## 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® (dupilumab) 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.

**Key reminders**

* You may consider including a letter of medical necessity 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**

PA or appeal form recommended by the health plan

Chart notes

* Date of initial diagnosis
* Relevant health conditions or symptoms
* Response to all prior therapies (proton pump inhibitors, swallowed topical corticosteroids, dietary therapy)
* Date and result of last endoscopic esophageal biopsy, including eosinophil levels
* Date and result of prior esophageal dilation procedure

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 for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATION:** DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

**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.

 **Please see additional Important Safety Information throughout and accompanying full** [**Prescribing Information**](https://www.regeneron.com/downloads/dupixent_fpi.pdf)**.**

[Insert office letterhead here] **EXAMPLE**

[Date] Re: [Patient Full Name]

[Plan name] Date of birth: [Patient date of birth]

[Plan Street address] Member ID: [Patient ID number]

[Plan City, State ZIP code] 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 First Name]’s disease, information about [his/her/their] 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 conditions:

[Indicate any relevant health conditions]

[Include date and result of last endoscopic esophageal biopsy, including eosinophil levels]

[Indicate any relevant symptoms]

Summary of patient history:

* [Response to all prior therapies (proton pump inhibitors, swallowed topical corticosteroids, dietary therapy)]
* [Prior esophageal dilation procedures]
* [Note any contraindications to available treatment options]

[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] [Patient/Legal Representative’s Signature, if required]

[Treating Physician’s Name, MD/DO/NP/PA] [Patient/Legal Representative’s Name]

Enclosures: [See Checklist on previous page]

**IMPORTANT SAFETY INFORMATION (cont’d)**

**WARNINGS AND PRECAUTIONS (cont’d)**

**Acute Asthma Symptoms or Deteriorating Disease:** Do not use DUPIXENT to treat acute asthma symptoms, acute exacerbations, 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.

**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 the 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 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 ≥2%) are injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.

**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**](https://www.regeneron.com/downloads/dupixent_fpi.pdf)**.**