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Nasal and Sinus Surgery

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current peer-reviewed scientific literature. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and acceptable standards of medical practice. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0123 (IL HB 1384) Coverage for Reconstructive Services requires the following policies amended, delivered, issued, or renewed on or after January 1, 2025 (Individual and family PPO/HMO/POS; Student; Group [Small Group; Mid-Market; Large Group Fully Insured PPO/HMO/POS] or Medicaid), to provide coverage for medically necessary services that are intended to restore physical appearance on structures of the body damaged by trauma.

Coverage

Nasal and sinus surgery for the procedures listed below **may be considered medically necessary** when the specified criteria are met.

Rhinoplasty

Rhinoplasty with or without septoplasty **may be considered medically necessary** when performed to correct any one of the following:

- Nasal deformity secondary to congenital craniofacial deformity (e.g., cleft lip, cleft palate, or maxillonasal dysplasia); OR
- Significant external nasal pyramid collapse or septal deformity following documented trauma or injury; OR
- Significant deformity following removal of a nasal malignancy, an abscess, or osteomyelitis; OR
- Significant deformity in individuals with documented obstructive sleep apnea.

NOTE 1: Documentation to support medical necessity, as appropriate for the specific procedure being performed, should include **all** of the following:

- Historical medical record documentation of previous injury or trauma; AND
- Historical medical record documentation of symptoms and interventions; AND
- Results of imaging and diagnostic studies; AND
- Operative, laboratory and procedure reports.

Rhinoplasty to repair an external nasal deformity not causing functional impairment **is considered cosmetic.**

Reconstructive Nasal and Sinus Surgery for Congenital or Acquired Functional Nasal Deformities

Nasal surgery performed on the outside or inside of the nose **may be considered medically necessary** when performed as a reconstructive procedure to correct congenital or acquired functional nasal deformities that meets any one of the specific medical necessity criteria for rhinoplasty as listed above.

NOTE 2: This section includes cartilage grafts (e.g., Batten grafts) or skin flap procedures for treatment of symptomatic nasal valve collapse.

Other Nasal and Sinus Surgical Procedures

Procedures that are performed to reshape the normal structures of the nose and improve the appearance, whether performed separately or in combination with another procedure, **are considered cosmetic**. These procedures include:

- Changing the size of the nose; OR
- Changing the shape of the nose; OR
- Narrowing the nostrils; OR
- Changing the angle between the nose and lips.

Cosmetic services that are requested or performed because of psychiatric or emotional problems attributed to the actual or perceived defect being treated **are considered cosmetic**.

Turbinate Resection

Turbinate Resection **may be considered medically necessary** when one of the following clinical criteria are met:

1. Chronic nasal obstruction related to inferior turbinate hypertrophy; AND nasal obstruction/ symptoms unresponsive to medical management (e.g., medications, and/or assessment and treatment for allergies if appropriate); OR
2. Turbinate hypertrophy that prevents surgical access to other intranasal areas when such access is required to perform medical necessary surgical procedures (e.g., septum, sinuses); OR
3. Turbinate hypertrophy in individuals with documented clinically significant obstructive sleep apnea who have failed medical management. (See medical policy 706.009 for criteria and exclusions that may apply).

Septoplasty

Septoplasty **may be considered medically necessary** when any of the following clinical criteria are met:

1. Septal deformity related to nasal airway obstruction resulting in nasal congestion unresponsive to a trial of conservative medical management including the use of any of the following: antibiotics, decongestants, topical nasal corticosteroids, allergy evaluation and therapy, etc.; OR
2. Septal deformity in individuals with documented clinically significant obstructive sleep apnea (See medical policy 706.009); OR
3. Frequent nosebleeds, related to a septal deformity and unresponsive to medical management; OR
4. Asymptomatic deformity that prevents surgical access to other intranasal areas when such access is required to perform medical necessary surgical procedures (e.g., turbinates, sinuses); OR
5. When done in association:
   - With cleft lip/cleft palate repair, or
   - Reduction of facial fractures (e.g., LeFort I, LeFort II), or
   - With orthognathic surgery.

Balloon septoplasty for treatment of septal deviation **is considered experimental, investigational and/or unproven.**

Endoscopic Sinus Surgery, Functional (FESS)

Functional endoscopic sinus surgery **may be considered medically necessary** when medical management has failed or is unavailable for the following diagnoses:

- Chronic sinusitis refractory to medical treatment;
- Recurrent sinusitis;
- Nasal polyposis;
- Antrochoanal polyps;
- Sinus mucoceles;

- Excision of selected tumors;
- Cerebrospinal fluid (CSF) leak closure;
- Orbital decompression (e.g., Graves ophthalmopathy);
- Optic nerve decompression;
- Dacryocystorhinostomy (DCR);
- Choanal atresia repair;
- Foreign body removal; OR
- Epistaxis control.

Nasal Valve Suspension and Radiofrequency Procedures

- Nasal Valve Suspension: Nasal valve suspension as a surgical technique for the repair of nasal valve collapse **is considered experimental, investigational and/or unproven**.
- Radiofrequency Treatment for Nasal Valve Obstruction: The use of radiofrequency to the nasal valve region (e.g., VivAer [Aerin Medical]) for the treatment of nasal airway obstruction **is considered experimental, investigational and/or unproven**.

Drug-Eluting Sinus Implants

Placement of a mometasone furoate sinus implant (Propel®, Propel mini, or Propel contour sinus implant), by a physician trained in otolaryngology, consistent with the U.S. Food and Drug Administration (FDA) device-approved indications for that specific product (See **NOTE 3**) **may be considered medically necessary** in conjunction with an appropriately indicated sinus surgery for that product when the following criteria are met:

- Individual ≥18 years of age; AND
- Documentation of date of sinus surgery required; AND
- Individual had inadequate response, intolerance, or contraindication to medical therapy (e.g., oral antihistamines, intranasal sprays); AND
- Individual has no contraindications to the use of mometasone furoate.

Placement of a mometasone furoate sinus implant (Sinuva), by a physician trained in otolaryngology, consistent with the FDA drug- approved label, **may be considered medically necessary** for the treatment of chronic rhinosinusitis with nasal polyps in patients who have had ethmoid sinus surgery and meet ALL of the following criteria:

- Individual ≥ 18 years of age; AND
- Documentation of date of sinus surgery required; AND
- Individual had inadequate response, intolerance, or contraindication to medical therapy (e.g., oral antihistamines, and intranasal sprays); AND
- Individual has no contraindications to the use of mometasone furoate.

Placement of a mometasone furoate sinus implant **is considered experimental, investigational and/or unproven** in all other situations in which the above criteria are not met.

Repeat Administration

Repeat administration of the mometasone furoate sinus implant device (e.g., Propel®, Propel mini, or Propel contour sinus implant) **is considered experimental, investigational and/or unproven.**

One repeat administration of the mometasone furoate sinus implant drug (e.g., Sinuva) within 12 months **may be considered medically necessary** when ALL of the following criteria are met:

- Individual ≥ 18 years of age; AND
- Documentation of date of sinus surgery required; AND
- Ethmoid sinus polyps grade ≥ 1 on any side.

NOTE 3: See the Policy Guidelines section for indications for the following devices:

- PROPEL Sinus Implant,
- PROPEL Mini Sinus Implant, and
- PROPEL Contour Sinus Implant.

NOTE 4: See the Regulatory Status section of this medical policy for additional information concerning drugs and devices containing mometasone furoate and their indications.

Policy Guidelines

PROPEL Sinus Implant

This device is indicated for use in patients ≥ 18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative interventions such as surgical adhesion lysis and/or use of oral steroids.

PROPEL Mini Sinus Implant

This device is indicated for use in patients ≥ 18 years of age following ethmoid/frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening.

PROPEL Contour Sinus Implant

This device is indicated for use in patients ≥ 18 years of age to maintain patency of the frontal and maxillary sinus ostia following sinus surgery and locally deliver steroids to the sinus mucosa.

Description

Nasal surgery is a grouping term for procedures performed to correct a variety of nasal deformities. A nasal deformity may be external and/or internal. Nasal deformities may be grouped into four categories:

- Congenital: Deformities resulting from developmental anomalies;
- Acquired: Deformities due to trauma, infections, cancer, disease, or previous surgery;

- Aesthetic (Cosmetic): Conditions, exclusive of congenital and/or acquired deformities, for which the patient desires a change in nasal appearance to enhance self-image; and
- Functional: Conditions with impaired nasal breathing unrelated to appearance.

Rhinoplasty
Rhinoplasty is a surgical procedure to alter the appearance of the nose, the width of the nostrils, and/or change the angle between the nose and the upper lip. It is performed alone or in combination with other procedures, such as septoplasty and turbinoplasty, to correct deformities that result from nasal trauma, either acquired or iatrogenic, airway obstruction related to septal and bony deviations, turbinate hypertrophy, or congenital defects.

Reconstructive Nasal and Sinus Surgery for Congenital or Acquired Functional Nasal Deformities
Nasal deformities may be congenital, (e.g., cleft palate) or acquired (e.g., trauma, disease).

Congenital birth defects have a variety of presentations, including cleft nasal deformity, which may be associated with cleft lip and/or cleft palate, where the nasal structures are distorted and abnormally developed. Some congenital abnormalities may not be fully evident until some years later. Surgical correction of congenital birth defects may involve staged procedures, flaps, or grafts. Since the clefts of palate and lip vary considerably in size, shape, and degree of deformity, the planning of the stages of surgery should be individualized. Nasal correction associated with cleft lip/palate may be delayed until adolescence or performed at the time of initial repair. Children with cleft lip and/or palate usually have a deviated nasal septum due to the asymmetric bony base associated with the defect. Initially, the deviation may not cause airway problems due to the facial cleft providing a patent, low-resistance airway passage. As a result of the repair of the facial cleft, the nasal resistance increases, and the deviated septum may then cause nasal airway obstruction.

Acquired nasal deformities may result from disease (i.e., tumors) or trauma (i.e., motor vehicle accidents, sports injuries). These can be repaired with various techniques depending upon presentation.

Turbinate Resection
The nasal turbinates are responsible for warming and humidifying air as it passes through the nasal cavity. There are three pairs of turbinates that are located within the nasal passageway. The turbinates swell and contract to regulate the moisture content in the nasal passageway. The inferior turbinates due to their location, are the first turbinates to come into contact with inhaled air and also have a roll in immune surveillance. The inferior turbinates may become excessively enlarged (hypertrophied) and cause nasal obstruction. There are times when conservative treatment to reduce the nasal obstruction may fail, if this occurs turbinate surgery/resection may be considered.

Septoplasty

The septum is the bone and cartilage within the nasal passageway that divides the two nostrils. A crooked (deviated) septum is not uncommon, however if the septum is very deviated it can obstruct one side of the nose, making it difficult to breathe through that nostril, causing a sensation of nasal blockage. While conservative treatment is available and may relieve symptomatic nasal obstruction enough to prevent surgical intervention, it cannot correct the deviated septum. In the event that conservative therapy has been unsuccessful in relieving symptoms, septoplasty (straightening of the nasal septum) to correct septal deviation may be considered.

Balloon Septoplasty

A proposed treatment for a deviated septum is balloon septoplasty. This purported treatment involves advancing a balloon device into the nasal cavity, inflating the device, then deflating and withdrawing the device.

Endoscopic Sinus Surgery, Functional (FESS)

Techniques for functional endoscopic sinus surgery (FESS), in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. FESS has largely replaced various open techniques for chronic rhinosinusitis (CRS) (e.g., Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (e.g., endonasal tumors).

FESS encompasses a variety of degrees of sinus access and tissue removal and is described based on the sinuses accessed. The Draf classification is used to describe degrees of endoscopic frontal sinusotomy (see Table 1).

Table 1. Draf Classification for Endoscopic Frontal Sinusotomy

Type	Description
Draf I	Anterior ethmoidectomy without altering frontal sinus ostium
Draf IIA	Removal of ethmoid cells that extend into frontal sinus
Draf IIB	Removal of frontal sinus floor between the middle turbinate and the lamina papyracea
Draf III[a]	Removal of frontal sinus floor from orbit to orbit with contiguous portions of the superior nasal septum

[a] Modified Lothrop procedure

This procedure can also be used to access the ethmoid sinuses, which may involve creation of drainage into the maxillary sinuses (maxillary antrostomy).

Nasal Airway Obstruction

Nasal Valve Suspension

Nasal valve collapse is a common cause of nasal airway obstruction. Nasal valve suspension refers to a surgical approach for nasal valve repair that involves attaching a suture to the orbital rim, which is passed through the collapsed valve, then returned to the anchor site at the orbital

rim and tied, thus resulting in a repaired nasal valve that presumably allows for less obstructed airflow.

Radiofrequency Treatment for Nasal Valve Obstruction

The VivAer® Stylus is a disposable, handheld device capable of delivering bipolar radiofrequency energy to tissue. The stylus consists of an array of bipolar electrodes positioned on a non-conductive tip which is attached to a handle via a non-conductive shaft. A temperature sensor is located on the tip to monitor tissue temperature during treatment. The VivAer® Stylus modifies the soft tissues of the nasal airway through the use of low doses of radiofrequency energy. The low-power radiofrequency generates heat within the submucosal tissue, creating a coagulation lesion. As the lesion heals, the tissue retracts and stiffens; decreasing the nasal airflow resistance. (1)

Drug-Eluting Sinus Implants

Endoscopic sinus surgery involves the removal of small pieces of bone, polyps, and débridement of tissue within sinus cavities. There are a number of variations on the specific approach, depending on the disorders being treated and the preferences of the treating surgeon. For all procedures, there is substantial postoperative inflammation and swelling, and postoperative care is, therefore, a crucial component of endoscopic sinus surgery.

There are a number of postoperative treatment regimens, and the optimal regimen is uncertain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity débridement. Several randomized controlled trials (RCTs) have evaluated treatment options, but not all strategies have been rigorously evaluated. (3-6) A 2011 systematic review has evaluated the evidence for these therapies. (2), Reviewers concluded that the evidence was not strong for any of these treatments but that some clinical trial evidence supported improvements in outcomes. The strongest evidence supported use of nasal saline irrigation, topical nasal steroid spray, and sinus cavity débridement.

Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications. (7) Middle meatal spacers are splint-like devices that prop open the sinus cavities post-endoscopic sinus surgery but are not designed for drug delivery. There is some RCT evidence that middle meatal spacers may reduce the formation of synechiae following endoscopic sinus surgery, although the available studies have significant heterogeneity in this outcome. (8)

Drug-eluting sinus implants are another option for postoperative management following endoscopic sinus surgery. These implants are intended to stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They can also be infused with medication that can be delivered topically over an extended period of time, and this local delivery of medications may be superior to topical application in the postoperative setting.

REGULATORY STATUS

Radiofrequency Treatment for Nasal Valve Obstruction

In December 2017, the Vivaer ARC Stylus (K172529) received FDA clearance for the following indications for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area. The Vivaer ARC Stylus was the predicate device for VivAer® Stylus. (9)

In April 2020, the VivAer Stylus (K200300) received FDA clearance for the following indications for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area. (1)

Drug-Eluting Sinus Implants

Sinus Implant Under FDA Device Approvals

In 2011, the PROPEL® system (Intersect ENT, Menlo Park, CA) was approved by the FDA through the premarket approval process (P100044). This device is a self-expanding, bioabsorbable, steroid-eluting stent intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger included with the device. Steroids (mometasone furoate) are released over an approximate duration of 30 days. The device dissolves over several weeks and therefore does not require removal. In 2012, a smaller version of the PROPEL device, the PROPEL Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL Contour sinus implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus. FDA product code: OWO.

Sinus Implant under FDA Drug Approvals

SINUVA™ Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at day 90 or earlier using standard surgical instruments. The SINUVA™ Sinus Implant is indicated for the treatment of nasal polyps in adult patients ≥ 18 years of age who have had ethmoid sinus surgery. In 2023, the indications for Sinuva were revised to include the treatment of chronic rhinosinusitis with nasal polyps in adult patients ≥18 years of age who have had ethmoid sinus surgery. (10)

Rationale

Nasal surgery may be considered reconstructive when performed to alter structure and restore function. It is considered cosmetic when done only to improve appearance. This policy defines the criteria for making this distinction to allow appropriate benefit coverage determinations. Reconstructive nasal surgery is considered medically necessary and therefore eligible for

benefit coverage when specific criteria are met. Cosmetic surgery may be a specific exclusion from benefits and coverage.

Rhinoplasty
Reconstructive surgery is performed on structural abnormalities of the body that are due to congenital or developmental anomalies, trauma, infection, tumors, or disease. The goal is to improve function and restore or approximate normal structure that is necessary to achieve improved function. In many cases the shape of the inside of the nose, mainly the septum which separates the nostrils, prevents adequate air passage, impeding proper breathing. In other cases, the shape of the nose may become deformed due to disease or trauma resulting in blocked nasal passages. Rhinoplasty is medically indicated when these conditions exist. When rhinoplasty is performed primarily to alter the external appearance of the nose (cosmetic purpose), the procedure has no medical benefit and is considered not medically necessary.

Balloon Septoplasty
No published studies could be identified for the use of a balloon device for septal deviation.

Endoscopic Sinus Surgery, Functional (FESS)
Rhinosinusitis Refractory to Medical Therapy
Patel et al. (2017) conducted a systematic review of cohort and crossover studies to compare appropriate medical therapy with endoscopic sinus surgery in adults with chronic rhinosinusitis (CRS) who had undergone at least 3 weeks of antibiotics, with or without corticosteroids (Table 2). (11) Six observational or crossover studies were selected; no randomized controlled trial (RCT)s were available for analysis. Included in the meta-analysis were studies by Smith et al. (2011, n=130), Smith et al. (2014, n=31), and Luk et al. (2015, n=212). In Smith et al. (2011) patients self-selected continued medical therapy (n=55) or surgical therapy (n=75). Smith et al. (2014) was a crossover study of patients who failed medical therapy. Luk et al. (2015) included 40 patients in their medical cohort and 152 patients in their surgical cohort.

For the pooled analysis of disease-specific quality of life (QoL) measures, the 2 studies by Smith et al. (2011, 2014; n=180 patients) were included. The studies used different outcome measures, the Rhinosinusitis Disability Index and Sino-Nasal Outcome Test (SNOT)-22, and were therefore pooled using the standardized mean difference. There was significant heterogeneity ($p<0.001$, $I^2=97\%$) but both studies favored surgery. For the pooled analysis of endoscopic grading scores, 2 studies by Smith et al. and Luk et al. (n=241 patients) were combined, again with significant heterogeneity ($p=0.004$, $I^2=88\%$). Mean scores in both studies favored surgery. For missed days of work, there was no significant difference between the medical therapy and surgical groups (the same 3 studies). Other studies assessed olfaction, health utility quality of life, and economic impact. No studies evaluated adverse events. A limitation of the cohort studies included in this systematic review is the lack of comparable groups; patients who selected surgery had lower disease-specific quality of life at baseline.

Table 2. Systematic Review and Meta-analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration

Patel et al. (2017) (11)	2005-2016	6	Patients with CRS who had undergone ≥ 3 weeks of antibiotics, with or without corticosteroids, and received continued medical therapy or surgery	(31 to 280)	Analysis of prospective cohorts and crossover studies that compared surgery to continued medical therapy. Meta-analysis was conducted on 3 studies.	6- to 12-month follow-up

CRS: chronic rhinosinusitis.

Other systematic reviews with meta-analyses have summarized pre- and post-data from cohort studies, finding improvements in sleep quality (12), fatigue (13), and SNOT-22 outcomes (14) following FESS. However, these systematic reviews did not describe whether patients included in the primary studies had failed maximal medical therapy, limiting their interpretation. Criteria for "maximal medical therapy" used before endoscopic sinus surgery is attempted have been reported in a minority (21%) of published studies of FESS. (15) The criteria used vary across studies, but studies that have reported specific criteria most often report using topical steroids (91.4%; mean duration, 8.4 weeks) and oral antibiotics (87.7%; mean duration, 23 days) systemic corticosteroids (61% mean duration 18 days), saline irrigations (39%), oral antihistamines (11%), oral mucolytics (10%), and topical/oral decongestants (10%).

Randomized Controlled Trial

Ragab et al. (2004) reported on the results of an RCT comparing medical management to FESS in 90 patients who had CRS, with or without nasal polyposis, who had failed initial medical management (6-week regimen of a corticosteroid spray and an alkaline nasal douche). (16) Eligible patients had 1 of the following: 8 or more weeks of persistent signs and symptoms and signs at least 2 major or 1 major and 2 minor symptoms (major: nasal congestion obstruction, nasal discharge, facial pain or pressure, headache, olfactory disturbance; minor: fever, halitosis [97% of patients]) or 4 episodes per year of recurrent acute rhinosinusitis each lasting at least 10 days in association with persistent changes on computed tomography. Patients who had persistent symptoms and changes in computed tomography scan following initial medical therapy were randomized to a FESS group, which received FESS performed by 1 of 2 surgeons, or to a medical therapy group, which received a 12-week course of oral erythromycin, alkaline nasal douche, and topical nasal corticosteroids.

Both patient-reported (SNOT-20, SF-36 and VAS) and objective (nasal examination with scoring, acoustic rhinometry, saccharine clearance time, total nasal nitric oxide levels) outcomes were used, without blinding of outcome assessment. At 6- and 12-month follow-up visits, both groups demonstrated significant improvements in subjective outcomes, with no significant between-group differences. For example, the percent change in visual analog scale (VAS) score at 6 months was 49.7% in the FESS group compared with 45.3% in the medical therapy group ($p>0.05$). There were no significant differences between the 2 groups in the change in SNOT-20 or SF-36 scores or in any objective measurements at 6- or 12-month follow-up visits, with the exception of total nasal volume at 6 months in patients without polyposis (mean percent change from baseline, 21.8% in the FESS group vs 3.2% in the medical therapy group; $p<0.01$).

Non-Randomized Comparative Study

A National Institutes of Health-funded multicenter study by Mattos et al. (2021) evaluated improvements in olfactory function in patients undergoing FESS after failed medical therapy. (17) Pre- and postoperative scores of 113 patients from "sniffin' stick pens" were compared with 164 non-affected volunteers of similar age and gender. Secondary outcomes included the Questionnaire of Olfactory Dysfunction (QOD) and olfactory cleft endoscopy scores. Threshold, discrimination, identification (TDI) scores pre-operatively were 6.8 (95% CI, 4.9 to 8.7) points lower than controls. There was an improvement of 3.7 (95% CI, 2.2 to 5.2) points postoperatively, with post-operative TDI scores of 25.7 (8.6 standard deviation) compared to 28.8 (7.0 standard deviation) in controls. Secondary outcomes showed similar improvements, and about half of patients had post-operative scores that were at least as good as the controls. Multivariate regression found decreased odds of improvement in patients with nasal polyposis and previous FESS, while septoplasty increased the odds of improvement.

Nasal Polyposis

Alobid et al. (2005) reported on an RCT comparing FESS with oral steroids for individuals who had nasal polyposis, with a focus on nasal symptoms, polyp size, and QoL. (18) Eligible patients had nasal polyposis, defined by the presence of both of the following: visualization of polyps under endoscopic examination and bilateral opacification of paranasal sinuses on computed tomography scan. Patients were randomized to 14 days of oral prednisone (n=52) or to FESS (n=56). All patients received 1 year of intranasal budesonide for 12 months. Symptoms were patient-reported on a 0-to-3 scale, while nasal polyp score was endoscopically assessed on a scale ranging from 0 to 3. At the 6- and 12-month follow-ups, patients in both groups reported improvements in nasal symptoms. At six months, the FESS group had greater improvements than the medical therapy group in nasal symptom scores (1.6 for FESS vs 1.2 for medical therapy, $p<0.05$), loss of smell scores (0.9 for FESS vs 0.5 for medical therapy, $p<0.05$), and polyp size score (2.3 for FESS vs 0.8 for medical therapy, $p<0.05$).

Antrochoanal Polyps

Eski et al. (2012) reported on 41 patients (24 males, 17 females; mean age 34.7 years; range 14 to 78 years); between January 2002 and December 2009, the data was retrospectively analyzed. (19) Patients were divided into two groups according to treatment modality: group 1

included 26 patients who underwent endoscopic sinus surgery alone and group 2 included 15 patients who underwent endoscopic sinus surgery in combination with Caldwell Luc procedure. Both groups were compared for recurrence and complication rates. The following results were reported; 17 of 41 patients were diagnosed with right-sided lesions, while 24 patients had left-sided lesions. Recurrence was seen in three patients, including two were in the group 1 and one was in the group 2. There was no statistically significantly difference between the groups in terms of recurrence and complication rate ($p>0.05$). Mean follow-up was 50.5 months (range 15 to 94 months). The authors concluded that the current approach for the treatment of antrochoanal polyps is endoscopic sinus surgery. However, combined approaches should be performed to avoid recurrences, unless removal of antral part of the antrochoanal polyp completely by endoscopic resection is possible. Selection of the combined techniques depends on the surgeon familiarity with the procedure and whether the patient is pediatric case. Combined approach with Caldwell Luc is a safe procedure in adults.

Sinus Mucoceles

In 2013, Scangas et al. performed a retrospective chart review on 102 patients with a total of 133 paranasal sinus mucoceles. The authors were characterizing the natural history, clinical characteristics, management principles and outcomes of paranasal sinus mucoceles. Results the authors included noted patients were diagnosed with a mucocele on average 5.3 years following prior functional endoscopic sinus surgery (FESS), 17.7 years following prior paranasal sinus trauma, and 18.1 years following prior open sinus surgery. The most common sites were the frontal, frontoethmoidal, and ethmoid sinuses. (20) Fifty-seven mucoceles (44.9%) had intraorbital extension, intracranial extension, or both. Out of 133 mucoceles, 114 underwent endoscopic sinus surgery without complication. The authors concluded that the length of time between prior surgery or trauma and mucocele presentation highlights the importance of long-term follow-up in both patient care and in the understanding and reporting of surgical outcomes. In this study, most patients exhibited nonspecific symptomatology despite extensive mucoceles and a significant incidence of orbital and skull-base erosion. The endoscopic approach can be safely used for the management of such lesions.

Excision of Selected Tumors

In 2016 Selleck et al. in a review in the management of frontal sinus tumors, noted that the most common primary tumors of the frontal sinus are osteomas and inverted papillomas, although a variety of other tumors involving this space have been reported. (21) With the advent of new surgical techniques and instrumentation, an endoscopic approach to this region has become feasible. The preoperative assessment and decision making must take into account the complexity of frontal sinus anatomy, tumor type, tumor location, and associated attachments. These procedures allow adequate visualization, tumor removal, and postoperative monitoring, and preserve fairly normal sinus function. Open techniques may also be required and should be in the surgeon's armamentarium.

Other authors have reported on endoscopic approaches for Pituitary Adenoma (Pablo 2019) (22) and (Pinar 2015) (23); and endoscopic sinus surgery on the quality of life of patients with early nasopharyngeal carcinoma (Si 2017). (24)

Other Indications

Review of literature identified articles addressing use of endoscopic sinus surgery for repair of cerebrospinal fluid rhinorrheoea (Sharma 2015) (25), follow-up of patients with thyroid eye disease treated with endoscopic orbital decompression (Gulati 2015) (26), endoscopic surgical decompression in traumatic optic neuropathy (Dhaliwal 2016) (27); Endoscopic dacryocystorhinostomy for acquired nasolacrimal duct obstruction (Saratziotis 2014) (28); repair of bilateral congenital choanal atresia (Eladi 2016) (29) as well as consensus recommendations from the International Pediatric Otolaryngology Group on the Diagnosis, pre-operative, operative and post-operative pediatric choanal atresia care (Moreddu 2019) (30); foreign body removal (Aukstakalnis 2018) (31); and epistaxis control (Cassano 2010) (32).

Nasal Airway Obstruction

Nasal Valve Suspension

Most of the articles that could be located regarding nasal valve suspension were anecdotal in nature. Two small nonrandomized pilot studies reported subjective self-assessment data included in the results and included no long-term outcome data. (33-36)

Radiofrequency Treatment for Nasal Valve Obstruction

Seren (2009) reported on a prospective study to describe a technique for internal nasal valve collapse using radiofrequency-induced thermotherapy on 28 patients with nasal obstruction due to inspiratory nasal valve collapse. (37) The main measure of outcome was the visual analog scale score (VAS). The severity of obstruction scores improved in all patients with the mean score improving at the left nostril from 8.2 before treatment to 3.4 after treatment and at the right nostril from 8.9 before treatment to 4.1 after treatment. The outcomes were measured using visual analog scale score before treatment and at 16 weeks after treatment. Improvement was shown in severity of obstruction ($P < .001$). The author concluded that the new method appears to be safe, quick, bloodless, and painless. These good, encouraging preliminary results must be confirmed by further study and long-term follow-up.

In a prospective study to evaluate the safety and efficacy of Vivaer system for the treatment of narrowed nasal valves and to measure changes in the symptoms of nasal obstruction and snoring, Brehmer et al. (2019) evaluated 31 patients presenting form September 1, 2017 to May 1, 2018. (38) Participants had the following symptoms: nasal obstruction and snoring. All patients had an improvement in nasal breathing measured by Nasal Obstruction Symptom Evaluation (NOSE) score, sleep quality by Snore Outcomes Survey (SOS) questionnaire and quality of life as measured by EQ-5D and SNOT-22. Some of the limitations addressed in the study include absence of a placebo group (non-treatment group), short follow-up period (average 3 months); some of the strengths noted in the study include: prospective study design since many studies investigating the effectiveness in the improvement of nasal breathing are retrospective studies, use of a validated questionnaire such as NOSE and SNOT 20-other studies only have a VAS as the measuring instrument. Conclusions noted were Vivaer intranasal remodeling can provide a durable and well-tolerated non-invasive treatment for those patients who are suffering congestion due to narrowness or collapse of the internal nasal valve.

In a prospective, nonrandomized, multicenter case series, Jacobowitz et al. (2019) reported on the safety and effectiveness of an in-office bipolar radiofrequency treatment for nasal valve obstruction. (39) Patient selection included: adult patients with a NOSE score ≥60. Patients were clinically diagnosed with dynamic or static internal nasal valve obstruction as primary or significant contributor to obstruction and were required to have a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral radio-frequency treatment was applied intranasally using a novel device, under local anesthesia in a single session. Safety and tolerance were assessed by event reporting, inspection, and Visual Analogue Scale (VAS) for pain. Efficacy was determined using the NOSE score and patient-reported satisfaction survey at 26 weeks. Fifty patients received treatment. No device or procedure-related serious adverse events occurred. Soreness, edema, and crusting resolved by 1 month. The mean baseline NOSE score was 79.9 (SD 10.8, range 60-100), and all had severe or extreme obstruction. At 26 weeks, mean NOSE score was 69% lower at 24.7 (P< .0001) with 95% two-sided confidence intervals 48.5 to 61.1 for decrease. The decrease in NOSE score did not differ significantly between patients who did or did not have prior nasal surgery. Patient satisfaction mean by survey was 8.2 of 10. The authors noted the weaknesses and strengths of the study and included its uncontrolled, nonrandomized, unblinded design which can be prone to selection bias. The NOSE score is a validated outcome tool but consists of subjective reporting. While placebo effect cannot be excluded, the high magnitude of response is supportive for a true clinical response. The study was limited to 50 patients. The authors further note: A placebo-controlled study with a larger and more diverse population would be desirable. Also, the endpoint analysis was performed at 26 weeks postprocedure, thus relatively short term. Follow-up for outcome over several years is needed to assess longevity of the patients' outcome.

Ephrat et al. (2020) reported on 2-year results from a multicenter prospective clinical trial of 39 adult patients from an original cohort of 49 patients with severe to extreme NOSE Scale scores and dynamic or static internal nasal valve obstruction. (40) Patients received intranasal bilateral radiofrequency treatment in a clinical study with a follow-up to 6 months, and were prospectively evaluated at 12, 18, and 24 months at 8 community-based otolaryngology practices. The patient-reported NOSE Scale score and 21 QoL questions were assessed. Results reported included: Clinically significant improvement from baseline in NOSE Scale score change demonstrated at 6 months (mean, 55.9; standard deviation [SD], 23.6; $p < 0.0001$) was maintained through 24 months (mean, 53.5; SD, 24.6; $p < 0.0001$). Responders (≥15-point improvement) consisted of 92.3% of participants at 6 months and 97.2% at 24 months. Responses to the QoL questions also showed improvement in patients' QoL. The authors concluded that the treatment of the nasal valve with an in-office, transnasal temperature-controlled radiofrequency procedure was associated with stable and lasting improvement in symptoms of nasal obstruction and QoL through 24 months in this noncontrolled, single-arm study.

Jacobowitz et al. (2022) reported on the 48 months follow-up in a cohort of patients from Ephrat et al. (2020) study noted above. The initial study was a prospective, single-arm multicenter study that enrolled patients with chronic severe nasal obstruction with nasal valve

collapse identified as the primary cause of obstruction. (41) Patients with prior nasal valve surgery or other surgical nasal procedures within the past 12 months were excluded. Medication use was not controlled during the study, but patients were medically treated before surgery. Patients underwent bilateral treatment with a Vivaer device (Aerin Medical). Extended follow-up assessments included use of the validated Nasal Obstruction Symptom Evaluation (NOSE) scale score, completed in person, by telephone, or through mail at 36 and 48 months postprocedure. Responders included patients with a decrease of ≥15 points on NOSE score. Results noted of the 49 patients in the initial study, 39 agreed to participate in follow-up through 24 months; and of these, 29 patients agreed to extended follow-up through 48 months (five declined participation, three did not respond to the invitation, and two had a surgical procedure for nasal airway obstruction and were ineligible to continue). Demographic and baseline characteristics were presented for initial and long-term follow-up cohorts, including those who declined to participate. Compared with baseline, mean total NOSE scores significantly improved after treatment and were maintained throughout the 48 months. Limitations noted for this study include use of a single-arm design without randomized control, no control of medication usage, and significant patient attrition relative to the primary study.

Silvers et al. (2021) reported on a prospective, multicenter, single-blinded, randomized controlled trial (RCT), patients were assigned to bilateral temperature-controlled RF treatment of the nasal valve (n = 77) or a sham procedure (n = 41), in which no RF energy was transferred to the device/treatment area. (42) The device was applied to the mucosa over the lower lateral cartilage on the lateral nasal wall. The primary endpoint was responder rate at 3 months, defined as a ≥20% reduction in Nasal Obstruction Symptom Evaluation (NOSE)-scale score or ≥1 reduction in clinical severity category. Results included: At baseline, patients had a mean NOSE-scale score of 76.7 (95% confidence interval [CI], 73.8to 79.5) and 78.8 (95% CI, 74.2 to 83.3) ($p = 0.424$) in the active treatment and sham-control arms respectively. At 3 months, the responder rate was significantly higher in the active treatment arm (88.3% [95% CI, 79.2%-93.7%] vs 42.5% [95% CI, 28.5%-57.8%]; $p < 0.001$). The active treatment arm had a significantly greater decrease in NOSE-scale score (mean, -42.3 [95% CI, -47.6 to -37.1] vs -16.8[95% CI, -26.3 to -7.2]; $p < 0.001$). Three adverse events at least possibly related to the device and/or procedure were reported, and all resolved. Limitations and strengths noted by the authors included: Physicians were not blinded to treatment-arm assignment, which may have been a source of bias, but this was mitigated by patient blinding and use of patient-reported outcome measures (i.e., NOS scale, ease-of-breathing VAS, pain VAS). Results reported were through 3 months.

Han et al. (2022) reported on 12 month follow-up to the individuals addressed in the Silvers (2021) study noted above; NCT04549545. This was a cohort follow-up of a prospective, single-blinded (patient) RCT with a sham procedure control arm. The design was a superiority trial with crossover available to eligible sham control-arm patients after 3-month follow-up and primary end point analysis. The objective of the trial was to determine if active treatment of the nasal valve with a temperature-controlled radiofrequency (TCRF) device, previously demonstrated superior to a sham procedure at 3 months, was safe and associated with sustained improvements in symptoms of nasal airway obstruction through 12 months. (43) The

combined active treatment group contains patients from the index active treatment arm and the crossover active treatment arm. Initially, a total of 108 patients received active treatment (77 as index active treatment, 31 after crossover). At 6 months the total of 100 individuals were analyzed and at 12 months the total analyzed was 88 individuals. Outcome instruments used were the NOSE Scale and the Epworth Sleepiness Scale. The primary end point measure was responder rate, defined as 20% or greater reduction in NOSE Scale score or 1 or greater reduction in NOSE Scale clinical severity category. At 12 months (n = 88), the responder rate was 89.8% (95% CI, 81.7%-94.5%). The NOSE Scale score improved from baseline (mean change, -44.9 [95% CI, -52.1 to -37.7]). No device/procedure-related serious adverse events were reported. Some limitations noted by the authors included medication use was not dictated by the protocol and could potentially have had some confounding effect on symptom relief; however, an overall decrease in medication use was observed. The results reported here are through 12 months, and although consistent with previously reported data for this technology, continued follow-up in this trial will provide additional data on the longer-term durability of effect. The authors note that the trial will continue follow-up through 2 years.

Silvers et al. (2024) reported on the two-year outcomes for 108 patients (NCT04549545), all patients who underwent active treatment (index active treatment patients and treated crossover patients) were collapsed into a single analysis group for follow-up from 3 months through 2 years. (54) A responder was defined as ≥20% reduction in NOSE score or ≥1 reduction in severity class. The 2-year responder rate was 90.4% and NOSE score treatment effect was -41.7; 54.7% improvement. Of 57 patients using medications/nasal dilators at baseline, 45 (78.9%) either stopped all use (33.3%) or stopped/decreased (45.6%) use in ≥1 class at 2 years. Throughout the 2 years, 15 patients were lost to follow-up, 8 withdrew, and 12 had an additional nasal procedure. Of the 23 patients lost to follow-up/withdrawn, 19 (82.6%) had an improvement in NOSE score from baseline and 15 (65.2%) were responders at their last trial visit. Three patients had their additional nasal procedures between 1 and 2 years (the rest were prior to 1 year), all of which were trial responders before the additional procedure: 1 patient had balloon sinuplasty for chronic sinusitis, 1 patient had bilateral functional endoscopic sinus surgery, and 1 patient had a bioabsorbable implant for nasal airway obstruction, drainage, and pressure and also underwent TCRF ablation of the posterior nasal nerve for chronic rhinitis. The authors concluded TCRF device treatment of nasal valve dysfunction resulted in significant and sustained improvements in the symptoms of nasal airway obstruction at 2 years, accompanied by a substantial reduction in medication/nasal dilator use. Limitations noted included patient attrition, medication/nasal dilator use was not dictated by protocol, and The NOSE score is a patient-reported outcome measure, which is considered subjective.

Yao et al. (2023) reported on the two-year outcomes of a prospective, single-arm, multicenter study in patients >18 years with nasal airway obstruction due to nasal valve collapse. (44) Nasal Obstruction Symptom Evaluation (NOSE) Scale score ≥60. Patients were treated in the nasal valve region with a temperature-controlled radiofrequency (TCRF) treatment device and followed through 2 years. A responder was defined as a patient ≥20% reduction NOSE Scale score or ≥1 severity class improvement from baseline. A total of 122 patients were treated and 91 reached 2 years. The mean baseline NOSE Scale score was 80.3 (95% CI, 78.1–82.6). The

adjusted mean change in score at 2 years was -45.8 (95% CI, -53.5 to -38.1), p < 0.001; a 57.0% improvement. The 2-year responder rate was 90.1% (95% CI, 82.3%–94.7%). The authors noted that non-blinded, single-arm studies may contribute bias, however this study employed a before-and-after design using a validated patient reported outcome measure (i.e., NOSE Scale score) rather than physician assessments to assess symptoms before and after treatment to mitigate such bias.

Systematic Reviews and Meta-analyses

Casale et al. (2023) performed a systematic review and meta-analysis. Two researchers independently reviewed the literature up to December 2021. (55) Studies on patients seeking treatment for nasal obstruction due to nasal valve collapse were included in the analysis. Four studies (218 patients) met the inclusion criteria and treated the nasal valve regions bilaterally with the Aerin Medical Vivaer™ System. After the treatment, the NOSE score was reduced at three months postoperatively. Minor adverse events were reported in the included studies, and two showed no complications. None of the studies reported changes in the external appearance of the nose. The authors noted an essential advantage of this minimally invasive technique is the possibility of performing the procedure both in the operating room with septoplasty and/or turbinate surgery, and in the clinic setting as a stand-alone procedure or in conjunction with turbinate reduction. Additionally, the authors noted given the moderate heterogeneity of the results and the limited number of studies investigating small populations with short follow-up periods, the outcomes of this review must be considered with caution. More extensive comparative studies and well-designed randomized clinical trials with validated patient-reported outcome measures are required to provide more definitive recommendations.

Han et al. (2024) performed a systematic review and meta-analyses comparing TCRF of the nasal valve with surgical techniques. (56) Of 2529 initial articles, 5 studies describing TCRF treatment and 63 studies describing functional rhinoplasty were included. The authors noted the results of their systematic review and meta-analyses showed outcomes for TCRF treatment of the internal nasal valve were comparable to functional rhinoplasty in terms of effect size and durability through 12 months. Additionally, the authors noted the wide variety of included studies and techniques also resulted in high heterogeneity scores with the included studies being of moderate to poor quality due to many factors – both of which must be taken into account when interpreting the outcomes of these meta-analyses.

<u>ECRI</u>

In 2024 ECRI provided a clinical evidence assessment on Vivaer Nasal Airway Remodeling Stylus for treating nasal airway obstruction, and noted the evidence was “Favorable”. (59) Information noted in the Conclusions included that Vivaer improves nasal breathing and quality of life and reduces nasal obstruction symptoms at 3-month and up to 24-month follow-up for patients with NAO [nasal airway obstruction], based on evidence from a randomized controlled trial (RCT) and additional pre-/post-treatment studies. However, a systematic review (SR) that indirectly compared Vivaer with functional rhinoplasty procedures and nasal valve surgery, and the majority of studies included in the SR, provided very-low-quality evidence and do not

enable conclusions about Vivaer's comparative effectiveness. Comparison studies with appropriately matched patients that account for patient prognosis or studies making head-to-head comparisons are needed.

Section Summary: Radiofrequency Treatment for Nasal Valve Obstruction

Several studies included a small number of participants or short follow-up times. Two studies had longer term follow-up data; in one study 48 months of follow-up was reported on 29 patients, and in the other study, 2 year follow-up was reported on 91 patients. Non-blinding was noted in several studies as possible source of bias; however the authors noted the use of a before and after design using a validated patient reported outcome measure was used to mitigate such bias. In another two-year follow-up of a cohort of 108 participants was reported, 23 patients were lost to follow-up/withdrawn and 12 had an additional nasal procedure. Two-year responder rate was 90.4% and NOSE score treatment effect was -41.7; 54.7% improvement; a substantial reduction in medication/nasal dilator use was noted. Two systematic reviews and meta-analyses were reported on. In one, the authors noted that temperature-controlled radiofrequency treatment of the internal nasal valve for nasal valve dysfunction was associated with sustained effects comparable to functional rhinoplasty addressing the nasal valve only, rhinoplasty without concomitant turbinate treatment, and all rhinoplasty. In the other, it was noted that radiofrequency treatment using the Vivaer device can be useful for treating nasal valve collapse, improving significantly subjective breathing symptom scores. In one meta-analysis article the authors noted given the moderate heterogeneity of the results and the limited number of studies investigating small populations with short follow-up periods, the outcomes of this review must be considered with caution. In the other meta-analysis, the authors noted the wide variety of included studies and techniques also resulted in high heterogeneity scores with the included studies being of moderate to poor quality due to many factors – both of which must be taken into account when interpreting the outcomes of these meta-analyses. At this time, the evidence for treatment of nasal valve obstruction due to nasal valve collapse with radiofrequency is insufficient to determine the effects of the technology on health outcomes.

Steroid-Eluting Sinus Implants

Steroid-Eluting Implants under FDA Device Approvals as an Adjunct to ESS

Randomized Controlled Trials

RCTs are shown in Tables 3 and 4. There are 4 RCTs of the PROPEL, PROPEL mini, and PROPEL Contour steroid-eluting sinus stents, all sponsored by the device manufacturer (Intersect ENT). These trials used an intrapatient control design, with each patient receiving a drug-eluting stent on 1 side and a non-drug-eluting stent or medical treatment on the other via random assignment.

The two trials of PROPEL for the ethmoid sinus had similar designs. (45-46) Both compared an implant that is steroid-eluting with an identical non-steroid-eluting implant. Thus, these trials tested the value of drug delivery via a stent. The primary efficacy outcome in Murr et al. (2011) was degree of inflammation rated by the treating physician. (45) In Marple et al. (2012) the primary outcome was reduction in the need for postoperative interventions at day 30

postprocedure. (46) A panel of 3 independent experts, blinded to treatment assignment and clinical information, viewed the endoscopic results and determined whether an intervention was indicated. The need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm and in 46.9% in the non-steroid-eluting arm (p=0.028). The reduction in interventions was primarily driven by a 52% reduction in lysis of adhesions (p=0.005). The primary safety hypothesis was met, because there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period postprocedure.

The RCTs by Smith et al. (2016) and Luong et al. (2017), implanted either a PROPEL Mini Sinus Implant or a PROPEL Contour Sinus Implant in the frontal sinus with a control of surgery alone on the contralateral side. (47, 48) The primary outcome was the need for postoperative intervention (e.g., surgery or steroids) determined by an independent blinded physician. Both trials showed a reduction in the need for additional surgical intervention by approximately 22%, with no adverse effects of treatment. The number needed to treat was 4.7 to prevent 1 patient from undergoing postoperative intervention. (48) No stent-related adverse events were noted.

Table 3. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Participants	Interventions	
				Active	**Comparator**
Murr et al. (2011) (45)	U.S.	4	38 patients with refractory CRS	Unilateral PROPEL steroid-eluting stent in the ethmoid sinus	Non-drug-eluting stent on the contralateral side
Marple et al. (2012) (46) (ADVANCE II)	U.S.	11	105 patients with refractory CRS	Unilateral PROPEL steroid-eluting stent in the ethmoid sinus	Non-drug-eluting stent on the contralateral side
Smith et al. (2016) (47)	U.S.	11	80 patients with CRS who were scheduled to undergo primary or revision bilateral frontal sinusotomy	Unilateral PROPEL Mini Sinus Implant in the frontal sinus	Surgery alone on the contralateral side
Luong et al. (2017) (48)	U.S.	12	80 patients with CRS who were scheduled to	Unilateral PROPEL Contour Sinus Implant in the frontal sinus	Surgery alone on the contralateral side

			undergo primary or revision bilateral frontal sinusotomy		

ADVANCE II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants; CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

Table 4. Summary of Key RCT Results

Study	**Primary Outcome Measure**	**Polypoid Changes**	**Adhesions /scarring**		**Implant-Related Adverse Events**
Murr et al. (2011) (45)	**Degree of Inflammation at 21 Days Post-Procedure (100mm VAS)**				
N	37	37			
PROPEL steroid-eluting Stent		18.4%	5.3%		
Non-steroid-eluting stent		36.8%	21.1%		
Diff	18 points				
p-value	NR	0.039	0.03		
Marple et al. (2012) (46)	**Need for Post-Operative Intervention Determined by 3 independent Reviewers**				
N	91				
PROPEL steroid-eluting Stent	33.3%				
Non-steroid-eluting stent	46.9%				
Diff	13.6%				
p-value	0.028				
Smith et al. (2016) (47)	**Need for Post-Operative Intervention at 30**	**Need for Post-Operative**		**Occlusion/ Restenosis**	

	Days (Independent Reviewer) n (%)	Intervention at 90 Days		Rate at Day 30	
N	67 (adequate video for independent review)	79			
PROPEL mini-sinus steroid-eluting stent	26 (38.8%)			16 (21.1%)	none
SOC without a stent	42 (62.7%)			35 (46.1%)	
p-value	0.007	0.013	0.023	<0.001	
Luong et al. (2017) (48)	**Need for Post-Operative Intervention at 30 Days (Independent Reviewer) n (%)**	**Need for Surgical Intervention at 30 Days (Independent Reviewer n (%)**		**Occlusion/ Restenosis Rate at Day 90**	
N	61	58		69	
PROPEL Contour steroid-eluting stent	7 (11.5)	4 (6.9)		16 (23.2)	
SOC without a stent	20 (32.8)	15 (25.9)		28 (40.6)	
Diff (95% CI)	21.3% (35.1% to 7.6%)	19.0% (32.8% to 5.1%)		−17.4% (−28.6% to −6.1%)	
NNT	4.7				
Summary	Range 13.6% to 23.9%				

CI: confidence interval; Diff: difference; NNT: number needed to treat; NR: not reported; RCT: randomized controlled trial; SOC: standard of care; VAS: visual analog scale.

Subsection Summary: Sinus Implant under FDA Device Approvals as an Adjunct to ESS

The most direct evidence relating to use of steroid-eluting nasal stents as an adjunct to ESS comes from 4 RCTs comparing steroid-eluting stents with either a non-steroid-eluting stent or medical management. The need for post-operative intervention at 30 days was reduced by 14% to 24%, translating to a number needed to treat of 4.7 or more.

Steroid-Eluting Implant for Recurrent Polyposis

Two sham-controlled RCTs, RESOLVE (A Randomized, Controlled, Blinded Study of Bioabsorbable Steroid-eluting Sinus Implants for In-office Treatment of Recurrent Sinonasal

Polyposis) and RESOLVE II (A Phase 3 Trial of Mometasone Furoate Sinus Implants for Chronic Sinusitis with Recurrent Nasal Polyps) with a total of 400 patients have addressed outcomes after placement of steroid-eluting absorbable sinus stents in the office setting due to recurrent or persistent nasal polyposis after ESS (see Tables 5 and 6). (49-51)

In RESOLVE, for endoscopically measured outcomes, at 90 days of follow-up, the treatment group had a greater reduction in polyp grade than the control group (-1.0 vs. -0.1; p=0.016) and a greater reduction in percent ethmoid obstruction on a 100-mm VAS (-21.5 mm vs. 1.3 mm; p=0.001), both respectively. For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion scores between groups. Six-month outcomes from RESOLVE were reported by Forwith et al. in 2016. Differences in polyp grade and ethmoid obstruction scores remained significantly improved in the intervention group at 6 months, but the difference between groups in patient reported symptom scores was not statistically significant at 6 months (See Table 6) (51) In RESOLVE II the implant group showed significant reductions in nasal congestion, polyp grade, and ethmoid obstruction at 90 days compared to sham controls. Out of 200 patients treated with the implant, 39% were indicated for sinus surgery at 3 months compared to 63.3% of controls (p<0.001).

Table 5. Summary of Key RCT Characteristics

Study; Trial	**Countries**	**Sites**	**Dates**	**Participants**	**Interventions**	
					Active	**Comparator**
Han et al. (2014) (49); Forwith et al. (2016) (51) RESOLVE	U.S.	18	2013-2014	100 patients with recurrent nasal polyposis after ESS who had chronic rhinosinusitis, had undergone prior bilateral total ethmoidectomy more than 3 months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient.	53 patients who received office-based placement of a mometasone-eluting nasal stent.	47 patients who received sham treatment.

Kern et al. (2018) (50); RESOLVE II	U.S.	34	2014-2016	300 adults with refractory chronic rhinosinusitis with nasal polyps who were candidates for repeat surgery. To be indicated for repeat ESS, a patient had to: 1) be using intranasal corticosteroid daily; 2) receive at least 1 course of high-dose steroid therapy or refused such therapy due to side effects within the past 1 year; 3) continue to have moderate-to-severe symptoms of nasal obstruction/ congestion; and 4) have endoscopic evidence of bilateral ethmoid sinus obstruction due to polyposis.	201 patients who received a SINUVA(TM) mometasone-eluting bioabsorbable nasal stent.	99 patients who received sham treatment consisting of insertion and removal of implants.

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps; ESS: endoscopic sinus surgery; RCT: randomized controlled trial.

Table 6a. Summary of Key RCT Results

Study	Nasal obstruction/ congestion score change (scale 0–3) at 90 days	Nasal obstruction/ congestion score change (scale 0–3) at 6 months	Change in Polyp Grade at 90 Days (scale 0 to 8)	Change in Polyp Grade at 6 Months (scale 0 to 8)
Han et al. (2014) (49); Forwith et al. (2016) (51) RESOLVE				
Drug-eluting nasal implant		-1.06	-1.0	-.071
Sham		-0.44	-0.1	0.02
P-value		.124	0.016	.018

Kern et al. (2018) (50); RESOLVE II				
Drug-eluting nasal implant mean (SD)	−0.80 (0.73)		−0.56 (1.06)	
Sham mean (SD)	−0.56 (0.62)		−0.15 (0.91)	
Diff or OR (95% CI)	−0.23 (−0.39 to −0.06)		−0.35 (−0.60 to −0.09)	
P-value	0.007		0.007	

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps; CI: confidence interval; Diff: difference; OR: odds ratio; RCT: randomized controlled trial; SD: standard deviation.

Table 6b. Summary of Key RCT Results (continued)

Study	Reduction in Ethmoid Obstruction (scale 100) at 90 Days	Reduction in Ethmoid Obstruction (scale 100) at 6 Months	Patients Indicated for Sinus Surgery at 3 months n (%)
Han et al. (2014) (49); Forwith et al. (2016) (51) RESOLVE			
Drug-eluting nasal implant	-21.5 mm	-17.1 mm	47%
Sham	1.3 mm	-5.6 mm	77%
P-value	0.001	.010	NR
Kern et al. (2018) (50); RESOLVE II			
Drug-eluting nasal implant mean (SD)	−11.3 (18.1)		78/200 (39.0%)
Sham mean (SD)	−1.9 (14.4)		62/98 (63.3%)
Diff or OR (95% CI)	−7.96 (−12.10 to −3.83)		2.69 (1.63 to 4.44)
P-value	<0.001		<0.001

RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis; RESOLVE II: a phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps; CI: confidence interval; Diff: difference; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; SD: standard deviation.

Subsection Summary: Sinus Implant for Recurrent Polyposis

Two RCTs were identified evaluating the use of steroid-eluting nasal implant for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of these trials included use of a sham control and adequate power for its primary outcome.

Practice Guidelines and Position Statements

International Consensus Statement on Allergy and Rhinology

In 2021, the International Consensus Statement on Allergy and Rhinology was updated and included the following recommendation:
"Corticosteroid-eluting implants can be considered as an option in a previously operated ethmoid cavity with recurrent nasal polyposis." (52)

The recommendation noted, "Corticosteroid eluting implants have been shown to have beneficial impact on ethmoid polyposis and obstruction, and 1 study has shown them to be cost-effective in preventing revision ESS. Experience is early and although evidence is high level, only short-term outcomes are currently available."

American Academy of Otolaryngology-Head and Neck Surgery

A position statement on Nasal Valve Repair from the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (2023) included an overview of nasal valve dysfunction and addressed both diagnosis and techniques that treat nasal valve dysfunction. (53) The position statement notes that the AAO-HNS recognizes surgical repair of the nasal valve as a distinct surgical procedure that can improve nasal obstruction symptoms for appropriately selected patients with nasal valve collapse. The position statement also notes that the treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or radiofrequency treatment aimed at stabilizing the nasal valve. Surgical repair of the nasal valve can be performed as a standalone surgical procedure or in conjunction with other procedures to improve nasal obstruction.

In 2021 the AAO-HNS provided clinical indicators for both Septoplasty and Inferior Turbinate Surgery. Both clinical indicators addressed history, physical examination, tests, postoperative observations, and outcome review as well as patient information. The following history and physical examination information is noted in the indicators for Septoplasty (57):

Septoplasty
1. History (one or more required) 1. Nasal airway obstruction (unilateral or bilateral) causing any of the following: mouth breathing, snoring, nasal congestion, sleep apnea, unresponsive to medical management. 2. Frequent nosebleeds, unresponsive to medical management, and for which deviation is a causative factor. 3. Atypical facial pain of nasal origin. (Positive response to topical anesthetic, where deformed septum contacts a turbinate or lateral wall, supports, but may not prove, septal causation or contribution.) 4. Asymptomatic deformity that prevents surgical access to other intranasal or paranasal areas, e.g., sinuses, turbinates.
2. Physical Examination (all appropriate findings required) 1. Description of complete intranasal exam. 2. Document presence or absence of nasal polyps, tumors, turbinate hypertrophy, nasal valve compromise, or other causes of obstruction.

3. Documentation of suspected bleeding site if the purpose of surgery is to control epistaxis.

The following history and physical examination information is noted in the indicators for Inferior Turbinate Surgery (58):

Inferior Turbinate Surgery
1. History (required) 1. Chronic nasal obstruction due in part to inferior turbinate hypertrophy. 2. Failure of directed medical management with continued nasal symptoms (medications, allergy treatment, and duration of therapy). 3. Failure of medical treatment of rhinitis medicamentosa. 4. Symptoms of obstructive sleep apnea.
2. Physical Examination (required) 1. Inferior turbinate description before and after decongestion. 2. Description of nasal anatomy, documenting presence or absence of other intranasal pathology.

Balloon Septoplasty

No practice guidelines or position statements were identified that address balloon septoplasty as a treatment for septal deviation.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	30120, 30130, 30140, 30150, 30400, 30410, 30420, 30430, 30435, 30450, 30469, 30520, 30999, 31237, 31299
HCPCS Codes	J3490, J7402, S1091

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
09/15/2024	Document updated with literature review. The following changes were made to Coverage: 1) Added criteria for septoplasty and turbinate resection; 2) Added criteria to the Drug-Eluting Sinus Implants section; 3) Added: Repeat Administration coverage statements for mometasone furoate products; and 4) Replaced information on NOTE 3 with indications for the PROPEL family of devices; 5) Added: "Balloon septoplasty for treatment of septal deviation is considered experimental, investigational and/or unproven." References added: 10, 41, 43-44, 52-59.
11/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Clarified the section addressing Drug-Eluting Sinus Implants; 2) Removed the section on Cryotherapy for Treatment of Rhinitis from this policy, it has been relocated to SUR706.020 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis. References added: 16, 39-40, and 47.
07/01/2021	Document updated with literature review. The following change was made to Coverage: Added "Cryosurgical ablation of the posterior nasal nerve region (e.g., ClariFix®) to decrease symptoms associated with chronic rhinitis is considered experimental, investigational and/or unproven". References added: 2, 39-43.
03/15/2021	Document updated with literature review. The following changes were made to Coverage: 1) Added the following statement: "The use of radiofrequency to the nasal valve region (e.g. Vivaer [Aerin Medical]) for the treatment of nasal airway obstruction is considered experimental, investigational and/or unproven."; 2) Added NOTES 2 and 3 and NOTES were renumbered, and 3) Removed Coverage statements pertaining to Balloon Ostial Dilation. Information on the topic of balloon ostial dilation for the treatment of chronic rhinosinusitis is now located on medical policy SUR706.019. References added: 1, 9, 11-15, 17-30, 35-37.
04/15/2020	Document updated with literature review. The following changes were made to Coverage: For Rhinoplasty: 1) Added septoplasty and septal deformity to the rhinoplasty statements; 2) Added the following: OR significant deformity

	in individuals with documented obstructive sleep apnea. For Balloon Ostial Dilation: 3) Coverage separated into Coverage for adults and children; 4) NOTE 2 added defining adult chronic rhinosinusitis; 5) Added NOTE 3: Balloon sinus ostial dilation may be performed either as a stand-alone procedure or as part of FESS when criteria are met; 6) Added Balloon sinus ostial dilation is considered experimental, investigational and/or unproven for patients with chronic rhinosinusitis that have nasal polyps. 7) NOTE 4 added defining pediatric chronic rhinosinusitis. Added references: 9-10, 26, 39-40, 42, and 45. Information on Balloon Dilation of the Eustachian Tube has been removed from this document and is now housed on Medical Policy SUR706.018 Balloon Dilation of the Eustachian Tube.
01/15/2019	Document updated with literature review. The following changes were made to Coverage: 1) added coverage under Drug-eluting Sinus Implants to address FDA drug approved sinus implant 2) clarification of coverage per the FDA device or FDA drug approved indications for drug-eluting sinus implants and 3) added the following: NOTE 2: See the Regulatory Status section of this medical policy for additional information concerning drug and devices containing mometasone furoate and their indications. Added references: 54-55.
05/01/2018	Document updated with literature review. The following coverage criteria for Rhinoplasty was changed: within the previous 12 months, was removed from the following statement: Significant external nasal pyramid collapse following documented trauma or injury within the previous 12 months. PROPEL Contour was added to the coverage statements for Drug-eluting Sinus Implants.
07/01/2017	Document updated with literature review. The following coverage statement was added: Balloon dilation of the Eustachian tube for persistent Eustachian tube dysfunction is considered experimental, investigational and/or unproven.
11/15/2016	Document updated with literature review. The following changes to coverage were made: 1) Rhinoplasty coverage criteria changed from 5 criteria to the following 3 criteria: Rhinoplasty may be considered medically necessary when performed to correct any one of the following: Nasal deformity secondary to congenital craniofacial deformity (e.g. cleft lip, cleft palate, or maxillonasal dysplasia); OR Significant external nasal pyramid collapse following documented trauma or injury within the previous 12 months; OR Significant deformity following removal of a nasal malignancy, an abscess or osteomyelitis. 2) Balloon Ostial Dilations coverage changed to the following: Balloon ostial dilation using a U. S. Food and Drug Administration (FDA) approved catheter-based inflatable device performed in accordance with the device's FDA-approved labeling for the treatment of medically refractory chronic sinusitis in adults may be considered medically necessary as a minimally invasive alternative to functional endoscopic sinus surgery. The use of a balloon ostial dilation device, with a FDA approved

	device specified for children, (children age 17 and under) may be considered medically necessary when treating the maxillary sinus space as a minimally invasive alternative to functional endoscopic sinus surgery for the treatment of medically refractory chronic sinusitis. The use of a balloon ostial dilation device, with a FDA approved device specified for children, (children age 17 and under) is considered experimental, investigational and/or unproven in all other sinus spaces but the maxillary sinus space as a minimally invasive alternative to functional endoscopic sinus surgery for the treatment of medically refractory chronic sinusitis. 3) the following coverage statement was changed under the Drug-eluting Sinus Implants section: Placement of a mometasone furoate sinus implant (Propel®/Propel® mini) may be considered medically necessary in conjunction with ethmoid sinus and/or frontal sinus surgery when criteria are met.
05/01/2015	Document updated with literature review. Coverage language clarified for balloon ostial dilation. Coverage for implantable sinus stent has changed to may be considered medically necessary when listed criteria are met.
07/01/2012	Document updated with literature review. CPT/HCPCS code(s) updated. The following was added to Sinus Spacers and Other implantable Devices: Bioabsorbable sinus implants (e.g. Propel™) are considered experimental, investigational and unproven for all indications, including delivery of steroids to the sinus cavities.
06/01/2012	Document updated with literature review. CPT/HCPCS code(S) updated. The following was added to coverage: Use of a catheter-based inflatable device (balloon sinuplasty) for the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to functional endoscopic sinus surgery. Information regarding catheter –based inflatable balloon device found in the pricing section was removed.
12/01/2010	Document updated with literature review. Explained when FESS is medically necessary (not a new indication); Use of a spacer (e.g. Relieva Stratus™ MicroFlow Spacers and Deployment Guides) for all indications, including delivery of steroids to the sinus cavities, is considered experimental, investigational and unproven.
04/15/2009	Policy revised with literature search, no coverage change.
01/01/2009	Revised/Updated Entire Document
04/15/2008	Coverage revised
05/01/2007	Coverage revised
03/01/2007	Revised/Updated Entire Document
01/01/2007	Codes revised/added/deleted
11/01/2006	Codes revised/added/deleted
01/01/2005	Revised/Updated Entire Document
06/01/2001	Codes revised/added/deleted
11/01/1999	Revised/Updated Entire Document

05/01/1996	Revised/Updated Entire Document
03/01/1996	Revised/Updated Entire Document
01/01/1993	Revised/Updated Entire Document
05/01/1990	New Medical Document