Prior Authorization
Enspryng™ (satralizumab-mwge for subcutaneous injection)

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Coverage Policy
Cigna covers satralizumab products (Enspryng™) 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 Enspryng. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Enspryng as well as the monitoring required for adverse events and long-term efficacy, approval requires Enspryng 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):

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Cigna National Preferred Formulary Coverage Policy: NPF388
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 Uplizna™ (inebilizumab-cdon injection) for neuromyelitis optica spectrum disorder. Individuals who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent.
iv. Individual has a history of at least one 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) Individual is Currently Receiving Enspryng. 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 Enspryng; 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

Satralizumab (Enspryng™) 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 Uplizna™ (inebilizumab-cdon injection). There is no evidence to support additive efficacy of combining Enspryng with rituximab, Soliris or Uplizna.

Background

Overview

Enspryng, an interleukin-6 receptor antagonist, is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in individuals ≥ 18 years of age who are anti-aquaporin-4 antibody positive.elijkin-6 receptor antagonist, is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in individuals ≥ 18 years of age who are anti-aquaporin-4 antibody positive.1

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 resulting in blindness or impaired mobility.3 Individuals may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, uncontrolled motor functions, and complications can lead to death.

Other Therapies

Soliris® (eculizumab injection for intravenous infusion) and Uplizna™ (inebilizumab-cdon injection for intravenous infusion) are two other FDA-approved medications for treatment of NMOSD in adults who are anti-AQP4 antibody-positive.4,5 For acute attacks, typical treatment is high-dose intravenous corticosteroids.6,7 Plasma exchange may be effective in individuals 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. Preventative maintenance therapies include corticosteroids, azathioprine, mycophenolate mofetil, and rituximab (off-label).

**References**


**Last Revision Details**

| Selected Revision | Neuromyelitis Optica Spectrum Disorder. Initial therapy approval duration was changed from 6 months to 1 year. The requirement for tried systemic therapies verbiage of “used in the maintenance setting” was removed. The addition of two relapses in the last 2 years was added as an option and (acute attack from neuromyelitis optica spectrum disorder) was removed from the history of relapses criteria. Concomitant use with Soliris® (eculizumab injection) or Uplizna™ (inebilizumab-cdon injection). Rituximab was added as a product not to be used concomitantly with Enspryng. | 09/09/2020 |

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