STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Uplizna (inebilizumab-cdon)
PAM–035

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	07/01/2021
Revision Number:	3	**Last Rev Date:**	07/21/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/19/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	07/16/2021

Overview

Medication: [1]	inebilizumab-cdon
Brand Name:	Uplizna®
Pharmacologic Category:	CD19-directed cytolytic antibody
FDA-Approved Indication(s):	Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
How Supplied:	One carton containing three 100 mg/10 mL single-dose vials
Dosage and Administration:	• Intravenous (IV) infusion • Initial dose: 300 mg on days 1 and 15 • Subsequent doses: 300 mg every 6 months (starting 6 months from first infusion)
Benefit Category:	Medical

Descriptive Narrative

Neuromyelitis optica spectrum disorders (NMOSD, previously known as Devic disease or neuromyelitis optica) are inflammatory disorders of the central nervous system. Features of NMOSD include acute attacks characterized by bilateral or rapidly sequential optic neuritis (leading to visual loss), acute transverse myelitis (often causing limb weakness and bladder dysfunction), and the area postrema syndrome (with intractable hiccups or nausea and vomiting). Recovery from attacks is often incomplete, resulting in residual and accumulating impairment, such as blindness and paralysis.

The incidence of NMOSD in females is up to 10 times higher than in males. The median age of onset is 32 to 41 years of age, but cases are described in children and older adults. NMOSD has a relapsing course in 90 percent or more of cases. Because the natural history of NMOSD is one of stepwise deterioration (due to recurrent attacks and accumulated disability), long-term immune-therapy is indicated for the prevention of attacks as soon as the diagnosis of NMOSD is made.

Traditionally considered a variant of multiple sclerosis, NMOSD was recognized as a distinct clinical entity based on unique immunologic features following the identification of a NMOSD

disease-specific autoantibody referred to as the aquaporin-4 (AQP4) autoantibody. Serum AQP4 autoantibody titers at the nadir of clinical attacks have been shown to correlate with the length of longitudinally extensive spinal cord lesions. In addition, serum anti-AQP4 titers have been shown in several studies to correlate with clinical disease activity, drop after immunotherapy, and remain low during remissions.[2]

Guidelines

Consensus diagnostic criteria for Neuromyelitis Optica Spectrum Disorders (NMOSD) were last published by the International Panel for NMO Diagnosis (IPND) in 2015.[3]

Treatment of NMOSD focuses on acute attacks as well as attack prevention. Treatment of acute attacks is recommended for all patients with suspected NMOSD. High-dose IV methylprednisolone is the treatment of choice, with concomitant therapeutic plasma exchange for patients with severe symptoms or vision loss that is unresponsive to glucocorticoids (exchange every other day up to a total of seven exchanges).

Criteria

Prior authorization is required.

Uplizna® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD), with a positive test for anti-aquaporin-4 (AQP4) antibody positive (AQP4) antibodies; **AND**
2. Member is 18 years of age or older; **AND**
3. Prescribed by, or in consultation with, a neurologist; **AND**
4. Member has a history of one or more relapses that required rescue therapy within the past 12 months, or of two or more relapses that required rescue therapy within the previous 24 months (prior to initiation of therapy). Rescue therapy involves the administration of IV corticosteroids. For severe attacks, adjunctive plasma exchange is also utilized; **AND**
5. Member does not have active or untreated latent tuberculosis, or an active hepatitis B infection; **AND**
6. Uplizna® is not prescribed concurrently with rituximab, eculizumab (Soliris®), or satralizumab-mwge (Enspryng™); **AND**
7. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved regimen, regimen (including dosage) must be supported by clinical practice guidelines (supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling).

Uplizna® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy (e.g., a decrease in the frequency of relapses, improvement or stabilization of visual acuity, etc.); **AND**
3. Prescribed by, or in consultation with, a neurologist; **AND**
4. Uplizna® is not prescribed concurrently with rituximab, eculizumab (Soliris®), or satralizumab-mwge (Enspryng™); **AND**
5. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved regimen, regimen (including dosage) must be supported by clinical practice guidelines (supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling).

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	12 months	12 months
Quantity Limits	Two 300 mg loading doses, then 300 mg every 6 months thereafter	300 mg every 6 months

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J1823	Injection, inebilizumab-cdon, 1 mg

ICD-10	Description
G36.0	Neuromyelitis optica (Devic)

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units/Pkg
75987-0150-03	Horizon Therapeutics USA, Inc.	1 mg	10	3	300

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Uplizna prescribing information (7/2021). Horizon Therapeutics USA, Inc.: Deerfield, IL. Available online at www.upliznahcp.com. Accessed July 9, 2023.

[2] Glisson DO. Neuromyelitis optica spectrum disorders. Gonzalez-Scarano MD, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed July 9, 2023.

[3] Wingerchuk DM, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. American Academy of Neurology. Jul 2015, 85 (2) 177-189.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

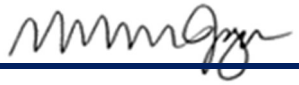
Criteria Change History

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review. Updated labeler to Horizon Therapeutics USA, Inc. (from Viela Bio).	3
Signature William (Bill) Jagiello, DO			

Criteria Change History *(continued)*

Change Date	Changed By	Description of Change	Version
07/15/2022	CAC	Added to criteria: regimen/dosing prescribed must align with FDA-approved dosing.	2
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
07/16/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee