CHANGE THEIR STORY TOGETHER

BY PARTNERING WITH A SPECIALIST

GET ANSWERS TO FREQUENTLY ASKED QUESTIONS ABOUT DUPIXENT

6+ MONTHS OF AGE

FOR UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS

DUPIXENT IS THE FIRST AND ONLY BIOLOGIC APPROVED FROM INFANCY TO ADULTHOOD

Real patients being treated with DUPIXENT. Individual results may vary.

STUCK IN A CYCLE OF FLARE, TREAT, REPEAT?

ARE THEY DU? FOR A CHANGE

IDENTIFY PATIENTS WHO MAY BENEFIT FROM SEEING A DERMATOLOGIST OR ALLERGIST

PARTNER WITH A SPECIALIST

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 throughout and click here for full Prescribing Information.

DUPIXENT® (dupilumab) Injection

200mg · 300mg

FREQUENTLY ASKED QUESTIONS ABOUT DUPIXENT

DUPIXENT® (dupilumab) Injection
200mg · 300mg

ABOUT DUPIXENT

WHAT IS DUPIXENT?

DUPIXENT is the first and only biologic approved for patients from infancy (6+ months of age) to adulthood for uncontrolled moderate-to-severe atopic dermatitis when topical Rx therapies are not enough. DUPIXENT inhibits IL-4 and IL-13 signaling, two sources of type 2 inflammation, to proactively treat the disease.[1] The mechanism of dupilumab action has not been definitively established.

WHAT FORM OF ECZEMA IS DUPIXENT INDICATED FOR?

DUPIXENT is indicated for the treatment of adult and pediatric patients 6+ months of age with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.[1]

IS DUPIXENT AN IMMUNOSUPPRESSANT?

DUPIXENT is not an immunosuppressant or a steroid. There is no initial lab testing or ongoing lab monitoring, according to the Prescribing Information. There are no known drug-to-drug interactions and DUPIXENT is not metabolized through the liver or excreted through the kidneys. DUPIXENT has no boxed warning.[1]

Please see additional Warnings and Precautions in the Prescribing Information and Important Safety Information throughout.

WHO MAY BE AN APPROPRIATE PATIENT FOR DUPIXENT?

When topical Rx therapies are not enough, patients aged 6 months and older with moderate-to-severe atopic dermatitis may be appropriate for DUPIXENT. Consider DUPIXENT if they:

- Have given ≥1 topical Rx therapy an adequate trial but are still uncontrolled[1-3,a]
- Feel that their itch is not well controlled[2,4]
- Have ≥10% of their body covered with lesions and/or lesions that may involve problem areas, such as the face, hands, and feet[1]

Ask yourself 2 simple questions to assess your patients aged 6+ months with moderate-to-severe atopic dermatitis uncontrolled with topical Rx therapy

- DU they still itch?

  or

- DU they still have burdensome lesions?

If you answer "Yes" to either of these questions, THEY MAY BE DU FOR A CHANGE.

[a] According to an expert panel of the International Eczema Council, adequate topical Rx therapy is defined as an induction period (to gain control of a flare) with medium- to high-potency topical corticosteroids (TCS) applied once or twice daily for 1 to 4 weeks, followed by a proactive maintenance period with medium-potency TCS applied 2 or 3 times weekly to normal-appearing skin at sites of frequent flare.[2]

IMPORTANT SAFETY INFORMATION

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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FREQUENTLY ASKED QUESTIONS ABOUT DUPIXENT (cont'd)

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ABOUT DUPIXENT

HOW IS DUPIXENT TYPICALLY PRESCRIBED?

DUPIXENT is typically prescribed by a specialist, such as a dermatologist or allergist. If you have a patient aged 6+ months with uncontrolled moderate-to-severe atopic dermatitis who you think might be appropriate for DUPIXENT, consider partnering with a dermatologist or allergist.
For help finding a specialist, click **here**.

Sanofi US and Regeneron do not endorse or recommend any particular physician, and search results do not include a comprehensive list of doctors in your area.

WHY PARTNER WITH A SPECIALIST

WHY SHOULD I CONSIDER PARTNERING WITH A SPECIALIST FOR A BIOLOGIC THERAPY?

Atopic dermatitis is a chronic, systemic disease which will be a lifelong condition for many patients. Patients with uncontrolled disease despite topical Rx therapy may need continuous, systemic treatment to adequately control their chronic itch and skin lesions.[5-7]

In the United States, ≈2.6 million patients (6+ months of age) with moderate-to-severe atopic dermatitis have uncontrolled disease despite treatment.[4,8,9,a]

PATIENTS CAN BE DISRUPTED BY UNPREDICTED FLARES DAY AND NIGHT:

- 86% of adults reported daily itch[10,b]
- ≈136 days per year on average are spent living in flare (as reported by caregivers of children ages 2 to 13 years and patients aged 14 years and older)[11,c]
- Among parents and caregivers, on average **22 hours** per week are spent in atopic dermatitis-related tasks[12,c,d]

A specialist such as a dermatologist or allergist can confirm which patients with uncontrolled moderate-to-severe atopic dermatitis may need another approach and prescribe a biologic like DUPIXENT—the first and only biologic approved from infancy (6+ months of age) to adulthood.[1]

[a] In adult patients (aged 18+ years), classification of inadequate control was based on physician assessment and defined as either currently flaring atopic dermatitis, deteriorating or changeable atopic dermatitis, or physician dissatisfaction with current control. In patients aged 6 months to 17 years, uncontrolled moderate disease was defined as ≥2 prescriptions of medium- to super-potent corticosteroids/topical calcineurin inhibitors over a 1-year observation period and all severe patients are determined as uncontrolled.[4,8]
[b] Data from a study of adult patients with moderate-to-severe atopic dermatitis with chronic disease for ≥3 years (n=380).[10]
[c] Telephone interviews conducted in 2004 included 779 caregivers of children aged 2 to 13 years, 125 adolescents aged 14 to 17 years, and 1098 adults with moderate-to-severe atopic dermatitis from 8 countries (including the United States). Caregivers of patients aged 2 to 13 years reported 122 days per year with flares and 9 flares per year with each lasting an average of 14 days. Patients aged 14 to 17 years reported 116 days per year with flares, and 8 flares per year with each lasting an average of 15 days. Adults reported 146 days per year with flares and 10 flares per year with each lasting an average of 15 days.[11]
[d] In an international online survey of self-reported caregivers (N=235) of children and adolescent patients with atopic dermatitis across all severities.[5]

IMPORTANT SAFETY INFORMATION

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.

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FREQUENTLY ASKED QUESTIONS ABOUT DUPIXENT (cont'd)

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SAFETY PROFILE

WHAT WERE THE MOST COMMON ADVERSE EVENTS SEEN IN CLINICAL TRIALS?

The most common adverse reactions (incidence ≥1%) in patients with atopic dermatitis were injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, dry eye, and eosinophilia. The safety profile of DUPIXENT in pediatric patients through Week 16 was similar to that of adults with atopic dermatitis. The 52-week safety profile of DUPIXENT + TCS in adults was generally consistent with the Week 16 adult safety profile. 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.[1]

WERE SAFETY PROFILES CONSISTENT ACROSS AGE GROUPS?

DUPIXENT demonstrated a generally consistent safety profile across infants to preschoolers (6 months to 5 years of age), children (6-11 years of age), adolescents (12-17 years of age), and adults.[1]

ADMINISTRATION

HOW IS DUPIXENT ADMINISTERED?

DUPIXENT is an injectable medicine that is administered by subcutaneous injection. DUPIXENT is intended for use under the guidance of a healthcare provider. DUPIXENT may be administered at home and is given every 2 or 4 weeks, based on age and weight.[1]

The DUPIXENT pre-filled pen is for use in adult and pediatric patients aged 2 years and older. The DUPIXENT pre-filled syringe is for use in adult and pediatric patients aged 6 months and older. A caregiver or patient 12 years of age and older may inject DUPIXENT using the pre-filled syringe or pre-filled pen. In pediatric patients 12 to 17 years of age, it is recommended that DUPIXENT be administered under the supervision of an adult. In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.[1]

IMPORTANT SAFETY INFORMATION

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.

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.

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FREQUENTLY ASKED QUESTIONS ABOUT DUPIXENT (cont'd)

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ACCESS AND SUPPORT

WHAT MIGHT ACCESS BE LIKE FOR MY PATIENTS?

DUPIXENT has the best access among specialty systemic therapies indicated for atopic dermatitis[4,a,b]:

- [**99%**] of commercial patients (6+ months of age) nationally are covered for DUPIXENT
- [**91%**] of commercial patient lives have to fail only 1 or 2 prescription topical treatments

WHAT SUPPORT IS AVAILABLE TO PATIENTS WHO TAKE DUPIXENT?

DUPIXENT MyWay® provides support and education to help patients start and stay on track with therapy. Support includes supplemental injection training as well as refill and injection reminders.

We're committed to helping patients get access to DUPIXENT and are provided with assistance in navigating the insurance process. Eligible patients covered by commercial insurance may pay as little as $0[c] copay per fill of DUPIXENT (maximum of $13,000 per patient per calendar year).[d] Terms and conditions apply.

TRIAL RESULTS: The primary endpoint in CHRONOS and AD-1526 was the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) and ≥2-point improvement at Week 16 (39% of adults treated with DUPIXENT + TCS vs 12% with placebo + TCS in CHRONOS, *P*<0.0001; and 24% of adolescents treated with DUPIXENT vs 2% with placebo in AD-1526, *P*<0.001). In AD-1652 and AD-1539, the primary endpoint was the proportion of subjects with an IGA 0 or 1 at Week 16 (39% of children ≥30 kg treated with DUPIXENT + TCS vs 10% with placebo + TCS, 30% of children <30 kg treated with DUPIXENT + TCS vs 13% with placebo + TCS in AD-1652; and 28% of infants to preschoolers treated with DUPIXENT + TCS vs 4% with placebo + TCS in AD-1539, *P*<0.0001). Other endpoints included the proportion of subjects with EASI-75 at Week 16 (69% of adults treated with DUPIXENT + TCS vs 23% with placebo + TCS in CHRONOS, *P*<0.0001; 42% of adolescents treated with DUPIXENT vs 8% with placebo in AD-1526, *P*<0.001; 75% of children ≥30 kg treated with DUPIXENT + TCS vs 26% with placebo + TCS, and 75% of children <30 kg treated with DUPIXENT + TCS vs 28% with placebo + TCS in AD-1652; and 53% of infants to preschoolers treated with DUPIXENT + TCS vs 11% with placebo + TCS in AD- 1539, *P*<0.0001) and ≥4-point improvement in the Peak Pruritus NRS at Week 16 (59% of adults treated with DUPIXENT + TCS vs 20% with placebo + TCS in CHRONOS, *P*<0.0001; 37% of adolescents treated with DUPIXENT vs 5% with placebo in AD-1526, *P*<0.001; 61% of children ≥30 kg treated with DUPIXENT + TCS vs 13% with placebo + TCS and 54% of children <30 kg treated with DUPIXENT + TCS vs 12% with placebo + TCS in AD-1652), and ≥4-point improvement in the Worst Scratch/Itch NRS at Week 16 (48% of infants to preschoolers treated with DUPIXENT + TCS vs 9% with placebo + TCS in AD-1539, *P*<0.0001).[1,13-16]

TRIAL DESIGNS: 251 adolescents (12-17 years) in AD-1526, 162 infants to preschoolers (6 months to 5 years) in AD-1539 (16 weeks each), and 421 adults in CHRONOS (52 weeks) with moderate-to-severe atopic dermatitis and 367 children (6-11 years) in AD-1652 (16 weeks) with severe disease inadequately controlled with topical prescription therapies were randomized to DUPIXENT or placebo. All patients in CHRONOS, AD-1652, and AD-1539 received concomitant TCS. All DUPIXENT-treated adults and adolescents ≥60 kg received 300 mg Q2W after a 600 mg loading dose, adolescents <60 kg and children ≥30 kg but <60 kg received 200 mg Q2W after a 400 mg loading dose, children 15 kg but <30 kg received 300 mg Q4W after a 600 mg loading dose; infants to preschoolers 15 kg but <30 kg received 300 mg Q4W, and infants to preschoolers 5 kg but <15 kg received 200 mg Q4W. In CHRONOS, AD-1526, and AD-1539 patients had an IGA score ≥3 on a scale of 0 to 4, an EASI score ≥16 on a scale of 0 to 72, and BSA involvement ≥10%. In AD-1652, patients had an IGA score of 4, an EASI score ≥21, and BSA involvement ≥15%. At baseline, 52.5% of adults, 46% of adolescents, and 23% of infants to preschoolers had an IGA score of 3 (moderate); 47.5% of adults, 54% of adolescents, and 77% of infants to preschoolers had an IGA of 4 (severe); mean EASI score was 32.9 for adults; mean EASI score was 36 for adolescents, 37.9 for children, and 34.1 for infants to preschoolers; weekly averaged Peak Pruritus NRS was 7.3 for adults, 8 for adolescents, and 7.8 for children on a scale of 0 to 10; and weekly average of daily Worst Scratch/Itch NRS was 7.6 for infants to preschoolers on a scale of 0 to 10.[1,13,14]

BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numerical rating scale; Q2W, once every 2 weeks; Q4W, once every 4 weeks; TCS, topical corticosteroids.

[a] MMIT Analysis, [June 2024]. Analysis included DUPIXENT, tralokinumab, upadacitinib, and abrocitinib.
[b] Based on available published commercial UM coverage criteria.
[c] Approval is not guaranteed. Program has an annual maximum of $13,000.[d] **THIS IS NOT INSURANCE**. Not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs including any state pharmaceutical assistance programs. This program is not valid where prohibited by law, taxed, or restricted. DUPIXENT *MyWay* reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Any savings provided by the program may vary depending on patients' out-of-pocket costs. The program is intended to help patients afford DUPIXENT. Patients may have insurance plans that attempt to dilute the impact of the assistance available under the program. In those situations, the program may change its terms. Additional terms and conditions apply.
[d] Annual maximum subject to change.

IMPORTANT SAFETY INFORMATION

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.

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IMPORTANT SAFETY INFORMATION

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 during treatment with DUPIXENT.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1%) in 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 click here for full Prescribing Information.

Visit DiscoverDupixent.com to learn more and to find an eczema specialist near you

Regeneron and Sanofi do not endorse or recommend any particular physician.

References: 1. DUPIXENT Prescribing Information. **2.** Simpson EL, Bruin-Weller M, Flohr C, et al. When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. *J Am Acad Dermatol*. 2017;77(4):623-633. **3.** Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):E43-E56. **4.** Data on file, Regeneron Pharmaceuticals, Inc. **5.** De Benedetto A, Rafaels NM, McGirt LY, et al. Tight junction defects in patients with atopic dermatitis. *J Allergy Clin Immunol*. 2011;127(3):773-786. **6.** Leung DYM, Boguniewicz M, Howell MD, Nomura I, Hamid QA. New insights into atopic dermatitis. *J Clin Invest*. 2004;113(5):651-657. **7.** Kim JP, Chao LX, Simpson EL, Silverberg JI. Persistence of atopic dermatitis (AD): a systematic review and meta-analysis. *J Am Acad Dermatol*. 2016;75(4):681-687. **8.** Wei W, Anderson P, Gadkari A, et al. Extent and consequences of inadequate disease control among adults with a history of moderate to severe atopic dermatitis. *J Dermatol*. 2018;45(2):150-157. **9.** Paller AS, Siegfried EC, Vekeman F, et al. Treatment patterns of pediatric patients with atopic dermatitis: a claims data analysis. *J Am Acad Dermatol*. 2020;82(3):651-660. **10.** Simpson EL, Bieber T, Eckert L, et al. Patient burden of moderate to severe atopic dermatitis (AD): insights from a phase 2b clinical trial of dupilumab in adults. *J Am Acad Dermatol*. 2016;74(3):491-498. **11.** Zuberbier T, Orlow SJ, Paller AS, et al. Patient perspectives on the management of atopic dermatitis. *J Allergy Clin Immunol*. 2006;118(1):226-232. **12.** Capozza K, Gadd H, Kelley K, Russell S, Shi V, Schwartz A. Insights from caregivers on the impact of pediatric atopic dermatitis on families: "I'm tired, overwhelmed, and feel like I'm failing as a mother". *Dermatitis*. 2020;31(3):223-227. **13.** Paller AS, Simpson EL, Siegfried EC, et al. Dupilumab in children aged 6 months to younger than 6 years with uncontrolled atopic dermatitis: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2022;400(10356):908-919. **14.** Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet*. 2017;389(10086):2287-2303. **15.** Simpson EL, Paller AS, Siegfried EC, et al. Efficacy and safety of dupilumab in adolescents with uncontrolled moderate to severe atopic dermatitis: a phase 3 randomized clinical trial. *JAMA Dermatol*. 2020;156(1):44-56. **16.** Paller AS, Siegfried EC, Thaçi D, et al. Efficacy and safety of dupilumab with concomitant topical corticosteroids in children 6 to 11 years old with severe atopic dermatitis: a randomized, double-blinded, placebo-controlled phase 3 trial. *J Am Acad Dermatol*. 2020;83(5):1282-1293.

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