**FUNCTIONAL ENDOSCOPIC SINUS SURGERY (FESS)**

**Policy Number:** ENT 022.3 T2  
**Effective Date:** October 1, 2017

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**INSTRUCTIONS FOR USE**

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document (e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)) may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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**CONDITIONS OF COVERAGE**

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<thead>
<tr>
<th>Applicable Lines of Business/ Products</th>
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<tr>
<td>Authorization Required (Precertification always required for inpatient admission)</td>
<td>Yes&lt;sup&gt;1,2&lt;/sup&gt;</td>
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| Special Considerations                 | ¹Precertification with review by a Medical Director or their designee is required.  
                                          ²Precertification is required for services covered under the Member's General Benefits package when performed in the office of a participating provider. For Commercial plans, precertification is not required, but is encouraged |
Special Considerations (continued)

for out-of-network services performed in the office that are covered under the Member's General Benefits package. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Functional endoscopic sinus surgery (FESS) is medically necessary for one or more of the following:

- Patients with chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) with both of the following:
  - Chronic rhinosinusitis of the sinus to be operated on is confirmed on computed tomography (CT) scan by one or more of the following:
    - Mucosal thickening
    - Bony remodeling
    - Bony thickening or
    - Obstruction of the ostiomeatal complex
    - Opacified sinus
  - Symptoms persist despite medical therapy with one or more of the following:
    - Nasal lavage
    - Antibiotic therapy, if bacterial infection is suspected
    - Intranasal corticosteroids
- Mucocele documented on CT scan
- Concha bullosa documented on CT scan
- Complications of sinusitis such as abscess
- Tumor documented on CT scan (such as polyposis or malignancy)
- Recurrent acute rhinosinusitis (RARS)

Drug eluting stents or drug eluting implants are unproven and not medically necessary for maintaining sinus ostial patency after sinus surgery.

The evidence is insufficient to determine whether drug eluting sinus stents or drug eluting implants improve outcomes when used postoperatively following endoscopic sinus surgery. Further randomized clinical trials are needed that compare the devices to postoperative care without the device to determine whether they can improve postoperative outcomes for patients undergoing endoscopic sinus surgery.

DEFINITIONS

Acute Rhinosinusitis (ARS): ARS is a clinical condition characterized by inflammation of the mucosa of the nose and paranasal sinususes with associated sudden onset of symptoms of purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both of up to 4 weeks duration (American Academy of Otolaryngology-Head and Neck Surgery).

Chronic Rhinosinusitis (CRS): Chronic rhinosinusitis is one of the more prevalent chronic illnesses in the United States and is an inflammatory process that involves the paranasal sinuses and persists for longer than 12 weeks.

Functional Endoscopic Sinus Surgery (FESS): FESS is a minimally invasive, mucosal-sparing surgical technique utilized to treat medically refractory CRS with or without polyps or recurrent acute rhinosinusitis.
Recurrent Acute Rhinosinusitis (RARS): RARS has been defined as four episodes per year of acute rhinosinusitis with distinct symptom free intervals between episodes.

Sinus Stents: Sinus stents are devices that are used postoperatively following endoscopic sinus surgery (ESS). The intent of these devices is to maintain patency of the sinus openings in the postoperative period, and/or to serve as a local drug delivery vehicle.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

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<tr>
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DESCRIPTION OF SERVICES

Rhinosinusitis, also referred to as sinusitis, is inflammation of the mucosal membrane lining the nasal cavities and the paranasal sinuses. Rhinosinusitis lasting more than 12 weeks is classified as chronic rhinosinusitis (CRS). (Rosenfeld et al. 2015; Peters et al. 2014)

The goals of treating CRS are to eliminate underlying causes, reduce sinus inflammation, and drain nasal passages. Medical therapy is the first-line treatment for CRS. Treatments recommended may include nasal saline sprays, nasal lavage, antibiotic therapy, nasal corticosteroids, oral or injected corticosteroids, decongestants, over-the-counter pain relievers, leukotriene modifiers, and antihistamines. Patients who do not respond to medical therapy are candidates for sinus surgery. (Marple et al. 2011)

Functional endoscopic sinus surgery (FESS) is a set of minimally invasive surgical techniques which allow direct visual examination and opening of the sinuses for the treatment of chronic rhinosinusitis which has not responded to medical treatment.

FESS may be compromised by postoperative inflammation, polyposis and adhesions, which often require further intervention. Bioabsorbable, steroid-eluting sinus stents are inserted into the nose, sinuses or to prevent stenosis of the sinus openings. The slow release of corticosteroid aims to decrease mucosal edema and improve wound healing. (Huang et al. 2015) This technology is being evaluated as a treatment option following sinus surgery.

The PROPEL™ steroid-releasing implant (Intersect ENT) provides a controlled drug delivery directly to the sinus tissue. This device is a self-expanding, bioabsorbable, steroid-eluting stent that is intended for use in the ethmoid sinus. Steroids (mometasone furoate) are administered via a sustained release over an approximate duration of 30 days. (Kennedy 2012)
CLINICAL EVIDENCE

Functional Endoscopic Sinus Surgery (FESS)

Dalziel et al. (2006) performed a systematic review of safety and effectiveness of functional endoscopic sinus surgery (FESS) for the removal of nasal polyps. All randomized controlled trials, nonrandomized comparative studies, and case series studies that described outcomes associated with FESS for the excision of nasal polyps were included. Forty-two publications comprised of 3 randomized controlled trials, 4 nonrandomized comparative studies, and 35 case series studies were included in the review. FESS was compared with endoscopic polypectomy, Caldwell-Luc, radical nasalization, and intranasal ethmoidectomy. In general, studies were of poor quality and lacked description of important variables influencing surgical outcome. Overall complications for FESS from case series studies ranged from 0.3 to 22.4%. Major complications ranged from 0 to 1.5% and minor complications ranged from 1.1 to 20.8% (median, 7.5%). The potentially most serious complications were cerebrospinal fluid leaks, injury to the internal carotid artery, dural exposure, meningitis, bleeding requiring transfusion, periorbital/orbital fat exposure, and orbital penetration. Symptomatic improvement ranged from 78 to 88% for FESS compared with 43 to 84% for comparative procedures. From case series, symptomatic improvement ranged from 40 to 98% (median, 88%). The authors concluded that FESS may offer some advantages in safety and effectiveness over comparative techniques, but wide variation in reported results and methodological shortcomings of studies limit the certainty of these conclusions.

Higgins et al. (2011) conducted a systematic review with a pooled-data analysis to compare outcomes of endoscopic versus craniofacial resection of sinonasal malignancies. The review included 15 case series with individual data on 226 patients. The overall 5-year survival rate for the sample was 56.5%. Because of the paucity of data with endoscopic resection of high-stage malignancies, the outcome results were highly variable and no useful comparison could be made. Among low-stage malignancies (T1-2 or Kadish A-B), the endoscopic and open approaches demonstrated no statistically significant difference in outcome results. The 5-year overall survival was 87.4% in the endoscopic group versus 76.8% for open approaches; disease-specific survival was 94.7% versus 87.7%; and locoregional control rate was 89.5% versus 77.2%. The authors concluded that transnasal endoscopic resection appears to be a reasonable alternative to craniofacial resection in the management of low-stage sinonasal malignancies.

In a systematic review, Vlastarakos et al. (2013) evaluated the quality of evidence in the use of FESS for the treatment of chronic rhinosinusitis in children, regarding the respective changes in the quality-of-life (QoL) and the outcome that follows the operation. Fifteen studies were systematically analyzed. Four represented Level II, five Level III, and six Level IV evidence. The total number of treated patients was 1301. Thirteen research groups reported that pediatric FESS is an effective treatment for chronic rhinosinusitis; the respective positive outcome ranged between 71 and 100% of operated children. Five studies concluded that this treatment modality is associated with significant improvement in the children's postoperative QoL. Systemic diseases and environmental factors may have unfavorable prognostic effects; cystic fibrosis is associated with at least 50% recurrence rate. The rate of major complications following pediatric FESS is 0.6%, and the respective rate of minor complications 2%. The authors concluded that surgical management with FESS in children with chronic rhinosinusitis is effective when optimal medical treatment proves unsuccessful (grade B strength of recommendation), and is associated with improvement in the children's QoL (grade B strength of recommendation). FESS also improves the sinusitis-associated symptoms and QoL in children with cystic fibrosis (grade C strength of recommendation). According to the authors, most complications of pediatric FESS reported in the literature are minor, and associated with difficulties in the postoperative assessment and care of pediatric patients.

Regab et al. (2004) conducted a prospective, randomized, controlled trial evaluating and comparing the medical and surgical treatment of polyoid and nonpolyoid chronic rhinosinusitis (CRS). Ninety patients with CRS were equally randomized either to medical or surgical therapy. All patients underwent pre- and posttreatment assessments before starting the treatment, after 6 months, and after 1 year. Both the medical and surgical treatment of CRS significantly improved almost all the subjective and objective parameters of CRS, with no significant difference being found between the medical and surgical groups, except for the total nasal volume in CRS and CRS without polyposis groups, in which the surgical treatment demonstrated greater changes. The authors concluded that CRS should be initially targeted with maximal medical therapy (e.g., a 3 month course of a macrolide antibiotic, douche, and topical steroid), with surgical treatment being reserved for cases refractory to medical therapy. The authors indicated that the presence of nasal polyps is not a poor prognostic factor for the efficacy of CRS therapy, either surgical or medical.

Wood et al. (2017) performed a prospective study to prospectively assess treatment outcomes of chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery (FESS) and post-operative medical treatment over a prolonged follow-up period. The study included 200 non-consecutive patients in the tertiary referral practice of a single surgeon. Symptoms were scored by patients pre-operatively and over a minimum follow-up period of 12 months. The median pre-operative symptom score was 16 (out of a maximum of 25). Symptom scores reduced to a median of 7 after 12 months of follow up. The median symptom score improved for all symptoms and across all patient subgroups. The authors concluded that extensive functional endoscopic sinus surgery offers significant and
durable symptom improvement in patients with chronic rhinosinusitis refractory to medical treatment and prolonged medical therapy is recommended after FESS.

Venkatachalam and Jain (2002) conducted a comparative evaluation study that included 50 patients with signs and symptoms of chronic sinusitis who were refractory to medical treatment. The patients were divided at random into two groups of 25 patients each. Group A (study group) patients were treated with functional endoscopic sinus surgery (FESS) and group B (control group) patients were treated by conventional surgery. The age of the patients varied from 16 - 55 years (mean 29.1). Out of 25 patients in the study group, 19(76%) had complete relief of symptoms, 4(16%) had partial relief of symptoms and 2(8%) had no relief of symptoms in the follow-up period of 15-33 months (mean 19.2 months). Out of 25 patients in the control group, 15(60%) had complete relief of symptoms, 4(16%) had partial relief of symptoms and 6(24%) had no relief of symptoms in the follow-up period of 15-33 months (mean 19.2 months). The authors concluded that the results of this series showed that FESS had the combined advantages of precise, atraumatic removal of the disease with minimal morbidity and at the same time retaining the physiological function of the nose and paranasal sinuses.

A number of nonrandomized, uncontrolled studies reported that FESS may be safe and effective for treating sinusitis (Damm et al. 2002; Khalid et al. 2004; Toros et al. 2007), mucocele (Scangas et al. 2013), and tumors (Pagella et al. 2012) including polyposis. (Humayun et al. 2013; Djukic et al. 2015; Ehnhage et al. 2009)

**Professional Societies**

**American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)**

In a 2015 Clinical Practice Guideline (update) for Adult Sinusitis, the AAO-HNS indicates that clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of chronic rhinosinusitis (CRS). Surgical management of CRS is not discussed “because of insufficient evidence (e.g., randomized controlled trials) for evidence-based recommendations.” (Rosenfeld et al. 2015)

The AAO-HNS clinical indicators for endoscopic sinus surgery for adults state that the indications for endoscopic sinus surgery include a history of one of more of the following: (AAO-HNS, 2015)

- Chronic rhinosinusitis with or without nasal polyps with persistent symptoms and objective evidence of disease by endoscopic and/or CT imaging that is refractory to medical treatment
- Allergic fungal rhinosinusitis
- Unilateral paranasal sinus opacification, symptomatic or asymptomatic, consistent with chronic rhinosinusitis with or without nasal polyps, fungus ball, or benign neoplasm (i.e., inverted papilloma)
- Complications of sinusitis, including extension to adjacent structures such as orbit or skull base
- Sinonasal polyposis with nasal airway obstruction or suboptimal asthma control
- Mucocele
- Recurrent acute rhinosinusitis

**American Academy of Allergy Asthma and Immunology (AAAA), the American College of Allergy Asthma and Immunology (ACAAI), and the Joint Council of Allergy Asthma and Immunology (JCAAI)**

In a practice parameter for the diagnosis and management of rhinosinusitis, the AAAA, ACAAI, and JCAAI recommends that although medical therapy is the mainstay of disease management, FESS should be considered when medical therapy fails. According to the AAAA, ACAAI, and JCAAI, indications for surgical intervention include the following: (Peters et al. 2014)

- When nasal polyps obstruct sinus drainage and persist despite appropriate medical treatment
- When there is recurrent or persistent infectious rhinosinusitis despite adequate trials of medical management that at least includes topical nasal steroids and nasal irrigations;
- For biopsy of sinonasal tissue to rule out granulomatous disease, neoplasm, ciliary dyskinesia, or fungal infections
- When maxillary antral puncture is required (as for culture-directed therapy)
- When anatomic defects obstruct the sinus outflow tract, particularly the ostiomeatal complex (and adenoidal tissues in children)
- For rhinosinusitis with threatened complications (such as threat of brain abscess, meningitis, cavernous sinus thrombosis, or frontal bone osteomyelitis)

Regarding medical management for chronic rhinosinusitis, the AAAA, ACAAI, and JCAAI indicate that the role of antibiotics in chronic rhinosinusitis CRS is controversial. For CRS associated with suspected bacterial infection, a longer duration of therapy beyond the usual 10 to 14 days is suggested; the choice of appropriate antibiotic therapy may need to consider the possible presence of anaerobic pathogens. Because CRS is an inflammatory disease, intranasal corticosteroids (INSs) are indicated for treatment. Other adjunctive therapy, such as intranasal antihistamines, decongestants, saline irrigation, mucolytics, and expectorants, might provide symptomatic benefit in select cases. (Peters et al. 2014)
**American College of Radiology (ACR)**

The ACR Appropriateness Criteria for Sinonasal Disease states:

- Most cases of uncomplicated acute and subacute rhinosinusitis are diagnosed clinically and should not require any imaging procedure.
- Computed tomography (CT) of the sinuses without contrast is the imaging method of choice in patients with recurrent acute sinusitis or chronic sinusitis, or to define sinus anatomy prior to surgery.
- Immunocompromised patients are at high risk for invasive fungal sinusitis.
- In patients with suspected sinonasal mass or suspected orbital and/or intracranial complication of sinusitis, MRI and CT are complementary studies. (ACR, 2013, reaffirmed 2017)

**Drug Eluting Stents or Drug Eluting Implants Following Endoscopic Sinus Surgery**

Zhao et al. (2013) performed a systematic review of nonabsorbable and absorbable steroid-eluting spacers following endoscopic sinus surgery. After excluding studies that did not meet the inclusion criteria and 30 duplicate studies, 22 randomized clinical trials were reviewed. Of these reviewed, 6 trials were included comparing nonabsorbable vs absorbable spacers and 5 trials were included comparing steroid impregnated vs plain spacers. A nonsignificant trend favoring absorbable stents was noted but the trend was not apparent if nonabsorbable stents are left in for greater than 48 hours after surgery. There was inconsistent reporting of adhesions; only two studies demonstrated less adhesion in the steroid spacer group. The authors concluded that steroidal spacers may reduce adhesions, but more consistent data reporting is required for meta-analysis. (Zhao 2013)

A March 2017 Hayes Prognosis Snapshop concluded that there is insufficient published evidence to draw firm conclusions on whether Propel implants substantially improve clinical outcomes of ESS compared with usual postoperative regimens. Published evidence supporting the use of the Propel Mini in frontal sinuses is limited to the pivotal PROGRESS trial and further study is needed to validate these findings. The best available evidence on use of the Propel Mini in ethmoid sinuses also precludes firm conclusions on clinical benefits relative to standard ESS postoperative protocols.

In a prospective, multi-center, randomized, blinded trial using an intra-patient control design, Smith et al. (2016) evaluated the safety and effectiveness of a steroid-releasing implant in improving surgical outcomes when placed in the frontal sinus opening (FSO) following endoscopic sinus surgery (ESS) in patients with chronic rhinosinusitis (CRS). Eighty adult CRS patients who underwent successful bilateral frontal sinusotomy were randomized to receive a steroid-releasing implant in one FSO and the contralateral control side received no implant. Implants were successfully placed in all 80 frontal sinuses. At 30-days post-ESS, the reviewer concluded that steroid-releasing implants provided a reduction in the need for postoperative interventions compared to surgery alone representing 38% relative reduction. This reduction in the need for postoperative interventions on the treatment sides persisted through 90 days. Clinical investigators also reported a 55.6% reduction in the need for oral steroid interventions, 75% reduction in the need for surgical interventions, 16.7% reduction in inflammation score, 54.3% reduction in restenosis rate, and 32.2% greater diameter of FSO on treated sides compared to control at 30 days. No implant-related adverse events were reported. The authors concluded that the study demonstrated that placement of steroid-releasing sinus implants in the frontal sinus opening significantly reduces the need for postoperative interventions in CRS patients undergoing frontal sinus surgery and optimizes wound healing by reducing the potential for inflammation and scarring. A potential for bias exists due to manufacturer sponsorship. The study is limited by a small sample size and short follow-up period.

Forwith et al. (2016) published the 6 month results of the RESOLVE study. At 6 months, it was reported that Propel treated patients experienced significant improvement in Nasal Obstruction Symptom Evaluation (NOSE) score and greater than 2-fold improvement in mean nasal obstruction/congestion score compared to controls. Endoscopically, treated patients experienced significant reduction in ethmoid sinus obstruction and bilateral polyg grade compared to controls. Panel review confirmed a significant reduction in ethmoid sinus obstruction and 2-fold improvement in bilateral polyg grade, which reached statistical significance, in a subset of 67 subjects with baseline polyg burden greater than or equal to 2 bilaterally. At 6 months, control patients were at 3.6 times higher risk of remaining indicated for ESS than treated patients. The authors concluded that the symptomatic and endoscopic improvements observed confirm the efficacy of the steroid-eluting implant for in-office treatment of chronic rhinosinusitis with nasal polyps after ESS. This study is limited by a small study population.

Huang Z et al. (2015) identified 21 trials that studied the effects of steroid-eluting sinus stents compared to non-steroid-eluting sinus stents, nasal packing or no treatment in adult patients with chronic rhinosinusitis (CRS) who underwent Functional Endoscopic Sinus Surgery (FESS). These trials had to be excluded because they met some but not all of the inclusion criteria. Therefore no trials could be included in the review. They were unable to provide evidence to establish whether steroid-eluting sinus stents have potential advantages and disadvantages for patients with CRS undergoing FESS. According to the authors, high-quality trials are needed to assess whether or not steroid-eluting sinus stents confer any beneficial effects, over those of surgery alone, when compared to non-steroid sinus stents.
A systematic review is to evaluate the efficacy and safety of bioabsorbable steroid eluting intranasal devices was performed by Rizan et al. (2015). Seven studies met the inclusion criteria, including five prospective randomized controlled trials and two prospective single-cohort studies. Patients were followed up for 2 to 6 months. Six studies demonstrated stent efficacy with statistical significance (P<0.05). Steroid-eluting bioabsorbable intranasal devices were effective in reducing adhesion formation, polyp formation, inflammation, Lund-Kennedy scores, and perioperative sinus endoscopy scores. The devices improved patient-reported outcomes and olfaction while reducing postoperative interventions. According to the authors, there is limited data available and further studies are required to determine whether they are safe and effective adjuncts post endoscopic sinus surgery. Future studies are needed to optimize the dosing regimen, compare devices, and provide long-term outcomes.

A meta-analysis of randomized controlled trials CONSENSUS II and ADVANCE II was conducted by Han et al. (2012). The following two randomized controlled trials were included in the meta-analysis:

- The (Marple et al. 2012) ADVANCE II trial was a prospective, multicenter, randomized, controlled, double-blind trial using an intra-patient control design (n=105) to compare the effect of drug-releasing to non-drug-releasing sinus stents. When comparing sinuses with a non-drug-releasing stent, the drug-releasing stent provided a 29.0% relative reduction in postoperative interventions and a 52% decrease in lysis of adhesions. The relative reduction in frank polyposis was 44.9%. Follow-up assessments occurred prior to release and at post-operative days 14, 30, 60 and 90. The need for postoperative oral steroids or surgery was lower in the drug-eluting group (33%) than in the control group (47%). No high intraocular pressure occurred in any patient. The rate of grade 2-3 frank polyposis was lower in the drug-eluting group (19%) than in the control group (34%). This study suggests that steroid-eluting implants are effective at improving surgical outcomes by reducing the need for postoperative interventions, with negligible ocular safety risk.

- The (Murr et al. 2011) CONSENSUS II randomized trial was a prospective, multicenter, randomized, double-blind clinical trial (n=43) conducted to assess safety and efficacy of steroid-eluting sinus stents. One group (n = 38) used an intra-patient control design comparing drug-eluting to non-drug-eluting stents. The other group (n = 5) received bilateral drug-eluting stents to assess systemic safety. Follow-up was performed for 60 days. Compared to the control stent, the drug-eluting stent provided a reduction in inflammation at days 21 to 45, frequency of polyp formation, and frequency of significant adhesion.

The authors of the meta-analysis concluded that the steroid-eluting stent is effective in improving wound healing by preserving sinus patency, reducing inflammation, and minimizing adhesions via controlled local steroid delivery.

A 2017 ECRI Health Technology Report noted the best-available evidence on this technology came from three randomized controlled trials with no comparative studies assessing the quality of life. No studies compared Propel with postoperative nondevice management or Propel Mini with postoperative device management. No studies compared adverse events for Propel or Propel Mini with adverse events for other methods of postoperative management. Studies do not report symptom improvement/ recurrence after 90-day follow-up, rate of postoperative surgical interventions after 30-day follow-up and rate of postoperative oral steroid interventions after 30-day follow-up. They recommend that studies reporting longer-term outcomes are needed to better understand the influence Propel and Propel Mini have on the need for postoperative interventions and whether these devices influence long-term maintenance of endoscopic sinus surgery benefits and patient quality of life.

Han and colleagues (2014) reviewed a randomized, controlled, blinded study (n=100) which evaluated the safety and efficacy of a bioabsorbable steroid-eluting implant with 1350 μg of mometasone furoate for its ability to dilate obstructed ethmoid sinuses, reduce polyposis, and reestablish sinus patency. Treated patients underwent in-office bilateral placement. Control patients underwent a sham procedure. At 3 months, treated patients experienced a significant reduction in bilateral polyp grade and ethmoid sinus obstruction compared to controls. Treated patients also experienced a 2-fold improvement in the nasal obstruction. This improvement reached statistical significance in patients with greater polyp burden (grade ≥2 bilaterally). At 3 months, 53% of treated patients compared to only 23% of controls were no longer recommended for repeat sinus surgery. The group concluded the study results demonstrated that the steroid-eluting implant represents a safe and effective alternative to current management for this patient population. Limitations noted by the authors included the following: the inability to control prior treatment variability, professionals performing the endoscopic grading were not blinded to the treatment assignment and a short duration of follow-up.

**Professional Societies**

**American Rhinologic Society (ARS)**

In a September 2016 position statement, the ARS endorses the utilization of drug-eluting implants into the sinus cavities. Results in sinus surgery are often dependent on proper healing of the sinus cavity and the reduction of inflammation. They state that the reduction of polyp burden and inflammation can result in a decrease in the use of oral medications as well as delaying the time until revision surgery.
American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

In a September 2015 Position Statement, the AAO has determined that the use of FDA-approved biomaterials can be utilized in sinonasal procedures to improve patient outcomes and reduce complications. These items, such as implants, stents, and packing materials, have functions including, but not limited to, local drug delivery, stenting, and hemostasis. FDA-approved biomaterials for rhinologic application are not investigational, and the final decision regarding use of these biomaterials should be determined by the treating physician, factoring in best available scientific evidence, surgeon experience and the clinical situation, and individual patient preference.

National Institute for Health and Care Excellence (NICE)

A 2016 NICE Intervenational procedure guidance indicates that the evidence on efficacy is limited; there is some evidence of improving sinus patency in the short term, but there is inadequate evidence on patient-reported outcomes and quality of life. NICE encourages further research on corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery and controlled studies where outcomes include symptom scores, quality of life and the need for retreatment in the long term.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Functional endoscopic sinus surgery (FESS) is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

The PROPEL™ system (Intersect ENT, Palo Alto, CA) was granted United States Food and Drug Administration (FDA) approval under the premarketing approval (PMA) program in August 2011. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100044a.pdf. (Accessed February 26, 2017)

In August 2012, FDA approved Intersect ENT’s PMA supplement for the Propel Mini. The Propel Mini is a smaller version of the device that may be used in patients with less extensive surgery or smaller anatomy. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100044s018a.pdf. (Accessed February 26, 2017)

In March 2016, the FDA expanded the approved indications for the Propel Mini to include treatment of patients undergoing frontal sinus surgery.

The Propel Contour sinus implant (formerly called the Nova implant), a second-generation, bioabsorbable steroid-releasing sinus implant was FDA approved in February 2017 for use in patients ≥ 18 years of age with chronic sinusitis to maintain patency of the frontal and maxillary sinus ostia following sinus surgery. See the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p100044s023. (Accessed March 8, 2017)

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T0578C]


### POLICY HISTORY/REVISION INFORMATION

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| 10/01/2017 | • Revised coverage rationale:  
|            |   o Updated coverage criteria for patients with chronic rhinosinusitis; replaced criterion requiring “chronic rhinosinusitis is confirmed on computed tomography (CT) scan” with “chronic rhinosinusitis of the sinus to be operated on is confirmed on computed tomography (CT) scan”  
|            |   o Added language to indicate functional endoscopic sinus surgery (FESS) is medically necessary for concha bullosa documented on CT scan  
|            |   Updated list of applicable CPT codes; removed 31239  
|            |   Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references  
|            |   Archived previous policy version ENT 022.2 T2 |