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MEDICAL POLICY – 7.01.134

Steroid-Eluting Sinus Stents and Implants

BCBSA Ref. Policy:	7.01.134
Effective Date:	May 1, 2025
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Replaces:	N/A

RELATED MEDICAL POLICIES:

- 7.01.559 Sinus Surgery
- 7.01.168 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis
- 7.01.558 Rhinoplasty

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Endoscopic sinus surgery (ESS) is a surgery where a thin tube is inserted through the nose to find and remove blockages in the nose and sinuses. After ESS, common treatments used to reduce swelling and prevent further blockages include: salt solution rinses, nasal packs, nasal sprays or oral drugs that reduce swelling and infection, and sinus suctioning. Another treatment option is the use of sinus stents that are implanted during ESS. These devices contain steroids or other drugs that are released directly into the tissues of the nasal passages or sinuses to help them heal and stay open over an extended period of time. The use of sinus stents containing steroids or other drugs for ESS is unproven (investigational). More studies are needed to see if this treatment is as good or better than proven methods.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Steroid-eluting sinus stents and implants	**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.** ***Note:** 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.
Steroid-eluting sinus stents and implants	**The use of steroid-eluting sinus stents and implants is considered investigational in all other conditions.**

Coding

Code	Description
CPT	
31299	Unlisted procedure, accessory sinuses
HCPCS	
C2625	Stent, noncoronary, temporary, with delivery system
J3490	Unclassified drugs
J7402	Mometasone furoate sinus implant, (Sinuva), 10 mcg
S1091	Stent, non-coronary, temporary, with delivery system (Propel)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

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.

Evidence Review

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.

Background

Chronic Rhinosinusitis

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

Treatment

ESS is typically performed on individuals with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with high rates of improvement in up to 90% of more appropriately selected individuals. 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 they 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.

Summary of Evidence

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes RCTs and two systematic reviews. The 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. The 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. 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.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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 one 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."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Intraoperative Steroid-Eluting Sinus Stents

In 2011, the PROPEL system (Intersect ENT, Menlo Park, CA) was approved by the US 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 individuals older than age 18 years following ethmoid sinus surgery maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval (PMA) supplement. The PROPEL Contour Sinus Implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

Postoperative Steroid-Eluting Sinus Stents

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 individuals who have had ethmoid sinus surgery.

FDA product code: OWO

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History

Date	Comments
09/01/19	New policy, approved August 13, 2019, effective December 5, 2019. Add to Surgery section. This policy was previously archived but is now being reinstated. Policy created with literature review through December 2018. The use of steroid-eluting or drug-eluting sinus stents is considered investigational.
05/01/20	Annual Review, approved April 7, 2020. Policy updated with literature review through December 2019; no referenced added. Policy statements unchanged.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through December 16, 2020; references added. Terminology in indication 2 changed from "stent" to "implant" and policy title changed to reflect this distinction. Minor edit made to policy statement to increase consistency with policy title; intent of statements unchanged. Added HCPCS codes J7402 and S1091.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through January 3, 2022; no references added. Policy statements unchanged. Removed HCPCS code J7401.
05/04/22	Minor update, added related policy 7.01.168 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis.
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through January 6, 2023; reference added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Date	Comments
07/01/23	Coding update. Added HCPCS code C2625 for Propel stent.
05/01/24	Annual Review, approved April 8, 2024. Policy updated with literature review through January 5, 2024; references added. Policy statements unchanged except for minor edits for clarity only.
05/01/25	Annual Review, approved April 7, 2025. Policy updated with literature review through December 16, 2024; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.