MASSACHUSETTS

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Medical Policy

Steroid-Eluting Sinus Stents

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Policy Number: 800

BCBSA Reference Number: 7.01.134 (For Plan internal use only)
LCD/NCD: N/A

Related Policies

Balloon Sinuplasty for Treatment of Chronic Sinusitis, #582

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

The use of mometasone furoate sinus implant (Sinuva), as an alternative to revision functional endoscopic sinus surgery may be considered **MEDICALLY NECESSARY** when the following criteria are met:

- Individual is 18 and older, **AND**
- Documented recurrence of nasal polyposis, **AND**
- Optimal medical therapy has been attempted and failed, as indicated by the following:
  - Allergy evaluation, education, and optimal treatment,
  - Maximal use of decongestants,
  - Topical and/or systemic corticosteroids for at least 8 weeks,
  - Saline nasal irrigation for at least 8 consecutive weeks, **AND**
  - Education on environment irritants including tobacco smoke.

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

The use of drug-eluting sinus stents is considered **INVESTIGATIONAL** in all other conditions.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following HCPCS codes are considered medically necessary for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified

The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
S1091	Stent, non-coronary, temporary, with delivery system (propel)

Description

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.

Summary
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.

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. 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 (ie, 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 including measurable reduction of nasal polyps, reduced nasal obstruction, and limiting the need for repeat sinus surgery. Sinuva is implanted in an office setting by a Physician and lasts approximately 90 days. In January of 2023, the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) published an updated position statement supporting the use of Sinuva in individuals who have undergone ESS. The evidence is sufficient to determine the technology results in an improvement in the net health outcome.

Policy History

Date	Action
9/2023	New medically necessary indications for Sinuva added. Summary and references updated. 9/1/2023. Clarified coding information.
4/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Clarified coding information. Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2020	Clarified coding information.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	Clarified coding information.
4/2019	Annual policy review. Ongoing Investigational statements clarified. Title changed to reflect the currently available steroid-eluting stents. Effective 4/1/2019.
1/2019	Clarified coding information.
3/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2016	Annual policy review. Investigational policy statement added for the use of sinus stents for recurrent sinonasal polyposis. Sinus Disease added to title. Effective 7/1/2016.
1/2016	Clarified coding information.
12/2014	Annual policy review. New references added.
1/2014	BCBSA National medical policy review. Removed “spacers” language throughout policy for consistency.
8/2013	Annual policy review. New references added.
2/04/2013	New policy describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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