

Multidisciplinary consensus on a stepwise treatment algorithm for management of nasal polyp patients

– Cover Sheet

Background

With multiple FDA-approved treatment options for the management of nasal polyps, experts proposed a stepwise treatment algorithm published in the International Forum of Allergy and Rhinology. This algorithm includes the use of steroid-eluting sinus implants for postoperative management and for the management of persistent disease in patients who have had sinus surgery. Intersect ENT, Inc., is providing this publication to facilitate treatment decision-making and elucidate where experts have positioned SINUVA™ (mometasone furoate) sinus implant and PROPEL™ mometasone furoate sinus implants in the algorithm for the management of nasal polyps.

Key Points

- Sinus surgery is recommended for the majority of patients with refractory nasal polyps
- PROPEL is recommended for postoperative management
 - Other recommendations include saline irrigation, steroid irrigation, INS, or EDS-FLU
- SINUVA implant is indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery
 - Other recommendations for patients who have had sinus surgery include biologics, revision sinus surgery, ASA desensitization, or a short burst of oral steroids

This publication contains information about the following Intersect ENT product(s): PROPEL (mometasone furoate sinus implants) and SINUVA (mometasone furoate) sinus implant.

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ASA, aspirin; EDS-FLU, exhalation delivery system delivering fluticasone; INS, intranasal corticosteroids.

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

Indication

SINUVA Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps, in patients ≥ 18 years of age who have had ethmoid sinus surgery.

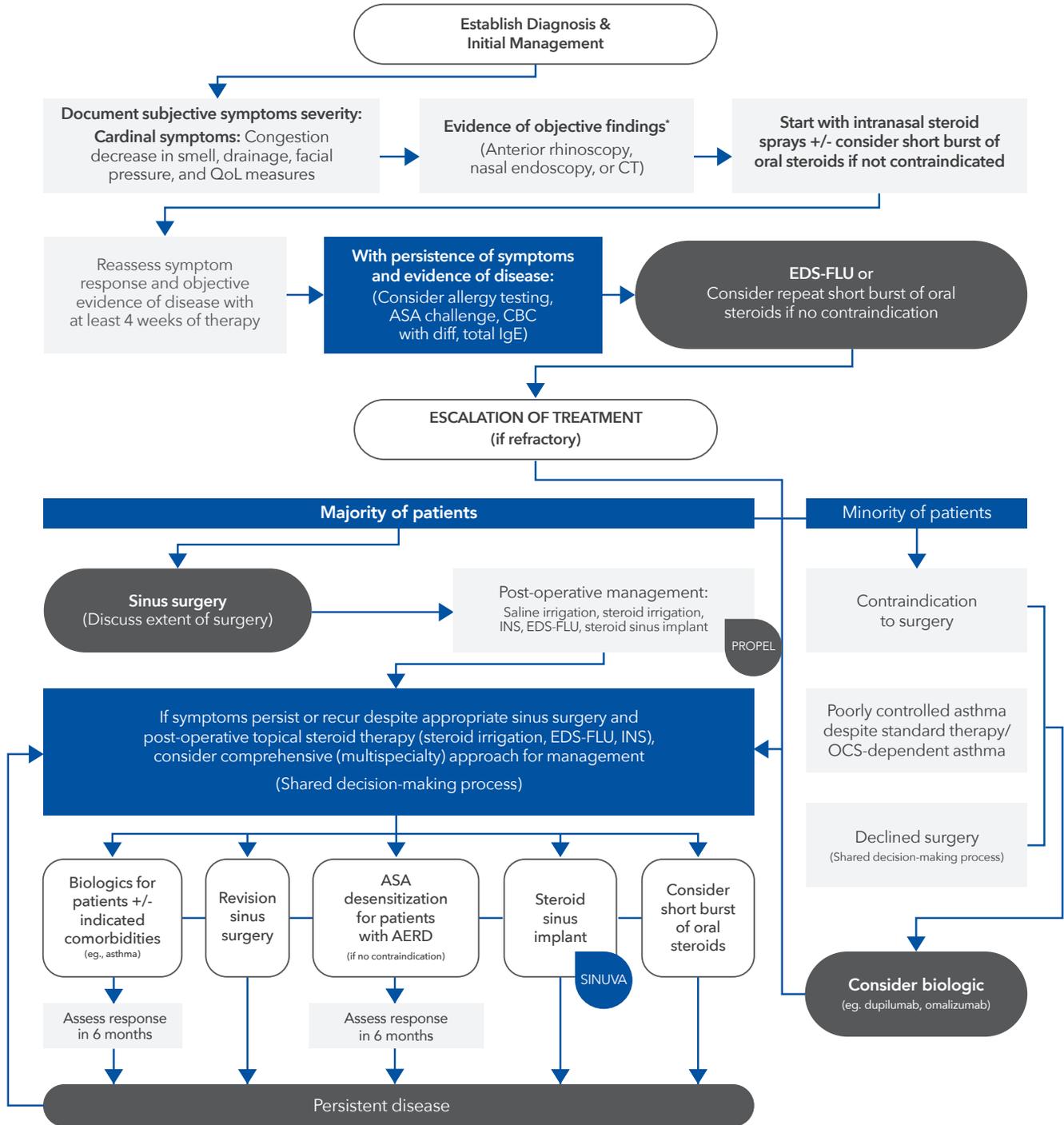
Important safety information

Contraindications

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA Sinus Implant.

Please see additional Important Safety Information for SINUVA implant on the next page.

Management algorithm for nasal polyps



AERD, aspirin-exacerbated respiratory disease; CBC, complete blood count; CT, computed tomography; EDS-FLU, exhalation delivery system delivering fluticasone; IgE, immunoglobulin E; OCS, oral corticosteroids; QoL, quality of life.

*Evaluate for bilateral versus unilateral to rule out neoplasm.

Adapted with permission from Han et al 2021.

Please see additional Important Safety Information for SINUVA (mometasone furoate) sinus implant on the next page.

Important safety information (continued)

Warnings and precautions

Local Effects: Monitor nasal mucosa adjacent to the SINUVA Sinus Implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Ocular effects: Monitor patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts closely.

Hypersensitivity reactions: Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids.

Immunosuppression: Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and adrenal suppression: If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal.

Adverse reactions

The most common adverse reactions observed (> 1% of subjects and that occurred more frequently in the treatment group compared to control) in clinical studies were asthma, headache, epistaxis, presyncope, bronchitis, otitis media, and nasopharyngitis.

Postmarketing experience

The following adverse reactions have been identified during post-approval use of the SINUVA sinus implant. These events include implant migration, lack of efficacy, nasal pain, headache, epistaxis.

Rx only. Please see Full Prescribing Information for SINUVA at www.SINUVA.com/PI.

Medtronic