Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 155.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ocrevus (ocrelizumab)

I. Policy:
Ocrevus (ocrelizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Ocrevus (ocrelizumab)

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:
Ocrevus (ocrelizumab) is an anti-CD20 monoclonal antibody. The precise mechanism of ocrelizumab is unknown, but presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, ocrelizumab results in antibody-dependent cellular cytolysis and complement-mediated lysis.

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

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Ocrevus (ocrelizumab) will be considered medically necessary for commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation of age $\geq$ 18 years **AND**
- Medical record documentation Ocrevus is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- One of the following:
    - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
    - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND

- For members with a diagnosis of a relapsing form of multiple sclerosis, medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary alternative.

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 authorization: 12-month duration with quantity limit of 3 doses
Re-authorization: 12-month duration with quantity limit of 2 doses

NOTE: Currently approved medications for the treatment of multiple sclerosis include, but are not limited to:

1. Aubagio (teriflunomide)
2. Avonex (interferon beta-1a)
3. Bafiertam (monomethyl fumarate)
4. Betaseron (interferon beta-1b)
5. Briumvi (ublituximab-xiiy)
6. Copaxone (glatiramer acetate)
7. Extavia (interferon beta-1b)
8. Gilenya (fingolimod)
9. Glatopa (glatiramer acetate)
10. Kesimpta (ofatumumab)
11. Lemtrada (alemtuzumab)
12. Mavenclad (cladribine)
13. Mayzent (siponimod)
14. Mitoxantrone
15. Ocrevus (ocrelizumab)
16. Plegridy (peginterferon beta-1a)
17. Ponvory (ponesimod)
18. Rebif (interferon beta-1a)
19. Tecfidera (dimethyl fumarate)
20. Tascenso ODT (fingolimod)
21. Tysabri (natalizumab)
22. Vumerity (diroximel fumarate)
23. Zeposia (ozanimod)

Ocrevus (ocrelizumab) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation Ocrevus is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- One of the following:
    - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
    - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

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 authorization: 12-month duration with quantity limit of 3 doses
Re-authorization: 12-month duration with quantity limit of 2 doses

NOTE: Currently approved medications for the treatment of multiple sclerosis include, but are not limited to:

1. Aubagio (teriflunomide)
2. Avonex (interferon beta-1a)
3. Bafiertam (monomethyl fumarate)
4. Betaseron (interferon beta-1b)
5. Briumvi (ublituximab-xiiy)
6. Copaxone (glatiramer acetate)
7. Extavia (interferon beta-1b)
8. Gilenya (fingolimod)
9. Glatopa (glatiramer acetate)
10. Kesimpta (ofatumumab)
11. Lemtrada (alemtuzumab)
12. Mavenclad (cladribine)
13. Mayzent (siponimod)
14. Mitoxantrone
15. Ocrevus (ocrelizumab)
16. Plegridy (peginterferon beta-1a)
17. Ponvory (ponesimod)
18. Rebif (interferon beta-1a)
19. Tecfidera (dimethyl fumarate)
20. Tascenso ODT (fingolimod)
21. Tysabri (natalizumab)
22. Vumerity (diroximel fumarate)
23. Zeposia (ozanimod)

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. Ocrevus [prescribing information]. South San Francisco, CA: Genetech Inc; August 2022.

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

Devised: 7/18/17

Revised: 9/19/17 (alternatives), 9/27/18 (grandfather), 9/17/19 (MS definition), 7/19/22 (Hep B, formulary alternative, LOB carve out), 7/19/23 (Medicare business segment, added list of alternatives), 12/30/23 (references added)

Reviewed: 8/30/18, 9/10/20, 9/8/21, 7/10/24

MA UM Committee approval: 12/31/23