Prior authorization checklist for DUPIXENT® (dupilumab)

A patient's health plan is likely to require a PA before it approves DUPIXENT for patients aged 18 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). However you choose to submit a PA request (eg, fax, website, phone), this checklist can help guide you through the information health plans may need from you.

Please keep in mind that PA requirements are likely to vary, so check with your patient's health plan to ensure you have an accurate list of requirements before you submit.

Tips for handling PA requirements from health plans

- [ ] Obtain the appropriate PA form after initiating your patient through one of the following:
  - *DUPIXENT MyWay®*
  - Specialty pharmacy
  - Insurance provider
  - CoverMyMeds®[a]
- [ ] Fill out PA form completely. Make sure you include:
  - Patient and provider contact information
  - Individual provider ID
  - Patient ID, found on the patient's pharmacy benefit card
- [ ] Attach a letter of medical necessity or medical exception, if required
- [ ] Photocopy the front and back of the patient's pharmacy benefit card
- [ ] Verify with the health plan to ensure all information and documentation was received and is clear
- [ ] Sign all necessary forms
- [ ] Ensure you document the following information according to your patient's diagnosis of inadequately controlled CRSwNP
  - The appropriate ICD-10-CM code (eg, J33.___)
  - Date of diagnosis
  - Documentation of diagnosis such as:
    - Rhinoscopy
    - Nasal endoscopy
    - CT scan
  - Dates and results of last CT scan or endoscopy, including polyp location/characterization, if applicable
  - Prior/current medical treatments, documenting treatment name and dose, duration of use, adherence, contraindications, and response to:
    - Oral corticosteroids
    - Intranasal corticosteroids
  - Dates and results of prior sinonasal surgeries and procedures in the last 2 years (eg, FESS/polypectomy)
  - Documentation of ongoing symptoms, such as:
    - Nasal obstruction or discharge
    - Facial pain or pressure
    - Reduction in or loss of smell
  - Any relevant comorbidities
  - Reasons the patient may not be a candidate for surgery, if applicable

Check all documentation before you submit your PA request. Incomplete information or clerical errors can often lead to a denial for DUPIXENT

! Please attach office chart notes relevant to diagnosis and therapy

INDICATION

DUPIXENT is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

Please see additional Important Safety Information on next page and click here for full Prescribing Information.

CT=computerized tomography; FESS=functional endoscopic sinus surgery; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; PA=prior authorization.

[a]CoverMyMeds® is a registered trademark of CoverMyMeds, LLC.

DUPIXENT® (dupilumab) Injection 300mg

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum, anaphylaxis and serum sickness or serum sickness-like reactions, were reported in <1% of subjects who received DUPIXENT in clinical trials. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Conjunctivitis and Keratitis: Conjunctivitis occurred more frequently in subjects with chronic rhinosinusitis with nasal polyposis who received DUPIXENT. There were no cases of keratitis reported in the CRSwNP development program. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Eosinophilic Conditions: Patients being treated for asthma may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis (EGPA), conditions which are often treated with systemic corticosteroid therapy. These events may be associated with the reduction of oral corticosteroid therapy. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adult patients who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult patients who participated in the asthma development program as well as in adult patients with co-morbid asthma in the CRSwNP development program. A causal association between DUPIXENT and these conditions has not been established.

Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation with DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Patients with Co-Morbid Asthma: Advise patients with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physician.

Parasitic (Helminth) Infections: It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1%) in patients with CRSwNP are injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.

DRUG INTERACTIONS: Avoid use of live vaccines in patients treated with DUPIXENT.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of DUPIXENT in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

Please click here for full Prescribing Information.

For any questions or concerns, or to report side effects with a Sanofi and Regeneron product while enrolled in *DUPIXENT MyWay®*, please contact **1-844-DUPIXEN(T)** (1-844-387-4936) Option 1, Monday–Friday, 8 AM–9 PM Eastern time.

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