Uncontrolled chronic rhinosinusitis with nasal polyposis

DUPIXENT® (dupilumab) Injection 300mg

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 in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

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.

DUPIXENT myway®

Contents

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.

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.

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 a draft PA form prepopulated with your patient's demographic information for your review. Complete and sign the form and fax it 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
  and/or
  medical exception letter; see Example #2
- Include a copy of your chart notes with details of diagnosis, disease severity, and treatment history (eg, date of initial diagnosis, relevant health conditions or symptoms, response to all prior therapies [eg, oral corticosteroids or intranasal corticosteroids], and dates and results of the patient's last endoscopy, computed tomography [CT] scan, and prior surgeries, such as functional endoscopic sinus surgery [FESS] and/or polypectomy)

1

2

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 (cont'd)

Conjunctivitis and Keratitis: Conjunctivitis occurred more frequently in subjects with chronic rhinosinusitis with nasal polyposis who received DUPIXENT. There were no cases of keratitis reported in the CRSwNP development program. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Please see Important Safety Information throughout.
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Understanding the appeal process

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

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
- The appeal 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]**
- Up to 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. https://www.gao.gov/assets/320/316699.pdf. Accessed July 23, 2020.

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 example letter that discusses those issues.

Reason for denial	See example #
The patient did not have prior surgery and is not a candidate for surgery	3 page 12
The patient's condition did not meet the plan's severity criteria	4 page 14
DUPIXENT is not covered on the patient's health plan's formulary or is not covered for any other reason	5 page 16

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 CRSwNP 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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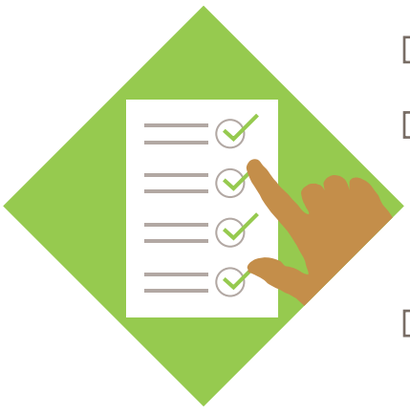
Example letters

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

To download electronic versions of these example 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.

Appeal 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, relevant health conditions or symptoms, response to all prior therapies (eg, oral corticosteroids or intranasal corticosteroids), and dates and results of the patient's last endoscopy, CT scan, and prior surgeries, such as FESS and/or polypectomy
- ☐ 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® (dupilumab)
- ☐ 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)

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

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Example #1:
Letter of medical necessity

DUPIXENT® (dupilumab) Injection 300mg

This letter provides an example of the information that may be required when responding to a prior authorization (PA) or appeal request for DUPIXENT® (dupilumab) from a patient's health plan regarding medical necessity. 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

- ☐ PA or appeal form recommended by the health plan
- ☐ Chart notes
  - Date of initial diagnosis
  - Relevant health conditions or symptoms
  - Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)
  - Date and result of last endoscopy
  - Date and result of last computed tomography (CT) scan
  - Date and result of prior functional endoscopic sinus surgery (FESS) and/or polypectomy
- ☐ Explanation of medical necessity, including why the patient's recent symptoms, severity of condition, and impact of disease warrant treatment with DUPIXENT
- ☐ 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)

Patients with Co-Morbid Asthma: Advise patients with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.

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

DUPIXENT myway®

Example #1

[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 medical necessity, including 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 conditions

[Indicate any relevant health conditions such as uncontrolled chronic rhinosinusitis with nasal polyposis]

[Indicate any symptoms such as nasal congestion or loss of smell, etc.]

Summary of patient history

- [Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)]
- [Date and result of last endoscopy]
- [Date and result of last CT scan]
- [Prior surgeries, such as prior FESS and/or polypectomy]

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

In order for me to provide appropriate care for my patient, it is important [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:
Letter of medical exception

DUPIXENT® (dupilumab) Injection 300mg

This example includes the types of information that may be required 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 a letter like this if coverage for DUPIXENT is denied because of the health plan's policy or if DUPIXENT is subject to a national drug code block
- Medical exception letters should be signed by **both** the patient and the physician
- Be sure to populate an appropriate *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code matching your patient's diagnosis

Checklist summary

- ☐ Chart notes
  - Date of initial diagnosis
  - Relevant health conditions and symptoms
  - Treatment history, including duration of each therapy
  - Response to all prior therapies
  - 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 Important Safety Information throughout.
Please click here for full Prescribing Information.

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Example #2

[Date]
[Plan name]
[Plan Street address]
[Plan City, State ZIP code]

Re: [Patient Full Name]
Date of Birth: [Patient date of birth]
Member ID: [Patient ID number]
Group Number: [Patient group number]

Dear [Contact Name]:

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

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

Current symptoms and conditions

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

Summary of patient history

- [Treatment history, including duration of each therapy]
- [Response to all prior therapies]
- [Date(s) and result(s) of last diagnostic test(s), if applicable]

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

Based upon the patient's clinical condition and a review of the supporting documentation, I am confident you will agree that [Patient Full Name] should be treated with DUPIXENT. In order for me to provide appropriate care for my patient, it is important that [Plan Name] provide adequate coverage for this treatment.

On behalf of [Patient Full Name], we appreciate your consideration. Please call me at [Primary Treating Site Phone Number] if I can be of further assistance or you require additional information. Thank you in advance for your immediate attention and prompt review of this request.

Sincerely,

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

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

Enclosures: [See Checklist on previous page]

Example #3:
Patient is noncandidate for surgery

DUPIXENT® (dupilumab) Injection 300mg

This letter provides an example of the information that may be required when appealing a denial decision for DUPIXENT® (dupilumab) from a patient's health plan when a patient is not a candidate for surgery. 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 your patient is not a candidate for surgery to treat their condition
- 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
  - Relevant health conditions and symptoms
  - Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)
  - Date and result of last endoscopy
  - Date and result of last computed tomography (CT) scan
- ☐ Reason why surgery is not an option for the patient
- ☐ History prior to your care, if applicable
- ☐ Supportive literature
- ☐ DUPIXENT Prescribing Information
- ☐ Patient's narrative

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1%) in patients with CRSwNP are injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.

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

DUPIXENT myway®

Example #3

[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 [1st/2nd] appeal for approval of DUPIXENT® (dupilumab), which was originally denied to [Patient Full Name] on [Date of Denial]. It is my professional judgment that DUPIXENT should be approved for my patient because [he/she] is not a viable candidate for surgery to treat [diagnosis] based on [provide reason patient is not a candidate for surgery].

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 reasons why [Patient's First Name] is not a candidate for surgery to treat [his/her] condition, 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 conditions

[Indicate any relevant health conditions such as uncontrolled chronic rhinosinusitis with nasal polyposis]
[Indicate any symptoms such as nasal congestion or loss of smell, etc.]

Summary of patient history

- [Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)]
- [Date and result of last endoscopy]
- [Date and result of last CT scan]
- [Reason why surgery is not an option for this patient]

[Explain why patient's recent symptoms, severity of condition, and impact of disease warrant 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 #4:
Appeal letter for denial due to severity

DUPIXENT® (dupilumab) Injection 300mg

This letter provides an example of the information that may be required when appealing a denial decision for DUPIXENT® (dupilumab) from a patient's health plan. 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
- 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
  - Relevant health conditions or symptoms
  - Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)
  - Date and result of last endoscopy
  - Date and result of last computed tomography (CT) scan
  - Date and result of prior functional endoscopic sinus surgery (FESS) and/or polypectomy
- ☐ Explanation of why the patient's recent symptoms, severity of condition, and impact of disease warrant treatment with DUPIXENT
- ☐ History prior to your care, if applicable
- ☐ 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 Important Safety Information throughout.
Please click here for full Prescribing Information.

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Example #4

[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 [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 conditions

[Indicate any relevant health conditions such as uncontrolled chronic rhinosinusitis with nasal polyposis]
[Indicate any symptoms such as nasal congestion or loss of smell, etc.]

Summary of patient history

- [Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)]
- [Date and result of last endoscopy]
- [Date and result of last CT scan]
- [Prior surgeries, such as prior FESS and/or polypectomy]

[Explain why patient's recent symptoms, severity of condition, and impact of disease warrant 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 #5:
Appeal letter for denial due to nonformulary status or other reason

DUPIXENT® (dupilumab) Injection 300mg

This letter provides an example of the information that may be required when appealing a denial decision for DUPIXENT® (dupilumab) from a patient's health plan. 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 health plan formulary of the patient or it 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
  - Relevant health conditions or symptoms
  - Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)
  - Date and result of last endoscopy
  - Date and result of last computed tomography (CT) scan
  - Date and result of prior functional endoscopic sinus surgery (FESS) and/or polypectomy
- ☐ 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:** 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 see Important Safety Information throughout.
Please click here for full Prescribing Information.

DUPIXENT myway®

Example #5

[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 [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 conditions

[Indicate any relevant health conditions such as uncontrolled chronic rhinosinusitis with nasal polyposis]
[Indicate any symptoms such as nasal congestion or loss of smell, etc.]

Summary of patient history

- [Response to all prior therapies (oral corticosteroids or intranasal corticosteroids)]
- [Date and result of last endoscopy]
- [Date and result of last CT scan]
- [Prior surgeries, such as prior FESS and/or polypectomy]

[Explain why patient's recent 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 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]

INDICATION

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

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 occurred more frequently in subjects with chronic rhinosinusitis with nasal polyposis who received DUPIXENT. There were no cases of keratitis reported in the CRSwNP development program. 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 (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 CRSwNP development program. A causal association between DUPIXENT and these conditions has not been established.

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.

Patients with Co-Morbid Asthma: Advise patients with co-morbid asthma 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: The most common adverse reactions (incidence ≥1%) in patients with CRSwNP are injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.

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 for full Prescribing Information.

DUPIXENT® (dupilumab) Injection 300mg

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**

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