Enspryng (satralizumab-mwge)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Enspryng (satralizumab-mwge) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Enspryng is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Immunoassay used to confirm anti-aquaporin-4 (AQP4) antibody is present
- For continuation of therapy request: medical records (e.g., chart notes, laboratory tests) demonstrating positive clinical response from baseline

Criteria for Initial Approval

A. Enspryng (satralizumab-mwge) may be considered **medically necessary** for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults when all of the following criteria are met:
   1. Member is anti-aquaporin-4 (AQP4) antibody positive
   2. The medication is being prescribed by, or in consultation with, a neurologist
   3. Member exhibits one of the following core clinical characteristics of NMOSD:

a. Optic neuritis
b. Acute myelitis
c. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
d. Acute brainstem syndrome
e. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions
f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

4. Member has a history of at least one or more relapses that required rescue therapy within the previous 12 months prior to initiating therapy
5. Member has had an inadequate response, intolerable adverse event, or documented contraindication to rituximab therapy
6. The member will not receive the requested drug concomitantly with any of the following:
   a. Complement-inhibitors (i.e., eculizumab, ravulizumab)
   b. Anti-CD20 therapy (i.e., rituximab)
   c. Anti-CD19 antibody (i.e., inebilizumab-cdon)

Approval will be for up to **6 months**

Continuation of Therapy

Enspryng (satralizumab-mwge) may be considered **medically necessary** for the continued treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive when the medication is being prescribed by, or in consultation with, a neurologist and the member demonstrates a positive clinical response to therapy from baseline, as demonstrated by a reduction or maintained reduction in the number and/or severity of relapses.

Approval will be for **12 months**

Enspryng is considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Prior to initiation of therapy, all individuals should receive HBV screening, TB screening, and liver transaminase/bilirubin screening. Individuals should also receive all immunizations according to guidelines at least 4 weeks prior to initiating therapy for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of therapy for non-live vaccine.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits:

Trade Name	Generic Name	Quantity Limit
Enspryng®	Satralizumab-mwge	Initiation of therapy: 2 x 120 mg syringes per first 28 days (4 weeks) Maintenance: 1 x 120 mg syringe per 28 days

CLINICAL RATIONALE

Background

Neuromyelitis optica spectrum disorder (NMOSD) is a rare, autoimmune, demyelinating disease of the central nervous system (CNS) that may be severely disabling and life-threatening. Patients with NMOSD most commonly present with either optic neuritis or transverse myelitis. Many patients experience severe relapses which often cause marked disability early in the course of illness, with unpredictable relapses causing cumulative, permanent, neurological damage and disability. Recovery from the attacks is often incomplete, resulting in residual and accumulating impairment, such as blindness and paralysis. Patients also can lose bladder and bowel control, suffer nerve pain and experience respiratory failure. Since disability progression in NMOSD is primarily due to consequences of attacks, the goals of pharmacotherapy are to aggressively treat acute inflammatory attacks and prevent future relapses, minimize CNS damage, and ultimately preserve neurological function. The best evidence for maintenance therapy is off label immunosuppressive therapies including rituximab, mycophenolate mofetil, and azathioprine with prednisone when necessary. Treatment with these agents was associated with significant reductions in annualized relapse rates in the range of 72%-88%. Enspryng is a humanized monoclonal antibody targeting the interleukin 6 (IL-6) receptor and is given via subcutaneous injection every 4 weeks. Enspryng is the third FDA-approved agent for patient with AQP4 antibody-positive NMOSD and the first self-administered product available. It follows the approval of Soliris and Uplizna.

Efficacy

The efficacy of Enspryng was evaluated in two phase 3, double-blind, placebo-controlled trials in adults with AQP4 antibody-seropositive or -seronegative NMOSD. SAkuraSky evaluated Enspryng when added to immunosuppressant therapy (IST) and SAkuraStar evaluated Enspryng when use as monotherapy. In SAkuraSky, 26 anti-AQP4 antibody positive adult patients were randomized to and received Enspryng and 26 received placebo. All patients were receiving either concurrent azathioprine (42%), oral corticosteroids (52%), or mycophenolate mofetil (6%) during the trial. In SAkuraStar, 41 anti-AQP4 antibody positive adult patients were randomized to and received Enspryng and 23 received placebo. The primary efficacy endpoint for both studies was the time to first relapse. In both studies, the time to the first relapse was significantly longer in patients treated with Enspryng compared to patients who received placebo. In SAkuraSky, there was a 78% risk reduction in the anti-AQP4 antibody positive population and no evidence of benefit in the anti-AQP4 antibody negative patients. In SAkuraStar there was a 74% risk reduction in the anti-AQP4 antibody positive population and no evidence of benefit in the anti-AQp4 antibody negative patients.

Safety

Enspryng is contraindicated in patients with known hypersensitivity to Enspryng or any of the active ingredients, active Hepatitis B infection, and active or untreated latent tuberculosis. Administration should be delayed in patients with an active infection. Enspryng can cause elevated liver enzymes as well as a decrease in neutrophil counts. The most common adverse reactions (incidence ≥ 15%) in the clinical trials were nasopharyngitis, headache, upper respiratory infection, gastritis, rash, arthralgia, extremity pain, fatigue, and nausea.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Not applicable (N/A)

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POLICY HISTORY

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