CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Soliris (eculizumab)
BILLING CODE	J1300
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 1,800 mg for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Soliris (eculizumab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)

For **initial** authorization:

1. Member has diagnosis of aHUS supported by the absence of Shiga toxin-producing E. coli infection and with ADAMTS13 activity level >5% documented in chart notes; AND
2. Member has ALL of the following documented in chart notes:
   a) Platelet count ≤150 x 10^9/L;
   b) Evidence of hemolysis (e.g., an elevation in serum Lactic Acid Dehydrogenase (LDH));
   c) Serum creatinine above the upper limits of normal, without the need for chronic dialysis; AND
3. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
4. Member does **not** have ANY of the following:
   a) History of malignancy within 5 years;
   b) HIV;
   c) Infection-related or identified drug exposure-related hemolytic-uremic syndrome (HUS);
   d) HUS related to bone marrow transplant (BMT) or to vitamin B12 deficiency;
   e) Systemic Lupus Erythematosus (SLE) or antiphospholipid antibody positivity or syndrome;
   f) Member is on chronic intravenous immunoglobulin (IVIG) within 8 weeks or chronic Rituximab therapy within 12 weeks.
5. **Dosage allowed:** 3,600 mg/28 days for initial fill, then 2,400 mg/28 days for subsequent fills.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has an increase in mean platelet counts from baseline and signs of complement-mediated thrombotic microangiopathy (TMA) activity were reduced with Soliris (eculizumab) therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

GENERALIZED MYASTHENIA GRAVIS (gMG)

For **initial** authorization:

1. Member is 18 years of age or older with diagnosis of gMG as confirmed by ALL of the following criteria documented in chart notes:
   a) Positive serologic test for anti-AChR antibodies;
   b) MG-Activities of Daily Living (MG-ADL) total score ≥ 6;
   c) Failed treatment with any **one** of the following:
      i) At least 2 immunosuppressive therapies (e.g. corticosteroid, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) over 1 year or more; OR
      ii) At least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); AND
2. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
3. Member does **not** have a history of thymectomy (within the past 2 months) or thymus cancer; AND
4. Member did **not** use:
   a) Rituximab within 6 months prior to therapy; OR
   b) IVIG or PE within 4 weeks prior to therapy.
5. **Dosage allowed:** 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement in MG-ADL score while on Soliris (eculizumab) therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

For **initial** authorization:

1. Member with diagnosis of PNH as confirmed by flow cytometry (PNH type III red cells or GPI-AP-deficient polymorphonuclear cells (PMNs)); AND
2. Medication is prescribed by a hematologist or nephrologist; AND
3. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
4. Member has LDH levels >1.5 times the upper limit of normal documented in chart notes; AND
5. Member has **one** or more of the following documented in chart notes:
   a) History of at least 1 blood transfusion within the past 24 months due to anemia or anemia related symptoms or personal beliefs precluding transfusion;
   b) Presence of organ damage due to chronic hemolysis.
6. **Dosage allowed:** 2,400 mg/28 days for initial fill then 1,800 mg/28 days for subsequent fills.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Soliris (eculizumab) therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource

CareSource considers Soliris (eculizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

DATE	ACTION/DESCRIPTION
11/14/2017	New policy for Soliris created.

References:

1. Soliris (eculizumab) [prescribing information]. New Haven, CT: Alexion Pharmaceuticals Inc; January 2017.
2. Eculizumab. In: Lexi-Drugs Online, Hudson, OH: Lexi-Comp, Inc. 2009; [July 17, 2017. Accessed July 17, 2017.] http://online.lexi.com.
3. Hillmen P, Young NS, Schubert J, et. al. The complement inhibitor eculizumab in paroxysmal nocturnal hemoglobinuria. N Eng J Med. 2006;355:1233-1243. Doi: 10.1056/NEJMMoa061648.
4. Brodsky RA, Young NS, Antonioli E, et. al. Multicenter phase 3 study of the complement inhibitor eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobulinemia. Blood. 2008;111:1840-1847. Doi: 10.1182/blood-2007-06-094136.
5. Legendre CM, Licht C, Muus P, et. al. Terminal complement inhibitor eculizumab in atypical hemolytic-uremic syndrome. N Eng J Med. 2013;368:2169-2181. Doi: 10.1056/NEJMMoa1208981.
6. Sahin F, Akay OM, Ayer M, et. al. Pesg PNH diagnosis, follow-up, and treatment guidelines. Am J Blood Res. 2016;6(2):19-27. Available at www.ajblood.us/files/ajbr0031541.pdf. Accessed July 17, 2017.
7. Parker C, Omine M, Richards S, et. al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005;106(12):3699-3709. Doi: 10.1182/blood-2005-04-1717.
8. Kaplan BS, Ruebner RL, Spinale JM, Copelovitch L. Current treatment of atypical hemolytic uremic syndrome. Intractable Rare Dis Res. 2014;3(2):34-35. Doi: 10.5582/irdr.2014.01001.
9. Cheong H, Jo SK, Yoon SS, et. al. Clinical practice guidelines for the management of atypical hemolytic uremic syndrome in Korea. J Korean Med Sci. 2016;31:1516-1528. Doi: 10.3346/jkms.2016.31.10.1516.
10. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016 Jul 26;87(4):419-25. doi: 10.1212/WNL.0000000000002790.
11. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT00838513. Open Label Controlled Trial of Eculizumab in Adult Patients With Plasma Therapy-sensitive Atypical Hemolytic Uremic Syndrome aHUS (aHUS); July 23, 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT00838513?term=eculizumab&recrs=adef&cond=ATYPICAL+HEMOLYTIC+UREMIC+SYNDROME+%28aHUS%29&rank=2.
12. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT00844545. Open Label Controlled Trial of Eculizumab in Adult Patients With Plasma Therapy-Resistant aHUS (aHUS). July 23, 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT00844545?term=eculizumab&recrs=adef&cond=ATYPICAL+HEMOLYTIC+UREMIC+SYNDROME+%28aHUS%29&rank=6.
13. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT00844844. Open Label Controlled Trial of Eculizumab in Adolescent Patients With Plasma Therapy-Resistant aHUS (aHUS). July 23, 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT00844844?term=eculizumab&recrs=adef&cond=ATYPICAL+HEMOLYTIC+UREMIC+SYNDROME+%28aHUS%29&rank=7.
14. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT01997229. Safety and Efficacy of Eculizumab in Refractory Generalized Myasthenia Gravis (REGAIN Study). March 3, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT01997229?term=eculizumab&recrs=adef&cond=GENERALIZED+MYASTHENIA+GRAVIS&rank=1.
15. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT00098280. Eculizumab to Treat Paroxysmal Nocturnal Hemoglobinuria. March 4, 2008. Available at: https://clinicaltrials.gov/ct2/show/NCT00098280?term=eculizumab&recrs=adef&cond=PAROXYSMAL+NOCTURNAL+HEMOGLOBINURIA&draw=1&rank=9.

Effective date: 11/29/2017
Revised date: 11/14/2017