Memorial Healthcare System

RAVULIZUMAB-CWVZ (ULTOMIRIS)

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 Ultomiris (ravulizumab-cwvz).

- **NOTE:** Ravulizumab-cwvz (ULTOMIRIS) is available only through the REMS ULTOMIRIS/SOLIRIS (https://www.ultsolrems.com) to mitigate the risk of serious meningococcal infections.
- 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. Monitor closely for signs/symptoms of worsening infection if administering ravulizumab to patients with active systemic infections.
- Vaccinate patients against meningococcal infection (serogroups A, C, W, Y and B) according to current ACIP recommendations at least 2 weeks prior to initiation of ULTOMIRIS (ravulizumab).
- If urgent ULTOMIRIS (ravulizumab) initiation is indicated in patients who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with 2 weeks of oral antibacterial drug prophylaxis and administer these vaccines as soon as possible.
- Treatment discontinuation for PNH: Monitor closely for at least 16 weeks to detect hemolysis and other reactions, e.g., elevated LDH along with sudden decrease in PNH clone size or hemoglobin, or re-appearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, shortness of breath [dyspnea], major adverse vascular event [including thrombosis], dysphagia, or erectile dysfunction).

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:*** Every visit

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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: Ravulizumab-cwvz (Ultomiris)

□ **Loading Dose (Day 1) :**

□ **[40 KG TO 59 KG]** 2400 mg in NS 0.9% 24 mL x 1 dose over 48 minutes

□ **[60 KG TO 99 KG]** 2700 mg in NS 0.9% 27 mL x 1 dose over 36 minutes

□ **[100 KG OR MORE]** 3000 mg in NS 0.9% 30 mL x 1 dose over 24 minutes

□ **Maintenance Dose (Day 14 and Every 8 Weeks thereafter):**

□ **[40 KG TO 59 KG]** 3000 mg in NS 0.9% 30 mL over 54 minutes

□ **[60 KG TO 99 KG]** 3300 mg in NS 0.9% 33 mL over 42 minutes

□ **[100 KG OR MORE]** 3600 mg in NS 0.9% 36 mL over 30 minutes

- **Number of Doses:** _____

Route: ☒ IV □ SQ □ IM

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:

Administer through a dedicated line using a 0.2 micron in-line filter. Line should be primed with drug. Observe for infusion and hypersensitivity reactions during and for at least 60 minutes post infusion. Flush with 0.9% NS after the infusion is complete.

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.