New agent is first injectable for moderate to severe atopic dermatitis

FDA recently approved dupilumab (Dupixent—Regeneron), the first injectable treatment for adults with moderate to severe atopic dermatitis (AD) that is not adequately controlled with topical therapies. Thought to affect 3% of adults in the United States, AD is the most common form of eczema and is believed to result from genetic, immune, or environmental factors. It causes itchy red bumps on the skin, and with repeated scratching, the skin will swell, crack, and weep clear fluid. Eventually the skin will become coarse and thick.

Atopic dermatitis can interfere with a patient’s sleep and overall function, but it can also exact an emotional toll, said Kim Benner, PharmD, BCPS, FASHIP, FPPAG, professor of pharmacy practice at Samford University McWhorter School of Pharmacy in Birmingham, AL. “It has a significant effect on self-confidence. Even though the condition is not associated with significant mortality, it does affect quality of life.”

Effective but not first line
Researchers assessed dupilumab’s effectiveness in three placebo-controlled clinical trials involving 2,119 adults whose moderate to severe AD was not adequately controlled by topical medication. After 16 weeks, more participants in the treatment groups had achieved clear or almost-clear skin and had experienced a greater reduction in itching than those in the placebo groups.

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Trials are under way to assess dupilumab’s safety and effectiveness in children aged 6 months to 11 years who have severe AD and adolescents aged 12 to 17 years who have moderate to severe AD.

“It would be great if [FDA] approved this for children, because AD affects 10% to 20% of children, and 60% of patients with AD get diagnosed in the first year of life,” said Benner. “But I’ll stress that treatment should still be topicals first, especially in kids. We’d want to see how it works in adults before we try it in children.”

Clinical pearls
Injection site reactions were the most common adverse event associated with dupilumab in trials, followed by conjunctivitis, blepharitis, oral herpes, and keratitis.

Patients will administer the drug to themselves via S.C. injections, so they need education on proper technique, said Benner. “As with any injection, the pharmacists should instruct patients where to inject and how to clean injection sites, as well as how to inject on a 45-degree angle. Patients should learn to rotate injection sites and avoid bruised or damaged areas.”

Dupilumab can only be obtained through a specialty pharmacy. Scott noted that specialty pharmacies may have different options for patient education, including using Skype or sending home health professionals to visit patients and teach them how to administer the injections.

Patient counseling
Patients will need to learn how to give themselves S.C. injections, including how to choose, prepare, and rotate injection sites and how to inject at a 45-degree angle. Dupilumab should not be shaken, and it should be refrigerated in the original carton to protect it from light.

Dupilumab (Dupixent)
Manufacturer: Regeneron
Drug class: Interleukin-4 receptor alpha agonist
Indication: Treatment of moderate to severe atopic dermatitis in adults whose disease is not adequately controlled with topical therapies
Dosage: Two initial 300-mg injections at different injection sites, followed by one 300-mg injection every other week
Of note: After injection site reactions, most adverse events involve the eyes. Patients taking dupilumab should not receive live vaccines.