Uplizna (inebilizumab-cdon)
Policy Number: C20171-A

CRITERIA EFFECTIVE DATES:

<table>
<thead>
<tr>
<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
<th>NEXT REVIEW DATE</th>
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<tbody>
<tr>
<td>3/1/2016</td>
<td>8/20/2020</td>
<td>8/20/2021</td>
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J CODE TYPE OF CRITERIA LAST P&T APPROVAL/VERSION
NOC RxPA Q4 2020 20201028C20171-A

PRODUCTS AFFECTED:
Uplizna (inebilizumab-cdon)

DRUG CLASS:
Immunosuppressive Agents-Monoclonal Antibodies

ROUTE OF ADMINISTRATION:
Intravenous infusion

PLACE OF SERVICE:
Specialty Pharmacy or Buy and Bill

The recommendation is that medications in this policy will be for medical benefit coverage and the IV infusion products administered in a place of service that is a non-hospital facility-based location (i.e., home infusion provider, provider’s office, free-standing ambulatory infusion center) unless the therapy/patient meets the Site of Care exceptions. (See appendix for excerpt from Specialty Medication Administration Site of Care Policy)

AVAILABLE DOSAGE FORMS:
Available as: 100 mg/10 mL (10 mg/mL) solution in a single-dose vial

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: neuromyelitis optica spectrum disorder (NMOSD)

REQUIRED MEDICAL INFORMATION:
A. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
   1. Documentation of diagnosis of NMOSD confirmed by blood serum test for anti-aquaporin-4 antibody positive
      AND
   2. Prescriber attests that member has been screened for hepatitis B virus (HBV) and tuberculosis (TB) prior to initiating treatment and member does not have an active infection
      AND
Prior Authorization Criteria

3. 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

4. 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

5. Documentation that member has a history of: (a) one or more relapses that required rescue therapy within the previous 12 months OR (b) 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

6. Documentation that member has a baseline Expanded Disability Status Scale (EDSS) score ≤ 8 AND

7. Documentation of baseline relapse rate and visual acuity AND

8. Documentation that member has previously tried, has a labeled contraindication or clinically significant adverse event to the following: (i) ONE of oral therapies: Azathioprine, Corticosteroid, OR Mycophenolate mofetil AND (ii) Rituximab

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy 12 months

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

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with a neurologist. Submit consultation notes if applicable.

NOTE: Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually.

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
1. Adherence to therapy as verified by Prescriber and member’s medication fill history (review Rx history for compliance), including adherent to the prescribed medication regimen, tolerance to therapy and no severe adverse reactions or drug toxicity 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 AND

3. There is absence of unacceptable toxicity from the drug (e.g.: serious infusion reactions, serious systemic infections, etc.)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Uplizna (inebilizumab-cdon) that are not an FDA-approved indication or not included in the ‘Coverage Criteria’ section of this policy are considered experimental/investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at Molina Healthcare, Inc. confidential and proprietary © 2020
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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 respond 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.

APPENDIX:
Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:
1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the member’s first dose of the medication or it is being re-initiated after at least 12 months*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at an non-hospital facility based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

Note: a hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary

REFERENCES:


