



**AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY**

**AAO-HNS Statement on Reimbursement of Balloon Sinus Ostial Dilation
(September 2014)**

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), with approximately 12,000 members nationwide, is the national medical association of physicians dedicated to the care of patients with disorders of the ears, nose, throat, and related structures of the head and neck. The medical ailments treated by this specialty are among the most common that afflict all Americans, old and young, including hearing loss, balance disorders, chronic ear infections, rhinological disorders, snoring and sleep disorders, swallowing disorders, facial and other cranial nerve disorders, and head and neck cancer.

Chronic rhinosinusitis (CRS) has been a significant health care problem worldwide for many years. Medical management is generally accepted as the first-line treatment for non-complicated CRS. Surgical management for patients that have failed medical management has progressed from open surgical procedures to functional endoscopic sinus surgery (FESS) to balloon sinus ostial dilation (BSOD).

The AAO-HNS supports the use of a balloon as a tool in a standard approach to sinus ostial dilation along with other indicated endoscopic surgery, and strongly encourages all payers to consider its use as a covered service.

We remain concerned with payer policies that designate stand-alone ostial dilation as “experimental/investigational” and/or “not medically necessary” given of the significance of the available evidence indicating the contrary.

AAO-HNS Position Statement: *Dilation of Sinuses, Any Method (e.g., balloon, etc.)*¹

<http://www.entnet.org/Practice/Balloon-Dilation.cfm>.

According to the AAO-HNS official Position Statement, “Sinus ostial dilation (e.g. balloon ostial dilation) is an appropriate therapeutic option for selected patients with sinusitis. This approach may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (eg, microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.”

Revised: 12/6/2010

Adopted: 6/28/2010

Reaffirmed: 12/8/2012

¹ Important Disclaimer Notice (updated 7/31/14)

Position statements are approved by the American Academy of Otolaryngology—Head and Neck Surgery, Inc. or Foundation (AAO-HNS/F) Boards of Directors and are typically generated from AAO-HNS/F committees. Once approved by the Academy or Foundation Board of Directors, they become official position statements and are added to the existing position statement library. In no sense do they represent a standard of care. The applicability of position statements, as guidance for a procedure, must be determined by the responsible physician in light of all the circumstances presented by the individual patient. Adherence to these clinical position statements will not ensure successful treatment in every situation. As with all AAO-HNS/F guidance, this position statement should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results. Position statements are not intended to and should not be treated as legal, medical, or business advice.

Our Position Statements designate official policies of the AAO-HNS by drawing upon the best evidence and quality products available. They are routinely reviewed by experts of appropriate clinical committees and the Academy's Physician Policy Payment (3P) Workgroup before final approval by the Academy's Executive Committee and Board of Directors. Given the level of evidence used, process to create, and the purpose of these guidance documents, the AAO-HNS encourages all payers to consider Position Statements when establishing policy, especially when a coverage determination has the potential to impact the quality of care available to patients. For these reasons, we urge payers to incorporate the AAO-HNS' Position Statement: *Dilation of Sinuses, Any Method (e.g., balloon, etc.)* as a leading reference and basis for coverage when evaluating the use of a balloon as a tool in a standard approach to sinus ostial dilation.

Updated References and New Randomized Control Trials

Further, the AAO-HNS encourages all payers to review the list of updated and expanded references to the *Dilation of Sinuses, Any Method (e.g., balloon, etc.)* statement. More specifically, five additional peer-reviewed references have been included, which are noted in bold below. In addition, we urge consideration of three recently published randomized control trials (RCTs), also noted in bold below.

The Academy supports efforts by to develop and publish results of RCTs and additional peer-reviewed literature, which we hope private payers will take into consideration when reviewing the updated materials. Such materials, along with the ***wide spread use, clinical experience, approval by the Food and Drug Administration, and the positions of numerous other insurers demonstrate that the use of a balloon as a tool in a standard approach to a sinus ostial dilation is indeed acceptable and should be a covered service.***

Below are the updated references included in the AAO-HNS Position Statement: *Dilation of Sinuses, Any Method (e.g., balloon, etc.)*, for use in appeals with private payers.

REFERENCES

- 1. Achar P., Duvvi S. & Kumar B.N. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. Acta Otorhinolaryngol Ital. 2012; 32, 314-319.**
2. Atkins J, Truitt T. In-office balloon dilation of the ethmoid infundibulum. Operative Techniques in Otolaryngology. 2010; 21:102-106.
3. Bolger WE, Brown CL, Church CA, et al. Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. Otolaryngol Head Neck Surg. 2007; 137(1):10-20.
- 4. Brodner D, Nachlas N, Mock P, et al. Safety and outcomes following hybrid balloon and balloon-only procedures using a multifunction, multisinus balloon dilation tool. Int Forum Allergy Rhinol. 2013 Aug;3(8):652-8.**
5. Brown CL, Bolger WE. Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: a preliminary investigation. Ann Otol Rhinol Laryngol. 2006; 115(4):293-299. Sep;27(5):416-22. doi: 10.2500/ajra.2013.27.3970. Epub 2013 Aug 5.
6. Christmas DA, Mirante JP, Yanagisawa E. Endoscopic view of balloon catheter dilation of sinus ostia (balloon sinuplasty). Ear Nose Throat J. 2006; 85(11): 698, 700.

- 7. Cutler J., Bikhazi N., Light J., Truitt T., Schwartz M. & Investigators A.T. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial. Am J Rhinol Allergy. 2013. Sep;27(5):416-22. doi: 10.2500/ajra.2013.27.3970. Epub 2013 Aug 5.**
8. Friedman M, Schalch P, Lin HC, et al. Functional endoscopic dilatation of the sinuses: patient satisfaction, postoperative pain, and cost. Am J Rhinol. 2008; 22(2):204-209.
- 9. Karanfilov B, Silvers S, Pasha R, et al. Office-based balloon sinus dilation: a prospective, multicenter study of 203 patients. Int Forum Allergy Rhinol. 2013; 3(5):404-411.**
10. Kuhn FA, Church CA, Goldberg AN, et al. Balloon catheter sinusotomy: one-year follow-up--outcomes and role in functional endoscopic sinus surgery. Otolaryngol Head Neck Surg. 2008; 139(3 Suppl 3):S27-37.
11. Levine HL, Sertich AP 2nd, Hoisington DR, et al.; PatiENT Registry Study Group. Multicenter registry of balloon catheter sinusotomy outcomes for 1,036 patients. Ann Otol Rhinol Laryngol. 2008; 117(4):263-270.
- 12. Levine SB, Truitt T, Schwartz M, Atkins J. In-Office Stand-Alone Balloon Dilation of Maxillary Sinus Ostia and Ethmoid Infundibula in Adults With Chronic or Recurrent Acute Rhinosinusitis: A Prospective, Multi-institutional Study With 1-Year Follow-Up. Ann Otol Rhinol Laryngol 2013;122:665-671.**
13. 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.
14. Ramadan HH, McLaughlin K, Josephson G, et al. Balloon catheter sinuplasty in young children. Am J Rhinol Allergy. 2010; 24(1):e54-56.
- 15. Soler ZM, Smith TL. Quality-of-life outcomes after endoscopic sinus surgery: how long is long enough? Otolaryngol Head Neck Surg. 2010; 143:621-5.**
16. Stankiewicz J, Tami T, Truitt T, et al. Impact of chronic rhinosinusitis on work productivity through one-year follow-up after balloon dilation of the ethmoid infundibulum. Int Forum Allergy Rhinol. 2011 Jan-Feb; 1 (1): 38-45.
17. Stankiewicz J, Tami Y, Truitt T. et al. Transantral, endoscopically guided balloon dilatation of the ostiomeatal complex for chronic rhinosinusitis under local anesthesia. Am J Rhinol Allergy. 2009; 23(3):321-327.
- 18. Stankiewicz J, Truitt T, Atkins J, et al. Two-year results: transantral balloon dilation of the ethmoid infundibulum. Int Forum Allergy Rhinol. 2012; 2:199-206.**
- 19. Tomazic PV, Stammberger H, Braun H, et al. Feasibility of balloon sinuplasty in patients with chronic rhinosinusitis: the Graz experience. Rhinology. 2013; Jun;51(2):120-7.**
20. Vaughn WC. Review of balloon sinuplasty. Curr Opin Otolaryngol Head Neck Surg. 2008; 16:2-9.
21. Weiss RL, Church CA, Kuhn FA, et al. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. Otolaryngol Head Neck Surg. 2008; 139(3 Suppl 3):S38-46.
22. Wittkopf ML, Becker SS, Duncavage JA, Russell PT. Balloon sinuplasty for the surgical management of immunocompromised and critically ill patients with acute rhinosinusitis. Oto – Head & Neck Surg. 2009 Apr; 140(4); 596-598.