I. Policy

The use of implantable sinus stents for postoperative treatment following endoscopic sinus surgery 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 Sinuplasty for Treatment of Chronic Sinusitis
II. PRODUCT VARIATIONS

[N] Capital Cares 4 Kids  [N] Indemnity
[N] PPO                [N] SpecialCare
[N] HMO                [N] POS
[N] SeniorBlue HMO     [Y] FEP PPO*
[N] SeniorBlue PPO

* The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND

Sinus stents are devices that are used postoperatively following endoscopic sinus surgery (ESS). The intent of these devices is to maintain patency of the sinus openings in the postoperative period, and/or to serve as a local drug delivery vehicle. Reducing postoperative inflammation and maintaining patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery.

Endoscopic sinus surgery (ESS) is typically performed in patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with improvements in symptoms in up to 90% of more appropriately selected patients. 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 U.S. (1) 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 the sinus cavities. There are a number of variations on the specific approach, depending on the disorders that are being treated and the preferences of the treating surgeon. For all procedures, there is a substantial amount of 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 not certain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity debridement. There have been a number of randomized controlled trials (RCTs) that have evaluated various treatment options, but all different strategies have not been rigorously evaluated. (2-5) A systematic review evaluated the evidence for these therapies. (1) The authors of this review 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 was for 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. (1) Middle meatal stents are splint-like devices that prop open the sinus cavities post-ESS, but are not capable of drug delivery. There is some RCT evidence that middle meatal stents may reduce the formation of synechiae following ESS, although the available studies have significant heterogeneity in this outcome. (6)

Implantable sinus stents are another option for postoperative management following ESS. These implants are inserted via catheters under endoscopic guidance. These devices may stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They also have the capability of being infused with medication that can be 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
The PROPEL™ system was granted U.S. Food and Drug Administration (FDA) approval under the premarketing approval (PMA) program in August 2011. This device is a self-expanding, bioabsorbable, steroid-eluting stent that is intended for use in the ethmoid sinus. 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 is dissolvable over a period of several weeks, and thereby does not require removal.

The Relieva Stratus™ MicroFlow spacer is a balloon-based device that acts as a spacer and medication delivery system. It was FDA approved under the 510(k) program in October 2011. It 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.
IV. RATIONALE

Randomized controlled trials (RCTs) are important in this area in order to adequately compare a stents to alternative treatment regimens and to minimize the effects of confounders on outcomes. Case series and trials without control groups offer little in the way of relevant evidence, as improvement in symptoms is expected post-endoscopic sinus surgery (ESS) and because there are multiple clinical and treatment variables which may confound outcomes.

The most relevant comparison for sinus stents is unclear because there is not a standardized optimal postoperative treatment regimen. A concern with controlled trials is that the control arm may not be treated with optimal intensity, thereby leading to a bias in favor of the device. An example of this is a study design that compares a steroid-eluting stent with a non-steroid-eluting stent. This design will primarily evaluate the efficacy of steroids when delivered by the device, but will not evaluate the efficacy of a stent itself. If the control group does not receive topical or oral steroids postoperatively, then this might constitute undertreatment in the control group and result in a bias favoring the treatment group. Another concern is for the comparison of efficacy of a drug with the efficacy of a drug delivery system. For example, if a steroid-eluting spacer is compared to a control of saline irrigation alone, then it will be difficult to separate the efficacy of the drug itself (steroids) from drug delivery system (stent).

LITERATURE REVIEW

The literature consists of a few, small randomized trials, single-arm case series, and systematic reviews of these studies.

Randomized, controlled trials
There are two small RCTs of the Propel™ sinus implant. (7, 8) The two Propel™ trials are of similar design and both are sponsored by the manufacturer (Intersect ENT™, Palo Alto, CA.). Both compare an implant that is steroid-eluting versus an identical implant that is not steroid-eluting. Thus these trials test the value of drug delivery via a stent, but do not test the value of a stent itself versus treatment without a stent.

Murr et al. (8) The first RCT of this implant was published in 2011. A total of 38 patients with refractory chronic rhinosinusitis were included in the efficacy evaluation, and an additional 5 patients were enrolled for a safety evaluation. An intra-patient control design was used, meaning that each patient received a drug-eluting stent on one side and a non-
drug-eluting stent on the other via random assignment. Patients were not permitted to use topical or oral steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary endpoint was the degree of inflammation recorded on follow-up endoscopy at day 21 post-procedure, as scored by a 100 mm visual analogue scale (VAS). There were also semi-quantitative grading performed for polypoid changes, middle turbinate position, and adhesions/synechiae. The clinicians recording the outcomes were not blinded to treatment assignment. One patient withdrew prior to study completion.

The difference in inflammation scores at 21 days was significant in favor of the steroid-eluting group. The estimated difference in scores from graphical representation was approximately 18 units on the 0-100 VAS scale. The percent of patients having polypoid changes was 18.4% in the steroid-eluting group versus 36.8% in the non-steroid-eluting group (p=0.039). Adhesions were also significantly less common in the steroid-eluting group (5.3% vs. 21.1%, p=0.03). There were no significant differences in the appearance or position of the middle turbinate.

Advance II trial. (7) The Advance II trial was an RCT of the Propel™ sinus implant for 105 patients with chronic rhinosinusitis refractory to medical management. This study also used an intra-patient control design with each patient receiving a drug-eluting stent on one side and a non-drug-eluting stent on the other via random assignment. Patients were not permitted to use topical or oral steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary efficacy outcome was reduction in the need for postoperative interventions at day 30 following the procedure. A panel of 3 independent experts, who were blinded to treatment assignment and clinical information, viewed the endoscopy results and determined whether an intervention was indicated. The primary safety endpoint was the absence of clinically significant increased ocular pressure through day 90.

There were 3 patients lost to follow-up (2.9%), and 9 patients (8.6%) could not be evaluated because the video of the endoscopy could not be graded. Two patients had the device removed within 30 days of placement. Of the remaining patients, the need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm versus 46.9% in the non-steroid-eluting arm (p=0.028). According to the judgments of the clinical investigators, who were not blinded to treatment assignment, intervention was required in 21.9% of the steroid-eluting group and 31.4% of the non-steroid-eluting group (p=0.068). The reduction in interventions was primarily driven by a 52% reduction in lysis of adhesions (p=0.005). The primary safety hypothesis was met, as there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period following the procedure.
Non-randomized studies
The ADVANCE study (9) was a prospective, multicenter single-arm trial of 50 patients who were scheduled to undergo ESS. The endpoints evaluated on follow-up endoscopies were the degree of inflammation scored on a 100 mm visual analogue scale (VAS) and semiquantitative grading for polypoid changes, middle turbinate position, and adhesions. By day 7 post-procedure, the inflammation scores were in the “minimal” range and remained there for the rest of the time points. At one month, polypoid lesions were present in 10% of patients, adhesions in 1.1%, and middle turbinate lateralization in 4.4%. Scores on the Sino-Nasal Outcome Test-22 and the Rhinosinusitis Disability Index improved significantly in the first month post-procedure.

A case series was published of 23 patients with refractory rhinosinusitis who underwent ESS and were treated postoperatively with the Relieva Stratus Microflow Spacer Device infused with triamcinolone. (10) Over a period of 6 months, there were significant improvements on multiple sinus-related outcome measures such as the Sino-Nasal Outcome Test-20 and the Lund-McKay CT (computed tomography) scan scores. There were no significant intraoperative or postoperative complications reported.

Systematic reviews
A systematic review of early postoperative care following ESS was published in 2011. (11) This review evaluated a number of different postoperative regimens, including stents. The review included one RCT by Cote et al. and 2 non-randomized studies. Some of the devices included in these studies are considered middle meatal stents and not included in the review of evidence for this policy. The overall level of evidence was judged as B (RCT with limitations). The authors concluded that topical steroids delivered by the “non-standard” route required further study and that the results of current studies could not be extrapolated to larger populations. Based on this evidence, they did not recommend use of stents but considered them an “option” for postoperative care.

Han et al. performed a meta-analysis of the 2 published RCTs of the Propel™ implant, (12) both of which compared a steroid-eluting stent with a non-steroid-eluting stent. The results of the 2 RCTs were combined at the patient level, with re-analysis of the endoscopy videos by a panel of 3 independent ear, nose, and throat experts. The combined results were that the steroid-eluting device reduced postoperative interventions by 35% (p=0.0008), reduced lysis of adhesions by 51% (p=0.0016), and reduced the need for oral steroids by 46% (p<0.0001).

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received through 1 Physician Specialty Society and 3 Academic Medical Centers while this policy was under review in 2012. While the various Physician Specialty Societies and Academic Medical Centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the Physician Specialty Societies or Academic Medical Centers, unless otherwise noted. Input was received from 4 academic medical centers. Input overall was mixed, without consensus achieved among the respondents. Some reviewers expressed support for use of these devices post-ESS. Reviewers who supported use cited the RCTs reviewed in this policy as the main source of evidence. Other reviewers did not support use in general following ESS, but considered that a subset of patients may benefit, but there was no consensus on what population this subgroup would include.

**Summary**
Implantable sinus stents have been used post-ESS with the intent of maintaining patency of the sinuses and delivering local steroids. Two RCTs have compared the Propel™ device with steroids to the same device without steroids and reported that the steroid-eluting device reduced postoperative inflammation, reduced the need for oral steroids, and reduced the need for postoperative re-interventions. These trials primarily evaluate the efficacy of topical steroids when delivered by an implanted device, but do not evaluate the efficacy of the device itself versus standard care. The improvements reported in these trials reflect the impact of local steroids, which were withheld in the control arm, as well as the impact of the spacer device itself.

This evidence is insufficient to determine whether sinus stents improve outcomes when used postoperatively following ESS. Further RCTs are needed that compare the devices to optimal postoperative care without the device to determine whether they can improve postoperative outcomes for patients undergoing ESS.

**Practice Guidelines and Position Statements**
None

V. **DEFINITIONS**
N/A
VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’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. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

MEDICAL POLICY

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<th>POLICY TITLE</th>
<th>IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY</th>
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IX. CODING INFORMATION

**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.

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<tr>
<td>S1090</td>
<td>Mometasone furoate sinus implant, 370 micrograms</td>
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### X. POLICY HISTORY

<table>
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<tr>
<th>MP-1.140</th>
<th>CAC 7/30/2013 New policy Adopting BCBSA investigational statement.</th>
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<td>CAC 5/20/14 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.</td>
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