Memorial Healthcare System

ECULIZUMAB AND BIOSIMILARS

PATIENT INFORMATION / REFERRAL STATUS

Referral Status: □ New Referral □ Updated Order □ Order Renewal **Date:** _____

Patient Name: _____ DOB: _____

ICD-10 Code: _____ ICD-10 Description/Diagnosis: _____

Allergies: □ NKDA Allergies: _____ Weight: _____ □ lbs/□ kg Height: _____

Patient Status: □ New to Therapy □ Continuing Therapy Last Treatment Date: _____ Next Due Date: _____

PROVIDER / PRACTICE INFORMATION

Ordering Provider: _____ Provider NPI: _____

Referring Practice Name: _____ Phone: _____ Fax: _____

Practice Address: _____ City: _____ State: _____ Zip: _____

Referral Coordinator Name: _____ Email: _____ Alternative Phone Number: _____

REFERRING PROVIDER COMMUNICATIONS

☐ I have reviewed the prescribing information and medication guide for Soliris/Epysqli/Bkemv (eculizumab/eculizumab-aagh,-aeeb).

- Neuromyelitis optica spectrum disorder (NMOSD). Please use Soliris (only) as biosimilars are not indicated.
- NOTE: REMS Programs: eculizumab and its biosimilars are only available through a REMS program to mitigate the risk of serious meningococcal infections.
- Prescribers must maintain enrollment in the specific REMS program required for each medication they prescribe. Biosimililar products may require separate enrollment.
- May increase the risk for susceptibility to encapsulated bacterial infections, especially infections caused by Neisseria meningitidis but also Streptococcus pneumoniae, Haemophilus influenzae, and, to a lesser extent, Neisseria gonorrhoeae.
- Please verify if patient has received meningococcal vaccine (serogroups A, C, W, Y and B) according to current ACIP recommendations at least 2 weeks prior to initiating treatment.
- If urgent initiation is indicated in patients who are not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with oral antibacterial drug prophylaxis against meningococcal infections and administer these vaccines as soon as possible. Patients should continue to take antibacterial drug prophylaxis for as long as their doctor tells them to even after vaccinations are completed.

NURSING PROTOCOL COMMUNICATIONS

☒ Provide nursing care, vital signs, monitoring according to Memorial Outpatient Procedures. Establish/maintain IV access and administer medication as ordered. Remove peripheral IV access after infusion completion if applicable. Follow infusion-related/hypersensitivity reactions management according to MHS Outpatient Adverse Reaction Protocol available for review on at mhs.net/services/pharmacy/infusion-services/outpatient-infusion.

☒ Discharge/Follow-up instructions according to Memorial Outpatient Procedures.

LABORATORY ORDERS

☐ ***Pregnancy, Urine for females of childbearing potential who have not undergone a hysterectomy****:* Once a month prior to visit

☐ ***CBC with Diff:*** ☐ Once ☐ Every ____ months

☐ ***Comprehensive Metabolic Panel:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***LDH:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Bilirubin, fractionated:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Urinalysis with reflex microscopy:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Haptoglobin:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Complement, Total (CH50)****:* ☐ Once ☐ Every Visit ☐ Every ____ months

PRE-MEDICATION ORDERS (30-60 Minutes Prior to Therapy)

□ Acetaminophen (Tylenol) 650 mg PO

□ Diphenhydramine (Benadryl) □ 25 mg □ 50 mg □ PO □ IV **OR**

□ Cetirizine (Zyrtec) or Loratadine (Claritin) 10 mg PO

□ Methylprednisolone (Solu-Medrol) □ 40 mg □ 125 mg IV **OR**

□ Dexamethasone (Decadron) □ 8 mg □ 20 mg PO

□ Other: _____ Dose: _____ Route: _____ Frequency/Timing: _____

THERAPY PLAN

Medication Name: Eculizumab/eculizumab-aagh,-aeeb (Soliris/Epysqli/Bkemv)

Dose:

Neuromyelitis optica spectrum disorder (NMOSD)

□ **Loading Dose: (Soliris)** 900 mg in 90 mL 0.9% NS weekly x 4 doses

□ **Maintenance Dose: (Soliris)** 1200 mg in 120 mL 0.9% NS ONCE on week 5 then every 2 weeks thereafter until discontinued

- **Number of Doses:** _____

Generalized Myasthenia Gravis (gMG), or Atypical Hemolytic Uremic Syndrome (aHUS)

(Not for Shiga toxin Escherichia coli-related)

□ **Loading Dose:**

□ **Soliris** 900 mg in 90 mL 0.9% NS weekly x 4 doses

□ **Bkemv** 900 mg in 90 mL 0.9% NS weekly x 4 doses

□ **Epysqli** 900 mg in 90 mL 0.9% NS weekly x 4 doses

□ **Maintenance Dose:**

□ **Soliris** 1200 mg in 120 mL 0.9% NS ONCE on week 5 then every 2 weeks thereafter until discontinued

□ **Bkemv** 1200 mg in 120 mL 0.9% NS ONCE on week 5 then every 2 weeks thereafter until discontinued

□ **Epysqli** 1200 mg in 120 mL 0.9% NS every 2 weeks thereafter until discontinued

- **Number of Doses:** _____

THERAPY PLAN (CONTINUED)

Supplemental dosing for patients receiving IVIG, fresh frozen plasma infusion, plasmapheresis or plasma exchange

☐ Soliris ☐ Bkemv ☐ Epysqli

☐ 300 mg in 30 mL 0.9% NS ☐ 600 mg in 60 mL 0.9% NS

☐ Once ☐ Other: _____

Route: ☒ IV ☐ SQ ☐ IM

Infuse over: ☐ 30 minutes ☐ 1 Hour ☐ 2 Hours ☒ Other: 35 minutes

*****Diluent/Volume/Concentration/Special tubing/Filters will be in accordance with the product package insert.*****

☒ Flush with 0.9% sodium chloride at completion per protocol or medication-specific instructions

Additional Administration Instructions:

Check for Meningococcal Vaccine(s) status prior to first infusion. Protect from light. Observe for infusion and hypersensitivity reactions during and for at least 60 minutes post infusion.

Note to Pharmacy/Comments:

_____

_____

Refills: ☐ Zero ☐ for 12 months ☐ Other:_____

(if not indicated, order will expire one year from date signed)

_____	_____	_____
Provider Name (Print)	***Provider Signature***	***Date***

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Adverse Reaction Management Protocol (Adult)

Observe patient for infusion related and hypersensitivity reactions such as fever, chills, rigors, pruritus, rash, cough, sneezing, throat irritation, nausea, vomiting.

If reaction occurs:

- Stop infusion and assess patient.
- Maintain or establish vascular access if needed
- **Administer emergency medication(s) according to symptoms:**

☒ Acetaminophen 650 mg PO once PRN headache, pain, fever >100.4F, chills or rigors.

☒ Diphenhydramine 50 mg IV once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction **OR**

☒ Diphenhydramine 50 mg IM once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction (if no IV access)

☒ Dexamethasone 10 mg IV once PRN shortness of breath or wheezing **OR**

☒ Dexamethasone 10 mg IM once PRN shortness of breath or wheezing (if no IV access)

☒ Ondansetron 4 mg IV once PRN nausea, vomiting **OR**

☒ Ondansetron 4 mg IM once PRN nausea, vomiting (if no IV access)

- May re-start therapy if appropriate when symptoms resolve. Resume infusion at 50% of the previous rate and increase per manufacturer's guidelines.

If a severe allergic/anaphylactic reaction occurs

- Symptoms are rapidly progressing or continuing after administration of PRN medications and/or signs and symptoms of severe allergic/anaphylactic reaction (angioedema, swelling of the mouth, tongue, lips, or airway, dyspnea, bronchospasm with or without hypotension or hypertension)

☒ Notify the Rapid Response / Rescue Alert Team / Blue Alert / 911.

☒ Initiate BLS/ Cardiopulmonary resuscitation if necessary.

☒ Administer Epinephrine 0.3 mg intramuscularly, every 5 MIN PRN rapidly progressing or continuing after administration of PRN medication or signs and symptoms of severe allergic/anaphylactic reaction. Administer every 5-15 minutes as needed preferably in the outer thigh.

☒ Place the patient in a recumbent position, elevate lower extremities.

☒ Continuously monitor vital signs (blood pressure, pulse oximetry, and heart rate).

☒ Contact and notify the referring provider on the day of occurrence once patient is stabilized.

☒ Document reaction in the medical record and complete an incident report once patient is stabilized.