Cigna National Preferred Formulary Coverage Policy

NPF Coverage Policy

Cigna covers inebilizumab-cdon (Uplizna™) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Uplizna. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Uplizna as well as the monitoring required for adverse events and long-term efficacy, approval requires Uplizna to be prescribed by or in consultation with a physician who specializes in the condition being treated.

FDA Indication(s)

1. Neuromyelitis Optica Spectrum Disorder. Approve if the individual meets ONE of the following criteria (A or B):
   A) Initial Therapy. Approve for 1 year if the individual meets the following criteria (i, ii, iii, iv, and v):
      i. Individual is ≥ 18 years of age; AND
      ii. Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive; AND
iii. Individual is currently receiving or has previously tried two of the following systemic therapies (a, b, c, or d):
   a. Azathioprine; OR
   b. Corticosteroid; OR
   c. Mycophenolate mofetil; OR
   d. Rituximab; AND
   Note: An exception to the requirement for a trial of a systemic therapy can be made if the individual has already tried Soliris® (eculizumab injection) or Enspryng™ (satralizumab-mwge for subcutaneous injection) for neuromyelitis optica spectrum disorder. Individuals who have already tried Soliris or Enspryng for neuromyelitis optica spectrum disorder are not required to try another systemic agent for neuromyelitis optica spectrum disorder.

iv. Individual has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years; AND

v. The medication is being prescribed by or in consultation with a neurologist.

B) Individuals Currently Receiving Uplizna. Approve for 1 year if the individual meets the following (i, ii, iii, and iv):
   i. Individual is ≥ 18 years of age; AND
   ii. Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive; AND
   iii. According to the prescriber, individual has had clinical benefit from the use of Uplizna; AND
   Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing progression in symptoms.
   iv. The medication is being prescribed by or in consultation with a neurologist.

Conditions Not Covered

Inebilizumab-cdon (Uplizna™) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. Concomitant use with a rituximab product, Soliris® (eculizumab injection), or Enspryng™ (satralizumab-mwge injection). There is no evidence to support additive efficacy of combining Uplizna with rituximab, Soliris, or Enspryng.

Background

Overview
Uplizna, a CD19-directed cytolytic antibody, is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in patients ≥ 18 years of age who are anti-aquaporin-4 antibody positive.¹ The recommended dose is 300 mg administered as an intravenous infusion under the close supervision of an experienced healthcare professional. The initial infusion is followed 2 weeks later by a second infusion. Starting 6 months from the first infusion, subsequent doses are administered once every 6 months.

Disease Overview
NMOSD is a rare, relapsing, autoimmune disorder of the brain and spinal cord with optic neuritis and/or myelitis as predominate characteristic symptoms.² NMOSD often causes significant, permanent damage to vision and/or spinal cord function causing blindness or impaired mobility.³ 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 injection for intravenous infusion) and Enspryng™ (satralizumab-mwge for subcutaneous injection) are two other FDA-approved medications for treatment of NMOSD in adults who are anti-AQP4 antibody-positive.⁴⁵ For acute attacks, typical treatment is high-dose intravenous corticosteroids.⁶⁷ 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 as first-line therapy. While all are considered off-label use, corticosteroids, azathioprine, mycophenolate mofetil, and rituximab are treatments prescribed as preventative therapy.

References


Last Revision Details

| Selected Revision | Neuromyelitis Optica Spectrum Disorder. Criteria was separated into Initial Therapy and Patients Currently Receiving Uplizna. For both sections, criteria for approval duration, age restriction, diagnosis confirmation, and specialist requirement remained the same as before. For Initial Therapy, Soliris was removed as an option for previously tried systemic therapies. A Note was created to allow an exception to previously tried systemic therapies for patients who have tried Enspryng or Soliris. Criteria for a history of previous relapses were added. For Patients Currently Receiving Uplizna, criteria was added to show the patient is receiving a clinical benefit from Uplizna. Concomitant use with a rituximab product, Soliris® (eculizumab injection), or Enspryng™ (satralizumab-mwge injection) was added as a condition not recommended for approval. | 09/16/2020 |

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