

Ravulizumab (ULTOMIRIS)

Infusion Therapy Plan Orders

Page 1 of 4

Name: _____
Kaiser Permanente Member I.D. # _____
Date of Birth _____

Instructions to Provider

Review orders and note any changes. All orders with will be placed unless otherwise noted. Please fax completed order form to the infusion center where the patient will be receiving treatment (see fax numbers at the end of this protocol). Lab orders are not included on this form – place orders via usual method. Lab monitoring is the responsibility of the ordering physician.

Please complete all of the following:

<input type="checkbox"/> Pre-Service Authorization has been obtained by Kaiser Permanente Fax: 1-888-282-2685 Voice: 1-800-289-1363	
Order Date: _____ Weight: _____ kg	Diagnosis: ICD-10 code (<i>REQUIRED</i>): _____ ICD-10 description _____

General Plan Communication

- This protocol defaults administration in an adult patient with weight greater than or equal to 40 kg. For weights less than 40 kg, drug dose and possibly dosing interval will need to be modified.

Provider Information

~ The following vaccination schedule is based on the administration of the preferred products, Menveo, Men ACWY quadrivalent conjugate, Bexsero, and serogroup Men B.

~ Ideally, complete or update meningococcal vaccination at least 2 weeks prior to administering first dose of complement inhibitor; however, patients can initiate complement inhibitor therapy before meningococcal vaccination has been completed if benefit outweighs risks.

~ For serogroup MenB (Bexero), patients will receive 3 injections as part of the initial series. Immunize with second dose of serogroup MenB (Bexero) 1 to 2 months after the initial dose, and administer third dose of serogroup MenB (Bexero) 6 months after the initial dose. For MenACWY-CRM (Menveo), patients will receive 2 injections as part of the initial series. Immunize with second dose of MenACWY-CRM (Menveo) 2 or more months after initial dose.

~ If treatment is ongoing BOOSTER doses are required while risk remains:

- Bexsero (Men B): 1 year post initial vaccination, followed by every 2-3 years.
- Menveo (Men ACWY): Every 5 years

~ If other vaccine products are used, please refer to package insert AND CDC recommendations for patients receiving complement inhibitors for specific vaccination schedule(s).

~ Recommend antibiotic prophylaxis in consultation with infectious disease specialist to further reduce the risk of invasive meningococcal disease.

~ Ravulizumab treatment of aHUS should be a minimum duration of 6 months. Due to heterogeneous nature of aHUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized.

~ aHUS: after discontinuing treatment, closely monitor for at least 16 weeks to detect hemolysis and other reactions.

~ PNH: After ravulizumab discontinuation for PNH, monitor LDH for at least 16 weeks.

~ Ravulizumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

~ Each region must assure that their prescribers are enrolled via <https://ultomirisrems.com/> Telephone: 1-888-765-4747.

~ Verify patient meets criteria for REMs program.

Provider Signature: _____ **Date:** _____

Printed Name: _____ **Phone:** _____ **Fax:** _____

Ravulizumab (ULTOMIRIS)

Name: _____
Kaiser Permanente Member I.D. # _____
Date of Birth _____

Infusion Therapy Plan Orders

Page 2 of 4

Premedications

- No default premedications

Dose Guidance

Please choose dosing from Advanced Order Group (AOG) based on patient's **weight**.

Note: Orders default to 1 hour infusion time.

- 40 - 59.9 kg: Ravulizumab (2400 mg Loading Dose) then Ravulizumab (3,000 mg Maintenance Dose)
 60 - 99.9 kg: Ravulizumab (2700 mg Loading Dose) then Ravulizumab (3,300 mg Maintenance Dose)
 100 kg or greater: Ravulizumab (3000 mg Loading Dose) then Ravulizumab (3,600 mg Maintenance Dose)

Infusion Therapy

Loading dose: Orders default to maximum infusion rate per labeling.

- 40 – 59.9 kg:** Ravulizumab-cwvz (ULTOMIRIS) 2,400 mg [**loading**] in 0.9% sodium chloride 48 mL (50 mg/mL) IVPB. Infuse at 64 mL/hr.
- 60 – 99.9 kg:** Ravulizumab-cwvz (ULTOMIRIS) 2,700 mg [**loading**] in 0.9% sodium chloride 54 mL (50 mg/mL) IVPB. Infuse at 92 mL/hr.
- 100 kg or greater:** Ravulizumab-cwvz (ULTOMIRIS) 3,000 mg [**loading**] in 0.9% sodium chloride 60 mL (50 mg/mL) IVPB. Infuse at 144 mL/hr.

Route: Intravenous

Frequency: Once

Maintenance dose (Due 14 days after Loading dose, then Q56 days):

Orders default to maximum infusion rate per labeling.

- 40 – 59.9 kg:** Ravulizumab-cwvz (ULTOMIRIS) 3,000 mg [**maintenance**] in 0.9% sodium chloride 60 mL (50 mg/mL) IVPB. Infuse at 65 mL/hr.
- 60 – 99.9 kg:** Ravulizumab-cwvz (ULTOMIRIS) 3,300 mg [**maintenance**] in 0.9% sodium chloride 66 mL (50 mg/mL) IVPB. Infuse at 99 mL/hr.
- 100 kg or greater:** Ravulizumab-cwvz (ULTOMIRIS) 3,600 mg [**maintenance**] in 0.9% sodium chloride 72 mL (50 mg/mL) IVPB. Infuse at 144 mL/hr.

Route: Intravenous

Frequency: Q56 days

IV Line Care

- 0.9% sodium chloride infusion 250 mL
Rate: 30 mL/hr Route: Intravenous Frequency: Run continuously to keep vein open
 Start peripheral IV if no central line

Infusion Reaction Meds

- Acetaminophen (TYLENOL) 325 mg tab. Take 2 tablets PO every 4 hours PRN for fever (greater than 100.4 F), myalgias, arthralgias or headache.
- Alteplase (CATHFLO ACTIVASE) Inj 2 mg INTRACATHETER PRN x 2 doses. Instill 2 mg to affected port(s) of central venous catheter if sluggish or occluded. Allow to dwell for 30 minutes, if unable to aspirate blood allow to dwell for an additional 90 minutes. May repeat one time if unsuccessful.
- diphenhydrAMINE (BENADRYL) 50 mg injection. Give IV push over 2 minutes one time, if needed for hives, rash, itching, flushing, and/or swelling in a suspected hypersensitivity reaction. Notify provider if patient experiences a hypersensitivity reaction.

Provider Signature: _____ **Date:** _____

Printed Name: _____ **Phone:** _____ **Fax:** _____

Ravulizumab (ULTOMIRIS)

Name: _____
Kaiser Permanente Member I.D. # _____
Date of Birth _____

Infusion Therapy Plan Orders

Page 3 of 4

- Famotidine (PEPCID) (PF) Inj 20 mg. Give IV push over 2 minutes for hives, rash, itching, flushing, and/or swelling in a suspected hypersensitivity reaction. Give immediately after diphenhydrAMINE. Notify provider if patient experiences a hypersensitivity reaction.
- methylPREDNISolone Sod Succ (PF) Inj 125 mg (SOLU-Medrol PF). Give 125 mg IV push one time PRN for shortness of breath, bronchospasm, or other symptoms of a suspected hypersensitivity reaction not otherwise specified. Notify provider if patient experiences a hypersensitivity reaction.
- Sodium Chloride 0.9% IV bolus 1,000 mL. Give IV over 1 hour one time PRN for hypotension due to presumed anaphylaxis. Notify provider if patient experiences a hypersensitivity reaction.
- EPINEPHrine 0.3 mg/0.3 mL IM Auto-injector. Give IM one time PRN for severe cardiovascular or respiratory symptoms (e.g., dyspnea, wheeze/bronchospasm, stridor, hypoxemia) of a suspected hypersensitivity reaction. Provider must be present upon giving medication. Va

Lab Review for Nursing

Baseline Labs (one time draw, prior to first cycle): CBC, SCr, LDH, Hep-B sAg, Hep-B cAb

**** Intermittent Labs:**

aHUS: After ravulizumab discontinuation for aHUS, monitor CBC, SCr, LDH for at least 12 months

PNH: After ravulizumab discontinuation for PNH, monitor LDH for at least 16 weeks

Additional treatment evaluations

- ~ Immunize with first dose of Bexsero (Men B) AND Menveo (Men ACWY) vaccines at least two weeks prior to beginning therapy unless risk of treatment delay outweighs risk of developing meningococcal disease.
- ~ Immunize with second dose of Bexsero (Men B) at 1 month or more AND Menveo (Men ACWY) at 2 or more months after first dose.
- ~ If treatment is ongoing BOOSTER doses are required while risk remains:
 - Bexsero (Men B): 1 year post initial vaccination, followed by every 2-3 years.
 - Menveo (Men ACWY): Every 5 years
- ~ If other vaccine products are used, please refer to package insert for specific vaccination schedule.

Nursing Orders

RAVULIZUMAB

- ~ Immunize with first dose of Bexsero (Men B) AND Menveo (Men ACWY) vaccines at least two weeks prior to beginning therapy unless risk of treatment delay outweighs risk of developing meningococcal disease.
- ~ Immunize with second dose of Bexsero (Men B) at 1 month or more AND Menveo (Men ACWY) at 2 or more months after first dose.
- ~ If treatment is ongoing BOOSTER doses are required while risk remains:
 - Bexsero (Men B): 1 year post initial vaccination, followed by every 2-3 years.
 - Menveo (Men ACWY): Every 5 years
- ~ If other vaccine products are used, please refer to package insert for specific vaccination schedule.
- ~ Administer ravulizumab through in-line filter.
- ~ Observe patient for 1 hour following initial infusion and for subsequent infusions in patients with a history of reaction.
- ~ Infusion Reaction: STOP infusion immediately; begin primary solution at wide open rate, notify MD, begin monitoring vital signs, and administer prn medication for infusion reaction; once symptoms have resolved, consult with pharmacy or MD on rate to resume infusion. Complete Chemotherapy/Medication Reaction Documentation Flowsheet.
- # Ensure that patient knows to contact healthcare provider if experiencing any signs and symptoms of meningitis (i.e., headache with either fever, nausea and vomiting, or stiff neck/back, sensitivity to light).

Provider Signature: _____ **Date:** _____

Printed Name: _____ **Phone:** _____ **Fax:** _____

Ravulizumab (ULTOMIRIS)

Infusion Therapy Plan Orders

Page 4 of 4

Name: _____
Kaiser Permanente Member I.D. # _____
Date of Birth _____

References

[Ultomiris Package insert](#)

Kaiser Permanente Infusion Locations

Please refer to the link below for the current list:

<https://wa-provider.kaiserpermanente.org/patient-services/ambulatory-infusion>

Provider Signature: _____ Date: _____

Printed Name: _____ Phone: _____ Fax: _____