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: Keystone First Community HealthChoices	**Submission Date**: 2/1/2024
Policy Number: ccp. 1441	**Effective Date:** 2/2020 **Revision Date:** January 1, 2024
Policy Name: Latera absorbable nasal implant	

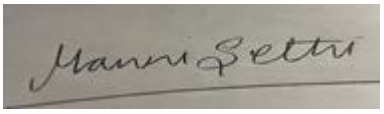
Type of Submission – Check all that apply:

- **New Policy**
- x **Revised Policy***
- **Annual Review – No Revisions**
- **Statewide PDL**

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

Please provide any clarifying information for the policy below:

See tracked changes below.

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

Keystone First
Community HealthChoices

Latera absorbable nasal implant

Clinical Policy ID: CCP.1441

Recent review date: 1/2024

Next review date: 5/2025

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

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Keystone First Community HealthChoices 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. Keystone First Community HealthChoices' 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. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The Latera® absorbable nasal implant (Stryker, Plymouth, Minnesota) is investigational/not clinically proven and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

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 (Camacho, 2016; Ishii, 2013). The patient's subjective experience is not always consistent with findings on physical examination (clinician-observed anomalies may not be troubling to the patient, while the patient may experience symptoms, the source of which is not clear on 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.

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).

The Latera absorbable nasal implant is a minimally invasive procedure designed to reduce nasal airway obstruction (U.S. Food and Drug Administration, 2019). It received 510(k) approval from the U.S. Food and Drug Administration 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.

Findings

The American Rhinologic Society (2022) supports the use of a bioabsorbable nasal implant to treat nasal obstruction due to nasal valve collapse as an effective option in treating nasal valve collapse and improving patient quality of life. The Society supports the use of a bioabsorbable nasal implant to treat nasal obstruction due to nasal valve collapse, citing the results of three studies mentioned in the previous findings of this policy (San Nicoló, 2018; Stolovitzky, 2018, 2019) but without considering the study design limitations that affect the validity of the results.

In a consensus statement, the American Academy of Otolaryngology — Head and Neck Surgery (2023) recommended nasal implants as one of several nasal valve repair options 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.

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).

A literature review of treatment of patients undergoing rhinoplasty found that while the standard of care remains autologous cartilage, a trend towards greater use of the Monarch nasal implant, absorbable valve implant, and titanium butterfly implant rather than traditional cartilaginous grafts is occurring (Ho, 2019).

The study with the longest follow-up period was published by San Nicoló (2018), who 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.

Sidle (2020; ClinicalTrials.gov identifier NCT02964312) reported on a study that enrolled 161 participants and followed them for up to 12 months. Of these, 100 received Latera alone, while 61 received Latera plus concurrent inferior turbinate reduction. All procedures were performed in an office setting. Scores on the Nasal Obstruction Symptom Evaluation were reduced in both groups ($P < .001$); there was also a significant reduction in Visual Analogue Scale scores ($P < .001$).

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).

Stolovitzky (2019; ClinicalTrials.gov identifier NCT03400787) reported on a single-blinded, sham-controlled randomized study of 137 patients followed for up to three months after implantation. The two arms were the treatment arm (70 participants) and sham control arm (67 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.

In sum, the completed studies were based on small samples of participants who were followed for relatively short time periods, reducing validity. Study populations in Sidle (2020) and Stolovitzky (2018) overlapped. Only 25 participants were followed for the longest observed period of 24 months. Potential sources of bias include the limited use of blinding: Only one study mentioned using blinding, which was limited to the participant, not the provider. Additionally, the assessment measures appear to be primarily subjective. These limitations preclude a thorough assessment of safety, efficacy, and durability.

In 2022, we added one long-term follow-up study. 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.

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.

The first study compared retrospectively 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).

References

On November 13, 2023, 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.