SmartPA Criteria Proposal

Drug/Drug Class:	Uplizna Clinical Edit
First Implementation Date:	TBD
Proposed Date:	September 17, 2020
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 Uplizna™ (inebilizumab-cdon)

Why Issue Selected: Uplizna™ (inebilizumab-cdon), a CD19-directed cytolytic antibody, was FDA approved on June 11, 2020, for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. 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 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 is given as a 300 mg 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. Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Uplizna therapy.

Program-Specific Information:

Date Range FFS 7-1-2019 to 6-30-2020			
Drug	**Claims**	**Cost per vial**	**Cost per infusion**
UPLIZNA 100MG/10ML VIAL	0	$43,666.67 WAC	$131,000.00 WAC

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: Uplizna™ (inebilizumab-cdon)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

Initial Therapy:

- Participant is aged 18 years or older **AND**
- Prescribed by or in consultation with an immunologist, hematologist, or other specialist in the treated disease state **AND**
- Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in the past 2 years **AND**
- Participant is seropositive for anti-aquaporin-4 (AQP4) antibodies **AND**
- Participant is not currently pregnant **AND**
- Participant (female of appropriate age) is utilizing concurrent birth control methods **AND**
- Documented baseline number and frequency of acute attacks

Continuation of Therapy:

- Initial approval is for 9 months, renewal of prior authorization may be for up to 12 months following documentation of decrease or stabilization in number and frequency of acute attacks from baseline

Denial Criteria

- Therapy will be denied if no approval criteria are met

Required Documentation

Laboratory Results:	X	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

- Uplizna (inebilizumab-cdon) [package insert]. Gaithersburg, MD: Viela Bio; 2020.
- IPD Analytics. New Drug Review: Uplizna (inebilizumab-cdon). June 2020.
- Cree BAC, et al/ Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-Momentum): a double-blind, randomised placebo-controlled phase 2/3 trial. *The Lancet.* 2019;394(10206):1352-1363. doi: 10.1016/S0140-6736(19)31817-3.
- 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) website. Neuromyelitis Optica Spectrum Disorder. https://rarediseases.org/rare-diseases/neuromyelitis-optica/