Clinical Policy Title:	satralizumab-mwge
Policy Number:	RxA.662
Drug(s) Applied:	Enspryng®
Original Policy Date:	12/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Member has a clinically confirmed diagnosis of neuromyelitis optica spectrum disorder and is anti-aquaporin-4 antibody positive;
2. Member has clinical evidence of at least one documented episode in the past 12 months;
3. Member is negative for hepatitis B virus and tuberculosis;
4. Trial and failure of rituximab at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Enspryng is prescribed as monotherapy or in combination with immunosuppressive therapy (i.e. azathioprine, mycophenolate or oral corticosteroids);
6. Enspryng is not being used for acute treatment of NMOSD relapse;
7. Enspryng is not prescribed concurrently with rituximab, Soliris®, or Uplizna®.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Center for Drug Evaluation and Research Clinical Review: Application 761149Orig1s000. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761149Orig1s000MedR.pdf. Accessed August 28, 2024.
2. Yamamura T, Kleiter I, Fujihara K, et al: Trial of satralizumab in neuromyelitis optica spectrum disorder. N Engl J Med 2019; 381(22):2114-2124.Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1901747. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	09/26/2020	12/07/2020

Policy was reviewed 1. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. Reference was reviewed and updated.	10/20/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.9 Updated to include new combination therapy criteria Enspryng is not prescribed concurrently with rituximab, Soliris®, or Uplizna® 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Reference was reviewed and updated.	08/31/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated verbiage for trial and failure of rituximab and appropriate use of Enspryng. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Removed reauthorization requirement for positive response to therapy. 7. Updated approval duration verbiage. 8. References were reviewed and updated.	08/28/2024	09/13/2024