Medical Coverage Policy

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Drug-Eluting Devices for Use Following Endoscopic Sinus Surgery

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Related Coverage Resources

Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation
Rhinoplasty, Vestibular Stenosis Repair and Septoplasty

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Overview

This Coverage Policy addresses drug-eluting devices proposed for maintaining postoperative sinus ostial patency following endoscopic sinus surgery and for the treatment of nasal polyps following ethmoid sinus surgery.

Coverage Policy

A drug-eluting device for the treatment of nasal polyps following ethmoid sinus surgery (e.g., Sinuva) is considered experimental, investigational or unproven.

A drug-eluting device for maintaining postoperative sinus ostial patency following endoscopic sinus surgery (e.g., Propel™ Steroid-Releasing Implants, Sinu-Foam Spacer) is not covered or reimbursable.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Functional endoscopic sinus surgery (FESS) is typically performed for chronic rhinosinusitis (CRS) unresponsive to medical management. FESS involves the removal of small pieces of bone, polyps and debridement of tissues within the sinus cavity. Postoperative treatment may include saline irrigation, nasal packs, foam dressings, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity debridement. A variety of adjunctive devices have been applied to the sinuses during FESS to keep the middle meatus open, with varying degrees of success. These devices have included packing materials, injectable space-filling gels or structured stents. In some instances, packing materials have been soaked with a drug, but the uncontrolled and inconsistent release of the drug resulted in erratic outcomes. Therefore, drug-eluting stents, implants or spacers have been proposed to help maintain postoperative sinus ostial patency by reducing scarring and adhesions following FESS. A stent/spacer is a device that is placed into a sinus cavity temporarily to keep it open, promote wound healing and relieve an obstruction. Stents/spacers are used temporarily and removed after a period of time (e.g., 14-30 days). Some middle meatal drug-infused spacers have been attempted by the treating surgeon who determines

the type and dosage of steroid. There is unknown drug release with these spacers, and they are not FDA approved (Parikh, 2014; Catalano, et al., 2011).

Drug-eluting stents (DESs) or implants are surgically inserted scaffolds that are proposed to aid in healing the affected tissue by locally and continuously releasing a loaded drug or saline in a controlled manner for the desired period of time. Some drug-eluting stents are made of a biodegradable material and are absorbed by the body. Commonly used drugs for nasal stents include corticosteroids (e.g., dexamethasone, fluticasone and mometasone) and antibiotics. Proposed advantages of these devices include removing the issues of noncompliance and adequate drug delivery seen with traditional topical medical therapy techniques. However, there is a risk of inducing inflammation from a foreign material and the potential of unintended systemic absorption of medication when an implant is used. The Propel™ (Intersect ENT, Palo Alto, CA), a mometasone-eluting biodegradable implant, is an example of a drug-eluting stent. A smaller version of the drug delivery system, Propel™ Mini, is also available (Intersect ENT, 2019; Parikh, 2014; Rudmik, 2012; Catalino, et al., 2011).

Outcomes from the published, peer-reviewed literature show varying degrees of success in the use of drug-eluting implants following FESS. Studies primarily report short-term follow-ups and include small patient populations. Data showed variability in the outcomes including maintaining sinus patency. The impact of these foreign materials implanted in the body is unknown. Reported complications include implant blockage and granulation build-up. The effects of the drug released onto the sinus mucosa are unclear. There is insufficient evidence to support the safety and effectiveness of these devices.

In 2017, Sinuva™ (Intersect ENT, Palo Alto, CA) was FDA approved as a drug for implantation for the treatment of nasal polyps in patients who have had ethmoid sinus surgery and have recurrent polyposis. Sinuva contains 1350 mcg of mometasone furoate and is proposed for implantation in the physician's office. The implant is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. It may be left in the sinus for up to 90 days to allow gradual release of the corticosteroid. It is removed at day 90 or earlier at the physician's discretion. There is insufficient evidence to support the safety and effectiveness of Sinuva for the treatment of recurrent polyposis.

US Food and Drug Administration (FDA)

The Relieva Stratus MicroFlow Spacer was FDA 510(k) approved in 2009 as a Class I frontal sinus spacer. The MicroFlow Spacer is indicated "for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery". The device is also approved to prevent obstruction, and it maintains its position by a self-retention mechanism. The spacer is a balloon-based device that acts as a reservoir to allow bathing of the ethmoid sinus. A second surgical procedure is needed to remove the device. The 2011 FDA 510(k) approval for the Relieva Stratus Pro MicroFlow Spacer (Frontal) was approved for "use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction." The FDA summary noted that the safety and effectiveness of injecting solutions other than saline solution in the catheter have not been established. 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.

The Propel® implant (Intersect ENT, Palo Alto, CA) was approved through the premarket approval application (PMA) process. The implant is intended "for use in patients >18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids. The Propel separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions,

and reduces edema." The implant is manufactured from a synthetic bioabsorbable copolymer, poly (L-lactideco-glycolide) (PLG) and contains 370 µg mometasone furoate (active ingredient), a synthetic corticosteroid with anti-inflammatory activity. The implant is designed to accommodate the size and variability of the post-surgical ethmoid sinus anatomy. The device is dissolvable over a period of several weeks, and thereby does not require removal (FDA, 2011). The Propel Mini was FDA PMA approved in 2012 as a shortened version of the Propel and is indicated for use in a patient ≥ 18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids. The Mini also contains 370 µg mometasone furoate (FDA, 2012). In 2016, The Propel Mini FDA indication was expanded to include treatment of the frontal sinus. The Propel Contour Sinus Implant was FDA PMA approved in February 2017 as a supplement to the Propel FDA PMA approval. This device is indicated for use in patients ≥ 18 years of age to maintain patency of the frontal and maxillary sinus ostia following sinus surgery. Per Intersect (2017), the Contour has an hourglass shape and is proposed to conform to sinus ostia, propping the sinuses open while delivering the medication. Like the other Propel devices, the Contour releases 370 µg mometasone furoate.

Sinu Foam (Arthrocare Corp., Austin, TX) is made from an FDA approved carboxymethylcellulose polysaccharide material that forms a gel when hydrated. The gel is placed within the ethmoid cavity at the completion of a FESS procedure. The dexamethasone Sinu-Foam™ spacer has been evaluated following FESS for CRS without polyps (Parikh, et al., 2014; Rudmik, et al., 2012). The spacer is currently not FDA approved (Rudmik, et al., 2012).

Sinuva (Intersect ENT, Palo Alto, CA) is a corticosteroid-eluting implant that was FDA approved (NDA 209310) as a drug for the "treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery". One Sinuva implant system contains 1350 mcg of mometasone furoate and a sterile delivery system. The implant is made of bioabsorbable polymers designed to gradually soften over time, must be implanted under endoscopic visualization, and can be removed 90 days following insertion. The FDA decided that the drug had more of an effect than the device and approved Sinuva as a drug as opposed to a drug/device system (e.g., Propel). Clinical studies did not include sufficient numbers of subjects age ≥ 65 years to determine if they responded differently from subjects ages 18–64 years. Repeat administration has not been studied (FDA, 2018).

Literature Review

All Devices: In a Cochrane review, Huang et al. (2015) conducted a systematic review of randomized controlled trials (RCTs) to evaluate the effectiveness of steroid-eluting sinus stents for improving symptoms of CRS following functional endoscopic sinus surgery (FESS). The search 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. A total of 159 records were retrieved. Twenty-one had the potential to be included given that they had tested sinus stents, spacers and packing materials for patients with CRS undergoing FESS. However, the trials did not meet all of the inclusion criteria. Inclusion criteria included adult patients with CRS, with or without nasal polyps, undergoing FESS. CRS was diagnosed based on the presence of symptoms for 12 weeks, including nasal obstruction, nasal discharge, and either endoscopic signs or CT images showing mucosal changes within the ostiomeatal complex, sinuses, or both. Randomized controlled trials that were within patient control design were excluded. Studies did not report subjective measurements of sinonasal symptoms. The primary outcome measure was improvement in symptom scores per visual analogue scale or Sino-Nasal Outcome Test-22 (SNOT-22). Secondary outcomes included improvement in quality of life, adverse events, endoscopic score, and Lund-Mackay radiographic scores.

Propel (Mometasone Furoate) Sinus Implants: There are three sinus implants in the "Propel family" of dissolvable implants made by Intersect for the treatment of CRS: the Propel, Propel Mini and Propel Contour.

Rawl et al. (2020) showed no significant improvement in postoperative outcomes using PROPEL steroid-eluting stents when compared with nonabsorbable packs. In an 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 debridement up to three 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 two 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 ten 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 three 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 first post-operative visit. Furthermore, patients with this type of packing observed improvements in their SNOT-22 scores at the 20-day post-operative visit. Additionally, this study showed there was no significant improvement in post-operative outcomes with drug-eluting stents when compared to non-absorbable packing.

Singh and colleagues (2019) reported the pooled analysis of two randomized controlled trials (RCTs) previously reported by Smith (2016) and Luong (2017). A total of 160 subjects were enrolled in the two 2 RCTs. After surgery, subjects were randomized to receive an implant in one frontal sinus ostia (FSO) with the contralateral side as control. Data through day 90 from the two studies were pooled and subgroup analyses were performed. The objective was to evaluate the effect of drug eluting sinus implants (Propel Mini and Propel Contour) on outcomes of patients undergoing bilateral frontal sinus surgeries with diagnosis of chronic rhinosinusitis (CRS). Included were patients aged 18 and greater with diagnosis of CRS scheduled to undergo bilateral endoscopic sinus surgery (ESS) of the frontal sinuses. Endoscopic evaluations were performed by clinical investigators through 90 days after implant placement. Implants were removed at day 21 to allow blinded assessment by an independent sinus surgeon at day 30 based on a centralized review of video-endoscopies, which were edited to remove all patient identifying information. At day 30 post-procedure, Propel treated ostia were reported to have reduced need for postoperative interventions, surgical interventions, and oral steroid interventions (no p-values provided). One hundred twenty-eight of the 160 subjects were evaluable on both sides by the centralized reviewer for assessment of the primary efficacy end point due to issues with video quality on endoscopy. Analysis of the pooled data documented reduced need for postoperative interventions by 46.8% (95% confidence interval [CI], -60.7 to -27.9); surgical interventions by 51.2% (95% CI, -68.2 to -25.2); and oral steroid interventions by 37.2% (95% CI, -54.6 to -13.1). At day 90, statistically significant reductions ($p < 0.05$) in the need for postoperative interventions (relative reduction [RR], 30.2%), restenosis/occlusion rate (RR, 31.7%), and inflammation score (absolute difference, −6.0), and increase in estimated FSO diameter (absolute difference, 1 mm), favoring the treated side, were observed. Subgroup analyses of the pooled data showed statistically significant improvements ($p < 0.05$) at day 90 in restenosis/occlusion rate, and estimated FSO diameter, favoring the treated side across subgroups, with no statistically significant subgroup by treatment interactions. Twenty percent (32 of 160) of video recordings were unable to be graded

by the centralized reviewer. Limitations were acknowledged and included: study design which precluded assessment of patient reported outcomes between treatment groups; confounding effect of underlying comorbidities and concomitant medication use on efficacy outcomes; clinical investigators unblinded to treatment assignment when the 90-day endoscopic grading occurred; and combination of data from the trials of two different devices. Further limitations include small patient populations, short term follow-up and heterogeneity of postoperative treatment regimens. This study was funded by Intersect ENT, the manufacturer of Propel steroid releasing sinus implants. The authors concluded that Propel improved outcomes of frontal sinus surgery through 90 days, irrespective of asthma status, previous endoscopic sinus surgery, extent of surgery, extent of polyps, or Lund-Mackay computed tomography stage in the frontal sinus opening.

Luong et al. (2017) conducted a randomized intrapatient controlled (n=80) trial to assess the safety and efficacy of the Propel Contour sinus implant in improving postoperative outcomes when placed in the frontal sinus ostia (FSO) following endoscopic sinus surgery (ESS) in adult patients with chronic rhinosinusitis (CRS). Patients were scheduled to undergo primary or revision bilateral ESS and had evidence on CT scan of bilateral frontal sinus disease with a Lund-Mackay (L-M) score of ≥ 1 on each side. Fourteen days following implant, intranasal steroids were allowed. Oral steroids were prescribed as needed, and inhaled steroids were allowed for asthma control. The primary outcome measure was the reduction in need for postoperative interventions 30 days following surgery based on video endoscopic evaluation by a blinded sinus surgeon reviewer. Implants were removed at day 21 to allow blinded assessment of 30 day video endoscopies. Patients needing postoperative interventions (surgical, oral steroids) by independent reviewer were lower in the implant group (7/61) vs. controls (20/61). Based on clinical investigators at day 30, 12/75 implant patients vs. 25/75 controls required postoperative interventions. Based on clinical investigators at day 90, implant patients had less inflammation (26/76 vs. 32/77) and occlusion/restenosis (16/69 vs. 28/69), larger diameter of frontal sinus ostial (mean 5.7 mm vs. mean 4.7 mm), and improvement in frontal opacification as seen by a reduction in the total Lund-Mackay CT score (mean 0.7 vs. mean 0.9) compared to baseline. There were three adverse events that may have been related to the implant (i.e., headache, epistaxis, acute sinusitis). Limitations of the study include the intrapatient study design, small patient population, removal of implant at day 21, patients lost to follow-up and short-term follow-up.

Smith et al. (2016) conducted a multicenter randomized controlled trial (N=80) to assess the safety and efficacy of the Propel mini steroid-releasing implant following endoscopic sinus surgery (ESS). Each patient was their own control with one side receiving propel and the contralateral side receiving no implant. Subjects were age ≥ 18 years, diagnosed with CRS, scheduled to undergo primary or revision bilateral ESS, and had evidence of frontal sinus disease based on computed tomography. The primary outcome measure was the reduction in need for postoperative interventions 30 days post-ESS based on video-endoscopic evaluation by an independent, blinded reviewer. Postoperative intervention was defined as either surgical intervention to debride obstructive adhesions or scar tissue formation in the frontal recess/frontal sinus opening (FSO) and/or oral steroid intervention needed to resolve recurrent inflammation or polypoid edema in the frontal recess/FSO. The implants were removed at day 21 to maintain blinding of the independent reviewer. Following ESS, a 10-day course of antibiotics was required. Intranasal steroid sprays were allowed starting 14 days post-ESS, and oral steroids were prescribed, if warranted, based on the investigator's discretion. Orally inhaled steroids for control of asthma were prescribed as needed. Patients were encouraged to use saline sprays or irrigation as needed. If oral steroids or surgical intervention was warranted at day 7 or day 21 and received, the grading was revised by the clinical investigator. At the 30-day follow-up, based on clinical investigator judgment, the need for postoperative intervention in the FSO was significantly lower in the implant side vs. the control side (p=0.0070) which remained true when analysis was adjusted for three patients who received postoperative interventions (p=0.0107). The reduction in postoperative interventions remained true at the 90-day follow-up (p=0.0129). Significant

differences in favor of the implant group were also seen in oral steroid intervention (p=0.0015), relative reduction (75.0%) in need for surgical intervention (p=0.0225), inflammation scores (p<0.0001), lower number of restenosed or occluded sinuses (p=0.0002), and a greater FSO diameter (p<0.0001). Endoscopic assessments showed that the implant sides had a significantly lower frequency of adhesion and scarring warranting surgical interventions (p=0.0225) and a significant reduction in expanded polypoid edema at day 30 (p=0.0226) by clinical investigators. Five adverse events including headache, left upper eyelid swelling, epistaxis, recurrent chronic sinusitis, and increased sinus pressure were judged by the clinical investigators to have an indeterminate relationship to the implant. Limitations of the study include the small patient population, short-term follow-up and heterogeneity of postoperative treatment regimen. Author-noted limitations included the intrapatient design which precluded evaluation of the effect of treatment on patient symptoms and other quality-of-life assessments, and removal of the implant at day 21 may have caused additional mucosal trauma hindering normal healing on the treatment sides.

Han et al. (2012) conducted a meta-analysis of two multicenter, randomized controlled trials (n=143) (Murr, et al., 2011 and Marple, et al., 2011). The treatment arm of both studies utilized versions of the Propel implant which were not FDA approved at the time of the studies. Both trials were FDA-regulated trials. Patients served as their own control with subjects receiving the drug-releasing implant on one side and a placebo control implant on the contralateral side. Both studies enrolled patients with similar baseline characteristics and enrolled subjects who were adults (mean age 48) with a diagnosis of CRS with and without polyps who were scheduled to undergo primary or revision FESS with bilateral ethmoidectomy and were candidates for implants. CRS was defined as inflammation of the mucosa of the nose and paranasal sinuses for at least eight consecutive weeks' duration with presence of bilateral ethmoid disease. All implants were successfully inserted. Significantly fewer adhesions were seen postoperatively in the implant group (4.2% vs. 14.1%) (p=0.0013). The need for postoperative intervention (e.g., lysis of adhesion, need for oral steroid) was 50.8% on control sides compared to 32.8% on treatment sides (p=0.0008). Significantly fewer implant patients required surgical intervention for adhesions (13.2 vs. 29.1%) (p=0.0016) and oral steroids (22.1% vs. 37.25%) (p=0.0023). The rate of frank polyposis was significantly fewer in the implant group as well (19.8% vs. 36.9%) (p<0.0001). Author-noted limitations of the analysis included: some patients could not be evaluated for some of the endpoints when one or both sinus sides was unable to be graded due to inadequate imaging of relevant anatomy or suboptimal video quality; the required intervention decisions (e.g., oral steroids) were made by the independent panel without consideration of individual clinical factors impacting the patient or recovery process; and since both the sinuses had implants there was no comparison without any implant. Another limitation is the small patient population.

Forwith et al. (2011) conducted a prospective case series (n=50 patients/90 sinuses) of patients with CRS who underwent FESS using bilateral and unilateral drug-eluting implants (Propel). Subjects were adult patients, with or without nasal polyps, scheduled to undergo primary or revision FESS, and in whom placement of the sinus stents was feasible and medically appropriate. Oral and topical steroids were withheld for 60 days postoperatively. Endoscopic follow-ups were performed for up to 60 days, and patient questionnaire scores (the Sino-Nasal Outcome Test-22 Questionnaire, Rhinosinusitis Disability Index) were collected for up to six months. Outcomes were assessed by inflammation grading, polyp formation, adhesions, and middle turbinate position. Safety assessment included ocular exams at baseline and 30 days. All devices were successfully implanted. At the one-month follow-up, the prevalence of polypoid edema was 10.0%, significant adhesions were 1.1%, and middle turbinate lateralization was 4.4%. Improved changes from baseline in patient-reported outcomes were statistically significant (p<0001). No clinically significant changes from baseline in intraocular pressure occurred. Limitations of the study include the lack of a comparator, the small patient population and the short-term follow-ups.

Hayes Inc. published two Prognosis Overview reports (2016) for bioabsorbable steroid-releasing sinus implants including Propel, Propel Mini and the Propel Contour. Regarding Propel and Propel Mini, Hayes concluded that there is insufficient evidence to draw firm conclusion on whether the Propel implants improve clinical outcomes following ESS compared to conventional postoperative regimens. Available studies preclude firm conclusions on the clinical benefits of these devices relative to standard postoperative ESS treatment. Currently, there are no published studies supporting the safety and efficacy of the Propel Contour. According to Hayes, the Relieva Stratus MicroFlow Spacer (Acclarent Inc.) is no longer marketed in the US.

Hayes (2017; updated 2019) conducted a technology assessment brief to assess the safety and efficacy of the Propel and Propel Mini sinus stent for the treatment of chronic rhinosinusitis in adults. Three randomized controlled trials and two prospective case series met inclusion criteria. The eligible studies included both primary and revision endoscopic sinus surgery and patients with CRS without nasal polyps as well as high-risk patients with nasal polyps. Revision results were limited by the short-term follow-up periods (i.e., thirty days to six months) which prevented conclusions regarding the durability of effect and long-term adverse events. Due to the intrapatient nondrug-eluting stent control used in two studies, measurement of patient-reported reduction of symptoms related to the study group did not allow for an evaluation of the potential therapeutic contribution of the expandable polymer (L-lactide-co-glycolide) (PLG) scaffold used in the Propel devices. No comparative study was designed to adequately assess patient-reported alleviation of symptoms. Individual study quality ranged from poor to good. The outcomes suggested that patient-reported symptoms improved with the use of the drug-eluting stent and the short-term safety results did not identify any safety signals. However, the studies were limited by: the observational study designs in two studies; small, heterogeneous patient populations and short-term follow-ups. Very limited evidence was available with respect to patient selection criteria for the use of the Propel and Propel Mini stent. Additional randomized controlled trials with large patient populations and long-term follow-ups are needed to support the safety and efficacy of these drug eluting stents. Hayes updated the technology assessment in 2019 with no change in recommendation.

Sinuva (Mometasone Furoate) Sinus Implant: Stolovitzky (2019) reported on the pooled data of the RESOLVE and RESOLVE II trials conducted by Forwith, Han and Kern. Their studies are described in subsequent paragraphs. Stolovitzky conducted a pooled analysis of the aforementioned randomized controlled trials (RCTs) with an objective to evaluate efficacy of Sinuva implants in specific subgroups of patients with nasal polyposis (NP). Included were adults (age 18 and older) with a confirmed diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) with prior endoscopic sinus surgery (ESS) indicated with repeat endoscopic sinus surgery (RESS) secondary to recurrent bilateral NP despite ongoing treatment with oral and intranasal corticosteroid (INCS). Patients with bilateral polyp grade (BPG) of IV were excluded. There were 375 subjects who successfully completed the studies. Patients were randomized to treatment or control/sham groups. The treatment group underwent insertion of bilateral Sinuva stents under local anesthesia. The sham group underwent insertion and withdrawal of the Sinuva stents while under local anesthesia. All stents were removed at day 60. All patients (treatment and control) were required to use mometasone furoate nasal spray (MFNS) (Nasonex) through day 90; Preexisting stable regimens for allergic rhinitis and asthma, including immunotherapy and inhaled corticosteroids, were maintained. At day 90, when compared to controls using nasal spray alone, subjects receiving SINUVA implants and nasal spray were reported to have experienced significant improvements in nasal obstruction/congestion score ($p<0.0095$), bilateral polyp grade (BPG, $p<0.0008$), and ethmoid sinus obstruction ($p<0.0001$). A lower number of SINUVA subjects remained surgical candidates vs. control subjects (41.0% vs. 69.3%, $p<0.0001$). All subgroups experienced significant treatment effects, except nasal obstruction/congestion in smokers ($p<0.0509$) and subjects without altered smell ($p<0.1873$). Subgroups without asthma and with only one prior ESS experienced the largest treatment effect on nasal obstruction/congestion.

Subjects who had undergone surgery less than 24 months prior and had a BPG > 5 showed the largest effect on endoscopic end points and need for RESS. Control subjects with ESS less than 24 months prior to treatment with SINUVA were seven times more likely to undergo RESS ($p<0.0001$). Study limitations included the use of different outcome scales between the two original studies; short term follow-up of 90 days; unblinded investigators at 90 days; and use of ancillary therapies that may have confounded the results. The subgroup analyses revealed that MF sinus implants may play an important role in management of NP patients, especially those who have allergic rhinitis, expanded polyposis, altered sense of smell, and most recent ESS within 24 months.

Kern et al. (2018) conducted a phase 3 randomized controlled trial (n=300), RESOLVE II, to evaluate the safety and efficacy of the Sinuva sinus implant. Patients were randomized (2:1) to Sinuva (n=201) or sham (n=99) and participated in a 14-day run-in screening period using topical intranasal corticosteroid sprays (INCS) prior to the procedure. Included patients met the following criteria: age ≥ 18 years, confirmed diagnosis of refractory chronic rhinosinusitis with nasal polyps (CRSwNP), previously endoscopic sinus surgery (ESS) including bilateral total ethmoidectomy and a candidate for repeat ESS. Candidates for repeat ESS had been using INCS daily for ≥ 14 days; received ≥ 1 course of high-dose steroids or refused therapy due to side effects within the past year; had moderate-to-severe symptoms of nasal obstruction/congestion; and had endoscopic evidence of bilateral ethmoid sinus obstruction due to polyposis. Exclusion criteria included: patients with grade 4 nasal polyps, extensive adhesions/synechiae that would interfere with access to either ethmoid sinus, allergy or intolerance to corticosteroids, or clinical evidence of acute bacterial sinusitis or invasive fungal sinusitis. Leading up to the baseline procedure, there was a 30-day restriction for use of parenteral injection of steroids and a 14-day restriction for use of oral steroids, budesonide drops/irrigations and nebulized steroids. Primary outcomes included changes from baseline to post-operative day 30 in nasal obstruction/congestion score via self-assessment and degree of change from baseline in bilateral polyp grade at post-operative day 90 determined by an independent, blinded panel. During 90-day follow-up, both treatment and control groups were required to self-administer mometasone furoate nasal spray (MFNS) 200 μg once daily (Nasonex Nasal Spray; Merck & Co., Inc., Whitehouse Station, NJ). Pre-existing asthma and allergy regimens, including inhaled corticosteroids, leukotriene receptor antagonists, and immunotherapies were maintained throughout the 90 day trial. Patients who received prohibited steroids or surgery were allowed to continue in the study and were analyzed according to their assigned treatment group, and their most recent scores and videos prior to intervention were used for analysis of subsequent time points. The Sinuva implants were removed at day 60 following implantation to provide blinded grading of the polyps. At day 30, implant patients reported significant reduction in nasal obstruction/congestion ($p=0.0074$) and had improved polyp grade ($p=0.0073$). At the 90-day follow-up, significantly fewer patients receiving Sinuva were still eligible for repeat ESS ($p=0.0004$), had a significantly greater decrease in the percent of ethmoid sinus obstruction ($p=0.0007$), and experienced sustained symptomatic improvements in nasal obstruction/congestion ($p=0.0248$) and sense of smell ($p=0.0470$). There was no significant difference between the groups in facial pain/pressure ($p=0.9130$). Following the procedure, oral steroids for ethmoid sinus obstruction were used by 13.9% of Sinuva patients compared to 18.2% of controls. Based on the clinical investigator scoring, 72% of patients who received implants achieved at least a 1.0-grade polyp reduction and 48% at least 2.0-grade polyp reduction by day 90, compared to 37% and 16% of sham, respectively. The authors noted that the magnitude of polyp shrinkage was greater when evaluated by the unblinded investigators than by the independent, blinded panel. The overall incidence of adverse events was similar in both groups, and the most common was sinusitis. Author noted limitations of the study included: absence of a defined medical regimen prior to enrollment; clinical investigators performing endoscopic grading and assessment of indication for repeat ESS at day 90 were not blinded to the treatment assignment; and the length of the trial was short at 90 days reflecting the time course of drug

release from the implant. An additional limitation of the study includes the unequal allocation (2:1) of subjects.

Forwith et al. (2016) reported outcomes of the Han et al. (2014) randomized controlled trial (n=100) on the steroid-eluting sinus implant for in-office treatment of recurrent ethmoid sinus obstruction after ESS. Three sinus surgeons (the panel) graded the baseline and three-month video-endoscopies in order to independently corroborate the findings reported by the clinical investigators. Implants were removed at day 60 to ensure the panel was blinded to the treatment assignment. Six-month clinical outcomes were also reported. The original study was a multi-center randomized controlled trial that assessed the safety and efficacy of office-based steroid-eluting sinus implants. The control group (n=43) underwent sham procedure. Patients, age ≥ 18 years, had CRS and were candidates for revision ESS based on recurrent symptoms and bilateral polyposis (minimum grade 2 on one side). Within six months of study enrollment, the polyposis had been treated with ongoing topical intranasal steroid irrigation or spray and repeated courses of treatment with oral steroids and/or sinus steroid irrigations. Patients were required to use topical steroid sprays up to the time of the baseline in-office procedure. Following the implant, both groups were required to take mometasone furoate nasal spray (Nasonex® 100 µg/nostril once daily) and encouraged to use saline sprays or irrigations, as needed. Patients were permitted to continue regimens of orally-inhaled steroids and sinus-related medical therapy (e.g., immunotherapy, leukotriene antagonists) during the 90-day follow-up. Antibiotics were used as needed for sinus infection. Follow-up occurred for six months. At six months, the study group experienced a significantly greater reduction in bilateral polyp grade (p=0.018) and percent ethmoid obstruction on 100-mm visual analog scale (p<0.001) compared to the control group according to clinical investigator judgment. These results were corroborated by the independent panel at three months. The study group reported a significant improvement in the Nasal Obstruction Symptom Evaluation (NOSE) score (p=0.021) and a two-fold reduction in nasal obstruction and congestion score (p=0.124; not statistically significant). Also, at six months 31% (16/52) of the study group patients were no longer indicated for repeat ESS vs. 11% (5/46) of controls. Adverse events included sinusitis, upper respiratory tract infection, epistaxis, nasopharyngitis, asthma, headache, and presyncope and were similar between the two groups. An author-noted limitation is the fact that the clinical investigators performing endoscopic grading were not blinded to the treatment assignment. Also, the study entry criteria required patients to be surgical revision candidates while concurrently allowing for one sinus side to have only grade 1 polyposis which may have resulted in enrollment of patients with less opportunity for improvement from baseline. Other limitations are the small patient population and short-term follow-up. This device was not FDA approved at the time of the study.

Han et al. (2014) conducted a multicenter, randomized controlled trial (n=100) to evaluate the safety and efficacy of a bioabsorbable steroid-eluting implant with 1350 μg of mometasone furoate (Intersect ENT, Menlo Park, CA). Subjects were age 18 years or older, had CRS, and had undergone bilateral total ethmoidectomy more than three months earlier. Patients were randomized to the implant group or to the placebo group following FESS and underwent in-office bilateral implants. Three months post procedure, compared to the control group, the implant group experienced a significant reduction in bilateral polyp grade (p=0.0269), ethmoid sinus obstruction (p=0.0001), and a 2-fold improvement in the mean nasal obstruction/congestion score. Also, 53% of treated patients compared to 23% of controls were no longer indicated for repeat FESS. The mean percentages of implants remaining at days 30, 45, and 60 were 92.5, 86.5, and 56.7, respectively. All implant remnants remaining at 60 days were removed. A total of 34 (64%) patients in the implant group and 35 (75%) in the control group experienced an adverse event including: sinusitis, nasopharyngitis, epistaxis, headache, upper respiratory infection and nasal congestion. No patient experienced a significant increase in intraocular pressure or any type of cataract. According to the authors limitations of the study included: there was not a defined medical treatment regimen prior to enrollment; there was no control over

patient prior treatment regimens and compliance; clinical investigators performing endoscopic grading were not blinded to the treatment (implant vs. placebo); and the study entry criteria required patients to be surgical revision candidates while concurrently allowing for one sinus side to have only grade one polyposis which may have impacted the outcomes and lessened the opportunity of generalizing these outcomes to other patients. Another limitation is the small patient population.

Relieva Stratus MicroFlow Spacer: Studies are primarily in the form of case series with small patient populations (n=23) and short-term follow-ups (six months) (Catalano, et al., 2011).

Sinu-Foam Spacer: Rudmik et al. (2012) conducted a randomized controlled trial (n=36) to evaluate the safety and efficacy of the off-label use of dexamethasone Sinu-Foam spacer following FESS for CRS without nasal polyposis. Subjects were age 18 years or older who had failed medical management (i.e., nasal saline irrigations, topical nasal steroids spray for three months, course of systemic steroids with a broad spectrum oral antibiotic), were eligible for minimum bilateral FESS procedure consisting of maxillary antrostomy and ethmoidectomy and were able to adhere to the follow-up schedule. Patients were randomized to the treatment arm (n=18) or the placebo control arm (n=18). Follow-ups occurred for up to three months and included sinonasal endoscopy and Lund-Kennedy scoring. Postoperatively, patients were treated with nasal saline irrigations and systemic steroids. Both groups showed significant improvement in endoscopic grading ($p<0.001$) following FESS, but there was no significant difference between the groups ($p>0.489$). Sinu-Foam did not improve outcomes following FESS.

Professional Societies/Organizations
American Rhinologic Society (ARS): The ARS position statement (2023) on drug-eluting implants stated that studies investigating drug-eluting implants have demonstrated improvement in outcomes by reducing inflammation, decreasing scarring and middle turbinate lateralization, and limiting the need for oral steroids. ARS "feels strongly that drug-eluting implants are not investigational and should be available to our patients, when selected by the physician, in order to maximize outcomes." This statement was not based on a systematic review of the evidence.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): In a position statement regarding drug-eluting sinus implants, AAO-HNS (January 2023) supported their use in the management of mucosal inflammation of the paranasal sinuses. They cited multiple studies demonstrating the efficacy and safety of drug-eluting implants in controlling sinonasal inflammation. Clinical evidence regarding the use of drug-eluting implants after sinus surgery had particularly shown enhanced wound healing via reduction of scar formation and anatomic obstruction. Additional studies highlighted the utility of drug-eluting implants in previously opened sinus cavities to decrease mucosal inflammation and improve associated patient-reported outcomes. The AAO-HNS further stated drug-eluting implants in the paranasal sinuses have been found to reduce the use of systemic corticosteroids, which are associated with undesired adverse effects, including elevations in blood glucose, bone demineralization, cataracts, and mood alterations. The American Academy of Otolaryngology-Head and Neck Surgery considers drug-eluting implants in the paranasal sinuses as a proven and effective therapeutic option for mucosal inflammation.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): In a position statement regarding FDA-approved biomaterials, AAO-HNS (2021) stated that these materials can be utilized in sinonasal procedures to improve patient outcomes and reduce complications. These devices include implants, stents, and packing materials and have functions including, but not limited to, local drug delivery, stenting, and hemostasis. According to AAO-HNS FDA-approved biomaterials for rhinologic application are not investigational, and the final decision regarding use

of these biomaterials should be determined by the treating physician, factoring in best available scientific evidence, surgeon experience, the clinical situation, and individual patient preference.

American College of Allergy, Asthma, and Immunology/American Academy of Allergy, Asthma & Immunology (ACAAI/AAAAI): In a position statement regarding the medical management of chronic rhinosinusitis with nasal polyposis, ACAAI/AAAAI (2023) offered a conditional recommendation of intranasal corticosteroids (INCS) versus no INCS secondary to low certainty of evidence. They indicated multiple delivery methods of INCS with stent, spray and exhalation delivery system (EDS) among the most beneficial. While they endorsed the safety of INCS spray with moderate certainty of evidence, the safety was variable among the other delivery options. There was low or very low certainty in the safety of INCS using delivery methods other than spray.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven for maintaining postoperative sinus ostial patency following endoscopic sinus surgery or the treatment of nasal polyps following ethmoid sinus surgery:

CPT®* Codes	Description
31299	Unlisted procedure, accessory sinuses

HCPCS Codes	Description
J7402	Mometasone furoate sinus implant, (Sinuva), 10 micrograms

Not covered or reimbursable when used to report a drug-eluting device for maintaining postoperative sinus ostial patency following endoscopic sinus surgery:

HCPCS Codes	Description
C1874	Stent, coated/covered, with delivery system
C1875	Stent, coated/covered, without delivery system
C1876	Stent, non-coated/non-covered, with delivery system

HCPCS Codes	Description
C1877	Stent, non-coated/non-covered, without delivery system
C2617	Stent, non-coronary, temporary, without delivery system
C2625	Stent, non-coronary, temporary, with delivery system
S1091	Stent, non-coronary, temporary, with delivery system (Propel)

ICD-10-CM Diagnosis Codes	Description
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses
J01.00	Acute maxillary sinusitis, unspecified
J01.01	Acute recurrent maxillary sinusitis
J01.10	Acute frontal sinusitis, unspecified
J01.11	Acute recurrent frontal sinusitis
J01.20	Acute ethmoidal sinusitis, unspecified
J01.21	Acute recurrent ethmoidal sinusitis
J01.30	Acute sphenoidal sinusitis, unspecified
J01.31	Acute recurrent sphenoidal sinusitis
J01.40	Acute pansinusitis, unspecified
J01.41	Acute recurrent pansinusitis
J01.80	Other acute sinusitis
J01.81	Other acute recurrent sinusitis
J01.90	Acute sinusitis, unspecified
J01.91	Acute recurrent sinusitis, unspecified
J31.0	Chronic rhinitis
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J34.1	Cyst and mucocele of nose and nasal sinus
J34.2	Deviated nasal septum
J34.3	Hypertrophy of nasal turbinates
J34.89	Other specified disorders of nose and nasal sinuses
J34.9	Unspecified disorder of nose and nasal sinuses
T70.1XXA	Sinus barotrauma, initial encounter
T70.1XXD	Sinus barotrauma, subsequent encounter
T70.1XXS	Sinus barotrauma, sequela

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No policy statement changes.	4/15/2025
Annual Review	No policy statement changes.	4/15/2024