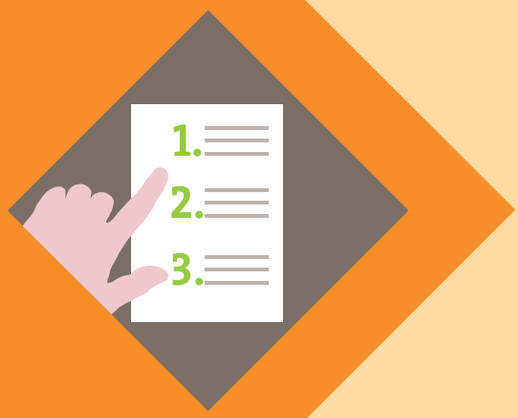
DUPIXENT®
(dupilumab) Injection
200mg · 300mg



Navigating prior authorizations and appeals for DUPIXENT® (dupilumab)

An informational guide with sample letters regarding coverage for DUPIXENT

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

DUPIXENT myway®

DUPIXENT® (dupilumab) Injection
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Contents

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 sample letters provided can help you understand the requirements of communicating effectively when requesting prior authorizations (PAs) and appealing PA denials for DUPIXENT coverage.

INDICATIONS

Atopic Dermatitis: DUPIXENT is indicated for the treatment of patients aged 12 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.

Asthma: DUPIXENT is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

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.

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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 FEV_1 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

FeNO=fractional exhaled nitric oxide; FEV_1=forced expiratory volume in 1 second; IgE=Immunoglobulin E.

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 Important Safety Information throughout.

Please click here for full Prescribing Information.

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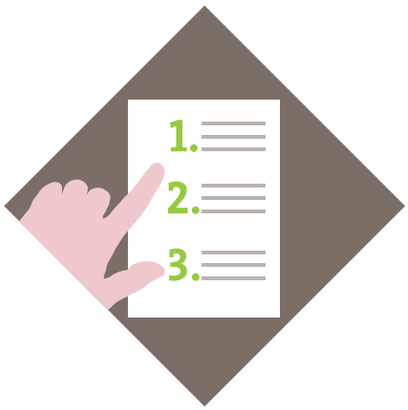

Understanding the appeals process

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 sample letters in this packet)

3
Add supporting documentation
(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 attempt[1]**
- 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. Private Health Insurance: Data on Application and Coverage Denials. March 2011. https://www.gao.gov/assets/320/316699.pdf. Accessed March 29, 2019.

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

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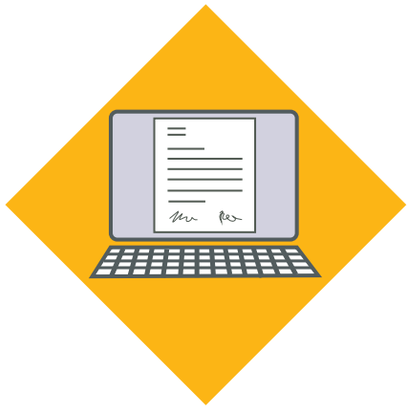

Writing the appeal letter

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

Reason for denial	See example #
The patient's condition did not meet the plan's severity criteria	2 page 10
DUPIXENT is not covered on the patient's health plan's formulary or is not covered for any other reason	3 page 12

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 in these patients. Among asthma subjects the frequency of conjunctivitis and keratitis was similar between DUPIXENT and placebo. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

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. Be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in patients with eosinophilia, which may be associated with a reduction of oral corticosteroids. Cases of eosinophilic pneumonia and of vasculitis consistent with eosinophilic granulomatosis with polyangiitis have been reported in adult patients who participated in the asthma development program. A causal association between DUPIXENT and these conditions has not been established.

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

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Sample 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**.

Appeals packet checklist

- ☐ A **letter of appeal** signed by the treating physician and patient, 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:

- ☐ **Chart notes** from the patient's treating physician with **medical and treatment history**, including date of initial diagnosis; eosinophil, IgE, and FeNO levels and last test dates; pre-bronchodilator FEV_1 and last test date; any comorbidities; the number of severe exacerbations in the past 12 months; and response to all prior therapies
- ☐ If appropriate, earlier treatment history from **previous physicians**, provided by the patient
- ☐ Any **clinical studies** or peer-reviewed articles documenting the medical effectiveness of DUPIXENT
- ☐ DUPIXENT full **Prescribing Information**, available at 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)

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.

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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Example #1:
Letter of medical necessity

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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
- ☐ 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.

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

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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]

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 FEV_1 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

DUPIXENT® (dupilumab) Injection
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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

- ☐ 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
- ☐ Patient's narrative

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS:

- **Atopic Dermatitis:** 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 adolescents through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile observed in adolescents through Week 52 was consistent with that seen in adults with atopic dermatitis.
- **Asthma:** The most common adverse reactions (incidence ≥1%) 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.

DUPIXENT myway®

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]

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 FEV_1 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]

Enclosures: [See Checklist on previous page]

Example #3:
Appeal letter for denial due to nonformulary status or other reason

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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 (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
- ☐ Patient's narrative

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** 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.

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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]

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 FEV_1 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]

INDICATIONS

Atopic Dermatitis: DUPIXENT is indicated for the treatment of patients aged 12 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.

Asthma: DUPIXENT is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with 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.

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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 in these patients. Among asthma subjects the frequency of conjunctivitis and keratitis was similar between DUPIXENT and placebo. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

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. Be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in patients with eosinophilia, which may be associated with a reduction of oral corticosteroids. Cases of eosinophilic pneumonia and of vasculitis consistent with eosinophilic granulomatosis with polyangiitis have been reported in adult patients who participated in the asthma 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.

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.

(Continued on next page)

Please click here for full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS:

- **Atopic Dermatitis:** 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 adolescents through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile observed in adolescents through Week 52 was consistent with that seen in adults with atopic dermatitis.
- **Asthma:** The most common adverse reactions (incidence ≥1%) are injection site reactions, oropharyngeal pain, and eosinophilia.

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

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** 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.

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DUPIXENT myway®

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

SANOFI GENZYME REGENERON