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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Miscellaneous Products	**Original Policy Date:**	July 10, 2020
Subject:	Uplizna	**Page:**	1 of 4

Last Review Date: December 8, 2023

Uplizna

Description

Uplizna (inebilizumab-cdon)

Background
Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody. CD19 is a cell surface antigen that presents on pre-B and mature B lymphocytes. Following binding to B lymphocytes, Uplizna results in antibody-dependent cellular cytolysis (1).

Regulatory Status
FDA-approved indication: Uplizna is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive (1).

Uplizna is contraindicated in patients with active hepatitis B infection or active or untreated latent tuberculosis. Prior to initiating Uplizna, patients should be screened for Hepatitis B virus (HBV) and patient should be evaluated for active tuberculosis and tested for latent infection (1).

Immunizations should be administered 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 (1).

Uplizna can cause fetal harm. Females of reproductive potential should be advised to use effective contraception while receiving Uplizna and for at least 6 months after the last dose (1).

The safety and effectiveness of Uplizna in pediatric patients less than 18 years of age have not been established (1).

Related policies
Enspryng, Soliris

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Uplizna may be considered **medically necessary** if the conditions indicated below are met.

Uplizna may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Neuromyelitis optica spectrum disorder (NMOSD)

AND ALL of the following:

a. Anti-aquaporin-4 (AQP4) antibody positive
b. **NO** active hepatitis B infection
c. **NOT** given concurrently with live vaccines
d. **NO** active or untreated latent tuberculosis
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Uplizna and for 6 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Neuromyelitis optica spectrum disorder (NMOSD)

AND ALL of the following:

a. Patient has had fewer relapses while on Uplizna therapy
b. **NO** active hepatitis B infection
c. **NOT** given concurrently with live vaccines
d. **NO** active or untreated latent tuberculosis
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Uplizna and for 6 months after the last dose

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 9 vials

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 6 vials

Duration 12 months

Rationale

Summary

Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody. CD19 is a cell surface antigen that presents on pre-B and mature B lymphocytes. Following binding to B lymphocytes, Uplizna results in antibody-dependent cellular cytolysis. The safety and effectiveness of Uplizna in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Uplizna while maintaining optimal therapeutic outcomes.

References

1. Uplizna [package insert]. Gaithersburg, MD: Viela Bio, Inc.; July 2021.

Policy History

Date	Action
July 2020	Addition to PA
September 2020	Annual review
December 2020	Annual review
December 2021	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.99.018
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.