

Sinuplasty

ACG: A-0478 (AC)

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- Clinical Indications
- Alternatives
- Evidence Summary
 - Background
 - Criteria
 - Inconclusive or Non-Supportive Evidence
 - Rationale
 - Related CMS Coverage Guidance
- References
- Codes

Clinical Indications

- Sinuplasty may be indicated when **ALL** of the following are present(1)(2):
 - Age 18 years or older
 - Chronic rhinosinusitis¹
 - Duration of symptoms of 3 months or longer
 - Imaging evidence of chronic rhinosinusitis on sinus CT scan(15)(16)
 - Inadequate response to appropriate medical therapy, as indicated by **ALL** of the following(14)(16):
 - Nasal corticosteroids(17)
 - Nasal saline irrigation

Alternatives

- Alternatives include(14)(18)(19)(20):

- o Functional endoscopic sinus surgery. See Functional Endoscopic Sinus Surgery (FESS) [AC](#) for further information.
- o Medical management of chronic rhinosinusitis(17)(21)(22)

Evidence Summary

Background

Sinuplasty, also referred to as balloon sinuplasty or balloon ostial dilation, treats ostial narrowing of the paranasal sinuses through the use of a balloon device to enlarge or open the outflow tracts of the maxillary, frontal, or sphenoid sinuses without disrupting the epithelial mucosa.(1)(3) **(EG 2)** Under direct vision or fluoroscopy, a catheter is inserted into the narrowed ostium and a balloon is inflated under pressure to enlarge the opening by stretching the mucous membrane and creating a small bony fracture.(4) **(EG 2)** Sinuplasty may be performed in the office or operating room setting, using local or general anesthesia, depending on patient tolerance.(1)(5) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 15 published peer reviewed articles and 2 specialty society or other evidence-based guidelines.

For chronic rhinosinusitis in adults, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review identified 18 randomized or observational studies comparing balloon sinus dilation with functional endoscopic sinus surgery, no treatment, or medical therapy in patients with chronic rhinosinusitis. In a meta-analysis of 2 randomized controlled trials and one observational study (186 patients) with adequate data for analysis, balloon sinuplasty was associated with significantly higher nasal quality of life, as measured by the Sino-Nasal Outcome Test-20 (SNOT-20), at follow-up, as compared with functional endoscopic sinus surgery (pooled difference in mean SNOT-20 score: 0.435); however, the authors noted that the difference may not be clinically meaningful. In qualitative analysis, the rate of revision surgery was comparable for balloon sinus dilation and other treatments. The authors stated that the available evidence was limited by a variety of sources of heterogeneity, including eligibility criteria, type of intervention, sinuses treated, outcome measures, and follow-up duration.(2) **(EG 1)** In a retrospective cohort study that included 159 patients with chronic rhinosinusitis without nasal polyposis who underwent maxillary balloon sinuplasty (77 patients) or endoscopic sinus surgery (82 patients), over a mean 5.3 and 9.8 years of follow-up, respectively, patients initially treated with balloon sinuplasty were more likely to require revision surgery (22% vs 7%). The authors noted that the study was limited by a retrospective design and lack of validated outcomes and recommended additional longer-term follow-up studies.(3) **(EG 2)** A specialty society clinical consensus statement found that balloon dilation of the sinuses can be appropriate when used as an adjunct procedure to functional endoscopic sinus surgery in patients with chronic sinusitis without nasal polyps; the statement also noted that there is a role for balloon dilation in patients with persistent sinus disease who had previous sinus surgery and in patients with recurrent acute sinusitis. The authors note that there was near consensus that balloon dilation of the sinuses is appropriate for patients with more limited sinus disease who meet criteria for surgery; however, there was not agreement about how to define limited disease.(1) **(EG 2)** An international position statement on rhinosinusitis states that balloon sinuplasty may have a role in the treatment of milder cases of chronic rhinosinusitis.(14) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For chronic rhinosinusitis in pediatric patients, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A prospective, randomized, blinded controlled trial including 25 children comparing adenoidectomy with maxillary sinus irrigation, with or without preoperative balloon catheter dilation in patients with rhinosinusitis refractory to maximal medical therapy, found at 12-month follow-up that both groups had similar improvement in quality-of-life scores and median Sinus and Nasal Quality of Life Survey (SN-5) scores in all domains (ie, number of sinus infections, nasal obstruction, allergy symptoms, emotional distress, and activity limitations). The authors concluded that the optimal role for balloon sinuplasty remains uncertain.(6) **(EG 1)** A prospective multicenter study of 50 pediatric patients (157 sinus dilations) evaluating sinuplasty for chronic rhinosinusitis found, at 6

months post procedure, significant improvement in functional nasal complaints and quality of life on the SN-5 and the Sino-Nasal Outcome Test (SNOT-22). The limitations of the study included the lack of a control group and the presence of an adjunctive procedure in 60% of the patients (most commonly adenoidectomy), preventing conclusions as to the relative contribution of the sinus procedure to the clinical outcomes.(7) **(EG 2)** A prospective study of 30 children with chronic rhinosinusitis refractory to medical therapy found, 1 year after balloon sinuplasty, that the procedure was associated with improved objective (endoscopic and Lund-Mackay CT scores) and subjective (visual analog scales, SN-5 scores, SNOT-22 scores) measures. However, there was no control group, and further long-term studies were recommended.(8) **(EG 2)** An observational study of 31 pediatric patients with chronic rhinosinusitis who failed medical therapy compared balloon sinuplasty and ethmoidectomy with functional endoscopic sinus surgery and reported that, at a mean follow-up of 9 months, there was no significant difference in overall improvement in sinus symptoms. Larger long-term studies were recommended to more accurately identify patients who would benefit from the procedures as well as to determine if balloon sinuplasty alone would provide a better outcome as compared with functional endoscopic sinus surgery.(9) **(EG 2)** Review articles evaluating the surgical treatment of pediatric rhinosinusitis note that there are no high-quality studies demonstrating equivalence or superiority of balloon sinuplasty to existing methods in terms of safety or efficacy.(10)(11)(12)(13) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(23); 42 CFR 422.101(24)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(25); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(26); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(27)

Medicare Coverage Determinations: Medicare Coverage Database(28)

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