

# Ravulizumab-cwvz (Ultomiris) Loading Followed by Maintenance Every 8 weeks

Ravulizumab-cwvz (Ultomiris) weight defined loading dose followed by maintenance every 8 weeks

## Protocol Types

Infusion Treatment 1, Infusion Treatment 2, Infusion Treatment 3, Infusion Treatment 4

Patient name: \_\_\_\_\_ DOB: \_\_\_\_\_

Please include: ☐ Patient face sheet ☐ Insurance authorization (if other than Medicaid or non-Advantage Medicare)

Diagnosis: \_\_\_\_\_

Review: Every 180 days

## Orders

|  | Interval | Defer Until | Duration |
|--|----------|-------------|----------|
|--|----------|-------------|----------|

### Provider Communication

|                                                            |             |                    |
|------------------------------------------------------------|-------------|--------------------|
| <input checked="" type="checkbox"/> Provider communication | Every visit | Until discontinued |
|------------------------------------------------------------|-------------|--------------------|

Until discontinued Starting when released Until Specified

Ravulizumab is part of FDA REMS Program. Providers MUST be enrolled in the ULTIMORIS REMS program and provide enrollment ID to proceed with infusion. Provide patient with both the Patient Safety Brochure and Patient Safety Card. Patient should carry the card with them at all times.

Immunize patients against meningococcal infection (serogroups A, C, W, Y, and B) according to current ACIP recommendations at least 2 weeks prior to initiation of ravulizumab. Meningococcal serogroups A, C, W, Y vaccine (MenACWY) -Menveo, Menactra, or MenQuadfi. These require booster shots every 5 years. Meningococcal serogroup B vaccine -Bexsero or Trumenba. These require booster shots 1 year after primary series and every 2 to 3 years thereafter. Prescriber must update the status of the patient's meningococcal vaccination, indication, and antibacterial drug prophylaxis into the ultsorems.com online portal.

At the time of first infusion, patient should have started antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least 2 weeks prior to the first dose of ravulizumab.

Administer vaccinations for the prevention of Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) infections according to ACIP recommendations.

### Labs

|                                                          |             |                    |
|----------------------------------------------------------|-------------|--------------------|
| <input checked="" type="checkbox"/> CBC and differential | Every visit | Until discontinued |
|----------------------------------------------------------|-------------|--------------------|

Status: Once, Expected: S, Clinic Collect, Blood, Venous, Blood, AH INTERNAL LAB (BEAKER), Routine

|                                                                   |             |                    |
|-------------------------------------------------------------------|-------------|--------------------|
| <input checked="" type="checkbox"/> Comprehensive metabolic panel | Every visit | Until discontinued |
|-------------------------------------------------------------------|-------------|--------------------|

Status: Once, Expected: S, Clinic Collect, Blood, Venous, Blood, AH INTERNAL LAB (BEAKER), Routine

|                                                           |             |                    |
|-----------------------------------------------------------|-------------|--------------------|
| <input checked="" type="checkbox"/> Lactate dehydrogenase | Every visit | Until discontinued |
|-----------------------------------------------------------|-------------|--------------------|

Status: Once, Expected: S, Clinic Collect, Blood, Venous, Blood, AH INTERNAL LAB (BEAKER), Routine

### Nursing Orders

|                                                          |             |                    |
|----------------------------------------------------------|-------------|--------------------|
| <input checked="" type="checkbox"/> Treatment conditions | Every visit | Until discontinued |
|----------------------------------------------------------|-------------|--------------------|

Until discontinued Starting when released Until Specified

Hold treatment and notify provider if patient is not up to date on meningococcal vaccination every 5 years for

|                                                                                                                                                                                                                             | Interval    | Defer Until | Duration           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|--------------------|
| MenACWY (Menveo, Menactra, or MenQuadfi) or 1 year after primary series and every 2 to 3 years thereafter for MenB (either Bexsero or Trumenba).                                                                            |             |             |                    |
| <input checked="" type="checkbox"/> Treatment conditions                                                                                                                                                                    | Every visit |             | Until discontinued |
| Until discontinued Starting when released Until Specified<br>Hold treatment and contact provider if patient has signs and symptoms of infection (fever, skin infection, need for antibiotics etc).                          |             |             |                    |
| <input checked="" type="checkbox"/> Nursing communication                                                                                                                                                                   | Every visit |             | Until discontinued |
| Until discontinued Starting when released Until Specified<br>VITAL SIGNS - Monitor and record vital signs, tolerance, and presence of infusion-related reactions prior to infusion and every 15 minutes throughout infusion |             |             |                    |
| <input checked="" type="checkbox"/> Nursing communication                                                                                                                                                                   | Every visit |             | Until discontinued |
| Until discontinued Starting when released Until Specified<br>Following infusion, monitor patient for signs and symptoms of reaction for 60 minutes.                                                                         |             |             |                    |

### Therapeutic Medications

|                                                                                                                                                                                                                                                                                                                                              |               |      |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------|--------------------|
| <input checked="" type="checkbox"/> ravulizumab (Ultomiris) infusion                                                                                                                                                                                                                                                                         | Once          |      | 1 treatment        |
| intravenous, Once, Starting when released<br>Patient weight 40 to LESS THAN 60 kg: 2400 mg in 48 mL. Infuse at a maximum rate of 60 mL/hr<br>Patient weight 60 to LESS THAN 100 kg: 2700 mg in 54 mL. Infuse at a maximum rate of 90 mL/hr<br>Patient weight GREATER THAN 100 kg: 3000 mg in 60 mL. Infuse at a maximum rate of 150 mL/hr    |               |      |                    |
| <input checked="" type="checkbox"/> ravulizumab (Ultomiris) infusion                                                                                                                                                                                                                                                                         | Every 56 days | S+14 | Until discontinued |
| intravenous, Once, Starting when released<br>Patient weight 40 to LESS THAN 60 kg: 3000 mg in 60 mL. Infuse at a maximum rate of 67 mL/hr.<br>Patient weight 60 to LESS THAN 100 kg: 3300 mg in 66 mL. Infuse at a maximum rate of 95 mL/hr.<br>Patient weight GREATER THAN 100 kg: 3600 mg in 72 mL. Infuse at a maximum rate of 144 mL/hr. |               |      |                    |

### Emergency Medications

|                                                                                                                                                                                                                                                                                                   |     |  |                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|--|--------------------|
| <input checked="" type="checkbox"/> Nursing communication                                                                                                                                                                                                                                         | PRN |  | Until discontinued |
| STAT, Until discontinued Starting when released Until Specified<br>If hypersensitivity reaction occurs, stop infusion IMMEDIATELY and CALL provider.                                                                                                                                              |     |  |                    |
| <input checked="" type="checkbox"/> Vital Signs                                                                                                                                                                                                                                                   | PRN |  | Until discontinued |
| STAT, Every 15 min Starting when released<br>If a hypersensitivity reaction occurs, perform vital signs every 15 minutes for one hour, then every 30 minutes for 2 hours.                                                                                                                         |     |  |                    |
| <input checked="" type="checkbox"/> Nursing communication                                                                                                                                                                                                                                         | PRN |  | Until discontinued |
| Once Starting when released<br>If hypersensitivity reaction occurs:<br>- Elevate head of bed 30 degrees and place patient's head at 30 degree angle if possible<br>- Start 2 liters oxygen per nasal cannula and maintain airway<br>- Change and maintain IV line with 1000 mL 0.9% Normal Saline |     |  |                    |
| <input checked="" type="checkbox"/> sodium chloride 0.9 % infusion                                                                                                                                                                                                                                | PRN |  | Until discontinued |
| 30 mL/hr, intravenous, Continuous PRN, KVO, Starting when released, for 1 day                                                                                                                                                                                                                     |     |  |                    |
| <input checked="" type="checkbox"/> albuterol 2.5 mg /3 mL (0.083 %) nebulizer solution 2.5 mg                                                                                                                                                                                                    | PRN |  | Until discontinued |
| 2.5 mg, nebulization, Every 4 hours PRN, Hypersensitivity reaction, Starting when released, for 1 day                                                                                                                                                                                             |     |  |                    |
| <input checked="" type="checkbox"/> albuterol HFA 90 mcg/act inhaler 2 puff                                                                                                                                                                                                                       | PRN |  | Until discontinued |
| 2 puff, inhalation, Every 4 hours PRN, Hypersensitivity reaction, Starting when released, for 1 day<br>SHAKE WELL                                                                                                                                                                                 |     |  |                    |
| <input checked="" type="checkbox"/> acetaminophen (Tylenol) tablet 650 mg                                                                                                                                                                                                                         | PRN |  | Until discontinued |
| 650 mg, oral, Once as needed, fever, GREATER THAN or EQUAL TO 38 C, Starting when released, for 1 dose<br>For mild/moderate reaction: flushing, rash, pruritus                                                                                                                                    |     |  |                    |
| <input checked="" type="checkbox"/> diphenhydramine (BENADryl) injection 25 mg                                                                                                                                                                                                                    | PRN |  | Until discontinued |

|                                                                                                                                                                                                                                                                             | Interval | Defer Until | Duration           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------|--------------------|
| 25 mg, intravenous, Administer over: 2 Minutes, Once as needed, Hypersensitivity reaction, Starting when released, for 1 dose<br>For mild/moderate reaction: flushing, rash, pruritus                                                                                       |          |             |                    |
| <input checked="" type="checkbox"/> diphenhydrAMINE (BENADryl) injection 50 mg                                                                                                                                                                                              | PRN      |             | Until discontinued |
| 50 mg, intravenous, Administer over: 2 Minutes, Once as needed, Hypersensitivity reaction, Starting when released, for 1 dose<br>For severe reaction: respiratory distress, stridor, wheezing, hypotension (SBP LESS THAN 100 mm Hg)                                        |          |             |                    |
| <input checked="" type="checkbox"/> hydrocortisone sodium succinate (Solu-CORTEF) injection 100 mg                                                                                                                                                                          | PRN      |             | Until discontinued |
| 100 mg, intravenous, Once as needed, Hypersensitivity reaction, Starting when released, for 1 dose<br>For mild/moderate reaction: flushing, rash, pruritus<br>- OR -<br>For severe reaction: respiratory distress, stridor, wheezing, hypotension (SBP LESS THAN 100 mm Hg) |          |             |                    |
| <input checked="" type="checkbox"/> EPINEPHrine (EpiPen;Adrenalin) injection solution 0.3 mg                                                                                                                                                                                | PRN      |             | Until discontinued |
| 0.3 mg, intramuscular, Once as needed, Hypersensitivity reaction, Starting when released, for 1 dose<br>For severe reaction: respiratory distress, stridor, wheezing, hypotension (SBP LESS THAN 100 mm Hg)                                                                 |          |             |                    |

### Appointment Requests

|                                                                                                                                               |               |      |                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------|------|--------------------|
| <input checked="" type="checkbox"/> Infusion Appointment Request                                                                              | Once          |      | 1 treatment        |
| Status: Once, Expected: S, Sched. Duration: 120 minutes, Sched. Tolerance: Schedule appointment at most 3 days before or at most 3 days after |               |      |                    |
| <input checked="" type="checkbox"/> Infusion Appointment Request                                                                              | Every 56 days | S+14 | Until discontinued |
| Status: Once, Expected: S, Sched. Duration: 120 minutes, Sched. Tolerance: Schedule appointment at most 3 days before or at most 3 days after |               |      |                    |

\*Provider signature

Provider printed name

\*Date

Time

\*Provider phone#

**\*Denotes field that must be completed by healthcare worker**