MEDICAL POLICY

POLICY TITLE	STEROID-ELUTING SINUS STENTS
POLICY NUMBER	MP 1.140

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**11/1/2024**

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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:

For Propel (mometasone furoate 370 mcg) sinus implant:
- Member is 18 years of age and older; AND
- Has undergone a medically necessary ethmoid sinus surgery procedure; AND
- Limited to one implant per ethmoid sinus cavity

For Propel Mini (mometasone furoate 370 mcg) sinus implant:
- Member is 18 years of age and older; AND
- Has undergone a medically necessary ethmoid or frontal sinus surgery procedure; AND
- Limited to one implant per ethmoid and/or frontal sinus cavity

For Propel Mini SD (mometasone furoate 370 mcg) sinus implant:
- Member is 18 years of age and older; AND
- Has undergone a medically necessary ethmoid sinus surgery procedure; AND
- Limited to one implant per ethmoid sinus cavity

For Propel Contour (mometasone furoate 370 mcg) sinus implant:
- Member is 18 years of age and older; AND
- Has undergone a medically necessary frontal or maxillary sinus surgery procedure; AND
- Limited to one implant per maxillary sinus cavity

For Sinuva (mometasone furoate 1350 mcg) sinus implant:
- Member is 18 years of age and older; AND
- Has undergone a medically necessary ethmoid sinus surgery procedure; AND
- Demonstrated history of nasal polyps; AND

- Limited to one implant per ethmoid sinus cavity

Repeat use of mometasone furoate sinus implant has not been medically proven to be effective and is considered investigational.

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 Dilation for the Treatment of Chronic Rhinosinusitis
MP 1.152 Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis

II. PRODUCT VARIATIONS TOP

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 TOP

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 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.

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

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N/A

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

TOP

1. *Berlucchi M, Castelnuovo P, Vincenzi A, et al. Endoscopic outcomes of resorbable nasal packing after functional endoscopic sinus surgery: a multicenter prospective randomized controlled study. Eur Arch Otorhinolaryngol. Jun 2009;266(6):839-845. PMID 18946677*
2. *Catalano PJ, Thong M, Weiss R, et al. The MicroFlow Spacer: A drug-eluting stent for the ethmoid sinus. Indian J Otolaryngol Head Neck Surg. May 28, 2011;63(3):279-284. PMID 22754810*
3. *Cote DW, Wright ED. Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. Laryngoscope. Jun 2010;120(6):1269-1273. PMID 20513050*
4. *Forwith KD, Chandra RK, Yun PT, et al. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. Laryngoscope. Nov 2011;121(11):2473-2480. PMID 22020898*
5. *Freeman SR, Sivayoham ES, Jepson K, et al. A preliminary randomised controlled trial evaluating the efficacy of saline douching following endoscopic sinus surgery. Clin Otolaryngol. Oct 2008;33(5):462-465. PMID 18983380*
6. *Han JK, Forwith KD, Smith TL, et al. RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. Int Forum Allergy Rhinol. Nov 2014;4(11):861-870. PMID 25266981*
7. *Han JK, Marple BF, Smith TL, et al. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. Int Forum Allergy Rhinol. Jul-Aug 2012;2(4):271-279. PMID 22550039*
8. *Huang Z, Hwang P, Sun Y, et al. Steroid-eluting sinus stents for improving symptoms in chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery. Cochrane Database Syst Rev. Jun 10, 2015;6(6):CD010436. PMID 26068957*
9. *Lavigne F, Miller SK, Gould AR, et al. Steroid-eluting sinus implant for in-office treatment of recurrent nasal polyposis: a prospective, multicenter study. Int Forum Allergy Rhinol. May 2014;4(5):381-389. PMID 24599580*
10. *Lee JM, Grewal A. Middle meatal spacers for the prevention of synechiae following endoscopic sinus surgery: a systematic review and meta-analysis of randomized controlled trials. Int Forum Allergy Rhinol. Nov 2012;2(6):477-486. PMID 22648984*
11. *Marple BF, Smith TL, Han JK, et al. Advance II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. Otolaryngol Head Neck Surg. Jun 2012;146(6):1004-1011. PMID 22301107*
12. *Matheny KE, Carter KB, Jr., Tseng EY, et al. Safety, feasibility, and efficacy of placement of steroid-eluting bioabsorbable sinus implants in the office setting: a prospective case series. Int Forum Allergy Rhinol. Oct 2014;4(10):808-815. PMID 25224654*
13. *Murr AH, Smith TL, Hwang PH, et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. Int Forum Allergy Rhinol. Jan-Feb 2011;1(1):23-32. PMID 22287304*
14. *Ow R, Groppo E, Clutter D, et al. Steroid-eluting sinus implant for in-office treatment of recurrent polyposis: a pharmacokinetic study. Int Forum Allergy Rhinol. Oct 2014;4(10):816-822. PMID 25256638*
15. *Rotenberg BW, Zhang I, Arra I, et al. Postoperative care for Samter's triad patients undergoing endoscopic sinus surgery: a double-blinded, randomized controlled trial. Laryngoscope. Dec 2011;121(12):2702-2705. PMID 21997904*

16. *Rudmik L, Mace J, Mechor B. Effect of a dexamethasone Sinu-Foam™ middle meatal spacer on endoscopic sinus surgery outcomes: a randomized, double-blind, placebo-controlled trial. Int Forum Allergy Rhinol. Jan 17, 2012;2(3):248-251. PMID 22253199*
17. *Rudmik L, Soler ZM, Orlandi RR, et al. Early postoperative care following endoscopic sinus surgery: an evidence-based review with recommendations. Int Forum Allergy Rhinol. Nov-Dec 2011;1(6):417-430. PMID 22144050*
18. *Sedaghat AR. Chronic rhinosinusitis. Am Fam Physician. Oct 15, 2017;96(8):500-506. PMID 29094889*
19. *Xu JJ, Busato GM, McKnight C, et al. Absorbable steroid-impregnated spacer after endoscopic sinus surgery to reduce synechiae formation. Ann Otol Rhinol Laryngol. March 2016;125(3):195-198. PMID 26391092*
20. *Hamilos DL. Management of chronic rhinosinusitis. UpToDate. May 11, 2022*
21. *Kern RC, Stolovitzky JP, Silvers SL, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol.2018;8:471–481.*
22. *Ernst F, Imhoff R, Deconde A, Manes R. Budget impact of a steroid-eluting sinus inplant versus sinus surgery for adult chronic sinusitis patients with nasal polyps. JMCP. 2019.*
23. *Han JK, Kern RC. Topical therapies for management of chronic rhinosinusitis: steroid implants. Int Forum Allergy Rhinol. 2019;9:S22–S26.*
24. *Forwith KD, Han JK, Stolovitzky JP, et al. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes from a randomized, controlled, blinded study. Int Forum Allergy Rhinol. 2016;6(6):573-81.*
25. *American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Drug-Eluting Sinus Implants. January 17, 2023*
26. *American Rhinologic Society. ARS Position Statement: Criteria for Drug-Eluting Implants. January 28, 2023*
27. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.134, Steroid-Eluting Sinus Stents and Implants. March 2024.*

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 Administrative 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 Administrative Update. New codes added to policy.
	09/27/2021 Administrative Update. FEP language revised**.**
	08/03/2022 Minor Review. Sinus stents moved from INV to MN with criteria.
	03/02/2023 Consensus Review. No changes to policy statements. Updated references.
	01/19/2024 Administrative Update. Added Clinical Benefit to header.

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	05/24/2024 Minor Review. Updated policy statement with additional criteria for sinus implants. Reviewed and updated references.

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