Effective Date: 09.08.2022

Nevada Health Solutions LLC

NHS MEDICAL POLICY

Soliris (eculizumab)
Medicine 2022-001

Soliris is a humanized monoclonal IgG antibody that binds to complement protein C5, blocking the formation of membrane attack complex (MAC); which prevents breakdown of RBC.

Soliris maybe approved if General universal precautions and 1 of the following are met:

1	General universal precaution when prescribing Soliris: • No active Meningococcal infection. • Meningococcal vaccine has been administered at least two weeks prior to first dose or documentation that risks of delaying outweigh risk of meningococcal infection.
2	Soliris maybe indicated when one of the following are present:
3	Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • 18 years of age or older • Flow cytometry confirms GPI deficient cells • LDH greater than 1.5 times the upper limit of normal and history of clinical PNH related symptom. (Anemia or embolic event, etc.) • Prescribed by or in consultation with hematologist/oncologist Duration of treatment: 6 months duration. Continuation if documentation of: A. Stabilization of hemoglobin levels; **OR** B. Reduction in number of transfusions required, **OR** C. Improvement in hemolysis (for example, normalization or decrease of LDH levels).
4	Diagnosis of atypical hemolytic uremic syndrome (aHUS) • 18 years of age or older The diagnosis of aHUS is supported by the absence of Shiga toxin-producing E. coli infection; **AND**

	Thrombotic thrombocytopenic purpura has been ruled out [for example, normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor, or if thrombotic thrombocytopenic purpura cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement; **AND** • Prescribed by or in consultation with one of the following: Hematologist Oncologist Requests for continued use of Soliris (eculizumab) in aHUS may be approved if the following criteria are met: 1. There is clinical improvement after the initial trial (for example, increased platelet count or laboratory evidence of reduced hemolysis) until an individual becomes a candidate for physician-directed cessation as evidenced by the following (Merrill 2017): A. Complete clinical remission has been achieved (that is, resolution of thrombocytopenia and mechanical hemolysis, and normalization or new baseline plateau of renal function) and improvement of precipitating illness is clinically apparent. **AND** B. Duration of clinical remission has been stable for 2 months. Requests for resumption of Soliris (eculizumab) in aHUS may be approved if the following criteria are met: 1. Documentation is provided that individual experienced a relapse after discontinuation of therapy as defined by: A. Reduction in platelet count to less than 150,000/mm3 or greater than 25% from baseline, OR B. Mechanical hemolysis (having 2 or more features of hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 2 times upper limit of normal, undetectable haptoglobin, or presence of schistocytes on smear); OR C. Acute kidney injury with serum creatinine increase greater than 15% from baseline levels.
5	Diagnosis of generalized myasthenia (gMG) • Anti-acetylcholine receptor (AChR) antibody positive • Myasthenia Gravis foundation of America (MGFA) clinical classification II to IV • Documentation is provided that individual has a positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab). • MG activities of daily living (MG-ADL) total score 6 or greater • Documentation of 12-month Trial and failure, contraindication, or intolerance to two or more immunosuppressive therapies such as: ➢ glucocorticoids ➢ azathioprine ➢ cyclosporine ➢ mycophenolate mofetil ➢ methotrexate ➢ tacrolimus

	OR • Documentation is provided that individual has had an inadequate response to, is intolerant of, or has a contraindication to one or more immunosuppressive drug agents as monotherapy or in combination therapy and requires chronic plasma exchange or plasmapheresis or intravenous immunoglobulin therapy. • Prescribed by or in consultation with a neurologist Initial Approval Duration: 26 weeks • Requests for continued use of Soliris (eculizumab) in gMG may be approved if the following criteria are met: 1. Individual has experienced a clinical response as evidenced by both of the following: A. Reduction in signs or symptoms that impact daily function; AND B. Documentation is provided to show at least a 3-point reduction in MG-ADL total score from baseline. Requests for Soliris (eculizumab) may not be approved for the following: 1. Individual is using in combination with ravulizumab, rituximab, inebilizumab, or satralizumab, **OR** **2.** Individual is using in combination with pegcetacoplan for more than 4 weeks for PNH; **OR** 3. When the above criteria are not met and for all other indications.
6	Diagnosis of neuromyelitis optics spectrum disorder (NMOSD) • 18-year-old and diagnosis confirmed with Anti-aquaporin-4 (AQP4) antibody positive **AND** Documentation is provided that individual has a history of at least 2 acute attacks or relapses in the last 12 months prior to initiation of therapy. **OR** Documentation is provided that individual has a history of at least • Member exhibits one of the following core clinical characteristics of NMOSD ➢ 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 NMSOD typical diencephalic MRI lesions ➢ Symptomatic cerebral syndrome with NMSOD typical brain lesions • Prescribed by or in consultation with one of the following Neurologist Ophthalmologist

	Continuation of Soliris maybe indicated when: No evidence of unacceptable toxicity. Documentation of a positive response to therapy.

SOURCES

Aetna Clinical Policy Bulletins/Medical Clinical Bulletins Number :0807 Effective date: 10/08/2010
Last update: 11/26/2022
Anthem Blue Cross/Blue Shield web page: Soliris Effective Date 07/25/2022
https://www.anthem.com/ms/pharmacyinformation/clinicalcriteria.html

MCG CAREWEBQI 25th Edition Guideline A-0676
OptumRX SP Prior Authorization Guidelines Soliris Effective Date: 4/1/2022
United Healthcare Soliris Policy Number: 2022D0049S Effective Date: January 1, 2022

CODE REFERENCE

J1300

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/23/2023	Annual Review and approval by UM/QM Committee
08/23/2024	Annual Review and approval by UM/QM Committee