MADISON NEUROLOGY LLC

608 403 0000

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

Soliris®

Eculizumab

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

GENERIC NAME	eculizumab
BRAND	SOLIRIS®
MEDICATION CLASS	Complement C5 inhibitor monoclonal antibody
PRESENTATION	300 mg/30 mL (10 mg/mL) single-dose vial — dilute to 120 mL in 0.9% NaCl / LR / D5W
ROUTE	IV infusion over 35 minutes in adults (25–45 minute labeled range)
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.
Boxed warning: life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors — including in VACCINATED patients. Vaccination reduces but does not eliminate risk; any febrile illness on this drug is a same-day emergency evaluation.

REMS-restricted program.
Available only through the Soliris REMS. Prescribers must enroll, counsel every patient on meningococcal risk, provide the Patient Safety Card (patients must carry it at all times during and for 3 months after treatment), and verify vaccination status or antibiotic prophylaxis before the first dose.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ Meningococcal vaccination — BOTH MenACWY (quadrivalent conjugate) and MenB series REQUIRED, completed ≥2 weeks BEFORE the first dose. If urgent dosing precedes the 2-week window: antibacterial prophylaxis until ≥2 weeks after vaccination.

- ☐ Document the antibody confirming the labeled population: AQP4-IgG for NMOSD; AChR-Ab for gMG.
- ☐ Baseline disease severity measure (EDSS for NMOSD; MG-ADL for gMG).
- ☐ CBC baseline; active-infection review.
- ☐ Pregnancy test when relevant.

B. Vaccinations

- ☐ MenACWY and MenB: complete per the current ACIP schedule for complement-inhibitor recipients; BOOSTERS continue per ACIP for the entire duration of therapy.
- ☐ Antibiotic prophylaxis bridging if dosing cannot wait for the 2-week vaccine window.
- ☐ Routine adult vaccines per schedule; complement blockade may reduce vaccine effectiveness — time them before dosing when feasible.

C. Clinical assessments & counseling

- ☐ Meningococcal-risk counseling with the safety card: fever PLUS headache, stiff neck, photophobia, confusion, or rash = emergency department NOW, and the card comes with them.
- ☐ Baseline brain/spine MRI (NMOSD) and attack history documentation.
- ☐ Confirm the center's after-hours pathway for febrile patients on C5 inhibitors.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
Unresolved serious meningococcal infection	Labeled contraindication.
Not currently vaccinated against meningococcus (unless deferral risk exceeds infection risk + prophylaxis given)	REMS-gated; do not infuse without the vaccination/prophylaxis plan documented.
Active serious systemic infection	Defer until resolved.
Hypersensitivity to eculizumab	Do not administer.

Section 2 — Order Set

Premedication

- ☐ None required by label; premedicate per institutional practice after a prior mild infusion reaction.

Dosing schedule

Induction	900 mg IV weekly × 4 doses (each over 35 minutes).
Fifth dose	1,200 mg IV 1 week after the fourth dose.
Maintenance	1,200 mg IV every 2 weeks thereafter.
Observation	Monitor during and for at least 1 hour after each infusion for hypersensitivity/infusion reactions.

Standing orders — every infusion

- ☐ Verify meningococcal booster currency at every visit (REMS documentation).
- ☐ Infection screen before every dose; suspected meningococcal infection → treat empirically WITHOUT waiting for confirmation.
- ☐ Vital signs baseline, during, and completion.

Missed or delayed dose

Administer a missed dose as soon as possible and resume the every-2-week schedule. Avoid extended gaps: in NMOSD, attack risk returns when C5 blockade lapses.

Contraception & pregnancy

Limited pregnancy data; discuss planning individually.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Meningococcal infection surveillance	Continuous — entire treatment and for months after discontinuation	Any febrile illness → emergency evaluation; educate at every dose.
Meningococcal booster status	Per ACIP schedule throughout therapy	Overdue booster → schedule before/with next dose.
NMOSD relapse surveillance after any discontinuation	Closely for at least 12 weeks	Rebound attacks can be severe; a transition plan must exist before stopping.
Disease severity (EDSS / MG-ADL)	Every 3–6 months	Document response for continuation reviews.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Active serious infection	Hold until resolved; suspected meningococcemia is an emergency, not a scheduling issue.
Meningococcal booster overdue	Coordinate catch-up; do not let vaccination lapse on a C5 inhibitor.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Confirmed meningococcal infection	Manage per infectious disease; resumption of complement blockade is a specialist decision.

Anaphylaxis or serious hypersensitivity to eculizumab	Discontinue.
Planned switch to ravulizumab or another mechanism	Execute the switch deliberately (see ravulizumab protocol for the 2-week transition rule).

Section 5 — Notes & Practical Points

- ☐ The meningococcal safety card is not paperwork — patients on C5 inhibitors should present it at any urgent-care or ED visit for the entire treatment period plus 3 months.
- ☐ In NMOSD, never stop complement inhibition without a same-day alternative plan; rebound attacks within weeks of interruption are well documented.

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.