

MEDICAL POLICY

POLICY TITLE	STEROID-ELUTING SINUS STENTS
POLICY NUMBER	MP 1.140

CLINICAL BENEFIT	<input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	5/1/2024

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I. POLICY

The use of mometasone furoate sinus implant (e.g., Propel, Sinuva) may be considered medically necessary when used at the time of sinus surgical procedures when all of the following criteria are met:

- Member is 18 years of age and older; AND
- Has undergone a medically necessary ethmoid sinus surgery procedure

The use of mometasone furoate sinus implant not meeting the criteria as indicated in this policy is considered investigational. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Sinus stents are defined as implantable devices that are specifically designed to improve patency and/or deliver local medication. These are distinguished from sinus packing and variations on packing devices that are routinely employed post-sinus surgery.

Foam dressings, such as SinuFoam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used post-ESS. These are considered different types of nasal packing.

Middle meatal stents are related but separate devices that are intended to maintain sinus patency post-ESS. They are splint-like devices that are inserted directly rather than under endoscopic guidance, and they do not have the capability of delivering local medication.

Cross-reference:

- MP 1.119** Balloon Ostial Dilatation for the Treatment of Chronic Rhinosinusitis
- MP 1.152** Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis

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II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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Chronic Rhinosinusitis

Chronic rhinosinusitis is an inflammatory sinus condition that has a prevalence between 1% and 5% in the U.S. population.

Treatment

Endoscopic sinus surgery (ESS) is typically performed on patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with high rates of improvement in up to 90% of more appropriately selected patients. However, there are no high-quality randomized controlled trials comparing functional ESS with continued medical management or alternative treatment approaches. Because of the high success rates and minimally invasive approach, these procedures have rapidly increased in frequency, with an estimated 250,000 procedures performed annually in the United States. They can be done either in the physician's office under local anesthesia or in the hospital setting under general anesthesia.

ESS involves the removal of small pieces of bone, polyps, and debridement of tissue within sinus cavities. There are a number of variations on the specific approach, depending on the disorders being treated and the preferences of the treating surgeon. For all procedures, there is substantial postoperative inflammation and swelling, and postoperative care is therefore a crucial component of ESS.

There are a number of postoperative treatment regimens, and the optimal regimen is uncertain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity debridement. Several randomized controlled trials have evaluated treatment options, but not all strategies have been rigorously evaluated. A 2011 systematic review has evaluated the evidence for these therapies. Reviewers concluded that the evidence was not strong for any of these treatments but that some clinical trial evidence supported improvements in outcomes. The strongest evidence supported use of nasal saline irrigation, topical nasal steroid spray, and sinus cavity debridement.

Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications. Middle meatal spacers are splint-like devices that prop open the sinus cavities post-ESS but are not designed for drug delivery. There is some randomized controlled trial evidence

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that middle meatal spacers may reduce the formation of synechiae following ESS, although the available studies have significant heterogeneity in this outcome.

Implantable Sinus Stents

Implantable sinus stents are another option for postoperative management following ESS. These implants are intended to stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They can also be infused with medication delivered topically over an extended period of time, and this local delivery of medications may be superior to topical application in the postoperative setting.

Regulatory Status

In 2011, the PROPEL™ system (Intersect ENT, Palo Alto, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. This device is a self-expanding, bioabsorbable, steroid-eluting stent intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger included with the device. Steroids (mometasone furoate) are embedded in a polyethylene glycol polymer, which allows sustained release of the drug over an approximate duration of 30 days. The device dissolves over several weeks, and therefore does not require removal. In 2012, a smaller version of the PROPEL™ device, the PROPEL™ mini–Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery.

SINUVA™ Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at Day 90 or earlier using standard surgical instruments. The SINUVA™ Sinus Implant is indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery.

FDA product code: OWO

IV. RATIONALE

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Summary of Evidence

Several published studies and a meta-analysis have examined the efficacy of these devices. The meta-analysis included two randomized trials with a total of 143 patients and found that drug-eluting implants, compared with nondrug implants, substantially reduced postoperative interventions, lysis of adhesions, and the need for oral corticosteroids by 35, 51, and 40 percent, respectively. Another study concluded that the implants could be inserted in-office into the ethmoid cavity for treatment of recurrent polyposis following endoscopic sinus surgery with resultant reduction in NP size, ethmoid sinus obstruction, and improvement in nasal obstruction symptom scores achieved for six months.

V. DEFINITIONS

N/A

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Medically necessary when used to report the placement of implantable sinus stents:

Procedure Codes							
J7402	S1091	31237	31299				

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.140	02/04/2020 Consensus review. No changes to policy statements. Title changes to “Steroid-Eluting Sinus Stents”. Previously titled as “Implantable Sinus Stents for Postoperative use following Endoscopic Sinus Surgery and for Recurring Disease”.
	05/29/2020 Admin update. New codes effective 7/1/2020 added to policy.
	12/23/2020 Consensus review. No changes to policy statements, coding, or references. Deleted codes removed from policy.
	01/21/2021 Consensus review. No changes to policy statements.
	04/01/2021 Admin update. New codes added to policy.
	09/27/2021 Admin update. FEP language revised.
	8/3/2022 Minor review. Sinus stents moved from INV to MN with criteria.
	3/2/2023 Consensus review. No changes to policy statements. Updated references.
	1/19/2024 Admin update. Added Clinical Benefit to header.

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