

Sample letter of medical necessity for DUPIXENT® (dupilumab)

This letter provides an example of the information that may be required when responding to a prior authorization (PA) or appeal request for DUPIXENT from a patient's health plan regarding medical necessity. Use of the information in this letter does not guarantee that the health plan will provide reimbursement for DUPIXENT and is not intended to be a substitute for or an influence on the independent medical judgment of the physician. This sample letter is provided for informational purposes only and should not be construed as medical advice.

Key reminders

- You may consider including a letter of medical necessity with your PA request to emphasize why, based on your clinical judgment, DUPIXENT is medically necessary for your patient. You may also include a medical necessity letter in addition to your appeal letter, as needed.
- Letters of medical necessity should be **signed by the physician only**
- Be sure to populate an appropriate *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)* code based on your patient's diagnosis

Checklist summary

- PA or appeal form recommended by the health plan
- Chart notes
 - Date of initial diagnosis
 - Post-bronchodilator FEV₁/FVC
 - Post-bronchodilator FEV₁ (% predicted) and last test date
 - Number of moderate or severe exacerbations in the past 12 months
 - Documentation of chronic obstructive pulmonary disease (COPD) symptoms (eg, dyspnea, chronic cough, sputum production, wheezing, or chest tightness)
 - Dyspnea questionnaire (mMRC) and last test date
 - Multidimensional symptom questionnaires (eg, CAT, CCQ) and last test date
 - Smoking status
 - Blood eosinophil levels and last test date
 - Response to current and prior therapies (LABA, LAMA, ICS, PDE 3/4 inhibitors, and/or antibiotics)
 - Patient will continue to receive maintenance therapy with DUPIXENT
 - Any relevant comorbidities or contraindications
 - If appropriate, treatment history from previous or current physicians provided by the patient
- Explanation of medical necessity, including why the patient's recent symptoms, severity of condition, and impact of disease warrant treatment with DUPIXENT
- History prior to your care, if applicable
- Supportive literature
- DUPIXENT Prescribing Information
- Patient's narrative

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 pages 3-4 and accompanying full [Prescribing Information](#).

[Insert office letterhead here]

EXAMPLE

[Date]
[Plan Name]
[Plan Street address]
[Plan City, State ZIP code]

Re: [Patient Full Name]
Date of birth: [Patient date of birth]
Member ID: [Patient ID number]
Group number: [Patient group number]

Dear [Contact Name]:

Since [Date], [Patient Full Name] has been under my care for [diagnosis] (ICD-10-CM code: [insert code]). This letter serves as my determination of medical necessity for DUPIXENT® (dupilumab) for this patient.

I have included a detailed explanation of medical necessity, including the severity of [Patient's Full Name]'s disease and relevant medical history, a statement summarizing my treatment rationale, and a copy of the Prescribing Information for DUPIXENT, which is indicated for this condition.

Current diagnosis and severity:

- [Date of initial diagnosis]
- [Post-bronchodilator FEV₁/FVC and last test date]
- [Post-bronchodilator FEV₁(% predicted) and last test date]
- [Number of moderate or severe exacerbations in the past 12 months]
- [A full account of the patient's COPD symptoms (eg, dyspnea, chronic cough, sputum production, wheezing or chest tightness)]
- [Dyspnea questionnaire (mMRC) and last test date]
- [Multidimensional symptom questionnaires (eg CAT, CCQ) and last test date]
- [Smoking status]
- [Blood eosinophil levels and last test date]
- [Any relevant comorbidities]

Summary of patient history:

- [LABA, LAMA]
- [ICS]
- [PDE 3/4 inhibitors]
- [Antibiotics]

[Explain why patient's recent symptoms, severity of condition, and impact of disease warrant treatment with DUPIXENT]

In order for me to provide appropriate care for my patient, it is important that [Plan Name] provide adequate coverage for this treatment. Please call me at [Primary Treating Site Phone Number] if I can be of further assistance or you require additional information. Thank you in advance for your immediate attention and prompt review of this request.

Sincerely,

[Treating Physician's Signature]
[Treating Physician's Name, MD/DO/NP/PA]

[Patient/Legal Representative's Signature, if required]
[Patient/Legal Representative's Name]

Enclosures: [See Checklist on previous page]

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 and keratitis occurred more frequently in COPD subjects who received DUPIXENT versus placebo. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings. Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis. Advise patients or their caregivers 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.

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.

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

IMPORTANT SAFETY INFORMATION (cont'd)

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](#).

CAT, COPD Assessment Test; CCQ, Clinical COPD Questionnaire; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; ICS, inhaled corticosteroid; LABA, long-acting beta-agonist; LAMA, long-acting muscarinic antagonists; mMRC, modified Medical Research Council; PDE, phosphodiester.