Prior authorization checklist

For DUPIXENT in adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

A patient's health plan is likely to require a prior authorization (PA) before it approves DUPIXENT as add-on maintenance treatment for appropriate patients with inadequately controlled COPD and an eosinophilic phenotype. 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.

INDICATION

DUPIXENT is indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm.

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.

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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, J40._ - J44._.)
- Date of diagnosis
- Forced spirometry
  - Post-bronchodilator FEV_1/FVC <0.7
  - Post-bronchodilator FEV_1 % predicted
- Absolute blood eosinophil count and latest test date
- Documentation of COPD symptoms such as:
  - Dyspnea
  - Chronic cough
  - Sputum production
  - Wheezing or chest tightness
  - Fatigue
- Documentation of mMRC Dyspnea Scale ≥2
- Multidimensional questionnaire results (eg, CAT, CCQ, SGRQ, CRQ)
- Number of moderate or severe exacerbations in the past 12 months defined as
  - Moderate Exacerbation: An event that requires either systemic corticosteroids and/or antibiotics
  - Severe Exacerbation: An event that requires hospitalization or an emergency department/urgent care facility visit
- Documentation of smoking status (current or former smoker)

☐ **Treatment history:**
- Current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy.[a] Examples of requirements include
  - Long-acting bronchodilators (long-acting beta-agonists and long-acting muscarinic antagonists)
  - Inhaled corticosteroids
  - PDE 3 and/or 4 inhibitors
  - Chronic antibiotics

☐ **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

CAT, COPD Assessment Test; CCQ, Clinical COPD Questionnaire; CRQ, Chronic Respiratory Disease Questionnaire; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; *ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification*; mMRC, modified Medical Research Council; PDE, phosphodiesterase; SGRQ, St. George's Respiratory Questionnaire.

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

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, Keratitis, and Blepharitis: Conjunctivitis and keratitis occurred more frequently in COPD subjects who received DUPIXENT versus 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.

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

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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)

Conjunctivitis, Keratitis, and Blepharitis (cont'd): 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.

Acute Symptoms of Chronic Obstructive Pulmonary Disease or Acute Deteriorating Disease: Do not use DUPIXENT to treat acute symptoms or acute exacerbations of COPD, acute bronchospasm, or status asthmaticus. Patients should seek medical advice if their COPD remains uncontrolled or worsens after initiation of DUPIXENT.

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 symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

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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 (incidence ≥2%) in patients with COPD are viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration reactions, rhinitis, eosinophilia, toothache, and gastritis.

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.

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