PRIOR AUTHORIZATION POLICY

POLICY: Enspryng Prior Authorization Policy
- Enspryng® (satralizumab-mwge subcutaneous injection – Genentech)

REVIEW DATE: 09/20/2023

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Enspryng, an interleukin-6 receptor antagonist, is indicated for the treatment of **neuromyelitis optica spectrum disorder** (NMOSD) in adults 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 predominant characteristic symptoms.[2] NMOSD often causes significant, permanent damage to vision and/or spinal cord function resulting in blindness or impaired mobility.[3] Patients may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, and uncontrolled motor functions. Complications can lead to death.

Other Therapies

Soliris® (eculizumab intravenous infusion) and Uplizna™ (inebilizumab-cdon intravenous infusion) are two other FDA-approved medications for treatment of NMOSD.[4,5] For acute attacks, typical treatment is high-dose intravenous corticosteroids.[6,7] 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. Preventative maintenance therapies include corticosteroids, azathioprine, mycophenolate mofetil, and rituximab (off-label).

POLICY STATEMENT

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 patients 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.

- **Enspryng® (satralizumab-mwge subcutaneous injection – Genentech)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Neuromyelitis Optica Spectrum Disorder**. Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND
     - **iii.** Patient 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 patient has already tried Soliris (eculizumab intravenous infusion) or Uplizna (inebilizumab-cdon intravenous infusion) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent.
     - **iv.** Patient 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)** Patient is Currently Receiving Enspryng. Approve for 1 year if the patient meets the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND

ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND

iii. According to the prescriber, patient 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 in progression of symptoms.

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

CONDITIONS NOT COVERED

- **Enspryng® (satralizumab-mwge subcutaneous injection – Genentech)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant Use with a Rituximab Product, Soliris (eculizumab intravenous infusion), or Uplizna (inebilizumab-cdon intravenous infusion).** There is no evidence to support concomitant use of Enspryng with a rituximab product, Soliris or Uplizna.

REFERENCES

1. Enspryng® subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; March 2022.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Updated July 2022. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed September 18, 2023.
3. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015;85(2):177-189.
4. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; November 2020.
5. Uplizna® intravenous infusion [prescribing information]. Gaithersburg, MD: Viela Bio; July 2021.
6. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. *Practical Neurology*. 2019;76-84.
7. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. Available at: https://wearesrna.org/wp-content/uploads/2018/06/About_NMOSD_2018.pdf. Accessed on September 18, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/31/2022
Annual Revision	No criteria changes.	09/20/2023