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Policy Number: C4867-A

Soliris (eculizumab), Ultomiris (ravulizumab) and Biosimilars

PRODUCTS AFFECTED

Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab), Ultomiris (ravulizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Paroxysmal nocturnal hemoglobinuria (PNH), Generalized Myasthenia Gravis (gMG), Atypical Hemolytic Uremic Syndrome (aHUS), Neuromyelitis optica spectrum disorder (NMOSD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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ALL INDICATIONS:

1. Prescriber attests that member has been vaccinated against meningococcal infection (at least 2 weeks prior to treatment, if not previously vaccinated).
   AND
2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to eculizumab and Ultomiris (ravulizumab) include: Patients with unresolved serious Neisseria meningitidis infection, Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection.]
   AND
3. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
   AND
   (b) If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]
   OR
4. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
   a. Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e., an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]

A. PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH):

1. Documented diagnosis of Paroxysmal nocturnal hemoglobinuria (PNH)
   AND
2. Documentation of baseline labs and status [DOCUMENTATION REQUIRED]:
   a. Hemoglobin level
      AND
   b. Documentation of Lactate dehydrogenase (LDH) level which is 1.5 times the upper limit of the normal range (within the last 30 days). Submit laboratory results with reference range.

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AND

c. Documentation that member is transfusion-dependent, defined by having a transfusion within the last 12 months and ONE of the following: hemoglobin level less than 9 g/dL in the presence of symptoms, or hemoglobin less than 7 g/dL without symptoms (*Lab should be drawn before transfusion or at least one (1) month since last transfusion)

AND

3. Documentation member meets ONE of the following criteria: Member has history of thrombotic event(s) attributable to PNH (i.e. arterial/venous thrombosis, hepatic vein thrombosis, etc.) or major adverse vascular events from thromboembolism, Member has symptoms of PNH that inhibit the patient's quality of life (i.e. Anemia, fatigue, difficulty swallowing, thromboses, frequent paroxysms of pain, recurrent abdominal pain, erectile dysfunction, chronic kidney disease, organ damage secondary to chronic hemolysis), OR Member is pregnant and the potential benefit outweighs potential fetal risk
   AND
4. FOR ECULIZUMAB AND ULTOMIRIS (RAVULIZUMAB): Documentation that member has a trial and failure, or FDA labeled contraindication to Empaveli (pegcetacoplan)

B. ATYPICAL HEMOLYTIC UREMIC SYNDROME:
1. Documentation of a definitive diagnosis of atypical Hemolytic Uremic Syndrome (aHUS)
   AND
2. Documentation of baseline Serum LDH, serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement [DOCUMENTATION REQUIRED]

C. GENERALIZED MYASTHENIA GRAVIS:
1. Documentation of diagnosis of myasthenia gravis
   AND
2. Documentation member has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV confirmed by positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab) [DOCUMENTATION REQUIRED]
   AND
3. Documentation member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score of greater than or equal to 6 [DOCUMENTATION REQUIRED]
   AND
4. (a) Documentation of inadequate response, serious side effects, or labeled contraindication to TWO or more immunosuppressive drugs used alone or in combination for at least 12 months [i.e., azathioprine (Imuran), mycophenolate mofetil (Cellcept), cyclosporine (Sandimmune), cyclophosphamide, methotrexate, tacrolimus, rituximab (Rituxan)]
   OR
   (b) Documentation of inadequate response, serious side effects, or labeled contraindication to ONE or more immunosuppressive drugs as monotherapy or in combination therapy AND requires chronic plasma exchange, plasmapheresis or intravenous immunoglobulin therapy

D. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
1. Documentation of diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
   AND
2. Documentation diagnosis has been confirmed by blood serum test for anti- aquaporin- 4 antibody positive (AQP4-IgG) [DOCUMENTATION REQUIRED]
   AND
3. Documentation of at least one core clinical characteristic from among the following: optic neuritis (ON), acute myelitis, acute postrema syndrome (APS, characterized by unexplained hiccups or nausea and vomiting), acute brainstem syndrome, symptomatic narcolepsy, or acute diencephalic clinical syndrome with NMOSD- typical diencephalic MRI lesions, and symptomatic cerebral syndrome with NMOSD-typical brain lesions
   AND

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4. Documentation of member baseline status [DOCUMENTATION REQUIRED]:
   (a) One or more relapses that required rescue therapy within the previous 12 months OR 2 or more relapses that required rescue therapy in 2 years prior to screening
   NOTE: Rescue therapies include: IV corticosteroids, and/or plasma exchange
   AND
   (b) Documentation that member has a baseline Expanded Disability Status Scale (EDSS) score ≤ 8
   AND
   (c) Documentation of baseline relapse rate
   AND
5. Prescriber attestation that member is not concomitantly receiving therapy with other immunosuppressant type drugs (i.e., alemtuzumab, natalizumab, cyclosporine, methotrexate, mitoxantrone, cyclophosphamide, tocilizumab, maintenance corticosteroids [not including pre-medications or rescue therapy, or doses of 20 mg or less a day], etc.)
   AND
6. Prescriber attestation that member will not be using in combination with IL-6 antagonist (i.e., satralizumab [Enspryng]) or anti-CD19-directed antibody (i.e., inebilizumab [Uplizna]) or anti-CD20-directed antibody (i.e., rituximab) therapies

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
   1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. PAROXYSMAL NOCTURNAL HEMOGLOBINURIA:
   1. Documentation of disease improvement or stabilization by any of the following: decrease in serum LDH, hemoglobin level above baseline, or reduction in the need for blood transfusions

C. ATYPICAL HEMOLYTIC UREMIC SYNDROME:
   1. Documentation of disease improvement or stabilization by any of the following: decrease in serum LDH, Increase or improvement in serum creatinine/eGFR, Increase or normalization of platelet counts, Decrease in plasma exchange/infusion requirement

D. GENERALIZED MYASTHENIA GRAVIS:
   1. Documentation of disease improvement or stabilization by ALL of the following: Improvement of at least 3 points (reduction in score) from pre-treatment baseline on the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) assessment, reduction in signs and symptoms of myasthenia gravis, and Stabilization, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting therapy.
      NOTE: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on therapy will be considered treatment failure.

E. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
   1. Documentation of disease improvement or stabilization by any of the following: frequency of relapse, EDSS, Reduction of hospitalizations, Reduction in plasma exchange treatments, or visual acuity

DURATION OF APPROVAL:

Initial authorization: 6 months; Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified hematologist, oncologist, immunologist, genetic specialist or neurologist. [If prescribed in consultation, consultation notes must be submitted with initial

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request and reauthorization requests]

AGE RESTRICTIONS:
Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh):
Atypical Hemolytic Uremic Syndrome (aHUS): 2 months of age and older
Paroxysmal Nocturnal Hemoglobinuria (PNH) to reduce hemolysis, Generalized Myasthenia Gravis (gMG): 18 years of age and older

Soliris (eculizumab):
Atypical Hemolytic Uremic Syndrome (aHUS): 2 months of age and older
Paroxysmal Nocturnal Hemoglobinuria (PNH) to reduce hemolysis: 18 years of age and older
Generalized Myasthenia Gravis (gMG): 6 years of age and older
Neuromyelitis Optica Spectrum Disorder (NMOSD): 18 years of age and older

Ultomiris (ravulizumab-cwvz):
Atypical Hemolytic Uremic Syndrome (aHUS), Paroxysmal Nocturnal Hemoglobinuria (PNH): one month of age and older
Generalized Myasthenia Gravis (gMG), Neuromyelitis Optica Spectrum Disorder (NMOSD): 18 years of age and older

QUANTITY:
Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab):
aHUS and gMG:
18 years of age and older: 900mg weekly for the first 4 weeks, followed by 1200mg for the 5th dose 1 week later, then 1200mg every 2 weeks thereafter
<18yo, 40kg and over: 900mg weekly for the first 4 weeks, followed by 1200mg for the 5th dose 1 week later, then 1200mg every 2 weeks thereafter
<18yo, 30kg to less than 40kg: 600mg weekly for the first 2 weeks, followed by 900mg for the 3rd dose 1 week later, then 900mg every 2 weeks thereafter
<18yo, 20kg to less than 30kg: 600mg weekly for the first 2 weeks, followed by 600mg for the 3rd dose 1 week later, then 600mg every 2 weeks thereafter
<18yo, 10kg to less than 20kg: 600mg x 1 dose, followed by 300mg for the 2nd dose 1 week later, then 300mg every 2 weeks thereafter
<18yo, 5kg to less than 10kg: 300mg x 1 dose, followed by 300mg for the 2nd dose 1 week later, then 300mg every 3 weeks thereafter

PNH: 600mg weekly for the first 4 weeks, followed by 900mg for the 5th dose 1 week later, then 900mg every 2 weeks thereafter

NMOSD: 900mg weekly for the first 4 weeks, followed by 1200mg for the 5th dose 1 week later, then 1200mg every 2 weeks thereafter

Ultomiris (ravulizumab):
aHUS, PNH:
100kg or greater: 3000mg loading dose, maintenance dose 3600mg every 8 weeks
60kg to less than 100kg: 2700mg loading dose, maintenance dose 3300mg every 8 weeks
40kg to less than 60kg: 2400mg loading dose, maintenance dose 3000mg every 8 weeks
30kg to less than 40kg: 1200mg loading dose, maintenance dose 2700mg every 8 weeks
20kg to less than 30kg: 900mg loading dose, maintenance dose 2100mg every 8 weeks
10kg to less than 20kg: 600mg loading dose, maintenance dose 600mg every 4 weeks
5kg to less than 10kg: 600mg loading dose, maintenance dose 300mg every 4 weeks
Start maintenance doses 2 weeks after loading dose

gMG, NMOSD:

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100kg or greater: 3000mg loading dose, maintenance dose 3600mg every 8 weeks
60kg to less than 100kg: 2700mg loading dose, maintenance dose 3300mg every 8 weeks
40kg to less than 60kg: 2400mg loading dose, maintenance dose 3000mg every 8 weeks
Start maintenance doses 2 weeks after loading dose

Maximum of 28-day supply per claim
See Appendix for Vial Optimization chart

Maximum Quantity Limits – Based on FDA label for indication, age, and weight
See Appendix for maximum allowed quantities by HCPCS units and NDC units

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for eculizumab and Ultomiris (ravulizumab-cwvz). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Complement C5 Inhibitor

FDA-APPROVED USES:
Ultomiris (ravulizumab-cwvz) is indicated for:

- the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)
- the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)
- the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti- acetylcholine receptor (AChR) antibody positive
- the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive

Soliris (eculizumab) is indicated for:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- The treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 6 years of age and older who are anti-acetylcholine receptor (AChR) antibody positive.
- The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Limitations of Use:
Soliris and Ultomiris are not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Bkemv (eculizumab-aeeb) is indicated for:

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- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- The treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Epysqli (eculizumab-aagh) is indicated for:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- The treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Limitations of Use:
Bkemv and Epysqli are not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

D59.3 Hemolytic-uremic syndrome, D59.5 Paroxysmal nocturnal hemoglobinuria, G70.00 Myasthenia gravis without (acute) exacerbation, G36.0 Neuromyelitis optica

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
A biosimilar is a highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.[1]
As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising patient satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed October 8, 2019.

Maximum Allowed Quantities by HCPCS units:
eculizumab aHUS (J1299, Q5151, Q5152):
Load: 900 mg/450 HCPCS units (2 mg per unit) weekly for the first 4 weeks
1200 mg/600 HCPCS units 1 week after the fourth dose
Maintenance: 1200 mg/600 HCPCS units every 2 weeks

eculizumab MG/NMOSD (J1299, Q5151, Q5152):
Load: 900 mg/450 HCPCS units weekly for the first 4 weeks
1200 mg/600 HCPCS units 1 week after the fourth dose
Maintenance: 1200 mg/600 HCPCS units every 2 weeks

eculizumab PNH (J1299, Q5151, Q5152):
Load: 600 mg/300 HCPCS units weekly for the first 4 weeks
900 mg/450 HCPCS units 1 week after the fourth dose

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Maintenance: 900 mg/450 HCPCS units every 2 weeks

Ultomiris (ravulizumab) (J1303):
Load: 3000 mg/300 HCPCS units (10 mg per unit)
Maintenance 3600 mg/360 HCPCS units every 8 weeks

Maximum Allowed Quantities by National Drug Code (NDC) Units
eculizumab aHUS 300 mg vials:
Load: 3 vials/90 mL weekly for the first 4 weeks
Maintenance: 4 vials/120 mL every 2 weeks

eculizumab MG/NMOSD 300 mg vials:
Load: 3 vials/90 mL weekly for the first 4 weeks
Maintenance: 4 vials/120 mL every 2 weeks

eculizumab PNH 300 mg vials:
Load: 2 vials/60 mL weekly for the first 4 weeks
Maintenance: 3 vials/90 mL every 2 weeks

Ultomiris (ravulizumab) IV Administration (300 mg/3 mL or 1100 mg/11 mL):
Load: 30 mL (of 100 mg/mL concentration)
Maintenance: 36 mL (of 100 mg/mL concentration) every 8 weeks

Vial Optimization

eculizumab 300mg/30ml (Single dose)								
Diagnosis	Age	Weight	Loading Dose/# of Vials	Frequency	# of Vials Needed for 3 Month Initial Approval (weeks 1-12)/# of Doses	Maintenance Dose/# of Vials	Frequency	# of Vials Needed for 6 month Continuation Approval (24 weeks)/# of Doses
PNH	≥ 18	N/A	600mg/2 vials	Weekly x 4 weeks	20 vials/8 doses	900mg/3 vials	Every 2 weeks	36 vials/12 doses
gMG/NMOSD	≥ 18	N/A	900mg/3 vials	Weekly x 4 weeks	28 vials/8 doses	1200mg/4 vials	Every 2 weeks	48 vials/12 doses
aHUS	<18	5 kg-<10 kg	300mg/1 vial	Once, Start maintenance Week 2	5 vials/5 doses	300mg/1 vial	Every 3 weeks	8 vials/8 doses
aHUS	<18	10 kg-<20 kg	600mg/2 vials	Once, Start maintenance Week 2	8 vials/7 doses	300mg/1 vial	Every 2 weeks	12 vials/12 doses
aHUS	<18	20 kg-<30 kg	600mg/2 vials	Weekly x 2 weeks	14 vials/7 doses	600mg/2 vials	Every 2 weeks	24 vials/12 doses
aHUS	<18	30 kg-<40 kg	600mg/2 vials	Weekly x 2 weeks	19 vials/7 doses	900mg/3 vials	Every 2 weeks	36 vials/12 doses
aHUS	<18	≥ 40kg	900mg/3 vials	Weekly x 4 weeks	28 vials/8 doses	1200mg/4 vials	Every 2 weeks	48 vials/12 doses
aHUS	≥ 18	N/A	900mg/3 vials	Weekly x 4 weeks	28 vials/8 doses	1200mg/4 vials	Every 2 weeks	48 vials/12 doses

Ultomiris 300mg/3ml (Single dose), 1100mg/11ml (Single dose)
Loading Dose

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Drug and Biologic Coverage Criteria

Weight	Initial Dose	# of 100mg/ml Vials (3ml – 300mg)	# of 100mg/ml Vials (11ml – 1100mg)	Frequency	Total # of Doses Needed for 3 Month Initial Approval (Weeks 1-12)
5 kg- <10 kg	600mg	2		1 dose	4
10 kg- <20 kg	600mg	2		1 dose	4
20 kg-<30 kg	900mg	3		1 dose	3
30 kg- <40 kg	1200mg	4		1 dose	3
40 kg-<60kg	2400mg	8		1 dose	3
60 kg- <100 kg	2700mg	9		1 dose	3
≥ 100kg	3000mg	10		1 dose	3
Maintenance Dose					
Weight	Maintenance Dose	# of 100mg/ml Vials (3ml – 300mg)	# of 100mg/ml Vials (11ml – 1100mg)	Frequency (Starting 2 weeks after initial dose)	Total # of Doses Needed for 6 month Continuation Approval (24 weeks)
5 kg- <10 kg	300mg	1		Every 4 weeks	6
10 kg- <20 kg	600mg	2		Every 4 weeks	6
20 kg-<30 kg	2100mg	7		Every 8 weeks	3
30 kg- <40 kg	2700mg	9		Every 8 weeks	3
40 kg-<60kg	3000mg	10		Every 8 weeks	3
60 kg- <100 kg	3300mg	0	3	Every 8 weeks	3
≥ 100kg	3600mg	1	3	Every 8 weeks	3

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BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

PNH is a rare acquired clonal disorder caused by a somatic mutation of the phosphatidylinositol glycan-complementation class A (PIG-A) gene in hematopoietic stem cells. The disorder results in a deficiency of glycosylphosphatidylinositol (GPI), which serves as an anchor for several cell surface proteins including the terminal complement regulator, CD59. The absence of CD59 from the surface of the affected PNH red blood cells (RBCs) renders them susceptible to terminal complement- mediated lysis. The subsequent chronic hemolysis is the primary clinical manifestation of the disease and leads to disabling morbidities that include anemia, fatigue, thrombosis, pain, and impaired quality of life. Lactate dehydrogenase (LDH) is released during RBC destruction and grossly elevated serum LDH is a common finding in patients with PNH.

Atypical hemolytic uremic syndrome (aHUS) is a genetic, chronic, and progressive inflammatory disease that affects patients of all ages. This syndrome is caused by defects in regulation of the complement system. These defects are inherited, acquired, or both, and they result in chronic, uncontrolled activation of the complement system which leads to platelet, leukocyte, and endothelial- cell activation and systemic thrombotic microangiopathy. Affected patients have a lifelong risk of systemic clinical complications of thrombotic microangiopathy, including damage to multiple organ systems (e.g., the central nervous system, kidneys, heart, and gastrointestinal tract). Eculizumab, which blocks complement C5 activation, has been demonstrated as an effective agent. Most cases of aHUS are genetic, although some may be acquired due to autoantibodies or idiopathic. The diagnosis of complement-mediated Ahus is made by excluding other forms of TMA. Therefore, aHUS is suspected in patients with TMA without a secondary cause and ADAMTS13 activity >10%, without evidence of STEC-HUS. Plasma exchange or infusion may transiently maintain normal levels of hematologic measures but does not treat the underlying systemic disease aHUS is often misdiagnosed as thrombotic thrombocytopenic purpura (TTP) or STEC-HUS because aHUS shares many of the presenting characteristics of the other thrombotic microangiopathies, and confirmatory genetic results are not available at the time of presentation, the diagnosis relies heavily on the recognition of a clinical syndrome consistent with the diagnosis in the absence of signs of an alternate cause of thrombotic microangiopathy. It is a distinctly different illness from the more common disorder known as typical hemolytic uremic syndrome, which is caused by E.coli-producing Shiga toxins (Stx HUS) and is generally foodborne.

Myasthenia gravis (MG) is relatively rare acquired autoimmune disorder caused by an antibody- mediated blockade of neuromuscular transmission resulting in skeletal muscle weakness. MG is characterized by a pattern of progressively reduced muscle strength with repeated use and recovery of muscle strength after a period of rest. MG is classified into 2 major clinical types: ocular MG and generalized MG (gMG). gMG is a debilitating, chronic and progressive autoimmune neuromuscular disease that can occur at any age. There is no known cure for MG. The mainstay of therapy for symptomatic treatment of MG involves use of acetylcholinesterase (AChE) inhibitors. If treatment with AChE inhibitors is not effective, or they are not suitable for long-term use, then short-term immunosuppression with oral corticosteroids such as prednisolone is used. Nonsteroidal immunosuppressive agents (azathioprine, cyclosporine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab, and tacrolimus) may be used in addition to steroids, with the aim of reducing the steroid dose over time. Approximately 10% to 15% of patients with MG have refractory gMG. These patients do not respond to long-term treatment with corticosteroids or multiple immunosuppressive treatments, or they have intolerable side effects to these therapies or require ongoing treatment with either intravenous immunoglobulin (IVIG) or plasma exchange

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(PE) (Howard et al., 2017). Patients with refractory gMG experience difficulties with speech, swallowing, and mobility, impairment of respiratory function, and extreme fatigue, and may have frequent exacerbations, which can be life-threatening and require hospital admission.

Eculizumab is a recombinant humanized monoclonal antibody that works by binding to complement protein C5, inhibiting its enzymatic cleavage, blocking formation of the terminal complement complex, and thus preventing red cell lysis. In those patients with paroxysmal nocturnal hemoglobinuria (PNH), eculizumab inhibits terminal complement mediated intravascular hemolysis. In patients with atypical hemolytic uremic syndrome (aHUS), impairment in the regulation of complement activity leads to uncontrolled terminal complement activation, resulting in platelet activation, endothelial cell damage and thrombotic microangiopathy. The precise mechanism by which eculizumab exerts its therapeutic effect in gMG patients is unknown but is presumed to involve reduction of terminal complement complex C5b-9 deposition at the neuromuscular junction. Ultomiris is a recombinant humanized monoclonal IgG2/4κ antibody. The antibody binds to the complement component C5 and prevents its cleavage to C5a and C5b, which is required for formation of the membrane attack complex (MAC). RBCs are normally protected from MAC formation by the glycosylphosphatidylinositol (GPI)-linked protein CD59 on their surface; PNH red blood cells (RBCs) lacking CD59 are susceptible to MAC formation. Ultomiris interferes with this step and thus reduces intravascular hemolysis. Approval of Ultomiris was based on two open-label, randomized, active-controlled, non-inferiority phase 3 studies: ALXN1210-PNH-301 (NCT02946463) and ALXN1210- PNH-302 (NCT03056040). Study 301 enrolled 246 patients with PNH who were complement inhibitor naïve and had active hemolysis. Study 302 enrolled 195 patients with PNH who were clinically stable after having been treated with Soliris for at least the past 6 months. In both trials, patients were randomized to receive either Ultomiris or Soliris. Patients randomized to Ultomiris received a loading dose followed by maintenance dosing every 8 weeks. Patients randomized to Soliris received a dose on Days 1, 8, 15, and 22, followed by maintenance treatment on Day 29 and every 2 weeks. The results of Study 301 demonstrated that Ultomiris had similar results to Soliris (non-inferior) – patients did not receive a transfusion and had similar incidence of hemolysis measured by the normalization of LDH levels in patients' blood (lactate dehydrogenase, or LDH, is an enzyme required during the process of turning sugar into energy in the body's cells).

The results of Study 302 demonstrated similar effects to Soliris (non-inferior) based on several clinical measures including hemolysis and avoiding transfusion. In Study 301, efficacy was established based upon transfusion avoidance and reduction of hemolysis as directly measured by normalization of LDH levels. Transfusion avoidance was defined as patients who did not receive a transfusion and did not meet the protocol specified guidelines for transfusion from baseline up to Day 183. Transfusion avoidance was seen in 73.6% and 66.1% of patients who received Ultomiris and Soliris, respectively (rate difference 6.8; 95% CI: -4.66, 18.14) and LDH normalization was seen in 53.6% and 49.4% of patients who received Ultomiris and Soliris, respectively (odds ratio 1.19; 95% CI: 0.80. 1.77). Supportive efficacy data included LDH percent change, breakthrough hemolysis and proportion of patients with stabilized hemoglobin levels. Non-inferiority of Ultomiris to Soliris was demonstrated across the endpoints. In Study 302, efficacy was established based on hemolysis as measured by LDH percent change from baseline to Day 183. LDH percent change was -0.82% and 8.4% for patients who received Ultomiris and Soliris, respectively (rate difference 9.2; 95% CI: -0.42, 18.8). Supportive efficacy data included transfusion avoidance, proportion of patients with stabilized hemoglobin and proportion of patients with breakthrough hemolysis. Non-inferiority of Ultomiris to Soliris was demonstrated across all endpoints.

The efficacy of Soliris for the treatment of NMOSD was established in NMOSD Study 1 (ECU-NMO- 301, NCT01892345), a randomized, double- blind, placebo-controlled, multi-center trial that enrolled 143 patients who were anti-AQP4 antibody positive. The primary endpoint was the time to the first adjudicated

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on-trial relapse. The time to the first adjudicated on-trial relapse was significantly longer in Soliris-treated patients compared to patients on placebo (relative risk-reduction 94%; hazard ratio 0.058; P<0.0001). The safety and efficacy of Ultomiris in adult patients with anti-AQP4 antibody positive NMOSD was assessed in an open-label multicenter study, Study ALXN1210- NMO-307 (NCT04291262). Patients participating in Study ALXN1210-NMO-307 received Ultomiris in the Primary Treatment Period that ended when the last enrolled patient completed (or discontinued prior to) 50 weeks on study, representing a median study duration of 73.5 weeks (minimum 13.7, maximum 117.7). Efficacy assessments were based on a comparison of patients in Study ALXN1210-NMO-307 with an external placebo control group from another study (Study ECU-NMO-301, NCT01892345) composed of a comparable population of adult patients with anti-AQP4 antibody positive NMOSD. The primary endpoint of Study ALXN1210-NMO-307 was the time to first adjudicated on-trial relapse as determined by an independent adjudication committee. No adjudicated on-trial relapses were observed in Ultomiris-treated patients during the Primary Treatment Period, representing a statistically significant difference between the Ultomiris and placebo treatment arms in time to first adjudicated on-trial relapse ($p < 0.0001$). The hazard ratio (95% confidence interval [CI]) for Ultomiris compared with placebo was 0.014 (0.000, 0.103), representing a 98.6% reduction in the risk of relapse (Figure 2). Ultomiris-treated patients experienced similar improvement in time to first adjudicated on-trial relapse with or without concomitant treatment.
DISEASE OVERVIEW Neuromyelitis optica spectrum disorder (NMOSD) is a rare, severe, disabling, and potentially life- threatening autoimmune neuroinflammatory disease characterized by acute optic neuritis (ON) and longitudinal transverse myelitis (TM). The disease can strike men and women of all races, backgrounds, and ages without warning, with a median age of onset of 39 years.
MORBIDITY AND MORTALITY Up to 92.7% of patients with AQP4 antibody-positive NMOSD have had unpredictable relapses, often leading to cumulative disability.3,7,8 In a study of anti-AQP4 antibody-positive NMOSD patients, morbidity was significant, with 18% experiencing permanent visual disability, 34% experiencing permanent motor disability, and 23% experiencing wheelchair dependency after a median disease duration of 75 months.3 Attacks that involve the brainstem can result in respiratory failure.4 The overall mortality rates of patients with NMOSD range from 7% to 9% (7% after a mean disease duration of 6.9 years; 9.4% after a median disease duration of 8.25 years). SIGNS AND SYMPTOMS In addition to vision loss and blindness, NMOSD patients experience immobility involving limb weakness and sensation loss that can give rise to paralysis.
Neuromuscular symptoms, such as cognitive challenges, pain, spasms, loss of bladder or bowel control, hiccups, nausea, vomiting, and seizures, can also arise. Ultimately, respiratory failure and encephalopathy can be among the most injurious consequences of NMOSD. NMOSD ASSOCIATED WITH AQP4 As 73% of patients with NMOSD are anti-AQP4 antibody positive, complement activation by AQP4 antibodies is a major determinant of disease pathogenesis in patients with NMOSD. AQP4 bound to immunoglobulin G (IgG) passes into the central nervous system through the blood-brain barrier and activates the complement system, causing the infiltration of immune leukocyte cells that cause the death of neural cells known as astrocytes and neurons.
Identifying AQP4-IgG in the blood facilitates clinical diagnosis and prognosis, as well as informing appropriate treatment selection. DIAGNOSIS The International Panel for NMO Diagnosis (IPND) established two sets of clinical criteria, both of which involve excluding alternative diagnoses. When patients test positive for blood AQP4-IgG, at least one core clinical characteristic must be identified from among the following: ON, acute myelitis, acute postrema syndrome (APS, characterized by unexplained hiccups or nausea and vomiting), acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, and symptomatic cerebral syndrome with NMOSD-typical brain lesions. In the absence of a confirmed AQP4-IgG test, at least two of the aforementioned core clinical characteristics must be identified, one of which must be ON, acute

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myelitis with longitudinally extensive transverse myelitis (LETM), or APS.

Ultomiris and Soliris REMS

SOLIRIS is available only through a restricted program under a REMS called ULTOMIRIS and SOLIRIS REMS, because of the risk of serious meningococcal infections.

Notable requirements of the ULTOMIRIS and SOLIRIS REMS include the following:

- Prescribers must enroll in the REMS.
- Prescribers must counsel patients about the risk of serious meningococcal infection.
- Prescribers must provide the patients with the REMS educational materials.
- Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of SOLIRIS.
- Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of SOLIRIS.
- Healthcare settings and pharmacies that dispense Soliris must be certified in the REMS and must verify prescribers are certified.
- Patients must receive counseling from the prescriber about the need to receive meningococcal vaccines per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the signs and symptoms of meningococcal infection.
- Patients must be instructed to carry the Patient Safety Card with them at all times during and for 3 months following treatment with SOLIRIS.

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

ULTOMIRIS is available only through a restricted program under a REMS called ULTOMIRIS and SOLIRIS REMS, due to the risk of meningococcal infections.

Notable requirements of the ULTOMIRIS and SOLIRIS REMS include the following:

• Prescribers must enroll in the REMS.
• Prescribers must counsel patients about the risk of meningococcal infection.
• Prescribers must provide the patients with the REMS educational materials.
• Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of ULTOMIRIS.
• Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of ULTOMIRIS.
• Healthcare settings and pharmacies that dispense ULTOMIRIS must be certified in the REMS and must verify prescribers are certified.
• Patients must receive counseling from the prescriber about the need to receive meningococcal vaccines per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the signs and symptoms of meningococcal infection.
• Patients must be instructed to carry the Patient Safety Card with them at all times during and for 8 months following treatment with ULTOMIRIS..

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

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Bkemv REMS

BKEMV is available only through a restricted program under a REMS called BKEMV REMS, because of the risk of serious meningococcal infections.
Notable requirements of the BKEMV REMS include the following:
• Prescribers must enroll in the REMS. • Prescribers must counsel patients about the risk of serious meningococcal infection.
• Prescribers must provide the patients with the REMS educational materials.
• Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y and B) and vaccinate if needed according to current ACIP recommendations 2 weeks prior to the first dose of BKEMV.
• Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of BKEMV.
• Healthcare settings and pharmacies that dispense BKEMV must be certified in the REMS and must verify prescribers are certified.
• Patients must receive counseling from the prescriber about the need to receive meningococcal vaccines per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the signs and symptoms of meningococcal infection.
• Patients must be instructed to carry the Patient Safety Card with them at all times during and for 3 months following treatment with BKEMV.
Further information is available at www.BKEMVREMS.com or 1-866-718-6927.

Bkemv (eculizumab-aeeb) is biosimilar* to Soliris (eculizumab). *Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of Bkemv has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Epysqli REMS

EPYSQLI is available only through a restricted program under a REMS called EPYSQLI REMS, because of the risk of serious meningococcal infections.
Notable requirements of the EPYSQLI REMS include the following:
• Prescribers must enroll in the REMS. • Prescribers must counsel patients about the risk of serious meningococcal infection.
• Prescribers must provide the patients with the REMS educational materials. This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda
• Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of EPYSQLI.
• Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of EPYSQLI.
• Healthcare settings and pharmacies that dispense EPYSQLI must be certified in the REMS and must verify prescribers are certified.
• Patients must receive counseling from the prescriber about the need to receive meningococcal vaccines per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the signs and symptoms of meningococcal infection.
• Patients must be instructed to carry the Patient Safety Card with them at all times during and for 3 months following treatment with EPYSQLI.
Further information is available at www.EPYSQLIREMS.com or 1-866-318-8144.

Epysqli (eculizumab-aagh) is biosimilar* to Soliris (eculizumab). * Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA approved biological product, known as a reference product, and that there are no clinically meaningful differences between

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the biosimilar product and the reference product. Biosimilarity of Epysqli has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of eculizumab and Ultomiris (ravulizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy Contraindications to eculizumab and Ultomiris (ravulizumab) include: Patients with unresolved serious Neisseria meningitidis infection, Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection.

OTHER SPECIAL CONSIDERATIONS:

Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab) and Ultomiris (ravulizumab) have a Black Box Warning for Serious meningococcal infection. Life- threatening and fatal meningococcal infections have occurred in patients treated with eculizumab and ravulizumab. Meningococcal infection may become rapidly life- threatening or fatal if not recognized and treated early.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1299	Injection, eculizumab, 2 mg
J1303	Injection ravulizumab-cwvz, 10mg
Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg
Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg

AVAILABLE DOSAGE FORMS:

Bkemv INJ 300/30ML
Epysqli INJ 300/30ML
Soliris SOLN 300MG/30ML
Ultomiris SOLN 300MG/3ML
Ultomiris SOLN 1100MG/11ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Policy Name Products Affected Required Medical Information Age Restrictions Quantity FDA Approved Uses Appendix Background Products Affected Coding/Billing Information Template Update Coding/Billing Information Available Dosage Forms References	Q2 2025
REVISION- Notable revisions: Quantity References	Q3 2024
REVISION- Notable revisions: Age Restrictions Quantity FDA-Approved Uses Background References	Q2 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Quantity Appendix Background Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file

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