

Clinical Policy: Inebilizumab-cdon (Uplizna)

Reference Number: CP.PHAR.458

Effective Date: 09.10.20

Last Review Date: 09.20

Line of Business: WellCare Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Inebilizumab-cdon (Uplizna™) is an anti-CD19 monoclonal antibody.

FDA Approved Indication(s)

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene/WellCare Corporation® that Uplizna is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neuromyelitis Optica Spectrum Disorder (must meet all):

1. Diagnosis of NMOSD;
2. Prescribed by or in consultation with a neurologist;
3. Age \geq 18 years;
4. Member has positive serologic test for anti-AQP4 antibodies;
5. Member has experienced at least one relapse within the previous 12 months;
6. Member meets one of the following (a or b):
 - a. History of at least one relapse requiring rescue therapy[†] during the previous 12 months;
 - b. History of two relapses requiring rescue therapy[†] during the previous 24 months;
- [†] Rescue therapies include: IV corticosteroids, IV immunoglobulin, and/or plasma exchange
7. Baseline expanded disability status scale (EDSS) score of \leq 8;
8. Failure of rituximab (Ruxience™ and Truxima® are preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for rituximab*
9. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests) or active or untreated latent tuberculosis;
10. Uplizna is not prescribed concurrently with rituximab or Soliris®;
11. Dose does not exceed a loading dose of 300 mg on Day 1 and Day 15.

Approval duration: 6 months (loading doses only)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Neuromyelitis Optica Spectrum Disorder (must meet all):

1. Currently receiving medication via Centene/WellCare benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy – including but not limited to improvement or stabilization in any of the following parameters:
 - a. Frequency of relapse;
 - b. EDSS;
 - c. Visual acuity;
3. Uplizna is not prescribed concurrently with rituximab or Soliris;
4. If request is for a dose increase, new dose does not exceed 300 mg every 6 months.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene/WellCare benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AQP-4: aquaporin-4

EDSS: expanded disability status scale

FDA: Food and Drug Administration

NMOSD: neuromyelitis optica spectrum disorder

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rituxan [®] /Ruxience [™] / Truxima [®] (rituximab)*	IV: 375 mg/m ² per week for 4 weeks as induction, followed by 375 mg/m ² biweekly every 6 to 12 months	See regimen

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

*Off-label

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): previous life-threatening reaction to infusion of Uplizna, active hepatitis B infection, active or untreated latent tuberculosis
- Boxed warning(s): none reported

Appendix D: General Information

- AQP-4-IgG-seropositive status is confirmed with the use of commercially available cell-binding kit assay (Euroimmun).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NMOSD	Loading dose: 300 mg IV, followed by a second 300 mg IV dose 2 weeks later Maintenance dose: 300 mg IV every 6 months, starting 6 months after the first infusion	See regimen

VI. Product Availability

Solution for injection in a single-dose vial: 100 mg/10 mL

VII. References

1. Uplizna Prescribing Information. Gaithersburg, MD: Viela Bio, Inc.; June 2020. Available at: <https://vielabio.com/products-pipeline/commercial/uplizna>. Accessed June 15, 2020.
2. Cree BA, Bennet JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOMentum): A double-blind, randomised placebo-controlled phase 2/3 trial. Lancet. 2019; 394(10206): P1352-1363.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.21.20	02.20
Drug is now FDA approved - criteria updated per FDA labeling: added requirement that member does not have active HBV or TB since both are contraindications; added requirement against concurrent use with rituximab or Soliris; modified approval durations from 26 weeks to 6 months; modified continued dose requirement from every 26 weeks to 6 months; references reviewed and updated.	07.28.20	11.20
3Q 2020 annual review: WCG taking the new drug's CNC criteria.	09.10.20	09.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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