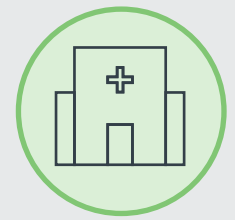


Prior Authorization Checklist for UPLIZNA for IgG4-RD



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*
 - Immunoglobulin G4-related disease (IgG4-RD): D89.84
- Patient must be at least 18 years of age
- Documentation of confirmed diagnosis of IgG4-RD
- History of flare
- ≥2 organ involvement
- 2019 ACR/EULAR Classification Criteria for IgG4-RD

Be sure to provide relevant clinical support, such as clinical notes, laboratory results, 2019 ACR/EULAR Classification Criteria for IgG4-RD score, 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 make any representation or guarantee for reimbursement or coverage.

ACR, American College of Rheumatology; EULAR, European Alliance of Associations for Rheumatology; HIPAA, Health Insurance Portability and Accountability Act; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IgG4-RD, immunoglobulin G4-related disease.

INDICATIONS

UPLIZNA® is indicated for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.

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](#) 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 flare, defined as new or worsening symptoms)
 - If medication was discontinued, list all reasons for discontinuation, including side effects, intolerance, nonadherence, or comorbidities, if applicable
- Any relevant clinical/chart notes (eg, organ involvement, history of flare, 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

- 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).

PA, prior authorization.



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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infusion Reactions: Can cause infusion reactions, including anaphylaxis. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions of UPLIZNA were observed in 7.4% of IgG4-RD patients during the RCP. 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](#) at UPLIZNAhcp.com.

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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:** An increased risk of infections has been observed with other B-cell depleting therapies. In the IgG4-RD RCP and open-label period, the most common infections reported by UPLIZNA-treated patients were upper respiratory tract infection (11%), nasopharyngitis (10%), urinary tract infection (9%), and influenza (6%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: UPLIZNA has not been studied in combination with other immunosuppressants. If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: Risk of HBV reactivation has been observed with other B-cell depleting antibodies. There have been no cases of HBV reactivation in patients treated with UPLIZNA, but patients with 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 hepatitis. For patients who are chronic carriers of HBV [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.

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.



