



Medication Use Evaluation of Lecanemab and Donanemab for Alzheimer's Disease in the Veterans Health Administration



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Real-time medication use evaluations for lecanemab and donanemab are feasible and support ongoing data collection and safety evaluation.

Background

- Lecanemab and donanemab (amyloid targeting therapies) trial data may not reflect real-world safety in complex US Veterans.
- The VA Center for Medication Safety (VAMedSAFE) implemented a national, real-time medication use evaluation (MUE) to monitor the safety of these medications.

Objectives

- To describe the MUE and assess safe and appropriate use of lecanemab and donanemab among Veterans.

Methods

- VAMedSAFE constructed a real-time, prospective MUE as a mandatory pharmacovigilance process initially for lecanemab and later for donanemab.
- Participating sites entered data into a secure abstraction tool.
- A retrospective analysis of Veterans who initiated lecanemab or donanemab between October 2023 and December 2025 was conducted.
 - Process Outcomes:
 - Utilization
 - Appropriateness of use
 - MRI monitoring
 - Safety Outcomes:
 - Incidence of adverse events, including amyloid-related imaging abnormalities (ARIA) and infusion reactions

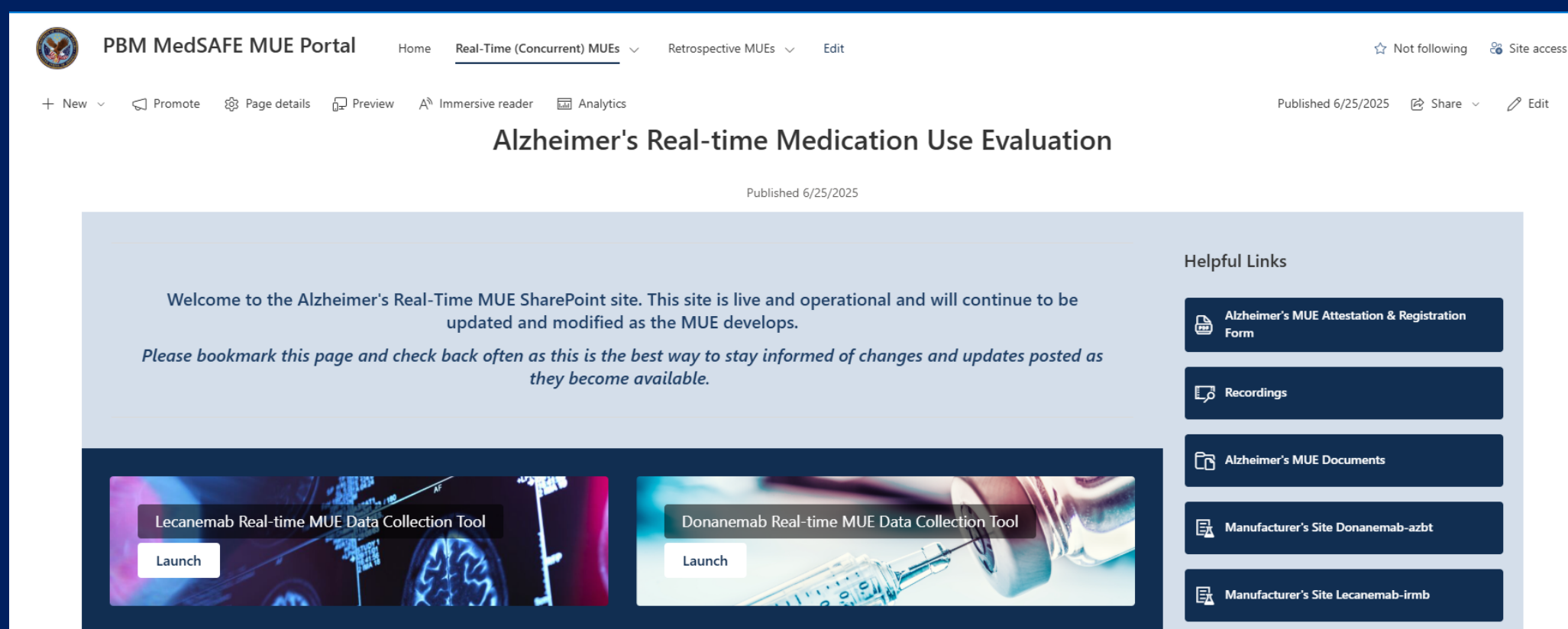


Figure 1. Sample screenshots of the secure Medication Use Evaluation (MUE) interface.

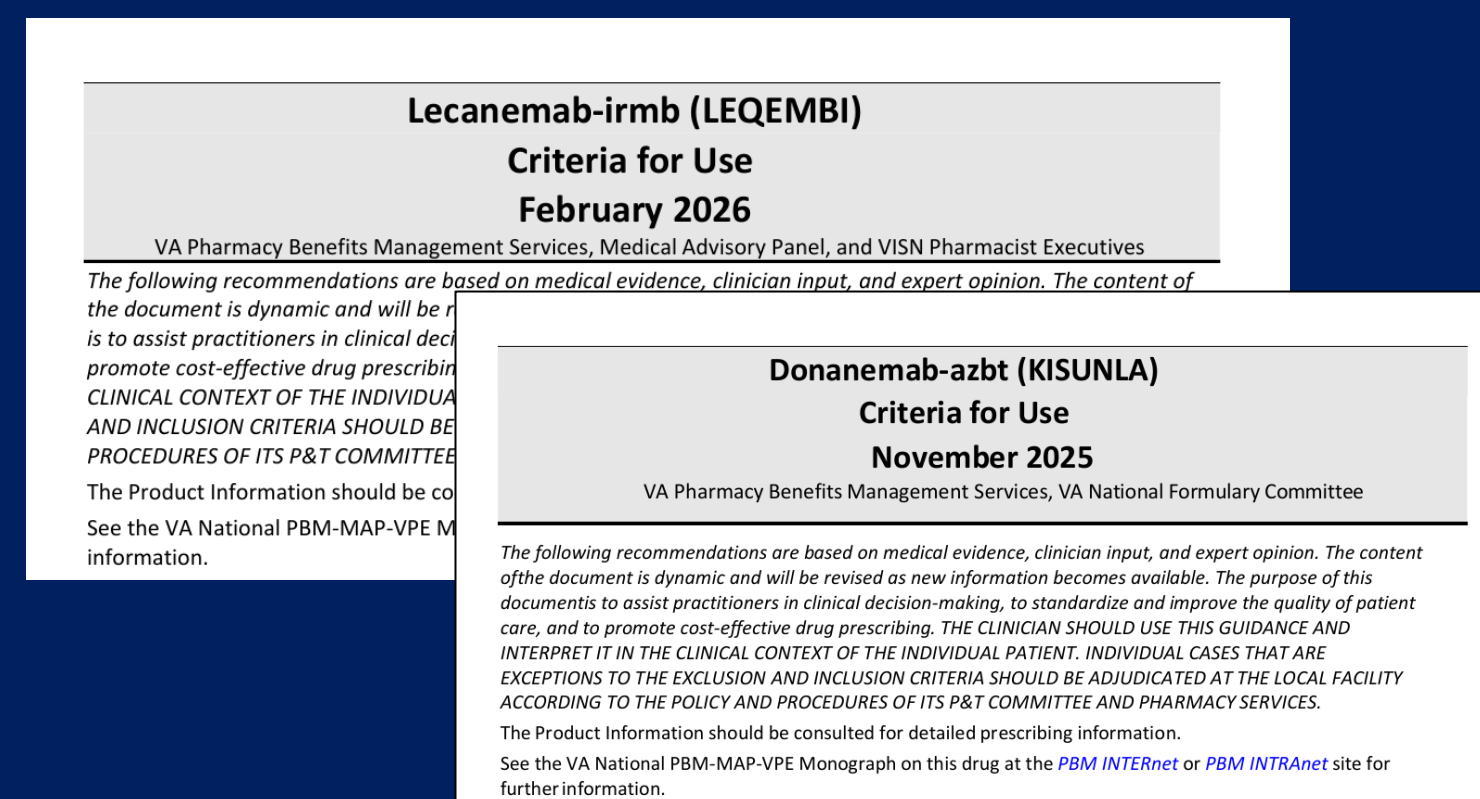


Figure 2. Sample screenshots of the Pharmacy Benefits Management (PBM) Criteria For Use (CFU)

Baseline Demographics and Clinical Characteristics

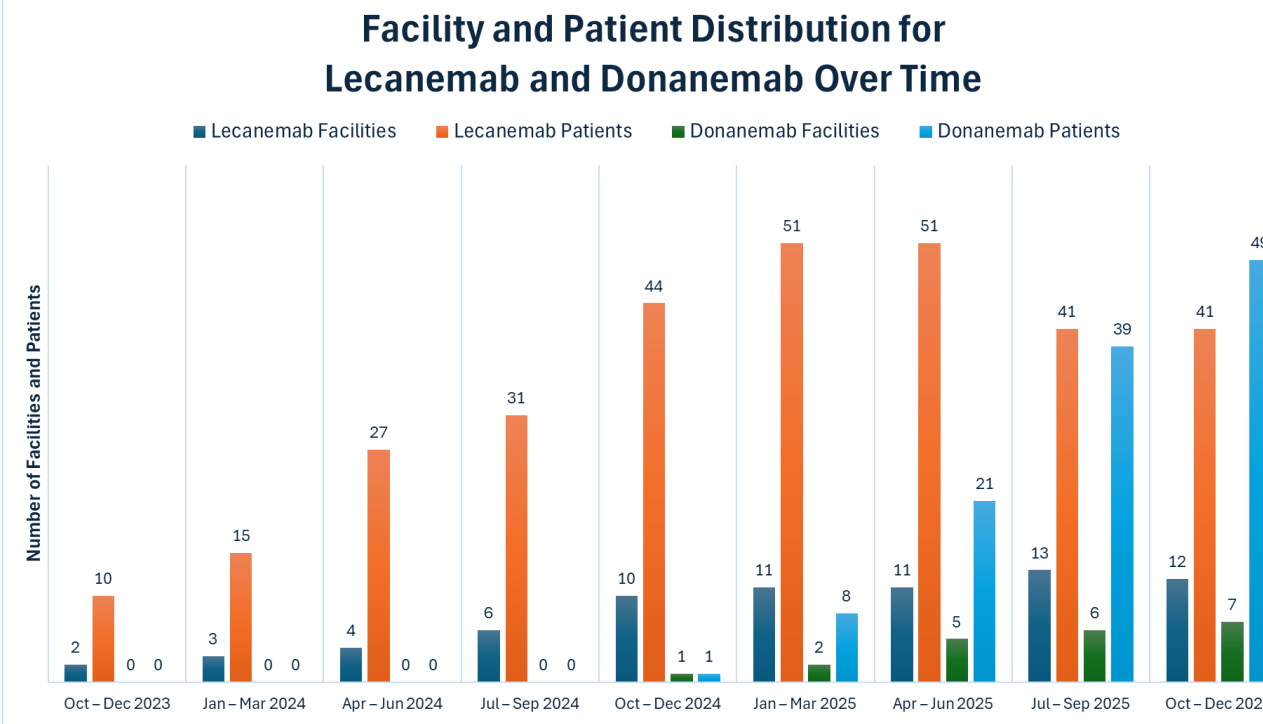
	Lecanemab (N=71)	Donanemab (N=57)
Patient Demographics ^a		
Age, mean ± SD, years	77.1±5.2	76.3±6.6
Birth sex, n (%)		
Male	70 (99%)	50 (88%)
Female	1 (1%)	7 (12%)
Race, n (%)		
White	63 (89%)	53 (93%)
Black	4 (6%)	1 (2%)
American Indian or Alaska Native	2 (3%)	0
Multiracial	0	1 (2%)
Declined/unknown	2 (3%)	2 (4%)
Ethnicity, n (%)		
Non-Hispanic	70 (99%)	56 (98%)
Hispanic	1 (1%)	1 (2%)
Patient clinical characteristics (reported in MUE) ^a		
Alzheimer's diagnosis, n (%)		
Mild cognitive impairment	28 (39%)	13 (23%)
Mild dementia	43 (61%)	44 (77%)
Baseline MoCA, mean (SD), n	21.1 (4), 44	20.7 (3), 7
Baseline MMSE Score, mean (SD), n	25.9 (3), 7	0
Baseline SLUMS Score, mean (SD), n	18 (2), 3	0
Patient clinical characteristics (chart review)		
APOE ε4 genotype, n (%)		
Non-carrier	28 (39%)	31 (54.4%)
Heterozygous	43 (61%)	26 (45.6%)
Patient clinical characteristics (extracted from CDW)		
Aspirin use, n (%)		
Baseline use	11 (15.5%)	16 (28.1%)
Subsequent use	8 (11.3%)	10 (17.5%)
Other antiplatelet medication use, n (%)		
Baseline use	0	0
Subsequent use	1 (1.4%)	0
Baseline anticoagulant, n (%)	0	3 (5.3%)
Baseline microhemorrhage(s) (≥1)	20 (28.2%)	18 (31.6%)

Abbreviations: APOE = Apolipoprotein E; CDW = Corporate Data Warehouse; MMSE = Mini-Mental State Exam; MoCA = Montreal Cognitive Assessment; SD = standard deviation; SLUMS = Saint Louis University Mental Status.
^aThere were 4 patients who had started on lecanemab or donanemab and switched to the other therapy and were counted in both categories.
^bPET scan, CSF testing, or FDA-approved blood biomarker. FDA-approved blood biomarker criteria was added in July 2025.
^cCholinesterase inhibitors examined were donepezil, rivastigmine, and galantamine.
^dNMDA receptor antagonist examined was memantine.

Safety Outcomes

Reported in the MUE	Lecanemab, N=71	Donanemab, N=57
Any AE, n (%)	28 (39%)	15 (26%)
Death, any cause, n (%) ^a	1 (1%)	1 (2%)
ARIA, n (%)	10 (14%)	8 (14%)
ARIA-E	7 (10%)	4 (7%)
ARIA-H	6 (9%)	7 (12%)
Both ARIA-E and ARIA-H	3 (4%)	3 (5%)
Other adverse events, n (%)		
Infusion reactions	11 (16%)	3 (5%)
Headache	5 (7%)	5 (9%)
GI symptoms	1 (1%)	0
Dizziness	2 (3%)	1 (2%)
Fall	2 (3%)	0
Other	7 (10%)	4 (7%)
Hospitalizations related to AE, n (%)	0	3 (5%)
ED/urgent care visits related to AE, n (%)		
ARIA	0	1 (2%)
Stroke	0	1 (2%)
Fall	0	1 (2%)
AE, n (%)		
ARIA	0	1 (2%)
Shakiness	1 (1%)	0
Dizziness	0	1 (2%)
Extracted from EHR Data		
Any ARIA, n (%)	14 (19.7%)	12 (21.1%)
ARIA-E	11 (15.5%)	5 (8.8%)
Mild	8 (11.3%)	3 (5.3%)
Moderate	0	1 (1.8%)
Not graded	6 (8.5%)	1 (1.8%)
ARIA-H	11 (15.5%)	10 (17.5%)
Mild	9 (12.7%)	9 (15.8%)
Not graded	5 (7.0%)	1 (1.8%)
Both ARIA-E and ARIA-H, n (%)	7 (9.9%)	3 (5.3%)
Acute stroke, n (%)	4 (5.6%)	3 (5.3%)

Abbreviations: AE = adverse event; ARIA = amyloid-related imaging abnormalities; ARIA-E = amyloid-related imaging abnormalities with edema and/or effusion; ARIA-H = amyloid-related imaging abnormalities with hemorrhage and/or superficial siderosis; CDW = Corporate Data Warehouse
^aOne patient on lecanemab died and one patient on donanemab died from causes unrelated to treatment.



^aThere were 4 patients who had started on lecanemab or donanemab and switched to the other therapy and were counted in both categories.
^bThere were 13 unique sites administering lecanemab and/or donanemab by the end of the data collection period.

Results

- The MUE tracked all thirteen VA sites administering lecanemab (N=71) or donanemab (N=57).
- Veterans on lecanemab and donanemab was predominantly non-Hispanic White males.
- Adherence to MRI monitoring protocols exceeded 90%.
- At two years, discontinuation rates were 47% for lecanemab and 25% for donanemab, most commonly due to amyloid clearance.
- Any ARIA was reported in 14% for lecanemab and 14% for donanemab.
- Rates of ARIA extracted from MRI radiology reports were higher, 20% for lecanemab and 21% for donanemab.

Conclusions

- The MUE provides a user-friendly interface that enables robust monitoring of drug administration and safety.
- Review of real-time data resulted in updates of the CFU.
- Rates of ARIA and other adverse events were similar to clinical trials.
- Real-time MUEs are feasible and support ongoing data collection and evaluation.