



Navigating prior authorizations and appeals for DUPIXENT® (dupilumab)

An informational guide with example letters regarding coverage for DUPIXENT

INDICATION

DUPIXENT is indicated as an add-on maintenance treatment of patients 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. <u>Limitation of Use</u>: 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.





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Important Safety Information

IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum, erythema multiforme, 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.

Overview

This guide was developed in case you need assistance understanding how to submit the paperwork that is necessary for your patients to gain access to DUPIXENT® (dupilumab). The information and example letters provided can 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 process 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.



Submitting a request for prior authorization



Once you submit the Enrollment Form to *DUPIXENT MyWay®*, 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 populated PA form for your review, which you should review, 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 copy of your chart notes with details of diagnosis, disease severity, and treatment history (eg, date of initial diagnosis; eosinophil, IgE, and FeNO levels and last test dates; pre-bronchodilator FEV₁ and last test date; any comorbidities; and the number of severe exacerbations in the past 12 months)



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

 ${\sf FeNO=fractional\ exhaled\ nitric\ oxide;\ FEV}_1 = {\sf forced\ expiratory\ volume\ in\ 1\ second;\ IgE=Immunoglobulin\ E.}$

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.





Understanding the appeals process

If a PA is denied, we've provided information in case you need help preparing an appeals 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

Dudixen

(dupilumab) Injection

(see appeals 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
- The appeals packet is submitted by the physician's office or the 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 attempt¹
- 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

Reference: 1. United States Government Accountability Office. Report to the Secretary of Health and Human Services and the Secretary of Labor. Private health insurance: data on application and coverage denials. March 2011. Accessed August 23, 2021. https://www.gao.gov/assets/320/316699.pdf







Writing the appeal letter

Identify the reason for your patient's DUPIXENT® (dupilumab) coverage denial and see the sample letter that discusses those issues.

Reason for denial

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

DUPIXENT is not covered on the patient's health plan's formulary or is not covered for any other reason

See example

page 10

3 page 12

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.





Example letters

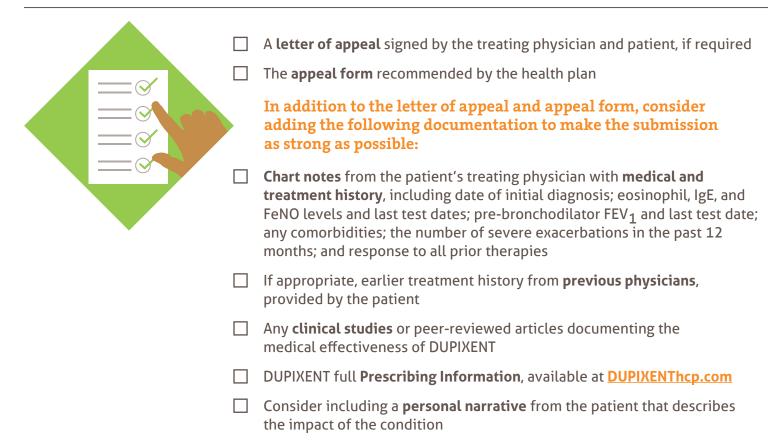
DUPIXENT® (dupilumab) sample letters are included in this guide to help provide the type of information that may be useful when responding to a health plan.

For electronic versions of these sample letters, visit **DUPIXENThcp.com**.

The following letters provide examples of the information that may be required when responding to a PA or appeal request for DUPIXENT from a patient's health plan regarding medical necessity. Use of the information within these letters 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.



Appeals packet checklist



IMPORTANT SAFETY INFORMATION (cont'd)

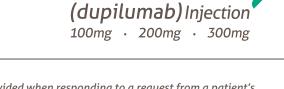
WARNINGS AND PRECAUTIONS (cont'd)

Risk Associated with Abrupt 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.



Example #1:

Letter of medical necessity



DUPIXEN

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 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 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
П	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. 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.



Example #1

[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]

DUPIXEN

(dupilumab) Injection
100mg · 200mg · 300mg

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
 - [Eosinophil levels (for eosinophilic phenotype) and test date]
 - [FeNO levels (if available) and last test date]
 - [IgE level (if available) and last test date]
 - [Pre-bronchodilator FEV₁ 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 duration of each type of therapy]
- [Response to past therapies]
- [Note any contraindications to available treatment options]

[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.

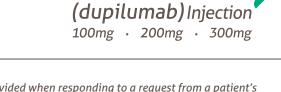
Sincerely,

[Treating Physician's Signature]
[Treating Physician's Name, MD/DO/NP/PA]

Enclosures: [See Checklist on previous page]

Example #2:

Appeal letter for denial due to severity



DUPIXEN

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 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 (for example, the number of exacerbations over a period of time did not meet the plan's criteria)
- 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

Ш	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
П	Patient's narrative

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout.

Please click here for full Prescribing Information.



Example #2

[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]

DUPIXEN

(dupilumab) Injection
100mg · 200mg · 300mg

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'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
 - [Eosinophil levels (for eosinophilic phenotype) and test date]
 - [FeNO levels (if available) and last test date]
 - [IgE level (if available) and last test date]
 - [Pre-bronchodilator FEV₁ 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 duration of each type of therapy]
- [Response to past therapies]
- [Note any contraindications to available treatment options]

[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,

[Treating Physician's Signature]
[Treating Physician's Name, MD/DO/NP/PA]

[Patient/Legal Representative's Signature, if required] [Patient/Legal Representative's Name]

[: ditelled Degat Representative s

Enclosures: [See Checklist on previous page]

PA request



3

Example #3:

Appeal letter for denial 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 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 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 (FEV₁) 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

IMPORTANT SAFETY INFORMATION (cont'd)

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 Important Safety Information throughout.

Please click here for full Prescribing Information.



Example #3

[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]

DUPIXEN

(dupilumab) Injection

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 test date]
 - [FeNO levels (if available) and last test date]
 - [IgE level (if available) and last test date]
 - [Pre-bronchodilator FEV₁ 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]

(dupilumab)Injection
100mg · 200mg · 300mg

INDICATION

DUPIXENT is indicated as an add-on maintenance treatment of patients 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. <u>Limitation of Use</u>: 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.

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum, erythema multiforme, 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.

Risk Associated with Abrupt 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.

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(Continued on next page)

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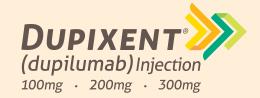
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USE IN SPECIFIC POPULATIONS

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 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.





1-844-DUPIXEN(T) (1-844-387-4936) Option 1

for live support: Monday–Friday, 8 AM–9 PM Eastern time

Fax: **1-844-387-9370**

DUPIXENThcp.com

