

CRITERIA FOR PRIOR AUTHORIZATION

Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents

BILLING CODE TYPE For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Eculizumab (Soliris®)
Inebilizumab (Uplizna™)
Satralizumab (Enspryng™)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Medication must be prescribed by, or in consultation with a neurologist.
- If the requested drug is for the treatment of NMOSD, patient must have had a positive serologic test for AQP4-IgG (cell-based assay).¹⁻³
- Patient must not be on concurrent therapy with another NMOSD agent listed in Table 1.
- Prescriber must provide the patient's baseline number of relapses experienced in the past 12 months before initiating treatment with the requested agent.

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed dosing limits listed in Table 1.
- Patient must have had a decrease or no increase in the number of clinical relapses in the most recent 12 months after initiating treatment with the requested agent.⁴
- Provider must attest patient is not on concurrent therapy with another NMOSD agent listed in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

APPROVED PA Criteria

Table 1. FDA-approved age and dosing limits for NMOSD Agents¹⁻³

Agents	Indication(s)	Age	Dosing Limits
C5 Complement Inhibitor			
Eculizumab (Soliris®)	Neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive	≥ 18 years	900 mg IV weekly for the first 4 weeks, then 1200 mg IV week 5, then 1200 mg IV every 2 weeks
CD19-directed Cytolytic Antibody			
Inebilizumab-cdon (Uplizna™)	NMOSD in patients who are AQP4 antibody positive	≥ 18 years	300 mg IV, followed by a second 300 mg IV 2 weeks later, then 300 mg IV every 6 months
Interleukin-6 (IL-6) Receptor Antagonist			
Satralizumab-mwge (Enspryng™)	NMOSD in patients who are AQP4 antibody positive	≥ 18 years	120 mg SQ at weeks 0, 2 and 4, followed by 120 mg SQ every 4 weeks

IV – intravenous; SQ - subcutaneous

References

1. Soliris (eculizumab) [prescribing information]. Ann Arbor, MI. Alexion Pharmaceuticals, Inc. November 2020.
2. Uplizna (inebilizumab-cdon) [prescribing information]. Gaithersburg, MD. Viela Bio, Inc. June 2020.
3. Enspryng (satralizumab-mwge) [prescribing information]. South San Francisco, CA. Genentech, Inc. August 2020.
4. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. Eur J Neurol. 2010;17(8):1019-32. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1468-1331.2010.03066.x>. Accessed October 1, 2020.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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