

MRN: \_\_\_\_\_

DOB: \_\_\_\_\_

## STANDARD Soliris® (eculizumab) PLAN OF TREATMENT for Myasthenia Gravis

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:

Myasthenia Gravis  **G70.00 without** acute exacerbation  **G70.01 with** acute exacerbation

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

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

Acetaminophen: <input type="checkbox"/> 650mgs PO <input type="checkbox"/> 500mgs PO <input type="checkbox"/> 325mgs PO	Diphenhydramine: <input type="checkbox"/> 25 mgs PO, <input type="checkbox"/> 50mgs PO, <input type="checkbox"/> 25 mgs IVP, <input type="checkbox"/> 50mgs IVP or Alternate oral antihistamine to diphenhydramine: <input type="checkbox"/> Cetirizine 10 mg, <input type="checkbox"/> Loratadine 10 mg, Fexofenadine <input type="checkbox"/> 60mgs or <input type="checkbox"/> 180mgs Other: _____
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\* **Prescriber must be enrolled in the Soliris (REMS) program, available at 1-888-765-4747 or at [www.solirisrems.com](http://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: 900 mg IV weekly for first 4 weeks followed by 1200 mg at week (5) five.

\_\_\_\_\_ Maintenance dosing: 1200 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 Myasthenia Gravis

(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](http://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 use and response to azathioprine, methotrexate, cyclosporine, mycophenylate, etc. Include positive serologic test for anti-AChR antibodies, any abnormal neuromuscular single-fiber electromyography (SFEMG), nerve stimulation studies, positive anticholinesterase test or other test/labs to support diagnosis.**

- Soliris® is indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who have met the following criteria: **1.** Positive serologic test for anti-AChR antibodies, **2.** Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, **3.** MG-Activities of Daily Living (MG-ADL) total score  $\geq 6$ , **4.** Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy, or failed at least (1) IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg).

\_\_\_\_ Other as requested: \_\_\_\_\_

### Pre-Screening:

\_\_\_\_ Positive serologic test for anti-AChR antibodies

\_\_\_\_ **Documented meningococcal vaccine administration of each of the following:**

- MenACWY (Menactra® or Menveo®), AND
- MenB (Bexsero® or Trumenba®)

**\*\* 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 ( $\geq 10\%$ ) 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. \*Supplemental dosing of Soliris® (eculizumab) is suggested within 60 minutes of Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusions. 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.