BlueCross BlueShield Federal Employee Program.

FEP 7.01.134 Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

Effective Date: July 15, 2018

Related Policies:
7.01.105 Balloon Sinuplasty for Treatment of Chronic Sinusitis

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

Description

Sinus stents are devices used postoperatively following endoscopic sinus surgery (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.

FDA REGULATORY STATUS

In 2011, the PROPEL™ system (Intersect ENT, Palo Alto, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. 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 embedded in a polyethylene glycol polymer, which allows sustained release of the drug 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. FDA product code: OWO

In 2009, the Relieva Stratus™ MicroFlow spacer, and in 2011, the Relieva Stratus™ Pro MicroFlow Spacer, both balloon-based devices, were cleared for marketing by FDA through the 510(k) process for use as a postoperative spacer to maintain an opening in the frontal sinus for 14 days after surgery. The labeling for the second device included that safety and effectiveness of injecting solutions other than saline had not been established. The devices were to be placed via a catheter under endoscopic guidance and required manual removal after 30 days, In May 2013, the manufacturer discontinued all sales of the Stratus™ and the company agreed to withdraw all FDA marketing clearances for the device, which is no longer commercially available in the United States.[9]

POLICY STATEMENT

The use of implantable sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **not medically necessary**.

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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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes 2 RCTs, a number of observational studies, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from 2 RCTs comparing steroid-eluting sinus stents with non-steroid-eluting stents, both of which showed some benefit with steroid-eluting stents. However, these trials had some limitations, including risk of bias. In addition, because of the comparison groups used in both, these trials primarily evaluated the efficacy of topical steroids when delivered by an implanted device, and not the efficacy of the device vs standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have recurrent sinonasal polyposis who have undergone endoscopic sinus surgery who receive implantable steroid-eluting sinus stents, the evidence includes an RCT and a single-arm study. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from the available RCT, which compared steroid-eluting stents plus topical steroids with steroids alone for individuals with recurrent polyposis after ESS. This trial had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be a relevant outcome for this indication, it would be important for decisions about repeat ESS or other treatments to be standardized and prespecified or be made by a clinician blinded to treatment group. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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POLICY HISTORY

Date	Action	Description
March 2014	New Policy	
March 2015	Update Policy	Policy updated with literature review. References 10-12 and 16 added. Policy statement unchanged.
March 2017	Update Policy	Policy updated with literature review references 9, 13, and 16 added. “And for Recurrent Sinus Disease” added to title and not medically necessary policy statement was expanded to include the use of sinus stents for recurrent sinonasal polyposis.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; references 1 and 9 added. Policy statement unchanged.