Prior authorization checklist

For DUPIXENT in adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery

A patient's health plan is likely to require a prior authorization (PA) before it approves DUPIXENT for appropriate patients aged 6 years and older with AFRS who have a history of sino-nasal surgery. 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.**

It is important to review each health plan's guidelines for obtaining PA, as elements and requirements vary by plan. Please note that following a health plan's guidelines does not guarantee the patient's health plan will provide reimbursement for DUPIXENT, and the guidelines are not intended to substitute or influence the physician's independent medical judgment.

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

INDICATIONS

Allergic Fungal Rhinosinusitis: DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.
Chronic Rhinosinusitis with Nasal Polyps: DUPIXENT is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (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.

DUPIXENT® (dupilumab) Injection
200mg · 300mg

Tips for handling PA requirements from health plans

Ensure that you document the following information according to your patient's diagnosis and as required by the patient's plan

- ☐ **Diagnosis information:**
  - The appropriate *ICD-10-CM* code (eg, B49, J32)
  - Date of diagnosis
  - Presence of nasal polyps assessed by anterior rhinoscopy or nasal endoscopy
  - Characteristic radiographic (CT scan) findings including hyperdensities, bony demineralization, bone erosion of the sinuses
  - Evidence of Type 1 hypersensitivity to a fungus by skin prick test or serum IgE testing
  - Evidence of eosinophilic mucin without fungal invasion into sinus tissue (assessed by microscopic review of mucosal specimen)
  - Fungi on staining

  Additional criteria to support AFRS diagnosis
  - Radiographic evidence of bone erosion
  - Presence of Charcot-Leyden crystals in surgical specimen
  - Documented fungal culture
- ☐ **Treatment history:**
  - Current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy, such as[a]:
    – Intranasal corticosteroids – Systemic corticosteroids – Systemic or topical antifungal therapy – Sino-nasal surgery – Fungal immunotherapy
  - Contraindications to alternative drug therapies and/or reasons why patient may not be an appropriate candidate for an additional sino-nasal surgery
- ☐ **If the request is for reauthorization for continuation of therapy:**
  – Documentation of clinically meaningful beneficial response to DUPIXENT

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

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

CT, computed tomography; *ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification;* IgE, immunoglobulin E.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

The safety profile of DUPIXENT in patients with AFRS was similar to the safety profile of DUPIXENT in patients with Chronic Rhinosinusitis with Nasal Polyps (CRSwNP).

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, Keratitis, and Blepharitis: Conjunctivitis occurred more frequently in adult subjects with CRSwNP who received DUPIXENT compared to those who received placebo. Conjunctivitis, keratitis, and blepharitis have been reported with DUPIXENT in postmarketing settings. Some patients reported varying degrees of transient or ongoing visual impairment including blindness associated with conjunctivitis, keratitis, or blepharitis leading to discontinuation of DUPIXENT and/or surgical intervention. Advise patients or their caregivers to promptly report new-onset or worsening eye symptoms to their healthcare provider. Consider discontinuation of DUPIXENT and prompt ophthalmological examination for patients who develop signs and symptoms suggestive of keratitis, or when conjunctivitis or blepharitis do not resolve following standard treatment, as appropriate. Use with caution in patients with significant dry eye disease, history of significant lid abnormalities/surgeries, or history of nasolacrimal surgery.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

DUPIXENT® (dupilumab) Injection
200mg · 300mg

Tips for handling PA requirements from health plans (cont'd)

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

- ☐ Obtain the appropriate PA form after initiating your patient through one of the following:
  - ***DUPIXENT MyWay®*** • CoverMyMeds • Insurance provider • Specialty pharmacy • Retail pharmacy
- ☐ Fill out all required patient and provider information on the PA form
- ☐ Attach a letter of medical necessity, if required
- ☐ Photocopy the front and back of the patient's pharmacy benefit card
- ☐ Note the payer's reauthorization time frame and requirements
- ☐ Sign all necessary forms. Both patient and HCP signatures may be required. Any and all forms may be rejected if a signature is missing
- ☐ Verify with the health plan to ensure all information and documentation was received and is clear

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions: Patients being treated for asthma may present with clinical features of eosinophilic pneumonia or eosinophilic granulomatosis with polyangiitis (EGPA). 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, kidney injury, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adults who participated in the asthma development program and cases of EGPA have been reported with DUPIXENT in adults who participated in the asthma development program as well as in adults with co-morbid asthma in the CRSwNP development program. Advise patients to report signs of eosinophilic pneumonia and EGPA. Consider withholding DUPIXENT if eosinophilic pneumonia or EGPA are suspected.

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 and Psoriatic Arthritis: 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. Cases of new-onset psoriatic arthritis requiring systemic treatment have been reported with the use of DUPIXENT. Advise patients to report new-onset or worsening joint symptoms. If the symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

DUPIXENT® (dupilumab) Injection
200mg · 300mg

Common reasons for coverage denials

Incomplete information may lead to a denial for DUPIXENT

Below are some of the most common reasons 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.

- 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
  - Consider indicating on your PA form the page on which the supporting clinical data can be found
- 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 (cont'd)

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 during treatment with DUPIXENT.

ADVERSE REACTIONS: The most common adverse reactions in patients with AFRS are similar to adverse reactions for CRSwNP. The most common adverse reactions (incidence ≥1%) in adult 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. 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 | REGENERON®

DUPIXENT® (dupilumab) Injection
200mg · 300mg