Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 196.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ultomiris (Ravulizumab-cwvz)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Ultomiris (Ravulizumab-cwvz)

II. Purpose/Objective:
To provide a policy of coverage regarding Ultomiris (Ravulizumab-cwvz)

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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

Commercial
Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare
Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP
Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid
Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

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:
Ultomiris (Ravulizumab-cwvz) is a humanized monoclonal antibody which is a terminal complement inhibitor that specifically binds to the complement protein C5 (with high affinity), inhibiting its cleavage to C5a (the proinflammatory anaphylatoxin) and C5b (the initiating subunit of the terminal complement complex [C5b-9]) and preventing generation of the terminal complement complex C5b9. The C5 inhibition of complement-mediated hemolysis achieved by ravulizumab in patients with paroxysmal nocturnal hemoglobinuria is immediate, thorough, and sustained. Additionally, ravulizumab inhibits terminal complement-mediated thrombotic microangiopathy (TMA) in patients with atypical Hemolytic Uremic Syndrome.

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

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

Paroxysmal Nocturnal Hemoglobinuria (PNH)
- Prescription is written by a hematologist **AND**
- Medical record documentation of 1 month of age or older **AND**
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
- Medical record documentation of patient being vaccinated with the meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations **AND**
- Physician documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 10 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment **OR**
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:
- Medical record documentation:
    - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
    - Reduced need or elimination of transfusion requirements OR
    - Stabilization of hemoglobin levels

Atypical Hemolytic Uremic Syndrome (aHUS)
- Medical record documentation of a diagnosis of atypical hemolytic uremic syndrome (aHUS) *(Ultomiris is used to inhibit complement-mediated thrombotic microangiopathy)*

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 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.

Myasthenia Gravis

- Medical record documentation supporting a confirmed diagnosis of anti-acetylcholine receptor (AchR) antibody positive myasthenia gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of medical team recommending meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND**
- Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline **AND**
- Medical record documentation of age > 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to Vyvgart.

AUTHORIZATION DURATION: Initial approval will be given for six months. Subsequent approvals will be for an additional six months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score.

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- 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 therapeutic failure on, intolerance to, or contraindication to Enspryng **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to eculizumab or biosimilar.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 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.

Ultomiris (Ravulizumab-cwvz) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescription is written by a hematologist **AND**
- Medical record documentation of 1 month of age or older **AND**
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
- Medical record documentation of patient being vaccinated with the meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations **AND**
- Physician documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 10 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment **OR**
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation:
    - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
    - Reduced need or elimination of transfusion requirements OR
    - Stabilization of hemoglobin levels

Atypical Hemolytic Uremic Syndrome (aHUS)

- Medical record documentation of a diagnosis of atypical hemolytic uremic syndrome (aHUS) *(Ultomiris is used to inhibit complement-mediated thrombotic microangiopathy)*

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 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.

Myasthenia Gravis

- Medical record documentation supporting a confirmed diagnosis of anti-acetylcholine receptor (AchR) antibody positive myasthenia gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of medical team recommending meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND**
- Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline **AND**
- Medical record documentation of age > 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids

AUTHORIZATION DURATION: Initial approval will be given for six months. Subsequent approvals will be for an additional six months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score.

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- 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 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 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.

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. Ultomiris [prescribing information]. Boston, MA: Alexion Pharmaceuticals; September 2024.
2. Bird, SJ, Shefner JM, Goddeau, R. Overview of the treatment of myasthenia gravis. UpToDate. 2023 Aug 7 [cited 2023 Dec 26. Avialable from: https://www.uptodate.com/contents/overview-of-the-treatment-of-myasthenia-gravis?search=myathenia%20gravis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
3. Sander DB, Wolf GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. American Academy of Neurology. Neurology; 2016 Jun 29. 87(4):419-425. Available from: https://www.neurology.org/doi/pdf/10.1212/WNL.0000000000002790

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

Devised: 5/21/19

Revised: 7/10/19 (Hgb level per DHS), 4/15/20 (aHUS), 10/27/21 (age, ACIP recommendations), 8/25/22 (MG, Medicaid PARP statement). 8/25/23 (LOB carve, Medicaid business segment), 12/29/23 (references added), 8/19/24 (NMOSD, LOB table, taglines)

Reviewed: 2/1/20, 3/31/21, 8/13/25

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25

DHS PARP approval: 9/17/25