Propel, Sinuva (mometasone furoate)

Background
The Propel drug-eluting sinus stent and Sinuva sinus implant (mometasone furoate) are corticosteroid-eluting implants indicated for the treatment of nasal polyps in patients 18 years of age and older who have had ethmoid 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 (1-2).

The sinus implants are loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. The implant is made from bio-absorbable polymers designed to gradually soften over time and may be left in the sinus to gradually release the corticosteroid over 90 days. The implant can be removed at day 90 or earlier at the physician’s discretion using standard surgical instruments. The sinus implants are to be used by physicians trained in otolaryngology. Repeat administration has not been studied (1-2).

Regulatory Status
FDA-approved indication: Sinus Implants are indicated for patients ≥ 18 years of age who have had ethmoid sinus surgery (1-2).
Monitor nasal mucosa adjacent to the Sinus Implants for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma (1-2).

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

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

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 in patients age 18 years of age or older for recurrent nasal polyp disease and if the conditions indicated below are met.

Sinus Implants are considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older

Diagnosis
Patient must have the following:
Post ethmoid 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**
None

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>1 per nostril per Lifetime</th>
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<tbody>
<tr>
<td>Duration</td>
<td>1 month</td>
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</table>

**Prior – Approval Renewal Limits**
None

**Rationale**

**Summary**
The Propel drug-eluting sinus stent and Sinuva sinus implant (mometasone furoate) are corticosteroid-eluting implants indicated for the treatment of nasal polyps in patients 18 years of age or older who have had ethmoid 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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>June 2018</td>
<td>Addition to PA</td>
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<tr>
<td></td>
<td>Annual editorial review</td>
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<tr>
<td>September 2018</td>
<td>Addition of intolerance or contraindication for oral corticosteroids and</td>
</tr>
<tr>
<td></td>
<td>changed length of trial from 3 months to 14 days, added glaucoma warning</td>
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<tr>
<td>March 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>May 2019</td>
<td>Addition of Propel drug-eluting sinus stent. Renamed policy Sinus Implants</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.