

# Prior Authorization Checklist for UPLIZNA for Anti-AChR Ab+ or Anti-MuSK Ab+ gMG



This checklist is for informational purposes only. For health plan-specific criteria, please contact an **Amgen By Your Side** representative. Amgen By Your Side, a patient support program, has team members who educate about navigating insurance processes and accessing treatment on your patient's behalf. Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form. Your patient must enroll in Amgen By Your Side and provide HIPAA consent to access these patient-focused services and resources.

Although requirements vary by plan, below are common criteria that may be requested for UPLIZNA. Patient Access Liaisons can provide education about navigating insurance processes and accessing treatment during your patient's access journey.

## 1 Benefits investigation

- Prior authorization (PA) requirements vary between plans. Contact the health plan to understand the process, step therapy requirements, duration of approval, and other relevant information

## 2 Common PA requirements

### Patient/Provider Information

- Name
- Date of birth
- Health plan
- Provider name
- Provider identification number

**Some plans may require documentation of specific information, while some may require physician attestation.**

### Diagnosis Information

- Diagnosis/ICD-10-CM code\*
  - G70.00,<sup>†</sup> Description: Myasthenia gravis without (acute) exacerbation
  - G70.01,<sup>†</sup> Description: Myasthenia gravis with (acute) exacerbation
- Documentation of diagnosis of confirmed anti-AChR Ab+ or anti-MuSK Ab+ gMG in consultation with a neurologist or a specialist
- Patient must be at least 18 years of age
- MG-ADL score
- Documentation of a baseline neurological examination (eg, QMG scale score)
- MGFA Clinical Classification II, III, or IV

**Be sure to provide relevant clinical support, such as clinical notes, laboratory results, etc.**

\*The ICD-10-CM code is not all-inclusive. Appropriate codes vary by patient, payer, and setting for care. Correct coding is the responsibility of the provider submitting the claim. Amgen does not guarantee coverage or reimbursement.

<sup>†</sup>Other potential codes relevant to generalized myasthenia gravis include: G70 (Category: Myasthenia gravis and other myoneural disorders); G70.0 (Category: Generalized myasthenia gravis). Healthcare professionals are responsible for selecting the most appropriate codes based on the patient's medical record and payer requirements.

AChR Ab+, acetylcholine receptor antibody positive; HIPAA, Health Insurance Portability and Accountability Act; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MuSK Ab+, muscle-specific tyrosine kinase antibody positive; QMG, Quantitative Myasthenia Gravis.

## INDICATIONS

UPLIZNA® (inebilizumab-cdon) is indicated in adult patients for the treatment of: anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD); Immunoglobulin G4-related disease (IgG4-RD); anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+) generalized myasthenia gravis (gMG).

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

**Please see additional Important Safety Information throughout and UPLIZNA [full Prescribing Information](#).**

## 2 Common PA requirements (cont'd)

### Treatment Information

- Documentation of failure or inadequate response to previous therapy
  - If medication was discontinued, list all reasons for discontinuation, including side effects, intolerance, nonadherence, or comorbidities, if applicable
- Any relevant clinical/chart notes (eg, MG-ADL score, QMG scale score)
- Note reauthorization criteria (ie, documentation of positive clinical response to UPLIZNA)

**Step therapy requirements may vary between plans.**

## 3 Additional documentation

### Screenings/Vaccinations

- Payers may require documentation of vaccinations for hepatitis B virus, quantitative serum immunoglobulins, and tuberculosis screening prior to initiating treatment

**Including this documentation can help facilitate a PA submission for all payers.**

## 4 PA submission

### Patient/Provider Information

- Include a letter of medical necessity with the PA to help avoid delays
- Confirm if the health plan has a general or UPLIZNA-specific PA form, and use the most up-to-date form for submission
- Verify that the PA (including the number of pages) was received
- Check with the patient's plan to see how long it typically takes for a PA to be reviewed
- Communicate with the team at Amgen By Your Side to follow up on status and see if any additional information is required

**A standard or expedited PA review can be requested based on patient need. Some payers may require additional documentation for an expedited request (eg, a copy of the UPLIZNA policy, documentation supporting the patient's need and the prescriber's rationale).**

MG-ADL, Myasthenia Gravis Activities of Daily Living; PA, prior authorization; QMG, Quantitative Myasthenia Gravis.



**Help your patients start their UPLIZNA access journey by completing a [Patient Enrollment Form](#)**

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

**Infusion Reactions:** Infusion reactions, including anaphylaxis, can occur. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions were observed in 9.3%, 7.4%, and 10.1% of patients treated with UPLIZNA during the randomized controlled periods (RCPs) of Study 1 in patients with NMOSD, Study 2 in patients with IgG4-RD, and Study 3 in patients with gMG, respectively. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions.

**Please see additional Important Safety Information throughout and UPLIZNA [full Prescribing Information](#).**



## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### • **Infusion Reactions (cont'd):**

Administer pre-medication with a corticosteroid, an antihistamine, and an antipyretic. For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

- **Infections:** Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with B-cell depleting therapies, including UPLIZNA. The most common infections reported by UPLIZNA-treated patients in the NMOSD randomized and open-label clinical trial periods for NMOSD were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection, influenza, and pneumonia. In the gMG RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection and nasopharyngitis. Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed with B-cell-depleting therapies, including UPLIZNA. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with B-cell depleting therapies. HBV reactivation was observed in a patient treated with UPLIZNA during the gMG clinical trial and in the postmarketing setting. Patients with active or chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for HBsAg and positive for HBcAb, or who are carriers of HBV (i.e., HBsAg+), consult liver disease experts before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no confirmed cases of PML were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

#### Tuberculosis

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA. Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

#### Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

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## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- **Infections (cont'd)**

- Vaccinations (cont'd)

- Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy*

- In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

- **Reductions in Immunoglobulins:** There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the levels of quantitative serum immunoglobulins during treatment with UPLIZNA, especially in patients with opportunistic or recurrent infections, and until B-cell repletion after discontinuation of therapy. Consider discontinuing UPLIZNA therapy if a patient with low immunoglobulin G or M develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.
- **Fetal Risk:** Based on animal data, UPLIZNA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to UPLIZNA even after B-cell repletion. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other B-cell-depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose.

### ADVERSE REACTIONS

- The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo): urinary tract infection and arthralgia in NMOSD; urinary tract infection and lymphopenia in IgG4-RD; headache and infusion-related reactions in gMG.

Please see UPLIZNA [full Prescribing Information](#).