LOUISIANA BLUE

Nasal Swell Body Ablation Reduction in the Treatment of Nasal Obstruction

Policy # 00724
Original Effective Date: 05/01/2021
Current Effective Date: 03/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Cryotherapy for the Treatment of Chronic Rhinitis is addressed separately in medical policy 00723.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers nasal septal swell body destruction, ablation, or coblation for the treatment of sinonasal disease, including but not limited to nasal obstruction, to be **investigational.***

Background/Overview

Nasal septal swell body has been described in the literature in various medical languages. These terminologies include nasal septal turbinate, septal turbinate, Kiesselbach's body, septal swell body, nasal septal body, septal body, nasal swell body, NSB, swell body, septal erectile body, septal cavernous body, anterior septum tuberculum, and intumenscentia septi nasi anterior.

The nasal septal swell body (NSB) is a distinct structure located in the anterior part of the nasal septum (NS), adjacent to the anterior part of the middle turbinate and superior part of the inferior turbinate (IT). Structurally, NSB contains bone and cartilage components of the NS and swell tissues involving bones and cartilages. Previous studies have suggested that NSB is a part of the nasal cavity and plays an essential role in regulating various physiological functions. The NSB has been a surgical target of interest and hence surgical procedures have also been attempted to reduce its volume in recent years.

To date, there have been no uniform criteria regarding the size of an NSB in healthy individuals and definition of NSB hypertrophy. Recently, Yu et al proposed a definition of NSB hypertrophy based on nasal endoscopic examination: bilateral symmetrical bulging, not ultimately seeing the middle turbinate from limen nasi, and a gap of < 3 mm between the NSB and the lateral nasal wall. However, these criteria have not been verified in a large sample population. Therefore, this definition needs to be validated in multicenter studies. In addition, the influence of the bony septum and septal cartilage should be considered while setting standards.

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The contribution of nasal swell body (NSB) presence to persistent nasal obstruction, and effects of treatment, are undefined.

Various surgical approaches have been identified for the reduction of enlarged nasal septal swell bodies including radiofrequency ablation (RFA), coblation, and the use of micro-debridement.

Coblation is a method of non-thermal volumetric tissue removal through molecular dissociation, similar to that of excimer lasers. Coblation uses the electrically conductive fluid employed in surgeries in the gap between the electrode and tissue. When electrical current is applied to this fluid, it turns into a charged layer of particles, called a plasma layer. Charged particles accelerate through the plasma and gain sufficient energy to break the molecular bonds within cells. This causes the cells to disintegrate molecule by molecule, so that tissue is volumetrically removed.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

In their prospective, multicenter, open-label, single-arm study, Pritikin et al. (2023) assessed the clinical use of a temperature-controlled radiofrequency (TCRF) device (VivAer) to treat septal swell body (SSB) hypertrophy to improve symptoms in adults with nasal airway obstruction (NAO). The study included 70 patients between 22 and 85 years old (mean age of 47.5 years, 51.4% male, 88.6% white) with severe (61.4%) or extreme (38.6%) NAO related to SBB hypertrophy. All patients received TCRF treatment in the SSB area with an average of 4.8 treatments per nostril (range 2 to 6). The primary endpoint was improvement in the Nasal Obstruction Symptom Evaluation (NOSE) score from baseline to 3 months post-procedure. One participant was lost to follow-up before the 3-month post-procedure assessment. The authors reported significant improvement in mean NOSE Scale scores from 73.5 at baseline to 27.9 at three months postprocedure with 4.3% of patients reporting no further breathing problems and 46.4% reporting mild NAO, 39.1% reporting moderate NAO, 10.1% continued to report severe NAO, and no patients reporting extreme NAO. The responder rate was reported by the authors to be 95.7%. In a subset of participants (n = 37) who underwent CT imaging to evaluate posttreatment changes in SBB size, the authors reported that the CT results at 3 months showed statistically significant reductions in SBB with the greatest reduction in the middle thickness. Limitations of the study include the study design (open-label, single arm), the homogeneity of the study population's race, lack of medication management of the participants, industry sponsorship, lack of a control, and the short-term follow-up (3 months postprocedure). According to authors, future research could incorporate a control treatment to minimize potential bias, incorporate TCRF treatment of the SSB in combination with other treatments addressing

additional NAO contributors, and have longer-term follow-up to allow for investigation of the durability of the procedure's effects. The authors concluded that the study demonstrated that TCRF treatment of SSB hypertrophy is well tolerated and effective for reducing both SSB size and symptoms of NAO at three months. The authors plan to follow the participants through 36 months post procedure.

Meng et al. (2021) conducted a systematic review of the existing knowledge on recent NSB developments. The review was performed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. PubMed, Embase, Web of Science, Ovid, Cochrane Library, and Google Scholar were used for the literature search. Of the 345 journal articles that were initially obtained in the literature search, 28 were included in the review. Three articles evaluated NSB treatment outcomes: Yu et al., Kim et al., and Catalano et al. Yu et al. conducted a prospective randomized controlled study that suggested a microdebrider-assisted procedure for inferior turbinate and NSB hypertrophy was superior to turbinoplasty alone. The review notes the limitations of Yu et al. were a small sample size (26 patients) and a short follow-up period. Kim et al. conducted a study on using coblation to treat patients with an abnormally thickened NSB. The review notes Kim et al. demonstrated that coblation is an effective treatment option for NSB hypertrophy. Catalano et al. treated 60 patients with a prominent NSB using radiofrequency ablation (RFA). Nose obstruction symptom evaluation scores and NSB size scores were assessed at 3 and 6 months postoperatively. Patients reported satisfactory results and improved nasal congestion. One patient developed septal perforation which required attention. The authors concluded that it is still unclear if surgical intervention of the NSB for nasal obstruction improves the long-term therapeutic effect. Additional evidence on NSB surgical intervention and physiologic effects of this structure is needed.

Ibrahim and associates (2020) retrospectively reviewed 25 patients (48 sides) with radiofrequency ablation (RFA) of NSB and 10 patients with untreated NSB. A subset of the NSB-treated patients (18 of 25) were compared with 10 control patients with pre- and post-treatment outcomes using 22-item Sino-Nasal Outcome Test (SNOT-22). NSB were successfully reduced with RFA in all 48 sides at 2 time points (early < 1 month and late with mean 7.3 months). Local crusting (22 of 23 patients, 95.6%) and bone exposure (4 of 23 patients, 17.3%) were transient and resolved by the late time-point. Significant reductions in SNOT-22 scores (-24, p= 0.001) and individual subdomain (-2, p=0.002) were seen in the RFA group compared to the smaller reduction seen in controls (-8 and -1, respectively).

In a retrospective, case-series study, Kim and associates (2016) presented the results of Coblation nasal septal swell body (NSB) reduction for the treatment of nasal obstruction in patients with abnormally thickened NSB. The study was conducted at a single tertiary medical center; 8 patients underwent Coblation NSB reduction. Pre-operative and post-operative nasal functions were evaluated by acoustic rhinometry and subjective symptom scales. These researchers also analyzed pre-operative CT scan images and nasal endoscopic findings. The mean maximal NSB width was

16.4 ± 2.2 mm on pre-operative coronal CT scan images. The mean VAS score for nasal obstruction was decreased from pre-operative 7.63 ± 0.99 points to 3.88 ± 0.92 points (post-operative 3 months), 4.16 ± 0.78 points (post-operative 6 months), and 4.63 ± 0.69 points (post-operative 1 year); 6 of the 8 patients were satisfied with the clinical outcome at 1 year after the procedure. The authors stated that, to the best of their knowledge, Coblation NSB reduction has not yet been reported in the medical literature; these findings showed that it can be an effective treatment modality for nasal valve narrowing in patients with abnormally thickened NSB.

These preliminary findings need to be validated by well-designed studies. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcomes.

References

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4. Pritikin J, Silvers S, Rosenbloom J, et al. Temperature-controlled radiofrequency device treatment of septal swell bodies for nasal airway obstruction: An open-label, single arm multicenter study. Int Forum Allergy Rhinol. 2023 Mar 13.
5. Meng X, Zhu G. Nasal septal swell body: a distinctive structure in the nasal cavity. Ear Nose Throat J. 2021 Apr 21:1455613211010093.

Policy History

Original Effective Date: 05/01/2021
Current Effective Date: 03/10/2025

02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. New policy.
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. No change to coverage.
02/06/2025	Medical Policy Committee review

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02/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. References added.
Next Scheduled Review Date: 02/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	30117, 30999, 31299
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.