MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Implantable sinus stents have been investigated for use following endoscopic sinus surgery (ESS) for the maintenance of sinus opening patency in the postoperative period. These devices may also serve as a local drug delivery vehicle. Implantable sinus stents are differentiated from routine sinus packing and packing devices in that the implantable devices are inserted under endoscopic guidance.

The Propel™ bioabsorbable, steroid-eluting sinus implant has been investigated for use following sinus surgery to reduce surgical edema and adhesions thereby reducing the need for post-operative interventions and the use of oral steroids. The Propel is designed to be inserted by a physician under endoscopic visualization and once inserted, the implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus. The Propel has received FDA premarket approval.

The Relieva Stratus™ Microflow spacer is a balloon-based device that acts as a spacer and medication delivery system. The device is for temporary use and manual removal is required. The Relieva Stratus Microflow spacer has received FDA 510K approval. This device is no longer marketed in the U.S.

IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY (cont.)

Criteria:

- Implantable sinus stents for postoperative treatment following endoscopic sinus surgery are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These implants include, *but are not limited to:*

  - Propel
  - Relieva Stratus Microflow spacer

Resources:

1. 7.01.134 BCBS Association Medical Policy Reference Manual. Implantable Sinus Spacers and Stents for Postoperative Use Following Endoscopic Sinus Surgery. Re-issue date 11/14/2013 issue date 07/12/2012.

2. Forwith KD, Chandra RK, Yun PT, Miller SK, Jampel HD. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope.* Nov 2011;121(11):2473-2480.

3. Han JK, Marple BF, Smith TL, et al. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinol.* May 1 2012.

4. Marple BF, Smith TL, Han JK, et al. Advance II: A Prospective, Randomized Study Assessing Safety and Efficacy of Bioabsorbable Steroid-Releasing Sinus Implants. *Otolaryngol Head Neck Surg.* Jun 2012;146(6):1004-1011.

5. Murr AH, Smith TL, Hwang PH, et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol.* Jan-Feb 2011;1(1):23-32.

IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY (cont.)

Resources: (cont.)

FDA Premarket Approval Database for Propel:

- FDA-approved indication: For use in patients ≥ 18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids. The Propel sinus implant separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces edema.

FDA 510K Summary for Relieva Stratus Pro MicroFlow Spacer (Frontal):

- FDA-approved indication: 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.