CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs
Uplizna® (inebilizumab-cdon)

Effective: February 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Uplizna was based on the N-MOmentum trial which was stopped before complete enrollment, as recommended by the independent data-monitoring committee, because of a clear demonstration of efficacy. Results showed that treatment with Uplizna in anti-AQP4 antibody positive patients reduced the risk of an NMOSD relapse by 77% when compared to the placebo treatment group. A smaller proportion of patients had an attack when treated with Uplizna compared to placebo (11.2 vs 42.3%). There was no evidence of a benefit in patients who were anti-AQP4 antibody negative.

Food and Drug Administration - Approved Indications

Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Uplizna for Members when all of the following criteria are met:

1. Documented diagnosis of neuromyelitis optica spectrum disorder

AND

2. Documentation of a positive serologic test for anti-aquaporin-4 antibodies

AND

3. The prescribing physician is a neurologist or an ophthalmologist

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1823	Injection, inebilizumab-cdon, 1 mg

References

1. Kessler RA, et al. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. Curr Treat Options Neurol. 2016;18(1):2
2. Cree BAC, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-

blind, randomized placebo-controlled phase 2/3 trial. The Lancet. 2019;394(10206):1352-1363.
3. Flanagan EP, et al. Epidemiology of aquaporin-4 Autoimmunity and Neuromyelitis Optica Spectrum. Ann Neurol. 2016;79(5):775-783.
4. Uplizna (inebilizumab-cdon) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc..; December 2020.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed the Limitations The health plan may authorize Uplizna (inebilizumab-cdon) for up to 12 months when coverage criteria are met and Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Added provider specialty requirements. Minor wording updates (eff 2/1/2024).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.