



# Prior authorization checklist

For DUPIXENT<sup>®</sup> (dupilumab) in eosinophilic esophagitis (EoE)

A patient's health plan is likely to require a prior authorization (PA) before it approves DUPIXENT for the treatment of patients aged 12 years and older weighing at least 40 kg with EoE. However you choose to submit a PA request (eg, fax, website, phone, CoverMyMeds<sup>®a</sup>), **this checklist can help guide you through the information health plans may need from you.**

<sup>a</sup>CoverMyMeds is a registered trademark of CoverMyMeds, LLC.

## INDICATION

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

## 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 on next page and accompanying full [Prescribing Information](#).

**DUPIXENT<sup>®</sup>**   
(dupilumab) Injection 300mg

## Tips for handling PA requirements from health plans

Ensure you document the following information according to your patient's diagnosis and as required by the patient's plan

- Diagnosis information:**
  - The appropriate ICD-10-CM code (eg, K20.\_\_\_\_)
  - Date of diagnosis
  - Documentation of EoE diagnosis via:
    - Endoscopic esophageal biopsy showing presence of eosinophilic infiltration (>15 eos/hpf) in >2 of 3 biopsied esophageal regions (ie, proximal, mid, or distal)
    - Signs and symptoms of esophageal dysfunction
  - Dates and results of last endoscopic esophageal biopsy
  - Documentation of endoscopic reference score (EREFS)
  - Documentation of ongoing symptoms, such as:
    - Dysphagia episodes (at least 2 episodes per week for >4 weeks)
    - Food impaction
    - Nausea
    - Chest pain
    - Reflux-like symptoms
    - Vomiting or regurgitation
    - Abdominal pain
    - Diarrhea
  - Any relevant comorbidities
- Treatment history:**
  - Prior/current medical treatments, documenting treatment name and dose, duration of use, adherence, contraindications, and response to:
    - High-dose proton pump inhibitor for at least 8 weeks
    - Swallowed topical corticosteroids (eg, fluticasone propionate, budesonide)
    - Dietary therapy (eg, avoidance of food allergen triggers)
- If the request is for reauthorization for continuation of therapy:**
  - Documentation of clinically meaningful beneficial response to DUPIXENT® (dupilumab)

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

\*Note the payer's reauthorization time frame and requirements.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

**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.

**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.

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## Tips for handling PA requirements from health plans (cont'd)

Please keep in mind that PA requirements are likely to vary, so check with your patient's health plan to ensure you have an accurate list of requirements before you submit

- Obtain the appropriate PA form after initiating your patient through one of the following:
  - DUPIXENT MyWay®
  - CoverMyMeds®
  - Insurance provider
  - Specialty pharmacy
- Fill out all required patient and provider information on the PA form
- Attach a letter of medical necessity or medical exception, if required
- Photocopy the front and back of the patient's pharmacy benefit card
- Verify with the health plan to ensure all information and documentation has been received and is clear
- Note the payer's reauthorization time frame and requirements
- Sign all necessary forms. Any and all forms may be rejected if a signature is missing

! Please attach chart notes relevant to diagnosis and therapy along with the PA form submission

## 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.

**Arthralgia:** Arthralgia has been reported with the use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization. Advise patients to report new onset or worsening joint symptoms. If 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.

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## Common reasons for coverage denials

### Incomplete information may lead to a denial for DUPIXENT® (dupilumab)

Below are some of the most common causes for denial. It is important that you double check your documentation when you submit your initial PA request to avoid these common causes for denial.

- Clerical error (ie, missing or incorrect ICD-10-CM code)
- Lack of documentation supporting appropriate diagnosis or other required documentation from most recent chart notes
- Did not include duration on current therapies or names of all therapies that were tried and failed
- Documentation did not support health plan's criteria for approval of DUPIXENT
- Patient was not treated with prior therapies required by plan
- No reason provided for discontinuation of previous therapy/therapies

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

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

**ADVERSE REACTIONS:** The most common adverse reactions (incidence  $\geq 2\%$ ) are injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.

### 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/dupilumab/>. 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**.

For any questions or concerns, or to report side effects with a Sanofi and Regeneron product while enrolled in *DUPIXENT MyWay*®, please contact **1-844-DUPIXEN(T)** (1-844-387-4936) Option 1, Monday–Friday, 8 AM–9 PM Eastern time.

**sanofi** **REGENERON**

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