7.01.134	Steroid-Eluting Sinus Stents and Implants		
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Section:	7.0 Surgery	**Page:**	Page 1 of 19

Policy Statement

I. The use of steroid-eluting sinus stents and implants for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **investigational**.

II. The use of steroid-eluting sinus stents and implants is considered **investigational** in all other conditions.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Sinus stents are defined as implantable devices specifically designed to improve patency and/or deliver local medication. These devices are inserted under endoscopic guidance and are distinguished from sinus packing and variations on packing devices routinely employed after sinus surgery.

Foam dressings, such as Sinu-Foam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used after endoscopic sinus surgery. They are considered different types of nasal packing.

Middle meatal spacers are related but separate devices intended to maintain sinus patency post-endoscopic sinus surgery. They are splint-like devices inserted directly rather than under endoscopic guidance and do not have the capability of delivering local medication.

Coding

See the Codes table for details.

Description

Steroid-eluting sinus stents are devices used postoperatively following endoscopic sinus surgery (ESS) or for treatment of recurrent sinonasal polyposis following ESS. These devices maintain patency of the sinus openings in the postoperative period, and/or serve as a local drug delivery vehicle. Reducing postoperative inflammation and maintaining patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery and/or reduce the need for additional surgery.

Summary of Evidence

For individuals who have chronic rhinosinusitis who have undergone endoscopic sinus surgery (ESS) who receive implantable steroid-eluting sinus stents, the evidence includes randomized controlled trials (RCTs) and two systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The findings from systematic reviews and meta-analyses are mixed. A Cochrane review reported insufficient high-quality evidence to assess the intervention, while a meta-analysis identified benefits of steroid-eluting stents compared to a control intervention, including reduced adhesion, mucosal inflammation, polyp recurrence, need for oral steroids post-surgery, and additional surgical procedures at 30 days follow-up. The most direct evidence relating to use of steroid-eluting nasal stents as an adjunct to ESS comes from 4 RCTs comparing steroid-eluting stents with either a non-steroid-eluting stent or medical management.

The need for post-operative intervention at 30 days was reduced by 14% to 24%, translating to a number needed to treat of 4.7 or more. Three trials used blinded assessors to evaluate post-implantation sinus changes, an important strength, but the trials had potentials for bias. To most accurately evaluate the benefit from PROPEL devices it is important to ensure that the comparison group is not undertreated (i.e., receives some form of packing, intranasal steroids, and irrigation). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have recurrent sinonasal polyposis who have undergone ESS who receive steroid-eluting sinus implants, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. Two RCTs were identified evaluating the use of steroid-eluting nasal implants for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of these trials included use of sham control and adequate power for its primary outcome. However, the trials had a high-risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be relevant outcomes for this indication, it would be more important if decisions about repeat ESS or other treatments were standardized and, in the trial setting, if decisions were prespecified or made by a clinician blinded to treatment group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

Related Policies

- Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2011, the PROPEL® system (Intersect ENT, Menlo Park, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100044). This device is a self-expanding, bioabsorbable, steroid-eluting stent intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger included with the device. Steroids (mometasone furoate) are released over an approximate duration of 30 days. The device dissolves over several weeks and therefore does not require removal. In 2012, a smaller version of the PROPEL device, the PROPEL Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL Contour sinus implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

SINUVA™ Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at Day 90 or earlier using standard surgical instruments. The SINUVA™ Sinus Implant is indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery.

FDA product code: OWO

Rationale

Background

Chronic Rhinosinusitis

Chronic rhinosinusitis is an inflammatory sinus condition that has a prevalence between 1% and 5% in the U.S. population.[1,]

Treatment

Endoscopic sinus surgery (ESS) is typically performed on patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with high rates of improvement in up to 90% of more appropriately selected patients. However, there are no high-quality randomized controlled trials (RCTs) comparing functional ESS with continued medical management or alternative treatment approaches. Because of the high success rates and minimally invasive approach, these procedures have rapidly increased in frequency, with an estimated 250,000 procedures performed annually in the United States.[2,] They can be done either in the physician's office under local anesthesia or in the hospital setting under general anesthesia.

ESS involves the removal of small pieces of bone, polyps, and débridement of tissue within sinus cavities. There are a number of variations on the specific approach, depending on the disorders being treated and the preferences of the treating surgeon. For all procedures, there is substantial postoperative inflammation and swelling, and postoperative care is, therefore, a crucial component of ESS.

There are a number of postoperative treatment regimens, and the optimal regimen is uncertain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity débridement. Several RCTs have evaluated treatment options, but not all strategies have been rigorously evaluated.[3,4,5,6,] A 2011 systematic review has evaluated the evidence for these therapies.[2,] Reviewers concluded that the evidence was not strong for any of these treatments but that some clinical trial evidence supported improvements in outcomes. The strongest evidence supported use of nasal saline irrigation, topical nasal steroid spray, and sinus cavity débridement.

Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications.[7,]Middle meatal spacers are splint-like devices that prop open the sinus cavities post-ESS but are not designed for drug delivery. There is some RCT evidence that middle meatal spacers may reduce the formation of synechiae following ESS, although the available studies have significant heterogeneity in this outcome.[8,]

Sinus Stents and Implants

Implantable sinus stents and implants are another option for postoperative management following ESS. These implants are intended to stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They can also be infused with medication delivered

topically over an extended period of time, and this local delivery of medications may be superior to topical applications in the postoperative setting.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

RCTs are important in the evaluation of sinus implants as an adjunct to endoscopic sinus surgery (ESS) to adequately compare implantable stents with alternative treatment regimens and to minimize the effects of confounders on outcomes. Case series and trials without control groups offer little in the way of relevant evidence, because improvement in symptoms is expected after ESS and because there are multiple clinical and treatment variables that may confound outcomes.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Steroid-Eluting Stents as an Adjunct to Endoscopic Sinus Surgery

Clinical Context and Therapy Purpose

The purpose of a steroid-eluting sinus stent in individuals who have chronic rhinosinusitis (CRS) who have endoscopic sinus surgery (ESS) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The population of interest is individuals who have ESS for CRS.

Interventions

The therapy being considered is a bioabsorbable steroid-eluting sinus stent (e.g., PROPEL Sinus Stent, PROPEL Mini Sinus Stent, PROPEL Countour Sinus Stent) for post-operative care following ESS.

Comparators
The most relevant comparison for sinus stents is unclear because there is no standardized optimal postoperative treatment regimen. Ideally, the "standard care" comparison group should include some form of packing, intranasal steroids, and irrigation. An important consideration in evaluating controlled trials is that the control arm may not be treated with optimal intensity, thereby leading to a bias in favor of the device. For example, a study design that compares a steroid-eluting stent with a non-steroid-eluting stent will primarily evaluate the efficacy of steroids when delivered by the device but will not evaluate the efficacy of a stent itself. If the control group does not receive topical or oral steroids postoperatively, then this might constitute undertreatment in the control group and result in a bias favoring the treatment group. Another concern is comparison of the efficacy of a drug with the efficacy of a drug delivery system. For example, if a steroid-eluting spacer is compared with a control of saline irrigation alone, it will be difficult to separate the efficacy of the drug itself (steroids) from the drug delivery system (stent).

Outcomes
The Perioperative Sinus Endoscopy score sums the combined scores determined from middle turbinate position, middle meatal status, ethmoid cavity appearance, as well as secondary sinus blockage (frontal and sphenoid). Each category is scored from 0-2, with 0 being not present, 1 as partially present, and 2 being fully present. The highest total score is 16, with scores ranging from 18-20 when the frontal and sphenoid sinuses are also included. The higher the score, the worse the status of the nasal cavity.

Post-ESS synechiae formation, the Sino-Nasal Outcome Test (SNOT-22) Questionnaire, and the Rhinosinusitis Disability Index may also be used to evaluate perioperative outcomes.

A beneficial outcome would be an improvement in symptoms.

A harmful outcome would be adverse events from the implantable stents.

The PROPEL series of sinus stents are bioabsorbable and elute steroids for 30 days. Therefore, outcomes should be assessed within 30 days.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies evaluating steroid-eluting sinus stents not approved for use in the US were excluded.

Review of Evidence
The literature consists of randomized trials, single-arm case series, and systematic reviews of these studies. The following is a summary of the key findings to date.

Systematic Reviews
A 2015 Cochrane review addressed steroid-eluting sinus stents for improving CRS symptoms in individuals undergoing ESS.[9,] Study eligibility criteria were RCTs that compared the effects of steroid-eluting sinus stents with non-steroid-eluting sinus stents, nasal packing, or no treatment in adults with CRS who underwent ESS. After an initial search, 21 RCTs were identified, including the RCTs reported by Murr et al (2011)[10,] and Marple et al. (2012)[11,] (described below). None of the trials met

authors' inclusion criteria. Reviewers concluded that there was no evidence from high-quality RCTs to demonstrate the benefits of steroid-eluting stents.

Zamali et al. (2024) evaluated the efficacy of steroid-eluting sinus stents on postoperative outcomes in CRS patients undergoing ESS.[12,] Seven RCTs (N=1122) were included; 6 of these trials used the contralateral sinus as the control group, while one was sham-controlled. Results suggested that steroid-eluting stents significantly reduced adhesion formation (odds ratio [OR]: 0.28; 95% Confidence Interval [CI]: 0.14 to 0.56), mucosal inflammation (mean difference [MD]: -13.09; 95% CI: -18.22 to -7.97), polyp reformation (OR: 0.31; 95% CI: 0.22 to 0.44), and the need for additional oral steroids (OR: 0.44; 95% CI: 0.25 to 0.78) or surgery (OR: 0.25; 95% CI: 0.12 to 0.50) relative to control group at 30 days post-surgery. Heterogeneity across all outcomes was 0%, and the authors determined there to be a moderate quality of evidence according to GRADE criteria. Improvements persisted for up to 90 days for some outcomes.

Randomized Controlled Trials

RCTs are shown in Tables 1 and 2. There are 4 RCTs of the PROPEL, PROPELMini, and PROPEL Contour steroid-eluting sinus stents, all sponsored by the device manufacturer (Intersect ENT). These trials used an intrapatient control design, with each patient receiving a drug-eluting stent on 1 side and a non-drug-eluting stent or medical treatment on the other via random assignment.

The 2 trials of PROPEL for the ethmoid sinus had similar designs.[10,11,] Both compared an implant that is steroid-eluting with an identical non-steroid-eluting implant. Thus these trials tested the value of drug delivery via a stent but did not test the value of a stent itself versus treatment without a stent. The primary efficacy outcome in Murr et al. (2011) was degree of inflammation rated by the treating physician.[10,] In Marple et al (2012) the primary outcome was reduction in the need for postoperative interventions at day 30 postprocedure.[11,] A panel of 3 independent experts, blinded to treatment assignment and clinical information, viewed the endoscopic results and determined whether an intervention was indicated. The need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm and in 46.9% in the non-steroid-eluting arm (p=.028). The reduction in interventions was primarily driven by a 52% reduction in lysis of adhesions (p=.005). The primary safety hypothesis was met because there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period postprocedure.

The RCTs by Smith et al. (2016) and Luong et al. (2017), implanted either a PROPEL Mini Sinus Implant or a PROPEL Contour Sinus Implant in the frontal sinus with a control of surgery alone on the contralateral side.[13,14,] The primary outcome was the need for post-operative intervention (e.g., surgery or steroids) determined by an independent blinded physician. Both trials showed a reduction in the need for additional surgical intervention by approximately 22%, with no adverse effects of treatment. The number needed to treat was 4.7 to prevent 1 patient from undergoing postoperative intervention.[14,] No stent-related adverse events were noted.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Participants	Interventions	
				Active	Comparator
Murr et al. (2011).[10,]	US	4	38 patients with refractory CRS	Unilateral PROPEL steroid-eluting stent in the ethmoid sinus	Non-drug-eluting stent on the other contralateral side
Marple et al. (2012)[11,] (ADVANCE II)	US	11	105 patients with refractory CRS	Unilateral PROPEL steroid-eluting stent in the ethmoid sinus	Non-drug-eluting stent on the contralateral side

Study; Trial	Countries	Sites	Participants	Interventions	
Smith et al. (2016)[13,]	US	11	80 patients with CRS who were scheduled to undergo primary or revision bilateral frontal sinusotomy	Unilateral PROPEL Mini Sinus Implant in the frontal sinus	Surgery alone on the contralateral side
Luong et al (2017)[14,]	US	12	80 patients with CRS who were scheduled to undergo primary or revision bilateral frontal sinusotomy	Unilateral PROPEL Contour Sinus Implant in the frontal sinus	Surgery alone on the contralateral side

ADVANCE II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants; CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

Table 2. Summary of Key RCT Results

Study	Primary Outcome Measure	Polypoid Changes	Adhesions/Scarring		Implant-Related Adverse Events
Murr et al. (2011).[10,]	*Degree of Inflammation at 21 Days Post-Procedure (100 mm VAS)*				
N	37	37			
PROPEL steroid-eluting Stent		18.4%	5.3%		
Non-steroid-eluting stent		36.8%	21.1%		
Diff	18 points				
p-value	NR	.039	.03		
Marple et al. (2012)[11,]	*Need for Post-Operative Intervention Determined by 3 Independent Reviewers*				
N	91				
PROPEL steroid-eluting Stent	33.3%				
Non-steroid-eluting stent	46.9%				
Diff	13.6%				
p-value	0.028				
Smith et al. (2016)[13,]	*Need for Post-Operative Intervention at 30 Days (Independent Reviewer) n (%)*	*Need for Post-Operative Intervention at 90 Days*		*Occlusion/ Restenosis Rate at Day 30*	
N	67 (adequate video for independent review)	79			
PROPEL mini-sinus steroid-eluting stent	26 (38.8%)			16 (21.1%)	none
SOC without a stent	42 (62.7%)			35 (46.1%)	
p-value	.007	.013	.023	<.001	
Luong et al. (2017)[14,]	*Need for Post-Operative Intervention at 30*	*Need for Surgical Intervention at 30 Days*		*Occlusion/ Restenosis Rate at Day 90*	

Study	Primary Outcome Measure	Polypoid Changes	Adhesions/Scarring	Implant-Related Adverse Events
	Days (Independent Reviewer) n (%)	*(Independent Reviewer) n (%)*		
N	61	58	69	
PROPEL Contour steroid-eluting stent	7 (11.5)	4 (6.9)	16 (23.2)	
SOC without a stent	20 (32.8)	15 (25.9)	28 (40.6)	
Diff (95% CI)	21.3% (35.1% to 7.6%)	19.0% (32.8% to 5.1%)	−17.4% (−28.6% to −6.1%)	
NNT	4.7			
Summary Values	Range 13.6% to 23.9%			

CI: confidence interval; Diff: difference; NNT: number needed to treat; NR: not reported; RCT: randomized controlled trial; SOC: standard of care; VAS: visual analog scale.

Limitations in relevance and in design and conduct are shown in Tables 3 and 4. The primary limitations for the studies by Murr et al. (2011) and Marple et al. (2012) on the PROPEL implant in the ethmoid sinus was whether the comparator had received the optimal treatment in terms of packing, intranasal steroids, and irrigation. For the studies by Smith et al. (2016) and Luong et al. (2017), there was a high percentage of patients who were not able to be evaluated due to video quality.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Murr et al. (2011).[10,]			3. The comparator may not have received the optimal treatment (some form of packing, intranasal steroids, and irrigation)		
Marple et al. (2012)[11,]			3. The comparator may not have received the optimal treatment (some form of packing, intranasal steroids, and irrigation)		
Smith et al. (2016)[13,]					
Luong et al. (2017)[14,]					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Murr et al. (2011).[10,]		3. Outcome assessed by				

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
		treating physician				
Marple et al. (2012)[11,]						
Smith et al. (2016)[13,]			2. Incomplete reporting of secondary outcomes	1. 12 (17%) patients did not have independent review at 30 days due to suboptimal video quality.		
Luong et al. (2017)[14,]				1. 19 (24%) patients did not have independent review at 30 days due to suboptimal video quality.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p-values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Comparative Studies

The largest nonrandomized study identified was reported by Xu et al. (2016).[15,] It evaluated post-ESS synechiae formation among 146 patients (252 nasal cavities) treated with a steroid-eluting absorbable spacer and 128 patients (233 nasal cavities) treated with a nonabsorbable spacer. Eligible patients included those who underwent ESS (at minimum, maxillary antrostomy, and anterior ethmoidectomy) for CRS with or without nasal polyps and were treated with a sinus spacer. Rates of synechiae formation at 1 month postoperatively did not differ significantly between groups (5 [2.0%] nasal cavities in the absorbable stent group vs. 13 [5.6%] nasal cavities in the nonabsorbable spacer group).

Section Summary: Steroid-Eluting Stents as an Adjunct to Endoscopic Sinus Surgery

The most direct evidence relating to use of steroid-eluting nasal stents as an adjunct to ESS comes from 4 RCTs comparing steroid-eluting stents with either a non-steroid-eluting stent or medical management. The need for post-operative intervention at 30 days was reduced by 14% to 24%, translating to a number needed to treat of 4.7 or more. Three trials used blinded assessors to evaluate postimplantation sinus changes, an important strength, but the trials had potentials for bias. The findings from systematic reviews and meta-analyses are mixed. A Cochrane review reported insufficient high-quality evidence to assess the intervention, while a meta-analysis identified benefits of steroid-eluting stents compared to a control intervention, including reduced adhesion, mucosal inflammation, polyp recurrence, need for oral steroids post-surgery, and additional surgical procedures at 30 days follow-up. To most accurately evaluate the benefit from PROPEL devices it is important to ensure that the comparison group is not undertreated (i.e., receives some form of packing, intranasal steroids, and irrigation).

Steroid-Eluting Implants for Recurrent Polyposis

Clinical Context and Therapy Purpose

The purpose of steroid-eluting implants in individuals who have recurrent polyposis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with recurrent polyposis after ESS.

Interventions

The therapy being considered is a steroid-eluting sinus implant (e.g., SINUVA).

This implant is bioresorbable and softens over time, but needs to be removed by 90 days.

Comparators

A sham treatment may be used to determine whether active treatment reduces the need for ESS.

Outcomes

The general outcomes of interest are symptoms, anatomic outcomes, and need for additional ESS. These outcomes may be measured by the nasal obstruction/congestion score change (scale 0–3), polyp grade change (scale 0 to 8), ethmoid sinus obstruction change (scale 0–100), and the percentage of patients still indicated for repeat sinus surgery.

A beneficial outcome would be an improvement in symptoms and reduction in repeat ESS.

A harmful outcome would be adverse events from the implant.

The steroid-eluting implants are kept in place for up to 90 days. Relevant outcomes would be measured at 90 days to evaluate the short-term effects of the treatment and at 1 or 2 years to evaluate the durability of this treatment.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies evaluating steroid-eluting sinus stents not approved for use in the US were excluded.

Review of Evidence

Two sham-controlled RCTs, RESOLVE (A Randomized, Controlled, Blinded Study of Bioabsorbable Steroid-eluting Sinus Implants for In-office Treatment of Recurrent Sinonasal Polyposis) and RESOLVE II (A Phase 3 Trial of Mometasone Furoate Sinus Implants for Chronic Sinusitis with Recurrent Nasal Polyps) with a total of 400 patients have addressed outcomes after placement of steroid-eluting absorbable sinus stents in the office setting due to recurrent or persistent nasal polyposis after ESS (see Tables 5 and 6).[16,17,18,]

In RESOLVE, for endoscopically measured outcomes, at 90 days of follow-up, the treatment group had a greater reduction in polyp grade than the control group (-1.0 vs. -0.1; p=.016) and a greater

reduction in percent ethmoid obstruction on a 100-mm VAS (-21.5 mm vs. 1.3 mm; p=.001), both respectively. For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion scores between groups. Six-month outcomes from RESOLVE were reported by Forwith et al in 2016. Differences in polyp grade and ethmoid obstruction scores remained significantly improved in the intervention group at 6 months, but the difference between groups in patient-reported symptom scores was not statistically significant at 6 months (See Table 6).[18,] In RESOLVE II the implant group showed significant reductions in nasal congestion, polyp grade, and ethmoid obstruction at 90 days compared to sham controls. Out of 200 patients treated with the implant, 39% were indicated for sinus surgery at 3 months compared to 63.3% of controls (p<.001).

Table 5. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Han et al. (2014); Forwith et al (2016)[16,;18,]; RESOLVE	US	18	2013-2014	100 patients with recurrent nasal polyposis after ESS who had chronic rhinosinusitis, had undergone prior bilateral total ethmoidectomy more than 3 months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient.	53 patients who received office-based placement of a mometasone-eluting nasal stent	47 patients who received sham treatment
Kern et al. (2018)[17,]; RESOLVE II	US	34	2014-2016	300 adults with refractory chronic rhinosinusitis with nasal polyps who were candidates for repeat surgery. To be indicated for repeat ESS, a patient had to: (1) be using intranasal corticosteroid daily ; (2) receive at least 1 course of high-dose steroid therapy or refused such therapy due to side effects within the past 1 year; (3) continue to have moderate-to-severe symptoms of nasal obstruction/congestion; and (4) have endoscopic evidence of bilateral ethmoid sinus obstruction due to polyposis.	201 patients who received a SINUVA(TM) mometasone-eluting bioabsorbable nasal stent	99 patients who received sham treatment consisting of insertion and removal of implants

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps; ESS: endoscopic sinus surgery; RCT: randomized controlled trial.

Table 6. Summary of Key RCT Results

Study	Nasal obstruction/congestion score change (scale 0–3) at 90 days	Nasal obstruction/congestion score change (scale 0–3) at 6 months	Change in Polyp Grade at 90 Days (scale 0 to 8)	Change in Polyp Grade at 6 Months (scale 0 to 8)	Reduction in Ethmoid Obstruction (scale 100) at 90 Days	Reduction in Ethmoid Obstruction (scale 100) at 6 months	Patients Indicated for Sinus Surgery at 3 months n (%)
Han et al. (2014); Forwith et al (2016)[16,;18,]; RESOLVE							
Drug-eluting		-1.06	-1.0	-.071	-21.5 mm	−17.1 mm	47%

Study	Nasal obstruction/congestion score change (scale 0–3) at 90 days	Nasal obstruction/congestion score change (scale 0–3) at 6 months	Change in Polyp Grade at 90 Days (scale 0 to 8)	Change in Polyp Grade at 6 Months (scale 0 to 8)	Reduction in Ethmoid Obstruction (scale 100) at 90 Days	Reduction in Ethmoid Obstruction (scale 100) at 6 months	Patients Indicated for Sinus Surgery at 3 months n (%)
nasal implant							
Sham		-0.44	-0.1	0.02	1.3 mm	−5.6 mm	77%
P-value		.124	.016	.018	.001	.010	NR
Kern et al. (2018)[17]; RESOLVE II							
Drug-eluting nasal implant mean (SD)	−0.80 (0.73)		−0.56 (1.06)		−11.3 (18.1)		78/200 (39.0%)
Sham mean (SD)	−0.56 (0.62)		−0.15 (0.91)		−1.9 (14.4)		62/98 (63.3%)
Diff or OR (95% CI)	−0.23 (−0.39 to −0.06)		−0.35 (−0.60 to −0.09)		−7.96 (−12.10 to −3.83)		2.69 (1.63 to 4.44)
P-value	.007		.007		<.001		<.001

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps; CI: confidence interval; Diff: difference; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; SD: standard deviation.

Limitations in relevance, design, and conduct are shown in Tables 7 and 8. A major limitation of RESOLVE II was the short duration of follow-up to determine the durability of the treatment. In addition, there is a potential for bias since outcomes were evaluated by the treating physician.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Han et al. (2014); Forwith et al (2016)[16,18]; RESOLVE					1. The 6-month follow-up is insufficient to evaluate the durability of this treatment.
Kern et al. (2018)[17]; RESOLVE II					1. The 90-day follow-up is insufficient to evaluate the durability of this treatment.

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Han et al. (2014); Forwith et al (2016)[16,18]; RESOLVE		3. Outcomes were assessed by the treating physician				3. Statistics were not reported for some outcome measures.
Kern et al (2018)[17]; RESOLVE II		3. Polyp grade and sinus obstruction were assessed by the treating physician				

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Steroid-Eluting Stents for Recurrent Polyposis

Two RCTs evaluated the use of steroid-eluting nasal implants for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of the trials included use of sham control and adequate power for the primary outcome. However, the trials had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be relevant outcomes for this indication, it would be more important if decisions about repeat ESS or other treatments were standardized and, in the trial setting, if decisions were prespecified or made by a clinician blinded to treatment group.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology-Head and Neck Surgery

In 2023, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) issued a position statement on the use of drug-eluting sinus implants for the management of mucosal inflammation of the paranasal sinuses. This statement was not based on a systematic review of the evidence.

"The AAO-HNS considers drug-eluting implants in the paranasal sinuses as a proven and effective therapeutic option for mucosal inflammation."[19,]

The recommendation states, "Multiple studies have demonstrated the efficacy and safety of drug-eluting implants in controlling sinonasal inflammation. Clinical evidence regarding the use of drug-eluting implants after sinus surgery has particularly shown enhanced wound healing through the reduction of both scar formation and anatomic obstruction."

American Rhinologic Society

In 2023, the American Rhinololgic Society (ARS) issued a position statement on the utilization of drug-eluting implants into the sinus cavities. This position statement was not based on a systematic review of the evidence.:
"ARS feels strongly that drug-eluting implants should in no way be considered investigational and should be available to patients, when selected by the physician, in order to maximize outcomes." [20,]
The recommendation notes, "There continues to be a growing level of high-quality evidence on the safety and efficacy of drug-eluting implants in the paranasal sinuses. These studies have demonstrated cost effectiveness as well as improvement of patient centered outcomes by reducing inflammation, maintaining ostial patency, decreasing scarring, and preventing middle turbinate lateralization while limiting the need for administration of oral steroids.."

International Consensus Statement on Allergy and Rhinology

In 2021, the International Consensus Statement on Allergy and Rhinology was updated and included the following recommendation:
"Corticosteroid-eluting implants can be considered as an option in a previously operated ethmoid cavity with recurrent nasal polyposis."[21,]

The recommendation noted, "Corticosteroid eluting implants have been shown to have beneficial impact on ethmoid polyposis and obstruction, and 1 study has shown them to be cost-effective in preventing revision ESS. Experience is early and although evidence is high level, only short-term outcomes are currently available."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03607175	Randomized Clinical Control Trial Comparing the Effects of a Steroid Eluting Implant Versus Triamcinolone-impregnated Carboxymethylcellulose Foam on the Postoperative Clinic Experience in Patients That Underwent Functional Endoscopic Surgery for Nasal Polyposis	30	Dec 2025
NCT05925985[a]	Propel Drug-Eluting Sinus Stent Family	200	Sep 2025
NCT06671561[a]	Product Surveillance Registry (PSR) Ear, Nose and Throat- PROPEL Drug-Eluting Sinus Stent Family EXTEND Cohort	100	Apr 2027
NCT06198894	Study on the Efficacy of in Office Steroid-eluting Sinus Stent Implantation in Chronic Rhinosinusitis Patients With Uncontrolled Postoperative Symptoms	96	Apr 2026

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
	31299	Unlisted procedure, accessory sinuses
HCPCS	C1874	Stent, coated/covered, with delivery system
	C2625	Stent, noncoronary, temporary, with delivery system
	J3490	Unclassified drugs

Type	Code	Description
	J7402	Mometasone furoate sinus implant, (Sinuva), 10 mcg
	S1091	Stent, noncoronary, temporary, with delivery system (Propel)

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/28/2013	BCBSA Medical Policy adoption
06/30/2015	Coding update
02/01/2016	Coding update
04/01/2016	Policy title change from Implantable Sinus Spacers and Stents for Postoperative Use Following Endoscopic Sinus Surgery Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
01/01/2019	Coding update
04/01/2019	Policy title change from Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease Policy revision without position change
11/01/2019	Coding update
04/01/2020	Annual review. No change to policy statement. Literature review updated.
04/01/2021	Annual review. Policy statement and literature review updated. Policy title changed from Steroid-Eluting Sinus Stents to current one.
05/01/2021	Coding update
05/01/2022	Annual review. No change to policy statement. Policy guidelines and literature updated.
04/01/2023	Annual review. No change to policy statement. Literature review updated.
04/01/2024	Annual review. No change to policy statement. Literature review updated.
04/01/2025	Annual review. No change to policy statement. Policy guidelines and literature updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Steroid-Eluting Sinus Stents and Implants 7.01.134 **Policy Statement:** I. The use of steroid-eluting sinus stents and implants for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **investigational**. II. The use of steroid-eluting sinus stents and implants is considered **investigational** in all other conditions.	**Steroid-Eluting Sinus Stents and Implants 7.01.134** **Policy Statement:** I. The use of steroid-eluting sinus stents and implants for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **investigational**. II. The use of steroid-eluting sinus stents and implants is considered **investigational** in all other conditions.