Sample medical exception letter for DUPIXENT® (dupilumab)

This example includes the types of information that may be required when writing a medical exception letter for DUPIXENT. 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 for DUPIXENT is denied because of the health plan's policy or if DUPIXENT is subject to a national drug code block
- Medical exception 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

- ☐ Current/recent chart notes
  - — Date of initial diagnosis
  - — Relevant health conditions and symptoms
  - — Treatment history, including duration of each therapy
  - — Response to all prior therapies (eg, name of therapy, dose, start/stop date, length of treatment, and clinical response)
  - — Date(s) and result(s) of last diagnostic test(s), if applicable
- ☐ History prior to your care, if applicable
- ☐ Supportive literature
- ☐ DUPIXENT Prescribing Information
- ☐ Patient's narrative

INDICATIONS

Atopic Dermatitis: 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.

Asthma: 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. Limitation of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

Chronic rhinosinusitis with nasal polyposis (CRSwNP): DUPIXENT is indicated as an add-on maintenance treatment in adult patients with inadequately controlled CRSwNP.

Eosinophilic Esophagitis: 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.

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]:

I am writing to request a medical exception for [Patient Full Name] for the treatment of [insert diagnosis] with DUPIXENT® (dupilumab). It is my professional opinion that DUPIXENT is medically appropriate and necessary and should be covered and reimbursed for this patient.

[Patient Full Name] has been under my care for [insert diagnosis] since [date of onset/diagnosis]. Included for your consideration is [Patient Full Name]'s medical history and diagnosis (ICD-10-CM code: [insert code]), a statement summarizing my reasons for treating [Patient Full Name] with DUPIXENT, and a copy of the Prescribing Information for DUPIXENT.

Current symptoms and conditions:
[Indicate any relevant health conditions or symptoms that warrant treatment with DUPIXENT]

Summary of patient history:

- [Treatment history, including duration of each therapy]
- [Response to all prior therapies (eg, name of therapy, dose, start/stop date, length of treatment, and clinical response)]
- [Date(s) and result(s) of last diagnostic test(s), if applicable]

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

Based upon the patient's clinical condition and a review of the supporting documentation, I am confident you will agree that [Patient Full Name] should be treated 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.

On behalf of [Patient Full Name], we appreciate your consideration. 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, with conjunctivitis being the most frequently reported eye disorder. Conjunctivitis also occurred more frequently in chronic rhinosinusitis with nasal polyposis subjects who received DUPIXENT compared to those who received placebo. 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.

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. Healthcare providers 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 subjects who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult subjects who participated in the asthma development program as well as in adult subjects with co-morbid asthma in the CRSwNP 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.

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 atopic dermatitis or CRSwNP who have 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. 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 in patients treated with DUPIXENT.

ADVERSE REACTIONS:

- **Atopic dermatitis:** The most common adverse reactions (incidence ≥1% at Week 16) in adult patients 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.
- **Asthma:** The most common adverse reactions (incidence ≥1%) are injection site reactions, oropharyngeal pain, and eosinophilia.
- **Chronic rhinosinusitis with nasal polyposis**: The most common adverse reactions (incidence ≥1%) are injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.
- **Eosinophilic esophagitis**: 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.

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