## Sample appeal letter for denial of DUPIXENT® (dupilumab) due to nonformulary status or other reason

This letter provides an example of the types of information that may be provided when responding to a request from an insurance company to provide a letter of appeal for DUPIXENT 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 to influence the independent medical judgment of the physician.

### Some key reminders

- You may consider a letter like this if coverage is denied because DUPIXENT is not on the patient's health plan's formulary or is not covered for any other reason
- Appeal letters should be signed by **both** the patient and the physician
- Be sure to populate an appropriate *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code matching 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 ($FEV_1$) and last test date
  - — Number of severe exacerbations in the past 12 months
  - — Level of asthma control
  - — Oral corticosteroid use
  - — 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 in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Limitation 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.

**EXAMPLE**

[Insert office letterhead here]

[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]:

This letter serves as the [first/second] appeal for approval of DUPIXENT® (dupilumab), which was originally denied to [Patient Full Name] on [Date of Denial] because [state reason given in denial letter—for example, it is not covered on the patient's formulary/other reason].

Since [Date], [Patient Full Name] has been under my care for [diagnosis] (ICD-10-CM code: [insert code]). I have included information about [Patient First Name]'s 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 $FEV_1$ and last test date]
  - [A full account of the patient's relevant comorbidities (eg, atopic dermatitis)]
  - [Number of severe exacerbations in the past 12 months]
  - [Level of asthma control]
  - [Oral corticosteroid use]
  - [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 type and duration]
- [Response to past therapies]
- [Note any contraindications to available treatment options]

[Summarize your reasons why DUPIXENT is medically necessary in this case]

Based upon the patient's clinical condition and a review of the supporting documentation, I am confident you will agree that DUPIXENT is an appropriate treatment option. In order for me to provide appropriate care for my patient, it is important that [Plan Name] provide adequate coverage for this treatment.

On behalf of [Patient Full Name], we appreciate your reconsideration. 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 generalized urticaria, rash, erythema nodosum, anaphylaxis and serum sickness or serum sickness-like reactions, were reported in <1% of subjects who received DUPIXENT in clinical trials. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

**Eosinophilic Conditions:** Patients being treated for asthma may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis (EGPA), conditions which are often treated with systemic corticosteroid therapy. These events may be associated with the reduction of oral corticosteroid therapy. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adult patients who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult patients who participated in the asthma development program as well as in adult patients with co-morbid asthma in the chronic rhinosinusitis with nasal polyposis development program. A causal association between DUPIXENT and these conditions has not been established.

**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.

**Reduction of Corticosteroid Dosage:** Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation with DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

**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.

**ADVERSE REACTIONS:** The most common adverse reactions (incidence ≥1%) in patients with asthma are injection site reactions, oropharyngeal pain, and eosinophilia.

**DRUG INTERACTIONS:** Avoid use of live vaccines in patients treated with DUPIXENT.

### USE IN SPECIFIC POPULATIONS

- **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.

**Click here** for full Prescribing Information.