FDA Approves At-Home Therapy for Melanoma Patients With Vitiligo

The topical cream Opzulera (ruxolitinib) can improv skin repigmentation in people with melanoma-associated vitiligo.

November 11, 2022 By Melanoma Research Alliance

On July 18, the U.S. Food & Drug Administration (FDA) approved the first topically-applied treatment for skin repigmentation for patients with vitiligo after strong results from two Phase 3 trials. Vitiligo, a chronic skin disease, affects 3 in 100 people who have melanoma, categorized as melanoma-associated vitiligo. The approval invites patients with vitiligo, including those with melanoma, to talk with their providers on how Opzelura (ruxolitinib) can serve their skin needs.

What Is Vitiligo?

Vitiligo is a chronic autoimmune condition where the body's immune response will target melanocytes, causing areas of the skin to lose pigment called melanin. Some patients with melanoma develop vitiligo as a side effect from checkpoint immunotherapy, where normal skin cells get caught in the crossfire between cancer cells and the medication. Although not physically painful, living with vitiligo is emotionally and psychologically challenging and affects wellbeing.

Until the July 18 FDA approval of Opzulera, patients facing melanoma-associated vitiligo had limited treatment options, which mainly consisted of light therapy. Light therapy requires doctor visits two to three times a week for upwards of six months before any noticeable change. The newly approved therapy for vitiligo expands the available options for repigmentation care while providing a friendlier routine of applying twice daily on affected areas.

What does it mean to have one's melanin return? For skin of color — or skin with more melanin — and for those whose vitiligo is located on more visible areas, it can be especially difficult to adjust to skin discoloration, and many encounter negative stigma associated with their appearance. Restoration of melanin can signal a return of comfort and confidence for people.

What Is Opzulera?

Opzulera (ruxolitinib) is a topical Janus kinase (JAK) inhibitor, which slows the body's hyperactive

inflammation to mitigate the body's attack of normal melanocytes (which have melanin and give skin its color). In trying to heal the body from a nonexistent threat, the overstimulated process of inflammation causes damage to melanocytes. Slowing down autoimmunity invites the gradual growth of more melanin-producing cells.

Opzulera was approved based on two Phase 3 clinical trials that assessed the safety and effectiveness of the cream in patients with non-segmental vitiligo (the most common type of vitiligo). After one year of using the experimental therapy, half of the patients treated with Opzulera achieved at least 75% improvement from their baseline facial pigmentation.

The cost of Opzelura is covered by some insurances. However, not all insurance companies consider care for vitiligo as medically necessary. This means that insurance companies may not cover Opzelura or may only do so with higher cost sharing. This is problematic because vitiligo-affected skin is more susceptible to sunburn due to the loss of melanocytes and have valid psychosocial needs. Learn more about insurance coverage and financial assistance programs.

If you are experiencing vitiligo as a side effect of your melanoma treatment, speak to your doctor to determine if Opzelura is right for you.

This post was originally published October 24, 2022, by the Melanoma Research Alliance. It is republished with permission.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.cancerhealth.com/blog/fda-approves-athome-therapy-melanoma-patients-vitiligo