MADISON NEUROLOGY LLC

608 403 0000

Neurology Care 7 days a Week. Because Your Brain Matters.

Ultomiris®

Ravulizumab-cwvz

COMPLETE CLINICAL PROTOCOL: PRE-TREATMENT CHECKLIST • ORDER SET • FOLLOW-UP • HOLD/DISCONTINUE CRITERIA

GENERIC NAME	ravulizumab-cwvz
BRAND	ULTOMIRIS®
MEDICATION CLASS	Long-acting complement C5 inhibitor monoclonal antibody
PRESENTATION	300 mg/30 mL (10 mg/mL); 1,100 mg/11 mL (100 mg/mL) vials — dose by weight band
ROUTE	IV infusion; duration by dose (approximately 45 minutes–2.5 hours)
US INDICATION (FDA)	NMOSD in adults who are anti-AQP4 antibody positive; gMG in adults who are anti-AChR antibody positive; also PNH and aHUS.

Class context.
Every-8-week maintenance roughly quarters the annual infusion burden versus every-2-week eculizumab — the main practical differentiator. The boxed meningococcal warning is identical.

REMS-restricted program.
Available only through the Ultomiris REMS — the same meningococcal framework as eculizumab: prescriber enrollment, patient counseling, Patient Safety Card, and vaccination/antibiotic-prophylaxis verification before the first dose.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ Meningococcal vaccination: MenACWY + MenB REQUIRED ≥2 weeks before the first dose, or antibiotic prophylaxis bridging if urgent.

☐ Document antibody status (AQP4-IgG or AChR-Ab) confirming the labeled population.

☐ Document ACTUAL BODY WEIGHT — dosing is weight-banded; re-weigh at intervals (band changes alter the dose).

☐ Baseline disease severity (EDSS / MG-ADL); infection review; pregnancy test when relevant.

B. Vaccinations

☐ MenACWY and MenB per ACIP for complement-inhibitor recipients, including ongoing boosters for the duration of therapy.

☐ Antibiotic prophylaxis bridging when dosing precedes the 2-week post-vaccination window.

C. Clinical assessments & counseling

☐ Meningococcal counseling + safety card (as for eculizumab).

☐ If switching from eculizumab: document the last eculizumab date — the ravulizumab loading dose is timed from it.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
Unresolved serious meningococcal infection	Labeled contraindication.
Unvaccinated without a documented prophylaxis plan	REMS-gated.
Active serious systemic infection	Defer until resolved.

Section 2 — Order Set

Premedication

☐ None required by label; premedicate per institutional practice after prior reactions.

Dosing schedule

Loading — 40 to <60 kg	2,400 mg IV once.
Loading — 60 to <100 kg	2,700 mg IV once.
Loading — ≥100 kg	3,000 mg IV once.
Maintenance — 40 to <60 kg	3,000 mg IV every 8 weeks, starting 2 weeks after the loading dose.
Maintenance — 60 to <100 kg	3,300 mg IV every 8 weeks, starting 2 weeks after the loading dose.
Maintenance — ≥100 kg	3,600 mg IV every 8 weeks, starting 2 weeks after the loading dose.
Switching from eculizumab	Give the ravulizumab LOADING dose 2 weeks after the last eculizumab dose, then maintenance every 8 weeks.
Observation	Monitor during and for at least 1 hour after each infusion.

Standing orders — every infusion

☐ Verify weight band before each preparation; verify meningococcal booster currency at each visit.

☐ Infection screen every dose; suspected meningococcal infection → empiric emergency treatment.

Missed or delayed dose

Give a missed dose as soon as possible and resume the every-8-week interval from that administration; avoid gaps (NMOSD rebound risk).

Contraception & pregnancy

Limited pregnancy data; individualized discussion.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Meningococcal surveillance	Entire treatment + months after	Febrile illness → emergency evaluation.
Weight review	At least annually	Crossed a band threshold → adjust dose.
Disease severity (EDSS / MG-ADL)	Every 3–6 months	Continuation documentation.
Post-discontinuation relapse watch (NMOSD)	Closely for ≥12 weeks	Rebound risk requires a transition plan before any stop.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Active serious infection	Hold until resolved.
Suspected meningococcal infection	Emergency treatment first; dosing decisions after.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Confirmed meningococcal infection	Specialist decision on any future complement blockade.
Anaphylaxis or serious hypersensitivity	Discontinue.

Section 5 — Notes & Practical Points

☐ Same boxed meningococcal warning as eculizumab; vaccination reduces but does not eliminate risk.

☐ Weight-based dosing means the pharmacy check is weight-band verification, not a fixed dose — build the weight check into the order-set workflow.

Prepared November 2026 by Madison Neurology LLC.

This document is an educational compilation and does not reproduce the complete prescribing information. Verify every element against the current FDA label and applicable REMS requirements before clinical use.

- Current U.S. prescribing information via NIH DailyMed — https://dailymed.nlm.nih.gov/dailymed/
- FDA Drugs@FDA database — https://www.accessdata.fda.gov/scripts/cder/daf/
- FDA drug safety and availability updates — https://www.fda.gov/drugs/drug-safety-and-availability

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Questions about infusion referrals: call 608 403 0000. Neurology Care 7 days a Week. Because Your Brain Matters.