SATRALIZUMAB-MWGE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	46781		GPI-10 (9940507040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - Diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - The patient has at least **ONE** of the following core clinical characteristics:
     - Optic neuritis
     - Acute myelitis
     - Area postrema syndrome
     - Acute brainstem syndrome
     - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
     - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
   - The patient will **NOT** use rituximab, inebilizumab or eculizumab concurrently with Enspryng

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #3mL.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1mL per 28 days (Enter a start date 3 weeks AFTER THE END DATE of the first approval).**

   APPROVAL TEXT: Renewal for NMOSD requires the patient had a reduction in relapse frequency from baseline.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:

   A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
   B. You are 18 years of age or older

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
E. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (inflammation that damages an eye nerve)
    2. Acute myelitis (sudden and severe inflammation of the spinal cord)
    3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. You will NOT use rituximab, inebilizumab, or eculizumab together with Enspryng

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND** meet the following criterion?
    - The patient had a reduction in relapse frequency from baseline

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, do not approve.

    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:
    A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
    B. You had a reduction in relapse frequency from baseline
    (Renewal denial text continued on the next page)

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GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES

Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/20
Created: 08/20
Client Approval: 07/20
P&T Approval: 07/20