AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Uplizna™ (inebilizumab-cdon) IV (J1823) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: Maximum Units (per dose and over time)

- 300 billable units on day 1 and 15, then 300 billable units every 6 months (beginning 6 months after the first dose)
- Initial dose: 300 mg IV infusion, followed by a second 300 mg IV infusion two weeks later
- Subsequent doses (starting 6 months from the first infusion): single 300 mg IV infusion every 6 months

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ Diagnosis: Neuromyelitis Optica Spectrum Disorder (NMOSD)

Initial Authorization: 12 months

- ❑ Prescribing physician must be a neurologist
- ❑ Member must be 18 years of age or older
- ❑ Provider must submit medical records (e.g., chart notes, laboratory values, etc.) to support a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) confirmed by **ALL** the following:
  - ❑ Past medical history of **ONE** of the following:
    - ❑ Optic neuritis
    - ❑ Acute myelitis
    - ❑ Acute brainstem syndrome
    - ❑ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - ❑ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
  - ❑ Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies **(must submit lab results)**
  - ❑ Diagnosis of multiple sclerosis or other diagnoses have been ruled out
- ❑ Member must meet **ONE** of the following [A historical relapse is defined as a new onset of neurologic symptoms or worsening of existing neurologic symptoms with an objective change on neurologic examination (clinical findings, magnetic resonance imaging findings, or both) that persist for more than 24 hours and/or the new onset of neurologic symptoms or worsening of existing neurologic symptoms that require treatment]:
  - ❑ Member has a history of at least one relapse during the previous 12 months prior to initiating Uplizna™
  - ❑ Member has a history of at least two relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Uplizna™
- ❑ Member must have documentation of an inadequate response, contraindication or intolerance with rituximab during the 12 months prior to initiating Uplizna™
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Member has been evaluated and screened for the presence of latent TB infection prior to initiating treatment
- ❑ Member has been evaluated and screened for the presence hepatitis B virus (HBV) prior to initiating treatment

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- ❑ Provider attests to monitoring serum immunoglobulin levels during treatment; discontinuation of Uplizna™ should be considered if the patient has low IgG or IgM levels, develops a serious opportunistic infection or prolonged hypogammaglobinemia requiring treatment with IVIG
- ❑ Uplizna™ will **NOT** be used in combination with disease-modifying therapies for the treatment of multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab))
- ❑ Uplizna™ will **NOT** be used in combination with other complement inhibitor therapy (e.g., eculizumab, ravulizumab), IL-6 inhibitors (e.g., toclizumab, satralizumab), anti-CD20 directed antibody therapy (e.g., rituximab)

❑ Diagnosis: Neuromyelitis Optica Spectrum Disorder (NMOSD)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Provider attests to an absence of unacceptable toxicity from therapy (i.e. tuberculosis (TB) infections, hepatitis B reactivation, infusion reactions, serious infections, Progressive Multifocal Leukoencephalopathy (PML), hypogammaglobulinemia)
- ❑ Provider must submit clinical notes documenting clinical improvement (fewer relapses from baseline) or stabilization of patient relapses while on Uplizna™ therapy

  Note: Add on, dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on therapy will be considered as treatment failure.

  Uplizna™ therapy has **NOT** been studied with other immunosuppressants

❑ Diagnosis: Immunoglobulin G4-related disease (IgG4-RD)

Initial Authorization: 12 months

- ❑ Member must be 18 years of age or older
- ❑ Medication must be prescribed by or in consultation with a Rheumatologist
- ❑ Provider must submit medical records (e.g. physical exam findings, imaging results, laboratory tests, pathological findings in involved organ/sites) to support a diagnosis of IgG4 -Related Disease confirmed by **ALL** the following:
  - ❑ At least one (1) organ: pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, or thyroid gland
  - ❑ And achieve at least 20 points inclusion according to the 2019 classification criteria for IgG4 related disease

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- ❑ Member is experiencing (or recently experienced) an IgG4-RD flare that required corticosteroid treatment within the last 90 days
- ❑ Member is at high risk of recurrent disease flares based on a history of disease in ≥2 organs/sites
- ❑ Member has had baseline serum immunoglobulins measured (IgG4) prior to the start of therapy
- ❑ Member does **NOT** have Active malignancy or history of malignancy, Multicentric Castleman, necrotizing vasculitis, and other autoimmune disorders

❑ Diagnosis: Immunoglobulin G4-related disease (IgG4-RD)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has experienced disease response as indicated by at least **ONE** of the following **(check all that apply)**:
  - ❑ Reduction in corticosteroid requirement for IgG4-RD flare treatment from baseline
  - ❑ Reduction in IgG4-RD flares from baseline
  - ❑ Stabilization/improvement in symptoms, physical exam findings, imaging results, laboratory tests, and/or pathological findings in IgG4-RD involved organ/sites compared to baseline

❑ Diagnosis: Generalized Myasthenia Gravis (gMG)

Initial Authorization: 12 months

- ❑ Member must be 18 years of age or older
- ❑ Prescribing physician must be a neurologist
- ❑ Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies (lab test must be submitted)
- ❑ Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination (e.g., including but not limited to the Quantitative Myasthenia Gravis (QMG) score) **(chart notes must be submitted)**
- ❑ Member has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least ≥ 6 **(results must be submitted)**
- ❑ Member must meet **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member has tried and had an inadequate response to pyridostigmine
  - ❑ Member has an intolerance, hypersensitivity or contraindication to pyridostigmine

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- ❑ Member must meet **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ **AChR+ disease**: member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
  - ❑ **MuSK+ disease**: member failed over 1 year of therapy with immunosuppressive therapy (e.g., corticosteroids, azathioprine, or mycophenolate) **AND rituximab**
- ❑ Member required at least one acute or chronic treatment with plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to the member's therapy required above
- ❑ Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Requested medication will **NOT** be administered with live-attenuated or live vaccines during treatment
- ❑ Medication will **NOT** be used in combination with other immunomodulatory biologic therapies (e.g., rituximab, eculizumab, ravulizumab, efgartigimod alfa-fcab, efgartigimod alfa and hyaluronidase-qvfc, zilucoplan, nipocalimab-aahu)

❑ Diagnosis: Generalized Myasthenia Gravis (gMG)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., infections, severe hypersensitivity reactions infusion reactions, aseptic meningitis)
- ❑ Member meets **ONE** of the following:
  - ❑ Member has demonstrated an improvement of at least 2 points in the MG-ADL total score from baseline sustained for at least 4 weeks (**results must be submitted to document improvement**)
  - ❑ Member has demonstrated an improvement of at least 3 points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks **(results must be submitted to document improvement)**

EXCLUSIONS – Therapy will NOT be approved if member has history of any of the following:

- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Use of rituximab within 6 months prior to treatment
- Use of IVIG or PE within 4 weeks prior to treatment
- Any active or clinically significant infections that has not been treated

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Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration: _____**

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~11/19/2020; 7/24/2025; 1/22/2026;~~ **7/23/2026**
REVISED/UPDATED/REFORMATTED: ~~4/1/2021; 6/14/2021, 6/7/2024; 8/18/2025; 2/16/2026;~~ **8/28/2026**