Clinical Policy: Satralizumab-mwge (Enspryng)

Reference Number: CP.PHAR.463
Effective Date: 08.14.20
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Satralizumab-mwge (Enspryng®) is an anti-interleukin-6 receptor antagonist.

FDA Approved Indication(s)

Enspryng is indicated for the treatment of:

- Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
- Thyroid eye disease (TED) regardless of TED activity or duration in adult patients.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Enspryng is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neuromyelitis Optica Spectrum Disorder (must meet all)**:**

1. Diagnosis of NMOSD;
2. Prescribed by or in in consultation with a neurologist
3. Age ≥ 18 years;
4. Member has positive serologic test for anti-AQP4 antibodies;
5. Member has experienced at least one relapse within the previous 12 months;
6. Member has a history of at least two relapses during the previous 24 months;
7. Baseline expanded disability status scale (EDSS) score of ≤ 6.5;
8. Failure of rituximab (*Ruxience™ and Truxima® are preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;†*
   †*For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
   **Prior authorization may be required for rituximab*
9. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests) or active or untreated latent tuberculosis;
10. Enspryng is not prescribed concurrently with rituximab, Bkemv™, Epysqli®, Soliris®, Uplizna®, or Ultomiris®;
11. Dose does not exceed 120 mg at weeks 0, 2, and 4, and every 4 weeks thereafter.

Approval duration:

Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Thyroid Eye Disease (must meet all)**:**
1. Diagnosis of Graves' disease with associated TED (i.e., Graves' ophthalmopathy, Graves' orbitopathy);
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. Weight ≥ 40 kg;
5. One of the following (a or b):
   a. Member is euthyroid with documentation of a recent (within the last 30 days) free thyroxine (FT4) and total triiodothyronine (T3) or free T3 (FT3) levels within the laboratory defined reference range;
   b. Member has a recent (within the last 30 days) free thyroxine (FT4) and total triiodothyronine (T3) or free T3 (FT3) levels less than 50% above or below the laboratory defined reference range and is undergoing treatment to correct the mild hypo- or hyperthyroidism to maintain a euthyroid state;
6. Member has not had previous surgical intervention for TED;
7. Member does not require surgical ophthalmological intervention;
8. Failure of a 4-week trial of a systemic corticosteroid (at up to maximally indicated doses), unless one of the following (a, b, or c):*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
   a. Clinically significant adverse effects are experienced or all are contraindicated;
   b. Member has significant proptosis (examples may include but are not limited to proptosis ≥ 3 mm above the upper limit for race and sex, or proptosis that impacts activities of daily life [e.g., reading, driving, computer work, and watching television]);
   c. Member has diplopia;
9. Enspryng is not prescribed concurrently with Lumvoa™ or Tepezza™;
10. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests) or active or untreated latent tuberculosis;
11. Dose does not exceed one of the following (a or b):
    a. For body weight 40-100 kg: 120 mg at weeks 0, 2, 4, and every 4 weeks thereafter starting at week 8;
    b. For body weight > 100 kg: 180 mg at weeks 0, 2, 4, and every 4 weeks thereafter starting at week 8.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Neuromyelitis Optica Spectrum Disorder (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy – including but not limited to improvement or stabilization in any of the following parameters:
   a. Frequency of relapse;
   b. EDSS;
   c. Visual acuity;
3. Enspryng is not prescribed concurrently with rituximab, Bkemv, Epysqli, Soliris, Uplizna, or Ultomiris;
4. If request is for a dose increase, new dose does not exceed 120 mg every 4 weeks.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Thyroid Eye Disease (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member has not had previous surgical intervention for TED;
3. Member does not require surgical ophthalmological intervention;
4. Enspryng is not prescribed concurrently with Lumvoa or Tepezza;

5. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. For body weight 40-100 kg: 120 mg every 4 weeks;
   b. For body weight > 100 kg: 180 mg every 4 weeks.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AQP-4: aquaporin-4
EDSS: expanded disability status scale
FDA: Food and Drug Administration
GO: Graves' ophthalmopathy
NMOSD: neuromyelitis optica spectrum disorder
RAI: radioactive iodine
TED: thyroid eye disease

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rituxan®/Riabni™/Ruxience™/ Truxima® (rituximab)*	**NMOSD**: 375 mg/m^2 per week for 4 weeks as induction, followed by 375 mg/m^2 biweekly every 6 to 12 months	See regimen
prednisone	**TED**: 30 mg/day PO	30 mg/day
methylprednisolone (SOLU-Medrol®)	**TED**: 500 mg IV once weekly for weeks 1 to 6, then 250 mg IV once weekly for weeks 7-12	500 mg/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): known hypersensitivity to satralizumab or any of the inactive ingredients, active hepatitis B infection, active or untreated latent tuberculosis
- Boxed warning(s): none reported

Appendix D: General Information
- AQP-4-IgG-seropositive status is confirmed with the use of commercially available cell-binding kit assay (Euroimmun).
- Use of systemic corticosteroids in TED is supported by the following treatment guidelines:
  - 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy: A combination of IV methylprednisolone and mycophenolate sodium is recommended as first-line treatment. If response to primary treatment is poor and Graves' ophthalmopathy (GO) is still moderate-to-severe and active, teprotumumab is considered a second-line option as longer-term data, availability, affordability, costs, and need for subsequent rehabilitative surgery are pending.
  - 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis: In the absence of any strong contraindication to GC, consider for coverage of mild active GO who are treated with radioactive iodine (RAI), even in the absence of risk factors for GO deterioration (weak recommendation, low-quality evidence). Additionally in mild GO patients who are treated with RAI, steroid coverage is recommended if there are concomitant risk factors for GO deterioration (strong recommendation, moderate-quality evidence).
  - 2022 American Thyroid Association Consensus Statement on the Management of Thyroid Eye Disease: Intravenous glucocorticoid therapy is a preferred treatment for active moderate-to-severe TED when disease activity is the prominent feature in the absence of either significant proptosis or diplopia.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NMOSD	120 mg SC at weeks 0, 2, 4, and every 4 weeks thereafter	See regimen

Indication	Dosing Regimen	Maximum Dose
TED	• For body weight 40-100 kg: 120 mg SC at weeks 0, 2, 4, then every 4 weeks thereafter starting at week 8 • For body weight > 100 kg: 180 mg SC at weeks 0, 2, 4, then every 4 weeks thereafter starting at week 8	See regimen

VI. Product Availability

- Single-dose prefilled syringe: 120 mg/mL
- Single-dose prefilled autoinjector: 120 mg/mL, 180 mg/1.5 mL

VII. References

1. Enspryng Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2026. Available at: https://www.enspryng.com/. Accessed October 20, 2026.

NMOSD

2. Yamamura T, Kleiter I, Fujihara K, et al. Trial of satralizumab in neuromyelitis optica spectrum disorder. N Engl J Med. 2019; 381: 2114-2124.
3. Traboulsee A, Greenberg BM, Bennett JL, et al. Safety and efficacy of satralizumab monotherapy in neuromyelitis optica spectrum disorder: a randomized, double-blind, multicentre, placebo-controlled phase 3 trial. Lancet Neurol. 2020; 19(5): 402-412.
4. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. European Journal of Neurology. 2010; 17: 1019–1032.
5. Kumpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. Journal of Neurology. 2023; 271: 141-176.

TED

6. Briceño CA, Idowu OO, Khong JJ, et al. Efficacy and safety of satralizumab for thyroid eye disease: Week 24 results from the phase III SatraGO-1 and SatraGO-2 randomized trials. Ophthalmology. Published online September 7, 2026. doi:10.1016/j.ophtha.2026.08.039
7. Ezra D, Collins A, Haskova, et al. Targeting IL-6 receptor signaling with satralizumab in thyroid eye disease: Design of the phase 3 SatraGO-1 and SatraGO-2 Trials. Ophthalmol Ther. 2025 Dec;14(12):3119-3132.
8. Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. Thyroid. 2016; 26:1343.
9. Mourits MP, Prummel MF, Wiersinga WM, Koornneef L. Clinical activity score as a guide in the management of patients with Graves' ophthalmopathy. Clin Endocrinol (Oxf). 1997; 47:9.
10. Patel KN, Yip L, Lubitz CC, et al. The American Association of Endocrine Surgeons guidelines for the definitive surgical management of thyroid disease in adults. Annals of Surgery. March 2020; 271 (3): e21-e93.
11. Bartalena L, Kahaly GJ, Baldeschi L, et al. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy. European Journal of Endocrinology: 27 August 2021; 185 (4): G43-G67.

12. Burch HB, Perros P, Bednarczuk T, et al. Management of thyroid eye disease: A consensus statement by the American Thyroid Association and the European Thyroid Association. Thyroid. 12 Dec 2022; 32 (12): 1439-1470.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; specified that Truxima is also a preferred rituximab product; references reviewed and updated.	09.15.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.28.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.03.22	02.23
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.18.23	08.23
3Q 2024 annual review: no significant changes; added Bkemv and Ultomiris to the list of therapies that Enspryng should not be prescribed concurrently with; references reviewed and updated.	05.15.24	08.24
3Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; added Epysqli to the list of therapies that Enspryng should not be prescribed concurrently with; revised continued approval duration from 6 to 12 months as NMOSD is a chronic condition; references reviewed and updated.	05.01.25	08.25
3Q 2026 annual review: added ICHRA line of business; extended initial approval durations for Medicaid/HIM from 6 to 12 months and revised all approval durations for Commercial to “6 months or to the member’s renewal date, whichever is longer” for this maintenance medication for a chronic condition; references reviewed and updated. RT4: added new single-dose prefilled autoinjector dosage form.	06.24.26	08.26
RT4: added newly approved indication for TED and new 180 mg/1.5 mL autoinjector strength.	10.20.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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