Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 3/1/2025
Policy Number: ccp.1441	Effective Date: Revision Date: 2/2025
Policy Name: Latera absorbable nasal implant	

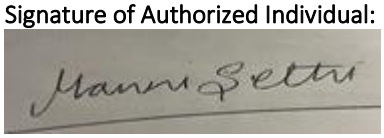
Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Please see tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Latera absorbable nasal implant

Clinical Policy ID: CCP.1441

Recent review date: 2/2025

Next review date: 6/2026

Policy contains: Latera; nasal implant; nasal valve obstruction, nasal wall collapse.

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania on a case by case basis when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.

Coverage policy

The Latera® absorbable nasal implant (Stryker Corporation, Portage, Michigan) is clinically proven and, therefore, may be medically necessary for treatment of symptomatic nasal airway obstruction caused by nasal valve collapse, when all of the following criteria are met (American Academy of Otolaryngology — Head and Neck Surgery, 2023; American Rhinologic Society, 2022; Bikhazi, 2022; Stolovitzky, 2019):

- Member age 18 and older.
- Nasal Obstruction Symptom Evaluation (NOSE) score ≥ 55.
- Dynamic bilateral nasal wall insufficiency as confirmed by Positive Modified Cottle Maneuver.
- Nasal and facial anatomy appropriate to receive the Latera Implant.
- Documented failure of benefit after at least four weeks of conservative medical management.

Limitations

All other uses of the Latera absorbable nasal implant, including for solely cosmetic reasons, are investigational/not clinically proven and, therefore, not medically necessary.

Contraindications to the Latera absorbable nasal implant include any of the following criteria (Stolovitzky, 2019):

- The member is unable to tolerate or not a candidate for procedures performed under local anesthesia.
- The member requires, or is anticipated to require, any other concurrent nasal procedure (e.g., Functional Endoscopic Sinus Surgery, rhinoplasty, sinuplasty, septoplasty, or turbinate reduction) outside of the index procedure within 12 months after the index procedure.
- The member has undergone Functional Endoscopic Sinus Surgery, sinuplasty, septoplasty, inferior turbinate reduction, or rhinoplasty within the previous six months.

- The member is using chronic systemic steroids or recreational intra-nasal drugs.
- The member is known or suspected to be pregnant or is lactating.
- The member has:
    - Concomitant inflammatory or infectious conditions or unhealed wounds in the treatment area (e.g., vestibulitis, vasculitis, active acne).
    - Cancerous or pre-cancerous nasal lesions, has had radiation in the treatment area, or is currently receiving chemotherapy.
    - A permanent nasal implant of any type (e.g., autologous, homologous, or synthetic graft) or dilator.
    - A history of a significant healing disorders including hypertrophic scarring, or keloid formation.
    - Poorly controlled diabetes mellitus.
    - Known or suspected allergy to materials in the Latera implant.
    - Severe obstructive sleep apnea and cannot or is unwilling to refrain from continuous positive airway pressure for up to two weeks post-procedure based on expected healing needs and mask types.

Alternative covered services

Nasal valve repair surgery; cartilage graft; nasal dilator.

Background

The nasal valve region, consisting of the septum, turbinate, and nasal sidewall, undergoes changes in pressure during inhalation (Ishii, 2013). While the septum and turbinate are typically rigid, the nasal sidewall is less so and, therefore, is generally the determinant of nasal valve rigidity. Even slight changes to the structures in this region can affect nasal airflow. Nasal obstruction affects up to one-third of the population (Hsu, 2018).

Many potential causes, frequently structural or inflammatory in nature, can account for nasal valve obstruction, with multiple coexisting factors leading to symptoms. Common structural causes include inferior turbinate hypertrophy, nasal septal deviation, and narrowing or collapse of the internal or external nasal valves (Schuman, 2018).

Diagnosis of the source of nasal valve obstruction is challenging. The patient's subjective experience is not always consistent with findings on physical examination. It can be difficult to determine which of the three structures of the nasal valve area is most responsible for nasal airway obstruction in any individual. Finally, several measures of nasal valve obstruction exist, most of which are subjective; however, there is no recognized standard for assessment (Camacho, 2016; Ishii, 2013).

Treatment of nasal valve dysfunction is aimed at stabilizing the nasal valve, relieving symptoms, and improving quality of life. Surgical repair may involve cartilage grafting and open surgical repair, suture suspension techniques, and office-based procedures such as radiofrequency treatment and implants. These procedures may be performed as standalone surgical procedures or in combination with other procedures (e.g., septoplasty, turbinate reduction, or endoscopic sinus surgery) to improve nasal obstruction (American Academy of Otolaryngology-Head and Neck Surgery, 2023).

While current surgical procedures can relieve nasal airway obstruction and improve quality of life, these procedures are invasive and potentially and permanently alter the patient's appearance. Absorbable nasal implants have been introduced to overcome these limitations. Absorbable nasal implants involve a minimally invasive approach designed to support upper and lower lateral wall cartilage and reduce nasal airway obstruction.

The Latera absorbable nasal implant received 510(k) premarket approval in 2016 based on a finding that it was substantially equivalent to legally marketed predicate devices. Latera is made of a polylactic acid copolymer that is placed within the nasal wall to support upper and lower lateral cartilage, reinforcing the nasal wall like traditional cartilage and polymer grafts. It may be implanted unilaterally or bilaterally under local anesthesia. After implantation, a fibrous capsule forms around the device, during which the implant retains integrity. Tissue continues to encapsulate the implant. Over time, the implant degrades and is absorbed. By 24 months after implantation, collagen replaces the implant (U.S. Food and Drug Administration, 2024).

Findings

Guidelines

The American Rhinologic Society (2022) supports the use of a bioabsorbable nasal implant to treat nasal obstruction due as an effective option in treating nasal valve collapse and improving patient quality of life. The Society cited the results of studies mentioned in this policy (San Nicoló, 2018; Stolovitzky, 2018, 2019).

In a consensus statement, the American Academy of Otolaryngology — Head and Neck Surgery (2023) stated that the nasal valve may be stabilized using office-based treatments such as nasal implants for appropriately selected patients with nasal valve collapse. The Academy did not specify type of implant but cited the Stolovitzky (2018) study described below as an evidence source.

Evidence review

Evidence from one randomized controlled study (Bikhazi, 2022; Stolovitzky, 2018, 2019) and other nonrandomized studies suggests the Latera absorbable nasal implant is safe and effective for treating nasal valve collapse caused by lateral wall insufficiency in adults with severe to extreme Nasal Obstruction Symptom Evaluation scores ≥ 55. The procedure can be performed in an office setting under local anesthesia. The treatment provides durable results for up to 24 months. All studies were sponsored by the manufacturer.

A systematic review of five studies (n = 396) of persons with nasal obstruction revealed bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion compared to pretreatment values and to sham surgery, and improved quality of life at 12 months post-procedure. An adverse effect rate of 5% was observed, and all were resolved without significant sequelae (Kim, 2020).

San Nicoló (2018) reported on safety and efficacy 24 months after implantation. The study was carried out in Germany and was sponsored by the manufacturer. All 30 participants received the device. Participants with a Nasal Obstruction Symptom Evaluation score ≥ 55 and isolated nasal valve collapse received a total of 56 implants. The devices were implanted under general anesthesia (n = 14) or local anesthesia (n = 16). Based on 24-month follow-up on the 25 participants who completed the study, the authors noted the implant appears to be effective, tolerable, and safe for most patients, but studies with a larger sample size, additional contemporaneous procedures, and follow-up longer than 24 months would be helpful in understanding the implant's longer term benefits.

A study of 101 persons with nasal wall insufficiency with a bioabsorbable implant were divided into 43 with implant alone and 58 with implant and adjunctive procedures. Improvements in both groups were documented in Nasal Obstruction Symptom Evaluation scores after six months ($P < .01$); in Visual Analog Scale scores after six months $P < .01$ for all); and in Lateral Wall Insufficiency scores ($P < .01$). The authors emphasized the need for a randomized, placebo-controlled trial to address the study design limitations and short-term follow-up (Stolovitzky, 2018; ClinicalTrials.gov identifiers NCT02952313 and NCT02964312).

Sidle (2021) reported outcomes through 24 months from two related multicenter, single-arm post-market studies in the United States (ClinicalTrials.gov identifiers NCT02952313 and NCT02964312). Adult participants with

severe to extreme nasal obstruction underwent implant alone or with concomitant inferior turbinate reduction performed in an office-setting or septoplasty performed in an inpatient setting. At 24 months after the initial surgery, 177 of the original 277 participants provided follow-up data. Significant reductions in Nasal Obstruction Symptom Evaluation and visual analog scale scores in implant recipients suggest sustained effectiveness at 24 months after treatment (both $P < .001$).

Nonserious adverse events were mild to moderate in severity, typically occurred within six months of implant, and resolved or were stable. There were no serious adverse events related to the device or implant procedure. Implant retrieval rate was 4.0% (22/543 implants). Responder rates for participants treated with the nasal implant alone were similar to those who underwent the implant with concomitant inferior turbinate reduction (88.3% to 94.5% versus 88.1% to 94.9%). Responder rates for participants who required septoplasty in addition to the nasal implant, with or without inferior turbinate reduction, ranged from 93.0 to 95.8%. Despite loss to follow-up, the authors believed the results at 24 months were reliable.

Stolovitzky (2019; ClinicalTrials.gov identifier NCT03400787) reported on a single-blinded, sham-controlled, randomized study of 127 patients followed for up to three months after implantation. The two arms were the treatment arm (63 participants) and sham control arm (64 participants). All procedures were performed in the office setting. After three months, there were improvements in the scores on both the Nasal Obstruction Symptom Evaluation ($P = .001$) and the Visual Analog Scale ($P < .0001$). All 19 procedure/implant-related adverse events resolved with no clinical sequelae. The investigators cited short-term follow-up and not blinding the physicians to treatment assignment as limitations to the study, although they used patient reported outcome measures to mitigate bias.

As a continuation to the Stolovitzky (2019) study, Bikhazi (2022) reported on 111 participants, of whom 70 completed 24 months follow up. The implant was safe with no serious device- or procedure-related adverse events reported. The implant migration/retrieval rate was 4.5% (10/222) of total implants or 9% of total participants (10/111). The implant was effective for providing significant and durable response rates up to 24 months based on improvements from baseline in the Nasal Obstructive Symptom Evaluation score, nasal obstruction visual analog scale, and the Epworth Sleepiness Scale outcome measures.

A retrospective study compared the patient-reported nasal obstruction severity outcomes following autologous cartilage repair (n = 24) and Latera nasal implantation (n = 39). Baseline demographic characteristics and quantitative Nasal Obstruction Symptom Evaluation scores ($P = .92$) were similar between groups, as were mean operative times ($P = .76$). Nasal Obstruction Symptom Evaluation scores significantly improved in both groups, but autologous cartilage grafts appeared to yield more favorable post-operative improvements at one month ($P = .002$), three months ($P = .034$), and six months ($P = .003$) (Clark, 2023).

An analysis of adverse events reported to the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience database between March 2017 and April 2022 identified 26 device reports associated with bioabsorbable nasal implants. The most frequently reported complications were abscess (13 reports) and implant protrusion (five). Facial pain/discomfort (three) and failure to absorb (three) occurred more than one year post-implantation. Adverse events were managed with antibiotics (nine), steroid injections (four), explantation (20), and biopsy of adjacent tissue (three) (Wilkins, 2023).

In 2022, we added one long-term follow-up study (Sidle, 2021). We found no guidelines that address absorbable nasal implants as a surgical alternative for nasal valve compromise. No policy changes are warranted at this time.

In 2023, we updated the references and added an earlier position statement by the American Rhinologic Society (2022). No policy changes are warranted.

In 2024, we updated the references and added one position statement and two studies to the policy that provide mixed results with respect to the relative and long-term efficacy of Latera absorbable nasal implants. No policy changes are warranted.

In 2025, we updated the references and changed the coverage to medically necessary based on guideline recommendations and findings from at least one randomized controlled trial showing that the Latera absorbable nasal implant is safe and has durable efficacy for up to 24 months.

References

On December 3, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Latera,” “nasal valve collapse,” and “nasal valve obstruction.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

12/2019: initial review date and clinical policy effective date: 2/2020

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

1/2024: Policy references updated.

2/2025: Policy references updated. Coverage modified.