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| <b>Policy Name:</b> | <b>Uplizna (inebilizumab)</b> | <b>Policy #:</b> | <b>2795P</b> |
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## Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Uplizna (inebilizumab).

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Uplizna (inebilizumab) under the specialty medical benefit when the following criteria have been met.

## Criteria

### 1. Coverage Criteria

- 1.1 Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) with chart notes indicating the member exhibits at least one of the core clinical characteristics:
  - Optic neuritis (inflammation of the optic nerve)
  - Acute myelitis (a type of inflammation of the spinal cord)
  - Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
  - Acute brainstem syndrome (lesions of the brain stem causing symptoms such as dizziness, vertigo, headache, facial pain, vision disturbances)
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions (resulting from a rare type of central nervous system tumor)
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- 1.2 Documentation that the patient is anti-aquaporin-4 (AQP4) antibody positive
- 1.3 Ordered by a neuro-ophthalmologist or specialist in the treatment of NMOSD
- 1.4 Documentation that the member has been on a stable dose of immunosuppressive therapy (such as azathioprine, mycophenolate mofetil, oral corticosteroids, etc.)
- 1.5 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Uplizna by both a pharmacist and a medical director

### 2. Exclusion Criteria

- 2.1 Uplizna will not be approved for use in combination with Enspryng or Soliris

### 3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Subsequent Approvals: 12 months with documented beneficial response (e.g., reduction in number of relapses)

## CPT Codes

## HCPCS Codes

|       |                                    |
|-------|------------------------------------|
| J1823 | Injection, inebilizumab-cdon, 1 mg |
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## References

1. Uplizna (inebilizumab) [prescribing information]. Deerfield, IL: Horizon Therapeutics USA Inc; July 2021.
2. Cree BAC, Bennett JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial. *Lancet* 2019; 394:1352.
3. Kessler RA, Mealy MA, Levy M. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. *Curr Treat Options Neurol*. 2016 Jan;18(1):2.

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### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.