

Inebilizumab-cdon (UPLIZNA) for Immunoglobulin G4-Related Disease (IgG4-RD) Criteria for Use April 2026

VA National Formulary Committee and Pharmacy Benefits Management Services

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 the answer to ANY item below is met, then the patient should NOT receive inebilizumab-cdon.

- Untreated active hepatitis B infection
- Untreated latent or active tuberculosis infection
- Active, clinically significant infection
- Concomitant therapy with another biologic therapy for immunoglobulin G4-related disease (IgG4-RD)
- Pregnancy

Inclusion Criteria

All of the following must be met.

- Care provided by VA or VA Community Care rheumatology provider or locally designated expert
- Completed hepatitis B screening (HBsAg, total anti-HBc and anti-HBs) and consult referral for hepatitis B management if either HBsAg or total anti-HBc positive¹
- Quantitative serum immunoglobulins tested. If low, the rheumatologist has documented risk/benefit assessment and/or an immunology expert was consulted prior to start
- All guideline recommended eligible immunizations administered at least 4 weeks prior to the start of treatment for live or live-attenuated vaccines, and whenever possible, at least 2 weeks prior to the start of treatment for inactivated vaccines
- Contraindication, intolerance, or lack of therapeutic response to rituximab

Additional Inclusion Criteria

Select if applicable:

- For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 6 months after stopping treatment

Footnotes

1. HBsAg: Hepatitis B surface antigen; anti-HBs: Hepatitis B surface antibody; anti-HBc: Hepatitis B core antibody

Prepared: December 2024 Contact: Natasha Antonovich, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services
