Upadacitinib (RINVOQ) in Atopic Dermatitis
Criteria for Use
August 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following is selected, then the patient will NOT meet criteria for upadacitinib.

- ☐ Uncontrolled active infection (however, upadacitinib may be started / restarted once treatment for the infection is initiated).
- ☐ Untreated latent or active tuberculosis.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.^1 Upadacitinib may be initiated after starting antiviral prophylaxis.
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with upadacitinib.
- ☐ Congenital or acquired immunodeficiency
- ☐ Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer unless it is documented that the treating dermatologist and oncologist agree that risk-benefits favor using the drug.
- ☐ Thrombosis or major adverse cardiovascular events in which potential harms are expected to outweigh the anticipated benefits.
- ☐ Lymphocytes < 500 cells/mm^3 confirmed by repeat testing, neutrophils < 1000 cells/mm^3, or hemoglobin < 8 g/dL. (Upadacitinib may be started / restarted once values normalize).
- ☐ Severe hepatic impairment (Child-Pugh class C).
- ☐ Concomitant therapy with biologic disease-modifying antirheumatic drugs (bDMARDs), other immunosuppressive biologics, or potent immunosuppressants (e.g., azathioprine, cyclosporine, tacrolimus).^2
- ☐ Concomitant therapy with strong CYP3A4 inducers.
- ☐ Pregnancy
- ☐ Breastfeeding
- ☐ Administration of inactivated, live, or live-attenuated vaccines within 2 weeks before initiation of upadacitinib therapy.^4

Inclusion Criteria

ALL of the following criteria must be selected to meet criteria.

- ☐ Diagnosis of **chronic atopic dermatitis**.
- ☐ Prescribed and monitored by a VA/VA Community Care dermatologist OR an immunologist, allergist, or locally designated expert in the management of atopic dermatitis *in consultation with* a VA/VA Community Care dermatologist.
- ☐ Within 2 weeks of starting upadacitinib therapy, determination of severity by either a Gestalt Assessment (GA) of "moderate" or "severe" OR Eczema Area and Severity Index (EASI) ≥ 16 (scale 0–72).^3
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^4
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].^5
- ☐ Completed hepatitis B screening (HBsAg, total antibody to hepatitis B core antigen [anti-HBc] and antibody to hepatitis B surface antigen [anti-HBs]).^5
- ☐ Current or past completion of hepatitis C screening. (Upadacitinib may be initiated while waiting for test results.)^5
- ☐ **Dupilumab** OR **tralokinumab-ldrm therapy (NO response after 12 weeks or inadequate response after 16 weeks)** is medically inadvisable,^6 not tolerated, not adequate, or lost response.

Additional Inclusion Criteria

- ☐ If HBsAg-negative but anti-HBc-positive and consult is deemed indicated: A GI/liver or infectious diseases expert has been (e-)consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.
- ☐ For females who are breastfeeding/providing breastmilk to an infant: Counseling provided on potential risks vs benefits of treatment.

Other Justification

- ☐ _____

Footnotes

1. Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.
2. Except overlaps during treatment transition. Co-use with antirheumatic doses of conventional immunomodulators such as methotrexate or leflunomide is acceptable.
3. When practical, two other instruments (SCORing Atopic Dermatitis [SCORAD] index and the Patient Oriented Eczema Measure (POEM) may be considered. Gestault Assessment refers to the physician's global gestalt impression based on expert clinical judgment rather than an instrument rating score.

[4] When possible, vaccinations should be updated before the patient initiates upadacitinib. Unless contraindicated, recombinant zoster (SHINGRIX equivalent) vaccine should be completed or at least initiated by the end of the first year of treatment with upadacitinib, preferably when upadacitinib dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.

[5] Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.

[6] If dupilumab or tralokinumab-ldrm is contraindicated, the therapies required prior to those biologic agents should still be tried before upadacitinib. See dupilumab or tralokinumab-ldrm criteria for details.

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