



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Beta Amyloid Imaging with Positron Emission Tomography (PET) for Alzheimer's Disease

**Policy #** 00381

**Original Effective Date:** 11/04/2013

**Current Effective Date:** 11/04/2013

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers beta amyloid imaging with positron emission tomography (PET) to be **investigational**.\*

### **Background/Overview**

A radioactive dye (florbetapir) has been developed that binds to beta amyloid and can be detected in vivo with PET. This technology is being evaluated to detect beta amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and/or other causes of cognitive decline.

The diagnosis of AD is divided into three categories: possible, probable, and definite AD. A diagnosis of definite AD requires post-mortem confirmation of AD pathology, including the presence of extracellular beta amyloid plaques and intraneuronal neurofibrillary tangles in the cerebral cortex. Probable AD dementia is diagnosed clinically when the patient meets core clinical criteria for dementia and has a typical clinical course for AD. A typical clinical course is defined as an insidious onset, with the initial and most prominent cognitive deficits being either amnesic or non-amnesic, e.g., language, visuospatial, or executive function deficits, and a history of progressively worsening cognition over time. A diagnosis of possible AD dementia is made when the patient meets the core clinical criteria for AD dementia but has an atypical course or an etiologically mixed presentation.

Mild cognitive impairment (MCI) may be diagnosed when there is a change in cognition, but not sufficient impairment for the diagnosis of dementia. Features of MCI are evidence of impairment in one or more cognitive domains, and preservation of independence in functional abilities. In some patients, MCI may be a prodementia phase of AD. Patients with MCI may undergo ancillary testing (e.g., neuroimaging, laboratory studies, and neuropsychological assessment) to rule out vascular, traumatic, and medical causes of cognitive decline and to evaluate genetic factors. Because clinical diagnosis can be difficult, particularly early in the course of disease, there has been considerable interest in developing biomarkers for AD. One biomarker that is being evaluated is amyloid plaque density in the brain detected in vivo by PET.

Positron emission tomography images biochemical and physiological functions by measuring concentrations of positron-emitting chemicals in the body region of interest. Radiopharmaceuticals used for beta amyloid imaging may be generated in a cyclotron or nuclear generator and introduced into the body by intravenous injection. A number of <sup>11</sup>C and <sup>18</sup>F-labeled PET radiopharmaceuticals have been investigated for imaging brain beta amyloid. However, due to the short half-life (20 minutes), <sup>11</sup>C radiotracers are not convenient for commercialization. Several <sup>18</sup>F beta amyloid radiotracers are currently in Phase II and III

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clinical trials. To date, only florbetapir ( $^{18}\text{F}$ -AV-45) has received approval for clinical use by the U.S. Food and Drug Administration (FDA).

## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

In 2012, the FDA approved florbetapir (Amyvid™, Avid Radiopharmaceuticals, a subsidiary of Eli Lilly)<sup>†</sup> as a radioactive dye for visualization of amyloid plaque in the brain. The FDA document prepared for the advisory committee meeting indicated that while florbetapir may detect pathology, there could be no claim of disease detection, since beta amyloid aggregates can be found in cognitively normal elderly individuals, as well as patients with AD.

Amyvid is indicated “for PET [positron emission tomography] imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline.”

Centers for Medicare and Medicaid Services (CMS)

Medicare currently does not cover beta amyloid PET imaging. Medicare addresses coverage of PET in section 220.6 of the National Coverage Determination (NCD) manual. .

## **Rationale/Source**

Studies of diagnostic tests can be divided into categories that are somewhat analogous to the phases designated in studies of pharmaceuticals (i.e., Phase I to Phase IV). Different schemes have been proposed. In this Policy, we will use the following categorization: 1) Phase I-technical performance; 2) Phase II- diagnostic accuracy (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients, such as those with mild cognitive impairment or suspected AD; and 3) Phase III-effect on patient outcomes, i.e., demonstration that the diagnostic information can be used to improve patient outcomes.

The gold standard for the diagnosis of AD is post-mortem neuropathologic examination. In the absence of comparisons with the gold standard, long-term clinical follow-up (e.g., conversion from mild cognitive impairment [MCI] to probable AD) may be used as a surrogate endpoint to evaluate the diagnostic performance of beta amyloid imaging with PET.

Beta amyloid imaging may be particularly helpful for the future study of novel therapeutic agents that target amyloid plaques. However, current clinical purposes of testing for beta amyloid plaque density would be to improve diagnostic accuracy (e.g., rule out AD) or predict conversion from MCI to AD. In general, evidence of a health benefit or clinical utility from testing requires demonstration that:

- incremental improvements in diagnostic or prognostic accuracy over current practice occur, *and*
- incremental improvements lead to improved health outcomes (e.g., by informing clinical management decisions), *and*
- these outcomes may be obtained (i.e., are generalizable) outside of the investigational setting.

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## Literature Review

A February 2013 TEC Assessment concluded that beta amyloid imaging with PET to evaluate suspected AD and other causes of cognitive decline does not meet the TEC criteria, based on the lack of direct evidence for clinical utility. The following is a summary of the main conclusions of the TEC Assessment:

Studies have shown that florbetapir F18 PET results correlate with histopathologic findings at autopsy. This finding is important. Studies have also suggested that florbetapir F18 PET has some ability to differentiate between cognitively normal adults and patients with AD. However, the studies are limited by small sample sizes, differences in determining outcomes (e.g., qualitative versus quantitative, unknown impact of training for physicians inexperienced with this modality), and the lack of evidence obtained from populations encountered in clinical practice. No information is available on the impact of this test on clinical outcomes, and few data are available on whether it can accurately identify patients with MCI who will develop AD.

Phase I-Technical Performance: Evidence on technical performance of this test should demonstrate that the test measures what it is intended to, i.e., beta amyloid plaque. The best evidence on this would be direct comparison with a gold standard test for measuring amyloid plaque, which is histopathologic examination of tissue. Other important measures of technical performance are the reliability of testing, including both test-retest reliability and interobserver reliability in reading test results.

Clark and colleagues published in August 2012 an extension of their previous U.S. FDA-regulated study. This study reported on 59 participants with cognitive status ranging from normal to advanced dementia). Twelve participants had no cognitive impairment, 5 had MCI that did not meet the criteria for dementia, 29 had AD, and 13 had other forms of dementia. All patients had direct measurement of amyloid burden by histopathologic examination, and images were interpreted by three readers using a semiquantitative visual analysis 0-4. The median semiquantitative rating was used. A significant correlation of 0.76 and 0.79 was found between amyloid burden in the brain measured by Amyvid and the gold standard of histopathology in patients who had an autopsy performed within 2 years and 12 month of imaging, respectively. This report adds additional participants to those reported in a 2011 study described below.

Data on technical performance of the test was included in an FDA-regulated study, which was published in 2011. This study was a Phase III multicenter trial with 2 separate cohorts. These cohorts were an autopsy cohort and a young, cognitively intact cohort. The autopsy cohort was drawn from 152 subjects who had a projected life expectancy of 6 months or less. Thirty-five individuals passed away and were autopsied within 12 months of PET imaging; 29 were included in the primary efficacy analysis. This cohort was composed of 9 subjects (31%) who were not cognitively impaired, 2 (7%) who were mildly impaired, 13 (45%) with a clinical diagnosis of AD, and 5 (17%) with a clinical diagnosis of a non-AD dementia.

All patients had direct measurement of amyloid burden by histopathologic examination, and 52% met the pathologic criteria for AD. A significant correlation of 0.78 was found between amyloid burden in the brain measured by Amyvid and the gold standard of histopathology; however, there was not an exact match between the 2 measures. The correlation between quantitative whole-brain florbetapir image scores and post-mortem silver stain was 0.71. In the young controls (specificity cohort to evaluate false positives), the primary efficacy endpoint was the exclusion of amyloid in 47 young subjects who were negative for the

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apolipoprotein E  $\epsilon 4$  (*APOE4*) allele, randomly interspersed with PET scans of 40 subjects in the autopsy cohort. The study achieved specificity of 100% in this cohort, although it is noted that the young controls are outside of the intended use population.

Reproducibility of the readings was assessed using 3 trained readers who were blinded to the clinical information. Using a binary scale (positive or negative for amyloid), sensitivity ranged from 55% to 90% for the 3 readers, and in 24-45% of the images (depending on the sample), at least one reader would have had a different interpretation of amyloid status from the other readers. Subsequent reanalysis for publication used the majority rating of 3 nuclear medicine physicians as the primary outcome variable, resulting in 96% agreement between florbetapir-PET images and histopathologic results in the 29 subjects in the primary analysis cohort.

### Conclusions:

Evidence on technical performance is mainly from the FDA-sponsored study. A strength of this study is the comparison of florbetapir imaging with the gold standard of post-mortem histopathology. Limitations include the small sample size, a majority rating for assessing diagnostic accuracy, and having only 2 patients in the mildly impaired category, which is the population for whom the test is most likely to be used. Evidence from this study indicates that the agreement between histopathology and beta amyloid testing by PET is good but not perfect. There is evidence for inter-observer variability in reading the test; using a majority of 2/3 readers leads to a high agreement with histopathology.

### Phase II- Diagnostic Accuracy:

Diagnostic Accuracy was reported by Clark and colleagues in the FDA-regulated study published in 2011 and the extension study published in August 2012. The extension study used majority consensus of 5 independent reviewers rating the images on a binary scale of amyloid positive or negative as the final test reading. Sensitivity and specificity were calculated compared to the gold standard of histopathology. In 46 participants with a scan to autopsy time of less than 12 months, the sensitivity, specificity and accuracy were 96% (80-100), 100% (78-100) and 98% (87-100), respectively. For those with a scan to autopsy time of less than 2 years, the sensitivity, specificity and accuracy were 92% (78-98), 100% (78-100) and 95% (85-99), respectively. The FDA-regulated study used the majority consensus of 3 independent reviewers as the final test reading; sensitivity and specificity was calculated compared to the gold standard of histopathology. Of 15 subjects who met pathologic criteria for AD, 14 had positive florbetapir scans (sensitivity of 93%). Of the 14 subjects who did not meet pathologic criteria for AD, all 14 had negative scans (specificity of 100%). Scans from all of the young subjects (27 *APOE4+* and 47 *APOE-*) were negative. Exploratory analysis indicated that in 3 subjects (20%), the clinical diagnosis did not match with the final autopsy diagnosis.

These measures of diagnostic accuracy for both the FDA-regulated study and the extension study are limited by the patient population, which is not representative of the population that the test is intended to be used for, and the use of a majority reading based on multiple independent experts, which is not likely to be used in clinical care.



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An industry-funded multicenter study by Fleisher et al. pooled data from 4 Phase I and II trials of florbetapir-PET imaging for a total of 210 participants, including 68 subjects with probable AD, 60 subjects with MCI, and 82 older unimpaired controls. Quantitative standard uptake value ratio (SUVRs) thresholds were determined from the Phase III trial described above. Although there were significant differences in mean SUVRs across groups, there was considerable overlap in the range of values. The percentage of subjects meeting threshold levels of amyloid with clinical AD, MCI and cognitively healthy controls was 80.9%, 40.0%, and 20.7%, respectively. The percentage of subjects with any identifiable florbetapir signal was 85.3%, 46.6%, and 28.1%, respectively. Among healthy controls, the percentage of subjects with any florbetapir positivity increased linearly by age, ranging from 11.8% for subjects 55 to 60 years of age to 41.7% for subjects 81 years of age or older. *APOE4* carriers in the control group had about twice the percentage of florbetapir positivity as noncarriers, although this comparison did not reach statistical significance.

In 2012, Camus et al. reported the diagnostic performance of florbetapir-PET in a clinical setting. Included were 13 subjects with AD, 12 with MCI, and 21 older unimpaired controls. PET images were assessed visually by 2 readers who were blinded to any clinical information and quantitatively by the SUVR of cortical regions compared to the cerebellum. Sensitivity and specificity were calculated based on clinical diagnosis as the comparison standard. Agreement in visual analysis between the 2 readers gave a kappa value of 0.71. Comparing visual assessment with the initial clinical diagnosis, 11 of 13 AD patients (85%), 6 subjects with MCI (50%) and 13 of 21 control subjects (60%) had positive scans, resulting in sensitivity of 84.6% and a specificity of 38.1% for discriminating AD patients from control subjects. A quantitative assessment of the global cortex SUVR showed a sensitivity of 92.3% and specificity of 90.5% at a cutoff value of 1.12 (ROC [receiver operating characteristics] area under the curve 0.894). Although the study is limited by the small number of subjects and the use of clinical diagnosis as a reference standard, these results suggest a high number of false positives with visual assessment of the images. In addition, quantitative analysis was not able to differentiate subjects with MCI from unimpaired controls.

### Conclusions:

Evidence on the diagnostic performance of beta amyloid testing is limited, and the available studies all have methodologic limitations that limit the validity of reported results. As a result, it is not possible to determine the sensitivity and specificity of testing. Some evidence suggests that there are a high number of false-positive results in patients without AD. However, the FDA study reports high specificity, so the true rate of false positives is uncertain. Further high-quality studies using populations of patients that represent those presenting in clinical care are needed to better define the diagnostic performance of this test.

Phase III- Effect on Patient Outcomes: No trials have been identified that reported health outcomes following florbetapir-PET imaging, thus there is no direct evidence for clinical utility.

Possible clinical uses of beta amyloid testing could include confirming the diagnosis of AD in order to begin medications at an earlier stage, or ruling out AD, which may lead to further diagnostic testing to determine the etiology of dementia and/or avoidance of anti-Alzheimer's medications that would be unnecessary.



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Since the sensitivity and specificity of beta amyloid testing has not yet been established, it is not possible to determine an indirect chain of evidence that would indicate that health outcomes are improved. Because of the presence of beta amyloid in elderly patients who do not have AD, it is not likely that the test will have a high positive predictive value, and therefore it may have limited utility in confirming AD. It is possible that the negative predictive value of testing may be high and that the test may be useful in ruling out AD. If this is true, it is not certain how many patients would benefit from additional testing to determine etiology, or whether a substantial number of patients would avoid unnecessary medications that would otherwise be given.

### Conclusions.

Evidence on clinical utility, i.e. that health outcomes are improved by testing, is lacking. There are no studies that report on clinical outcomes following testing. The diagnostic accuracy of testing is too uncertain to determine whether testing is likely to impact management and/or lead to improved outcomes.

### **Ongoing Clinical Trials**

A search of the online site [www.clinicaltrials.gov](http://www.clinicaltrials.gov) in May 2013 identified a number of trials on amyloid imaging with PET. Of particular interest are the following:

- An industry sponsored Phase IV randomized trial to evaluate the effectiveness of Florbetapir PET imaging to change patient management and to evaluate the relationship between Florbetapir PET scan status and cognitive decline (NCT01703702). This study has an estimated enrollment of 600 subjects with completion of primary outcome measure and final study completion in December 2014.

### **Summary**

Literature on the use of florbetapir-PET imaging to aid in the diagnosis of patients with suspected AD is limited. The pivotal Phase III trial, although to be commended for its use of the gold standard of histopathology, has a number of limitations including small sample size, use of a majority rating of 3 physicians, and having few patients in the mildly impaired category. This study reported a moderately high correlation of amyloid plaque with histopathologic examination. The sensitivity and specificity of this test have not yet been adequately determined in an appropriate population, including a larger number of patients with mild cognitive impairment.

The clinical utility of this technology is uncertain. The test is not likely to be useful for confirming AD in patients who present with cognitive impairment. It may have a role in ruling out AD, but this has yet to be established with certainty. Questions also remain about the use of this test outside of the investigational setting, particularly regarding the accuracy of visual interpretation of images and how best to apply this test in routine clinical practice.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	78811, 78814
HCPCS	AQ9586
ICD-9 Diagnosis	294.1, 331.0
ICD-9 Procedure	92.11

## **Policy History**

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08/01/2013 Medical Policy Committee review  
08/21/2013 Medical Policy Implementation Committee approval. New policy.  
Next Scheduled Review Date: 08/2014

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