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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Respiratory Agents	**Original Policy Date:**	June 8, 2018
Subject:	Sinus Implants	**Page:**	1 of 5

Last Review Date: September 6, 2024

Sinus Implants

Description

Propel, Sinuva (mometasone furoate)

Background

The Propel drug-eluting sinus stent and Sinuva sinus implant (mometasone furoate) are corticosteroid-eluting implants intended for use in patients 18 years of age and older who have had sinus surgery. These implants are designed to maintain the opening created by surgery and deliver mometasone furoate to keep it from becoming blocked. Mometasone furoate is a corticosteroid demonstrating potent anti-inflammatory activity. The precise mechanism of corticosteroid action on inflammation is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation (1-2).

The sinus implants are loaded into a delivery system and placed in the sinus cavity under endoscopic visualization. The implants are made from bio-absorbable polymers designed to gradually soften over time and may be left in the sinus to gradually release the corticosteroid. Sinuva sinus implants release the corticosteroid over 90 days and can be removed at day 90 or earlier at the physician’s discretion using standard surgical instruments. Propel sinus implants deliver the corticosteroid over 30 days and dissolve within 45 days. Sinuva sinus implants are to be used by physicians trained in otolaryngology. The safety of repeat administration of the Sinuva sinus implant was evaluated in a repeat placement study in patients with ethmoid sinus polyps grade ≥1 on any side. Repeat administration has not been studied in patients using Propel (1-3).

Regulatory Status

FDA-approved indications: (1-2)

- **Sinuva** 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
- **Propel** sinus implant is intended for use in patients ≥ 18 years of age following ethmoid sinus surgery
- **Propel mini** sinus implant is intended for use in patients ≥ 18 years of age following ethmoid/frontal sinus surgery
- **Propel Contour** sinus implant is intended for use in patients ≥ 18 years of age to maintain patency of the frontal and maxillary sinus ostia following sinus surgery

Monitor nasal mucosa adjacent to the Sinuva sinus implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma (1).

Patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts should be monitored closely (1).

Sinuva sinus implants may cause potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex. More serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections (1).

If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal (1).

The safety and effectiveness of Sinus Implants in pediatric patients have not been established (1-2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sinus Implants may be considered **medically necessary** if the conditions indicated below are met.

Sinus Implants may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Post sinus surgery

AND ALL of the following:

1. Inadequate response to a 3-month trial of **TWO** nasal corticosteroid sprays (i.e., mometasone, fluticasone, budesonide, or triamcinolone)
2. Inadequate response, intolerance, or contraindication to a 14 day trial of an oral corticosteroid (i.e. prednisone, methylprednisolone, or dexamethasone)
3. The administering physician is an Otolaryngologist (ENT)

Prior – Approval *Renewal* Requirements

Sinuva ONLY

Age 18 years of age and older

Diagnosis

Patient must have the following:

Post sinus surgery

AND ALL of the following:

1. Ethmoid sinus polyps grade ≥ 1 on any side
2. The administering physician is an Otolaryngologist (ENT)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 1 per nostril

Duration 12 months

Prior – Approval *Renewal* Limits

Sinuva ONLY (no renewal for Propel)

Quantity 1 per nostril

Duration 12 months (one renewal **only** for Sinuva)

Rationale

Summary

The Propel drug-eluting sinus stent and Sinuva sinus implant (mometasone furoate) are corticosteroid-eluting implants intended for use in patients 18 years of age or older who have had sinus surgery. Mometasone furoate is a corticosteroid demonstrating potent anti-inflammatory activity. The precise mechanism of corticosteroid action on inflammation is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. The safety and effectiveness of Sinus Implants in pediatric patients have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sinus Implants while maintaining optimal therapeutic outcomes.

References

1. Sinuva [package insert]. Menlo Park, CA: Intersect ENT, Inc.; January 2023.
2. Propel/Propel Mini/Propel Contour [package insert]. Menlo Park, CA: Intersect ENT, Inc.; December 2023.

3. Post-Surgical sinus drug Delivery Stent. (2019, April 22). Retrieved April 02, 2021, from https://www.intersectent.com/products/propel.

Policy History

Date	Action
June 2018	Addition to PA Annual editorial review
September 2018	Addition of intolerance or contraindication for oral corticosteroids and changed length of trial from 3 months to 14 days, added glaucoma warning to regulatory status per SME
March 2019	Annual review
May 2019	Addition of Propel drug-eluting sinus stent. Renamed policy Sinus Implants
June 2019	Annual review
March 2020	Annual review
May 2020	Added renewal criteria for repeat administration of Sinuva
June 2020	Annual review
April 2021	Removed nasal polyps from general indication under Background and Summary sections per FEP. Updated indications for different Propel implants. Changed initiation indication from post ethmoid sinus surgery to post sinus surgery. Changed continuation indication from nasal polyps to post sinus surgery.
June 2021	Annual review and reference update
September 2022	Annual review
September 2023	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.