Pharmacy Drug Policy Checklist

POLICY NAME	Ultomiris (ravulizumab)	POLICY #	2735P

Criteria

Coverage Criteria for Atypical hemolytic uremic syndrome (aHUS)

- ☐ **1.1** Documented diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS) with all necessary laboratory results, signs, and/or symptoms and evidence of complement gene abnormality or factor antibodies (e.g. thrombocytopenia, microangiopathic hemolysis, thrombotic microangiopathy, acute renal failure)
- ☐ **1.2** Prescribed by or in consultation with a hematologist (blood disorder doctor) or nephrologist (kidney doctor) in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- ☐ **1.3** Age 1 month or older
- ☐ **1.4** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ **1.5** Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Ultomiris by both a pharmacist and medical director

Coverage Criteria for Paroxysmal Nocturnal Hemoglobinuria (PNH)

- ☐ **2.1** Documented diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) with all necessary laboratory results, signs, and/or symptoms attributed to PNH (e.g. abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, enexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension)
- ☐ **2.2** Prescribed by or in consultation with a a hematologist (blood disorder doctor) or nephrologist (kidney doctor) in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- ☐ **2.3** Age 1 month or older
- ☐ **2.4** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ **2.5** Review of chart notes and labs documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Ultomiris by both a pharmacist and medical director

Coverage Criteria for Generalized Myasthenia Gravis (gMG)

- ☐ **3.1** Documented diagnosis of Generalized Myasthenia Gravis as supported by the following:
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV
  - Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score greater than or equal to 6
- ☐ **3.2** Serologic test (blood serum test) showing anti-acetylcholine receptor antibody-positive (AChR+)
- ☐ **3.3** Prescribed by, or in consultation with a neurologist (doctor of the nervous system) in the Ultomiris REMS program
- ☐ **3.4** Age 18 years or older Pharmacy Drug Policy & Procedure
- ☐ **3.5** Previous trial with at least one immunosuppressant drug (e.g. azathioprine, mycophenolate, cyclosporine, methotrexate, etc)
- ☐ **3.6** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ **3.7** Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Ultomiris by both a pharmacist and medical director.

Coverage Criteria for Neuromyelitis Optica Spectrum Disorder (NMOSD)

- ☐ **4.1** Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) with chart notes indicating the member exhibits at least one of the core clinical characteristics:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- ☐ **4.2** Documentation that the patient is anti-aquaporin-4 (AQP4) antibody positive
- ☐ **4.3** Ordered by a neuro-ophthalmologist (brain and eye doctor) or specialist in the treatment of NMOSD in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- ☐ **4.4** Age 18 years or older
- ☐ **4.5** Documentation that the member has been on a stable dose of immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, oral corticosteroids, etc.)
- ☐ **4.6** Lab cultures rule out any unresolved serious Nesseria meningitidis infection, if patient was diagnosed with N meningitidis infection recently
- ☐ **4.7** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)

- [ ] **4.8** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- [ ] **5.1** Ultomiris cannot be used in combination with another terminal complement inhibitor, such as Soliris (eculizumab)
- [ ] **5.2** Ultomiris cannot be used in patients with Shiga toxin E. coli-related hemolytic uremic syndrome (STEC- HUS)
- [ ] **5.3** Patients with unresolved Neisseria meningitides infection or who are not vaccinated against Neisseria meningitides (unless treatment cannot be delayed)