality of life and sinus opacification scores are demonstrated among a restricted adult population with CRS, but additional study is needed to further evaluate the role for this technology in specific settings and participant subgroups. The authors concluded that the current evidence base is incomplete since the eligible studies had restricted populations due to extensive exclusion criteria and the majority of studies were affected by inherent bias and conflicts of interest.

Hayes Health Technology Assessment

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 CRS and RARS without nasal polyps that is refractory to medical management. However, definitive patient selection criteria have not been established (Hayes, September 2019, updated September 2022).

A Hayes Health Technology Assessment for 'Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Pediatric Patients' indicated that there is a small, low-quality body of evidence that suggests that pediatric patients with CRS have symptom relief and improved quality of life after balloon sinuplasty. No firm conclusions could be made regarding the safety in children because of limited evidence In addition, the review identified only a few studies comparing BOD with other treatments; therefore, no conclusions can be made regarding the relative efficacy with other treatments. (Hayes, October 2019, updated December 2022).

National and Specialty Organizations

The **American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS)** developed a clinical consensus statement (CCS) for balloon sinuplasty in adults with chronic sinusitis since the evidence is limited to support a guideline (Piccirillo et al., 2018). The AAO-HNS published this CCS of the following statements that reached consensus:

- May improve short-term quality-of-life outcomes in patients with limited CRS without polyposis, and may be effective in frontal sinusitis
- Can be performed
  - Alone or with traditional ESS
  - Under local anesthesia, with or without sedation
- CT imaging
  - CT scanning of the sinuses is a requirement before BOD 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
  - BOD 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
  - BOD 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 BOD in patients with persistent sinus disease who have had previous sinus surgery.

There is a role for BOD in managing patients with RARS.

In 2017, the AAO-HNS endorsed a position statement addressing the use of BOD:

> '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 computed tomography of the paranasal sinuses. This approach may be used alone to dilate an obstructed sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (for example, microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.'

The **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:

- 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 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 (Peters et al. 2014).
- 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 are indicated for treatment. Other adjunctive therapy, such as intranasal antihistamines, decongestants, saline irrigation, mucolytics, and expectorants, might provide symptomatic benefit in select cases (Peters et al. 2014).

The **American Rhinologic Society (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, 2017). This statement is endorsed by the AAO-HNS.

The **National Institute for Health and Care Excellence (NICE)** published guidance in 2016 addressing XprESS multi sinus dilation system for treating chronic sinusitis and indicated that the case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis is supported by the evidence. The guidance indicated that XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anesthesia (NICE, 2016). The recommendation was based on the results of the REMODEL study: the committee "considered that the evidence from REMODEL demonstrated that balloon dilation

(with either XprESS or FinESS) is clinically non-inferior to FESS in terms of alleviating symptoms in patients with uncomplicated chronic sinusitis." Single-arm observational studies were of lower quality but were consistent with the findings of the REMODEL study.

SUPPLEMENTAL INFORMATION

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. Clinical indicators for endoscopic sinus surgery for adults. 2012, Updated 2015).

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

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

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.

BSOD Devices

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

CODING & BILLING INFORMATION

CPT Codes

CPT	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 Code

NOTE: This document applies to following HCPCS code only when the device is associated with a BSOD procedure listed above

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

NOTE: BSOD when used as an adjunctive procedure during FESS in the same sinus cavity is an integral part of the primary procedure and not separately reimbursable.

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

12/14/2022	Policy reviewed, no changes to criteria; updates made in policy that do not impact coverage.
12/8/2021	New Policy. IRO Peer Review. 11/30/21. Practicing Physician. Board certified in otolaryngologist, Head and Neck Surgery.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS.
2. Food and Drug Administration (FDA). 510(k) premarket notification database: Next Generation Balloon Dilation System Summary (no. K201115). Published August 27, 2020. Available from FDA. Accessed December 2022.

Peer Reviewed Publications

1. Achar P, Duvvi S, Kumar BN. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: A pilot study. Acta Otorhinolaryngol Ital. 2012 Oct;32(5):314-9.
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. Bikhazi N, Light J, Truitt T, Schwartz M, Cutler J. 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;28(4):323-329.
4. Bizaki AJ, Numminen J, Taulu R, Kholova I, Rautiainen M. Treatment of rhinosinusitis and histopathology of nasal mucosa: A controlled, randomized, clinical study. Laryngoscope. 2016c;126(12):2652-2658.
5. Bizaki AJ, Numminen J, Taulu R, Rautiainen M. A controlled, randomized clinical study on the impact of treatment on antral mucociliary clearance: Uncinectomy versus balloon sinuplasty. *Ann Otol Rhinol Laryngol*. 2016b;125(5):408-414.
6. Bizaki AJ, Numminen J, Taulu R, Rautiainen M. Decrease of nasal airway resistance and alleviations of symptoms after balloon sinuplasty in patients with isolated chronic rhinosinusitis: A prospective, randomised clinical study. *Clin Otolaryngol*. 2016a;41(6):673-680.
7. Bizaki AJ, Taulu R, Numminen J, Rautiainen M. Quality of life after endoscopic sinus surgery or balloon sinuplasty: A randomized clinical study. *Rhinology*. 2014;52(4):300-305.
8. 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.
9. 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.
10. Gould J, Alexander I, Tomkin E, Brodner D. In-office, multisinus balloon dilation: 1-Year outcomes from a prospective, multicenter, open label trial. Am J Rhinol Allergy 2014; 28(2): 156-163.
11. Hathorn I, Habib AR, Santos RD, et al. The safety and performance of a maxillary sinus ostium self-dilation device: a pilot study. Int Forum Allergy Rhinol. 2014 Aug;4(8):625-31.
12. Kutluhan A, Çetin H, Kale H, et al. Comparison of natural ostiodilatation and endoscopic sinus surgery in the same patient with chronic sinusitis. Braz J Otorhinolaryngol. 2018. Epub ahead of print. October 22, 2018.
13. Levy JM, Marino MJ, McCoul ED. Paranasal sinus balloon catheter dilation for treatment of chronic rhinosinusitis: A systematic review and meta-analysis. Otolaryngol Head Neck Surg. 2016; 154(1):33-40.
14. Marzetti A, Tedaldi M, Passali FM. The role of balloon sinuplasty in the treatment of sinus headache. Otolaryngol Pol. 2014 Jan-Feb;68(1):15-9.

15. Minni A, Dragonetti A, Sciuto A, et al. Use of balloon catheter dilation vs. traditional endoscopic sinus surgery in management of light and severe chronic rhinosinusitis of the frontal sinus: A multicenter prospective randomized study. Eur Rev Med Pharmacol Sci. 2018;22(2):285-293.
16. 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.
17. Payne SC, Stolovitzky P, Mehendale N, et al. Medical therapy versus sinus surgery by using balloon sinus dilation technology: A prospective multicenter study. Am J Rhinol Allergy. 2016; 30(4):279-286.
18. Plaza G, Eisenberg G, Montojo J, Onrubia T, Urbasos M, O'Connor C. Balloon dilation of the frontal recess: A randomized clinical trial. Ann Otol Rhinol Laryngol. 2011 Aug;120(8):511-8.
19. Saltagi MZ, Comer BT, Hughes S, et al. Management of recurrent acute rhinosinusitis: A systematic review. Am J Rhinol Allergy. 2021 Feb 23:1945892421994999.
20. Sikand A, Ehmer DRJ, Stolovitzky JP, McDuffie CM, Mehendale N, Albritton FD. In-office balloon sinus dilation versus medical therapy for recurrent acute rhinosinusitis: A randomized, placebo-controlled study. Int Forum Allergy Rhinol. 2019;9(2):140-148.

National and Specialty Organizations

1. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Dilation of sinuses, any method (e.g., balloon, etc.). March 12, 2017.
2. American Rhinologic Society (ARS). Ostial balloon dilation position statement. Published March 14, 2017. Accessed on December 9, 2022.
3. Brietzke SE, Shin JJ, Choi S, et al. Clinical consensus statement: Pediatric chronic rhinosinusitis. Otolaryngol Head Neck Surg. 2014; 151(4):542-553.
4. Piccirillo JF, Payne SC, Rosenfeld RM, et al. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) clinical consensus statement: Balloon dilation of the sinuses. Otolaryngol Head Neck Surg. 2018; 158(2):203-214.
5. Orlandi RR, Kingdom TT, Hwang PH, et al. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis. Int Forum Allergy Rhinol 2016; 6 Suppl 1:S22. Available here. Accessed on December 9, 2022.
6. Peters AT, Spector S, Hsu J, Joint Task Force on Practice Parameters representing AAAAI/ACAAI/JCAAI, et al. Diagnosis and management of rhinosinusitis: A practice parameter update. Ann Allergy Asthma Immunol. 2014; 113(4):347-85.
7. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) clinical practice guideline (update): Adult sinusitis. Otolaryngol Head Neck Surg. Apr 2015;152(2 Suppl):S1-S39. PMID 25832968. Available here.

Evidence Based Reviews and Publications

1. DynaMed. Chronic rhinosinusitis (record no. T115673). Updated January 27, 2022. Accessed December 2022 Available from DynaMed. Registration and login required.
2. Hayes, Inc. Health technology assessment: Balloon sinuplasty for treatment of chronic rhinosinusitis in adult patients. Available from Hayes. Published September 26, 2019. Updated September 30, 2022. Accessed December 10, 2022. Registration and login required.
3. Hayes, Inc. Health technology assessment: Balloon sinuplasty for treatment of chronic rhinosinusitis in pediatric patients. Available from Hayes. Published October 9, 2019. Updated December 9, 2022. Accessed December 10, 2022. Registration and login required.
4. Hamilos, DL. Holbrook EH. Chronic rhinosinusitis: Management. Available from UpToDate. Updated September 19, 2022. Accessed December 10, 2022. Registration and login required.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Ahmed J, Pal S, Hopkins C, Jayaraj S. Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. Cochrane Database Syst Rev. 2011;(7):CD008515.
2. [DEFINITION] Kay DJ, Rosenfeld RM. Quality of life for children with persistent sinonasal symptoms. Otolaryngol Head Neck Surg 2003;128:17-26.
3. [DEFINITION] Piccirillo JF, Edwards D, Haiduk A, et al. Psychometric and clinimetric validity of the 31-item rhinosinusitis outcome measure (RSOM-31). Am J Rhinol 1995;9:297-306.
4. [DEFINITION] Piccirillo JF, Merritt MG Jr, Richards ML. Psychometric and clinimetric validity of the 20-Item Sino-Nasal Outcome Test (SNOT-20). Otolaryngol Head Neck Surg 2002;126:41-7.
5. Fokkens WJ, Lund VJ, Mullol J, Bachert C, Alobid I, Baroody F, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. *Rhinology.* 2012;50:1–12.
6. Sedaghat AR. Chronic Rhinosinusitis. Am Fam Physician. 2017 Oct 15;96(8):500-506. PMID: 29094889.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Centers for Medicare & Medicaid Services (CMS)

CMS does not have a National Coverage Determination (NCD) for balloon sinuplasty. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers. No Local Coverage Determinations (LCD) or Local Coverage Article (LCA) for balloon sinuplasty was located (December 2021).