RESOURCE

CME OUTFITTERS

Quick-Reference ATT Landscape

Purpose

Amyloid-targeting therapies (ATTs) are reshaping the care of early Alzheimer's disease (AD). This quick guide equips pharmacists with essential, at-a-glance information on how these therapies work, who they're for, how to monitor them safely, and what operational steps are needed for successful implementation.

This resource is intended as a quick, at-a-glance reference to support learning during the activity and practical application afterward.

From Trial Data to Treatment Decisions

Pharmacy-Supported Stepwise Patient Selection for ATT Success

PURPOSE

Provide pharmacists with a structured, stepwise framework to translate amyloid-targeting therapy (ATT) trial data into real-world patient selection decisions, supporting appropriate use, safety, and timely initiation while avoiding unnecessary treatment delays.

1 CONFIRM INDICATION

DECISION QUESTION

Does the patient fall within the approved disease stage for amyloid-targeting therapy?

Eligible stages:

- ✓ Mild Cognitive Impairment (MCI) due to Alzheimer's disease (AD)
- ✓ Mild Alzheimer's dementia

Not indicated:

- ✗ Preclinical/asymptomatic AD
- ✗ Moderate or severe dementia

Pharmacy role:

Verify that the documented diagnosis aligns with regulatory labeling and evidence-based recommendations before initiating biomarker confirmation, imaging, or infusion workflows. Clarify staging discrepancies with the treating clinician to prevent premature or inappropriate treatment initiation.

2 CONFIRM ALZHEIMER'S PATHOLOGY

DECISION QUESTION

Is amyloid pathology documented using an appropriate diagnostic method?

Acceptable confirmation methods:

- Amyloid positive emission tomography (PET)

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- CSF Aβ42/40 ratio
- Plasma amyloid biomarkers (screening tool; typically require PET or cerebrospinal fluid [CSF] confirmation)

Pharmacy role:

Verify that amyloid confirmation is documented and meets diagnostic standards before advancing to safety screening, imaging, or treatment planning. Proactively identify incomplete or preliminary results to avoid downstream delays in authorization, scheduling, or care coordination.

EU CONSIDERATIONS

- PET availability varies by country and region
- CSF biomarkers are more commonly used in some EU health systems
- Plasma biomarkers may be used for triage but usually require confirmatory testing
- Diagnostic pathways may be centralized at tertiary centers

TRIAL POPULATIONS VS REAL-WORLD PATIENTS

DECISION QUESTION

Can trial evidence be reasonably extrapolated to this patient?

Clinical trial populations typically included:

- Early symptomatic AD
- Limited comorbidity burden
- magnetic resonance imaging (MRI) eligibility and protocol adherence
- Reliable access to ongoing monitoring

Real-world patients may differ by:

- Use of concomitant therapies (e.g., anticoagulants)
- Health system or logistical constraints
- Only ~5-8% meet strict clinical trial eligibility criteria
- Presence of common comorbidities (e.g., vascular disease, diabetes)

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Pharmacy role:

Support thoughtful extrapolation of trial evidence by distinguishing manageable real-world differences from true safety or feasibility barriers. Help prevent unnecessary treatment delays or exclusions based solely on rigid trial criteria.

EVALUATE DRUG-SPECIFIC OPERATIONAL CONSIDERATIONS

DECISION QUESTION

Do drug-specific requirements align with the patient's clinical profile and the care setting's monitoring and workflow capacity?

Lecanemab considerations:

- Primarily targets soluble Aβ protofibrils
- Fixed dosing schedule
- No routine clinical tau PET requirement
- Amyloid PET required at baseline only

Donanemab considerations:

- Targets pyroglutamate-modified plaque Aβ
- Treat-to-clear strategy
- Tau PET used for trial stratification
- Follow-up amyloid PET used to confirm clearance

Pharmacy role:

Support alignment of therapy selection with infusion cadence, imaging requirements, monitoring burden, and institutional capacity, in collaboration with the treating clinician and care team.

EU CONSIDERATIONS

- Follow-up amyloid PET for donanemab may be limited by imaging capacity
- Fixed-schedule therapies may be easier to operationalize in settings with constrained PET access
- Tau PET availability varies substantially across EU health systems

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5 ASSESS PATIENT-SPECIFIC RISK

DECISION QUESTION

Are there patient-specific factors that increase safety risk or implementation complexity?

Key risk considerations include:

Genetic and biological factors:

- APOE ε4 carrier status (if known)

Imaging-related factors:

- Baseline MRI findings (e.g., microhemorrhages, superficial siderosis, small-vessel disease)

Clinical and treatment-related factors:

- Anticoagulation use or elevated bleeding risk

Practical feasibility factors:

- Ability to undergo serial MRI
- Caregiver support and transportation reliability

Pharmacy role:

Identify elevated risk or complexity early and facilitate timely multidisciplinary discussion to determine appropriateness, monitoring intensity, or need for additional safeguards.

6 ADDRESS BORDERLINE OR UNCERTAIN CASES

DECISION QUESTION

Does the patient meet core eligibility criteria while also having factors that warrant additional deliberation before proceeding?

Common scenarios may include:

- Higher tau burden or mixed pathology
- Multiple or competing comorbidities
- Limited access to MRI or PET imaging
- Elevated amyloid-related imaging abnormalities (ARIA) risk in the setting of strong patient motivation

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Pharmacy-supported strategies:

- Facilitate multidisciplinary case review to align on appropriateness and safeguards
- Clarify feasibility of required monitoring, follow-up, and care coordination
- Support individualized risk–benefit discussions with the care team and patient
- Help avoid unnecessary delays once eligibility and feasibility are confirmed

EU CONSIDERATIONS

- Access limitations may contribute to borderline eligibility determinations
- Centralized referral pathways can delay case review and treatment decisions
- Pharmacists can support navigation of regional workflows and coordination of care transitions

SHARED DECISION-MAKING READINESS

DECISION QUESTION

Are the patient and caregiver informed, aligned, and prepared to proceed with treatment?

Readiness considerations include:

- Understanding that treatment slows disease progression but does not reverse symptoms
- Awareness of the monitoring burden (e.g., MRI requirements, infusion visits)
- Recognition of ARIA risk and the importance of symptom vigilance
- Clarity regarding anticipated duration of therapy and reassessment points

Pharmacy role:

Reinforce consistent, realistic messaging across the care team and help confirm that patient and caregiver expectations align with the planned treatment and monitoring approach.

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FINAL DISPOSITION & NEXT STEPS

DECISION QUESTION

Based on the preceding steps, what is the most appropriate disposition at this time?

Outcome pathways:

Appropriate candidate

Initiate ordering, scheduling, and monitoring workflows in coordination with the care team

Conditional candidate

Proceed with additional safeguards, specialist input, or enhanced monitoring as appropriate

Not appropriate at this time

Document the rationale and plan for reassessment as clinical status, access, or patient preferences evolve

Pharmacy role:

Once criteria are met, facilitate timely progression to implementation and help prevent avoidable delays or fragmentation in care.

EU CONSIDERATIONS

- Treatment initiation may depend on hospital formulary status
- National or regional HTA decisions may influence access and timing
- Scheduling and monitoring are often coordinated through centralized centers

References

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KEY **TAKEAWAYS**

1. Trial data inform amyloid-targeting therapy decisions but do not replace clinical judgment
2. Real-world ATT use requires structured extrapolation beyond strict trial criteria
3. Both drug-specific and patient-specific factors influence appropriateness and feasibility
4. Pharmacists play a central role in supporting safe, timely, and coordinated ATT initiation
5. A stepwise framework promotes consistent, evidence-based decision-making across practice settings and regions