SmartPA Criteria Proposal

Drug/Drug Class:	Neuromyelitis Optica Spectrum Disorder (NMOSD) Clinical Edit
First Implementation Date:	April 22, 2021
Proposed Date:	October 17, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of agents for neuromyelitis optica spectrum disorder (NMOSD)

Why Issue Selected: Neuromyelitis optica spectrum disorder (NMOSD) is a rare, autoimmune disease of the central nervous system that primarily attacks the optic nerves and spinal cord resulting in inflammation of the optic nerve (optic neuritis) and spinal cord (myelitis) leading to accumulating neurological damage and disability. NMOSD is characterized as repeated acute attacks separated by periods of remission that may be weeks, months, or years in length. NMOSD is very commonly confused with multiple sclerosis; only within the last 10 years has NMOSD became differentiated from multiple sclerosis due to the discovery of the anti-aquaporin-4 (AQP4) antibody which is now an identifier of the disease. It is estimated that 10,000 patients in the United States have NMOSD with 8,000 cases being anti-AQP4 antibody positive.

Uplizna® (inebilizumab-cdon), a CD19-directed cytolytic antibody, was FDA approved in June 2020, for the treatment of NMOSD in adult patients who are anti-AQP4 antibody positive. Uplizna is given as a 300 mg IV infusion over 90 minutes. The first infusion is followed by another 2 weeks later; then subsequent dosing is every 6 months (beginning 6 months after the first infusion). Premedication with a corticosteroid, antihistamine, and antipyretic is required prior to every infusion.

Enspryng™ (satralizumab-mwge), an interleukin-6 (IL-6) receptor antagonist, was FDA approved in August 2020, for the treatment of NMOSD in adult patients who are anti-AQP4 antibody positive. Enspryng is the first self-administered subcutaneous therapy to be approved for NMOSD. It is administered as a loading dose of 120 mg by subcutaneous injection at weeks 0, 2, and 4, followed by a maintenance dose of 120 mg every 4 weeks.

Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of agents for NMOSD.

Program-Specific Information:

Date Range FFS 7-1-2022 to 6-31-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ENSPRYNG 120 MG/ML SYRINGE	2	$33,040	$16,520
UPLIZNA 100 MG/10 ML VIAL	0	-	-

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Agents for neuromyelitis optica spectrum disorder (NMOSD)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

Initial Therapy:

- Must meet all of the following:
  - Prescribed by or in consultation with an immunologist, neurologist, or other specialist within the treated disease state;
  - Participant is aged 18 years or older;
  - Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD);
  - Participant is seropositive for anti-aquaporin-4 (AQP4) antibodies; **AND**
  - Documented baseline number and frequency of acute attacks
- Additional approval criteria for Uplizna only:
  - Documented therapeutic trial of Enspryng (trial defined as at least 6 months of therapy)
- Initial approval period: 9 months

Continuation of Therapy:

- Must meet all of the following:
  - Documentation of decrease or stabilization in number and frequency of acute attacks from baseline
- Continuation approval period: 12 months

Denial Criteria

- Therapy will deny with presence of one of the following:
  - Any approval criteria are not met;
  - Participant is currently pregnant; **OR**
  - Participant (female of appropriate age) is not utilizing concurrent birth control methods

Required Documentation

Laboratory Results:		Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)

Rule Type: CE

Default Approval Period

9 months

References

- Enspryng® (satralizumab-mwge) [package insert]. San Francisco, CA: Roche, Inc; March 2022.
- Uplizna® (inebilizumab-cdon) [package insert]. Gaithersburg, MD: Viela Bio; July 2021.
- IPD Analytics. New Drug Review: Uplizna (inebilizumab-cdon). June 2020.
- IPD Analytics. New Drug Review: Enspryng (satralizumab-mwge). September 2020.
- Kessler R.A, Mealy M.A, et al. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. Curr Treat Options Neurol. 2016;18(1):2. doi: 10.1007/s1140-015-0387-9.
- National Organization for Rare Disorders (NORD). Neuromyelitis Optica Spectrum Disorder. Neuromyelitis Optica Spectrum Disorder - NORD (National Organization for Rare Disorders) (rarediseases.org). Accessed May 16, 2022.