MADISON NEUROLOGY LLC

608 403 0000

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

Kisunla®

Donanemab-azbt

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

GENERIC NAME	donanemab-azbt
BRAND	KISUNLA®
MEDICATION CLASS	Anti-amyloid beta monoclonal antibody
PRESENTATION	350 mg/17.5 mL (20 mg/mL) single-dose vial — dilute per label
ROUTE	IV infusion over at least 30 minutes, every 4 weeks
US INDICATION (FDA)	Alzheimer's disease — initiate in patients with mild cognitive impairment or mild dementia stage of disease (the studied population), with confirmed amyloid beta pathology.

Class context.
Same boxed ARIA warning as the class. The distinctive feature is the label-supported STOPPING rule: consider discontinuing once amyloid plaque is reduced to minimal levels on PET — therapy may be finite, which changes both counseling and cost conversations.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ Confirm amyloid beta pathology BEFORE initiation (amyloid PET, or CSF/plasma biomarker pathway per label).

☐ Baseline brain MRI — REQUIRED; same class exclusionary findings (ARIA-E, siderosis, >4 microhemorrhages, hemorrhage >1 cm, vasogenic edema).

☐ APOE ε4 genotyping — encouraged for risk counseling; homozygotes at substantially higher ARIA risk; document shared decision-making.

☐ Confirm MCI or mild dementia staging (MoCA/MMSE, CDR) — not indicated for moderate/severe dementia.

☐ Anticoagulant/antiplatelet review with explicit documented risk-benefit discussion.

☐ Pregnancy test when relevant.

B. Vaccinations

☐ No label restrictions; routine adult vaccines per primary care.

C. Clinical assessments & counseling

☐ Baseline cognitive and functional assessment with caregiver.

☐ ARIA education (patient + caregiver) and the fixed MRI schedule; confirm urgent-MRI access.

☐ Set the finite-therapy expectation: PET re-imaging for the clearance decision belongs in the care plan from the start.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
No confirmed amyloid pathology	Do not start.
Exclusionary baseline MRI findings	Do not start.
Moderate or severe dementia	Outside the studied population.
High hemorrhage-risk medication profile without specialist review	Hold initiation pending documented risk-benefit.

Section 2 — Order Set

Premedication

☐ None required by label; premedicate subsequent infusions after a prior mild reaction.

Dosing schedule

Titration	700 mg IV every 4 weeks for the first 3 doses.
Maintenance	1,400 mg IV every 4 weeks thereafter.
Infusion	Over at least 30 minutes; observe for hypersensitivity/infusion reactions.
Stopping for clearance	Consider discontinuation when amyloid PET shows plaque reduction to minimal levels per the label.

Standing orders — every infusion

☐ ARIA symptom review (patient + caregiver) before every dose.

☐ Verify surveillance MRI completion before doses 2, 3, 4, and 7 — do not infuse past an overdue MRI.

☐ Medication review each cycle.

Missed or delayed dose

Give a missed dose as soon as possible and resume every-4-week dosing.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Brain MRI (ARIA surveillance)	Before the 2nd, 3rd, 4th, and 7th infusions per label; immediate MRI for any ARIA symptom; enhanced surveillance for APOE ε4 carriers per current label	ARIA → apply the label's severity-based hold/resume algorithm.
Amyloid PET (clearance decision)	At the label-specified interval when assessing stopping	Plaque cleared to minimal → consider discontinuation.
Cognitive/functional assessment	Every 6–12 months	Continuation documentation.
Medication review	Every cycle	New anticoagulation → hold and re-evaluate.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
ARIA on MRI	Hold per the label algorithm; resume per resolution and severity.
New neurologic symptoms	MRI before next dose.
New anticoagulation or planned thrombolysis	Hold; re-evaluate.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Amyloid plaque cleared to minimal levels on PET	Label-supported completion of therapy — document the decision.
Serious/recurrent symptomatic ARIA or significant hemorrhage	Discontinue.
Progression beyond mild stage	Individualized continuation decision.
Anaphylaxis/serious hypersensitivity	Discontinue.

Section 5 — Notes & Practical Points

- ☐ The clearance-based stopping rule is a genuine differentiator versus lecanemab — but only if the PET re-imaging is actually scheduled; build it into the protocol at initiation.
- ☐ Anticoagulation + anti-amyloid therapy compounds hemorrhage risk; document the stroke-alert plan with the family.

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.