Upadacitinib (RINVOQ) in Giant Cell Arteritis

Criteria for Use

July 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 are selected, the patient will NOT meet criteria for upadacitinib.

- ☐ Uncontrolled active infection, including undrained abscess; however, upadacitinib may be started/restarted once the infection treatment has been initiated.
- ☐ Untreated latent or active tuberculosis infection.
- ☐ 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.
- ☐ Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or cervical cancer, unless it is documented that the treating rheumatologist and oncologist agree that risk-benefits favor using the drug.
- ☐ At increased risk of thrombosis or major adverse cardiovascular events where 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).
- ☐ At increased risk of gastrointestinal perforation (e.g., history of diverticulitis, concomitant glucocorticoids) where potential harms of therapy are expected to outweigh the anticipated benefits.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of upadacitinib.^2
- ☐ Concomitant JAK inhibitors, biologic immunomodulators (e.g., tocilizumab, abatacept), or potent immunosuppressants such as azathioprine and cyclosporine.^3
- ☐ Ingestion of food or drink containing grapefruit during therapy.
- ☐ Concomitant strong CYP3A4 inDUCers.
- ☐ Pregnancy (during therapy and for 4 weeks after the last dose of upadacitinib).
- ☐ Breastfeeding/providing breastmilk to an infant (during therapy and for 6 days after the last dose).

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- ☐ Definite or provisional diagnosis of active giant cell arteritis.
- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist or locally designated expert
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].
- ☐ Completed hepatitis B screening (HBsAg, total antibody-to-hepatitis-B-core-antigen (anti-HBc) and antibody to hepatitis B surface antigen [anti-HBs]).^4
- ☐ Current or past completion of hepatitis C screening. Upadacitinib may be initiated while waiting for test results.^4
- ☐ Initiated concurrently or after glucocorticoid therapy unless glucocorticoids are medically inadvisable.

Additional Inclusion Criteria

Select if applicable.

- ☐ If HBsAg-negative but anti-HBc-positive and patient's practitioner deems consult is 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: Pregnancy status verified. Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 4 weeks after discontinuation of therapy.

Other Justification

- ☐ _____

Footnotes

1 Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.

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

3 Concomitant use of antirheumatic doses (≤25 mg/WEEK) of methotrexate is allowable but may increase risks of immunosuppression and infection.

4 Routine rescreening for hepatitis B or hepatitis C is not required for prescription renewals. Retesting in high-risk patients should be considered.

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