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February 5, 2020

Blue Cross Blue Shield  
Federal Employee Program  
1310 G Street, N.W.  
Washington, DC 20005

RE: FEP 7.01.105 Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis

Dear Dr. Yoder:

On behalf of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)<sup>1</sup>, we wish to offer comments regarding Blue Cross Blue Shield's Federal Employee Program (BCBS FEP) Medical Coverage Policy on Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis (FEP 7.01.105), effective July 2019. Considering the decisions by other major insurers (e.g., Anthem<sup>2</sup> and United Healthcare<sup>3</sup>) to cover this procedure, and for the reasons set forth below, **the AAO-HNS respectfully disagrees with BCBS FEP's position designating this procedure as investigational.** We urge BCBS FEP to revisit and amend its policy given the strong evidence supporting balloon sinus ostial dilation (BSOD) as efficacious in improving outcomes in patients with chronic rhinosinusitis (CRS). We detail and reference the relevant evidence concerning BSOD below.

**I. Standard of Care and Rationale on Currently Available Medical Evidence**

BSOD has become an accepted alternative procedure to functional endoscopic sinus surgery (FESS) for the treatment of CRS in a select subset of patients as described in the AAO-HNS Clinical Consensus Statement<sup>4</sup> on BSOD. BSOD improves ventilation of and facilitates drainage of obstructed sinuses. The balloon procedure is less invasive and traumatic than FESS causing minimal bleeding and scarring, resulting in less postoperative pain and a more rapid

<sup>1</sup> The AAO-HNS is the nation's largest medical organization representing specialists who treat the ear, nose, throat, and related structure of the head and neck. The Academy represents approximately 10,000 otolaryngologist-head and neck surgeons who diagnose and treat disorders of those areas.

<sup>2</sup> [https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl\\_pw\\_d080140.html](https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl_pw_d080140.html)

<sup>3</sup> <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/balloon-sinus-ostial-dilation-cs.pdf>

<sup>4</sup> Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Sinuses. Otolaryngology-Head and Neck Surgery 2018, Vol. 158(2) 203-214.

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recovery time.<sup>5,6,7,8</sup> As cited by the studies included in the medical policy, BSOD is effective at improving symptoms and reducing acute exacerbations of CRS during the observation periods of the studies which ranged from 1 to 2 years. BSOD can be safely performed in the office setting for the frontal, sphenoid, and maxillary sinuses under local anesthesia as well as in the outpatient and hospital settings. The office-based availability allows the surgeon the ability to offer this treatment to patients who are not candidates for a general anesthetic as well as reduces the cost of performing BSOD.

The AAO-HNS disagrees with BCBS FEP's interpretation of and conclusions drawn from the evidence outlined in the REMODEL randomized clinical trial (RCT). BCBS FEP's policy correctly states that the REMODEL trial included unblinded outcomes assessment, but the vast majority of data obtained from this study was totally objective and would not have been enhanced by this type of unblinded assessment. The questions addressed by this study include:

- 1) whether balloon dilation improves patients with respect to their baseline status;
- 2) whether particular subsets of balloon dilation patients have consistently better worse outcomes; and
- 3) whether BSOD is comparable in efficacy to FESS.

The results obtained from the final cohort of 135 patients clearly indicated benefit to the patient population that was similar to that of FESS with the additional benefits of less postoperative pain, fewer debridements, and a more rapid recovery time. BCBS FEP also lists the differential dropout between study groups as a limitation of the study. While there was a difference in the rate of completion in each arm, there are more than adequate numbers of patients in each arm to validate and justify the conclusions reached. The AAO-HNS feels it is critical to note that the improvements in sinus symptoms after BSOD are maintained for patients observed at the two-year mark following the procedure.

Several of the references included in the policy suggest limitations within the SNOT-20, 20+1, and 22 questionnaires. The AAO-HNS is committed to continuing the development of relevant patient reported outcome measures and collecting data through our registry, Reg-ent. While this effort is under development, however, the SNOT tests remain standard measurements within our specialty which have been validated many times. Subjective patient reporting will never be perfect, but these tests have been

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<sup>5</sup> Hayes, Inc. Directory. Balloon sinuplasty for treatment of chronic rhinosinusitis. Lansdale, PA: Hayes, Inc.: Sept 15, 2016.

<sup>6</sup> Hepworth EJ. Balloon Sinuplasty. [Ed] Meyers AD. Medscape. Feb 23, 2016. Accessed Feb 28, 2017. Available at URL address: <http://emedicine.medscape.com/article/1574031-overview#showall>

<sup>7</sup> American Rhinologic Society. Sinuplasty. Feb 17, 2015, Accessed Feb 28, 2017. Available at URL address: <http://care.american-rhinologic.org/sinuplasty>

<sup>8</sup> Ahmed J, Pal S, Hopkins C, Jayaraj S. Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. Cochrane Database Syst Rev. 2001 Jul 6;(7):CD008515.

the most commonly used comparators over decades of sinus research. Significant work has also been done to demonstrate these questionnaires do correlate with overall quality of life<sup>9,10</sup>.

***The AAO-HNS strongly disagrees with categorization of a catheter-based inflatable device (BSOD) in the treatment of sinusitis as investigational. We would request that this designation be removed from BSOD based on the continuing accumulation of evidence demonstrating efficacy and safety comparable to FESS.***

## II. Clinical Consensus Statement (CCS) on Balloon Sinus Ostial Dilation

In February 2018, a CCS on balloon dilation of the sinuses was published in the *Otolaryngology-Head and Neck Surgery Journal*. An expert panel of otolaryngologists, representing AAO-HNSF and relevant subspecialty societies, reached consensus on 13 statements. The statements, which must be considered as a whole, include the following:

- Patient Criteria
  - Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT.
  - Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
  - Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
  - CT scanning of the sinuses is a requirement before balloon dilation can be performed.
  - Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
  - Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
  - There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
  - There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and the CT evidence of ostial occlusion and mucosal thickening.
- Perioperative Criteria
  - Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the FDA for reprocessing such devices and ensure that they are followed.
  - Balloon dilation can be performed under any setting as long as proper precautions are taken, and appropriate monitoring is performed.
  - Balloon dilation can be performed under local anesthesia with or without sedation.

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<sup>9</sup> Remenschneider AK, D'Amico L, Litvack JR, Gray ST, Holbrook EH, Gliklich R, Metson R. Long-term Outcomes in Sinus Surgery: A New Tool for Measuring Health Related Quality of Life. *Otolaryngol Head Neck Surg*. 2014 Jul; 151(1):164-70.

<sup>10</sup> Rudmik L, Mace J, Soler ZM, et al. Long-term Utility Outcomes in Patients Undergoing Endoscopic Sinus Surgery. *Laryngoscope*. 2014 Jan; 124(1):19-23.

- Outcomes
  - Balloon dilation can improve short term quality of life outcomes in patients with limited CRS without polyposis.
  - Balloon dilation can be effective in frontal sinusitis.

The AAO-HNS would also like to draw attention to the role of BSOD in managing patients with recurrent acute rhinosinusitis (RARS). By omitting mention of the RARS patient population in its evidence review, BCBS FEP is overlooking a significant patient population treated by using BSOD appropriately. Based on symptoms and CT evidence of ostial occlusion and mucosal thickening, we believe that BSOD is also appropriate for the management of properly selected patients with RARS. This assertion is also supported by current literature.<sup>11</sup>

***The AAO-HNS strongly recommends BCBS FEP update its medical coverage policy, taking the Clinical Consensus Statement into consideration.***

### III. Pediatric Use of Balloon Sinus Ostial Dilation

Lastly, while the medical coverage policy does not address pediatric use of balloon sinus ostial dilation (i.e., patients under 12 years of age), there is literature which shows the efficacy of this procedure for persons in this age category. In some pediatric patients, the AAO-HNS believes the use of balloons does meet medical necessity. Therefore, if prior authorization is received, the procedure should be allowed and covered for certain pediatric cases. ***The AAO-HNS requests that language be added to this policy to allow for BSOD coverage for certain pediatric cases, at the discretion of the treating physician.***<sup>12,13</sup>

### IV. Conclusion

In summary, we strongly recommend that BCBS FEP modify its Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis medical policy based on our recommendations. We appreciate the opportunity to comment on this medical policy and would welcome the opportunity to discuss our feedback. Should you have any questions, please contact us at [healthpolicy@entnet.org](mailto:healthpolicy@entnet.org) or (703) 535-3725.

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<sup>11</sup> 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. Nov; 122(11): 665-71.

<sup>12</sup> Soler, Zachary M. Prospective, Multicenter Evaluation of Balloon Sinus Dilation for Treatment of Pediatric Chronic Rhinosinusitis. Combined Otolaryngology Spring Meetings. Hyatt Regency Chicago, Chicago, IL. May 18, 2016. Presentation.

<sup>13</sup> Soler ZM, Rosenbloom JS, Skarada D, et al. Prospective, multicenter evaluation of balloon sinus dilation for treatment of pediatric chronic rhinosinusitis. *Int Forum Allergy Rhinol.* 2017 Mar; 7(3): 221–229.

Sincerely,

*James C. Denny III*

James C. Denny III, MD, FACS  
Executive Vice President and CEO

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