# Dermatomyositis: Why an oral JAK inhibitor changes everything

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Dermatomyositis, a rare autoimmune disease, has long presented a therapeutic challenge, often requiring complex regimens to manage its debilitating muscle weakness and characteristic skin rash. Until now, systemic treatments have largely relied on immunosuppressants with significant side effect profiles and inconvenient administration. The recent FDA approval of Lisraya (ruxolitinib) marks a significant shift, introducing the first oral therapy specifically indicated for this condition.1

KEY TAKEAWAYS

- The Pivot: Lisraya is the first oral Janus kinase (JAK) inhibitor approved for dermatomyositis, expanding treatment options beyond traditional immunosuppressants.
- The Data: JAK inhibitors like ruxolitinib target the JAK-STAT pathway, regulating immune response and cell growth.1
- The Action: Clinicians now have an oral, targeted therapy for dermatomyositis, requiring careful monitoring for infections and thromboembolic events.

Dermatomyositis is a chronic inflammatory myopathy affecting both muscle and skin, leading to progressive muscle weakness and a distinctive rash. Patients often face significant morbidity, including dysphagia, interstitial lung disease, and an increased risk of malignancy. Current management strategies frequently involve corticosteroids, immunosuppressants like methotrexate or azathioprine, and intravenous immunoglobulins, all of which carry substantial burdens in terms of side effects and administration. The need for more targeted, convenient, and effective therapies has been clear for years.

Lisraya, a Janus kinase (JAK) inhibitor, offers a new approach by targeting the JAK-STAT pathway, a critical signaling cascade involved in immune response and cell growth.1 This pathway mediates cytokine signaling, which plays a central role in the pathogenesis of various autoimmune and inflammatory conditions, including dermatomyositis. By blocking this pathway, JAK inhibitors aim to regulate the overactive immune response characteristic of these diseases.

The approval of Lisraya for dermatomyositis follows a growing trend of JAK inhibitor utilization in dermatology and rheumatology, where they have already demonstrated efficacy in conditions such as rheumatoid arthritis, psoriatic arthritis, and atopic dermatitis.1

## The JAK Inhibitor Landscape in Dermatology

The field of dermatology has seen increasing interest in JAK inhibitors due to their broad immunomodulatory effects. Tofacitinib, for example, is already FDA-approved for psoriatic arthritis and shows promise in treating psoriasis.1

Ruxolitinib, the active compound in Lisraya, has previously gained regulatory approval as a first-in-class, selective, topical therapy for atopic dermatitis.1 Oral upadacitinib also received approval for active psoriatic arthritis, and both abrocitinib and upadacitinib have demonstrated efficacy in atopic dermatitis.1 These prior approvals established a precedent for the use of JAK inhibitors in dermatological conditions, laying the groundwork for Lisraya's entry into the dermatomyositis treatment pipeline. The shift towards oral therapies for chronic inflammatory conditions is a welcome development for many patients.

The therapeutic potential of JAK inhibitors extends beyond these approved indications, with ongoing investigations into their use in alopecia areata, vitiligo, and other inflammatory dermatoses.1 This broad applicability stems from their mechanism of action, which allows them to modulate a wide array of cytokine-mediated inflammatory processes. For dermatomyositis, specifically, the ability to target the underlying immune dysregulation offers a more precise intervention compared to broad immunosuppression. The Oxford Handbook of Rheumatology provides a concise overview of these complex immune pathways and their therapeutic targets.

## Safety Profile and Clinical Considerations

While effective, JAK inhibitors are not without their risks. The adverse event profile for JAK inhibitors appears similar to that of biologic drugs.1 Common adverse effects include an increased risk of infections and thromboembolic events.1 Clinicians prescribing Lisraya will need to carefully monitor patients for signs of infection, including serious bacterial, fungal, and viral infections, and assess their risk for venous thromboembolism. This necessitates a thorough patient history and ongoing vigilance throughout treatment. The balance between efficacy and safety is a critical consideration, particularly in a patient population already vulnerable due to their underlying autoimmune condition and potential comorbidities.

The long-term safety profile of JAK inhibitors, particularly in rare diseases like dermatomyositis, requires further investigation.1 Understanding the full utility of this drug class within dermatology also remains an area of active research.1 The approval of Lisraya represents a significant step forward, but it also underscores the ongoing need for robust post-marketing surveillance and additional clinical trials to fully characterize its benefits and risks across diverse patient populations. This is particularly relevant given the heterogeneity of dermatomyositis presentation and severity. For example, some patients may present predominantly with skin manifestations, while others have severe muscle involvement or interstitial lung disease, each potentially responding differently to targeted therapies.

Still, the availability of an oral treatment option for dermatomyositis is a substantial improvement for patients who have historically faced limited choices. Oral administration can significantly enhance patient adherence and quality of life compared to intravenous or subcutaneous therapies. This convenience factor alone can be a powerful driver of treatment success, assuming the efficacy and safety profile are manageable in a real-world setting. The FDA's decision provides a new tool for clinicians managing this challenging condition, allowing for a more personalized approach to treatment. This move aligns with broader trends in medicine to provide more targeted and patient-friendly therapies.

> **CLINICAL IMPLICATIONS**
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> The FDA's approval of Lisraya for dermatomyositis is a genuine shift for a disease with few effective, convenient options. Clinicians now have an oral JAK inhibitor, ruxolitinib, to consider, moving beyond the

traditional reliance on corticosteroids and broad immunosuppressants. This offers a more targeted approach to managing the immune dysregulation at the heart of the condition.

But, as with all JAK inhibitors, the known risks of infection and thromboembolic events demand careful patient selection and ongoing monitoring. These are not trivial concerns, especially in a patient population that may already be immunocompromised or have other risk factors. The convenience of an oral pill must be weighed against these potential complications.

For patients, this approval means a new lease on managing their disease without the burden of injections or infusions. Improved adherence is a likely benefit, potentially leading to better long-term outcomes. But, the cost and access to this novel therapy will undoubtedly become a new hurdle for many.

The industry's focus on JAK inhibitors for dermatological and rheumatological conditions continues to expand. This approval reinforces the therapeutic potential of targeting the JAK-STAT pathway, but also highlights the need for further research into long-term safety and comparative effectiveness against existing, albeit less convenient, therapies.

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## REFERENCES

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