



Prior authorization checklist

For DUPIXENT[®] (dupilumab) in the treatment of appropriate adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment

A patient's health plan is likely to require a PA before it approves DUPIXENT for appropriate patients. However you choose to submit a PA request (eg, fax, website, phone, CoverMyMeds^{®a}), **this checklist can help guide you through the information health plans may need from you.**

It is important to review each health plan's guidelines for obtaining PA, as elements and requirements vary by plan. Please note that following a health plan's guidelines does not guarantee the patient's health plan will provide reimbursement for DUPIXENT, and the guidelines are not intended to substitute or influence the clinician's independent medical judgment.

^aCoverMyMeds is a registered trademark of CoverMyMeds LLC.

INDICATION

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: DUPIXENT is not indicated for treatment of other forms of urticaria.

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 and accompanying full [Prescribing Information](#).

DUPIXENT[®] 
(dupilumab) Injection
200mg • 300mg

Tips for handling PA requirements from health plans

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
 - Retail pharmacy
- Ensure you document the following in the most recent chart notes:
 - Patient's diagnosis, using the appropriate ICD-10-CM code (eg, L50.____)
 - Itch severity score, if required by payer
 - Hives severity score, if required by payer
 - Urticaria activity score, if required by payer
 - Patient's current age and months/years since diagnosis
 - Disease impact on patient's health (eg, physical or other)
 - Current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy, such as:
 - H1/H2-antihistamines
 - Antidepressants
 - Leukotriene receptor antagonists (LTRA)
 - Bruton's tyrosine kinase (BTK) inhibitors
 - Oral corticosteroids (OCS)
 - Biologics/biosimilars
 - Immunosuppressants
 - Other
 - All prior therapies and/or if any recommended therapies are considered inappropriate or contraindicated
- Fill out all required patient and provider information on the PA form
- Attach a letter of medical necessity, 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 was 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

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

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.

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Common reasons for coverage denials

Incomplete information may lead to a denial for DUPIXENT

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 the most recent chart notes
 - Consider indicating on the PA form the page on which the supporting clinical data can be found
- Did not include duration of current therapies or names of all therapies that were tried and failed
- Documentation did not support the health plan's criteria for approval of DUPIXENT
- Patient was not treated with prior therapies required by the health plan
- No reason provided for discontinuation of previous therapy or therapies

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

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 not to adjust or stop their asthma treatments without consultation with their physicians.

Arthralgia and Psoriatic Arthritis: 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. 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 symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

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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.

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.

ADVERSE REACTIONS: The most common adverse reactions (incidence $\geq 2\%$) in patients 12 years of age and older with chronic spontaneous urticaria are injection site reactions.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to DUPIXENT during 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 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-DUPIXENT(T)** (1-844-387-4936), option 1, Monday–Friday, 8 AM–9 PM Eastern time.

