MADISON NEUROLOGY LLC

608 403 0000

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

Lemtrada®

Alemtuzumab

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

GENERIC NAME	alemtuzumab
BRAND	LEMTRADA®
MEDICATION CLASS	Anti-CD52 monoclonal antibody (lymphocyte-depleting)
PRESENTATION	12 mg/1.2 mL (10 mg/mL) single-dose vial — dilute in 100 mL 0.9% NaCl or D5W
ROUTE	IV infusion over ~4 hours
US INDICATION (FDA)	Relapsing forms of MS in adults who have had an inadequate response to two or more MS therapies (restricted indication reflecting its safety profile).

Class context.
Boxed warnings: serious (sometimes fatal) autoimmune conditions (ITP, nephropathies including anti-GBM disease), serious and life-threatening infusion reactions, stroke and arterial dissection, and malignancies (thyroid, melanoma, lymphoproliferative).

REMS-restricted program.
Available only through the Lemtrada REMS Program. Prescriber, patient, pharmacy, and infusion facility must be certified; baseline labs must be reviewed before the first course and monthly results reviewed before each subsequent course; the program must be notified of key adverse events.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ CBC with differential, serum creatinine, urinalysis (with microscopy), and TSH — baseline AND then MONTHLY until 48 months after the last infusion course. This 4-year tail is the program's core obligation; patients unable to commit should not start.

- ☐ TB screening (IGRA) before initiation; treat latent TB before dosing.
- ☐ HBV and HCV screening before initiation.
- ☐ HPV screening in females, then annual cervical screening (HPV reactivation risk).
- ☐ Varicella serology: antibody-negative patients complete varicella vaccination ≥6 weeks before treatment (live vaccine).
- ☐ Baseline and yearly skin examination (melanoma surveillance).
- ☐ Thyroid-function and thyroid-exam baseline; document any pre-existing autoimmunity (relative contraindication review).
- ☐ Pregnancy test — must be negative; counsel on contraception during and 4 months after each course.

B. Vaccinations

- ☐ Complete ALL necessary immunizations ≥6 weeks before a course; live/live-attenuated vaccines are contraindicated during and after treatment until lymphocyte reconstitution (CD4+ recovery).
- ☐ If blood transfusion is ever needed after treatment: irradiated blood products only (institutional/label practice for lymphocyte-depleted patients).

C. Clinical assessments & counseling

- ☐ Baseline neurologic examination, EDSS, and brain MRI.
- ☐ Dental evaluation and treatment of active infection before each course.
- ☐ Listeria-prevention counseling: avoid high-risk foods (deli meats, unpasteurized dairy, soft cheeses) starting 1–2 weeks before, during, and for at least 1 month after each course.
- ☐ Document ≥2 inadequate DMT responses (required by the indication and by payers).
- ☐ Educate on the delayed-autoimmunity calendar: ITP (petechiae, bleeding), nephropathy (edema, hematuria), thyroid disease (weight/mood change), autoimmune hepatitis (jaundice), acquired hemophilia A (bruising/bleeding with prolonged aPTT).

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
HIV infection	Labeled contraindication.
Active infection	Postpone the course until resolved.
Active malignancy or uncontrolled autoimmune disease	Do not start; specialist review.
Live vaccine within 6 weeks	Defer course.
Inability/unwillingness to complete 48 months of monthly monitoring	Do not start — monitoring is integral to the risk-benefit.

Section 2 — Order Set

Premedication

- ☐ Methylprednisolone 1,000 mg IV (or equivalent) immediately BEFORE alemtuzumab on each of the first 3 days of each course.
- ☐ Antihistamine (e.g., diphenhydramine 50 mg) and antipyretic (e.g., acetaminophen 650 mg) before each infusion.
- ☐ Antiviral prophylaxis against herpes (e.g., acyclovir 200 mg twice daily or equivalent) from day 1, continued for at least 2 months after the course OR until CD4+ ≥200 cells/µL, whichever is longer.
- ☐ Anti-emetics as needed; PPI per institutional practice during the steroid days.

Dosing schedule

Course 1	12 mg IV daily × 5 consecutive days, each dose over ~4 hours.
Course 2	12 mg IV daily × 3 consecutive days, 12 months after course 1.
Additional courses	12 mg IV daily × 3 days, ≥12 months after the prior course, only if disease activity recurs.
Observation	Monitor during and for at least 2 hours after each infusion; stroke, PRES, myocardial ischemia, and cardiopulmonary events cluster around dosing — REMS sites must have emergency capability.

Standing orders — every infusion

- ☐ Verify the current month's labs (CBC, creatinine, UA, TSH) are drawn and reviewed before each course — and before the annual go/no-go decision.
- ☐ Vital signs before, during, and after each infusion per REMS infusion guidance.
- ☐ Daily infection and bleeding review during course weeks.
- ☐ Confirm antiviral prophylaxis adherence at each visit.

Missed or delayed dose

Courses are annual; a delayed course proceeds once infection is excluded and labs are acceptable. Never compress the 12-month minimum interval between courses.

Contraception & pregnancy

Effective contraception during and for 4 months after each course. Thyroid autoimmunity and other endocrine effects are pregnancy-relevant — coordinate any planned pregnancy with neurology and endocrinology.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
CBC with differential	Monthly until 48 months after the last course	Thrombocytopenia → urgent ITP evaluation (petechiae/bleeding = same-week review); severe cytopenias hold further dosing.
Serum creatinine + urinalysis	Monthly for 48 months	Hematuria/proteinuria or rising creatinine → nephrology referral for anti-GBM/nephropathy evaluation.

TSH	Monthly until 48 months	Abnormal → endocrine evaluation; thyroid disease is the most common alemtuzumab autoimmunity.
Skin examination	Yearly	Suspicious lesions → dermatology (melanoma signal).
Cervical HPV screening	Yearly (females)	Per gynecology follow-up.
LFTs / aPTT	With symptoms	Jaundice → autoimmune-hepatitis work-up; unexplained bleeding with prolonged aPTT → acquired hemophilia A work-up.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Active infection	Delay dosing until resolved.
Grade 3–4 lab abnormality (cytopenia, creatinine rise, abnormal UA)	Hold and evaluate before further doses.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Autoimmune complication requiring systemic treatment (ITP, anti-GBM nephropathy, autoimmune hepatitis, acquired hemophilia A)	No further courses; specialist management.
Malignancy, stroke/PRES, or serious life-threatening infusion reaction	Discontinue.
PML or other serious opportunistic infection	Discontinue; specialist management.

Section 5 — Notes & Practical Points

- ☐ Autoimmunity peaks in years 1–3 but is reported through year 5+ — the 48-month monthly lab schedule is the single most important safety element of this protocol.
- ☐ Re-treatment decisions weigh disease activity against cumulative autoimmunity exposure; many patients need only the two labeled courses.

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.