Inebilizumab-cdon (UPLIZNA) for Myasthenia Gravis
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 to receive inebilizumab-cdon.

☐ Care provided by a VA/VA Community Care neurologist or locally designated expert
☐ Acetylcholine receptor (AChR) antibody positive or muscle-specific tyrosine kinase (MuSK) antibody positive generalized myasthenia gravis
☐ Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV[1]
☐ Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 5[2]
☐ 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 positive[3]
☐ Quantitative serum immunoglobulins tested. If low, the neurologist 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

Additional Inclusion Criteria

One of the following must be met.

☐ For AChR+ chronic therapy: Inadequate symptom control to maximally tolerated pyridostigmine and at least two immunosuppressive agents separately trialed for at least 6 months each [e.g., azathioprine, cyclosporine, mycophenolate, etc.]
☐ For MuSK+ chronic therapy: Inadequate symptom control to rituximab trialed for at least 6 months
☐ For AChR+ or MuSK+ chronic therapy: History of intolerance or contraindication preventing trial of above immunosuppressive agents

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. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification can be found at: https://myasthenia.org/Portals/0/MGFA%20Classification.pdf
2. Myasthenia Gravis Activities of Daily Living (MG-ADL) can be found at: https://myasthenia.org/Portals/0/ADL.pdf
3. HBsAg: Hepatitis B surface antigen; anti-HBs: Hepatitis B surface antibody; anti-HBc: Hepatitis B core antibody

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