Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 225.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Uplizna (inebilizumab-cdon)

I. Policy:
Uplizna (inebilizumab-cdon)

II. Purpose/Objective:
To provide a policy of coverage regarding Uplizna (inebilizumab-cdon)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Uplizna (inebilizumab-cdon) is an anti-CD19 monoclonal antibody directed against pre-B and mature B-cell lymphocytes, which express the cell surface antigen CD19. Following binding to CD19, inebilizumab causes antibody-dependent cellular cytolysis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Uplizna (inebilizumab-cdon) will be considered medically necessary for the commercial, exchange, CHIP and Medicaid lines of business when ALL of the following criteria are met:

- Prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that member is 18 years or older **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to Enspryng

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMIT:
Initial 12-month Authorization: Rx count of 3
Subsequent 12 month authorizations: 30 mL per 180 days; max qty supply: 30; min day supply: 168; max day supply: 180

Uplizna (inebilizumab-cdon) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that member is 18 years or older **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMIT:
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Subsequent 12 month authorizations: 30 mL per 180 days; max qty supply: 30; min day supply: 168; max day supply: 180

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Uplizna [prescribing information]. Deerfield, IL: Therapeutics USA Inc; July 2021.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/17/20

Revised: 1/19/21 (Enspryng), 1/17/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment), 12/28/23 (references added)

Reviewed: 1/18/22, 1/9/24

MA UM Committee approval: 12/31/23