Original Effective Date: 03/01/2016
Current Effective Date: 08/30/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C20171-A

Uplizna (inebilizumab-cdon)

PRODUCTS AFFECTED

Uplizna (inebilizumab-cdon)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neuromyelitis optica spectrum disorder (NMOSD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
1. Documentation of diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by blood serum test for anti- aquaporin- 4 antibody positive (AQP4-IgG) [DOCUMENTATION REQUIRED]
   AND
2. Documentation of at least one core clinical characteristic from among the following: optic

neuritis (ON), acute myelitis, acute postrema syndrome (APS, characterized by unexplained hiccups or nausea and vomiting), acute brainstem syndrome, symptomatic narcolepsy, or acute diencephalic clinical syndrome with NMOSD- typical diencephalic MRI lesions, and symptomatic cerebral syndrome with NMOSD-typical brain lesions
AND

3. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
4. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
   AND
5. Prescriber attestation that member is not concomitantly receiving therapy with other immunosuppressant type drugs (i.e., alemtuzumab, natalizumab, cyclosporine, methotrexate, mitoxantrone, cyclophosphamide, tocilizumab, maintenance corticosteroids [not including pre-medications or rescue therapy, or doses of 20 mg or less a day], etc.)
   AND
6. Prescriber attestation that member will not be using in combination with complement- inhibitor (i.e., eculizumab, ravulizumab) or anti-CD20-directed antibody (i.e., rituximab) therapies
   AND
7. Documentation of member baseline status [DOCUMENTATION REQUIRED]:
   (a) One or more relapses that required rescue therapy within the previous 12 months OR 2 or more relapses that required rescue therapy in 2 years prior to screening
   NOTE: Rescue therapies include: IV corticosteroids, and/or plasma exchange
   AND
   (b) Documentation that member has a baseline Expanded Disability Status Scale (EDSS) score ≤ 8
   AND
   (c) Documentation of baseline relapse rate and visual acuity

CONTINUATION OF THERAPY:

A. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
   AND
2. Documentation therapy has resulted in clinical improvement or stabilization from baseline or from the previous authorization, including but not limited to frequency of relapse; EDSS, Reduction of hospitalizations, Reduction in plasma exchange treatments or Visual acuity [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity from the drug (e.g., serious infusion reactions, serious systemic infections, etc.)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with a neurologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Initial dose: 300 mg IV infusion, followed by 2 weeks later a second 300 mg IV infusion
Subsequent doses (starting 6 months from the first infusion): single 300 mg IV infusion every 6 months

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Uplizna (inebilizumab-cdon). For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous infusion

DRUG CLASS:
Immunosuppressive Agents-Monoclonal Antibodies

FDA-APPROVED USES:
Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin- 4 (AQP4) antibody positive

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
NMOSD is a rare, relapsing, autoimmune disorder of the brain and spinal cord with optic neuritis and/or myelitis as predominate characteristic symptoms. NMOSD often causes significant, permanent damage to vision and/or spinal cord function causing blindness or impaired mobility.
Patients may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, uncontrolled motor functions, and complications can cause death. Soliris® (eculizumab for intravenous use), a complement inhibitor, is the only other FDA-approved medication for treatment of NMOSD in adult patients who are anti-aquaporin-4 antibody positive. For acute attacks, typical treatment is high-dose intravenous corticosteroids. Plasma exchange may be effective in patients who suffer acute severe attacks that do not response to intravenous corticosteroids. For long-term control of the disease a variety of immunosuppressive drugs are utilized by providers as first-line therapy. While all are considered off-label use, corticosteroids, azathioprine, mycophenolate mofetil, and rituximab are treatments prescribed as preventative therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Uplizna (inebilizumab-cdon) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Uplizna (inebilizumab-cdon) include: previous life-threatening infusion reaction to Uplizna, active hepatitis B infection, active or untreated latent tuberculosis.

OTHER SPECIAL CONSIDERATIONS:
Administer all immunizations according to immunization guidelines 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.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J1823	Injection, inebilizumab-cdon, 1 mg

AVAILABLE DOSAGE FORMS:
Uplizna SOLN 100 mg/10 mL (10 mg/mL) single-dose vial

REFERENCES

1. Uplizna (inebilizumab-cdon) [package insert]. Viela Bio, Inc. Gaithersburg, MD. July 2021.
2. FDA Approves New Therapy for Rare Disease Affecting Optic Nerve, Spinal Cord. U.S. Food & Drug Administration. June 11, 2020.
3. Cree BAC, Bennett JL, Kim HJ, et al; N-MOmentum study investigators. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-blind, randomized placebo-controlled phase 2/3 trial. Lancet. 2019 Oct 12;394(10206):1352-1363. doi: 10.1016/S0140-6736(19)31817-3. Epub 2019 Sep 5.
4. Trebst C, Jarius S, Berthele A, et al. Update on the diagnosis and treatment of neuromyelitis optica: recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol 2014; 261:1
5. ClinicalTrials.gov. A Double-masked, Placebo-controlled Study With Open Label Period to Evaluate MEDI-551 in Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders. NCT02200770.
6. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/.
7. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015;85(2):177-189.
8. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. Practical Neurology. 2019;76-84.
9. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. https://wearesrna.org/wpcontent/uploads/2018/06/About_NMOSD_2018.pdf. Accessed June 19, 2020

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Other Special Considerations Available Dosage Forms	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file