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Section 1
Disclaimer

The information in this guide is provided for the benefit of Intersect ENT customers and offers general coverage, coding and payment information for procedures associated with the use of PROPEL, PROPEL Mini and PROPEL Contour sinus implants, hereinafter generally referred to as PROPEL sinuses implants except where coding differentiation is required. The information provided is intended to facilitate appropriate coverage and reimbursement for providers in various sites of service.

This guide includes coding information for the PROPEL family of products (PROPEL, PROPEL Mini, and PROPEL Contour sinus implants) for informational purposes only. PROPEL and PROPEL Mini sinus implants are approved by the FDA for use in the ethmoid sinuses following sinus surgery. PROPEL Mini sinus implants are approved by the FDA for use in the frontal sinuses following sinus surgery. PROPEL Contour sinus implants are approved by the FDA for use in the frontal and maxillary sinuses following sinus surgery. Codes that apply to procedures performed in other sinuses or nasal anatomy are not applicable to PROPEL, PROPEL Mini and PROPEL Contour sinus implants. Such codes are presented for informational purposes only because sinus surgery procedures often involve concurrent procedures on other nasal and sinus anatomy.

Users of this guide should understand that this is general information, not legal guidance and is not advice about how to code, complete, or submit any particular claim for payment. Information provided is not intended to increase or maximize reimbursement by any payor. The information provided represents Intersect ENT’s understanding of current reimbursement policies. The suggested codes are to be used only to facilitate appropriate coding and should not be construed as recommended guidelines in the establishment of policy or practice. Any descriptions of services contained in this guide are for the purpose of illustrating typical clinical services and not intended to represent practice guidelines or standards of care.

Intersect ENT makes no representations or warranties with respect to the contents of this guide and disclaims any implied guarantee or warranty of fitness for any particular purpose. Intersect ENT will not be liable to any individual or entity for any losses or damages that may be incurred by the use of this guide. Furthermore, Intersect ENT specifically disclaims any liability or responsibility for the results or consequences of any actions taken in reliance on the statements, opinions, or suggestions in this guide.

It is always the provider’s responsibility to determine coverage and submit appropriate codes and charges for services rendered. Providers should check and verify current policies and requirements with the payor for any particular patient. It is important to verify coverage for each patient as policies and guidelines can vary by payor and plan.

The key in all coding and billing to payors is to be truthful and not misleading and make full disclosures to the payor about how the product has been used and the procedures necessary to implant the product when seeking reimbursement for any product or procedure.

Information in this guide was last reviewed on March 31, 2017.
Section 2

Technology Overview

The PROPEL sinus implant is a first of its kind product that provides controlled localized delivery of steroids directly to the sinus cavity. Currently, there is no other technology that provides localized steroid delivery, sustained over 30 days, to the sinuses while also providing mechanical support without obstructing the cavity. The PROPEL Mini sinus implant is a smaller version designed for smaller sinus anatomy and the frontal sinus recess. The PROPEL Contour sinus implant is an hourglass-shaped implant designed to conform to the sinus ostium (opening).

Safety and efficacy of the PROPEL mometasone furoate sinus implants have been studied in five rigorous prospective clinical trials conducted in the United States enrolling a total of 365 patients:

- The CONSENSUS II randomized, controlled double-blind pilot study
- The ADVANCE single cohort safety study
- The ADVANCE II randomized, controlled double-blind clinical trial
- The PROGRESS Study: Mini cohort randomized, controlled blinded clinical study
- The PROGRESS Study: Contour cohort randomized, controlled blinded clinical study

The PROPEL sinus implant clinical studies assessed the safety and efficacy of PROPEL sinus implants in chronic rhinosinusitis (CRS) patients post functional endoscopic sinus surgery (FESS). A meta-analysis of data from CONSENSUS II and ADVANCE II provides the first Level 1-A evidence demonstrating clinically and statistically significant benefits of localized steroid delivery in the post-FESS period, including:1

- 35% reduction in post-FESS medical/surgical therapies, including adhesion lysis and oral steroid therapy (p=0.0008)
- 40% reduction in need for oral steroids (p=0.0023)
- 46% reduction in frank polyposis (p<0.0001)
- 75% reduction in middle turbinate lateralization (p=0.0225)

---

The PROGRESS study: Mini cohort evaluated the use of PROPEL Mini sinus implants when placed in the frontal sinus opening following sinus surgery. This randomized controlled blinded study demonstrated statistically significant improvement in outcomes when added to standard postoperative care when compared to surgery with standard postoperative care alone. These outcomes include:²

- 38% reduction in need for post-operative medical or surgical intervention (p=0.0070)
- 54% reduction in frontal sinus restenosis/occlusion (p=0.0002)
- 56% reduction in the need for oral steroids (p=0.0015)
- 75% reduction in need post-operative surgical intervention (p=0.0225)

The PROGRESS study: Contour cohort evaluated the use of PROPEL Contour sinus implants when placed in the frontal sinus ostium following sinus surgery. This randomized controlled blinded study demonstrated statistically significant improvement in outcomes when added to standard postoperative care when compared to surgery with standard postoperative care alone. These outcomes include:³

- 65% reduction in need for post-operative medical or surgical intervention (p=0.0023)
- 63% reduction in frontal sinus restenosis/occlusion (p=<0.0001)
- 73% reduction in need post-operative surgical intervention (p=0.0156)

The safety of PROPEL sinus implants has been well-documented in these studies. There have been no clinically significant changes from baseline in intraocular pressure or lens opacities and no evidence of systemic steroid absorption or adrenal-pituitary axis suppression.

Reducing scarring and inflammation is essential to improve long-term outcomes and reduce the need for revision surgery.⁴,⁵ Therefore, the value of PROPEL sinus implants in reducing postoperative complications translates to long-term clinical value for patients and payors.

The PROPEL sinus implants are intended for use after sinus surgery to maintain patency and to locally deliver steroid to the sinus mucosa: PROPEL for use in the ethmoid sinus, PROPEL Mini for use in the ethmoid sinus and frontal sinus opening, and PROPEL Contour for use in the frontal and maxillary sinus ostia. The implants are intended for use in patients ≥18 years of age. Contraindications include patients with intolerance to mometasone furoate (MF) or a hypersensitivity to bioabsorbable polymers. Safety and effectiveness of the implants in pregnant or nursing females have not been studied. Risks may include, but are not limited to, pain/pressure, displacement of implant, possible side effects of intranasal MF, sinusitis, epistaxis, and infection. For complete prescribing information see IFU at www.IntersectENT.com. Rx only.

Caution: Federal law (USA) restricts this product to sale by or on the order of a physician.

³ Data on file. N=80 in ITT population, with N=61 evaluable patients where both sinuses available for composite endpoint. Primary endpoint results judged by independent reviewer. Secondary efficacy results were judged by Clinical Investigators (Implanting Physician) and adjusted for Holm’s step-down method to control for familywise type 1 error.
Section 3

Physician Coding & Payment

ICD-10-CM Diagnosis Codes

Below is a list of diagnosis codes which are relevant to common surgical procedures for chronic sinusitis. This list is not intended to be all inclusive, however these codes may be appropriate to support medical necessity for the procedures in which all PROPEL sinus implant products may be used. Most payors have completed their conversion from ICD-9-CM to ICD-10-CM, however a crosswalk is provided below.

### Diagnosis Codes for Chronic Sinusitis

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>Descriptor</th>
<th>ICD-10-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>473</td>
<td>Chronic sinusitis</td>
<td></td>
</tr>
<tr>
<td>473.0</td>
<td>Maxillary</td>
<td>J32.0</td>
</tr>
<tr>
<td>473.1</td>
<td>Frontal</td>
<td>J32.1</td>
</tr>
<tr>
<td>473.2</td>
<td>Ethmoidal</td>
<td>J32.2</td>
</tr>
<tr>
<td>473.3</td>
<td>Sphenoidal</td>
<td>J32.3</td>
</tr>
<tr>
<td>473.8</td>
<td>Other chronic sinusitis</td>
<td>J32.8</td>
</tr>
<tr>
<td></td>
<td>Chronic pansinusitis</td>
<td>J32.4</td>
</tr>
<tr>
<td>473.9</td>
<td>Chronic sinusitis, unspecified</td>
<td>J32.9</td>
</tr>
</tbody>
</table>

### Current Procedural Terminology Codes (CPT® Codes) 6

Physicians use Current Procedural Terminology (CPT®) codes to report services rendered. These codes are accepted by most payors. Most government and commercial payors use a fee schedule to pay physicians for their professional services, assigning a flat payment amount to each CPT code. Under Medicare’s Resource Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as the relative value units or RVUs, which is the sum of the physician work, practice expense and professional liability insurance multiplied by the geographic practice cost index (GPCI) for each of these elements.

Many other payors use Medicare’s RBRVS fee schedule or a variation of it. Use of CPT codes is governed by various coding guidelines published by the American Medical Association (AMA) and have input from other sources such as physician specialty societies. In addition, the National Correct Coding Initiative (NCCI), a set of CPT coding edits created and maintained by the Centers for Medicare and Medicaid Services (CMS), has become a national standard.

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6 CPT Copyright 2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.
**PROPEL and PROPEL Mini sinus implants are intended for use following ethmoid sinus surgery. The PROPEL Mini sinus implant is also intended for use following frontal sinus surgery. The PROPEL Contour sinus implant is intended for use following frontal and maxillary sinus surgery. Multiple CPT codes may apply to ethmoid, frontal, or maxillary sinus surgery procedures. When a PROPEL sinus implant is placed as an adjunct to a sinus surgery procedure, the work associated with placement of a drug-eluting sinus implant is already included in the work RVU calculation for these codes; therefore separate reporting of implant placement is not appropriate when performed with these procedures. The only procedure codes reported in these scenarios are the CPT codes relevant to the procedures performed (refer to the common list of sinus surgery procedure codes on the following page).**

In some scenarios, a PROPEL sinus implant may be placed as a standalone procedure following sinus surgery, during which no additional sinus surgery procedure is performed on that sinus. In such cases, code selection is determined by the sinus in which the implant(s) is/are placed. Specifically, for placement of an implant in the **ethmoid** sinus, these codes apply:

<table>
<thead>
<tr>
<th>CPT*</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, <strong>ethmoid</strong> sinus, placement of drug eluting implant</td>
</tr>
<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, <strong>ethmoid</strong> sinus, placement of drug eluting implant; with polypectomy, biopsy or debridement</td>
</tr>
</tbody>
</table>

(These codes cannot be reported in conjunction with the following procedures because the work of implant placement is already included in the RVU calculation: 31200, 31201, 31205, 31240, 31254, 31255, 31288, and 31290. These codes cannot be reported in conjunction with 31231 and 31237 because they are mutually exclusive.)

If a PROPEL Mini sinus implant is placed in the **frontal sinus opening** or a PROPEL Contour sinus implant is placed in the **frontal or maxillary sinus ostium**, and separate reporting of implant placement is appropriate, the following code may apply:

<table>
<thead>
<tr>
<th>CPT*</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
</tr>
</tbody>
</table>

Regardless of the CPT codes reported to describe services rendered, a HCPCS code for the PROPEL sinus implant(s) should always be reported in addition. See Section 4 for additional information.

On the following page is a list of common sinus surgery procedures which may occur in the same setting as endoscopic placement of a drug-eluting sinus implant. This is not a complete list of procedure codes in the code set.
## COMMON SINUS SURGERY PROCEDURE CODES

### 2017 MEDICARE PHYSICIAN FEE SCHEDULE RATES – NATIONAL MEDICARE AVERAGE

(Not a complete list)

<table>
<thead>
<tr>
<th>CPT®</th>
<th>DESCRIPTION</th>
<th>GLOBAL</th>
<th>FACILITY</th>
<th>NON-FACILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>30100</td>
<td>Biopsy, intranasal</td>
<td>0</td>
<td>$70</td>
<td>$143</td>
</tr>
<tr>
<td>30110</td>
<td>Excision, nasal polyp(s), simple</td>
<td>10</td>
<td>$133</td>
<td>$234</td>
</tr>
<tr>
<td>30115</td>
<td>Excision, nasal polyp(s), extensive</td>
<td>90</td>
<td>$439</td>
<td>n/a</td>
</tr>
<tr>
<td>30140</td>
<td>Submucous resection, inferior turbinate, partial or complete, any method</td>
<td>90</td>
<td>$447</td>
<td>n/a</td>
</tr>
<tr>
<td>30200</td>
<td>Injection into turbinate(s), therapeutic</td>
<td>0</td>
<td>$61</td>
<td>$114</td>
</tr>
<tr>
<td>30520</td>
<td>Septoplasty or submucous resection, with or without cartilage scoring,</td>
<td>90</td>
<td>$633</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>contouring or replacement with graft</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30560</td>
<td>Lysis of adhesions</td>
<td>10</td>
<td>$140</td>
<td>$272</td>
</tr>
<tr>
<td>30801</td>
<td>Ablation, soft tissue of inferior turbinate, unilateral or bilateral, any</td>
<td>10</td>
<td>$139</td>
<td>$232</td>
</tr>
<tr>
<td></td>
<td>method (e.g., electrocautery, radiofrequency ablation, or tissue reduction);</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>superficial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30802</td>
<td>Ablation, soft tissue of inferior turbinate, unilateral or bilateral, any</td>
<td>10</td>
<td>$193</td>
<td>$295</td>
</tr>
<tr>
<td></td>
<td>method (e.g., electrocautery, radiofrequency ablation, or tissue reduction);</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>intramural (i.e. submucosal)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31000</td>
<td>Lavage by cannulation; maxillary sinus (antrum puncture or natural</td>
<td>10</td>
<td>$108</td>
<td>$187</td>
</tr>
<tr>
<td></td>
<td>ostium)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31002</td>
<td>Lavage by cannulation; sphenoid sinus</td>
<td>10</td>
<td>$194</td>
<td>n/a</td>
</tr>
<tr>
<td>31090</td>
<td>Sinusotomy, unilateral, 3 or more paranasal sinuses (frontal, maxillary,</td>
<td>90</td>
<td>$1,042</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>ethmoid, sphenoid)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31200</td>
<td>Ethmoidectomy; intranasal, anterior</td>
<td>90</td>
<td>$583</td>
<td>n/a</td>
</tr>
<tr>
<td>31201</td>
<td>Ethmoidectomy; intranasal, total</td>
<td>90</td>
<td>$753</td>
<td>n/a</td>
</tr>
<tr>
<td>31205</td>
<td>Ethmoidectomy; extranasal, total</td>
<td>90</td>
<td>$917</td>
<td>n/a</td>
</tr>
<tr>
<td>31231</td>
<td>Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)</td>
<td>0</td>
<td>$67</td>
<td>$212</td>
</tr>
<tr>
<td>31237</td>
<td>Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement</td>
<td>0</td>
<td>$165</td>
<td>$263</td>
</tr>
<tr>
<td></td>
<td>(separate procedure)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31240</td>
<td>Nasal/sinus endoscopy, surgical; with concha bullosa resection</td>
<td>0</td>
<td>$165</td>
<td>n/a</td>
</tr>
<tr>
<td>31254</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)</td>
<td>0</td>
<td>$281</td>
<td>n/a</td>
</tr>
<tr>
<td>31255</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and</td>
<td>0</td>
<td>$411</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>posterior)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31256</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy</td>
<td>0</td>
<td>$203</td>
<td>n/a</td>
</tr>
<tr>
<td>31267</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal</td>
<td>0</td>
<td>$326</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>of tissue from maxillary sinus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31276</td>
<td>Nasal/sinus endoscopy, surgical with frontal sinus exploration; with or</td>
<td>0</td>
<td>$518</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>without removal of tissue from frontal sinus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31287</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy</td>
<td>0</td>
<td>$238</td>
<td>n/a</td>
</tr>
<tr>
<td>31288</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue</td>
<td>0</td>
<td>$276</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>from the sphenoid sinus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium</td>
<td>0</td>
<td>$168</td>
<td>$2,057</td>
</tr>
<tr>
<td></td>
<td>(e.g. balloon dilation), transnasal or via canine fossa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g.</td>
<td>0</td>
<td>$202</td>
<td>$2,098</td>
</tr>
<tr>
<td></td>
<td>balloon dilation)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium</td>
<td>0</td>
<td>$165</td>
<td>$2,060</td>
</tr>
<tr>
<td></td>
<td>(e.g. balloon dilation)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
<td></td>
<td></td>
<td>Payor-determined</td>
</tr>
<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant</td>
<td></td>
<td></td>
<td>Payor-determined</td>
</tr>
<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>with polypectomy, biopsy or debridement</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rates listed reflect policies adopted in the CY 2017 Medicare Physician Fee Schedule Final Rule as published on November 2, 2016, as revised by the Medicare Access and CHIP Reauthorization Act of 2015, which adjusted the Conversion Factor for 2017 to 35.8887. All rates shown are national averages and do not include adjustments for geographic cost variations costs or the 2% reduction in Medicare’s share of the payment due to sequestration under the Budget Control Act of 2011. The “n/a” indicator applies to procedures which are rarely or never performed in the non-facility setting. If performed and approved in that setting, the payment is the same as the facility rate listed.

**SEE DISCLAIMER ON PAGE 2**
Modifiers

When submitting a particular service on a claim, it is sometimes necessary to report a modifier with the CPT code. A modifier allows a provider to indicate that a service or procedure that has been performed has been altered by some specific circumstance but not changed in its definition or code. Modifiers also enable health care professionals to effectively respond to payment policy requirements established by other entities. Some modifiers apply to either physician or hospital outpatient claims; some may only be relevant for one or the other.

The following modifiers are the most applicable to sinus surgery procedures in which PROPEL implants may be used. This list is not all inclusive and is not intended to represent all applicable modifiers. Refer to the current CPT and/or Healthcare Common Procedure Coding System (HCPCS) manual for a complete list of modifiers, descriptors and instructions.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>-22</td>
<td>Increased procedural services</td>
</tr>
<tr>
<td>-50</td>
<td>Bilateral procedure*</td>
</tr>
<tr>
<td>-51</td>
<td>Multiple procedure</td>
</tr>
<tr>
<td>-52</td>
<td>Reduced services*</td>
</tr>
<tr>
<td>-53</td>
<td>Discontinued procedures</td>
</tr>
<tr>
<td>-58</td>
<td>Staged or related procedure or service by the same physician during the postoperative period*</td>
</tr>
<tr>
<td>-59</td>
<td>Distinct procedural service*</td>
</tr>
<tr>
<td>-73</td>
<td>Discontinued outpatient hospital/ambulatory surgery (ASC) procedure PRIOR TO the administration of anesthesia*</td>
</tr>
<tr>
<td>-74</td>
<td>Discontinued outpatient hospital/ambulatory surgery (ASC) procedure AFTER the administration of anesthesia*</td>
</tr>
<tr>
<td>-79</td>
<td>Unrelated procedure or service by the same physician during the postoperative period*</td>
</tr>
<tr>
<td>-99</td>
<td>Multiple modifiers</td>
</tr>
<tr>
<td>-LT</td>
<td>Left side</td>
</tr>
<tr>
<td>-RT</td>
<td>Right side</td>
</tr>
</tbody>
</table>

Note: Not all modifiers can be used in all settings of care. The * denotes modifiers approved for Hospital Outpatient use. Check CPT instructions.
Section 4

Physician Office Billing

PROPEL and PROPEL Mini sinus implants are intended for use following ethmoid sinus surgery. PROPEL Mini sinus implants are also intended for use following frontal sinus surgery. PROPEL Contour sinus implants are intended for use following frontal and maxillary sinus surgery.

When placement of a drug-eluting sinus implant occurs as an adjunct procedure following an ethmoid or frontal sinus surgery procedure performed in the non-facility (i.e. physician office) setting, providers should continue to report the codes deemed appropriate by the provider for the procedure(s) performed. The work associated with implant placement is included in the work of sinus surgery procedure codes. Therefore, when an implant is placed as an adjunct procedure, no additional codes should be reported to describe the work of implant placement. The implant itself (i.e. PROPEL, PROPEL Mini or PROPEL Contour sinus implants) should be reported separately with a HCPCS code as described below.

When placement of a drug-eluting sinus implant is a stand-alone procedure and no other procedure is performed on that sinus during the encounter, the work associated with implant placement should be reported. In addition, the implant itself (i.e. PROPEL, PROPEL Mini or PROPEL Contour sinus implants) should be reported with a HCPCS code as described below. Reporting of stand-alone placement of a drug-eluting sinus implant is as follows:

For the ethmoid sinus:

<table>
<thead>
<tr>
<th>CPT®</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant</td>
</tr>
<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with polypectomy, biopsy or debridement</td>
</tr>
</tbody>
</table>

If this procedure is performed bilaterally, these CPT codes should be appended with modifier -50.

For the frontal or maxillary sinus opening:

<table>
<thead>
<tr>
<th>CPT®</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
</tr>
</tbody>
</table>

If bilateral implant placement is performed in the frontal or maxillary sinus opening and reporting of CPT 31299 is appropriate, modifier -50 cannot typically be appended to an unlisted procedure code. Therefore, the bilateral work should be included in the description provided to support code selection and negotiation of payment.
HCPCS reporting of PROPEL, PROPEL Mini and PROPEL Contour sinus implants is as follows:

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
<th>Payor</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1090</td>
<td>Mometasone furoate sinus implant, 370 Micrograms</td>
<td>Most Commercial Payors</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
<td>Medicare Contractors and Some Commercial Payors</td>
</tr>
</tbody>
</table>

When using HCPCS J3490, most payors will require providers to submit additional information in item 19 of the CMS 1500 form to describe the name of the product, the dose, and the National Drug Code (NDC) code (a universal product identifier assigned by FDA) for PROPEL, PROPEL Mini and PROPEL Contour:

<table>
<thead>
<tr>
<th>NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10599-0000-01</td>
<td>PROPEL (Mometasone furoate sinus implant, 370 micrograms)</td>
</tr>
<tr>
<td>10599-0001-01</td>
<td>PROPEL Mini (Mometasone furoate sinus implant, 370 micrograms)</td>
</tr>
<tr>
<td>10599-0002-01</td>
<td>PROPEL Contour (Mometasone furoate sinus implant, 370 micrograms)</td>
</tr>
</tbody>
</table>

Regardless of the HCPCS code selected for reporting, it is important to note that in the case of bilateral procedures, HCPCS codes (e.g. S1090, J3490) cannot be appended with modifier -50. Rather, bilateral placement should be indicated as two (2) units in the appropriate field on the billing form (e.g. box 24G on the CMS-1500 form). In procedures where four units are used (e.g. two units placed in the ethmoid sinus and two units placed in the frontal sinus), four (4) units should be reported on the billing form.
Section 5
Category III and Unlisted Procedure Code Billing

Effective January 1, 2016, the following Category III CPT codes apply when a drug-eluting sinus implant (e.g. PROPEL or PROPEL Mini sinus implants) is placed in the ethmoid sinus either:

- as a standalone procedure; or
- with a procedure to perform biopsy, polypectomy, or debridement

0406T – Nasal endoscopy, surgical, ethmoid sinus; placement of drug eluting implant
0407T – Nasal endoscopy, surgical, ethmoid sinus; with biopsy, polypectomy or debridement

(Do not report 0406T, 0407T in conjunction with 31200, 31201, 31205, 31231, 31237, 31240, 31254, 31255, 31288, 31290 when performed on the same side)
(Do not report 0407T in conjunction with 0406T if performed on the same side)

The Category III codes 0406T and 0407T cannot be reported with codes identified in the parenthetical note above since placement of an implant is already included in the work of those codes.

As described in Section 4, there is currently no specific CPT code for the endoscopic placement of a drug-eluting sinus implant in the frontal or maxillary sinus opening. Therefore, CPT code 31299 (Unlisted procedure, accessory sinus) may apply when describing this procedure. Unlisted codes exist in the current CPT code set to describe services or procedures performed by physicians or other qualified healthcare professionals when no other code adequately describes the service or procedure. When reporting an unlisted code to describe a procedure or service, it is typically necessary to submit supporting documentation with the claim to provide an adequate description of the nature, extent, and need for the procedure, and the time, effort, and equipment necessary to provide the service.” (CPT Assistant, September 2012, Volume 22 Issue 9)

When reporting Category III or Unlisted Procedure CPT codes, providers should consider:

1. When a Category III or Unlisted Procedure CPT code is used, a description of the service or procedure should be included.
2. Coverage of Category III and Unlisted Procedure CPT codes is generally based on payer policies and medical review of documentation submitted.
3. Category III and Unlisted Procedure CPT codes do not have RVUs or payment rates established at the national level. Physicians are responsible for negotiating payment for the procedure with payors based on procedures which are comparable in time, work, practice expense and malpractice expense.

As a benchmark for negotiations with payors, providers may consider using the following baseline procedures as a starting point. Other codes may also be appropriate.

<table>
<thead>
<tr>
<th>CPT®</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31231</td>
<td>Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)</td>
</tr>
<tr>
<td>31237</td>
<td>Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)</td>
</tr>
</tbody>
</table>
The following is a list of items that should be provided to the payor for both prior authorization and claim submission when using Category III or Unlisted Procedure CPT codes:

- Patient’s medical history and chronicity of disease
- Medical necessity for the procedure including past therapies
- Complexity of symptoms, diagnosis, physical findings, and concurrent problems
- Diagnostic test results
- Detailed description of procedure(s) performed
- Indications for Use (IFU)
- FDA approval letter
- Product information
- Clinical data bibliography
Section 6
Outpatient Surgery Coding and Payment

Hospital Outpatient Prospective Payment System (HOPPS) Methodology

Services rendered to Medicare beneficiaries in the hospital outpatient setting typically are covered and paid under Medicare Part B. Medicare reimburses outpatient hospital services under the HOPPS, which bases payment on Ambulatory Payment Classifications (APCs), groups of clinical services, supplies, drugs, and devices that are similar clinically and in terms of resource costs. Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes map to APCs, and each APC has an assigned Medicare hospital outpatient payment rate for the service. Depending upon the services provided, hospitals may receive payment for one or more APC(s) per patient encounter.

Payment for common sinus surgery procedures is for Medicare’s hospital outpatient prospective payment system and is the Medicare national average without geographical adjustment.

Ambulatory Surgery Center (ASC) Payment Methodology

Not all procedures are approved for payment in the ASC setting by Medicare. For those which are approved, Medicare payment for most procedures performed in an ASC is based on the APC methodology for hospital outpatient payment. Commercial payors often mimic this payment methodology.

As with payment in the hospital outpatient setting, CPT and HCPCS codes map to APCs with an assigned Medicare rate for the service.

Payment for common sinus surgery procedures is for Medicare’s ASC payment system and is the Medicare national average without geographical adjustment.

*For procedures performed in either the HOPPS or ASC setting, payment to the physician is separate and is based on the “facility” rate as indicated in Section 3. Also, in the ASC setting, the ability to report HCPCS codes separately is determined by the status indicator of the related procedure, as described later in this section.*
Considerations for Outpatient Facility Payment

When evaluating the potential reimbursement for surgeries using PROPEL sinus implants, it is important to consider multiple factors.

1. Due to the nature of the sinus anatomy, most sinus surgery cases include multiple CPT codes. Therefore, providers should consider the total average “case” payment, not the payment per related CPT code.

2. Most patients who undergo sinus surgery are covered by commercial payors. It is estimated that up to 85% of patients with CRS are of working age (between 18-65) with the average mean age of 45.7,8 Since most patients will not be Medicare beneficiaries, providers should evaluate and consider commercial payor rates.

3. Payment varies by payor. Commercial payor rates may be higher or lower than Medicare rates based on the contract negotiated between the provider and the payor. One study found that commercial payors typically pay at a rate higher than Medicare, often in the range of 135% of Medicare rates.9

4. Some commercial payor contracts provide separate payment for supplies and/or implants. This is contract dependent. Providers should consult each payor’s policies to determine reimbursement rates for the procedure(s) planned for the patient.

5. The charge amount will vary by provider. Hospital outpatient departments and ASCs may set charges based on their charge master (which reflects their costs and includes a markup), current contracts with payors and established billing protocols associated with the service or procedure, which reflect the required resources (supplies, time, staff, etc.). It is important for providers to have supporting documentation to justify their costs and established charges for a service/procedure.

7 Thompson Reuters Market Scan, 2011.
9 Avalere Health Analysis of American Hospital Association Annual Survey Data, 2011, for community hospitals.
### COMMON SINUS SURGERY PROCEDURES

2017 MEDICARE HOPPS & ASC FACILITY PAYMENT – NATIONAL MEDICARE AVERAGE

(Not a complete list)

<table>
<thead>
<tr>
<th>CPT*</th>
<th>DESCRIPTION</th>
<th>APC</th>
<th>HOPPS</th>
<th>S.I.</th>
<th>ASC</th>
<th>S.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>30100</td>
<td>Biopsy, intranasal</td>
<td>5163</td>
<td>$1,038</td>
<td>T</td>
<td>$104</td>
<td>P3</td>
</tr>
<tr>
<td>30110</td>
<td>Excision, nasal polyp(s), simple</td>
<td>5163</td>
<td>$1,038</td>
<td>T</td>
<td>$165</td>
<td>P3</td>
</tr>
<tr>
<td>30115</td>
<td>Excision, nasal polyp(s), extensive</td>
<td>5164</td>
<td>$2,173</td>
<td>J1</td>
<td>$940</td>
<td>A2</td>
</tr>
<tr>
<td>30140</td>
<td>Submucous resection, inferior turbinate, partial or complete, any method</td>
<td>5164</td>
<td>$2,173</td>
<td>J1</td>
<td>$940</td>
<td>A2</td>
</tr>
<tr>
<td>30200</td>
<td>Injection into turbinate(s), therapeutic</td>
<td>5162</td>
<td>$442</td>
<td>T</td>
<td>$83</td>
<td>P3</td>
</tr>
<tr>
<td>30520</td>
<td>Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft</td>
<td>5164</td>
<td>$2,173</td>
<td>J1</td>
<td>$940</td>
<td>A2</td>
</tr>
<tr>
<td>30560</td>
<td>Lysis intranasal synechie</td>
<td>5162</td>
<td>$442</td>
<td>T</td>
<td>$239</td>
<td>A2</td>
</tr>
<tr>
<td>30801</td>
<td>Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method; superficial</td>
<td>5163</td>
<td>$1,038</td>
<td>T</td>
<td>$561</td>
<td>A2</td>
</tr>
<tr>
<td>30802</td>
<td>Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method; intramural (i.e. submucosal)</td>
<td>5163</td>
<td>$1,038</td>
<td>T</td>
<td>$561</td>
<td>A2</td>
</tr>
<tr>
<td>31000</td>
<td>Lavage by cannulation; maxillary sinus (antrum puncture or natural ostium)</td>
<td>5161</td>
<td>$177</td>
<td>T</td>
<td>$96</td>
<td>P2</td>
</tr>
<tr>
<td>31002</td>
<td>Lavage by cannulation; sphenoid sinus (antrum puncture or natural ostium)</td>
<td>5163</td>
<td>$1,038</td>
<td>T</td>
<td>$561</td>
<td>A2</td>
</tr>
<tr>
<td>31090</td>
<td>Sinusotomy, unilateral, 3 or more paranasal sinuses (frontal, maxillary, ethmoid, sphenoid)</td>
<td>5165</td>
<td>$4,129</td>
<td>J1</td>
<td>$2,037</td>
<td>A2</td>
</tr>
<tr>
<td>31200</td>
<td>Ethmoidectomy; intranasal, anterior</td>
<td>5165</td>
<td>$4,129</td>
<td>J1</td>
<td>$2,037</td>
<td>A2</td>
</tr>
<tr>
<td>31201</td>
<td>Ethmoidectomy; intranasal, total</td>
<td>5164</td>
<td>$2,173</td>
<td>J1</td>
<td>$940</td>
<td>A2</td>
</tr>
<tr>
<td>31205</td>
<td>Ethmoidectomy; extranasal, total</td>
<td>5164</td>
<td>$2,173</td>
<td>J1</td>
<td>$940</td>
<td>A2</td>
</tr>
<tr>
<td>31231</td>
<td>Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)</td>
<td>5151</td>
<td>$146</td>
<td>T</td>
<td>$79</td>
<td>P2</td>
</tr>
<tr>
<td>31237</td>
<td>Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)</td>
<td>5153</td>
<td>$1,269</td>
<td>J1</td>
<td>$569</td>
<td>A2</td>
</tr>
<tr>
<td>31240</td>
<td>Nasal/sinus endoscopy, surgical; with concha bullosa resection</td>
<td>5153</td>
<td>$1,269</td>
<td>J1</td>
<td>$569</td>
<td>A2</td>
</tr>
<tr>
<td>31254</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31255</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31256</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy</td>
<td>5154</td>
<td>$2,430</td>
<td>J1</td>
<td>$1,117</td>
<td>A2</td>
</tr>
<tr>
<td>31267</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31276</td>
<td>Nasal/sinus endoscopy, surgical with frontal sinus exploration; with or without removal of tissue from frontal sinus</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31287</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoïdotomy</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31288</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoïdotomy; with removal of tissue from the sphenoid sinus</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g. balloon dilation), transnasal or via canine fossa</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>A2</td>
</tr>
<tr>
<td>31296</td>
<td>With dilation of frontal sinus ostium (e.g. balloon dilation)</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>P2</td>
</tr>
<tr>
<td>31297</td>
<td>With dilation of sphenoid sinus ostium (e.g. balloon dilation)</td>
<td>5155</td>
<td>$4,361</td>
<td>J1</td>
<td>$1,708</td>
<td>P2</td>
</tr>
<tr>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
<td>5161</td>
<td>$177</td>
<td>T</td>
<td>Not payable</td>
<td>n/a</td>
</tr>
<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant</td>
<td>5153</td>
<td>$1,269</td>
<td>Q2</td>
<td>Not payable</td>
<td>N1</td>
</tr>
<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with polypectomy, biopsy or debridement</td>
<td>5153</td>
<td>$1,269</td>
<td>Q2</td>
<td>Not payable</td>
<td>N1</td>
</tr>
</tbody>
</table>

All rates shown are national averages and do not include adjustments for geographic variations in costs or the 2% reduction in Medicare’s share of the payment due to sequestration under the Budget Control Act of 2011.
<table>
<thead>
<tr>
<th>INDEX OF STATUS INDICATORS (S.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2</td>
</tr>
<tr>
<td>J1</td>
</tr>
<tr>
<td>P2</td>
</tr>
<tr>
<td>P3</td>
</tr>
<tr>
<td>R2</td>
</tr>
<tr>
<td>T</td>
</tr>
<tr>
<td>X</td>
</tr>
</tbody>
</table>
Section 7

Facility Reporting for Supplies, Disposables and Implants

For surgical procedures performed in the facility setting (i.e. hospital outpatient or ambulatory surgery center), the cost for supplies, disposables, implants and other items are typically included in the facility payment for the procedure.

Reporting the cost for items such as PROPEL sinus implants with an applicable HCPCS code is important for future rate-setting purposes, especially for Medicare. Separate reporting may also be important to capture separate payment if contractually allowed by commercial payors. The selection of codes is based on payor guidelines and site of service. HCPCS codes applicable to PROPEL sinus implants include:

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
<th>Payor</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2625</td>
<td>Stent, non-coronary, temporary, with delivery system</td>
<td>Medicare Contractors and Some Commercial Payors*</td>
</tr>
<tr>
<td>S1090</td>
<td>Mometasone furoate sinus implant, 370 micrograms</td>
<td>Most Commercial Payors</td>
</tr>
</tbody>
</table>

*Note: In ASCs, check the status indicator for the procedure codes reported. C2625 is not reportable with all procedures in the ASC setting.

While HCPCS code S1090 is most descriptive of PROPEL sinus implants, “S” codes are not recognized by Medicare and some other payors. Therefore, the Centers for Medicare and Medicaid Services (CMS) has indicated C2625 most closely describes PROPEL sinus implants. This code may also be appropriate for commercial payor reporting. It is the provider’s responsibility to select the code which most appropriately describes PROPEL sinus implants and is applicable to the payor and setting of care.

Although there is no separate payment for most device C-codes, it is important for hospitals to report C2625 and an appropriate charge on their claims for each implant provided. This claims data is used by CMS to determine future APC payment rates and to ensure the cost of associated devices is appropriately accounted for in each APC. This also has payment implications for procedures performed in the ASC which have payment rates based on the HOPD APC calculation.

Further, capturing all costs associated with the provision of surgical services is also important for negotiation of appropriate payment with commercial payors.
Section 8
Hospital Inpatient Coding and Payment

Inpatient Prospective Payment System (IPPS) Overview

Medicare beneficiaries who are admitted into hospital inpatient settings typically have coverage through Medicare Part A. Medicare reimburses inpatient hospital services under the Inpatient Prospective Payment System (IPPS), which bases payment on diagnosis-related groups (DRGs), now Medicare Severity diagnosis-related groups (MS-DRGs). The MS-DRG payment system groups similar diagnoses into a single payment level, and reimburses the hospital according to the extent of resources typically required to treat patients with similar diagnoses undergoing similar treatments. All services and supplies provided during the inpatient admission are bundled into a single MS-DRG reimbursement rate, regardless of the length of the inpatient stay, the intensity of treatments, or the number of procedures performed for the specific individual. Hospitals will receive one global MS-DRG payment rate per patient admission, and the MS-DRG assignment is primarily determined by the patient’s principle diagnosis and/or principal procedure performed.

Medicare uses International Classification of Diseases, Tenth Revision (ICD-10-CM) codes to identify diagnoses and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) to identify procedures in the hospital inpatient setting. Hospitals must report the principal diagnosis using an appropriate ICD-10-CM code, as well as any secondary diagnoses – some of which may be considered CCs (Complications or Comorbidities) or MCCs (Major Complications or Comorbidities) for MS-DRG assignment. The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as “that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.” The circumstances of inpatient admission always govern the selection of principal diagnosis. Diagnosis codes should be reported to the highest level of specificity available. A minimum of one diagnosis code is required on all claims, and it is possible to report up to eighteen. Medicare may require additional clinical information specific to each patient to determine coverage and payment for the reported procedure.
ICD-10-CM Diagnosis Codes

Diagnosis codes which are commonly associated with admissions related to chronic sinusitis are included in Section 3.

ICD-10-PCS Procedure Codes

Effective October 1, 2015, ICD-9 procedure codes were replaced by ICD-10-PCS codes. For inpatient admissions involving procedures, hospitals must also report ICD-10-PCS procedure code(s) for the surgical and other procedures, up to six procedures on a claim.

The following codes apply to most common sinus surgery procedures.

<table>
<thead>
<tr>
<th>ICD-10-PCS codes; effective 10/01/2015:</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>095P4ZZ-09X4ZZ</td>
<td>Destruction of sinus, percutaneous endoscopic approach [accessory, maxillary, frontal ethmoid or sphenoid; includes codes 095P4ZZ, 095Q4ZZ, 095R4ZZ, 095S4ZZ, 095T4ZZ, 095U4ZZ, 095V4ZZ, 095W4ZZ, 095X4ZZ]</td>
</tr>
<tr>
<td>099P40Z-099X4ZZ</td>
<td>Drainage of sinus, percutaneous endoscopic approach [with or without device, accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 099P40Z, 099P4ZZ, 099Q40Z, 099Q4ZZ, 099R40Z, 099R4ZZ, 099S40Z, 099S4ZZ, 099T40Z, 099T4ZZ, 099U40Z, 099U4ZZ, 099V40Z, 099V4ZZ, 099W40Z, 099W4ZZ, 099X40Z, 099X4ZZ]</td>
</tr>
<tr>
<td>09BP4ZZ-09BX4ZZ</td>
<td>Excision of sinus, percutaneous endoscopic approach [accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 09BP4ZZ, 09BQ4ZZ, 09BR4ZZ, 09BS4ZZ, 09BT4ZZ, 09BU4ZZ, 09BV4ZZ, 09BW4ZZ, 09BX4ZZ]</td>
</tr>
<tr>
<td>09CP4ZZ-09CX4ZZ</td>
<td>Extirpation of matter from sinus, percutaneous endoscopic approach [accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 09CP4ZZ, 09CQ4ZZ, 09CR4ZZ, 09CS4ZZ, 09CT4ZZ, 09CU4ZZ, 09CV4ZZ, 09CW4ZZ, 09CX4ZZ]</td>
</tr>
<tr>
<td>09DP4ZZ-09DX4ZZ</td>
<td>Extraction of sinus, percutaneous endoscopic approach [accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 09DP4ZZ, 09DQ4ZZ, 09DR4ZZ, 09DS4ZZ, 09DT4ZZ, 09DU4ZZ, 09DV4ZZ, 09DW4ZZ, 09DX4ZZ]</td>
</tr>
<tr>
<td>09JY4ZZ</td>
<td>Inspection of sinus, percutaneous endoscopic approach</td>
</tr>
<tr>
<td>09NP4ZZ-09NX4ZZ</td>
<td>Release sinus, percutaneous endoscopic approach [accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 09NP4ZZ, 09NQ4ZZ, 09NR4ZZ, 09NS4ZZ, 09NT4ZZ, 09NU4ZZ, 09NV4ZZ, 09NW4ZZ, 09NX4ZZ]</td>
</tr>
<tr>
<td>09QP4ZZ-09QX4ZZ</td>
<td>Repair sinus, percutaneous endoscopic approach [accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 09QP4ZZ, 09QQ4ZZ, 09QR4ZZ, 09QS4ZZ, 09QT4ZZ, 09QU4ZZ, 09QV4ZZ, 09QW4ZZ, 09QX4ZZ]</td>
</tr>
<tr>
<td>09TP4ZZ-09TX4ZZ</td>
<td>Resection of sinus, percutaneous endoscopic approach [accessory, maxillary, frontal, ethmoid or sphenoid; includes codes 09TP4ZZ, 09TQ4ZZ, 09TR4ZZ, 09TS4ZZ, 09TT4ZZ, 09TU4ZZ, 09TV4ZZ, 09TW4ZZ, 09TX4ZZ]</td>
</tr>
</tbody>
</table>
Medicare Severity Diagnosis – Related Groups (MS-DRGs)

Hospital payment for inpatient services/procedures is usually based on Medicare Severity Diagnosis-Related Groups (MS-DRGs), case rates, per diem rates or a charge-based line-item payment methodology. Medicare pays hospital inpatient procedures under the MS-DRG system, while most other insurers usually pay the hospital on a contractual basis (i.e., case rate or per diem rate) that has been negotiated between the hospital and insurance carrier.

MS-DRGs are a system of classification for inpatient hospital services based on principal diagnosis, secondary diagnosis, surgical procedures, patient age, and the presence of complications and/or comorbidities. The system of classification is used as a financing mechanism to reimburse hospitals and selected other providers for services rendered. The cost of the equipment, supplies, operating room, patient room, nursing care, and all other services the patient receives is covered in the MS-DRG payment that the hospital receives.

Each MS-DRG is assigned a relative weight representative of the amount of resources required for the patient’s procedure/treatment. The relative weight is multiplied by the individual hospital’s base rate (adjusted depending on labor costs, non-labor costs, capital payments, type of hospital [e.g., teaching hospital or hospital that provides a disproportionate amount of care to the disadvantaged], etc.) to determine the payable amount.

MS-DRGs most commonly associated with inpatient sinus surgery admissions include:

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Description</th>
<th>Relative Weight</th>
<th>2017 Medicare National Average Payment(^\text{10}) (No geographic adjustment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>135</td>
<td>Sinus &amp; Mastoid Procedures with Complication/Comorbidity (CC)/Major CC</td>
<td>2.0142</td>
<td>$12,011</td>
</tr>
<tr>
<td>136</td>
<td>Sinus &amp; Mastoid Procedures without CC/MCC</td>
<td>1.1081</td>
<td>$6,608</td>
</tr>
</tbody>
</table>

\(^{10}\) MS-DRG 2017 national payment estimates are determined using 2017 figures released by CMS on September 30, 2016.
Other Payment Methodologies

Several other methodologies may apply to the contractual payment negotiated between provider and payor for both inpatient and outpatient hospital services. These include, but are not limited to:

**Case Rates**

Using the case rate method, a payor pays the provider a fixed rate based on the diagnosis and/or presenting condition. This rate covers all of the services and supplies the patient requires during the admission, observation stay, or specified outpatient procedure, if applicable. Commercial payor case rates are commonly based on the Medicare payment rate.

Case rates are typically established on the basis of major diagnostic categories and may be classified by a DRG, revenue center code, ICD-10-PCS procedure code, or CPT code. The case rate may or may not include:

- a specified number of days associated with the case rate;
- outlier provisions if billed charges exceed a specific dollar amount; or
- cost of supplies or instrumentation (e.g. implants).

In this model, the provider is accepting some significant risk but has considerable flexibility in how it meets the patient’s needs. However, the provider must fully understand costs and volume potential when negotiating case rates. This type of financial arrangement is often used for high-cost or high volume procedures.

As previously described, commercial payors may negotiate “carve-outs” to separately pay for procedures and services which are high cost, new technology, or for services that are only performed by specific providers, outside of the contracted network. Carve-outs are by definition an exception to the normal payment rate not included in the current contract. With respect to PROPEL, PROPEL Mini and PROPEL Contour sinus implants, many facility providers have negotiated carve-outs for implants, which may apply to PROPEL, PROPEL Mini and PROPEL Contour sinus implants based on the FDA-approved product description.

**Per Diem**

In the *per diem* billing system, the hospital and payor agree to a “per day” payment amount that will reimburse the hospital for all the services, supplies, etc. provided to the patient. Payments are usually limited to predetermined lengths of stay.
### Section 9

#### Place of Service and Revenue Codes

Place of Service Codes are two-digit codes used on professional claims to indicate the setting in which a service was provided. Listed below are commonly used Place of Service Codes and their descriptions. This list is not all-inclusive. It is highly recommended that providers check with individual payors for reimbursement policies surrounding use of these Place of Service Codes.

<table>
<thead>
<tr>
<th>Place of Service Code</th>
<th>Place of Service Name</th>
<th>Place of Service Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Office</td>
<td>Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.</td>
</tr>
<tr>
<td>19</td>
<td>Off Campus-Outpatient Hospital</td>
<td>A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)</td>
</tr>
<tr>
<td>21</td>
<td>Inpatient Hospital</td>
<td>A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.</td>
</tr>
<tr>
<td>22</td>
<td>On Campus-Outpatient Hospital</td>
<td>A portion of a hospital’s main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)</td>
</tr>
<tr>
<td>24</td>
<td>Ambulatory Surgical Center (ASC)</td>
<td>A freestanding facility, other than a physician’s office, where surgical and diagnostic services are provided on an ambulatory basis.</td>
</tr>
</tbody>
</table>
Revenue Codes

Revenue codes allow hospitals to categorize services provided by revenue center. Medicare utilizes revenue codes for cost reporting. For Medicare, revenue codes must be included for each service on a CMS 1450 (UB-04) claim form. Sample revenue codes that hospital facilities may use to track costs for services associated with sinus surgery procedures include:

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0250</td>
<td>Pharmacy – General</td>
</tr>
<tr>
<td>0270</td>
<td>Medical/Surgical Supplies – General</td>
</tr>
<tr>
<td>0271</td>
<td>Non-Sterile Supply</td>
</tr>
<tr>
<td>0272</td>
<td>Sterile Supply</td>
</tr>
<tr>
<td>0278</td>
<td>Medical/Surgical Supplies: Other Implants</td>
</tr>
<tr>
<td>0279</td>
<td>Medical/Surgical Supplies: Other Supplies/Devices</td>
</tr>
<tr>
<td>0320</td>
<td>Radiology – Diagnostic</td>
</tr>
<tr>
<td>0360</td>
<td>Operating Room Services – General</td>
</tr>
<tr>
<td>0361</td>
<td>Operating Room Services – Minor Surgery</td>
</tr>
<tr>
<td>0623</td>
<td>Surgical Dressing</td>
</tr>
</tbody>
</table>
Section 10

Coverage

Covered benefits under commercial health plans can vary by health plan and by the individual or group purchasing health plan coverage. Coverage for surgical procedures varies by payor and is typically determined by medical necessity guidelines intended to ensure other less invasive options have been exhausted. Each payor’s coverage policy should be reviewed to determine the implications of coverage policy upon payment and use based on payor guidelines.

Benefit Verification

Prior to pursuing coverage through the prior authorization process, it is first important to verify a patient’s eligibility for benefits. Eligibility for benefits is also directly related to a patient’s employment status, if benefits are provided through their employer. It is important to verify the specific benefits by group and plan of the patient being considered for surgery prior to rendering services.

Prior Authorization Process

Prior Authorization is a process that allows physicians and other health care providers to determine, prior to treating the patient:

- If the treatment is covered
- If the site of service for the treatment is covered
- The amount of co-payments/co-insurance, deductibles, and the patient’s maximum benefits

With respect to the use of any PROPEL sinus implant product, it is important to remember that:

1. Prior authorization for a PROPEL sinus implant itself may not be required unless the contract with the payor allows for separate payment of supplies or implants. In such scenarios, providers should simply secure approval for the surgical procedure(s) per usual.

2. When PROPEL sinus implants are used in the operating room setting (HOPD or ASC), in situations where prior authorization is necessary, securing such approval is typically the responsibility of the entity which purchases and bills for the implant (i.e. the facility), NOT the physician. However, the physician and hospital should communicate to ensure all appropriate authorizations are obtained prior to the procedure.
Prior Authorization clarifies benefits in advance, allowing the physician and patient to make informed decisions regarding treatment. For some procedures, providers will indicate “no prior authorization required.” However, this is not a guarantee of payment.

It is critical to consult the payor with respect to coverage policies and benefits specific to each patient’s coverage. Most commercial payors require that surgeries and procedures be authorized prior to the date of service. Medicare is the exception, as Medicare does not preauthorize services.

Prior Authorization is not a guarantee of payment. Final determination will be subject to valid eligibility, applicable benefits and medical necessity at the time of rendered services. Many payors no longer require or perform prior authorization for outpatient procedures or services. Instead, services are reviewed for medical necessity and coverage conditions when the claim is received. Accordingly, prior to treatment, providers should request patients sign a Waiver of Financial Liability (Non-Medicare), in the event of a non-coverage or partial coverage decision.

Once medical necessity has been established, the following steps should assist in the coverage process:

1. Verify insurance benefits (either via phone or electronically)
2. Determine if prior authorization is required for the planned procedure(s)
3. If prior authorization is not required consider pursuing a “pre-determination”
4. Consult the payor’s prior authorization documentation requirements and prepare and submit the prior authorization request with letter of medical necessity, including:
   - Copies of peer reviewed published studies supporting the patient’s treatment plan
   - PROPEL sinus implant product information
   - PROPEL sinus implant FDA approval letter
   - Copy of patient’s insurance card
   - Physician notes regarding patient’s history and current medical condition
   - Copies of previous surgical records
   - Results of imaging and other diagnostic tests
5. If the payor has not responded within 30 days, send a follow up request
6. Records should be sent by fax or by standard or express mail, with return receipt requested
7. Document all communication with the payor, including the name, date, department and contact phone number
8. Do not send protected health information through non-secure / non-encrypted e-mail
When pursuing coverage, there are numerous steps to consider to ensure medical necessity guidelines are satisfied. These include:

**Step 1: Prior Authorization**
- Prior authorization for surgical procedures is recommended before scheduling surgery.
- Allow sufficient lead time for consideration of coverage as outlined by the individual healthcare plan (typically 3-5 days).
- Medicare does not provide prior authorization.

**Step 2: First Appeal**
- If Prior Authorization is denied, pursue first level appeal (a.k.a. Pre-determination)
  - Submit request for re-determination and/or expedited appeal.
  - Request “peer-to-peer” review.
  - Decision timeline is usually 15 days.

**Step 3: Second Appeal**
- If First Level Appeal is denied, pursue second level appeal (a.k.a. Reconsideration)
  - Recommend review performed by an independent physician within same specialty.
  - Contact employer or patient groups for assistance with advocacy and dealing with health plan.

**Step 4: Other Options**
- If Second Level Appeal is denied, consider other options which may include:
  - A request for External Review by Independent Review Organization (IRO) Appeal may be sent to health plan who must forward to an IRO as established by each state insurance commissioner. Check plan guidelines and limitations.
  - If applicable, consider engaging the patient to contact the employer for intervention.
Resources: Prior Authorization Request/Letter of Medical Necessity

A sample Prior Authorization request for a procedure associated with the use of PROPEL sinus implants is included in the Appendix. As described above, this sample requires the provider to customize the letter to describe the patient’s past and present clinical condition.

Payors often require medical necessity to be established for a particular patient prior to any service or procedure being considered for coverage or payment. Individual payors develop their own criteria for medical necessity. Payors should be consulted for their medical necessity guidelines. A letter of medical necessity addressed to the Medical Director may be necessary, and typically includes:

- Patient information—name, date of birth, policy number
- Details of the patient’s medical history
- Current diagnosis(es)
- Duration and degree of illness
- Summary of past treatment(s) (i.e. medical management and/or other surgical interventions)
- Current status (why previous treatments failed)
- Reason for proposed treatment
- Description of the patient’s current status and treatment plan
- Current limitations to activities of daily living and ability to work
- Proposed surgical procedure(s) and rationale for treatment
- Proposed location of service and dates planned
- Anticipated billing codes
Section 11
Denials

Even with a comprehensive and meticulous approach to the prior authorization process, some claims will be denied payment for reasons that can often be appealed. The appeals process (often referred to as “Dispute Resolution”) is discussed in Section 9. The additional recommendations below are based on industry-standard appeals processes when products or services are denied due to non-coverage.

Overview

In general, there are three steps to the denials process. However, the process and guidelines may vary by payor, plan and patient.

1. First Level Appeal: The first appeal generally provides additional information to justify the medical necessity of a service. It may be important to include a description of the service, description of the outcomes, operative report and relevant supportive peer reviewed literature.

2. Second Level Appeal: In the second appeal, “specialty matched” external review by a Board Certified Physician with relevant expertise (i.e. Otolaryngologist) in current clinical practice should be requested.

3. Third Level Appeal: In the third appeal, review by an Independent Review Organization should be requested. It is important to review payor policies associated with this step since limitations and costs may apply.

Additional Recommendations

- Many denials are due to technical coding/billing errors. Thoroughly review the Explanation of Benefits to ensure the reason for the denial is clearly due to non-coverage of a service (e.g. due to experimental/investigational reasons).

- Be patient with the process (which can often take months) and ensure promptness with response to payors as deadlines and time limits may apply.

- Request a meeting with the Medical Director either face-to-face or over the phone to review current evidence and technology, as well as to discuss patient-specific needs, outcomes, and benefits of PROPEL. Review the clinical data for PROPEL sinus implants and be prepared to discuss the merits. When doing so, keep in mind that the Medical Director is not likely to be an ENT and likely has limited to no experience in sinus surgery.
• When communicating with the payor Medical Director (or other assigned staff), discuss your own personal experience with PROPEL sinus implants and how it can potentially benefit payors and their member patients.
  o Patient outcomes
  o Quality of life (QOL)
  o Return to normal activities
  o Cost (especially the reduction in need for revision surgery or surgical intervention for complications)

• Offer for the Medical Director to come see PROPEL sinus implants used in the OR or to your practice to see a patient with PROPEL sinus implants in place post-op to witness the benefits. Seeing is believing.

• If the Medical Director insists that PROPEL sinus implants will not be covered, ask specifically how you can work with him/her to re-evaluate the current Medical Policy through a review of current published clinical evidence (i.e. “What is a specific date for a possible Medical Policy review?”).

• Ask to be kept up to date (and involved) as the timeline progresses.

• Manage the patient’s expectations with the process and if necessary, request them to get engaged through their employee benefits department (if applicable).

• If you feel the patient’s case was not given thorough or responsible consideration, consider submitting a formal complaint to the State Department of Insurance.

• Don’t give up with this payor. Continue submitting requests for coverage and appealing denials. Policies don’t change without clinical demand.

Resources

Template appeal letters, which require customization to describe the actual patient’s condition, are available in the Appendix along with other tools which may assist your efforts in the appeals process.
Section 12
Payor Contracting

A careful review of payor contracts may help identify and manage risks which impact provider reimbursement. The most important tip is to be aware of “evergreen provisions” that may bind providers to terms year after year without a fee schedule review. The following is a list of other typical provisions to consider when entering into or re-evaluating payor agreements.

NOTE: The below information is for informational purposes only and should not be considered or used as legal or reimbursement advice. When entering into contracts, providers should seek their own legal counsel and not rely on any information provided in this guide.

1. Provisions that give the payor the right to arbitrarily adjust and pay claims at a lower level than submitted
Some contracts allow the payor to adjust claims and pay them at a lower level than submitted. A payor claims examiner may perform the down-coding, or it may be done by rules-based software. If state laws afford no protection from arbitrary down-coding, providers should seek to contractually limit the payor’s ability to adjust claims by asking for the contract to stipulate notification requirements and to explain any variances from the Centers for Medicare and Medicaid Services' Correct Coding Initiative (CCI). Further, asking for the right to appeal any claims adjustments could be helpful.

2. Provisions that allow for unlimited overpayment recovery or “take backs”
Providers should carefully review the Payment and Reimbursement section of the contract to fully understand any language pertaining to “take back” provisions. These “take backs” may cover claims that were previously paid or allow for unlimited overpayment recovery. Some provisions allow for recovery for an extended period of time (e.g. three years) and may allow withholding from future payment.

3. Covered providers in capitated contracts
Under a typical capitation contract, a fixed amount is paid per member per month regardless of the actual services rendered. Capitation contract payment may include services by other providers, including hospital services, lab, x-ray, or any other ancillary services. Some payors may “carve-out” or exclude certain services or products commonly used in a provider’s practice from the capitation agreement. Careful inspection of what is and is not included in the capitation payment and what can or cannot be paid separately is critical.

4. Withhold provisions
No matter how the payor presents it, a “withhold” is usually an additional discount taken from provider reimbursement, typically to cover payor losses. Withhold language is usually found under Payment and Reimbursement or may be included as a separate addendum or attachment. This language should be reviewed by an expert in risk contracting.
5. Limitations to covered services

In the process of establishing a contract, the payor typically provides an example of payment rates for a sample list of services. Providers should carefully review this list for codes relevant to their practice. Comparing this to a list of the highest volume procedures in the practice can expedite the review process.

6. 30-day appeal limitations

Limitations on timelines to submit a claim appeal places the burden of identifying claims processing errors on the provider. Be aware of this limitation on the right to appeal as it may create a very tight administrative turnaround process. Attempting to get a longer time frame for identifying claims processing errors in order to appeal may reduce this burden.

7. 30-day filing limitations

Some payors have filing limitations as short as 30 days from the date of service or EOB from the primary payor. This short timeline can create administrative challenges when “special circumstances” such as loss of key staff or significant equipment failure apply. If the contract does not identify a filing limitation, be aware that it might fall under an unwritten policy and procedure.

8. Language granting payors carte blanche authority to change payment terms during the middle of the contract period

Many provider agreements grant the payor authority to make unilateral, mid-term changes to the provider agreement. For example, while a contract may specify a one or two year term with reimbursement set at 150% of current Medicare rates, the fine details of the contract may stipulate that the payor may amend any portion of the contract at its sole discretion by giving the provider 30 days’ written notice. In essence, this makes the contract a 30 day agreement. To protect against such unilateral authority, contracts should allow the right to approve any mid-contract changes, or grant the right to a quick and easy termination if the changes are unacceptable.

9. Vague contract language

The use of language in contract provisions such as “As may be deemed necessary” and/or “from time to time” are less obvious ways to require providers to accept unilateral changes. The use of “as may be established by the Payor” (especially if it occurs “from time to time”) may obligate the provider to policies and procedures that haven’t even been established, but may be in the future. This caution also applies to any attachments or addendums that may be “modified or added at the discretion of the Payor.” It is best to review payor policy and procedure manuals that will apply to the provider before a contract is signed. This review process allows the provider to ensure compliance with those payor requirements.

10. Contract extension to payor “affiliates”

National payors and network PPOs may include a statement stipulating that the agreement is entered into by itself and its affiliates. Such a stipulation may extend discounts to these current (and potentially future) affiliates. Ask for a complete list of affiliates that will apply to the contract. This language may be found in the opening paragraph of the contract or in an Addendum.
Section 13

PROPEL Bibliography


Section 14
Appendix
Templates and Attachments

The following templates and tools are provided to assist your reimbursement efforts related to the use of PROPEL sinus implants. These tools are provided as examples only and are not a recommendation of clinical practice or billing practice. These templates should be customized to describe and apply to each individual patient’s clinical condition.

- Sample procedure description for endoscopic placement of a sinus implant
- Sample Prior Authorization template letter
- Sample First Level Appeal template letter
- Sample Second Level Appeal template letter

The PROPEL sinus implant Instructions for Use (IFU) and FDA Approval Letters are available upon request. Copies of clinical studies listed in the bibliography are also available as needed.
SAMPLE PROCEDURE DESCRIPTION: ENDOSCOPIC INSERTION OF SINUS IMPLANT

The insertion of a drug-eluting sinus implant can be performed immediately following a surgical procedure or in a separate encounter following surgery. During the surgical procedure, diseased or obstructive tissue and bony fragments are removed from the sinus cavity to ensure optimal mucosal contact. Debridement and/or surgical lysis of adhesions may also be required before the implant can be inserted.

Description of Service

Nasal/sinus endoscopy is performed to ensure the sinus cavity is fully anesthetized, inspected and prepared for insertion of the implant. This may require minimal debridement and/or additional removal of diseased or obstructive tissue. Local anesthesia (if applicable) of the sinus cavity is administered using cotton pledgets soaked in lidocaine (or equivalent) and Afrin (or equivalent) solution and placed into the middle meatus and/or against the inferior turbinate and sufficient time is allowed to ensure satisfactory local anesthesia. Sufficient time is allowed to ensure there is no additional bleeding following the surgical procedure, which may require additional bipolar cautery and use of hemostatic sponges or other materials. The hemostatic sponges or other packing materials are removed. The cavity is suctioned of any blood and secretions so as to allow complete endoscopic visualization.

A surgical probe is used to assess proper implant sizing and patient tolerance (if applicable). The middle turbinate is medialized if necessary. The cavity is then assessed endoscopically for the most appropriate implant placement. Using sterile technique, the implant is inspected, compressed (crimped) with a crimper provided with the delivery system, and inserted into the distal tip of the delivery system by the physician. The tip of the delivery system is then inserted in the patient’s nostril and advanced to the sinus cavity under endoscopic visualization. The physician positions the distal tip of the delivery system in the desired location and depresses the plunger of the delivery system to insert the implant. Upon insertion, the implant is designed to exert sufficient radial force to be self-retaining against the mucosa of the surgically enlarged sinus cavity and conforms to that space. Endoscopic instruments (e.g. elevator, cups forceps, ball-tipped seeker or other appropriate instrumentation) are utilized to manipulate the implant into the final position. This requires positioning and re-positioning to ensure accurate placement and mucosal contact. The placement and the implant stability are confirmed under endoscopic visualization. The delivery system is then removed and discarded. Once the implant is in place, the active drug is eluted over an extended period of time (e.g. 30-45 days) directly to the sinus mucosa. Additional patient instruction is required during the post-operative period to ensure appropriate care of the implant.
SAMPLE PRIOR AUTHORIZATION LETTER
[INSERT LETTERHEAD]

[PAYOR NAME]
[APPEAL ADDRESS]

Re: [PATIENT NAME]
[PATIENT IDENTIFIER FOR PAYOR]
[IDENTIFYING DATA – POLICY, GROUP OR CLAIM NUMBER]
[DATE OF BIRTH]

Dear [INSERT INDIVIDUAL, DEPARTMENT OR PAYOR NAME],

I have recommended a [INSERT PROCEDURE DESCRIPTION] for my patient [INSERT NAME]. I have already confirmed this patient’s eligibility for benefits. I am hereby requesting prior authorization for this procedure and pre-determination of payment.

[INSERT DETAILED DESCRIPTION JUSTIFYING APPROVAL OF THIS PROCEDURE AND USE OF PROPEL SINUS IMPLANTS. DESCRIPTION SHOULD INCLUDE CURRENT SYMPTOMS, HISTORY OF PRESENT ILLNESS, RADIOGRAPHIC FINDINGS, PRIOR FAILED THERAPIES, AND CLINICAL NECESSITY FOR PROPEL SINUS IMPLANTS]

Based on the above findings, it is my professional opinion that endoscopic surgical intervention is indicated at this time. I am requesting written prior authorization so that my office can comply with your company’s claims processing requirements.

<table>
<thead>
<tr>
<th>Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD10 Code Description</td>
</tr>
<tr>
<td>[LIST APPLICABLE CODES &amp; DESCRIPTIONS]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Planned Procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT® Code Description Estimated Charges</td>
</tr>
<tr>
<td>[LIST ALL APPLICABLE CODES &amp; DESCRIPTIONS]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS Code Description Estimated Charges</td>
</tr>
<tr>
<td>[LIST APPLICABLE CODE &amp; DESCRIPTIONS] [LIST COST PER IMPLANT WITH APPLICABLE MARK-UP]</td>
</tr>
</tbody>
</table>

Please confirm prior authorization and approval of this procedure.

Sincerely,
SAMPLE REIMBURSEMENT APPEAL LETTER
FIRST APPEAL OF DENIAL BASED ON “INVESTIGATIONAL/EXPERIMENTAL” DETERMINATION

[INSERT LETTERHEAD]

[INSURANCE NAME]
[APPEAL ADDRESS]

Re: [PATIENT NAME]
[ PATIENT IDENTIFIER FOR PAYOR]
[IDENTIFYING DATA – POLICY, GROUP OR CLAIM NUMBER]
[DATE OF BIRTH]

Dear [INSERT INDIVIDUAL, DEPARTMENT OR PAYOR NAME],

This letter is regarding your denial for [SELECT PRIOR AUTHORIZATION/PRE-DETERMINATION OR PAYMENT] of benefits for the use of [PROPEL SINUS IMPLANTS] during a [RECENT/UPCOMING] [INSERT SINUS] sinus surgery procedure performed on the above-referenced patient. According to the denial letter dated [XX/XX/XX], this product has been denied for payment because it has been deemed “investigational.”

I have extensive experience using PROPEL sinus implants and have been very impressed with the clinical outcomes associated with its use. [INSERT DESCRIPTION OF YOUR EXPERIENCE, E.G., NUMBER OF PATIENTS TREATED OR SURGERIES PERFORMED]

My patient, [INSERT NAME] is an ideal candidate for PROPEL sinus implants. [INSERT A BRIEF STATEMENT HERE FOR THIS PATIENT IN PARTICULAR – INCLUDE HISTORY OF PRESENT ILLNESS, PAST SURGERIES, FAILED MEDICAL THERAPIES, CURRENT SYMPTOMS AND ACTIVITY LIMITATIONS. IF POST-SURGERY DENIAL, DESCRIBE THE BENEFITS OF PROPEL SINUS IMPLANTS IN THIS PATIENT]

I am writing to appeal this denial to a higher level of review and to address several misconceptions that may have formed the basis for this coverage decision.

My primary goal in sinus surgery is to remove diseased bone and/or tissue, establish ventilation, facilitate drainage from the paranasal sinuses, create pathways to optimize topical delivery of medications directly to the sinonasal mucosa, restore proper ciliary clearance and reduce inflammatory load by removal of polyps. Topical drug therapy plays a critical role in post-surgical healing. Unfortunately, currently available modalities are not easily or effectively delivered to the target sinus anatomy. Historically, the only available techniques or products available to accomplish these surgical goals were packing materials that prop open the sinus cavities post-ESS, but are not FDA-approved for drug delivery, do not facilitate drainage/ventilation and typically require removal.

The PROPEL sinus implant is the only FDA-approved bioabsorbable drug-eluting ethmoid sinus implant. PROPEL sinus implants serve two critical roles in the post-operative period: mechanical support of the sinus cavity and extended local drug delivery, by virtue of the steroids which are embedded in the polymer layer. The FDA approved PROPEL sinus implants (mometasone furoate sinus implant) in August 2011 for use following ethmoid sinus surgery to maintain patency. The PROPEL Mini sinus implant was
approved by the FDA in March 2016 for use following frontal sinus surgery to maintain patency. Additionally, the PROPEL Contour sinus implant was approved by the FDA in February 2017 for use following frontal and maxillary sinus surgery to maintain patency. The PROPEL sinus implant separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces edema. Clinical experts agree and clinical evidence demonstrates that if persistent inflammation is adequately treated following ESS, the chance of revision surgical intervention is essentially eliminated over a nearly 8-year follow-up period.¹

The clinical benefits of PROPEL sinus implants are summarized in a level 1a meta-analysis by Han et. al.¹ and include a **35% relative reduction in the need for medical/surgical intervention (p = 0.0008), 40% relative reduction in need for oral steroids (p = 0.0023), 51% relative reduction in need for adhesion intervention (p = 0.0016) and 46% relative reduction in frank polyposis (p < 0.0001)**. These benefits of topical steroid delivery with the resulting decrease in surgical interventions and reduction in systemic steroids are very important for all of [INSERT PAYOR NAME'S] patients.

For these reasons, I do not agree with your assessment that PROPEL sinus implants are considered investigational, which implies a lack of evidence to support its value. I believe the level of evidence supporting this product is far greater than any other product used in this setting.

I respectfully recommend your re-assessment of the medical policy, as well as your re-consideration of this request for coverage/payment of PROPEL sinus implants for my patient. Thank you in advance for your thorough review of this information.

Sincerely,

---


SAMPLE REIMBURSEMENT APPEAL LETTER

SECOND APPEAL – LACK OF THOROUGH REVIEW & REQUEST FOR EXTERNAL REVIEW

[INSERT LETTERHEAD]

[INSERT PAYOR NAME]
[INSERT PAYOR ADDRESS]
[INSERT CURRENT DATE]

Re: [PATIENT NAME]
[ PATIENT IDENTIFIER FOR PAYOR]
[ IDENTIFYING INFORMATION FOR PAYOR – GROUP, POLICY OR CLAIM NUMBER]
[DATE OF BIRTH]

Dear [INSERT INDIVIDUAL, DEPARTMENT OR PAYOR NAME],

It is our understanding that the Level 1 Appeal related to the above-referenced patient was denied. Please accept this Level II Appeal of this decision and our request for expert review of this patient’s most up-to-date medical records and the enclosed peer-reviewed literature related to the denied treatment.

Please be advised that this patient’s treatment plan was developed with conscientious consideration for this patient’s unique medical condition and the current standards of quality care for chronic rhinosinusitis. As part of our dedication to offer quality medical care, our medical staff offers the most up-to-date treatment and techniques which are peer-reviewed and rigorously analyzed for safety and efficacy. Your response to our first appeal does not specifically address this literature, nor does it reference literature to refute this evidence, nor does it include an in-depth discussion of this patient’s individual clinical needs.

[INSERT A THOROUGH SUMMARY OF PATIENT’S HISTORY OF DISEASE, INCLUDING DURATION, DIAGNOSTIC STUDIES, PRIOR TREATMENTS ATTEMPTED, SYMPTOMATOLOGY, DISABILITY, ETC. AND RATIONALE FOR USE OF PROPEL SINUS IMPLANTS IN THIS PATIENT]

Attached please find several peer-reviewed publications which document the safety and effectiveness of the use of PROPEL sinus implants in the post-operative management of patients with chronic rhinosinusitis. This data is further described below.

There is a direct correlation between optimal post-surgical healing and long-term clinical outcome following functional endoscopic sinus surgery (ESS). To accomplish this, surgeons need access to a variety of surgical and post-operative tools, including microdebriders, shavers, surgical navigation and various forms of surgical packing/stenting. Topical drug therapy plays a critical role in post-surgical healing. Unfortunately, currently available modalities are not easily or effectively delivered to the target sinus anatomy. Existing packing materials prop open the sinus cavities post-FESS, but are not proven capable of drug delivery, do not facilitate drainage/ventilation and typically require removal. There are a number of complications, mundane to severe, that have been attributed to use of non-absorbable
nasal spacers including bleeding, infection, and aspiration. In fact, “the removal of nasal packing has been described as one of the more uncomfortable and even distressing features linked with sinonasal surgery.”

[SELECT APPROPRIATE PRODUCT] is a unique biodegradable sinus implant which delivers mometasone furoate to the [SELECT APPROPRIATE SINUS] sinus cavity over a period of 30-45 days post-operatively. The implant is constructed in a manner which simultaneously provides structural support to the post-surgical sinus cavity, thereby facilitating return to normal ventilation and allowing delivery of other intranasal and/or intra-sinus medications as needed. This is a great improvement over previous sinus packing materials, which do not offer the same benefits. This also avoids the challenges of oral steroid regimens, which are associated with poor compliance due to their side effects and are restricted in certain patient populations, especially diabetics.

We have used PROPEL sinus implants in many of our patients and have been very impressed with the clinical benefits associated with its use. As is demonstrated in two randomized controlled trials which led to FDA PMA approval in 2011, the use of PROPEL sinus implants is associated with a 35% relative reduction in the need for medical/surgical intervention (p = 0.0008), 40% relative reduction in need for oral steroids (p = 0.0023), 51% relative reduction in need for adhesion intervention (p = 0.0016) and 46% relative reduction in frank polyposis (p < 0.0001).

[PATIENT NAME] [EXPERIENCED/IS ANTICIPATED TO EXPERIENCE] these same benefits as a result of the use of PROPEL sinus implants, including [ELABORATE ON ACTUAL OR POTENTIAL BENEFITS FOR THIS PATIENT].

The current published clinical literature for PROPEL sinus implants irrefutably demonstrates the clinical benefits of this product in this challenging patient population. The two randomized controlled trials used an intra-patient control design (aka split-face design). This is a common study design in ENT because it controls for many variables, including the heterogeneity which exists in this patient population. This study design was evaluated and accepted by the FDA. The treated side received a PROPEL sinus implant, a steroid-coated sinus stent, while the contralateral side received the same stent without a steroid coating. The control side represents standard therapy since standard post-operative therapy generally consists of placing some form of packing/spacing materials. All patients had IV decadron at time of surgery, access to nasal saline irrigation, antibiotics and debridements as needed during the first post-op month and could receive steroids after 30 days as needed.

In these studies, the investigators were all blinded to treatment assignment. Further, an independent panel of physicians reviewed and rated the entire library of individual video endoscopies. This provided a completely blinded assessment of endoscopic outcomes, not only across the patient population but for each individual sinus as well. There was no interaction between the independent panel members and clinical sites. The panel members had only the videos to review and no other patient information was provided except that the videos were taken 30 days post-op. This information was obviously

important clinical data since the independent panel was asked to make a clinical judgment regarding the need for surgical intervention.

It is important to note that most sinus surgeries involve some form of packing or spacing materials. Therefore, it would have been inappropriate to utilize a stent in only one side. The use of the non-drug-coated stent in the contralateral side allowed for study blinding of patients, surgeons and the independent panel of physicians who assessed the need for surgical or medical intervention based on individual video endoscopies. Use of any other control would have resulted in un-blinded outcome assessments. Finally, oral steroids and nasal steroid sprays were permitted one month after surgery, if needed, which is generally consistent with standard post-operative care. Through this design, these studies evaluated whether the ADDITION of local steroid delivery provided a superior benefit to traditional post-operative care alone. These results are reported separately, and in a level 1a meta-analysis by Han et al. In fact, one of these studies was granted the Maurice Cottle Award for Best Clinical Science in 2010 by the American Rhinologic Society.

Numerous other publications describe the clinical value of this technology in post-surgical management of chronic rhinosinusitis patients, including:

In 2014, Parikh et al published an independent review of various products used following sinus surgery. The authors conclude “The biodegradable nature of these implants has eliminated most of the problems associated with metallic and other types of implants.” Similarly, in a review of various biomaterials used in sinus surgery by Cho et al, the authors conclude “absorbable biomaterials reduce the incidence of early postoperative bleeding and formation of adhesions, promoting faster healing of newly-operated, damaged mucosa.”

In a review by Campbell and Kennedy, the authors state the clinical evidence demonstrates implants placed in the ethmoid sinuses at the time of surgery significantly reduce postoperative adhesions, the recurrence of polyposis, middle turbinate lateralization, the need for postoperative oral steroids, and the need for additional postoperative interventions. The authors also highlight that “steroid-eluting sinus implants are unique in that they achieve a local, controlled release of a known dose of steroid whilst also serving to separate healing sinus tissue.”

Han and Lee published a technology evaluation which describes PROPEL sinus implants as a “revolutionary mode of localized drug delivery in CRS.” The authors state “Its utilization enhances wound healing, with diminished need for secondary postoperative medical and surgical interventions. Such novel technology has far-reaching implications, with future indications likely extending beyond the operating room into the clinic setting, to treat CRS patients, with inflammatory exacerbations or recurrent polypoid disease, who would otherwise require additional surgery.”

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A separate publication by Wei and Kennedy reviewed the mode of action and the evidence supporting the efficacy of this steroid eluting implant. The authors review three published clinical trials that demonstrate a mometasone furoate-eluting implant produced statistically significant reductions in inflammation, polyp formation, and postoperative adhesions. The authors state, “Although the placement of steroid-impregnated packing, sponges, and gels has previously been utilized in the postoperative sinus cavities, a mometasone furoate-eluting implant introduces a new mechanism for sustained, localized and controlled delivery of topical therapy directly to the nasal mucosa for CRS.”

Rudmik and Smith published an evidence-based practice review in 2012 evaluating the published evidence for nasal saline irrigations, debridement, topical steroid therapy, off-label topical steroid solutions, systemic steroids, systemic antibiotics, and drug-eluting stents (i.e. PROPEL sinus implants). The authors concluded that “middle meatal drug-eluting stents may significantly improve endoscopic outcomes for medically refractory CRS with nasal polyposis.”

In the recently completed PROGRESS study, PROPEL Mini sinus implants demonstrated superiority in reducing frontal restenosis and the need for post-operative interventions. The PROGRESS study was an 80 patient prospective, randomized, blinded, controlled trial which evaluated outcomes of frontal surgery using balloons and/or traditional instruments with PROPEL Mini sinus implants compared to the standard of care, surgery alone.

The American Rhinologic Society (ARS) published a medical position statement confirming its endorsement of utilization of drug-eluting implants for patients undergoing sinus surgery as follows:

“The American Rhinologic Society 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. Furthermore, 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. There have been a number of well-controlled studies on drug-eluting implants in the paranasal sinuses, specifically implants that release steroids to the local tissues. These studies have demonstrated improvement of patient outcomes by reducing inflammation, decreasing scarring and middle turbinate lateralization and limiting the need for oral steroids. The American Rhinologic Society thus feels strongly that drug-eluting implants are not investigational and should be available to our patients, when selected by the physician, in order to maximize outcomes.”

Similarly, the American Academy of Otolaryngology—Head and Neck Surgery (AAOHNS) published a medical position statement of FDA approved biomaterials to improve patient outcomes and reduce complications as follows:

“The American Academy of Otolaryngology—Head and Neck Surgery 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.”

It is important to note that PROPEL sinus implants are the only biomaterial FDA-approved to reduce complications following sinus surgery procedures.12

I request a specialty matched, board certified Otolaryngologist, who can review the current peer reviewed literature, specialty society opinions, and is able to assess the clinical facts regarding this patient’s situation and render an independent decision.

Thank you for your reconsideration of this coverage decision.

Sincerely,

[ATTACH BIBLIOGRAPHY AND COPIES OF PUBLICATIONS AS NEEDED]

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