Drug Eluting Devices for Use Following Endoscopic Sinus Surgery
Policy Number: PG0384
Last Review: 04/26/2018

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
_ Facility

DESCRIPTION
Rhinosinusitis, also referred to as sinusitis, is inflammation of the mucosal membrane lining the nasal cavities and the paranasal sinuses. Rhinosinusitis lasting more than 12 weeks is classified as chronic rhinosinusitis (CRS). The goals of treating CRS are to eliminate underlying causes, reduce sinus inflammation, and drain nasal passages. Medical therapy is the first-line treatment for CRS. Treatments recommended may include nasal saline sprays, nasal lavage, antibiotic therapy, nasal corticosteroids, oral or injected corticosteroids, decongestants, over-the-counter pain relievers, leukotriene modifiers, and antihistamines. Patients who do not respond to medical therapy are candidates for sinus surgery.

Functional endoscopic sinus surgery (FESS) is a set of minimally invasive surgical techniques which allow direct visual examination and opening of the sinuses for the treatment of chronic rhinosinusitis which has not responded to medical treatment. FESS may be compromised by postoperative inflammation, polyposis and adhesions, which often require further intervention. Bioabsorbable, steroid-eluting sinus stents are inserted into the nose, sinuses or to prevent stenosis of the sinus openings. The slow release of corticosteroid aims to decrease mucosal edema and improve wound healing. This technology is being evaluated as a treatment option following sinus surgery.

The PROPEL™ steroid-releasing implant (Intersect ENT) provides a controlled drug delivery directly to the sinus tissue. This device is a self-expanding, bioabsorbable, steroid-eluting stent that is intended for use in the ethmoid sinus. Steroids (mometasone furoate) are administered via a sustained release over an approximate duration of 30 days.

The Relieva Stratus™ MicroFlow spacer is a balloon-based device that acts as a spacer and medication delivery system is indicated for use as a postoperative spacer to maintain an opening to the sinuses within the first 14 days postoperatively. This device is temporary and requires manual removal after 30 days, with implantation of a new device if needed. It is approved for infusion with saline, but not for use with other medications such as steroids.

Sinu-Foam (Arthrocare Corp., Austin, TX), is a Food and Drug Administration (FDA) approved carboxymethylcellulose polysaccharide material that forms a gel when hydrated. The gel is placed within the ethmoid cavity at the completion of an FESS procedure. The dexamethasone Sinu-Foam™ spacer has been evaluated following FESS for CRS without polyps. The spacer is currently not FDA approved.

The Spirox Latera absorbable nasal implant is indicated for supporting nasal upper and lower lateral cartilage. It is used to treat nasal valve collapse, which leads to nasal obstruction and difficulty breathing. It is endoscopically placed inside the nasal wall in a minimally invasive procedure by otolaryngologists or plastic surgeons using the manufacturer provided accessory delivery device. It is composed of poly (l-lactic acid) (PLLA) and poly (d-lactic
acid) (PDLA) copolymer materials and is designed to be absorbed by the body within approximately 18 months after implantation. The implant and the delivery apparatus are both intended for single-patient use.

Many sinus devices have been proposed for use following FESS to aid in maintaining ostial patency, prevent adhesions, control bleeding and/or for the administration of topical medications. However, there is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of these devices. There are a limited number of published studies investigating these devices. Studies primarily report short-term follow-ups and include small patient populations. Data showed variability in the outcomes including maintenance of sinus patency. The impact of these foreign materials implanted in the body is unknown.

The FDA has approved the Sinuva™ (mometasone furoate) sinus implant, a new, office-based alternative to revision surgery for the treatment of recurrent nasal polyps in adults who have undergone previous ethmoid sinus surgery. Sinuva is a second-generation, bioabsorbable corticosteroid-releasing sinus implant. It is inserted in the ethmoid sinus in patients 18 years of age and older by physicians trained in otolaryngology. The insertion procedure is performed during an office visit. The implant is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. It may be left in the sinus for up to 90 days to allow gradual release of the corticosteroid. It is removed at day 90, or earlier at the physician's discretion. There is insufficient evidence to support the safety and effectiveness of Sinuva for the treatment of recurrent polyposis.

POLICY
The use of implantable sinus stents or drug-eluting implants (0406T, 0407T, S1090) for maintaining sinus ostial patency following endoscopic sinus surgery or for the treatment of recurrent nasal polyps are non-covered including but not limited to:
- Propel™ Steroid-Releasing Implant
- Relieva Stratus™ MicroFlow Spacer
- Sinu-Foam™ Spacer
- Spirox Latera Absorbable Nasal Implant
- Sinuva™ (mometasone furoate) Sinus Implant

COVERAGE CRITERIA
HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage
Paramount does not cover implantable sinus stents or drug-eluting implants for maintaining sinus ostial patency following endoscopic sinus surgery or for the treatment of recurrent nasal polyps because its use is considered experimental, investigational or unproven (this list may not be all-inclusive):
- Propel™ Steroid-Releasing Implant
- Relieva Stratus™ MicroFlow Spacer
- Sinu-Foam™ Spacer
- Spirox Latera Absorbable Nasal Implant
- Sinuva™ (mometasone furoate) Sinus Implant

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant;</td>
</tr>
<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement</td>
</tr>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
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HCPCS CODES
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S1090</td>
<td>Mometasone furoate sinus implant, 370 micrograms</td>
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REVISION HISTORY EXPLANATION

ORIGINAL EFFECTIVE DATE: 10/28/2016

10/28/16: Policy created to reflect the most current clinical evidence per The Technology Assessment Working Group (TAWG).

11/14/17: Policy reviewed and updated to reflect the most current clinical evidence per The Technology Assessment Working Group (TAWG).

03/22/18: Added Sinuva (mometasone furoate) Sinus Implant & Spirox Latera Absorbable Nasal Implant as examples of non-covered sinus devices. Policy reviewed and updated to reflect the most current clinical evidence per The Technology Assessment Working Group (TAWG).

04/26/18: Clarified that the use of sinus implants such as Sinuva™ (mometasone furoate) for the treatment of recurrent nasal polyps are non-covered. Policy reviewed and updated to reflect the most current clinical evidence per The Technology Assessment Working Group (TAWG).


REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.