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
Diagnostic Nasal/Sinus Endoscopy, Functional Endoscopic Sinus Surgery (FESS) and Turbinectomy
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.

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 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
C1877	Stent, non-coated/non-covered, without delivery system

HCPCS Codes	Description
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-J01.91	Acute sinusitis
J31.0	Chronic rhinitis
J32.0-J32.9	Chronic sinusitis
J33.0-J33.9	Nasal polyp
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

General Background

Chronic rhinosinusitis (CRS) is an inflammatory condition of the nasal and paranasal sinus mucosa that affects more than 10% of adults. It is characterized by persistent nasal obstruction, nasal drainage, facial pain or pressure, and reduced or lost sense of smell. CRS is classified as chronic rhinosinusitis with nasal polyps (CRSwNP) or without nasal polyps (CRSsNP) based on endoscopic findings. Chronic inflammation can lead to mucosal edema, impaired mucociliary clearance, and, in some individuals, nasal polyp formation that obstructs normal sinus drainage pathways. Initial management of CRS typically includes saline irrigation and intranasal corticosteroids (e.g., dexamethasone, fluticasone, mometasone) to reduce mucosal inflammation and improve sinonasal symptoms. In individuals with more severe or refractory disease, particularly those with CRSwNP, short courses of systemic corticosteroids may be used to decrease inflammatory burden and polyp size. However, clinical benefit is often temporary, and repeated or prolonged systemic corticosteroid use increases risks of adverse effects. When CRS is refractory to medical management surgical intervention may be recommended. In such cases functional endoscopic sinus surgery (FESS) is performed to reestablish sinus outflow tracts by removing inflamed tissue and bone. More than 250,000 endoscopic sinus surgeries (ESSs) are performed annually in the United States. However, because surgery does not address the underlying inflammatory drivers of CRS, ongoing postoperative medical management is required, and disease recurrence is common. Approximately 20% of patients require revision surgery within five years (Mularczyk et al., 2027; Schilling et al., 2022).

Implanted drug-eluting devices have been proposed to enhance postoperative healing and maintain sinus patency, particularly in anatomically challenging regions such as the frontal and

ethmoid sinuses, where topical delivery via sprays or irrigations may be limited. Drug-eluting stents (DESs) or implants are surgically placed scaffolds designed to support healing by providing localized, controlled release of a therapeutic agent (e.g. corticosteroid, antibiotic) over a defined period (e.g. 30–90 days). Some devices are composed of biodegradable materials that are gradually absorbed by the body. Advances in device design have extended the duration of corticosteroid release and enabled in-office placement, offering a potential nonsurgical alternative to revision procedures in select patients with recurrent nasal polyposis following prior endoscopic sinus surgery (ESS). Implanted drug-eluting devices are proposed to reduce local inflammation, limit scar formation, and decrease reliance on repeated courses of systemic corticosteroids. Randomized controlled trials have demonstrated improvements in endoscopic findings and symptom-based outcomes in selected postoperative populations; however, long-term comparative effectiveness data remain limited. At present, steroid-eluting sinus implants are not indicated for use in surgically naïve patients, although investigational studies are ongoing to evaluate their efficacy in patients with medically refractory disease who have not undergone prior surgery (Mularczyk et al., 2027; Schilling et al., 2022).

Reported adverse events associated with drug-eluting sinus implants include implant displacement or fragmentation, swallowing or aspiration of implant material, foreign body reaction with granulation tissue formation, epistaxis, mucosal irritation, ulceration, perforation, and infection. Mild nasal discomfort, pressure, and altered nasal odor have also been reported. Pharmacokinetic studies demonstrate negligible systemic absorption of intranasal corticosteroids delivered via these devices, and no clinically meaningful effects on cortisol levels or intraocular pressure have been observed. Use is contraindicated in individuals with known hypersensitivity to the medications emitted (e.g. corticosteroids, antibiotics) or to the polymer materials used in the implants (Mularczyk et al., 2027; Schilling et al., 2022).

Multiple drug-eluting devices for localized sinonasal drug delivery have been described in the literature, including packing materials, spacers, meshes, and structured sinus stents composed of biodegradable polymers. These systems vary in design, drug load, release duration, and anatomic application, and many remain investigational or in preclinical development (Schilling et al., 2022). At present, the only drug-eluting sinus implants approved by the U.S. Food and Drug Administration for controlled medication delivery are the Propel family of implants and Sinuva (Mularczyk et al., 2027; Schilling et al., 2022).

Propel™ (370 µg Mometasone Furoate) Sinus Implants

The PROPEL™ family of sinus implants consists of bioabsorbable, steroid-eluting implants intended for use in adults aged 18 years and older following sinus surgery. According to the manufacturer, these implants are designed to maintain patency of the sinus cavity or sinus openings while locally delivering mometasone furoate, a corticosteroid, directly to the sinus mucosa. The implants are self-expanding and are placed by a physician at the time of surgery. The PROPEL™ family includes multiple implant configurations to accommodate different sinus anatomies, including options intended for the ethmoid sinus, frontal sinus opening, and sinus ostia. The implants release 370 micrograms of mometasone furoate over 30 days and are designed to bioabsorb over approximately 30–45 days as healing occurs, eliminating the need for removal (Medtronic, 2026).

US Food and Drug Administration (FDA)

Three PROPEL™ sinus implant devices—PROPEL, PROPEL Mini, and PROPEL Contour—are FDA-regulated Class III medical devices approved through the Premarket Approval (PMA) pathway (PMA P100044; product code OWO). These devices are indicated for use in adults aged ≥18 years following ethmoid sinus surgery to maintain sinus patency and reduce the need for postoperative interventions, such as surgical adhesion lysis and/or systemic corticosteroid therapy. The FDA has approved the PROPEL implant for placement within the ethmoid sinuses following ethmoid sinus surgery. The PROPEL Mini (S001, S018) is indicated for use in the ethmoid sinus cavity and frontal

sinus opening, while the PROPEL Contour (S023) is indicated for maintaining patency of the frontal sinus opening and maxillary sinus ostia (FDA, 2026).

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

Steroid-eluting sinus implants in the PROPEL™ family have been evaluated in randomized controlled trials (RCTs), meta-analyses, prospective case series, and retrospective real-world evidence cohort studies. These studies assessed placement of bioabsorbable mometasone furoate–eluting implants following endoscopic sinus surgery compared with no implant, placebo implant, or standard postoperative care. Primary outcomes included the need for postoperative interventions such as surgical debridement or revision surgery, use of oral corticosteroids, endoscopic evidence of inflammation, restenosis or occlusion, frontal sinus ostial diameter, and healthcare resource utilization; secondary outcomes included patient-reported symptoms and safety outcomes. Early RCTs using intrapatient designs demonstrated significantly fewer postoperative interventions, reduced inflammation, lower rates of restenosis or occlusion, and larger frontal sinus ostial diameters on implant-treated sides compared with controls through 30 to 90 days following surgery (Luong et al., 2017; Smith et al., 2016). A meta-analysis pooling two small multicenter RCTs also reported significantly lower rates of adhesions, postoperative interventions, oral steroid use, and frank polyposis on implant-treated sides compared with control sides (Han et al., 2012). A prospective case series without a comparator reported improvements in endoscopic findings and patient-reported outcomes through up to six months but did not allow for comparative effectiveness assessment (Forwith et al., 2011). A 2015 Cochrane systematic review evaluating steroid-eluting sinus stents for adults with chronic rhinosinusitis undergoing functional endoscopic sinus surgery identified no randomized controlled trials that met inclusion criteria and concluded that there was insufficient evidence to determine whether steroid-eluting sinus stents provide benefit over surgery alone, non-steroid stents, nasal packing, or no treatment, highlighting the absence of high-quality trials assessing clinically meaningful outcomes and durability of effect (Huang et al., 2015). A large retrospective observational real-world study demonstrated reductions in healthcare resource utilization through 24 months following surgery among patients receiving steroid-eluting implants, including fewer outpatient and otolaryngology visits and fewer sinus endoscopic and debridement procedures, with a statistically significant reduction in revision surgery observed in patients with chronic rhinosinusitis with nasal polyps but not in those without nasal polyps (Hoffman et al., 2023). In contrast, a retrospective case-control study in patients undergoing challenging frontal sinus surgery found no statistically significant differences in postoperative interventions or revision surgery between implant and non-implant groups, despite improvements in some postoperative symptoms within groups (Beckmann et al., 2025). The overall body of evidence is limited by frequent use of intrapatient designs that preclude assessment of patient-level symptom outcomes, small sample sizes in clinical trials (approximately n=50–143), lack of control groups in case series, heterogeneity in postoperative medical management and short follow-up durations in RCTs (typically 30–90 days).

Fieux et al. (2025) conducted a randomized, intraparticipant-controlled trial evaluating whether a steroid-eluting implant (Propel Mini or Contour) provides benefit over postoperative steroid irrigation alone in maintaining frontal sinus patency following endoscopic sinus surgery (ESS). Sixty-two adults (mean age 55.7 years; 42.4% female) with chronic rhinosinusitis with nasal polyps (CRSwNP) and bilateral, equivalent frontal sinus disease refractory to medical therapy were enrolled; 59 completed the 24-week follow-up. All participants underwent bilateral Draf IIa frontal sinusotomies using identical techniques on both sides, with a minimum postoperative frontal sinus opening of 5 mm. One frontal sinus was randomized intraoperatively to receive a steroid-eluting

implant, while the contralateral side served as a surgery-only control. All participants received standardized postoperative care with high-volume saline irrigations containing budesonide (0.5 mg/2 mL), initiated on postoperative day one; no oral steroids, antibiotics, or biologics were used. Eligibility required adults (>18 years) with CRSwNP diagnosed per AAO-HNS criteria, bilateral frontal sinus disease of equivalent severity (CT Lund–Mackay score ≥1 per side), and no prior frontal sinus surgery. Individuals with aspirin-exacerbated respiratory disease, cystic fibrosis, primary ciliary dyskinesia, CRS without nasal polyps, invasive fungal sinusitis, immunodeficiency, or those requiring more extensive frontal procedures (e.g., Draf IIb or III) were excluded. The primary outcome was frontal sinus ostium (FSO) patency at 24 weeks. Secondary outcomes included scarring/adhesion formation, polypoid edema, and need for additional medical or surgical intervention. At 24 weeks, there were no statistically significant differences between treatment and control sides for patency, scarring/adhesions, edema, or need for further treatment (p=0.817, 0.878, 0.688, 1.00, and 1.00, respectively). Multivariable analysis adjusting for age, sex, and time demonstrated no added benefit of the steroid-eluting implant over steroid irrigation alone for any outcome. Study limitations include the single-center design, small sample size, participant attrition, and exclusion of individuals with significant comorbid conditions or those requiring more advanced frontal sinus surgery. The authors concluded that in individuals with CRSwNP who adhere to effective and sustained postoperative steroid irrigation, steroid-eluting frontal sinus stents do not confer additional benefit in reducing postoperative inflammation, maintaining long-term frontal sinus patency, or decreasing the need for additional medical or surgical intervention.

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.

Given the methodological limitations, heterogeneity of results, and lack of demonstrated long-term clinical benefit, strong evidence-based conclusions regarding the long-term safety, durability, and clinical effectiveness of steroid-eluting sinus implants, including PROPEL™, for maintaining postoperative sinus ostial patency cannot be made. Additional well-designed studies with long-term follow-up are needed.

Sinuva® (1,350 µg Mometasone Furoate) Sinus Implant

The SINUVA® sinus implant is a bioabsorbable, corticosteroid-eluting implant indicated for use in adults aged 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP) who have previously undergone ethmoid sinus surgery. According to the manufacturer, SINUVA® is designed to provide localized, sustained delivery of mometasone furoate directly to the sinus mucosa to reduce inflammation and polyp burden. The implant is placed by a physician during a non-surgical, in-office procedure using local anesthesia and is intended as an alternative to revision endoscopic sinus surgery. SINUVA® is self-expanding and delivers a total of 1,350 micrograms of mometasone furoate over approximately 90 days. The implant gradually softens over time and is subsequently removed in the office, rather than fully bioabsorbed. By providing targeted corticosteroid delivery at the site of disease, SINUVA® is intended to reduce nasal obstruction and related symptoms while minimizing systemic steroid exposure (Intersect ENT, Inc., 2026).

US Food and Drug Administration (FDA)

SINUVA® is regulated by the U.S. Food and Drug Administration (FDA) as a drug and approved through the New Drug Application (NDA) pathway (NDA 209310; Supplement S-006). It is indicated for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adults aged ≥18 years who have previously undergone ethmoid sinus surgery. Each implant contains 1,350 µg

of mometasone furoate and is intended to be removed by 90 days or earlier at the clinician's discretion. SINUVA® is contraindicated in individuals with known hypersensitivity to mometasone furoate or any component of the implant (FDA, 2023).

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Literature Review

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.

There is insufficient evidence in the published medical literature to demonstrate the safety and effectiveness of drug-eluting devices for the treatment of nasal polyps following ethmoid sinus surgery (e.g., Sinuva).

Other Drug-Eluting Devices

In addition to FDA-approved steroid-eluting sinus implants, a variety of other drug-eluting or drug-impregnated sinonasal devices have been proposed for use following endoscopic sinus surgery or for local treatment of chronic rhinosinusitis. These devices include absorbable nasal dressings, spacers, foams, stents, and investigational polymer-based implants designed to deliver corticosteroids, antibiotics, or other therapeutic agents directly to the sinonasal mucosa. Examples described in the literature include carboxymethylcellulose-based foams (e.g., Sinu-Foam), biodegradable spacers and packs soaked or impregnated with corticosteroids (e.g., Relieva Stratus™ MicroFlow Spacer), bioresorbable sinus stents under investigation (e.g., BISORB), and extended-duration polymeric implants such as LYR-210 and LYR-220. These devices vary widely in material composition, drug payload, mechanism of release, duration of drug delivery, and method

of placement, and are intended to improve local drug retention, reduce postoperative inflammation, or maintain sinus patency while minimizing systemic exposure. However, most have been evaluated only in early-phase clinical studies, small randomized trials, observational studies, or preclinical models, and clinical outcomes have been inconsistent across devices and study designs (Schilling et al., 2022).

US Food and Drug Administration (FDA)
Drug-eluting sinonasal devices other than PROPEL™ and SINUVA® are not approved by the U.S. Food and Drug Administration (FDA).

Literature Review
All Devices: Evidence assessing steroid-eluting and steroid-impregnated sinonasal devices, including a heterogeneous mix of FDA-approved and non-FDA-approved implants, following endoscopic sinus surgery (ESS) for chronic rhinosinusitis (CRS) has been evaluated in randomized controlled trials (RCTs), systematic reviews, and meta-analyses. These studies compare bioabsorbable steroid-eluting implants or steroid-impregnated spacers or packings to non-steroid implants or packing, surgery alone or no implant, sham procedures, or conventional postoperative management, including topical intranasal corticosteroids. Primary outcomes focus on postoperative endoscopic findings such as adhesions or synechiae (i.e., scar tissue bands that abnormally connect nasal tissues), mucosal inflammation, and polyp or polypoid recurrence, with secondary outcomes including the need for postoperative oral steroids, additional surgical intervention, and safety measures. While some studies report statistically significant short-term improvements favoring steroid-eluting or steroid-impregnated devices within approximately 30 days to 2–3 months after surgery, the overall evidence remains limited and inconsistent, and further large, high-quality studies are needed to confirm efficacy. Across studies, limitations include heterogeneity in device types and corticosteroids, variability in postoperative care, frequent use of intrapatient or contralateral study designs, small to moderate sample sizes, and predominantly short follow-up durations, most commonly ranging from approximately 30 days to 3 months, with limited data extending beyond 6 months (Zamaili et al., 2025; Calvo-Henríquez et al., 2024; Hwang et al., 2023; Goshtasbi et al., 2019; Rizan et al., 2016; Zhao et al., 2013).

BISORB® (652µg Mometasone Furoate) Sinus Implant
The BISORB® bioabsorbable steroid-eluting sinus stent (Puyi [Shanghai] Biotechnology Co., Ltd., China) is an implant intended for use in adult patients with chronic rhinosinusitis (CRS). BISORB® received approval from the China Food and Drug Administration (CFDA) in 2017 (approval number 20173460679) and has been marketed internationally, with supporting patent and bibliographic documentation available through Espacenet (e.g., BR112014028185, *Implanted System for Treating Sinusitis or Allergic Rhinitis*). According to available published data, BISORB® is designed for use following sinus surgery to provide dual therapeutic benefits through mechanical spacing of the sinus opening and localized corticosteroid delivery. The stent is composed of a bioabsorbable polylactide-co-glycolide (PLGA) polymer and is coated with approximately 652 micrograms (µg) of mometasone furoate. The corticosteroid is released in a controlled manner into the surrounding sinus mucosa over an estimated 30-day period, with an approximate daily release of 20 to 25 µg. By maintaining patency of the sinus opening during the postoperative healing phase while delivering localized anti-inflammatory therapy, BISORB® is intended to reduce mucosal inflammation associated with CRS. The stent is designed to be absorbed by the body over time, eliminating the need for device removal and offering a localized treatment approach intended to support sinus healing while minimizing systemic corticosteroid exposure (Huang et al., 2022).

Zhang et al. (2025) conducted a prospective, randomized controlled trial evaluating the efficacy of BISORB® steroid-eluting stents for the treatment of olfactory dysfunction in individuals with chronic rhinosinusitis with nasal polyps (CRSwNP) requiring endoscopic sinus surgery (ESS). Fifty-nine participants (mean age range 41.3–43.9 years; 67.8% male) were randomized to a

stent group (n=30) or a control group (n=29). Eligible participants were adults with CRSwNP and olfactory dysfunction. Exclusion criteria included age younger than 18 years or 80 years and older; comorbid conditions such as sinonasal tumors or fungal sinusitis; prior intracranial or olfactory region tumors; congenital anosmia; systemic conditions affecting olfaction (e.g., autoimmune disease, cystic fibrosis); allergy to device materials or degradation products; and a history of immunodeficiency, glaucoma or elevated intraocular pressure, cataract, severe diabetes, or hypertension. In the intervention group, a steroid-eluting stent (Xiangtong; Puyi Biotechnology, Shanghai, China) containing 652 µg of mometasone furoate with drug release for more than 30 days was implanted in the ethmoid sinus at the conclusion of ESS; no stent was placed in the control group. Postoperative management was comparable between groups and included hemostatic sponges, budesonide nasal spray (128 µg once daily), topical saline irrigation for 3 months, and systemic antibiotics for 3 days; oral glucocorticoids were not administered. Outcomes assessed included symptom severity, olfactory function (olfactory Visual Analogue Scale and T&T olfactometer), endoscopic findings (Lund-Kennedy score), and type 2 inflammatory mediators (IL-4, IL-5, IL-13, IL-33, eotaxin-3, periostin). Participants were followed for 3 months postoperatively. Postoperative olfactory Visual Analogue Scale scores, T&T olfactometer scores, Sinonasal Outcome Test-22 scores, and Lund-Kennedy scores were significantly lower in the stent group compared with the control group ($p<0.01$). Postoperative concentrations of IL-5, IL-13, and periostin were also significantly lower in the stent group ($p<0.05$), with no significant reductions observed in the control group. Study limitations include a small sample size, restriction to individuals with CRSwNP, and short-term follow-up.

Huang et al. (2022) conducted a multicenter, randomized, controlled, single-blinded clinical trial evaluating BISORB® bioabsorbable steroid-eluting sinus stents compared with absorbable Nasopore packing following endoscopic sinus surgery (ESS) for chronic rhinosinusitis (CRS). A total of 183 participants (mean age 42.4 years; 70.7% male) across eight medical centers were enrolled, including individuals with CRS with and without nasal polyps, as defined by EPOS 2020 criteria. Participants were randomized to receive a BISORB® steroid-eluting stent in one ethmoid sinus and Nasopore packing on the contralateral side; no steroids were added to the Nasopore. Eligibility criteria included age 18–65 years, ability to provide informed consent, bilateral CRS confirmed by CT imaging with a Lund–Mackay score of 26, and nonpregnant status for females. Key exclusions included hypersensitivity to device components, long-term systemic steroid use, immunosuppressive therapy or autoimmune disease, diabetes, glaucoma or ocular hypertension, and acute bacterial or fungal sinusitis. Postoperatively, all participants received a 7-day course of antibiotics, with routine nasal saline irrigation and oral mucolytics allowed during follow-up per clinician preference; intranasal steroid sprays were permitted beginning 30 days after ESS. The primary outcome was the rate of postoperative interventions within 30 days, guided by standardized endoscopic grading for polypoid tissue, middle turbinate (MT) lateralization, and adhesions. Surgical intervention was recommended when any of the following thresholds were met: polypoid tissue score ≥2, adhesion score ≥2, or MT lateralization score ≥3. Safety outcomes included intraocular pressure measured by Tono-Pen tonometry and slit-lamp examination of the crystalline lens. Follow-up was completed by 181 participants at 30 days and 175 participants at 90 days. At postoperative day 30, the need for postoperative interventions was significantly lower on steroid-eluting stent sides compared with Nasopore sides (14.38% and 33.7% vs 75% and 66.3%, respectively; $p<0.0001$). Intervention rates at day 90 were not assessed. Rates of polyp formation at postoperative days 14, 30, and 90 were significantly lower on stent-treated sides (16.57%, 22.65%, and 6.78%) compared with Nasopore sides (44.75%, 54.14%, and 25.42%; $p<0.0001$). No significant differences in grade 3 MT lateralization were observed between groups at any time point. Severe adhesions were significantly less frequent on steroid-eluting stent sides at day 90 (7.63% vs 25.42%; $p=0.0003$). No clinically significant differences in intraocular pressure or lens opacities were identified between baseline and postoperative assessments through day 90. Telephone contacts occurred at 180 and 365 days after the ESS, results of these assessments were not provided. Study limitations include modest sample size with predominantly

male study population, incomplete blinding, short-term follow-up, participant attrition, incomplete data reporting, and potential conflict of interest.

In a 2023 post-hoc subgroup analysis of the randomized controlled trial reported by Huang et al. (2022), Huang and colleagues evaluated whether comorbid asthma modified short-term postoperative outcomes among individuals with chronic rhinosinusitis with nasal polyps following endoscopic sinus surgery. The analysis included 151 individuals assessed on postoperative day 14; due to follow-up attrition, 144 and 91 individuals were evaluated on postoperative days 30 and 90, respectively. Using univariate logistic regression, comorbid asthma was identified as the only factor associated with poorer short-term outcomes on postoperative day 30 on the stent-treated side, with statistically significant associations observed for the need for postoperative intervention and for moderate-to-severe polypoid tissue formation. Blood eosinophil levels were not associated with treatment response. Comparative analyses demonstrated higher rates of postoperative intervention and grades 2–3 polypoid tissue formation on postoperative day 30 among individuals with asthma compared with those without asthma. Reported limitations included the small number of individuals with asthma, absence of quality-of-life outcomes, incomplete documentation of asthma severity and medication use, limited mucosal sampling, and the inherent constraints of post-hoc analyses. The authors concluded that comorbid asthma may impair the short-term efficacy of steroid-eluting sinus stents after endoscopic sinus surgery and emphasized the need for prospective randomized studies to confirm these findings.

Wang et al. (2022) conducted a prospective, multicenter, randomized, intraparticipant-controlled trial evaluating the efficacy and safety of BISORB® mometasone furoate–eluting stents following endoscopic sinus surgery (ESS) in individuals with eosinophilic chronic rhinosinusitis with nasal polyps (ECRSwNP). Chronic rhinosinusitis with nasal polyps (CRSwNP) may be subclassified as eosinophilic or non-eosinophilic based on mucosal eosinophilia, with ECRSwNP associated with more extensive disease, greater symptom severity, higher postoperative recurrence rates, and increased reliance on systemic corticosteroids. Ninety-eight individuals aged 18–65 years (mean 48.8 years; 51.6% male) across three centers in China with CT-confirmed ECRSwNP requiring bilateral full-house ESS were enrolled. Participants were excluded if they had known allergies to the device material or its degradation products, an oral steroid-dependent condition, history of immune deficiency, glaucoma or ocular hypertension, cataract, severe diabetes or hypertension, or acute bacterial or fungal sinusitis. Following surgery, one sinus was randomized to receive one or two absorbable steroid-eluting stents, while the contralateral sinus served as a surgery-only control. ECRSwNP was defined by tissue eosinophils exceeding 27% of inflammatory cells or >55 eosinophils per high-power field. Comorbid asthma (33.7%), allergy (35.8%), aspirin-exacerbated respiratory disease (2.1%), smoking (20.7%), and prior ESS (12.6%) were documented. All individuals underwent radical bilateral ESS with nasal polypectomy; septoplasty was permitted when clinically indicated. Standard postoperative care was provided, including topical nasal steroids, while systemic corticosteroids were prohibited through 12 weeks. The primary outcome was the Lund–Kennedy endoscopic score through 12 weeks postsurgery; secondary outcomes included symptom scores, nasal airflow metrics, nitric oxide levels, volumetric CT findings, and tissue eosinophilia. Ninety-five participants completed follow-up. At postoperative weeks 4, 8, and 12, endoscopic scores were significantly lower on the treated side compared with control ($p<0.01$), driven by reductions in edema, scarring, and later crusting. Polyp scores did not differ between sides. Nasal obstruction and total nasal symptom scores were significantly improved on the treated side at week 8 ($p<0.01$ and $p=0.001$ respectively). Volumetric disease burden in the ethmoid and frontal sinuses and tissue eosinophilia at week 4 were significantly lower on the treated side (ethmoidal sinus $p=0.011$; frontal sinus $p=0.032$). No differences were observed in nasal resistance, volume, minimal cross-sectional area, or nasal nitric oxide levels. No adrenal suppression or serious adverse events occurred. Study limitations include small sample size, lack of blinding, and short follow-up duration.

LYR-210 and LYR-220 (2500 µg or 7500 µg Mometasone Furoate) Sinus Implants
LYR-210 is an investigational, bioabsorbable, steroid-eluting sinonasal implant developed by Lyra Therapeutics for the treatment of chronic rhinosinusitis (CRS) in adults with surgically naïve anatomy who remain symptomatic despite medical management. The device is placed during an in-office endoscopic procedure and is designed to dynamically expand providing long-acting, localized anti-inflammatory therapy to the sinonasal mucosa. LYR-210 consists of a drug-eluting nasal mesh composed of biocompatible, bioabsorbable polymers that gradually soften and conform to sinonasal anatomy following placement and is subsequently removed in the office rather than fully bioabsorbed. The implant is engineered to deliver 2500 micrograms (µg) or 7,500 µg of mometasone furoate over a period of up to six months, with the intent of reducing mucosal inflammation and CRS-related symptoms while limiting systemic corticosteroid exposure. Clinical evaluation of LYR-210 is ongoing through the LANTERN trial and the ENLIGHTEN clinical program (Lyra Therapeutics, Inc., 2026; Cervin et al., 2022).

Similarly, LYR-220 is an investigational, bioabsorbable, steroid-eluting sinonasal implant designed for placement via a brief, in-office endoscopic procedure and provides localized, long-acting corticosteroid therapy directly to inflamed sinonasal tissues. LYR-220 is intended for use in adults with CRS who have previously undergone ethmoid sinus surgery and continue to experience persistent or recurrent symptoms. While based on the same proprietary drug-delivery platform as LYR-210, LYR-220 is larger in size and specifically engineered to conform to post-surgical sinonasal anatomy, including enlarged ethmoid cavities. The implant is composed of bioabsorbable polymeric materials and is intended to deliver continuous mometasone furoate to the sinonasal mucosa for up to six months following a single placement. Clinical evaluation of LYR-220 has been conducted in the BEACON trial (Lyra Therapeutics, Inc., 2026).

Senior et al. (2025) conducted a multicenter, randomized, controlled Phase 2 (BEACON) study to evaluate the safety, feasibility, and preliminary efficacy of LYR-220 for the treatment of chronic rhinosinusitis (CRS) in adults who had previously undergone bilateral endoscopic sinus surgery (ESS). Forty-two adults (59.5% female; 54.8% with nasal polyps) with persistent CRS following prior bilateral ethmoidectomy were enrolled. Eligible participants were ≥18 years of age, had undergone bilateral ethmoidectomy at least three months before screening, reported at least two cardinal CRS symptoms for a minimum of 12 weeks, demonstrated ethmoid disease on computed tomography, and had a SNOT-22 score ≥20 with a 7-day average composite score of the three cardinal symptoms (nasal congestion/blockage, nasal discharge, facial pain/pressure) ≥4.5 on a 0–9 scale. Participants were also required to have previously trialed at least two medical therapies for CRS, including at least one course of intranasal corticosteroid sprays. Key exclusion criteria included unilateral ethmoidectomy, nasal polyps extending beyond the middle meatus, anticipated seasonal allergic rhinitis during the study period, severe asthma, or perennial allergic rhinitis requiring intranasal corticosteroids. Additional exclusions included significant sinonasal scarring or adhesions, middle turbinate abnormalities that could interfere with device placement, mucosal erosion or septal perforation, recent systemic corticosteroid or biologic therapy, corticosteroid intolerance, pregnancy or breastfeeding, or those with a history or evidence of hypothalamic pituitary adrenal axis dysfunction, glaucoma or ocular hypertension, immunodeficiency, immunosuppression, intracranial or orbital complications, evidence of mycetoma/fungal ball, sinus mucocele, or invasive fungal rhinosinusitis. Following a 2- to 4-week run-in period with daily saline irrigation and electronic symptom diary recording, participants were randomized 1:1 to bilateral LYR-220 placement or a bilateral sham procedure. Blinding was maintained by using a sham procedure that closely mimicked device insertion; investigators and clinical staff were unblinded to treatment assignment, while the sponsor remained blinded. The primary endpoint was the occurrence of treatment-related serious adverse events (SAEs). Secondary efficacy endpoints included change from baseline in SNOT-22, three cardinal symptom scores, loss-of-smell, ethmoid percent opacification volume, and need for rescue treatment (systemic corticosteroids or sinonasal surgery). At 24 weeks, SNOT-22 scores demonstrated statistically significant improvement with

LYR-220 compared with sham beginning at week 2, with a between-group difference of −16.8 at week 24 (p = 0.007). Significant between-group differences favoring LYR-220 were also observed for the three cardinal symptoms (−1.50; p = 0.02), ethmoid percent opacification volume (−8.14; p = 0.035), and loss-of-smell from week 8 through week 24 (−0.87; p = 0.026). Use of systemic corticosteroids occurred in five individuals in the LYR-220 group and seven in the sham group. Nineteen participants in the LYR-220 group and seventeen in the sham group completed the treatment period. Adverse events were more frequently reported in the LYR-220 group (95.8%) than in the sham group (76.2%), with the most common events including sinusitis, nasopharyngitis, bronchitis, and COVID-19. Study- and procedure-related adverse events were more common with LYR-220 but were generally mild to moderate in severity. Two participants in the LYR-220 group withdrew due to an adverse event (acute sinusitis) or investigator decision (due to recurring bronchitis), while four participants in the sham group withdrew voluntarily. Study limitations included small sample size, participant attrition, limitations related to blinding, and short-term follow-up.

Cervin et al. (2022) conducted a multicenter, randomized, blinded, controlled, dose-ranging trial (LANTERN study) to evaluate the efficacy, safety, and tolerability of LYR-210 (2,500 µg and 7,500 µg) in adults with chronic rhinosinusitis (CRS) and surgically naïve anatomy who remained inadequately controlled despite prior medical management. Sixty-seven adults (55.2% female) with moderate-to-severe CRS, defined by Sino-Nasal Outcome Test-22 (SNOT-22) scores and composite 7-day average scores of the four cardinal CRS symptoms (4CS), were enrolled. CRS diagnosis was confirmed by nasal endoscopy and magnetic resonance imaging (MRI). Eligible participants were ≥18 years of age, had at least two of four cardinal CRS symptoms for a minimum of 12 weeks, and demonstrated a baseline 4CS composite score ≥7 (0–12 scale). Participants exhibited purulence, inflammation, and/or nasal polyps on nasal endoscopy and radiologic evidence of sinusitis on MRI. All had completed at least two prior medical treatment trials for CRS, including a minimum four-week course of intranasal corticosteroid sprays. Key exclusion criteria included prior functional endoscopic sinus surgery, significant mucosal injury, nasal septal perforation, severe nasal obstruction preventing visualization of the middle meatus, uncontrolled allergic rhinitis, severe asthma, low baseline Zinreich MRI scores, recent systemic corticosteroid use, intolerance to corticosteroids or topical anesthesia, immunodeficiency, or invasive sinonasal disease. Following a minimum 14-day washout period, participants were randomized (1:1:1) to bilateral in-office administration of LYR-210 (7,500 µg; n=21), LYR-210 (2,500 µg; n=23), or saline-irrigation-only control (n=23). To maintain blinding, control participants underwent a sham placement procedure. All participants received topical anesthetic and decongestant prior to the procedure and performed daily saline irrigations throughout the 24-week treatment period. Study investigators and clinical staff were unblinded to treatment assignment but blinded to LYR-210 dose, while the sponsor remained blinded. Implants were removed at week 24, and control participants underwent a sham removal. Efficacy was assessed over 24 weeks using participant-reported symptom outcomes, reduction in sinonasal inflammation, and need for rescue treatment. Daily symptom scores for the four cardinal CRS symptoms were collected using an electronic participant-reported outcome system, and SNOT-22 assessments were completed at baseline and prespecified intervals through week 24. Sinonasal inflammation was evaluated by MRI using Zinreich (modified Lund-Mackay) scoring by an independent imaging core laboratory. LYR-210 (7,500 µg) demonstrated statistically significant improvement compared with control in nasal blockage (weeks 16, 20, 24; p=0.013, p=0.007, p=0.005 respectively), facial pain/pressure (weeks 12, 16, 20, 24; p=0.048, p=0.011, p=0.005, p=0.007 respectively), and nasal discharge (weeks 16, 20, 24; p=0.012, p=0.017, p=0.007 respectively). In enrolled patients who exhibited moderate-to-severe anosmia at baseline (≥2 in loss of smell score), LYR-210 (7500 µg) showed a numerical improvement in smell over the control but this was not statistically significant. Statistically significant improvements in composite 4CS and SNOT-22 scores were observed with LYR-210 (7,500 µg; p<0.05) compared with control at multiple time points, with achievement of the minimal clinically important difference (MCID) in 100% of individuals receiving

the 7,500 µg dose at week 24, regardless of polyp status. MRI findings demonstrated dose-dependent improvement in bilateral ethmoid sinus opacification, with significant improvement in the 7,500 µg group. Use of rescue treatment was reduced in a dose-dependent manner, with significantly less rescue medication use in the 7,500 µg group compared with control. Safety assessments included adverse events (AEs), laboratory testing, vital signs, serum cortisol levels, nasal endoscopy, intraocular pressure, and slit-lamp examination. The most common AEs reported in the LYR-210 (2500 µg) arm were chronic sinusitis, epistaxis, and rhinorrhea (n=4 each); in the LYR-210 (7500 µg) arm they were chronic sinusitis and rhinitis (n=4 each); and in the control arm they were chronic sinusitis (n=7). Other less common AEs included upper respiratory tract infection, oropharyngeal pain, nasal congestion, facial pain, dizziness, and hyperkalemia. One serious adverse event occurred in the 2,500 µg group and was determined to be unrelated to study treatment. No clinically significant increases in intraocular pressure or evidence of adrenal insufficiency were observed. Study limitations included small sample size, participant withdrawals prior to study completion, and short-term follow-up duration.

Relieva Stratus MicroFlow Spacer
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.

Sinu-Foam Spacer
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).

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.

There is a paucity of evidence in the peer-reviewed literature evaluating other drug-loaded nasal packs, dressings, and spacer products, including but not limited to SinuBand™, GelFoam®, MeroGel, Chitogel, and antibiotic stents. The available literature consists largely of preclinical studies, early-phase clinical trials, and small heterogeneous investigations with short-term

follow-up, and does not establish long-term safety or effectiveness for the treatment of chronic rhinosinusitis (CRS) (Jia et al., 2024; Lim et al., 2024; Long et al., 2022; McCormick et al., 2022; Schilling et al., 2022; Vediappan et al., 2022; Zhang et al., 2021).

The current body of published medical evidence is insufficient to support conclusions regarding the safety and clinical effectiveness of other investigational drug-eluting or drug-impregnated sinonasal devices for the treatment of chronic rhinosinusitis (CRS), either as stand-alone therapy or in conjunction with surgical intervention.

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.

The **American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS)** issued an updated position statement in June 2025 regarding the use of FDA-approved biomaterials in sinonasal procedures. AAO-HNS states that FDA-approved biomaterials, including implants, stents, and packing materials, may be utilized in sinonasal procedures to improve outcomes and reduce complications, with applications including but not limited to local drug delivery, maintenance of sinus outflow patency, stenting, and hemostasis. The Academy notes that these biomaterials are not considered investigational when used for approved rhinologic indications, and that decisions regarding their use should be determined by the treating physician based on the best available scientific evidence, surgeon experience, the clinical situation, and individual preference. AAO-HNS further states that updated studies continue to demonstrate statistically significant efficacy of drug-eluting implants in maintaining sinus outlet patency following surgery when compared with standard nasal dressings in most clinical settings. The statement emphasizes that the decision to place stents, whether intraoperatively or in the office setting, should be made expeditiously based on endoscopic findings and surgical judgment, and should not be delayed by requirements to trial stepwise less invasive or less costly therapies, as clinically relevant findings may be evident within 2 to 4 weeks following surgery. It is also noted that AAO-HNS position statements are intended to provide professional guidance and do not constitute coverage determinations or evidence-based clinical practice guidelines.

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 (Rank et al., 2023).

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.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• No clinical policy statement changes.	4/15/2026
Annual Review	• No clinical policy statement changes.	4/15/2025
Annual Review	• No clinical policy statement changes.	4/15/2024