Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2022**
Policy Number: PA.CP.PHAR.458	**Effective Date: 10/2020** **Revision Date: 01/2022**
Policy Name: Inebilizumab-cdon (Uplizna)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2022 annual review: specified that Truxima is also a preferred rituximab product; updated HCPCS code; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Inebilizumab-cdon (Uplizna)

Reference Number: PA.CP.PHAR.458
Effective Date: 10/2020
Last Review Date: 01/2022

Coding Implications
Revision Log

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 PA Health & Wellness® 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 in consultation with a neurologist;
3. Age ≥ 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 ≤ 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, Soliris®, or Enspryng™;
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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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, Soliris, or Enspryng;
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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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®/Riabni™ 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.; July 2021. Available at: https://www.uplizna.com. Accessed September 15, 2021.
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.
3. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. European Journal of Neurology. 2010; 17: 1019–1032.

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
J1823	Injection, inebilizumab-cdon, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	10/2020
1Q 2021 annual review: no significant changes; references reviewed and updated.	01/2021
1Q 2022 annual review: specified that Truxima is also a preferred rituximab product; updated HCPCS code; references reviewed and updated.	01/2022