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 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 including a letter of medical necessity like this one 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
- ☐ Current/recent chart notes
  - — Date of initial diagnosis
  - — Severity and frequency of itch, nodules and/or lesions
  - — 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 patients with prurigo nodularis (PN).

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.

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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]:

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.

Assessment of severity:

— Itch [Describe the intensity, location and frequency]
— Redness [Describe the level of erythema and inflammation]
— Thickness [Describe the level of induration, papulation, and swelling]
— Excoriation [Describe the level of skin loss due to scratching]
— Lichenification [Describe the level of lined skin and prurigo nodules]

[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 (eg, name of therapy, dose, start date/stop date, length of treatment, and clinical response)]
- [Note any contraindications to systemic immunosuppressants]

[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]

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IMPORTANT SAFETY INFORMATION for DUPIXENT® (dupilumab) (cont'd)

Conjunctivitis and Keratitis: Conjunctivitis occurred more frequently in prurigo nodularis subjects who received DUPIXENT versus placebo; these subjects recovered or were recovering during the treatment period. There were no cases of keratitis reported in the PN development program. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, with some patients reporting visual disturbances (e.g., blurred vision). 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.

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 ≥2%) in patients with prurigo nodularis are nasopharyngitis, conjunctivitis, herpes infection, dizziness, myalgia, and diarrhea.

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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