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 have been included below and on pages 2 and 3.

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 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 is 18 years of age or older
- ☐ Any relevant clinical/chart notes
- ☐ Documentation of failure or of inadequate response to previous therapy (≥1 relapse in the past 12 months or ≥2 relapses in the past 24 months)
- ☐ Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist
- ☐ Specialized test results, if available, including CSF examination, spinal tap, MRI, or CT/CAT scan

*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. Horizon Therapeutics does not make any representation or guarantee for reimbursement or coverage.

CAT, computed axial tomography; CSF, cerebrospinal fluid; CT, computed tomography; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; MRI, magnetic resonance imaging.

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 additional Important Safety Information on page 4 and see Full Prescribing Information.

UPLIZNA® inebilizumab-cdon

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 Horizon 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 Horizon Therapeutics.

*Your patient must enroll in Horizon By Your Side and provide HIPAA consent to access these patient-focused services and resources.

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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APPEAL TIPS (cont'd)

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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 payor. 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 NMOSD and any clinical improvements. The Horizon By Your Side team works directly with patients to answer non-medical 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.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

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INDICATION AND IMPORTANT SAFETY INFORMATION

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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.