Palmetto Infusion Services COMPLIANCE

MRN:_____

Phone: 1-800-809-1265 Fax: 1-866-872-8920

DOB:_____

STANDARD Soliris® (eculizumab) PLAN OF TREATMENT for aHUS for Pediatric

(Re) Certification Period From_____to _____

NOTE: Patient ***may be ineligible*** to receive eculizumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, presents with any symptoms of meningococcal infections, and/or surgery.

1. Patient Name: _____Height (inches): _____Weight (lbs):_____

2. Allergies: _____

3. Primary Diagnosis: □ **D59.3 Atypical Hemolytic Uremic Syndrome (aHUS)**

□ **D58.8 Other specified hereditary hemolytic anemias** □ **D59.8 Other acquired hemolytic anemias**

□ **D59.4 Other non-autoimmune hemolytic anemias (including microangiopathic hemolytic anemia)**

□ **Other ICD-10 Code/Diagnosis description:**_____

4. Pre-medications: ☐ None ***OR*** ***Administered 30 minutes prior to infusion as selected:***

****Product information does not suggest any pre-medication prior to infusion***

Acetaminophen _____mgs PO or □ Liquid 160mg/5ml dose of ____mls as specified by referring MD
Diphenhydramine: _____mgs PO or _____mgs IV □ Liquid 12.5mg/5ml dose of ____mls as specified by referring MD
Pre-medicate with other: _____

*** Prescriber must be enrolled in the Soliris (REMS) program, available at 1-888-765-4747 or at www.solirisrems.com.**

Orders: **Soliris® (eculizumab)** IV dosing as selected to infuse over 35 minutes diluted in Sodium Chloride 0.9% with final volume is equal drug volume to diluent volume. Follow each infusion with a (1) one hour post infusion monitoring after each treatment.

* ***If the infusion is slowed, the total infusion time should not exceed 2 hours.***

5. Frequency/dose: (Final volume is drug volume + equal diluent volume)

Patient Body Weight	□ Induction	□ Maintenance
40 kg and over	900 mg weekly x 4 doses	1200 mg at week 5; then 1200 mg every 2 weeks thereafter
30 kg to less than 40 kg	600 mg weekly x 2 doses	900 mg at week 3; then 900 mg every 2 weeks thereafter
20 kg to less than 30 kg	600 mg weekly x 2 doses	600 mg at week 3; then 600 mg every 2 weeks thereafter
10 kg to less than 20 kg	600 mg weekly x 1 doses	300 mg at week 2; then 300 mg every 2 weeks thereafter
5 kg to less than 10 kg	300 mg weekly x 1 doses	300 mg at week 2; then 300 mg every 3 weeks thereafter

Special orders: _____

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES

6. Physician's Signature: _____/ _____Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____NPI: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms and Adverse Drug Reaction Guidelines are available at www.palmettoinfusion.com

Revised 6/26/18

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DOB:_____

Guidelines for Prescribing Soliris® (eculizumab) for aHUS for Pediatric

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:**_____

___ Soliris® (eculizumab) is restricted to credentialed prescribers enrolled in the Soliris (REMS) program. Available at 1-888-765-4747 or at www.solirisrems.com.

___ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-7)*
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

___ Include patient demographic information and insurance information. (Copy of insurance cards if available)

___ **Include supporting clinical MD notes that include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Any documentation that Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out, Shiga toxin E. Coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out, and/or other test/labs to support diagnosis.**

- **Atypical Hemolytic Uremic Syndrome (aHUS):** Soliris® is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. **Limitation of Use Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).**

___ Other as requested: _____

Pre-Screening:

___ Baseline serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirements

___ Documented meningococcal vaccine administration

** Warnings/Precautions: **SERIOUS MENINGOCOCCAL INFECTIONS:** Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris® and may become rapidly life-threatening or fatal if not recognized and treated early. **Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying therapy outweigh the risks of developing a meningococcal infection**. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected. **Adverse Drug Reactions:** The most frequently reported adverse reaction in the gMG placebo-controlled clinical trial (≥10%) is: musculoskeletal pain. **Other Infections:** Soliris® blocks terminal complement activation. Patients may have increased susceptibility to infections, especially with encapsulated bacteria. Additionally, Aspergillus infections have occurred in immunocompromised and neutropenic patients. Use caution when administering Soliris® to patients with any systemic infection. Pregnancy: review and discuss any pregnancy plans prior to start of therapy. See full prescribing information.

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.

Revised 6/26/18