

POLICY: Complement Inhibitors – Ultomiris Utilization Management Medical Policy – Advanced Clinical Evaluation

- Ultomiris™ (ravulizumab-cwvz intravenous infusion – Alexion)

EFFECTIVE DATE: 1/1/2021

LAST REVISION DATE: 09/15/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Ultomiris, a complement inhibitor, is indicated for the following uses:¹

- **Atypical hemolytic uremic syndrome (aHUS)**, to inhibit complement-mediated thrombotic microangiopathy in patients ≥ 1 month of age.
Limitation of use: Ultomiris is not indicated for the treatment of patients with Shiga toxin *Escherichia coli*-related hemolytic uremic syndrome.
- **Generalized myasthenia gravis (gMG)**, in adults who are anti-acetylcholine receptor (AChR) antibody-positive.
- **Neuromyelitis Optica Spectrum Disorder (NMOSD)**, in adults who are anti-aquaporin-4 (AQP4) antibody-positive.
- **Paroxysmal nocturnal hemoglobinuria (PNH)**, in patients ≥ 1 month of age.

Ultomiris has a Boxed Warning about serious meningococcal infections.¹ Ultomiris is only available through a restricted access program, Ultomiris and Soliris Risk Evaluation and Mitigation Strategy (REMS).

Disease Overview

Hemolytic uremic syndrome (HUS) is defined as the triad of non-immune hemolytic anemia, thrombocytopenia, and acute renal failure, in which the underlying lesions are mediated by systemic thrombotic microangiopathy.² aHUS should be distinguished from a more common condition referred to as typical HUS.³ aHUS is a sub-type of HUS in which thrombotic microangiopathy is the consequence of endothelial damage in the microvasculature of the kidneys and other organs due to a dysregulation of the activity of the complement system. The typical form is caused by infection with certain strains of *E. coli* bacteria that produce toxic substances called Shiga-like toxins; Ultomiris is not indicated for the treatment of Shiga toxin *E. coli*-related hemolytic uremic syndrome.^{1,3}

Myasthenia gravis (MG) is a chronic autoimmune neuromuscular disease that causes weakness in the skeletal muscles, which are responsible for breathing and moving parts of the body, including the arms and legs.⁴ The hallmark of MG is muscle weakness that worsens after periods of activity and improves after periods of rest. Acquired MG results from the binding of autoantibodies to components of the neuromuscular junction, most commonly the AChR.⁵ Ultomiris was studied in patients with gMG with anti-AChR antibodies with a Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV, and a Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6 .¹

NMOSD is a rare, relapsing, autoimmune disorder of the brain and spinal cord with optic neuritis and/or myelitis as predominate characteristic symptoms.⁶ NMOSD often causes significant, permanent damage to vision and/or spinal cord function resulting in blindness or impaired mobility.⁷ Patients may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, uncontrolled motor functions, and complications can cause death.

PNH is a rare, genetic disorder of hematopoietic stem cells.^{8,9} The mutation in the X-linked gene phosphatidylinositol glycan class A (PIGA) results in a deficiency in the glycosylphosphatidylinositol (GPI) protein, which is responsible for anchoring other protein moieties to the surface of the erythrocytes. Loss of anchoring of these proteins causes cells to hemolyze and leads to complications such as hemolytic anemia, thrombosis, and peripheral blood cytopenias. PNH is a clinical diagnosis that should be confirmed with peripheral blood flow cytometry to detect the absence or severe deficiency of GPI-anchored proteins on at least two lineages.^{8,10} Prior to the availability of complement inhibitors, only supportive measures in terms of managing the cytopenias and controlling thrombotic risk were available. Supportive measures include platelet transfusion, immunosuppressive therapy for patients with bone marrow failure, use of erythropoietin for anemias, and aggressive anticoagulation.

Recommendations

There are no formal guidelines for treatment of aHUS.

An international consensus guidance for the management of MG was published in 2016.⁵ The consensus guidance recommends pyridostigmine for the initial treatment in most patients with MG. The ability to discontinue pyridostigmine can indicate that the patient has met treatment goals and may guide the tapering of other therapies. Corticosteroids or immunosuppressant therapy should be used in all patients with MG who have not met treatment goals after an adequate trial of pyridostigmine. Nonsteroidal immunosuppressant agents used in MG include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, and tacrolimus. It is usually necessary to maintain some immunosuppression for many years, sometimes for life. Plasma exchange and intravenous immunoglobulin can be used as short-term treatments in certain patients. A 2020 update to these guidelines provides new recommendations for methotrexate, rituximab, and Soliris[®] (eculizumab intravenous infusion).¹¹ All recommendations should be considered extensions or additions to recommendations made in the initial international consensus guidance. Oral methotrexate may be considered as a steroid-sparing agent in patients with gMG who have not tolerated or responded to steroid-sparing agents. Rituximab should be considered as an early therapeutic option in patients with anti-muscle specific kinase antibody-positive MG who have an unsatisfactory response to initial immunotherapy. Soliris should be considered in the treatment of severe, refractory, anti-AChR antibody-positive gMG.

The Neuromyelitis Optica Study Group (NEMOS) published revised recommendations for the treatment of NMOSD in 2024.¹² The standard of care for the treatment of NMOSD attacks (for both AQP4-IgG-positive and double-negative cases) are high-dose glucocorticoids and/or apheresis therapy. Long term immunotherapy is recommended for patients with AQP4-IgG-positive NMOSD. NEMOS notes the first-choice therapies for the treatment of AQP4-IgG-positive NMOSD are Soliris, Ultomiris[®], Enspryng[®] (satralizumab-mwge subcutaneous injection), Uplizna[®] (inebilizumab-cdon intravenous infusion), and rituximab. The order of preference for these therapies is unclear and further comparative trials and real-world data are needed. The choice of treatment is dependent on several factors, including disease

activity and severity, mode and onset of action, possibility to combine it with immunosuppressive drugs, effect on autoimmune and other comorbidities, gender (family planning issues), frequency and route of administration, side effect profile, as well as patient and physician preference. In general, if a patient fails a first-choice treatment, another first-choice treatment should be tried; other options include use of a second-choice treatment (azathioprine, mycophenolate mofetil, low-dose oral glucocorticoids) or the addition of a second-choice treatment to the regimen.

A consensus statement for the diagnosis and treatment of PNH was published in 2021.⁸ Treatment options for PNH are supportive care, allogeneic hematopoietic stem cell transplantation, and complement blockade by the anti-C5 monoclonal antibody (Soliris). Supportive care include use of oral iron to replace the large urinary losses; folate and vitamin B₁₂ supplementation; red blood cell transfusion when these measures do not maintain adequate hemoglobin levels; use of antibiotics to treat bacterial infections as soon as possible since infections can exacerbate hemolytic crises in patients with PNH; use of corticosteroids to reduce the severity and duration of the hemolytic crises; use of Soliris as primary prophylaxis in patients with high PNH clone size (granulocyte close > 50%), high level of D dimer, pregnancy, perioperative condition, and other associated thrombophilia risk factors; and use of immunosuppressives in patients with PNH and aplastic anemia and bone marrow deficiency.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Ultomiris. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is provided in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ultomiris as well as the monitoring required for adverse events and long-term efficacy, approval requires Ultomiris to be prescribed by or in consultation with a physician who specializes in the condition being treated. All reviews will be forwarded to a Physician Medical Director for evaluation.

Documentation: Documentation is required for use of Ultomiris as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. Subsequent coverage reviews for a patient who has previously met the documentation requirements and related criteria in the *Complement Inhibitors – Ultomiris Advanced Clinical Evaluation Medical Policy*, and who is requesting reauthorization, the criteria utilized do NOT require re-submission of documentation for reauthorization, except for the criterion requiring documentation of a continued benefit from Ultomiris therapy.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ultomiris is recommended for requests meeting both the preferred product step therapy requirements and indication requirements.

Preferred Product(s): Epysqli

Non-Preferred Products(s): Ultomiris

Step Therapy Requirements:

Authorization for a non-preferred biologic product or biosimilar will be granted if the patient meets any one of the items listed below (A, B, C, D or E). Chart notes documenting the issue must be provided at time of request:

- A. The patient is *not* considered a new start to the non-preferred product (new start is defined as no use of the requested product in the previous 365 days) OR
- B. Allergic reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR
- C. Adverse reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR
- D. Therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure during an adequate trial of all preferred biologic products or biosimilars which allowed sufficient time for a positive treatment outcome documented by medical chart notes OR
- E. The patient has a diagnosis not included in the FDA-approved indications of all preferred products, but is included in the FDA-approved indications of the non-preferred product

Please note:

- Factors such as patient or prescriber preference or healthcare facility's or pharmacy's inability or unwillingness to order or stock the preferred product(s) will not be considered
- Common side effects to all products and infusion-related reactions are not considered documented allergic reactions to a preferred product as they would be expected with the innovator and biosimilar products.
- Generally, an adequate trial of a drug is considered to be three months or longer in order to allow time for efficacy to be established

FDA-Approved Indications

1. Atypical Hemolytic Uremic Syndrome. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A) Patient does not have Shiga toxin *Escherichia coli*-related hemolytic uremic syndrome; AND
- B) The medication is prescribed by or in consultation with a nephrologist.

Dosing. Approve ONE of the following (A or B):

Note: Ultomiris is administered as an intravenous infusion.

- A) Patient weighs ≥ 5 kg to < 20 kg: ≤ 600 mg for one dose, followed by maintenance doses (which start 2 weeks after the loading dose) of ≤ 600 mg every 4 weeks; OR
- B) Patient weighs ≥ 20 kg: $\leq 3,000$ mg for one dose, followed by maintenance doses (which start 2 weeks after the loading dose) of $\leq 3,600$ mg every 8 weeks.

2. Generalized Myasthenia Gravis. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
 - i. Patient is ≥ 18 years of age; AND
 - ii. Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis [**documentation required**]; AND
 - iii. Patient meets BOTH of the following (a and b):
 - a) Myasthenia Gravis Foundation of America classification of II to IV; AND
 - b) Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 6 ; AND
 - iv. Patient meets ONE of the following (a or b):
 - a) Patient previously received or is currently receiving pyridostigmine; OR
 - b) Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine; AND
 - v. Patient meets ONE of the following (a or b):
 - a) Patient previously received or is currently receiving two different immunosuppressant therapies for ≥ 1 year; OR
 - b) Patient had inadequate efficacy, a contraindication, or significant intolerance to two different immunosuppressant therapies; AND
Note: Examples of immunosuppressant therapies include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, and cyclophosphamide.
 - vi. Patient has evidence of unresolved symptoms of generalized myasthenia gravis; AND
Note: Evidence of unresolved symptoms of generalized myasthenia gravis includes difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).
 - vii. The medication is prescribed by or in consultation with a neurologist.
- B) Patient is Currently Receiving Ultomiris. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is ≥ 18 years of age; AND
 - ii. According to the prescriber, patient is continuing to derive benefit from Ultomiris; AND
Note: Examples of benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function.
 - iii. The medication is prescribed by or in consultation with a neurologist.

Dosing. Approve ONE of the following (A or B):

- A) Initial Therapy. $\leq 3,000$ for one dose, followed by maintenance doses (which start 2 weeks after the loading dose) of $\leq 3,600$ mg every 8 weeks.
- B) Patient is Currently Receiving Ultomiris: $\leq 3,600$ mg every 8 weeks.

3. Neuromyelitis Optica Spectrum Disorder. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
- i. Patient is ≥ 18 years of age; AND
 - ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND
 - iii. The medication is prescribed by or in consultation with a neurologist.
- B) Patient is Currently Receiving Ultomiris. Approve for 1 year if the patient meets ALL of the following criteria (i, ii, iii, and iv):
- i. Patient is ≥ 18 years of age; AND
 - ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND
 - iii. According to the prescriber, patient has had clinical benefit from the use of Ultomiris; AND
Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing progression in symptoms.
 - iv. The medication is prescribed by or in consultation with a neurologist.

Dosing. Approve ONE of the following (A or B):

- A) Initial Therapy. $\leq 3,000$ for one dose, followed by maintenance doses (which start 2 weeks after the loading dose) of $\leq 3,600$ mg every 8 weeks.
- B) Patient is Currently Receiving Ultomiris: $\leq 3,600$ mg every 8 weeks.

4. Paroxysmal Nocturnal Hemoglobinuria. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
- i. Diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages **[documentation required]**; AND
 - ii. The medication is prescribed by or in consultation with a hematologist.
- B) Patient is Currently Receiving Ultomiris. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i. According to the prescriber, patient is continuing to derive benefit from Ultomiris; AND.
Note: Examples of benefit from Ultomiris include stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score.
 - ii. The medication is prescribed by or in consultation with a hematologist.

Dosing. Approve ONE of the following (A or B):

- A) Initial Therapy. Approve ONE of the following (i or ii):
- i. Patient weighs ≥ 5 kg to < 20 kg: ≤ 600 mg for one dose, followed by maintenance doses (which start 2 weeks after the loading dose) of ≤ 600 mg every 4 weeks; OR
 - ii. Patient weighs ≥ 20 kg: $\leq 3,000$ mg for one dose, followed by maintenance doses (which start 2 weeks after the loading dose) of $\leq 3,600$ mg every 8 weeks.
- B) Patient is Currently Receiving Ultomiris: Approve ONE of the following (i or ii):
- i. Patient weighs ≥ 5 kg to < 20 kg: ≤ 600 mg every 4 weeks; OR
 - ii. Patient weighs ≥ 20 kg: $\leq 3,600$ mg every 8 weeks

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ultomiris is not recommended in the following situations:

- 1. Concomitant Use with Another Complement Inhibitor, Except Voydeya (danicopan tablets).**
There is no evidence to support concomitant use of Ultomiris with another complement inhibitor, except Voydeya.
Note: Examples of complement inhibitors are Empaveli (pegcetacoplan subcutaneous injection, Fabhalta (iptacopan capsule), PiaSky (crovalimab-akkz intravenous infusion or subcutaneous injection), and eculizumab intravenous infusion (Soliris, biosimilars).
- 2. Concomitant Use with a Rituximab Product, a Neonatal Fc Receptor Blocker, or Zilbrysq (zilucoplan subcutaneous injection).** There is no evidence to support concomitant use of Ultomiris with a rituximab product, a neonatal Fc receptor blocker, or Zilbrysq.
Note: Examples of neonatal Fc receptor blockers are Imaavy (nipocalimab-aahu intravenous infusion), Rystiggo (rozanolixizumab-noli subcutaneous infusion), Vyvgart (efgartigimod alfa-fcab intravenous infusion), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection).
- 3. Concomitant Use with Enspryng (satralizumab-mwge subcutaneous injection) or Uplizna (inebilizumab-cdon intravenous infusion).** There is no evidence to support concomitant use of Ultomiris with Enspryng or Uplizna.
- 4.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	<p>For the title and where applicable in the document, “intravenous” was added.</p> <p>Generalized Myasthenia Gravis: “intravenous” was added to Ultomiris to clarify product allowed for a patient who is currently receiving therapy. [documentation required] was added to the requirement for confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis.</p> <p>Paroxysmal Nocturnal Hemoglobinuria: “intravenous or subcutaneous” was added to Ultomiris to clarify product allowed for a patient who is currently receiving therapy.</p> <p>Concurrent Use with Another Complement Inhibitor or Vyvgart (efgartigimod alfa-fcab intravenous infusion): The title was changed to this instead of stating specific complement inhibitors. Vyvgart was also added as a product to this condition.</p>	08/31/2022
Selected Revision	<p>Generalized Myasthenia Gravis: Revised the Myasthenia Gravis Activities of Daily Living (MG-ADL) score to ≥ 6 to align with the prescribing information; previously it was $\text{MG-ADL} \geq 5$.</p>	05/31/2023
Annual Revision	<p>Generalized Myasthenia Gravis: Initial therapy, for the criterion regarding evidence of unresolved symptoms of generalized myasthenia gravis, the examples of evidence of unresolved symptoms of generalized myasthenia gravis were moved to a Note.</p> <p>Conditions Not Recommended for Approval: Criterion regarding concomitant use of Ultomiris IV with another complement inhibitor or Vyvgart was revised to add rituximab and other neonatal Fc receptor blockers (Vyvgart Hytrulo, Rystiggo). Examples of complement inhibitors and neonatal Fc receptor blockers were moved to a Note.</p>	09/20/2023
Update	<p>01/17/2024: No criteria changes.</p> <p>Conditions Not Recommended for Approval: Note regarding examples of complement inhibitors was updated to include Fabhalta and Zilbrysq.</p>	--
Selected Revision	<p>Neuromyelitis Optica Spectrum Disorder: This condition and criteria for approval were added to the policy.</p> <p>Conditions Not Recommended for Approval, Enspryng (satralizumab-mwge subcutaneous injection) and Uplisna (inebilizumab-cdon intravenous infusion) were added to the criterion “Concomitant Use with a Rituximab Product, Enspryng (satralizumab-mwge subcutaneous injection), or Soliris (eculizumab intravenous infusion)”; new criterion reads: “Concomitant Use with Another Complement Inhibitor, a Rituximab Product, or a Neonatal Fc Receptor Blocker, Enspryng (satralizumab-mwge subcutaneous injection), or Uplisna (inebilizumab-cdon intravenous infusion)”.</p>	04/10/2024
UCare P&T Review	<p>Policy reviewed and approved by UCare P&T committee. Annual review process</p>	09/16/2024
Annual Revision	<ul style="list-style-type: none"> • Ultomiris subcutaneous injection: All references to the subcutaneous formulation were removed – subcutaneous Ultomiris will not be marketed and has been removed from the Ultomiris prescribing information. • Paroxysmal Nocturnal Hemoglobinuria, Patient is currently receiving Ultomiris: “Improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score” was added to the Note of examples of benefit. • Conditions Not Recommended for Approval, Concomitant Use with Another Complement Inhibitor, a Rituximab Product, a Neonatal Fc Receptor Blocker, Enspryng (satralizumab-mwge subcutaneous injection), or Uplisna (inebilizumab-cdon intravenous infusion): This criterion was separated into 	09/25/2024

	<p>three criteria. The Note regarding neonatal Fc receptor blockers was moved to the relevant criterion.</p> <ul style="list-style-type: none"> – Concomitant Use with Another Complement inhibitor (except Voydeya [danicopan tablets]). PiaSky (crovalimab-akkz intravenous infusion or subcutaneous injection) was added to the Note of examples of complement inhibitors. – Concomitant Use with a Rituximab Product, a Neonatal Fc Receptor Blocker, or Zilbrysq (zilucoplan subcutaneous injection). – Concomitant Use with Enspryng (satralizumab-mwge subcutaneous injection) or Uplizna (inebilizumab-cdon intravenous infusion). <p>Policy name: Ultomiris Intravenous PA was changed to Ultomiris PA.</p>	
Annual Revision	<p>Atypical hemolytic uremic syndrome, dosing section: Dosing recommendations were further clarified to align with the prescribing information.</p> <p>Generalized myasthenia gravis, Neuromyelitis optica spectrum disorder, and Paroxysmal nocturnal hemoglobinuria, dosing section: Dosing recommendations were split for Initial Therapy and Patient is Currently Receiving Ultomiris. All dosing recommendations align with the prescribing information.</p> <p>Conditions Not Recommended for Approval:</p> <ul style="list-style-type: none"> • Concomitant Use with Another Complement Inhibitor, Except Voydeya (danicopan tablets): Biosimilars to Soliris were added to the Note of examples of complement inhibitors. • Concomitant Use with a Rituximab Product, a Neonatal Fc Receptor Blocker, or Zilbrysq (zilucoplan subcutaneous injection): Imaavy was added to the Note of examples of neonatal Fc receptor blockers. 	08/06/2025
Aspirus Policy Update	<p>Updated preferred product to Epysqli. Ultomiris will require a step through the preferred product effective 1/1/2026 for members on a Medicare plan. Updated step therapy criteria to require chart note documentation to support the need for a non-preferred product.</p>	09/15/2025
Aspirus P&T Review	<p>Policy reviewed and approved by Aspirus P&T committee. Annual review process</p>	09/15/2025