

Dear Healthcare Provider,

There are times when a prior authorization request may be denied by your patient's health plan. If that happens, an appeal can be submitted to the plan requesting that the decision be reconsidered. Appeal requirements can vary by health plan.

To use the sample letter provided as a separate Word document, modify the content as needed based on your medical judgment and discretion when providing a diagnosis and characterization of your patient's medical condition. For additional guidance, a checklist and helpful tips are included in this document.

Use of the information in this document does not guarantee that the health plan will provide coverage for UPLIZNA® (inebilizumab-cdon) and is not intended to be a substitute for, or an influence on, your independent medical judgment.

Before sending the appeal letter to the health plan, please ensure all variable text (as indicated by brackets in pink and open text fields) is filled in or deleted as needed.

## Appeal checklist

### Documents for filing a response to treatment denial

Each appeal may require different information based on the plan's requirements. Below is a list of materials that you may need to include in an appeal package. Review each denial letter and the health plan's requirements to determine what items to include.

#### 1 Commonly Required Documents Include

- Letter of appeal
- Letter of medical necessity
- Patient authorization and notice of release of information
- Copy of the patient's health plan and/or prescription card (front and back)
- Denial information, including the patient's denial letter and/or explanation of benefits

#### 2 Supporting Documentation

- UPLIZNA Prescribing Information
- UPLIZNA clinical studies

#### 3 Clinical Criteria

- Diagnosis/ICD-10-CM code:\*  
Immunoglobulin G4-related disease (IgG4-RD): D89.84
- Documentation of confirmed diagnosis of IgG4-RD
- History of flare
- ≥2 organ involvement
- 2019 ACR/EULAR Classification Criteria for IgG4-RD
- Patient is 18 years of age or older
- Any relevant clinical/chart notes

\*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; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

## INDICATIONS

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.

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](#).**



---

## Appeal tips

This document offers information that may be useful when creating an appeal letter. Some plans have specific coverage authorization forms that must be used. It is important to determine the plan's requirements and follow them when requesting an appeal for UPLIZNA to avoid further treatment delays. Please contact health plans directly for specific information about their current coverage policies. Please note that Amgen By Your Side is a patient support program that has team members who educate about navigating insurance processes and accessing treatment on your patient's behalf.\*



### Identify the reason for denial

Find out in writing why the authorization request has been denied. The denial letter from the patient's health plan or the explanation of benefits letter should outline the reason(s) for denial. These can be obtained from the health plan if you did not receive them. The reason for denial is also summarized in the health plan's online portal or should be available from the same party to which you submitted the prior authorization.



### Determine the appeal guidelines

Some health plans have short appeal periods, so it is important to contact the health plan to find out its deadline for submitting an appeal. Be sure to inquire about the number of appeals permitted (some plans allow only 1) and the mailing address or fax number to which the appeal should be sent. You may also need to schedule a peer-to-peer review.



### Contact the review department

The denial letter may include a telephone number for the review department. If so, the prescribing physician should call for further clarification about the denial. The reviewer may agree with the rationale and approve treatment during the call; if so, the appeal process is complete.

**NOTE:** As a reminder, do not send patient medical records to Amgen Inc.

\*Your patient must enroll in Amgen By Your Side and provide HIPAA consent to access these patient-focused services and resources. HIPAA, Health Insurance Portability and Accountability Act.

---

## 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. During the randomized clinical trial period (RCP), infusion reactions were observed with the first course of UPLIZNA in 9.3% of NMOSD patients. 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.

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.

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

**UPLIZNA**<sup>®</sup>  
inebilizumab-cdon



---

## Appeal tips (cont'd)

This document offers information that may be useful when creating an appeal letter. Some plans have specific coverage authorization forms that must be used. It is important to determine the plan's requirements and follow them when requesting an appeal for UPLIZNA to avoid further treatment delays. Please contact health plans directly for specific information about their current coverage policies. Please note that Amgen By Your Side is a patient support program that has team members who educate about navigating insurance processes and accessing treatment on your patient's behalf.\*



### Compose the appeal and schedule peer-to-peer review

The health plan will tell you what supporting documentation is needed. You may also need to schedule a peer-to-peer review.



### Provide additional supporting documentation

It is important to determine each plan's appeal requirements, as they may vary by payer. The appeal package should include all relevant medical documentation, including clinical notes and related test results, as well as any newly available information related to the patient's condition, lifestyle modifications as a result of living with IgG4-RD and any clinical improvements. The Amgen By Your Side team works directly with patients to answer nonmedical logistical questions and to provide information about insurance processes and treatment access.



### Follow up as needed

Contact the health plan to learn about the appeal review timeline. Though some plans may respond within 7 days, most health plans respond within 30 to 60 days of receipt of the appeal package.



### Maintain complete records

Retain a copy of all documentation submitted with the patient's appeal and record all subsequent communications made to the patient's health plan, including the date and the name of the person contacted.

**NOTE:** As a reminder, do not send patient medical records to Amgen Inc.

\*Your patient must enroll in Amgen By Your Side and provide HIPAA consent to access these patient-focused services and resources. HIPAA, Health Insurance Portability and Accountability Act; IgG4-RD, immunoglobulin G4-related disease.

---

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

**Infections:** An increased risk of infections has been observed with other B-cell depleting therapies. The most common infections reported by UPLIZNA-treated patients in the NMOSD RCP and open-label clinical trial periods were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). 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.

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

**UPLIZNA**<sup>®</sup>  
inebilizumab-cdon

## IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

### • Infections (cont'd):

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.

- **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 in NMOSD (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.
- The most common adverse reactions in IgG4-RD (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infections and lymphopenia.

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