POLICY TITLE	**STEROID-ELUTING SINUS STENTS** ***(FORMERLY IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY AND FOR RECURRENT SINUS DISEASE)***
POLICY NUMBER	**MP-1.140**

Original Issue Date (Created):	**7/30/2013**
Most Recent Review Date (Revised):	**2/4/2020**
Effective Date:	**7/1/2020**

I. POLICY

The use of implantable sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **investigational.** There is insufficient evidence to support a 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 BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

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FEP PPO: Refer to FEP Medical Policy Manual MP-7.01.134 Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery. The FEP Medical Policy Manual can be found at: www.fepblue.org

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

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. FDA product code: OWO

In 2009, the Relieva Stratus™ MicroFlow spacer, and in 2011, the Relieva Stratus™ Pro MicroFlow Spacer, both balloon-based devices, were cleared for marketing by FDA through the 510(k) process for use as a postoperative spacer to maintain an opening in the frontal sinus for 14 days after surgery. The labeling for the second device included that safety and effectiveness of injecting solutions other than saline had not been established. The devices were to be placed via a catheter under endoscopic guidance and required manual removal after 30 days, In May 2013, the manufacturer discontinued all sales of the Stratus™ and the company agreed to withdraw all FDA marketing clearances for the device, which is no longer commercially available in the United States.

IV. RATIONALE

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Summary of Evidence

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes 2 RCTs, a number of observational studies, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from 2 RCTs comparing steroid-eluting sinus stents with non-steroid-eluting stents, both of which showed some

benefit with steroid-eluting stents. However, these trials had some limitations, including risk of bias. In addition, because of the comparison groups used in both, these trials primarily evaluated the efficacy of topical steroids when delivered by an implanted device, and not the efficacy of the device vs standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have recurrent sinonasal polyposis who have undergone endoscopic sinus surgery who receive implantable steroid-eluting sinus stents, the evidence includes an RCT and a single-arm study. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from the available RCT, which compared steroid-eluting stents plus topical steroids with steroids alone for individuals with recurrent polyposis after ESS. This trial had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be a relevant outcome for this indication, it would be important for decisions about repeat ESS or other treatments to be standardized and prespecified or be made by a clinician blinded to treatment group. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's 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

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medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross 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.

Investigational; therefore, not covered when used to report the placement of implantable sinus stents:

CPT Codes®								
31237	31299							

HCPCS Code	Description
C9122	Mometasone furoate sinus implant, 10 micrograms (sinuva)
J7401	Mometasone furoate sinus implant, 10 mcg

IX. REFERENCES

TOP

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X. POLICY HISTORY

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MP-1.140	**CAC 7/30/2013** New policy Adopting BCBSA investigational statement.
	CAC 5/20/2014 Consensus review. Title of policy changed to refer to "sinus stents" Removed "spacers" language throughout policy for consistency. No change to the policy statement. Codes reviewed.
	CAC 6/2/15 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	Administrative 1/20/16: New 2016 codes added (0406T, 0407T)
	CAC 5/31/16 Minor review. Added "recurrent sinus disease" to title. Added "for treatment of recurrent sinonasal polyposis" to the investigational policy statement for the use of sinus stents. References and rationale updated. Coding reviewed.
	Administrative Update 11/22/16 Variation reformatting
	CAC 5/23/17 Consensus review. No changes to the policy statements. Rationale updated. No references added. Coding reviewed.
	12/20/17 Consensus review. No change to policy statements. References and rationale reviewed.
	1/1/19 Admin Update: Remove deleted codes 0406T, 0407T. Added unlisted codes for sinus procedures that may be billed once the T codes are no longer reportable.
	1/17/19 Consensus review. No change to policy statements. References and rationale reviewed. **4/1/19** Coding review- no changes.
	10/1/19 Admin coding review. New code J7401 added to policy, removed deleted code S1090.
	02/04/2020-Consensus review. No changes to policy statements. Title change 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.

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