Prior authorization checklist

For DUPIXENT® (dupilumab) in inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)

A patient's health plan is likely to require a PA before it approves DUPIXENT as an add-on maintenance treatment for patients aged 18 years and older with inadequately controlled CRSwNP. However you choose to submit a PA request (eg, fax, website, phone, CoverMyMeds®[a]), 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®*
  - CoverMyMeds
  - Insurance provider
  - Specialty pharmacy
- [ ] 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
    - Bilateral sinonasal polyposis (including documentation of the endoscopy or sinus CT scan findings)
  - 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[b]:
    - Oral corticosteroids
    - Intranasal corticosteroids
    - Biologics
  - 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
    - Rhinorrhea or postnasal drip
  - Any relevant comorbidities
  - Reasons the patient may not be a candidate for surgery, if applicable
- [ ] Fill out all required patient and provider information on the PA form
- [ ] 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
- [ ] Note the payer's reauthorization time frame and requirements
- [ ] Sign all necessary forms. Any and all forms may be rejected if a signature is missing

! Please attach chart notes relevant to diagnosis and therapy along with PA form submission

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 accompanying full Prescribing Information.

CT=computed 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.

[b]Note the payer's reauthorization time frame and requirements.

DUPIXENT® (dupilumab) Injection 300mg

Incomplete information may lead to a denial for DUPIXENT® (dupilumab)

Below are some of the most common causes for denial. It is important that you double check your documentation when you submit your initial PA request to avoid these common causes for denial.

Common reasons for coverage denials

- Clerical error (ie, missing or incorrect ICD-10-CM code)
- Lack of documentation supporting appropriate diagnosis or other required documentation from most recent chart notes
- Did not include duration on current therapies or names of all therapies that were tried and failed
- Documentation did not support health plan's criteria for approval of DUPIXENT
- Patient was not treated with prior therapies required by plan
- No reason provided for discontinuation of previous therapy/ therapies

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. 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 compared to those who received placebo. There were no cases of keratitis reported in the CRSwNP development program. Conjunctivitis and keratitis have been reported with DUPIXENT in post-marketing settings, with some patients reporting visual disturbances (e.g. blurred vision). Advise patients to report new onset or worsening eye symptoms to their healthcare provider. Consider ophthalmological examination for patients who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis, as appropriate.

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. Healthcare providers 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 subjects who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult subjects who participated in the asthma development program as well as in adult subjects with co-morbid asthma in the CRSwNP development program. A causal association between DUPIXENT and these conditions has not been established.

Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider. 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 physicians.

Arthralgia: Arthralgia has been reported with use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization. Advise patients to report new onset or worsening joint symptoms. If the symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

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.

Vaccinations: Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating DUPIXENT. Avoid use of live vaccines in patients treated with DUPIXENT.

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

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. To enroll or obtain information call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/. 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 see accompanying 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.

SANOFI GENZYME REGENERON

DUPIXENT® (dupilumab) Injection 300mg