Palmetto Infusion Services COMPLIANCE

MRN:_____

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

DOB:_____

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

(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:

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

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:	Diphenhydramine: □ 25 mgs PO, □ 50mgs PO, □ 25 mgs IVP, □ 50mgs IVP or
□ 650mgs PO	Alternate oral antihistamine to diphenhydramine:
□ 500mgs PO	□ Cetirizine 10 mg, □ Loratadine 10 mg, Fexofenadine □ 60mgs or □ 180mgs
□ 325mgs PO	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:** 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: _____

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 6/22/18

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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.

___ 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 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 ≥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

** 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. *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.

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 6/22/18