Devices for Post-Operative Use Following Endoscopic Sinus Surgery

Number: 0840

Policy

Aetna considers the use of the following sinus devices (not an all-inclusive list) for maintaining sinus ostial patency following endoscopic sinus surgery experimental and investigational because their effectiveness has not been established:

- BISORB Drug-Eluting Sinus Biopolymer Stent
- Propel sinus implant
- Relieva Stratus MicroFlow spacer
- Sinu-Foam spacer

Note: Resorbable steroid-eluting spacers are considered supplies integral to the sinus surgery and are not separately reimbursed.

See also

- CPB 0593 - Aerosolized or Irrigated Anti-infectives for Sinusitis,
- CPB 0621 - Drug-Eluting Stents
**Background**

Chronic rhino-sinusitis (CRS) is defined as an inflammatory condition involving the paranasal sinuses and linings of the nasal passages that lasts 12 weeks or longer, despite attempts at medical management. It is one of the most frequently diagnosed chronic medical conditions, affect patients of all ages and gender. Treatments of CRS include saline washes and sprays, topical and systemic glucocorticoids, antibiotics, anti-leukotriene agents, as well as anti-fungals. Surgery should be the last resort in most cases of CRS. Endoscopic sinus surgery (ESS) is the most commonly used surgical intervention to treat medically unresponsive CRS. It is intended to restore physiologic sinus ventilation and drainage (Hamilos, 2012). While ESS has become a well-established strategy for the treatment of CRS that is refractory to medical treatment, it is associated with various complications. The incidence of major complications of ESS was estimated to be 1 to 3 %, with cerebrospinal fluid leak being the most common; and the incidence of minor complications was approximately 7.0 %, with middle meatal (MM) synechiae being the most common (May et al, 1994; Ramakrishnan et al, 2012). Implantable sinus stents/spacers have been used following ESS to maintain patency of the sinuses and deliver local steroids. Self-dissolving sinus stents (eg, mometasone furoate sinus implant), deliver a sustained, localized, controlled release of medication (eg, corticosteroid). The device is implanted during sinus surgery where it expands to prop open the sinus, support the bony structures inside the nose and is purported to prevent scar formation.

**Steroid-Eluting Sinus Implants/Stents**

Goshtasbi et al (2019) stated that recently, there has been mounting evidence suggesting the efficacy of SES for management of CRS after ESS. In a meta-analysis, these researchers examined the efficacy of SES in improving post-operative outcomes after ESS. They carried out a systematic literature search of PubMed for articles published between 1985 and 2018. The outcome variables were reported at, on average, 30 days post-intervention; 7 of the 76 published studies, all of which were industry-sponsored, were included for a collective cohort of 444 SES and 444 control sinuses. In patients who received SES versus controls, collective odds ratios (ORs) for
post-operative need for intervention, surgery, and oral steroid were 0.45 (95 % CI: 0.33 to 0.62; p < 0.001), 0.30 (95 % CI: 0.18 to 0.52; p < 0.001), and 0.58 (95 % CI: 0.40 to 0.84; p = 0.004), respectively. In addition, collective ORs for frontal sinus ostia (FSO) patency, moderate-to-severe adhesion/scarring, and increase in polyp score were 2.53 (95 % CI: 1.61 to 3.97; p < 0.001), 0.28 (95 % CI: 0.13 to 0.59; p < 0.001), and 0.42 (95 % CI: 0.25 to 0.74; p = 0.002), respectively. Collective MDs for FSO/ethmoid inflammation and FSO diameter were -10.86 mm (p < 0.001) and +1.34 mm (p < 0.001), respectively. The authors concluded that aggregate evidence suggested that SES could improve ESS outcomes by reducing rates of post-operative intervention and recurrent polyposis and inflammation, while promoting FSO patency. It should be noted that all included and analyzed studies were industry-sponsored and ruling-out publication bias was not possible. These researchers stated that future independent and non-industry-sponsored studies to further evaluate SES’s long-term efficacy are needed.

In a systematic review, Rizan and Elhassan (2016) evaluated the safety and effectiveness of steroid-eluting bioabsorbable intranasal devices (SEBID). The secondary aim was to inform clinical recommendations and to introduce clinicians to this novel technology. Medline, PubMed, Embase, and Cochrane Database were searched according to Preferred Reporting Items for Systematic Review and Meta-Analyses guidelines. Original articles assessing the effectiveness of SEBIDs inserted after ESS. For each study, these researchers recorded the effectiveness end-points and safety outcomes. A total of 7 studies met the inclusion criteria from 737 initial articles identified, including 5 prospective RCTs and 2 prospective single-cohort studies involving 394 sinuses within treatment arms. Patients were followed-up for 2 to 6 months; 6 studies demonstrated SEBID effectiveness with statistical significance (p < 0.05). Steroid-eluting bioabsorbable intranasal devices were effective in reducing adhesion formation, polyp formation, inflammation, Lund-Kennedy scores, and peri-operative sinus endoscopy scores. The devices improved patient-reported outcomes and olfaction while reducing post-operative interventions. They were not associated with adverse events and posed no ocular safety risk. Complications in 3 SEBID applications were reported. The authors concluded that there is limited data available on SEBIDS; further studies are needed to examine if they are safe and effective adjuncts post-ESS. They stated that future studies are needed to optimize the dosing regimen, compare devices, and provide long-term outcomes.

An assessment by the National Institute for Health and Care Excellence (NICE, 2016) concluded: "Current evidence on the safety of corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis raises no major safety concerns. The evidence on efficacy is limited; there is some evidence of improving sinus patency in the short term, but there is inadequate evidence on patient-
reported outcomes and quality of life. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. . . NICE encourages further research on corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery and, specifically, controlled studies designed for between-patient (rather than within-patient) comparisons. Outcomes should include symptom scores, quality of life and the need for retreatment in the long term. All complications should be reported."

In a Cochrane review, Huang and colleagues (2015) evaluated the safety and effectiveness of steroid-eluting sinus stent placement in CRS patients after functional ESS (FESS). Data sources included the Cochrane Ear, Nose and Throat Disorders Group (CENTDG) Trials Search Co-ordinator searched the CENTDG Trials Register; Central Register of Controlled Trials (CENTRAL 2015, Issue 4); PubMed; Embase; CINAHL; Web of Science; Clinicaltrials.gov; ICTRP and additional sources for published and unpublished trials. The date of the search was May 14, 2015. These researchers included all RCTs comparing steroid-eluting sinus stents with non-steroid-eluting sinus stents, nasal packing or no treatment in adult CRS patients undergoing FESS. They used the standard methodological procedures expected by the Cochrane Collaboration. These investigators identified no RCTs that met the inclusion criteria. Among the 159 records retrieved using the authors’ search strategy, a total of 21 trials had the potential to be included given that they had tested sinus stents, spacers and packing materials for patients with CRS undergoing FESS. However, these researchers excluded these trials from the review because they met some but not all of the inclusion criteria. The authors were unable to provide evidence to establish whether steroid-eluting sinus stents have potential advantages and disadvantages for patients with CRS undergoing FESS. Moreover, they stated that future, high-quality RCTs are needed to determine whether or not steroid-eluting sinus stents confer any beneficial effects, over those of surgery alone, when compared to non-steroid sinus stents.

The International Consensus Statement on Allergy and Rhinology: Rhinosinusitis recommended that steroid-eluting stents are optional for the ESS (Orlandi, et al., 2016). However, the European Position Paper on Rhinosinusitis and Nasal Polyps 2020 (EPOS 2020) (Fokkens, et al., 2020) revealed that the postoperative placement of steroid-eluting stents compared to placebo has a significant effect on endoscopic scores but does not have an influence on symptomatology. The EPOS 2020 could not advise about the use of steroid-eluting stents following ESS because of steering group felt the quality of the evidence was low.

Furthermore, an UpToDate review on “Chronic rhinosinusitis: Management” (Hamilos and Holbrook, 2020) lists glucocorticoid-eluting sinus implants as one of the medical
adjuncts to sinus surgery. It states that “Mometasone-eluting sinus implants are approved by the US Food and Drug Administration to maintain the patency of the ethmoid or frontal sinus openings following endoscopic surgery. The approved implants deliver 370 mcg of mometasone furoate from a biodegradable, bioabsorbable polymer matrix over 30 days. Several published studies and a meta-analysis have examined the utility of these devices. The meta-analysis included 2 randomized trials with a total of 143 patients and found that drug-eluting implants, compared with nondrug implants, significantly reduced postoperative interventions, lysis of adhesions, and the need for oral glucocorticoids by 35, 51, and 40 %, respectively. Another study demonstrated 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 6 months”. However, glucocorticoid-eluting sinus implants are not mentioned in the “Summary and Recommendations” section of the review.

**Propel Sinus Implant**

The Propel sinus implant is a steroid-releasing sinus implant that is inserted into the ethmoid sinus. It is indicated for maintaining sinus patency after ESS in patients 18 years of age and older. This steroid-releasing implant is comprised of a synthetic bio-absorbable co-polymer and is self-expanding, which allows it to conform to the highly variable contours and size of the sinus anatomy. The Propel sinus implant is inserted into the ethmoid sinus cavity by a physician under endoscopic visualization. Upon insertion, the implant expands radially to conform to the sinus cavity. The delivery system is then removed and discarded. Once Propel is in place, mometasone furoate is released over a 30-day period. Dosages for Propel are measured in terms of the number of implants inserted in a patient’s sinus cavities. Each steroid-releasing implant contains 370 ug of mometasone furoate.

In a prospective, multi-center, single-cohort trial (Advance Trial), Forwith et al (2011) evaluated the safety and effectiveness of a bio-absorbable, steroid-eluting implant (the Propel device) used following ESS in patients with CRS (n = 50). The study allowed bilateral or unilateral steroid-eluting implant placement. Oral and topical steroids were withheld for 60 days post-operatively. Endoscopic follow-up was performed to 60 days. Patient-reported outcomes (22-item Sino-Nasal Outcome Test [SNOT-22 Questionnaire], Rhinosinusitis Disability Index) were collected to 6 months. Effectiveness was assessed by grading inflammation, polyp formation, adhesions, and middle turbinate position. Safety assessment included ocular examinations at baseline and 30 days. Implants were successfully placed in all 90 sinuses. Mean inflammation scores
were minimal at all time-points. At 1 month, the prevalence of polypoid edema was 10.0%, significant adhesions 1.1%, and middle turbinate lateralization 4.4%. Changes from baseline in patient-reported outcomes were statistically significant (p < 0.0001). No clinically significant changes from baseline in intra-ocular pressure (IOP) occurred. The authors concluded that this consecutive case-series study provided clinical evidence of the safety, effectiveness, and clinical utility of a bio-absorbable steroid-eluting implant for use in CRS patients. The implant was associated with favorable rates of sinus patency. At 1 month, minimal degrees of inflammation and adhesions were observed, suggesting a positive clinical impact of local steroid delivery without evidence of ocular risks.

In a prospective, multi-center, randomized, controlled, double-blind trial (Advance II Trial), Marple et al (2012) examined the safety and effectiveness of controlled delivery of mometasone furoate to the sinus mucosa via the Propel sinus implant deployed at the time of ESS. This study enrolled 105 patients with CRS undergoing bilateral ethmoidectomy to compare the effect of drug-releasing to non-drug-releasing implants using an intra-patient control design. Post-operative interventions, polyposis, and adhesions were assessed post-operatively. Effectiveness was determined through independent analysis of randomized video-endoscopies by 3 blinded sinus surgeons. Safety assessments included ocular examinations. Implants were successfully deployed in all 210 ethmoid sinuses. Compared with control sinuses with non-drug-releasing implants, the drug-releasing implant provided a 29.0% relative reduction in post-operative interventions (p = 0.028) and a 52% (p = 0.005) decrease in lysis of adhesions. The relative reduction in frank polyposis was 44.9% (p = 0.002). Similar reductions were observed in real-time grading performed by the clinical investigators. No clinically significant changes from baseline in IOP or cataracts were observed. The authors concluded that this study provided evidence that use of the Propel sinus implant that applied a sustained release of corticosteroid improved surgical outcomes by reducing synechiae formation, polyposis, and the need for post-operative interventions, with no observable ocular safety risk.

While the results of the 2 Advance Trials were promising, they were limited to small, heterogeneous inpatient populations with short-term follow-up. Furthermore, the trials were performed in a setting where both sinuses had implants, one with steroid and the other without. The 2 Trials discussed above did not compare the post-operative outcomes using this device with outcomes following standard ESS without an ostial implant but with topical steroid sprays, saline irrigation, debridement, and conventional post-operative packing. The available evidence is insufficient to determine whether sinus spacers and stents improve outcomes when used post-operatively following ESS. Further randomized controlled trials (RCTs) are needed to compare the Propel
device to optimal post-operative care without the device to examine if it can improve post-operative outcomes for patients undergoing ESS.

In a prospective, multi-center, randomized, blinded trial using an intra-patient control design, Smith et al (2016) evaluated the safety and effectiveness of a steroid-releasing implant in improving surgical outcomes when placed in the frontal sinus opening (FSO) following ESS in patients with CRS. A total of 80 adult (greater than or equal to 18 years) CRS patients who underwent successful bilateral frontal sinusotomy were randomized to receive a steroid-releasing implant in one FSO, whereas the contralateral control side received no implant. All patients received standard post-operative care. Endoscopic evaluations recorded at 30-day post-ESS were graded real time by clinical investigators and by an independent, blinded sinus surgeon to assess the need for post-operative interventions in the FSO. Implants were successfully placed in all 80 frontal sinuses, resulting in 100% implant delivery success. At 30-day post-ESS, steroid-releasing implants provided a statistically significant ($p = 0.0070$) reduction in the need for post-operative interventions compared to surgery alone by an independent reviewer, representing 38% relative reduction. Clinical investigators reported statistically significant reduction in this measure at 30 days ($p < 0.0001$) and 90 days ($p = 0.0129$). Clinical investigators also reported a 55.6% reduction in the need for oral steroid interventions ($p = 0.0015$), 75% reduction in the need for surgical interventions ($p = 0.0225$), 16.7% reduction in inflammation score, 54.3% reduction in re-stenosis rate ($p = 0.0002$), and 32.2% greater diameter of FSO ($p < 0.0001$) on treated sides compared to control at 30 days. No implant-related adverse events were reported. The authors concluded that the findings of this study demonstrated the effectiveness of steroid-releasing implants in improving outcomes of frontal sinus surgery. The major drawbacks of the study were:

1. the intra-patient design precluded evaluation of the effect of treatment on patient symptoms and other quality-of-life assessments, and

2. the study implants or their remnants were required to be removed on day 21 to allow for blinded assessment of day-30 video-endoscopies.
This implant removal procedure may have caused additional trauma to the adjacent mucosa; thereby hindering normal healing on the treatment sides.

Matheny and colleagues (2014) evaluated the safety, feasibility, and outcomes of steroid-eluting bioabsorbable sinus implants placed in the office after achieving hemostasis. A total of 20 patients with CRS underwent ESS including bilateral ethmoidectomy. A steroid-eluting bioabsorbable implant was deployed into each ethmoid cavity in the office within 7 days after ESS. Endoscopic appearance of the ethmoid cavities was evaluated at 1 week, 2 weeks, and 4 weeks post-operatively by the operating surgeon and an independent blinded evaluator. Procedural tolerance was assessed at week 2 using a patient preference questionnaire. The 20-item Sino-Nasal Outcome Test (SNOT-20) questionnaire was completed at baseline, week 2, and week 4. In-office placement of steroid-eluting bioabsorbable implants was well-tolerated, with 90% of patients very satisfied with the overall experience, and 80% very satisfied with the recovery process. At 1 month, there were no significant adhesions or frank polyposis, and middle turbinate lateralization was only 5%. Compared to baseline, ethmoid sinus inflammation was significantly reduced (p = 0.03), and the mean SNOT-20 score was significantly improved (p < 0.001). The authors concluded that in-office placement of steroid-eluting bioabsorbable implants after achieving hemostasis was well-tolerated and might improve local drug diffusion and surgical outcomes. This was a small study (n = 20) with short-term follow-up (4 weeks).

Pou and associates (2017) examined if the severity of pre-operative sino-nasal inflammation influences the post-operative changes in patient-reported quality of life (QOL) and endoscopic appearance following ESS with implant placement. Consecutive adult patients undergoing ESS for CRS with ethmoidectomy and placement of a steroid-eluting implant over a 18-month period were prospectively included for study. Pre-operative sinus computed tomography (CT) opacification was evaluated using the Lund-Mackay score (LMS); SNOT-22 scores and Lund-Kennedy endoscopic scores (LKES) for each patient were collected pre-operatively and at 3- and 6-month intervals post-operatively. Serum eosinophilia (greater than 6.0% on peripheral smear) and sinus tissue eosinophilia were recorded. A total of 136 patients were included for analysis. Of these, 36.7% had polyposis, 15.4% had serum eosinophilia and 64.0% had tissue eosinophilia. The mean (standard deviation) SNOT-22 score was 45.5 (19.4) pre-operatively, which improved post-operatively to 18.8 (14.1) at 3 months (p < 0.001) and 16.5 (14.0) at 6 months (p < 0.001). Similar results were found when stratified by the presence of polyposis, serum eosinophilia, tissue eosinophilia or high-grade CT findings (LMS greater than 6). Higher baseline LKES was observed for patients with eosinophilia or high-grade LMS, but these differences normalized at 6 months post-operatively. The authors concluded that patient-reported QOL and endoscopic appearance showed
improvement 6 months after placement of a steroid-eluting implant during ESS, irrespective of the presence of polyposis or eosinophilia. Moreover, they stated that although the present study indicated that improvements occurred regardless of the severity of pre-operative inflammation, it remained unclear how these effects would compare to cases in which an implant was not utilized. Future studies with controlled trials of patient-reported QOL following ESS with bioabsorbable steroid-eluting implants are needed, which may utilize post-operative objective markers of inflammation to supplement the effects on patient-reported QOL. Investigation of the effect of simultaneous additional symptom scores or QOL measures may help elucidate the confounding potential of septoplasty and inferior turbinate reduction in conjunction with ESS. Lastly, examination into specific items of the SNOT-22 score that are most affected by implant placement may result in better pre-operative counseling and patient selection.

The authors stated that this study had several drawbacks:

1. as a single-armed study without a comparison treatment group, conclusions about causation and comparative effectiveness are not possible,

2. although approximately 80% of patients continued to follow-up 6 months from the time of surgery, there is a risk of follow-up bias, as post-operative outcomes could have influenced both follow-up and completion of the forms, and

3. some patients in this study also received a septoplasty and/or inferior turbinate reduction, which may be a confounding variable that over-estimated the improvement in QOL measures.
Luong et al (2018) evaluated the safety and effectiveness of the hourglass-shaped, bioabsorbable, steroid-releasing sinus implant (370 ug mometasone furoate) in improving post-operative surgical outcomes when placed in the FSO following ESS in patients with CRS. A total of 80 adult (mean (SD) age of 49.5 (13.4) years; 53 (66 %) men and 27 (34 %) women) CRS patients who underwent bilateral frontal sinusotomy were randomized to receive a steroid-releasing implant in one FSO, whereas the contralateral control side received no implant. All patients received standard post-operative care. Endoscopic evaluations recorded at 30-day post-ESS were graded real time by clinical investigators and by an independent, blinded sinus surgeon to assess the need for post-operative interventions in the FSO. Also, endoscopic grading by the independent reviewer and clinical investigators at day 30 and day 90 and computed tomographic scan at day 90 were performed. Implants were successfully placed in all 80 frontal sinuses, resulting in 100 % implant delivery success. At 30-day post-ESS, steroid-releasing implants significantly reduced the need for post-operative interventions to 11.5 % compared with 32.8 % by surgery alone (mean difference [MD] -21.3 %; 95 % confidence interval [CI]: -35.1 to -7.6) as assessed by the independent reviewer. Real-time endoscopic assessment by clinical investigators at day 30 showed significant reduction in need for post-operative intervention (MD -17.3 %, 95 % CI: -27.9 % to -6.7 %), significant reduction in inflammation score (MD -12.3 mm, 95 % CI: -18.3 to -6.4), and significant reduction in rate of frontal re-stenosis or occlusion (MD -22.7 %, 95 % CI: -33.5 % to -11.9 %) on treated compared with control sides. The results favoring the treatment sides were sustained through day 90: reduced need for postoperative interventions (MD -11.7 %, 95 % CI: -21.0 % to -2.4 %) and reduction in re-stenosis and/or occlusion of the frontal sinus (MD -17.4 %, 95 % CI: -28.6 to -6.1 %). No implant-related adverse events were reported. The authors concluded that the hourglass-shaped, bioabsorbable, steroid-releasing sinus implant was safe and effective in maintaining FSO patency and improving surgical outcomes compared with surgery alone in the setting where no other immediate post-operative corticosteroids were administered.

The authors noted that this study had 2 major drawbacks:

I. the intra-patient design precluded evaluation of the effect of treatment on patient symptoms, and

II. the study implants or their remnants were required to be removed on day 21 to allow for blinded assessment of day-30 video-endoscopies.
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This implant removal procedure may have caused additional trauma to the adjacent mucosa; thereby hindering normal healing on the treatment sides.

Rawl et al (2020) showed no significant improvement in postoperative outcomes using PROPEL steroid-eluting stents when compared with nonabsorbable packs. In a RCT, Rawl et al (2020) compared non-absorbable packs to bio-absorbable SES as middle meatal spacers after ESS in patients with CRS. Patients were randomly assigned to receive either non-absorbable Merocel packs wrapped in non-latex glove material (packing type A) or Propel SES (packing type B). The SNOT-22 scores were collected pre-operatively and post-operatively during the initial 4 debridement up to 3 months. Recording of the nasal endoscopy was also collected during all post-operative visits. In addition, Lund-Kennedy scores and middle turbinate lateralization scores, using a new visual analog scale (VAS), were compared between the 2 types of packing. A total of 40 CRS patients were prospectively enrolled in this institutional review board (IRB)-approved study. Patients with packing type A had significantly lower middle turbinate lateralization scores at their 1st (approximately 10 days) post-operative visit (p = 0.02 and p = 0.04, for left and right sides, respectively). This difference disappeared by later post-operative visits (from 20 days to 3 months). Overall, patients receiving packing type A had significant lower SNOT-22 scores at 20 days post-surgery (p = 0.05). This difference also disappeared at 1 and 3 months post-operation. There were no statistically significant differences in Lund-Kennedy scores. The authors concluded that in this study, non-absorbable packing materials showed significant superior middle meatal spacing capacities as evidenced by greater middle turbinate medialization capability at the 1st post-operative visit. Furthermore, patients with this type of packing observed improvements in their SNOT-22 scores at the 20-day post-operative visit. In addition, this study showed that there was no significant improvement in post-operative outcomes with drug-eluting stents when compared to non-absorbable packing.

Javanbakht et al (2020) noted that CRS is one of the commonest chronic health problems among adults in the United Kingdom. Approximately 15% of CRS patients undergo FESS annually after failing medical treatment. However, as incomplete resolution of symptoms or complications post-operatively is common, the post-operative management is considered to be as important as the surgery itself. A bio-
absorbable corticosteroid-eluting sinus implant (CESI) (Propel mometasone furoate 370 µg) has been used as an alternative post-FESS treatment. These investigators examined the cost-effectiveness of the CESI versus non-corticosteroid-eluting spacer following FESS for treatment of patients with CRS. A decision-tree model was developed to estimate the cost and effectiveness in each strategy. Costs and effects were estimated from a United Kingdom National Health Service (NHS) and personal social services perspective over a 6-month time horizon. Model pathways and parameters were informed by existing clinical guidelines and literature and sensitivity analyses were conducted to examine uncertainties in base-case assumptions. Over a 6-month time horizon, inserting CESI at the end of FESS was less costly (£4,646 versus £4,655 per patient) and was the more effective intervention [total quality-adjusted life-years (QALYs) over 6 months 0.443 versus 0.444] than non-corticosteroid-eluting spacers; hence, it was a dominant strategy. The probabilistic analysis results indicated that CESI following FESS has a 62% probability of being cost effective at the £20,000/per QALY willingness-to-pay threshold and 56% probability of being a cost-saving intervention. The authors concluded that the use of CESI after FESS resulted in fewer post-operative complications than non-corticosteroid-eluting implants and may be a cost-saving technology over a 6-month time horizon; CESI may be a suitable alternative for post-FESS treatment. Although the cost of initial treatment with the CESI was greater, cost savings were made due to a reduction in the number of complications experienced.

The authors stated that as with all modelling studies, several limitations exist in this analysis that must be considered when interpreting the results. First, data to inform decrements in QOL associated with adverse events (AEs) were unavailable so were omitted from the analysis. Thus, the overall QALYs reported for each strategy may be an over-estimate. However, including decrements would likely have increased the cost-effectiveness of the CESI strategy because the intervention resulted in lower complication rates over a 6-month time horizon. There was also a lack of information available on longer-term clinical effectiveness of the 2 treatment strategies after 6 months. The meta-analysis from which clinical data were drawn only included effectiveness data over a 3-month time horizon and effectiveness beyond 3 months has been extrapolated. Although uncertainty was present in the model results because of these data limitations, this was addressed by applying probability distributions to parameters, where possible, and exploring parameter variation in sensitivity analyses.

Relieva Stratus MicroFlow Spacer
The Stratus MicroFlow Spacer is designed to provide slow release of steroids into the sinuses over a 2-week period with the intention of maintaining sinus ostial patency. This device may be used in either the frontal or ethmoid sinuses.

Catalano et al (2011) evaluated the safety and short-term outcomes of a newly introduced drug-eluting ethmoid stent (the MicroFlow Spacer) in 23 patients with a total of 40 implanted ethmoid sinuses. Patients with medically refractory CRS were treated with patient-appropriate ESS, with the modification of treating the ethmoid sinuses with an ethmoid stent infused with triamcinolone, instead of conventional endoscopic ethmoidectomy. Patients were then followed-up over 6 months. Safety was determined by adverse events. Outcomes were assessed by interval changes in SNOT-20 and Lund-MacKay CT scores. Overall, the pre-operative SNOT-20 mean score was 2.18, versus post-operative score of 1.02, an improvement of 1.16 that was both statistically (p < 0.001) and clinically significant. Ethmoid-specific and side-specific Lund-MacKay mean scores both also showed statistically significant improvements. Pre-operative ethmoid-specific Lund-MacKay mean score was 1.93, versus post-operative score of 1.10, an improvement of 0.83 (p < 0.001). Pre-operative side-specific Lund-MacKay mean score was 5.75, compared with post-operative score of 2.95, an improvement of 2.80 (p < 0.001). There were no significant intra-operative or post-operative complications encountered. The authors concluded that the MicroFlow spacer appeared safe and effective in treating chronic ethmoid sinus disease within the defined follow-up period. They noted that the ability to deliver medication directly to diseased mucosa held wide-ranging potential. The findings of this small study need to be validated by well-designed studies with long-term follow-up.

Taulu and associates (2015) stated that anatomical complexity presents the main challenge in the administration of topical corticosteroid therapy to the para-nasal sinus mucosa. This often led to suboptimal drug delivery due to low concentrations of the therapeutic agent to the intended target area. The Relieva Stratus MicroFlow Spacer (Relieva Stratus) is a drug-eluting stent that is temporarily implanted into the ethmoid sinus. The reservoir of the stent is filled with triamcinolone acetonide, which is then slowly released from the device into the ethmoid sinus mucosa. The Relieva Stratus provides local and targeted delivery of the anti-inflammatory agent to the diseased mucosa. This minimally invasive implant is an option when treating ethmoid sinusitis. From January 2011 to November 2013, a total of 52 Relieva Stratus implantations into the ethmoidal cells were performed at the Department of Ear and Oral Diseases at Tampere University Hospital, Finland; C-arm fluoroscopy guidance was employed for 26 sinuses (13 patients) and optical image-guided surgery (IGS)-assisted insertions were performed on another 26 sinuses (13 patients). The accuracy of fluoroscopic insertion was not optimal, but this method was accurate enough to prevent
the violation of the skull base and lamina papyracea. Image-guided surgery enabled the precise treatment of the diseased cells. From a technical perspective, IGS-guided insertion was a faster, safer and more exact procedure that guaranteed the optimal positioning and effectiveness of the implant. Moreover, IGS guidance did not entail the use of ionizing radiation. The findings of this small study (n = 25) need to be validated by well-designed studies.

In May 2013, Acclarent voluntarily discontinued all sales of the Stratus device and withdrew all approved FDA clearances, making the devices no longer available for sale in the United States.

Businco and colleagues (2016) evaluated the safety and effectiveness of the steroid-eluting ethmoidal stent (SEES; the Relieva Stratus MicroFlow Spacer) in the management of allergic CRS in comparison with the traditional endoscopic ethmoidectomy (EE). A total of 70 allergic patients who presented CRS were randomly divided into 2 groups and received respectively the SEES or EE. The most significant observation coming from the comparative analysis of the results was the substantial equivalence of the treatment with the SEES compared with EE in the management of ethmoid CRS with the exception of a reduction of overall discomfort and nasal secretion and better functional results at rhinomanometry in the SEES group. The authors concluded that in their experience, the SEES was effective in the treatment of allergic patients with ethmoidal CRS when conventional medical treatment had failed, or when wishing to avoid the classic EE; however, further long-term studies are needed to confirm the safety and stability, over time, of the results obtained.

In a prospective, randomized clinical trial, Taulu et al (2020) examined if an ethmoidal drug-eluting stent (DES) (the Relieva Stratus MicroFlow Spacer) could better prevent ESS than standard non-invasive therapy using corticosteroid nasal spray in patients suffering from CRS. A total of 63 adult patients with ethmoidal involvement in cone beam computerized tomography (CBCT) whose 1st-line medical treatment with topical corticosteroids had failed and who were candidates for ESS were randomized either to a DES group, which received triamcinolone acetonide stents (n = 34), or to a topical intra-nasal corticosteroid group (n = 29) that used optimally dosed triamcinolone acetonide nasal spray. Patients were followed-up prospectively for 6 months and at 36 months. Freedom from ESS was the primary end-point. In addition, these investigators identified those factors predicting ESS. At 6 months, ESS could be prevented in almost 50 % of the patients in both groups (DES 13/28, 46.4 %, nasal spray 14/29, 48.3 %). At 36 months, 20/28 (71.4 %) patients in the DES group and 18/29 (62.1 %) in the nasal spray group had been operated. The differences were not statistically significant at either time-point. Patients who smoked (14/19, 73.7 % versus 16/38, 42.1 %) were more
likely to be operated at 6 months. The authors concluded that ESS could be prevented using both therapies in the medium-term in almost 50 % of cases with neither therapy being statistically superior. This effect was somewhat diminished in the long-term with a trend towards more patients being operated in the DES group. The authors stated that, considering the additional costs, the need for general anesthesia and the potential side effects associated with DES, its potential clinical role appeared to be limited; smoking was significantly associated with ESS.

Sinu-Foam Spacer

Sinu-Foam is an Food and Drug Administration (FDA)-approved mixture, which is commonly mixed with saline and gently placed in the ethmoid cavity following FESS. A dexamethasone Sinu-Foam spacer has been studied to examine if it could promote wound healing of the nasal and sinus mucosa by reducing the inflammation associated with CRS. However, its clinical utility remains a debate since it does not improve endoscopic outcomes in the early post-operative period following FESS.

In a randomized, double-blind, placebo-controlled trial, Rudmik et al (2012) evaluated a dexamethasone Sinu-Foam spacer following ESS for CRS without nasal polyposis (CRSsNP). Patients with CRSsNP (n = 36) were enrolled into a double-blind, placebo-controlled trial and randomized into either a treatment arm (dexamethasone Sinu-Foam mixture; n = 18) or placebo arm (Sinu-Foam alone; n = 18). Therapeutic outcomes were evaluated at 1 week, 4 weeks, and 3 months using sino-nasal endoscopy and graded using the Lund-Kennedy scoring system. Post-operative care included nasal saline irrigations and a short course of systemic steroids. All patients completed the study follow-up period. Both study arms experienced significant improvement in endoscopic grading over the study duration (p < 0.001). There was no difference in average endoscopic scores between the treatment and placebo groups at 1 week, 4 weeks, and 3 months (all p > 0.489). The authors concluded that the findings of this study demonstrated that an off-label drug-eluting MM spacer of dexamethasone and Sinu-Foam did not improve endoscopic outcomes in the early post-operative period following ESS when combined with post-operative saline irrigations and a short course of systemic steroids.

Other Steroid Eluting Spacers

In a case-series study, Huang et al (2019) examined the efficacy of the BISORB Drug-Eluting Sinus Biopolymer Stent System, a bio-absorbable steroid-eluting stent (SES), in
improving post-operative outcomes following revision and re-revision Draf 3 procedures in patients with frontal diseases. Patients with recalcitrant chronic frontal rhino-sinusitis (FRS) and mucocele who underwent revision and re-revision Draf 3 procedures from 2015 to 2017 were included. Pre-operative disease parameters, demographics, and endoscopic and radiographic images were recorded. A total of 7 patients undergoing the Draf 3 procedure for recalcitrant chronic FRS (43 %) and mucocele after complete resection of benign tumors in the frontal sinus (57 %) were followed-up for a mean of 16.5 months. At the end of follow-up, 7 (100 %) patients were asymptomatic and all patients (100 %) had patent neo-ostia. The authors concluded that the use of bio-absorbable SES had no unanticipated consequences, and the drainage pathways of the frontal neo-ostium remained patent. These researchers stated that SES may decrease recurrence rates in revision cases where patients had extensive scarring or neo-osteogenesis of the operative field from prior Draf 2 or 3 procedures. They stated that further follow-up of the current cases and studies with larger cohorts are needed.

In summary, a variety of implants/spacers (e.g., the Propel sinus implant, the Relieva Stratus MicroFlow spacer, the BIOSORB Drug-Eluting Stent, and the Sinu-Foam spacer) have been employed to maintain patency of the sinuses and deliver local steroids with varying success in the reported literature. However, the available studies have significant heterogeneity in this outcome. There remains a continued debate on whether these devices actually improve the health outcomes following ESS.

Table: CPT Codes / HCPCS Codes / ICD-10 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>There are no specific CPT codes for insertion of these devices (e.g., the Propel™ sinus implant, the Relieva Stratus™ MicroFlow spacer, and the Sinu-Foam™ spacer):</td>
</tr>
<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
<td></td>
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<tr>
<td>31237-31294</td>
<td>Endoscopic sinus surgery</td>
</tr>
<tr>
<td>81247 - 81249</td>
<td>G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis</td>
</tr>
<tr>
<td>HCPCS codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>C2625</td>
<td>Stent, noncoronary, temporary, with delivery system</td>
</tr>
<tr>
<td>HCPCS codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td>A6215</td>
<td>Foam dressing, wound filler, sterile, per gram [Sinu-Foam™]</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>C1726</td>
<td>Catheter, balloon dilatation, non-vascular [Relieva Stratus® MicroFlow spacer]</td>
</tr>
<tr>
<td>C2625</td>
<td>Stent, noncoronary, temporary, with delivery system [not covered for propel]</td>
</tr>
<tr>
<td>S1090</td>
<td>Mometasone furoate sinus implant, 370 micrograms [Propel®]</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB (not all inclusive):

| J32.0 - J32.9 | Chronic sinusitis |

The above policy is based on the following references:

8. Hamilos DL. Medical management of chronic rhinosinusitis. UpToDate [serial online]. Waltham, MA: UpToDate; reviewed September 2012.


Devices for Post-Operative Use Following Endoscopic Sinus Surgery

There are no amendments for Medicaid.

revised 12/10/2020

Proprietary