

# Dupilumab (DUPIXENT™)

## Use in Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

### Criteria for Use

### September 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive dupilumab.

- History of hypersensitivity to dupilumab or any of its excipients
- Concurrent use of live (attenuated) vaccines or treatment with live (attenuated) vaccines within the previous 12 weeks
- Currently treated with omalizumab or another biologic agent
- Untreated parasitic (helminth) infection (treat infection prior to initiating dupilumab)

## Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA / VA Community Care (Allergy, Immunology or Otolaryngology [ear, nose and throat] specialist) or locally designated expert in managing CRSwNP
- Diagnosis of CRSwNP is confirmed

**AND symptoms of CRSwNP are uncontrolled and persistent despite use of ALL of the following:**

- Daily use and adherence to topical corticosteroid (CS) nasal spray (e.g., fluticasone)
- Daily use and adherence to nasal saline spray/irrigations
- Trial of nasal CS irrigation (e.g., 4-6 weeks budesonide- *added to topical CS and nasal saline sprays/irrigations*)
- Short-term course of systemic CS within the past 2 years (unless contraindicated)
- Sinonasal surgery has been performed (e.g., surgical/endoscopic intervention(s) to remove nasal polyps/tissue, unless patient is not a surgical candidate or surgery is not indicated) and continued adherence to maximal medical therapies (e.g., topical CS sprays, nasal saline sprays/irrigations and use of CS irrigations) after surgery has been confirmed with the patient.

## Supplementary Information

- Alternative treatments include mometasone furoate nasal implant (SINUVA) and a higher dose fluticasone propionate 93 mcg/106 nasal spray using a novel delivery system (exhalation delivery system). No studies have compared dupilumab to either of these agents directly.
- In SINUS-24 and SINUS-52, differences in outcomes between administering dupilumab every 2 weeks vs. every 4 weeks were not statistically different. However, FDA has only approved a 2-week dosing schedule for dupilumab in CRSwNP.
- Hypersensitivity reactions were reported in <1% of patients in clinical trials. Reactions included generalized urticaria, rash, erythema nodosum and serum sickness or serum sickness-like events. If a hypersensitivity reaction occurs, appropriate therapy should be instituted and dupilumab discontinued.

---

Prepared: September 2020. Contact: Cathy Kelley, [catherine.kelley@va.gov](mailto:catherine.kelley@va.gov), National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

---