Prior Authorization Checklist for UPLIZNA

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*
  - Neuromyelitis optica [Devic] G36.0
- ☐ Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by positive serologic test for aquaporin-4-immunoglobulin G (AQP4-IgG) antibodies
- ☐ Patient must be at least 18 years of age
- ☐ Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist

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, payor, and setting for care. Correct coding is the responsibility of the provider submitting the claim. Amgen does not make any representation or guarantee for reimbursement or coverage.

HIPAA, Health Insurance Portability and Accountability Act; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

INDICATION

UPLIZNA (inebilizumab-cdon) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Please see Important Safety Information throughout and on page 3 and Full Prescribing Information at UPLIZNAhcp.com.

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2 Common PA requirements (cont'd)

Treatment Information

- ☐ Documentation of failure or inadequate response to previous therapy (≥1 relapse within the last 12 months or ≥2 relapses within the last 24 months)
  - If medication was discontinued, list all reasons for discontinuation, including side effects, intolerance, nonadherence, or comorbidities, if applicable
- ☐ Any relevant clinical/chart notes (eg, EDSS score, attack history, contraindications, and/or side effects)
- ☐ Note reauthorization criteria (ie, documentation of positive clinical response to UPLIZNA)

Step therapy requirements may vary between plans.

3 Additional documentation

Screenings/Vaccinations

- ☐ Payors 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 payors.

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 payors 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).

EDSS, Expanded Disability Status Scale; PA, prior authorization.

AMGEN BY your side

Available Monday through Friday, 9 AM to 8 PM ET

1-844-469-4297

IMPORTANT SAFETY INFORMATION

UPLIZNA is contraindicated in patients with:

- A history of life-threatening infusion reaction to UPLIZNA
- Active hepatitis B infection
- Active or untreated latent tuberculosis

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INDICATION AND IMPORTANT SAFETY INFORMATION

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WARNINGS AND PRECAUTIONS

Infusion Reactions: UPLIZNA can cause infusion reactions, which can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or other symptoms. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions. Administer pre-medication with a corticosteroid, an antihistamine, and an anti-pyretic.

Infections: The most common infections reported by UPLIZNA-treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Increased immunosuppressive effects are possible if combining UPLIZNA with another immunosuppressive therapy.

The risk of Hepatitis B Virus (HBV) reactivation has been observed with other B-cell-depleting antibodies. Perform HBV screening in all patients before initiation of treatment with UPLIZNA. Do not administer to patients with active hepatitis.

Although no confirmed cases of Progressive Multifocal Leukoencephalopathy (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. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA.

Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

Reduction 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 level of immunoglobulins at the beginning, during, and after discontinuation of treatment with UPLIZNA until B-cell repletion especially in patients with opportunistic or recurrent infections.

Fetal Risk: May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping UPLIZNA.

Adverse Reactions: The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.

Please see Full Prescribing Information at UPLIZNAhcp.com.

AMGEN Rare Disease

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