Prior authorization checklist

For DUPIXENT® (dupilumab) in patients 6 months and older with uncontrolled moderate-to-severe atopic dermatitis (AD)

A patient's health plan is likely to require a prior authorization (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.**

[a]CoverMyMeds is a registered trademark of CoverMyMeds, LLC.

INDICATION

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months 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.

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® (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
- ☐ Ensure you document the following in the most recent chart notes:
  - Patient's diagnosis, using the appropriate ICD-10-CM code (eg, L20.__)
  - Patient's severity of atopic dermatitis (moderate or severe)
  - IGA score of 3 (moderate disease) or 4 (severe disease), if required by payer
  - Patient's current age and months/years since diagnosis
  - Percentage of body surface area affected (<10% or ≥10%)
  - Sensitive areas affected (eg, hands, feet, genitals/groin, scalp, intertriginous areas, other)
  - 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,[a] such as:
    - Topical corticosteroids
    - Topical calcineurin inhibitors
    - Topical PDE-4 inhibitor
    - Immunosuppressants
    - Phototherapy
    - Other
  - Documentation of 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

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

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; IGA=Investigator's Global Assessment.
[a]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.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

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
  - Consider indicating on your PA form the page on which the supporting clinical data can be found
- 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)

Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT versus placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, predominantly in atopic dermatitis patients. Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis. Advise patients to report new onset or worsening eye symptoms to their healthcare provider. Consider ophthalmological examination for patients who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis, as appropriate.

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Atopic Dermatitis Patients with Co-morbid Asthma: Advise patients 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.

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 ≥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, dry eye, and eosinophilia. The safety profile in pediatric patients through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile of DUPIXENT ± TCS in pediatric patients observed through Week 52 was consistent with that seen in adults with atopic dermatitis, with hand-foot-and-mouth disease and skin papilloma (incidence ≥2%) reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation.

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.

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.

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