MADISON NEUROLOGY LLC

608 403 0000

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

Briumvi®

Ublituximab-xiiy

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

GENERIC NAME	ublituximab-xiiy
BRAND	BRIUMVI®
MEDICATION CLASS	Anti-CD20 monoclonal antibody (cytolytic)
PRESENTATION	150 mg/6 mL (25 mg/mL) single-dose vial — dilute in 0.9% sodium chloride to 250 mL
ROUTE	IV infusion only; never IV push or bolus
US INDICATION (FDA)	Relapsing forms of MS (RMS) in adults — clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Class context.
Structurally distinct anti-CD20 with a shorter maintenance infusion (~1 hour) than ocrelizumab (~2 hours) — the practical differentiator for infusion-suite scheduling. No PPMS indication.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ HBV panel: HBsAg, anti-HBc, anti-HBs — REQUIRED before the first dose. Contraindicated with active HBV (HBsAg-positive). Anti-HBc-positive carriers: hepatology consult before and during treatment; consider antiviral prophylaxis per local HBV guidance.

☐ Quantitative serum immunoglobulins (IgG, IgA, IgM) — REQUIRED before the first dose; consult immunology if low. Continue monitoring after discontinuation until B-cell repletion when low.

☐ Liver function tests: ALT, AST, alkaline phosphatase, total bilirubin — baseline REQUIRED (anti-CD20 class postmarketing signal: drug-induced liver injury with marked enzyme elevation ± hyperbilirubinemia, weeks to months after dosing).

- ☐ CBC with differential; creatinine/BMP — baseline per institutional practice.
- ☐ Pregnancy test (hCG) for all females of reproductive potential — must be negative.

B. Vaccinations

- ☐ Live / live-attenuated vaccines: complete ≥4 weeks before the first infusion; NOT recommended during treatment or until B-cell repletion (CD19+) after discontinuation.
- ☐ Non-live vaccines: complete ≥2 weeks before the first infusion whenever possible; responses may be reduced under B-cell depletion.
- ☐ Infants of mothers exposed during pregnancy: defer live vaccines; measure CD19+ B-cell counts first (specialist consultation for the infant's inactivated schedule).

C. Clinical assessments & counseling

- ☐ Neurologic examination with documented EDSS at baseline.
- ☐ Baseline brain MRI (T1 post-contrast and T2) as reference; document relapse history and all prior DMTs with washout/switch intervals.
- ☐ Review concomitant medications — chronic immunosuppressive combinations not recommended (except corticosteroid relapse courses).
- ☐ Active-infection screen (history, exam, vitals) before every dose.
- ☐ Counseling: infusion reactions (up to 24 h post-infusion), infection signs, PML symptoms, pregnancy prevention, and duty to report intercurrent illness.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
Active HBV infection	Labeled contraindication.
History of life-threatening infusion reaction to ublituximab	Labeled contraindication.
Active infection	Defer until resolved.
Live vaccine <4 weeks ago / non-live vaccine <2 weeks ago	Defer to preserve safety windows.
Significantly low baseline immunoglobulins	Initiate only after immunology review.

Section 2 — Order Set

Premedication

- ☐ Methylprednisolone 100 mg IV (or equivalent oral corticosteroid) ~30 minutes before EVERY infusion.
- ☐ Antihistamine (e.g., diphenhydramine 25–50 mg PO/IV) ~30–60 minutes before EVERY infusion.
- ☐ Acetaminophen 650 mg PO ~30 minutes before infusion (optional antipyretic).

Dosing schedule

First infusion	150 mg IV over ~4 hours with gradual rate escalation per label rate table.
Second infusion	450 mg IV over ~1 hour, 2 weeks after the first infusion.
Maintenance	450 mg IV over ~1 hour every 24 weeks (first maintenance dose 24 weeks after infusion 1).
Observation	Observe ≥1 hour after infusions 1 and 2; thereafter at physician discretion unless a prior or current infusion reaction occurred.
Infusion-reaction management	Mild–moderate: interrupt/reduce rate, resume at half rate when resolved. Severe: stop infusion and treat. Life-threatening: permanently discontinue.

Standing orders — every infusion

- ☐ Infection screen before every infusion — hold until resolved.
- ☐ Pregnancy test before every infusion for females of reproductive potential.
- ☐ Vital signs at baseline, each rate change, and end of infusion.
- ☐ Remind patients that reactions can occur up to 24 hours after the infusion.

Missed or delayed dose

Administer a missed dose as soon as possible; do NOT wait for the scheduled date. Reset the schedule so the next dose is 24 weeks after the most recent infusion, and preserve a minimum interval (at least ~5 months) between doses.

Contraception & pregnancy

Effective contraception during treatment and for 6 months after the final dose (verify current label for the applicable interval).

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Infection screen	Before every infusion	Hold for active infection until resolved.
Quantitative immunoglobulins	During treatment; after discontinuation until B-cell repletion if low	Low IgG + recurrent/serious infections → immunology review.
Liver function tests	Baseline, then per clinical judgment	Marked transaminase elevation with hyperbilirubinemia → evaluate as possible drug-induced liver injury before further dosing.
MRI brain	Per monitoring plan; URGENT if PML suspected	PML-protocol MRI before any further dose.

CD19+ B-cell count	When timing vaccines or a subsequent DMT after discontinuation	No live vaccines until repletion documented.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Active infection	Delay until resolved.
Recent live vaccine (<4 weeks)	Defer dose.
Significant hypogammaglobulinemia with recurrent infections	Delay; immunology review.
Grade ≥3 infusion reaction	Hold pending evaluation and plan revision.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
PML — suspected or confirmed	Discontinue permanently; specialist work-up.
Life-threatening infusion reaction / anaphylaxis	Discontinue permanently.
HBV reactivation or significant drug-induced liver injury	Discontinue; hepatology management.

Section 5 — Notes & Practical Points

- ☐ B-cell depletion persists after the last dose — live vaccines remain contraindicated until CD19+ repletion is confirmed.
- ☐ When sequencing to another high-efficacy DMT, assess immune status (including CD19+ counts) before initiating the next agent.

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.