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MADISON NEUROLOGY LLC

608 403 0000

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

Uplizna®

Inebilizumab-cdon

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

GENERIC NAME	inebilizumab-cdon
BRAND	UPLIZNA®
MEDICATION CLASS	Anti-CD19 monoclonal antibody (B-cell depleting)
PRESENTATION	100 mg/10 mL (10 mg/mL) single-dose vial — dilute to 250 mL in 0.9% NaCl
ROUTE	IV infusion only; never IV push or bolus
US INDICATION (FDA)	NMOSD in adults who are anti-AQP4 antibody positive.

Class context.
Anti-CD19 depletes a broader B-cell lineage (including plasmablasts and some plasma cells) than anti-CD20 agents — expect a slow immunoglobulin drift downward over years and monitor it, particularly with recurrent infections.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

- ☐ HBV panel (HBsAg and anti-HBc) — REQUIRED; do NOT start with active HBV. Carriers: hepatology review and monitoring during and after treatment.
- ☐ TB screening (IGRA) — REQUIRED; treat latent TB BEFORE the first dose.
- ☐ Quantitative serum immunoglobulins — baseline REQUIRED; low baseline → immunology review before starting.
- ☐ CBC with differential — baseline; neutropenia and lymphopenia are expected pharmacology.
- ☐ Pregnancy test for females of reproductive potential.
- ☐ Confirm AQP4-IgG seropositivity documents the labeled population.

B. Vaccinations

- ☐ Live or live-attenuated vaccines: NOT recommended during treatment; complete ≥4 weeks before the first dose.
- ☐ Non-live vaccines: complete ≥2 weeks before the first dose when possible; blunted responses expected under depletion.
- ☐ Infants exposed in utero: defer live vaccines until the infant's B-cell recovery is confirmed.

C. Clinical assessments & counseling

- ☐ Baseline brain and spinal-cord MRI; document attack history and EDSS.
- ☐ Active-infection screen before every dose.
- ☐ Counseling: infusion reactions, infection signs, vaccination limits, contraception requirement.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
Active HBV infection	Labeled contraindication.
Active or untreated latent TB	Treat latent TB first; do not dose into active TB.
Active serious infection	Defer until resolved.
Life-threatening prior infusion reaction to inebilizumab	Labeled contraindication.

Section 2 — Order Set

Premedication

- ☐ Methylprednisolone 100 mg IV (or equivalent corticosteroid) ~30 minutes before each infusion.
- ☐ Antihistamine (e.g., diphenhydramine 25–50 mg) ~30–60 minutes before each infusion.
- ☐ Antipyretic (e.g., acetaminophen 650 mg) before each infusion.

Dosing schedule

First infusion	300 mg IV (diluted to 250 mL) with gradual rate escalation per label.
Second infusion	300 mg IV 2 weeks after the first dose.
Maintenance	300 mg IV every 6 months, starting 6 months after the first dose.
Observation	Monitor during the infusion and for at least 1 hour after completion.
Infusion-reaction management	Interrupt and manage by severity; resume at a reduced rate for mild–moderate reactions.

Standing orders — every infusion

- ☐ Infection screen and premedication verification before every dose.

☐ Pregnancy test before each dose for females of reproductive potential.

Missed or delayed dose

Give a missed maintenance dose as soon as possible and resume every-6-month dosing from that administration.

Contraception & pregnancy

Effective contraception during treatment and for 6 months after the last dose.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Quantitative immunoglobulins	Periodically during treatment; after discontinuation until B-cell repletion	Declining IgG + recurrent/serious infections → immunology review.
CBC with differential	Periodically	Neutropenia → hold and evaluate per severity.
Infection screen	Before every dose	Hold for active infection.
HBV / TB vigilance	Clinical review each cycle	Reactivation signs → hold and treat.
MRI brain/spine	Per NMOSD monitoring plan	New lesion activity → reassess mechanism.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Active infection	Hold until resolved.
Significant hypogammaglobulinemia with recurrent infections	Delay; immunology review.
Grade ≥3 infusion reaction	Hold pending evaluation.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Life-threatening infusion reaction	Discontinue permanently.
HBV reactivation or TB reactivation	Discontinue; specialist treatment.
PML or other serious opportunistic infection	Discontinue (class-level vigilance).

Section 5 — Notes & Practical Points

☐ No meningococcal vaccination requirement (unlike C5 inhibitors) and no REMS — the operational burden is materially lower than Soliris/Ultomiris for NMOSD.

☐ Immunoglobulin monitoring is the long game: schedule it on the calendar, not on symptoms.

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.