Navigating prior authorizations and appeals for DUPIXENT® (dupilumab)

An informational guide with example letters regarding coverage for DUPIXENT

INDICATION

DUPIXENT is indicated for the treatment of patients aged 6 years 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 Important Safety Information throughout. Please click here for full Prescribing Information.
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Important Safety Information

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Overview

This guide was developed to help you understand how to submit the paperwork that is necessary for your patients to gain access to DUPIXENT® (dupilumab). The information and example letters provided will help you understand the requirements of communicating effectively when requesting prior authorizations (PAs) and appealing PA denials for DUPIXENT coverage.

Use of the information and processes set forth in this guide does not guarantee that the health plan will cover DUPIXENT, and is not intended to be a substitute for or an influence on the independent medical judgment of the physician.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Submitting a request for prior authorization

If indicated on the DUPIXENT MyWay® Enrollment Form, our team will perform a benefits investigation and populate a health plan’s PA with certain demographic information from the form. Your DUPIXENT MyWay Coordinator will send you the draft PA form for your review, which you should complete, sign, and fax to the health plan. Your coordinator will follow up with the plan and communicate with you and your patient about status.

Suggestions to help make the strongest case for your patient:

- Include a letter of medical necessity; see Example #1
- Include a medical exception letter; see Example #2
- Include a copy of your current and/or recent chart notes with details of diagnosis, disease severity, and treatment history (e.g., BSA, date of diagnosis, parts of body affected)

BSA=body surface area.

If you still have questions about PAs, call DUPIXENT MyWay at 1-844-DUPIXEN(T) [1-844-387-4936] Option 1

IMPORTANT SAFETY INFORMATION (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.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Understanding the appeal process

If a PA is denied, you can refer to the information we’ve provided to help you prepare and submit an appeal packet. Here are the basic steps for filing an internal appeal, also known as an appeal for reconsideration.

1. **Fill out appeal form**
   (the one recommended by health plan)

2. **Write an appeal letter**
   (see example letters in this packet)

3. **Add supporting documentation**
   (see appeal packet checklist on page 7)

**Key points to remember**

- Adhere to the timelines and use the forms noted in the health plan’s letter of denial
- Depending on the health plan, your patient’s signature may be required on the appeal letter (if patient is a minor, a guardian’s signature is required)
- The appeal packet is submitted by your office or your patient
- The physician may ask to speak with a medical reviewer at the health plan for a “peer-to-peer” review
- **Although an appeal may be successful, it may take more than one attempt**
  - Two levels of internal review may be required before the health plan will notify you about your patient’s eligibility for an external appeal
    - In this case, the reviewer will be an independent party, typically board certified in the specialty, whose decision will be binding on the health plan
    - All documentation from previous reviews should be submitted in subsequent appeals


Please see additional Important Safety Information throughout. Please [click here](#) for full Prescribing Information.
Writing the appeal letter

Identify the reason for your patient’s DUPIXENT® (dupilumab) coverage denial and refer to the sample letter that addresses those issues.

Reason for denial

The patient’s condition did not meet the plan’s severity criteria

The patient did not receive an adequate trial of an immunosuppressant

The patient did not receive an adequate trial of a systemic corticosteroid

The patient did not receive an adequate trial of a topical corticosteroid, a topical calcineurin inhibitor, and/or a topical PDE-4 inhibitor

The treatment is not on formulary or not covered for any other reason

See example #

3 page 12

4 page 14

5 page 16

6 page 18

7 page 20

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example letters

DUPIXENT® (dupilumab) sample letters are included in this guide to help provide the type of information that may be useful when responding to a health plan.

Click here for electronic versions of these example letters, available on the DUPIXENT website.
Appeal packet checklist

- A letter of appeal signed by the treating physician and patient or caregiver, if required
- The appeal form recommended by the health plan

In addition to the letter of appeal and appeal form, consider adding the following documentation to make the submission as strong as possible:

- Current and/or recent chart notes from the patient’s treating physician with medical and treatment history, including date of initial diagnosis, extent and severity of flares in the past year, BSA with body location, and response to all prior therapies (eg, name of therapy, dose, start date/stop date, length of treatment, and clinical response)

- If appropriate, earlier treatment history from previous physicians, provided by the patient

- Recent photos of the patient’s condition; include treatment regimen when photos were taken

- Any clinical studies or peer-reviewed articles documenting the medical effectiveness of DUPIXENT® (dupilumab)

- DUPIXENT full Prescribing Information, available at www.DUPIXENThcp.com

- Consider including a personal narrative from the patient that describes the impact of the condition


IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

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.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #1: Sample letter of medical necessity

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 to influence the independent medical judgment of the physician.

Some key reminders

• You may consider including a letter of medical necessity, like this one, with your 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 matching your patient’s diagnosis
• Click here for a Word version of this letter, available on the DUPIXENT website

Checklist summary

☐ Appeal form recommended by health plan
☐ Current/recent chart notes
  — Date of initial diagnosis
  — Severity and frequency of flares
  — 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

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Atopic Dermatitis Patients with Comorbid Asthma: Advise patients not to adjust or stop their asthma treatments without consultation with their physicians.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
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.

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
  - *Assessment of severity:*
    - — 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]

Enclosures: [See Checklist on previous page]
This letter provides an example of the types of information that may be provided when writing a medical exception letter 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 to influence the independent medical judgment of the physician.

Some key reminders

• You may consider including a letter, like this one, 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 ICD-10-CM code matching your patient’s diagnosis

• Click here for a Word version of this letter, available on the DUPIXENT website

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 date/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

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

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.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #2

[Insert office letterhead here]

[Date]  [Plan name]  Re: [Patient Full Name]
[Plan street address]  Date of birth: [Patient date of birth]
[Plan city, state ZIP code]  Member ID: [Patient ID 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 date/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]  [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]

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #3:
Sample appeal letter for denial due to severity

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 to influence the independent medical judgment of the physician.

Some key reminders

• You may consider including a letter, like this one, 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 ICD-10-CM code matching your patient’s diagnosis

• Click here for a Word version of this letter, available on the DUPIXENT website

Checklist summary

☐ Appeal form recommended by health plan

☐ Current/recent chart notes
  — Date of initial diagnosis
  — Severity and frequency of flares
  — BSA involved with body location
  — Response to all prior therapies (e.g., 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

IMPORTANT SAFETY INFORMATION (cont’d)

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, and dry eye. The safety profile in children and adolescents 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 in adolescents and children observed through Week 52 was consistent with that seen in adults with atopic dermatitis.

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #3

[Insert office letterhead here]

[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]:

This letter serves as the [1st/2nd] appeal for approval of DUPIXENT® (dupilumab), which was originally denied to [Patient Full Name] on [Date of Denial] because the patient’s condition did not meet the plan’s severity criteria based on [indicate reasoning mentioned in denial letter].

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

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
  Assessment of severity:
  — 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 the patient’s condition warrants 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,

[Applicant’s Signature]

[Applicant’s Name, MD/DO/NP/PA]

Enclosures: [See Checklist on previous page]
Example #4:
Sample appeal letter for denial 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 to influence the independent medical judgment of the physician.

Some key reminders
• You may consider including a letter, like this one, if coverage is denied because, based on the health plan’s requirements, your patient did not receive an adequate trial of immunosuppressants
• Appeal letters should be signed by both the patient and the physician
• Be sure to populate an appropriate ICD-10-CM code matching your patient’s diagnosis
• Click here for a Word version of this letter, available on the DUPIXENT website

Checklist summary

☐ Appeal form recommended by health plan
☐ Current/recent chart notes
  — Date of initial diagnosis
  — Severity and frequency of flares
  — 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

IMPORTANT SAFETY INFORMATION (cont’d)

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

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #4

[Insert office letterhead here]

[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]:

This letter serves as the [1st/2nd] 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]  [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]

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #5:
Sample appeal letter for denial due to requirement for systemic corticosteroid 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 to influence the independent medical judgment of the physician.

Some key reminders

• You may consider including a letter, like this one, if coverage is denied because, based on the health plan’s requirements, your patient did not receive an adequate trial of systemic corticosteroids

• Appeal letters should be signed by both the patient or caregiver and the physician

• Be sure to populate an appropriate ICD-10-CM code matching your patient’s diagnosis

• Click here for a Word version of this letter, available on the DUPIXENT website

Checklist summary

☐ Appeal form recommended by health plan
☐ Current/recent chart notes
  — Date of initial diagnosis
  — Severity and frequency of flares
  — 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

IMPORTANT SAFETY INFORMATION (cont’d)

USE IN SPECIFIC POPULATIONS

• Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. Healthcare providers and patients may call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/ to enroll in or obtain information about the registry. 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.

Please see additional Important Safety Information throughout.
Please click here for full Prescribing Information.
Dear [Contact Name]:

This letter serves as the [1st/2nd] 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 corticosteroid(s) mentioned in denial letter].

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

[Summarize your specific reasons why systemic corticosteroids 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 corticosteroids, 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)]

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]
Example #6: Sample appeal letter for denial due to adequate trial of topical corticosteroid, topical calcineurin inhibitor, and/or topical PDE-4 inhibitor 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 to influence the independent medical judgment of the physician.

Some key reminders

- You may consider including a letter, like this one, if coverage is denied because, based on the health plan’s requirements, the patient did not receive an adequate trial of a topical corticosteroid, a topical calcineurin inhibitor, and/or a topical PDE-4 inhibitor
- Appeal letters should be signed by both the patient or caregiver and the physician
- Be sure to populate an appropriate ICD-10-CM code matching your patient’s diagnosis
- Click here for a Word version of this letter, available on the DUPIXENT website

Checklist summary

- Appeal form recommended by health plan
- Current/recent chart notes
  - Date of initial diagnosis
  - Severity and frequency of flares
  - 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

IMPORTANT SAFETY INFORMATION (cont’d)

USE IN SPECIFIC POPULATIONS (cont’d)

- 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 additional Important Safety Information throughout. Please click here for full Prescribing Information.
Dear [Contact Name]:

This letter serves as the [1st/2nd] 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 topical therapy(ies) 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 topical corticosteroids, topical calcineurin inhibitors, and/or topical PDE-4 inhibitors 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(s) of topical therapy, 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 also 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 the 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] [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]
Example #7:
Sample appeal letter for denial due to nonformulary status

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 to influence the independent medical judgment of the physician.

Some key reminders

• You may consider including a letter, like this one, if coverage is denied because DUPIXENT is not on the health plan’s formulary or not covered for any other reason
• Appeal letters should be signed by both the patient or caregiver and the physician
• Be sure to populate an appropriate ICD-10-CM code matching your patient’s diagnosis
• Click here for a Word version of this letter, available on the DUPIXENT website

Checklist summary

☐ Appeal form recommended by health plan
☐ Current/recent chart notes
  — Date of initial diagnosis
  — Severity and frequency of flares
  — 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

Please see additional Important Safety Information throughout. Please click here for full Prescribing Information.
Example #7

[Date]
[Plan name]
[Plan street address]
[Plan city, state ZIP code]

Dear [Contact Name]:

This letter serves as the [1st/2nd] 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:
  
  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]

Summary of patient history

• [Treatment history, including type and duration]
• [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]

[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]

Enclosures: [See Checklist on previous page]

Please see additional Important Safety Information throughout.
Please click here for full Prescribing Information.
INDICATION
DUPIXENT is indicated for the treatment of patients aged 6 years 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.

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.

Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

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.

Atopic Dermatitis Patients with Comorbid Asthma: Advise patients not to adjust or stop their asthma treatments without consultation with their physicians.

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% 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, and dry eye. The safety profile in children and adolescents 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 in adolescents and children observed through Week 52 was consistent with that seen in adults with atopic dermatitis.

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

USE IN SPECIFIC POPULATIONS

• Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. Healthcare providers and patients may call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/ to enroll in or obtain information about the registry. 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 [click here](https://mothertobaby.org/ongoing-study/dupixent/) for full Prescribing Information.