Inebilizumab-cdon (Uplizna™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Uplizna is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For initial requests: Immunoassay used to confirm anti-aquaporin-4 (AQP4) antibody is present.
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. CRITERIA FOR INITIAL APPROVAL

Neuromyelitis optica spectrum disorder (NMOSD)
Authorization of 12 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:

A. Anti-aquaporin-4 (AQPR) antibody positive
B. Member exhibits one of the following core clinical characteristics of NMOSD:
    1. Optic neuritis
    2. Acute myelitis
    3. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
    4. Acute brainstem syndrome
    5. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
C. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

IV. CONTINUATION OF THERAPY

Authorization of 12 months ~~for continuation of therapy~~ may be granted for continued treatment in members requesting reauthorization when all ~~both~~ of the following criteria are met:

A. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
B. The member demonstrates a positive response to therapy (e.g., reduction in number of relapses).
C. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Uplizna [package insert].Deerfield, IL: Horizon Therapeutics USA, Inc.; July 2021.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015; 85:177-189.

EFFECTIVE DATE

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