**MRN:**_____

DOB:_____

# STANDARD Soliris® (eculizumab) PLAN OF TREATMENT for PNH

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**: **D59.5 Paroxysmal Nocturnal Hemoglobinuria**

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

**4. Pre-medications:** ***Administered 30 minutes prior to infusion as selected:***

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

| | |
|---|---|
| Acetaminophen:<br>□ 650 mg PO<br>□ 500 mg PO<br>□ 325 mg PO | Diphenhydramine: □ 25 mg PO, □ 50mg PO, □ 25 mg IVP, □ 50 mg IVP or<br>Alternate oral antihistamine to diphenhydramine:<br>□ Cetirizine 10 mg, □ Loratadine 10 mg, Fexofenadine □ 60 mg or □ 180 mg<br>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)

☐ **Induction dose:** 600 mg IV weekly for first 4 weeks followed by 900 mg IV at week (5) five

☐ **Maintenance dosing:** 900 mg IV every two (2) weeks.

**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: _____

**MRN:**_____

DOB:_____

# Guidelines for Prescribing Soliris® (eculizumab) for PNH

**(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**.

☐ 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 documented history of aplastic anemia or myelodysplastic syndrome, PNH clones by flow cytometry diagnostic test, history of thrombotic events, history of transfusion dependency, and/or other test or labs to support diagnosis.**

- **Paroxysmal Nocturnal Hemoglobinuria (PNH):** Soliris® is indicated for the treatment of patients 18 years of age and older with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

☐ Other as requested: _____

**Pre-Screening:**

☐ Documented baseline values: serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion 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.

Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center 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.