

INTRODUCTION

Blood-based biomarkers (BBMs) represent a significant advancement in the early, non-invasive detection of Alzheimer's disease (AD) pathology. However, integrating these emerging tools into primary care workflows requires careful consideration.

Currently, most BBM assays have been validated in specialized research settings. In primary care, clinicians face unique diagnostic complexities, including broader patient populations with a wider mix of pathologies, which can result in a lower pre-test probability of disease, influencing comorbidities and a lack of standardized reference ranges.

Because BBMs are not intended as standalone diagnostic tools, this tool is designed to help primary care providers (PCPs) integrate biomarker testing into a comprehensive clinical assessment. It aims to support evidence-informed clinical reasoning while mitigating the risks of diagnostic uncertainty or unintended clinical cascades.

To learn more about BBMs, check out biomarker information and resources on [ALZPro](#).

Decision Support Tool for the Use of BBMs for Alzheimer's Disease Pathology in Primary Care

When might BBMs be considered?

- Patient, care partner or clinician has concerns about cognitive impairment and/or **changes in cognition** over at least the last six months (e.g., displacing items, missing appointments, forgetting medication) **and** the patient is over 50 years of age.*
- Brief **cognitive assessment** suggests impairment.
- The differential diagnosis includes symptomatic AD.
- Results would inform referral or further workup **and** access to appropriate pathways is available.



* Consider whether the patient, care partner(s) and/or clinician believe that knowing if AD pathology is present would affect decision-making and/or management (e.g., is patient eligible for/interested in disease-targeting treatment if diagnosed with AD?).

What to Consider When Using BBMs for AD Pathology

Below are considerations for each of the main phases of the use of BBMs.

Pre-Testing Phase

- Patient characteristics (≥ 50 years)
- Patient and/or care partner concerns
- Clinical assessment
- Cognitive assessment suggests **cognitive impairment**
- Imaging (MRI if available)
- Rule out other causes
- Patient counseling and shared decision-making
- **Ethical considerations**
- Psychological monitoring
- Pre-planning/management
- AD family history

Testing Phase

- Sensitivity and specificity of the test
- Kidney function testing, if no recent data is available
- If blood samples are collected locally, consult these **resources**
- Follow up with patients/care partners for the next stage

Post-Testing Phase

- Interpretation of test results
- Communication of test results with patients and care partners
- Psychological monitoring
- Clinical management
- Referral to specialist care where appropriate



Each phase should be adapted to local context, coverage and available resources.

How can primary care physicians navigate clinical decision-making?

The following conceptual decision-making flowchart is intended to support clinical reasoning. It outlines suggested steps that may inform decision-making but should not replace evidence-informed clinical judgment.

**START
HERE**



Patient/care partner(s) presents with concerns about progressive cognitive symptoms over the prior 6 months or more.

Note: Factors like medications, acute illnesses or modifiable risk factors can contribute to short-term cognitive changes (≤ 6 months).



Complete standard clinical and cognitive assessment.

Evaluate and manage any alternative causes of cognitive impairment.



If the clinician remains concerned that symptoms could be related to AD, consider whether the patient, care partner(s) and/or clinician believe that knowing if AD pathology is present would affect decision-making and/or management (e.g., *is patient eligible for/interested in disease-targeting treatment if diagnosed with AD?*)



If NO

Continue care without BBM testing.

If YES

AND follow-up pathways exist and are appropriate

1

Order the test with the highest acceptable accuracy available to you. Consider tests with regulatory clearance or approval and consult local lab or health system formulary for validated AD BBM performance data.

2

Interpret and integrate with wider clinical findings. Discuss results with patient/care partner(s). Note that a positive BBM test result does not constitute a clinical diagnosis of AD.

3

Many patients may undergo additional diagnostic evaluation and be diagnosed and managed within primary care depending on the clinical context, available resources and patient preferences. Primary care providers should also continue to address modifiable risk factors and emphasize lifestyle-based prevention, regardless of test result.

4

Referral to specialty care is appropriate when the patient is a potential candidate for disease-targeting therapy and is interested, when diagnostic uncertainty remains high or when further specialist workup is expected to change management.



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For additional information and professional resources, visit alz.org/ALZPro.

SUMMARY

The integration of blood-based biomarkers into primary care is a rapidly advancing area of Alzheimer's disease diagnostics. This tool provides a foundational, phased outline to support patient-centered BBM use today.

Because the clinical and regulatory landscape for BBMs is dynamic, this document is an iterative tool. The Alzheimer's Association will continue to refine this tool as new evidence, standardized reference ranges and primary care-specific clinical guidelines emerge.



Help shape the future of this tool.

Your real-world clinical experience is vital to ensuring our resources remain practical and highly relevant for primary care providers.

Please share your insights, workflow challenges and suggestions by completing our brief **User Feedback Survey**.

About the Alzheimer's Association

The Alzheimer's Association is a worldwide voluntary health organization dedicated to Alzheimer's care, support and research. Our mission is to lead the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection and maximizing quality care and support. Our vision is a world without Alzheimer's and all other dementia®. Visit alz.org or call 800.272.3900.