Corticosteroid-Eluting (Mometasone Furoate) Implants for the Treatment of Recurrent Nasal Polyps - Sinuva® and Propel®

Policy Number:	**M20200928103**
Effective Date:	**11/1/2020**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **Sinuva®** and **Propel®,** corticosteroid-eluting (mometasone furoate) implants for the treatment of recurrent **nasal polyps** associated with **chronic rhinosinusitis**.

Policy:

Commercial and Self-Funded

Sinuva®:

Mometasone furoate sinus implant, Sinuva® is considered medically necessary when all the following criteria are met:

- The member must be 18 years of age or older.
- The member must have a diagnosis of recurrent nasal polyps.
- The member has had ethmoid sinus surgery and has nasal obstruction/congestion symptoms despite use of intranasal steroid irrigations or sprays.
- The member has had previous treatment, contraindication, or intolerance to any of these conventional nasal polyp therapies:
    - leukotriene receptor antagonist
    - steroid taper
    - intranasal steroids

Propel®:

After a review of the available peer-reviewed evidence, mometasone furoate sinus implant, Propel®, for postoperative treatment following endoscopic sinus surgery or for the treatment of recurrent chronic rhinosinusitis with or without sinonasal polyps is considered investigational.

Medicare Advantage

The Centers for Medicare and Medicaid (CMS) does not address mometasone furoate sinus implants in either a National or Local Coverage Determination. However, CMS provides coverage for the HCPCS C-code assigned to this implant.

Medicare Advantage requests utilize the Commercial criteria above.

MediSource, MediSource Connect, Child Health Plus and Essential Plan

MediSource, MediSource Connect and Essential Plan cover Sinuva® utilizing the Commercial criteria when the procedure is billed with J7402 in an office setting.

MediSource, MediSource Connect and Essential Plan cover Sinuva® utilizing the Commercial criteria when the procedure is billed with C9122 in a free-standing ambulatory or facility setting.

MediSource, MediSource Connect and Essential Plan do not cover Propel® according to the Commercial criteria above.

Sinuva® or Propel® are not medically appropriate for Child Health Plus members under the age of 18 as they have not been FDA approved for individuals under the age of 18.

Background

Chronic rhinosinusitis is inflammation of the nose and paranasal sinuses characterized by the presence of two or more of the following symptoms for greater than 12 weeks duration: nasal blockage/obstruction/congestion; nasal discharge; facial pain/pressure; and reduction or loss of smell. Objective confirmation of the diagnosis is made by sinus CT scan or nasal endoscopy.

Medical therapies to treat nasal polyps associated with chronic rhinosinusitis include intranasal saline, intranasal glucocorticoids, nasal nebulized solutions, oral glucocorticoids, antibiotics for concomitant

infection and antileukotriene agents. Indications for surgical intervention include the failure of medical treatment, restoration of sinus ventilation (i.e., restoration of sinus ostial patency and removal of material from opacified sinuses), improve penetration of topical medical therapies, debulking of severe polyposis, or bony erosion or extension of disease beyond the sinus cavities.

Endoscopic sinus surgery is a minimally invasive procedure in which sinus air cells and sinus ostia are opened under direct visualization. The goal of this procedure is to restore sinus ventilation and normal function. Continued medical management is required in most patients with chronic rhinosinusitis postoperatively as sinus polyps are prone to recurrence.

Sinuva® is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. Sinuva® is made from bioabsorbable polymers designed to gradually soften over time and may be left in the sinus to gradually release the corticosteroid over 90 days. Removal of the Sinuva® implant can occur at day 90 or earlier at the physician's discretion using standard surgical instruments.

In 2011, the PROPEL® system (Intersect ENT, Palo Alto, CA) was approved by FDA through the premarket approval process for use in the ethmoid sinus cavity. Propel stents are coated with 370 micrograms of mometasone furoate, released locally to the mucosa over a 30-day period. The implant differs from Sinuva in that the Propel implant dissolves over several weeks, and therefore does not require removal. Supporting evidence consisted of limited sample sizes, short-follow-up, and manufacturer involvement in all eligible studies.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

Chronic rhinosinusitis is an inflammatory condition involving the paranasal sinuses and linings of the nasal passages that lasts 12 weeks or longer. The diagnosis requires objective evidence of mucosal inflammation. Among all patients with chronic rhinosinusitis, only about 25–30% have chronic rhinosinusitis with nasal polyps.

Nasal polyps are inflammatory outgrowths of sinonasal tissue that are estimated to occur in 1–4% of the US general population.

Propel® sinus device is a self-expanding bioabsorbable stent formed of a synthetic polymer in a lattice pattern, used post-operatively in patients undergoing endoscopic sinus surgery of the ethmoid sinus for CRS refractory to medical management.

Sinuva® sinus implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references
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Slack R, Bates G. Functional endoscopic sinus surgery. Am Fam Physician. 1998;58(3):707-718.

Stevens WW, Schleimer RP, Kern RC. Chronic Rhinosinusitis with Nasal Polyps. J Allergy Clin Immunol Pract. 2016;4(4):565-572.

Regulatory References
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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
12/1/2023	Health Care Services	Revised
12/1/2022	Health Care Services	Reviewed
12/1/2021	Health Care Services	Reviewed
1/1/2021	Health Care Services	Revised