

Uplizna (inebilizumab-cdon)
Effective 10/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody indicated for:

- Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive
- Treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients

Coverage Guidelines

Authorization may be granted for members new to the plan within the previous 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all of the following diagnosis-specific criteria are met: :

Neuromyelitis optic spectrum disorder (NMOSD)

1. Member has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
2. Anti-aquaporin-4 (AQP4) antibody positive confirmed by immunoassay
3. Member exhibits one of the following core clinical characteristics of NMOSD:
 - a. Optic neuritis
 - b. Acute myelitis
 - c. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
 - d. Acute brainstem syndrome
 - e. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions
 - f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
4. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

Immunoglobulin G4-Related Disease (IgG4-RD)

1. Member has a diagnosis of Immunoglobulin G4-Related Disease (IgG4-RD)

2. At least one organ/site is affected (e.g., pancreas, submandibular gland, lymph node[s], kidneys, bile duct/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, thyroid gland)
3. Member meets ONE of the following:
 - a. Member is currently being treated with a glucocorticoid (e.g., prednisone, methylprednisolone)
 - b. Trial and failure, contraindication, or intolerance to a glucocorticoid (e.g., prednisone, methylprednisolone)

Continuation of Therapy

Requests for reauthorization will be approved when the following diagnosis-specific criteria are met:

NMOSD:

1. Prescriber submits documentation of a positive response to therapy (e.g., reduction in number of relapses)
2. Member will not administer the requested drug concomitantly with other biologics for the treatment of NMOSD

IgG4-RD:

1. Prescriber submits documentation of a positive response to therapy (e.g., reduction in corticosteroid requirement from baseline, reduction in IgG4-RD flares from baseline, stabilization or improvement in signs or symptoms)

Limitations

1. Initial approvals and reauthorizations will be for 12 months.
2. The following quantity limits apply:

Uplizna 100mg/10mL	Loading dose: 60mL for 1 month
	Maintenance dose: 60mL per 12 months

References

1. Uplizna (inebilizumab-cdon) [prescribing information]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; April 2025.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015; 85:177-189.

Review History

01/23/2021 – Created and Reviewed Jan P&T. Effective 3/1/21.

07/09/2025 – Reviewed and Updated at July P&T. Updated NMOSD criteria to require that AQPR antibody is confirmed by immunoassay. Added criteria for supplemental indication of IgG4-RD to the policy. Effective 10/01/2025.

