RXADVANCE
2 Park Central Drive
Southborough, MA 01772

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

Background

Satralizumab-mwge is a recombinant, humanized interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optical spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Prior to the FDA approval of satralizumab-mwge, only two drugs are approved in the United States for the treatment of NMOSD. Eculizumab (Soliris®) was approved in 2019 for anti-AQP4 positive NMOSD patients; it has an annualized 96% reduction in relapse rate but costs are prohibitive. Inebilizumab-cdon (Uplizna™) was recently approved in June, 2020; it has an annualized reduction in relapse rate of 77%, which is comparable to satralizumab-mwge.

Prior to those approvals, drugs that had been approved for other indications and that targeted some aspect of the immune system that was perceived to be appropriate for the treatment of NMOSD were most commonly used for the treatment of NMOSD. Rituximab, azathioprine and mycophenolate are such examples. Rituximab has an annualized reduction in relapse rate of 88%.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
satralizumab-mwge (Enspryng™)	NMOSD	Loading Dose: 120 mg subcutaneously on weeks 0, 2 and 4 Maintenance Dose: 120 mg subcutaneously every 4 weeks. See dosing guidelines for delayed or missed doses guidelines.	Maintenance: 120mg per 28 days

Dosage Forms

- Injection: 120 mg/mL in a single-dose prefilled syringe

Clinical Policy

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

I. Initial Approval Criteria

A. Neuromyelitis Optica Spectrum Disorder

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 (1) documented episode in the past 12 months;
3. Prescribed by or in consultation with a neurologist;
4. Member is 18 years of age or older;
5. Member is negative for hepatitis B virus and tuberculosis;
6. Failure of rituximab at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
7. Member is treated with satralizumab-mwge as monotherapy or in combination with immunosuppressive therapy (i.e. azathioprine, mycophenolate or oral corticosteroids);
8. Member is not being treated with satralizumab-mwge for acute treatment of NMOSD relapse; and
9. Dosing does not exceed FDA-approved dosing guidelines.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Neuromyelitis Optica Spectrum Disorder

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (i.e. increase in time to relapse of NMOSD is indicative of efficacy); and
3. If request is for a dose increase, dose does not exceed FDA-approved dosing guidelines.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NMOSD: Neuromyelitis Optica Spectrum Disorder

APPENDIX B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
FDA Approved Therapies		
Soliris® (eculizumab)	900 mg IV weekly X 4, followed by 1200 mg for the 5th dose one week later, then 1200 mg every 2 weeks thereafter	1200 mg every 2 weeks
Uplizna™ (inebilizumab-cdon)	300 mg IV, initial dose and 2 weeks later, then 300 mg IV every 6 months	300 mg every 6 months
Non-FDA Approved Therapies		
rituximab	375 mg/m2 IV every week X 4	N/A
azathioprine	100 mg/day	100 mg/day
mycophenolate	1000 mg/day	1000 mg/day

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to satralizumab-mwge or any inactive ingredient(s)
  - Active hepatitis B virus (HBV) infection
  - Active or untreated latent tuberculosis (Tb)

- Boxed Warning(s):
  - None

References

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6. 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.
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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	09/26/2020	12/07/2020