

Sample letter of medical necessity for DUPIXENT® (dupilumab)

This letter provides an example of the types of information that may be provided when responding to a request from an insurance company to send a letter of appeal for DUPIXENT® (dupilumab) for a patient with moderate-to-severe asthma. 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 influence on the independent medical judgment of the physician.

Some key reminders

- Payer utilization management criteria, including step edits, may differ by patient age and indication
- You may consider including a letter of medical necessity like this with your prior authorization (PA) request to emphasize the medical necessity for DUPIXENT or 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

- Appeal form recommended by health plan
- Chart notes
 - Date of initial diagnosis
 - Eosinophil levels (for eosinophilic phenotype) and last test date
 - Fractional exhaled nitric oxide (FeNO) levels (if available) and last test date
 - Any relevant comorbidities
 - Immunoglobulin E (IgE) levels (if available) and last test date
 - Pre-bronchodilator forced expiratory volume in 1 second (FEV₁) and last test date
 - Number of exacerbations in the past 12 months
 - Level of asthma control
 - Oral corticosteroid use
 - Maximally tolerated inhaled corticosteroid dose
 - Response to all prior therapies
- 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 and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

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 throughout. [Click here](#) for 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 the severity of [Patient's First Name]'s disease, information about [his/her] medical history, a statement summarizing my treatment rationale, and a copy of the Prescribing Information for DUPIXENT, which is indicated for this condition.

Current symptoms and condition:

- **Severity**
 - [Eosinophil levels (for eosinophilic phenotype) and last test date]
 - [FeNO levels (if available) and last test date]
 - [IgE level (if available) and last test date]
 - [Pre-bronchodilator FEV₁ and last test date]
 - [A full account of the patient's relevant comorbidities (eg, atopic dermatitis)]
 - [Number of exacerbations in the past 12 months]
 - [Level of asthma control]
 - [Oral corticosteroid use]
 - [Maximally tolerated inhaled corticosteroid dose]
- [Explain why patient's recent symptoms, severity of condition, and impact of disease warrant treatment with DUPIXENT]

Summary of patient history:

- [Treatment history, including duration of each type of therapy]
- [Response to past therapies]
- [Note any contraindications to available treatment options]

[Summarize your reasons why DUPIXENT is medically necessary for this patient]

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 for DUPIXENT® (dupilumab) (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.

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.

Acute Symptoms of Asthma or Acute Deteriorating Disease: Do not use DUPIXENT to treat acute symptoms or acute exacerbations of asthma, acute bronchospasm, or status asthmaticus. Patients should seek medical advice if their asthma 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.

Psoriasis: Cases of new-onset psoriasis have been reported with the use of DUPIXENT for the treatment of asthma, including in patients without a family history of psoriasis. In postmarketing reports, these cases resulted in partial or complete resolution of psoriasis with discontinuation of dupilumab, with or without use of supplemental treatment for psoriasis (topical or systemic). Those who continued dupilumab received supplemental treatment for psoriasis to improve associated symptoms. Advise patients to report new-onset psoriasis symptoms. If symptoms persist or worsen, consider dermatologic evaluation and/or discontinuation of DUPIXENT.

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. Helminth infections (5 cases of enterobiasis and 1 case of ascariasis) were reported in pediatric patients 6 to 11 years old in the pediatric asthma development program.

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 $\geq 1\%$) in patients with asthma are injection site reactions, oropharyngeal pain, and eosinophilia.

Please see additional Important Safety Information throughout. [Click here](#) for full Prescribing Information.

IMPORTANT SAFETY INFORMATION for DUPIXENT® (dupilumab) (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](#).