DUPIXENT myway®

Navigating prior authorizations and appeals for DUPIXENT® (dupilumab)

For patients with uncontrolled chronic rhinosinusitis with nasal polyps (CRSwNP)

This guide provides information about health plan requirements that may be required when submitting prior authorizations (PAs) or appealing PA denials when seeking DUPIXENT coverage for your patients

INDICATION

DUPIXENT is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

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Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

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Your first step: Submitting a PA request

Prior authorization is a very common requirement of health plans before approving DUPIXENT® (dupilumab). Once you have verification of an appropriate patient's pharmacy benefit provider, you should begin the PA process. You can obtain the appropriate PA form through *DUPIXENT MyWay®*, CoverMyMeds®, or your patient's insurance provider or specialty pharmacy.

The following tips may help strengthen the case for your patient when you submit a PA on their behalf:

Document current and/or recent chart notes. This includes:

- Details of current diagnosis
- Disease severity
- Treatment history (eg, date of initial diagnosis and relevant health conditions or symptoms)
- Current and prior therapies (eg, oral corticosteroids, intranasal corticosteroids)
- 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

For more tips on handling PA requirements, ask your Field Representative for a **PA checklist for CRSwNP**

Consider including a letter that explains your patient's condition in detail. This may include a **letter of medical exception** or a **letter of medical necessity.** More information about these letters can be found on page 7.

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IMPORTANT SAFETY INFORMATION (cont'd)

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Conjunctivitis and Keratitis: Conjunctivitis occurred more frequently in adult subjects with chronic rhinosinusitis with nasal polyps who received DUPIXENT compared to those who received placebo. There were no cases of keratitis reported in the CRSwNP development program. Conjunctivitis and keratitis have been reported with DUPIXENT in post-marketing settings, with some patients reporting visual disturbances (e.g. blurred vision). Advise patients or their caregivers to report new-onset or worsening eye symptoms. Consider ophthalmological examination for patients who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis, as appropriate.

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Need assistance? We are here to help

If requested on the *DUPIXENT MyWay*® Enrollment Form, the *DUPIXENT MyWay* team can provide support during the PA process, including:

- Performing a **benefits investigation**
- Determining **PA requirements**
- **Pre-populating the PA form** with as much demographic information as possible
- Helping to **track the PA status** with the patient's health plan and communicating with you and your patient about the status

For additional information or if you have questions, contact your Field Representative or call *DUPIXENT MyWay* at **1-844-DUPIXEN(T)** (1-844-387-4936) Option 1, Monday–Friday, 8 AM–9 PM Eastern time.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions: Patients being treated for asthma may present with clinical features of eosinophilic pneumonia or eosinophilic granulomatosis with polyangiitis (EGPA). These events may be associated with the reduction of oral corticosteroid therapy. Healthcare providers should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, kidney injury, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adults who participated in the asthma development program and cases of EGPA have been reported with DUPIXENT in adults who participated in the asthma development program as well as in adults with co-morbid asthma in the CRSwNP development program. Advise patients to report signs of eosinophilic pneumonia and EGPA. Consider withholding DUPIXENT if eosinophilic pneumonia or EGPA are suspected.

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When PA is denied: Navigating the appeal process

If your patient's PA is denied, you can appeal the decision. A successful appeal may include the following checklist of information, compiled in an appeal packet.

- ☐ A letter of appeal signed by the treating physician and patient or caregiver, if required. Appeal letters can be customized depending on the reason a PA has been denied. See page 7 for a list of example letters that you can download and reference to appeal a PA denial
- ☐ The appeal form recommended by the health plan
- ☐ In addition to the letter of appeal and appeal form, consider including current and/or recent chart notes from the patient's treating physician to make the appeal as thorough as possible, including:
  - ☐ Date of initial diagnosis
  - ☐ Dates and results of the patient's last endoscopy, CT scan, and prior surgeries, such as FESS and/or polypectomy
  - ☐ Response to all prior therapies (eg, name of therapy, such as oral corticosteroids or intranasal corticosteroids, dose, start date/stop date, length of treatment, and clinical response)
  - ☐ Any relevant comorbidities or symptoms
  - ☐ If appropriate, earlier treatment history from previous physicians, provided by the patient
- ☐ *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code matching your patient's diagnosis
- ☐ Reasons why the patient's recent symptoms, severity of condition, and impact of disease warrant treatment with DUPIXENT® (dupilumab)
- ☐ Any clinical studies or peer-reviewed articles documenting the medical effectiveness of DUPIXENT
- ☐ DUPIXENT full Prescribing Information, available at **www.DUPIXENThcp.com**
- ☐ A personal narrative from the patient that describes the impact of their condition

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 of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

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

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When PA is denied: Navigating the appeal process (cont'd)

Key points to consider when filing an appeal on behalf of your patient:

- Adhere to the timelines and use the forms noted in the health plan's letter of denial
- Depending on the health plan, your patient's signature may be required on the appeal letter (if patient is a minor, a guardian's signature is required)
- The appeal packet should be submitted by your office or your patient
- Two levels of internal review may be required before the health plan will notify you of your patient's eligibility for an external appeal. If this occurs, the reviewer will be an independent party, typically board certified in the specialty. Their decision will be binding on the health plan
  - All documentation from previous reviews should be submitted in subsequent appeals

Remember, successful appeals may take more than 1 attempt.[1] Patients can also advocate for an appeal on their own behalf, and HCPs may request a peer-to-peer review with a medical reviewer at a health plan.

DUPIXENT MyWay® can **help educate your office** about the appropriate actions needed to **appeal a coverage denial**. ***DUPIXENT MyWay* Appeal Specialists** can help provide support throughout the appeal process.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Arthralgia and Psoriatic Arthritis: Arthralgia has been reported with use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization. Cases of new-onset psoriatic arthritis requiring systemic treatment have been reported with the use of DUPIXENT. Advise patients to report new-onset or worsening joint symptoms. If the symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

Parasitic (Helminth) Infections: It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves.

Vaccinations: Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating DUPIXENT. Avoid use of live vaccines during treatment with DUPIXENT.

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Example letters

The following example letters are templates for the information that may be required when responding to a PA or appeal request for DUPIXENT® (dupilumab) from a patient's health plan. 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.

Sample letter of medical necessity

Consider including this letter: To emphasize that DUPIXENT was prescribed because it is necessary for the patient's health and will result in better outcomes. This letter can be accompanied with a PA submission or in addition to your appeal letter, if needed

Who should sign this letter: HCP only

Sample medical exception letter

Consider including this letter: If coverage for DUPIXENT is denied because of the health plan's policy or if DUPIXENT is subject to a national drug code block. This letter can be accompanied with a PA submission or in addition to your appeal letter, if needed

Who should sign this letter: Both the patient and HCP

Denial due to severity

Consider including this letter: If coverage for DUPIXENT is denied because your patient's condition did not meet the plan's severity criteria for treatment with DUPIXENT

Who should sign this letter: Both the patient and HCP

Patient is noncandidate for surgery

Consider including this letter: If your patient is not a candidate for surgery to treat their condition

Who should sign this letter: Both the patient and HCP

Sample appeal letter for denial due to nonformulary status

Consider including this letter: If coverage is denied because DUPIXENT is not on the health plan's formulary or not covered for any other reason

Who should sign this letter: Both the patient and HCP

Click here to download these example letters

IMPORTANT SAFETY INFORMATION (cont'd)

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

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For more information, contact your Field Representative or call *DUPIXENT MyWay*® at **1-844-DUPIXEN(T)** (1-844-387-4936) Option 1, Monday–Friday, 8 AM–9 PM Eastern time

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 April 14, 2022. https://www.gao.gov/assets/320/316699.pdf

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 accompanying full Prescribing Information.

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