



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 12/06/22
LAST REVIEW DATE: 12/06/22
CURRENT EFFECTIVE DATE: 12/06/22
LAST CRITERIA REVISION DATE: 12/06/22
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2023

ABSORBABLE NASAL IMPLANT FOR TREATMENT OF NASAL VALVE COLLAPSE

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Nasal valve collapse is a readily identifiable cause of nasal obstruction. Specifically, the internal nasal valve represents the narrowest portion of the nasal airway with the upper lateral nasal cartilages present as supporting structures. The external nasal valve is an area of potential dynamic collapse that is supported by the lower lateral cartilages. Damaged or weakened cartilage will further decrease airway capacity and increase airflow resistance and may be associated with symptoms of obstruction. Individuals with nasal valve collapse may be treated with nonsurgical interventions in an attempt to increase the airway capacity but severe symptoms and anatomic distortion are treated with surgical cartilage graft procedures. The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in individuals with severe nasal obstruction. The concept is that the implant may provide support to the lateral nasal wall prior to resorption and then stiffen the wall with scarring as it is resorbed.

The U.S. Food and Drug Administration (FDA) cleared LATERA® (Entellus Medical/Stryker ENT, previously Spirox) for marketing by through the 510(k) process. LATERA® is the only commercially available absorbable nasal implant for the treatment of nasal valve collapse

Criteria:

- The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 12/06/22. We do not include marketing materials, poster boards and non-published literature in our review.



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Resources: (cont.)

Resources prior to 12/06/22 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Bikhazi N, Ow RA, O'Malley EM, Perkins N, Sidle DM, Stolovitzky P. Long-Term Follow-up from the Treatment and Crossover Arms of a Randomized Controlled Trial of an Absorbable Nasal Implant for Dynamic Nasal Valve Collapse. *Facial Plast Surg.* Dec 29 2021. doi:10.1055/s-0041-1740948
2. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. *Clin Otolaryngol.* Apr 2009;34(2):151-5. doi:10.1111/j.1749-4486.2009.01887.x
3. Howard BK, Rohrich RJ. Understanding the nasal airway: principles and practice. *Plast Reconstr Surg.* Mar 2002;109(3):1128-46; quiz 1145-6. doi:10.1097/00006534-200203000-00054
4. Lipan MJ, Most SP. Development of a severity classification system for subjective nasal obstruction. *JAMA Facial Plast Surg.* Sep-Oct 2013;15(5):358-61. doi:10.1001/jamafacial.2013.344
5. Olson MD, Barrera JE. A comparison of an absorbable nasal implant versus functional rhinoplasty for nasal obstruction. *Am J Otolaryngol.* Nov-Dec 2021;42(6):103118. doi:10.1016/j.amjoto.2021.103118
6. Rhee JS, Weaver EM, Park SS, et al. Clinical consensus statement: Diagnosis and management of nasal valve compromise. *Otolaryngol Head Neck Surg.* Jul 2010;143(1):48-59. doi:10.1016/j.otohns.2010.04.019
7. San Nicolo M, Stelter K, Sadick H, Bas M, Berghaus A. Absorbable Implant to Treat Nasal Valve Collapse. *Facial Plast Surg.* Apr 2017;33(2):233-240. doi:10.1055/s-0037-1598655
8. San Nicolo M, Stelter K, Sadick H, Bas M, Berghaus A. A 2-Year Follow-up Study of an Absorbable Implant to Treat Nasal Valve Collapse. *Facial Plast Surg.* Oct 2018;34(5):545-550. doi:10.1055/s-0038-1672213
9. Sidle DM, Stolovitzky P, O'Malley EM, Ow RA, Nachlas NE, Silvers S. Bioabsorbable Implant for Treatment of Nasal Valve Collapse with or without Concomitant Procedures. *Facial Plast Surg.* Oct 2021;37(5):673-680. doi:10.1055/s-0041-1726464
10. Sidle DM, Stolovitzky P, Ow RA, et al. Twelve-month outcomes of a bioabsorbable implant for in-office treatment of dynamic nasal valve collapse. *Laryngoscope.* May 2020;130(5):1132-1137. doi:10.1002/lary.28151



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Resources: (cont.)

11. Stewart MG, Witsell DL, Smith TL, Weaver EM, Yueh B, Hannley MT. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. *Otolaryngol Head Neck Surg.* Feb 2004;130(2):157-63. doi:10.1016/j.otohns.2003.09.016
12. Stolovitzky P, Senior B, Ow RA, Mehendale N, Bikhazi N, Sidle DM. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: a randomized control trial. *Int Forum Allergy Rhinol.* Aug 2019;9(8):850-856. doi:10.1002/alr.22362
13. Stolovitzky P, Sidle DM, Ow RA, Nachlas NE, Most SP. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. *Laryngoscope.* Nov 2018;128(11):2483-2489. doi:10.1002/lary.27242
14. Stryker. Latera. Accessed September 7, 2022. <http://www.spiroxmed.com/latera>.

Coding:

CPT: 30468, 30469

History:

Date:

Activity:

Medical Policy Panel

12/06/22

Approved guideline

Policy Revisions:



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkídkgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'idíłkídkgo beehaz'áanii hółq díí t'áa hazaadk'ehjí hákák a'doowołgo bee haz'ą doo baqah ílínígóó. Ata' halne'ígíí kojį' bich'į' hodíłnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

