



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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 is NOT concurrently using rituximab, inebilizumab or eculizumab

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have **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

If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**

- **FIRST APPROVAL:** Approve for 30 days with a quantity limit of #2mL per 28 days.
- **SECOND APPROVAL:** Approve for 11 months with a quantity limit of #1mL per 28 days (Enter a start date 2 days before the end date of the first approval).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

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
- 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 are not concurrently (at the same time) using rituximab, inebilizumab, or eculizumab
- F. 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

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.

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?
 - The patient had a reduction in relapse frequency from baseline
 - The patient is NOT concurrently using rituximab, inebilizumab or eculizumab

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
- C. You are not concurrently (at the same time) using rituximab, inebilizumab, or eculizumab

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.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/22

Created: 08/20

Client Approval: 05/22

P&T Approval: 04/22