Sample appeal letter for denial of DUPIXENT® (dupilumab) due to requirement for systemic immunosuppressant therapy

This letter provides an example of the types of information that may be provided when responding to a request from a patient's insurance company to provide a letter of appeal for DUPIXENT® (dupilumab). 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

- You may consider a letter like this if coverage is denied because your patient's condition did not meet the plan's severity criteria for treatment with DUPIXENT
- 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 based on your patient's diagnosis

Checklist summary

- ☐ Appeal form recommended by health plan
- ☐ Current/recent chart notes
  - — Date of initial diagnosis
  - — Severity and frequency of flares
  - — Body surface area (BSA) involved with body location
  - — Response to all prior therapies (eg, name of therapy, dose, start date/stop date, length of treatment and clinical response)
  - — Any relevant comorbidities
- ☐ History prior to your care, if applicable
- ☐ Photos, indicating therapy when taken
- ☐ Supportive literature
- ☐ DUPIXENT Prescribing Information
- ☐ Patient's narrative

INDICATION

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

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.

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[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]:

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 the patient did not meet the plan's requirement for an adequate trial of [indicate immunosuppressant(s) mentioned in denial letter].

Since [Date], [Patient Full Name] has been under my care for [diagnosis] (ICD-10-CM code: [insert code]).

[Summarize your specific reasons why systemic immunosuppressants are not or no longer appropriate for this patient, eg, not indicated, side effects, contraindicated for patient type, patient had previous trial prior to being under my care ***OR***
If your patient has, in fact, had a trial of immunosuppressants, give details, including duration and response to therapy]

Current symptoms and condition:

- Severity:
  Body surface area involved: [ ] less than 10% [ ] 10% or more

  Sensitive areas affected [Check all that apply]:

[ ] hands	[ ] feet	[ ] face and neck	[ ] [specify other area]
[ ] genitals/groin	[ ] scalp	[ ] intertriginous areas	

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

I have included information about [Patient First Name]'s medical history and a copy of the Prescribing Information for DUPIXENT, which is indicated for this condition.

Summary of patient history:

- [Treatment history, including duration of each type of therapy]
- [Response to past therapies (eg, name of therapy, dose, start date/stop date, length of treatment and clinical response)]
- [Note any contraindications for systemic immunosuppressants]

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® (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 atopic dermatitis subjects who received DUPIXENT versus placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, predominantly in atopic dermatitis patients. Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis. Advise patients 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.

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.

Atopic Dermatitis Patients with Co-morbid Asthma: Advise patients 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 ≥1% at Week 16) in adult patients with atopic dermatitis are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, dry eye, and eosinophilia. The safety profile in pediatric patients through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile of DUPIXENT + TCS in pediatric patients observed through Week 52 was consistent with that seen in adults with atopic dermatitis, with hand-foot-and-mouth disease and skin papilloma (incidence ≥2%) reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation.

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.

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