

<u>Referring Physician Forms</u>	<u>Version/Date</u>
Case Registration Form	Version 4.0 04-22-16
Pre-PET Clinical Assessment Form	Version 4.0 03-21-17
Post-PET Clinical Assessment Form	Version 4.0 03-21-17
Incomplete Study Form	Version 1.0 11-03-15

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## Case Registration

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- This form is to be completed with each new referral.
- 

**I certify that all of the following are correct:**

1. The patient is 65 years of age or older.  
 Yes  No
2. The patient is a Medicare beneficiary.  Yes  No
  - a. Specify beneficiary type:  
 Fee for service (traditional Medicare)  
 Medicare Advantage
3. The patient has had a diagnosis of MCI or dementia, according to DSM-IV and/or National Institutes of Aging-Alzheimer’s Association criteria, verified by a dementia specialist within 24 months.  
 Yes  No
4. The patient meets the Appropriate Use Criteria for Amyloid PET (all must be checked):
  - 4.1 Cognitive complaint with objectively confirmed impairment;  
 Yes  No
  - 4.2 The etiologic cause of cognitive impairment is uncertain after a comprehensive evaluation by a dementia specialist, including general medical and neurological examination, mental status testing including standard measures of cognitive impairment, laboratory testing, and structural neuroimaging as below;  
 Yes  No
  - 4.3 Alzheimer’s disease is a diagnostic consideration;  
 Yes  No
  - 4.4 Knowledge of amyloid PET status is expected to alter diagnosis and management.  
 Yes  No
5. The patient has had a head MRI and/or CT within 24 months prior to enrollment.  
 Yes  No
6. The patient has had a clinical laboratory assessment (including CBC, standard blood chemistry profile, TSH, vitamin B12) within 12 months prior to enrollment.  
 Yes  No
7. The patient is expected to be able to tolerate amyloid PET imaging as required by protocol, to be performed at a participating PET facility.

Yes  No

8. English or Spanish speaking (for purposes of informed consent).

Yes  No

9. Has signed consent to participate in IDEAS Study. Consent may be by proxy.

Yes  No

Consent provided by:

Patient  Proxy

Date consent signed: \_\_\_\_\_

Note: All of the assessments needed to determine eligibility are considered standard practice.

**The patient does not meet any of the exclusion criteria:**

- |  |                                   |
|--|-----------------------------------|
| 10. Normal cognition or subjective complaints that are not verified by cognitive testing.  | <input type="checkbox"/> verified |
| 11. Knowledge of amyloid status, in the opinion of the referring dementia expert, may cause significant psychological harm or otherwise negatively impact the patient or family.               | <input type="checkbox"/> verified |
| 12. Amyloid status already known to patient or referring clinician based on prior amyloid imaging or CSF analysis.   | <input type="checkbox"/> verified |
| 13. Current or previous enrollment in an anti-amyloid therapeutic trial.   | <input type="checkbox"/> verified |
| 14. Scan is being ordered solely based on a family history of dementia, presence of Apo-lipoprotein E (APOE) $\epsilon$ 4, or in lieu of genotyping for suspected autosomal mutation carriers. | <input type="checkbox"/> verified |
| 15. Scan is being ordered for nonmedical purposes (e.g., legal, insurance coverage or employment screening).   | <input type="checkbox"/> verified |
| 16. Cancer requiring active therapy (excluding non-melanoma skin cancer).  | <input type="checkbox"/> verified |
| 17. Hip/pelvic fracture within the 12 months prior to enrollment.  | <input type="checkbox"/> verified |
| 18. Body weight exceeds PET scanner weight limit.  | <input type="checkbox"/> verified |
| 19. Life expectancy less than 24 months based on medical co-morbidities.   | <input type="checkbox"/> verified |
| 20. Residence in skilled nursing facility.   | <input type="checkbox"/> verified |

**Image archive and additional research studies:**

The patient has consented to collection and archiving of his or her de-identified amyloid PET images for use in future research.

Yes  No

The IDEAS Study is collaborating with additional research studies investigating amyloid, cognitive decline, Alzheimer's disease and other types of dementia and the patient is willing to be contacted about other research studies for which he or she may be a candidate.

Yes  No

**PATIENT INFORMATION:**

**Enter patient name as it appears on their Medicare ID card.**

First Name : \_\_\_\_\_

Middle Name : \_\_\_\_\_

Last Name : \_\_\_\_\_

Address : \_\_\_\_\_

City : \_\_\_\_\_

State : \_\_\_\_\_

Zip Code : \_\_\_\_\_

Telephone (home): \_\_\_\_\_ (cell) \_\_\_\_\_

Email : \_\_\_\_\_

Date of Birth : \_\_\_\_\_

SSN : \_\_\_\_\_

Medicare ID : \_\_\_\_\_

Patient gender:  Male  Female  Other

Race: (Select all that apply)

- American Indian
- Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Pacific Islander
- White
- Not reported
- Unknown

Hispanic origin:  Not Hispanic or Latino  Hispanic or Latino  Not reported  Unknown

PET Facility where Amyloid PET has been scheduled: \_\_\_\_\_

Date Amyloid PET is scheduled: \_\_\_\_\_ (optional)

Name of Person responsible for the data on this form: \_\_\_\_\_

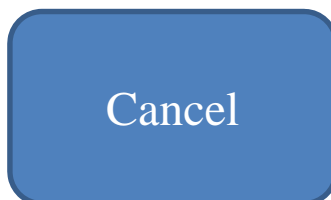
Name of Person Submitting this Form: \_\_\_\_\_

Referring Dementia Expert: \_\_\_\_\_

## Cancel Reason

**Please select the best response from the list below. Provide additional explanations in the box below.**

- Patient withdrew due to PET scheduling issues.
- Patient withdrew due to insurance or cost issues.
- Patient withdrew for other reasons (explain below).
- Patient unable to keep appointment for PET.
- PET facility could not complete the scan, and the patient could not or would not be rescheduled.
- Patient registered incorrectly (e.g. to wrong physician, prior to completion of entrance requirements, etc.)
- Patient found to be ineligible.
- Referring physician cannot locate patient (lost to follow-up)
- Duplicate entry. Practice accidentally registered the same patient more than once.
- Physician unavailable to see patient.
- Patient died before PET scan.
- Automatic: Pre-PET form was not submitted in time.
- Automatic: PET Completion form was not submitted in time.



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### PRE-PET CLINICAL ASSESSMENT FORM

*This form is intended to capture demographic and medical history data on your patient, as well as your diagnosis and management plan prior to amyloid PET. The management plan section asks that you describe your plan as if amyloid PET imaging were not available to your patient. This form must be submitted within 7 days of the patient's Pre-PET clinic visit.*

- 1. Before patient can proceed to A $\beta$ PET scan, Dementia Expert must certify that patient is aware of the ramifications of the test.**

I certify that I have discussed the medical and psychological ramifications of positive and negative amyloid scan results with the patient, family and caregivers, and they wish to proceed.

I have not discussed the medical and psychological ramifications of an amyloid scan. I understand that this makes the patient ineligible to proceed.

- 1a. Please verify the patient meets the Appropriate Use Criteria for Amyloid PET (all must be checked):**

**1.a.1. Cognitive complaint with objectively confirmed impairment;**

Yes  No

**1.a.2 The etiologic cause of cognitive impairment is uncertain after a comprehensive evaluation by a dementia specialist, including general medical and neurological examination, mental status testing including standard measures of cognitive impairment, laboratory testing, and structural neuroimaging;**

Yes  No

**1.a.3 Alzheimer's disease is a diagnostic consideration;**

Yes  No

**1.a.4 Knowledge of amyloid PET status is expected to alter diagnosis and management.**

Yes  No

**PATIENT DEMOGRAPHICS**

**2. Please specify marital status:**

- Married or domestic partnership
- Widowed
- Divorced or separated
- Never Married

**3. Please specify living arrangements:**

- Patient lives alone
- Patient lives with at least one other person

With whom does patient live (check all that apply):

- Spouse or domestic partner
- Child(ren)
- Other relative
- Caregiver/Household worker/Assisted Living
- Friend/Roommate/Other

**4. Please specify the highest level of education:**

- Doctoral or professional degree
- Master's Degree
- Bachelor's Degree
- Some college or associate degree
- High school graduate (including equivalency)
- Some high school
- Grade school
- No formal education

**5. What is patient's primary language?**

- English
- Spanish
- Other, specify \_\_\_\_\_

**6. In what language was the consent form completed?**

- English
- Spanish



**PATIENT CHARACTERISTICS**

**7. Please specify the level of cognitive impairment:**

- Mild cognitive impairment
  - Amnesic (single domain or mixed)
  - Non-amnesic (single domain or mixed)
- Dementia

**8. Please enter MMSE and/or MoCA score at last clinical evaluation:**

- a. MMSE:** \_\_\_\_\_
- b. MoCA:** \_\_\_\_\_

**9. Confirm the patient's amyloid status is not known to you or the patient:**

- Patient has had no prior amyloid imaging or results are not available
- Patient has had no prior CSF testing for A $\beta$ , or previous testing was equivocal

**10. Year of onset of cognitive impairment:** \_\_\_\_\_  **Year unknown:**

**11. Indicate diagnostic procedures which have been performed:**

**a. Confirm these required tests have been completed:**

- Basic laboratory work-up (complete metabolic panel, TSH, B12) within last 12 months (required)
- Structural brain imaging (CT or MRI) within past 24 months (required)

**b. Indicate all of the following that have been done:**

- Neuropsychological testing
- Additional serum laboratory tests (e.g. for infectious or auto-immune encephalopathies)
- Genetic testing for Apolipoprotein E genotyping
- Genetic testing for autosomal dominant mutations associated with AD (e.g. APP, PSEN1, PSEN2)
- Genetic testing for autosomal dominant mutations associated with other dementia (e.g. mutations associated with PD, FTD, etc.)
- Lumbar puncture for CSF studies excluding AD CSF biomarkers (CSF A $\beta$ 42, total tau, phosphorylated tau)
- FDG-PET
- SPECT- Dopamine transporter (DaTscan)
- SPECT- cerebral perfusion
- Polysomnogram
- Other brain imaging (Specify) \_\_\_\_\_
- Other, specify: \_\_\_\_\_

**12. Please indicate whether the patient is currently taking the following AD medications (Check all that apply):**

- Cholinesterase inhibitor (e.g. donepezil, rivastigimine, galantamine)
- Memantine

**PATIENT MEDICAL HISTORY**

**13. Please check all of the following items that are part of the patient's past or current medical history:**

- No clinically relevant medical history
- At least one condition is checked below (*Check all that apply*):
  - Congestive Heart Failure (with or without atrial fibrillation)
  - Atrial fibrillation
  - History of acute myocardial infarction
  - Ischemic heart disease (including angina pectoris and/or prior CABG)
  - Hypertension
  - Dyslipidemia
  - Chronic Kidney Disease
  - Chronic Obstructive Pulmonary Disease
  - Diabetes
  - Active Depression
  - Bipolar Affective Disorder
  - Schizophrenia
  - Prior History of Stroke and/or Transient Ischemic Attack (TIA)

***Please indicate timing of stroke or TIA:***

- Stroke or TIA occurred within past 24 months
  - Stroke occurred more than 24 months ago
- Cerebrovascular Disease without Stroke
  - Previous delirium
  - Epilepsy/Seizure Disorder
  - Parkinson's Disease
  - Multiple Sclerosis
  - Traumatic Brain Injury (TBI)

***Please indicate timing of TBI:***

- TBI occurred within past 24 months
- TBI occurred more than 24 months ago

- Tobacco use

***Please indicate timing of tobacco use:***

- Past
  - Current
- Family history of dementia
    - Family member diagnosed with Alzheimer's Disease
    - Family member diagnosed with other or unknown type of dementia

**DIFFERENTIAL DIAGNOSIS**

*PRIORITIZE your differential diagnosis of your patient's cognitive condition using this long list of options. For your convenience you may view the entire list in a separate window or print a copy of it for reference.*

- *You will be asked to SELECT the MOST likely etiologic cause of the condition.*
- *Then you will be asked to SELECT at least one, and up to 3, other causes from this list.*

*We have grouped the options by category, and alphabetized entries within category. Several categories include an option of "other." If "other" is selected, you will be asked to specify with free text the other cause of the condition.*

**Code Table for Differential Diagnoses**

**Neurodegenerative:**

**Alzheimer's disease (please specify below):**

- AD, clinically typical (memory-predominant)
- AD, clinically atypical (non-amnestic)
- AD, mixed pathology (e.g. mixed vascular, Lewy body, etc.)
- AD, NOS

**Non-AD neurodegenerative (please specify below):**

- Chronic traumatic encephalopathy (CTE)
- Diffuse Lewy body disease
- Frontotemporal dementia (includes behavioral and language-predominant presentations, corticobasal syndrome and progressive supranuclear palsy)
- Hippocampal sclerosis
- Parkinson's disease
- Vascular cognitive impairment (includes: multi-infarct, subcortical, intracerebral hemorrhage, other)
- Other non-AD neurodegenerative disease (Specify in space provided below)

**Other CNS conditions:**

- Auto-immune encephalopathy (e.g. CNS lupus, cerebral vasculitis, limbic encephalitis, paraneoplastic syndrome, etc.)
- Brain mass
- Encephalopathy NOS
- Epilepsy
- Hydrocephalus (idiopathic or secondary)
- Infectious encephalopathy (e.g. encephalitis or post-encephalitic encephalopathy, HIV, neurosyphilis, Lyme disease, etc.)
- Specify disease \_\_\_\_\_
- Multiple sclerosis
- Prion disease
- Traumatic brain injury (static)
- Other CNS condition (Specify in space provided below)

**Cognitive changes due to normal aging (no pathological process suspected)**

- Cognitive changes due to normal aging (no pathological process suspected)

**Primary psychiatric disease:**

- Bipolar affective disorder
- Major depression
- Schizophrenia
- Other primary psychiatric disease (Specify in space provided below)

**Toxic-metabolic encephalopathy:**

- Hypoxic-ischemic encephalopathy
- Nutritional deficiency (e.g. Vitamin B12, folate, thiamine)
- Polypharmacy or prescription drug side effects
- Primary systemic illness (e.g. hypo/hyperglycemia, CHF, COPD, kidney or liver failure, hypothyroidism, etc.)
- Substance abuse (alcohol or recreational drugs)
- Other toxic-metabolic encephalopathy (Specify in space provided below)

**Primary sleep disorder (e.g. insomnia, sleep apnea, etc.)**

- Primary sleep disorder (e.g. insomnia, sleep apnea, etc.)

**Other Diagnosis**

- Other diagnosis (Specify in space provided below)

**DIFFERENTIAL DIAGNOSIS.**

**14. Please enter the MOST likely etiologic cause of cognitive impairment**

Complete list will pop up

- a. If diagnosis listed above is among these, this question will appear:**  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 -----

**b. Indicate your confidence in your primary diagnosis:**

Not at all confident										Certain
	1	2	3	4	5	6	7	8	9	10
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**15. Please enter at least one (and up to 3) additional items on your current differential diagnosis, in your perceived order of likelihood.**

Complete list will pop up

- a. Additional differential diagnosis**
- i. If diagnosis listed above is among these, this question will appear:**  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 -----

**ii. Do you wish to add another diagnosis?**  
 Yes       No

Complete list will pop up

- b. Additional differential diagnosis (optional)**
- i. If diagnosis listed above is among these, this question will appear:**  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 -----

**ii. Do you wish to add another diagnosis?**  
 Yes       No

Complete list will pop up

- c. Additional differential diagnosis (optional)**
- i. If diagnosis listed above is among these, this question will appear:**  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 -----

**16. Please rate your estimated likelihood that AD pathology is present and causing or contributing to cognitive symptoms:**

Definitely not										Certain
	1	2	3	4	5	6	7	8	9	10
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**MANAGEMENT PLAN**

**INSTRUCTIONS:**

*Throughout this section, respond ASSUMING THAT YOUR PATIENT COULD NOT HAVE AN AMYLOID PET SCAN at any time in the near future.*

*The post-PET form, which will be due approximately 90 days after your patient has the A $\beta$ PET scan, will ask which items from this pre-PET management plan have been implemented.*

*Non-pharmaceutical interventions include counseling, new testing or imaging, new referrals to specialists or to clinical trials for cognitive conditions. You may also specify other interventions.*

*Pharmaceutical interventions include drugs or vitamins to treat the complaint with which this patient presented.*

**17. If your patient could not have an A $\beta$ PET scan, what would your management plan be at this time? (Consider both pharmaceutical and non-pharmaceutical interventions when answering this first question in this section.)**

- Watchful waiting only (i.e. The patient is not already taking drugs for cognition; I plan no drug additions or adjustments; and no new diagnostic tests, counselling or other referrals).
- I would recommend both non-pharmaceutical and either new pharmaceutical interventions or my patient is already taking drugs for their cognitive condition. (Select at least one option from Question 17a and at least one from 17b.)
- I would recommend non-pharmaceutical intervention(s), but no new drugs and the patient is not already taking drugs for their cognitive condition. (Select at least one option from Question 17a but do not respond to Question 17b.)
- I would recommend new or modified pharmaceutical intervention(s), or my patient is already taking drugs for their cognitive condition. I do not recommend any new diagnostic tests, counselling or other referrals. (Do not respond to Question 17a, but select at least one item from Question 17b.)

**17a. NON-PHARMACEUTICAL MANAGEMENT**

NON-PHARMACEUTICAL INTERVENTIONS	17a. Would you recommend this action?
(See next table/questions for drug management)	
<b>Counseling for safety, planning &amp; social support</b>	
Counseling about safety precautions (home safety, medication monitoring, driving)	<input type="checkbox"/> Recommend
Counseling about financial/medical decision making, advanced directives	<input type="checkbox"/> Recommend
Referral to community patient/caregiver support resources (e.g. social work, Alzheimer’s Association, Family caregiver Alliance, etc.)	<input type="checkbox"/> Recommend
Other (specify) – free text for pilot testing	<input type="checkbox"/> Recommend
Specify other counseling:	
<b>Additional diagnostic procedures</b>	
Neuropsychological testing referral	<input type="checkbox"/> Recommend
<b>Imaging (brain/head)</b>	
CT/CTA with/without contrast	<input type="checkbox"/> Recommend
MRI/MRA with/without contrast	<input type="checkbox"/> Recommend
Brain FDG-PET	<input type="checkbox"/> Recommend
DaTscan (Parkinson’s disease)	<input type="checkbox"/> Recommend
SPECT for regional cerebral perfusion	<input type="checkbox"/> Recommend
Other imaging (free text for pilot testing)	<input type="checkbox"/> Recommend
Specify other imaging:	
<b>Genetic tests</b>	
ApoE genotyping	<input type="checkbox"/> Recommend
Autosomal dominant mutations for AD	<input type="checkbox"/> Recommend
Autosomal dominant mutations for other conditions	<input type="checkbox"/> Recommend
<b>Laboratory testing (non-imaging)</b>	
Lumbar puncture:	
AD CSF biomarkers (CSF A $\beta$ 42, total tau, phosphorylated tau)	<input type="checkbox"/> Recommend
Other CSF studies	<input type="checkbox"/> Recommend
Serologic (RPR, HIV, auto-antibodies)	<input type="checkbox"/> Recommend
<b>Other Tests</b>	
EEG	<input type="checkbox"/> Recommend
Polysomnography	<input type="checkbox"/> Recommend
Other Tests	<input type="checkbox"/> Recommend
Specify other test:	

<b>NON-PHARMACEUTICAL INTERVENTIONS</b> <i>(See next table/questions for drug management)</i>		<b>17a. Would you recommend this action?</b> <i>For this question, you should assume that the patient DOES NOT HAVE ACCESS TO AMYLOID PET</i>
<b><i>Referral to non-pharmacological interventions</i></b>		
Other specialist (e.g. psychiatrist, sleep medicine)	<input type="checkbox"/> Recommend	
Surgical intervention (e.g. shunting for hydrocephalus)	<input type="checkbox"/> Recommend	
Substance abuse treatment/support programs	<input type="checkbox"/> Recommend	
Physical, occupational or speech therapy rehabilitation	<input type="checkbox"/> Recommend	
Cognitive rehabilitation	<input type="checkbox"/> Recommend	
<b><i>Clinical trial referral</i></b>		
Drug therapy or other therapeutic trial for AD (includes amyloid (+) MCI)	<input type="checkbox"/> Recommend	
Drug therapy or other therapeutic trial for non-AD disorder (please specify)	<input type="checkbox"/> Recommend	
Specify other type of clinical trial:		

**17b. PHARMACEUTICAL MANAGEMENT**

**INSTRUCTIONS:**

*a. ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time.*

*b. For any drug your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.*

<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>17.b.i. ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time</b>	<b>17.b.ii. For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing this drug</b>
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
Memantine	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
<b>Neuropsychiatric drugs impacting cognition</b>		
Anti-depressants, mood stabilizers	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
Anti-psychotics	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
Sedatives/sleep aids	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
<b>Non-neuropsychiatric drugs impacting cognition</b>		
Anti-cholinergic drugs, opiates, muscle relaxants, etc.	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
<b>Non-neurology/psychiatric pharmacologic therapies*</b>		
Treatment for medical/vascular risk factors (e.g. anti-platelets, anti-hypertensives, diabetes medications, lipid lowering, etc.)	<input type="radio"/> Currently taking <input type="radio"/> Recommend starting at this time	<input type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop



<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>17.b.i. ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time</b>	<b>17.b.ii. For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing this drug</b>
<b>Other neurologic condition</b>		
Treatment for Parkinson’s Disease (e.g. carbidopa/levodopa, dopamine agonists, MAO-B inhibitors, others)	<ul style="list-style-type: none"> <li><input type="radio"/> Currently taking</li> <li><input type="radio"/> Recommend starting at this time</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Continue</li> <li><input type="radio"/> Adjust</li> <li><input type="radio"/> Stop</li> </ul>
Treatment for Epilepsy (i.e. anti-epileptics)	<ul style="list-style-type: none"> <li><input type="radio"/> Currently taking</li> <li><input type="radio"/> Recommend starting at this time</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Continue</li> <li><input type="radio"/> Adjust</li> <li><input type="radio"/> Stop</li> </ul>
<b>Targeted therapies</b>		
Immunosuppressant (auto-immune/ inflammatory encephalopathy)	<ul style="list-style-type: none"> <li><input type="radio"/> Currently taking</li> <li><input type="radio"/> Recommend starting at this time</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Continue</li> <li><input type="radio"/> Adjust</li> <li><input type="radio"/> Stop</li> </ul>
Vitamin repletion (nutritional deficiency)	<ul style="list-style-type: none"> <li><input type="radio"/> Currently taking</li> <li><input type="radio"/> Recommend starting at this time</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Continue</li> <li><input type="radio"/> Adjust</li> <li><input type="radio"/> Stop</li> </ul>
Antimicrobials (infectious encephalopathy)	<ul style="list-style-type: none"> <li><input type="radio"/> Currently taking</li> <li><input type="radio"/> Recommend starting at this time</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Continue</li> <li><input type="radio"/> Adjust</li> <li><input type="radio"/> Stop</li> </ul>

**CERTIFICATIONS**

18. *All of the actions and prescriptions you planned are listed below. Please certify that this represents your complete management plan, if you could not order an AβPET scan.*

I certify that the list above is my complete management plan for this patient, assuming Amyloid PET were unavailable at this time.

I wish to make changes to my selections. Return to management plan questions.

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## Post-PET Clinical Assessment Form

### POST-PET CLINICAL ASSESSMENT FORM

*This form is used to record the revised diagnosis and actual management plan at 90 days post-PET clinical visit (allowable range is 75-105 days), now incorporating amyloid PET results. This form must be submitted within 15 days of the patient's Post-PET clinical visit.*

### FOLLOW-UP VISIT STATUS

*If 90-day follow-up cannot be completed because the patient died, withdrew from care by the dementia specialist, withdrew consent, or was lost to follow-up, the specific reasons must be recorded below.*

#### **1. Was the follow-up visit completed?**

- No (Complete question below, then complete the rest of the form with any information you have about your plan for this patient.)

#### **a. Specify the reason the 90-day follow up was not completed (check the most important reason):**

- Participant died

Date of death      \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

Date of death unknown

- Withdrew from care of dementia specialist
- Withdrew consent for participation in the IDEAS Study
- Was lost to follow up (*Dementia expert or designee is expected to make a minimum of three attempts to contact participant and/or proxy before declaring the participant lost to follow-up.*)

- Yes

#### **b. Date of clinic visit or patient contact: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_**

*Days since PET scan* \_\_\_\_\_ (*calculated by system*)

#### **c. If days since PET scan <75 or >105, indicate the reason(s) follow-up visit was not completed within the expected timeframe, and then complete the rest of the form:**

- Patient or caregiver was unable to make arrangements to return within window
- Patient developed intercurring illness that prevented return within window
- Dementia specialist was unavailable within window
- Other, specify: \_\_\_\_\_

#### **d. Was this follow-up visit a face-to-face meeting between the treating physician and the patient?**

- Yes
- No (Complete questions below to explain this protocol deviation. Note that some IRBs require reporting of protocol deviations either immediately or in an annual progress report.)

**d.1 If you, the physician who enrolled this case, did not see your patient for a face-to-face consultation, indicate how you collected the data for the Post-PET follow-up form (CHECK ALL THAT APPLY):**

- I spoke with the patient and/or patient's proxy via telephone
  - i. With whom did you speak? (CHECK ALL THAT APPLY):
    - Patient
    - Family member
    - Patient's care provider
    - Other proxy for patient

Role: \_\_\_\_\_

Proxy first name: \_\_\_\_\_

Proxy last name: \_\_\_\_\_

ii. What was the approximate duration of the call in minutes? \_\_\_\_\_

iii. The protocol requires that data for the Post-PET form be collected by the enrolling dementia expert physician. Please certify that you, the physician who enrolled this patient, collected the data yourself via telephone:

- I certify that I collected the data personally
- I did not collect the data myself

- Other method of gathering the data (*NOTE: Your response will be reviewed by IDEAS investigators to determine whether the method is acceptable. This may affect your final payment.*)

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**d.2 Why was it not possible to see the patient face-to-face?**

- Patient moved out of the area or was travelling during the allowed time window.
- Patient's physical health prevented a visit.
- Appointment could not be scheduled within the allowed time window.
- Other \_\_\_\_\_

**2. Please specify the results of the amyloid PET scan, as you understand them (select one):**

- Positive for cortical beta-amyloid
- Equivocal / Indeterminate for cortical beta amyloid
- Negative for cortical beta-amyloid
- Uninterpretable or technically inadequate study

**3. Did the patient, family or proxy report any adverse effects due to learning amyloid scan result?**

- No (*Skip to question 4*)
  - Yes (*Please describe the adverse effects of learning results of amyloid PET scan.*)
- 

**4. Since the date of the PET scan, has this patient**

**a. had any hospital admissions?**

- Yes
- No

**b. had any visits to an emergency room (in hospital or free standing, but not urgent care)?**

- Yes
- No

**DIFFERENTIAL DIAGNOSIS**

*PRIORITIZE your differential diagnosis of your patient's cognitive condition using this long list of options. For your convenience you may view the entire list in a separate window or print a copy of it for reference.*

- You will be asked to **SELECT** the **MOST** likely etiologic cause of the condition, given the results of the amyloid PET scan.
- Then you will be asked to **SELECT** at least one, and up to 3, other causes from this list.

*We have grouped the options by category, and alphabetized entries within category. Several categories include an option of "other." If "other" is selected, you will be asked to specify with free text the other cause of the condition.*

**Code Table for Differential Diagnoses**

**Neurodegenerative:**

**Alzheimer’s disease (please specify below):**

- AD, clinically typical (memory-predominant)
- AD, clinically atypical (non-amnestic)
- AD, mixed pathology (e.g. mixed vascular, Lewy body, etc.)
- AD, NOS

**Non-AD neurodegenerative:**

- Chronic traumatic encephalopathy (CTE)
- Diffuse Lewy body disease
- Frontotemporal dementia (includes behavioral and language-predominant presentations, corticobasal syndrome and progressive supranuclear palsy)
- Hippocampal sclerosis
- Parkinson’s disease
- Vascular cognitive impairment (includes: multi-infarct, subcortical, intracerebral hemorrhage, other)
- Other non-AD neurodegenerative disease (Specify in space provided below)

**Other CNS conditions:**

- Auto-immune encephalopathy (e.g. CNS lupus, cerebral vasculitis, limbic encephalitis, paraneoplastic syndrome, etc.)
- Brain mass
- Encephalopathy NOS
- Epilepsy
- Hydrocephalus (idiopathic or secondary)
- Infectious encephalopathy (e.g. encephalitis or post-encephalitic encephalopathy, HIV, neurosyphilis, Lyme disease, etc.)
- Specify disease* \_\_\_\_\_
- Multiple sclerosis
- Prion disease
- Traumatic brain injury (static)
- Other CNS condition (Specify in space provided below)

**Cognitive changes due to normal aging:**

- Cognitive changes due to normal aging (no pathological process suspected)

**Primary psychiatric disease:**

- Bipolar affective disorder
- Major depression
- Schizophrenia
- Other primary psychiatric disease (Specify in space provided below)

**Toxic-metabolic encephalopathy:**

- Hypoxic-ischemic encephalopathy
- Nutritional deficiency (e.g. Vitamin B12, folate, thiamine)
- Polypharmacy or prescription drug side effects
- Primary systemic illness (e.g. hypo/hyperglycemia, CHF, COPD, kidney or liver failure, hypothyroidism, etc.)
- Substance abuse (alcohol or recreational drugs)
- Other toxic-metabolic encephalopathy (Specify in space provided below)

**Primary sleep disorder**

- Primary sleep disorder (e.g. insomnia, sleep apnea, etc.)

**Other Diagnosis**

- Other diagnosis

**DIFFERENTIAL DIAGNOSIS.**

5. Please enter the **MOST** likely etiologic cause of cognitive impairment

Complete list will pop up

- a. *If diagnosis listed above is among these, this question will appear:*  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 \_\_\_\_\_

b. **Indicate your confidence in your primary diagnosis:**

Not at all confident										Certain
	1	2	3	4	5	6	7	8	9	10
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

6. You may select up to 3 additional diagnoses for this patient. **Enter additional diagnoses in your perceived order of likelihood.**

- Do you wish to add another diagnosis? (optional)  
 Yes                       No

a. **Additional differential diagnosis**

Complete list will pop up

- i. *If diagnosis listed above is among these, this question will appear:*  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 \_\_\_\_\_

- ii. **Do you wish to add another diagnosis?**  
 Yes                       No

b. **Additional differential diagnosis (optional)**

Complete list will pop up

- i. *If diagnosis listed above is among these, this question will appear:*  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 \_\_\_\_\_

- ii. **Do you wish to add another diagnosis?**  
 Yes                       No

c. **Additional differential diagnosis (optional)**

Complete list will pop up

- i. *If diagnosis listed above is among these, this question will appear:*  
 Other non-AD neurodegenerative disease, Other CNS condition, Other primary psychiatric disease, Other toxic-metabolic encephalopathy, or Other diagnosis  
**Specify your differential diagnosis:**  
 \_\_\_\_\_

**7. Please rate your estimated likelihood that AD pathology is present and causing or contributing to cognitive symptoms:**

Not at all likely										Certain
1	2	3	4	5	6	7	8	9	10	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



## **8. MANAGEMENT PLAN**

This section consists of 5 parts.

PART 1: Overview of Management Plan

PART 2: Status of Non-Pharmaceutical Interventions recommended on the Pre-PET form.

PART 3: NEW Non-Pharmaceutical Interventions recommended since the PET scan.

PART 4: Status of Pharmaceutical Interventions recommended on the Pre-PET form.

PART 5: NEW Pharmaceutical Interventions recommended since the PET scan.

You will be reminded of your selections on the Pre-PET form before each Part. You will only be shown parts that are applicable based on your Pre-PET responses and answers you give in Part 1.

### **PART 1: OVERVIEW OF MANAGEMENT PLAN**

***THIS IS THE MANAGEMENT PLAN YOU REPORTED PRIOR TO THE A $\beta$ PET SCAN.***

***Non-Pharmaceutical Interventions***

***Pharmaceutical Interventions***

*The Electronic Data Collection System will present items in this section **ADAPTIVELY**, based on your responses on the Pre-PET form. Some questions will not be available if no response is appropriate given your Pre-PET Management Plan.*

**If Watchful waiting was the plan you reported for this patient on the pre-PET form. Select the option from this list that matches your current plan.**

- Watchful waiting is still the plan. I have **NOT** recommended any **NEW** counselling, referrals to specialists or clinical trials for cognitive impairment, additional testing, or pharmaceutical therapy.
- Watchful waiting is no longer the plan. Since the PET scan, I have recommended **BOTH** non-pharmaceutical and pharmaceutical interventions.
- Watchful waiting is no longer the plan. Since the PET scan, **I have recommended non-pharmaceutical interventions** (counselling, referrals to specialists or clinical trials, or additional testing.) I have not recommended pharmaceutical intervention.
- Watchful waiting is no longer the plan. Since the PET scan, **I have recommended pharmaceutical interventions** (i.e. prescribed drugs or vitamins for cognitive condition) I have not recommended non-pharmaceutical interventions such as counselling, additional testing, referrals to specialists or referral to clinical trials.

You indicated at least one intervention, either non-pharmaceutical or pharmaceutical, on the Pre-PET form as your plan for managing this patient. **Have you ADDED any NEW interventions since the PET scan?**

- I have added **BOTH non-pharmaceutical and pharmaceutical interventions** to the management plan for this patient since the PET scan.
- I have added **NEW non-pharmaceutical interventions** to the management plan for this patient since the PET scan, but I have **NOT changed the plan for pharmaceutical management**.
- I have added **NEW pharmaceutical interventions** to the management plan for this patient since the PET scan, but I have **NOT added any non-pharmaceutical interventions** (e.g. referrals to specialists or clinical trials, additional tests, or counseling.)
- I have **NOT ADDED ANY NEW INTERVENTIONS** that were not part of the Pre-PET management plan for this patient.

**PART 2: STATUS OF NON-PHARMACEUTICAL INTERVENTIONS SELECTED ON THE PRE-PET FORM**

*Instructions:* Report the status of the non-pharmaceutical interventions you included in this patient's Pre-PET management plan. Complete EVERY ROW of this table, as each of the items shown is an intervention you selected on the Pre-PET form.

*These are the items you selected on the Pre-PET form for Non-Pharmaceutical Interventions*

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions that were part of your Pre-PET management plan for this patient.</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
<b>Counseling for safety, planning &amp; social support</b>		
Counseling about safety precautions (home safety, medication monitoring, driving, whether to continue working)	<ul style="list-style-type: none"> <li>○ Implemented                             <ul style="list-style-type: none"> <li>○ Completed as recommended on Pre-PET</li> <li>○ Significantly modified from Pre-PET</li> </ul> </li> <li>○ Not implemented</li> </ul>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<b>7a. Status of interventions that were part of your Pre-PET management plan for this patient.</b>	<b>7b. Did the amyloid PET results contribute significantly to this decision?</b>
Counseling about financial/medical decision making, advanced directives	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Referral to community patient/caregiver support resources (e.g. social work, Alzheimer’s Association, Family caregiver Alliance, etc.)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other (specify)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Additional diagnostic procedures</b>		
Neuropsychological testing referral	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Imaging (brain/head)</b>		
CT/CTA with/without contrast	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
MRI/MRA with/without contrast	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Brain FDG-PET	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
DaTscan (Parkinson’s disease)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions that were part of your Pre-PET management plan for this patient.</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
SPECT for regional cerebral perfusion	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other imaging	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Laboratory testing (non-imaging)</b>		
Lumbar puncture		
AD CSF biomarkers (CSF Aβ42, total tau, phosphorylated tau)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other CSF studies	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Serologic (RPR, HIV, auto-antibodies)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Genetic tests</b>		
ApoE genotyping	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Autosomal dominant mutations for AD	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Autosomal dominant mutations for other conditions	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions that were part of your Pre-PET management plan for this patient.</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
<b>Other testing</b>		
EEG	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Polysomnography	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other (specify)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Referral to non-pharmacological interventions</b>		
Other specialist (e.g. psychiatrist, sleep medicine)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Surgical intervention (e.g. shunting for hydrocephalus)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Substance abuse treatment/support programs	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Physical, occupational or speech therapy rehabilitation	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Cognitive rehabilitation	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions that were part of your Pre-PET management plan for this patient.</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
<b>Clinical trial referral</b>		
Drug therapy or other therapeutic trial for AD (includes amyloid (+) MCI)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Drug therapy or other therapeutic trial for non-AD disorder (please specify)	<input type="radio"/> Implemented <input type="radio"/> Completed as recommended on Pre-PET <input type="radio"/> Significantly modified from Pre-PET <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

**PART 3: NEW NON-PHARMACEUTICAL INTERVENTIONS RECOMMENDED AFTER THE PET SCAN WAS COMPLETED**

*Instructions:* Complete only the rows of this table for interventions you **recommended** since the PET scan. Items that were part of your pre-PET management plan are not shown here. List **all recommended interventions**, even if they have not yet been implemented.

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
<b>Counseling for safety, planning &amp; social support</b>		
Counseling about safety precautions (home safety, medication monitoring, driving, whether to continue working)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Counseling about financial/medical decision making, advanced directives	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Referral to community patient/caregiver support resources (e.g. social work, Alzheimer’s Association, Family caregiver Alliance, etc.)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<b>7a. Status of interventions</b>	<b>7b. Did the amyloid PET results contribute significantly to this decision?</b>
Other (specify)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Specify other counseling, planning or social support:		
<b>Additional diagnostic procedures</b>		
Neuropsychological testing referral	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Imaging (brain/head)</b>		
CT/CTA with/without contrast	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
MRI/MRA with/without contrast	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Brain FDG-PET	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
DaTscan (Parkinson's disease)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
SPECT for regional cerebral perfusion	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other imaging	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
<b>Laboratory testing (non-imaging)</b>		
Lumbar puncture		
AD CSF biomarkers (CSF Aβ42, total tau, phosphorylated tau)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other CSF studies	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Serologic (RPR, HIV, auto-antibodies)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Genetic tests</b>		
ApoE genotyping	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Autosomal dominant mutations for AD	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Autosomal dominant mutations for other conditions	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Other testing</b>		
EEG	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No



<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
Polysomnography	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Other	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Specify other testing:		
<b>Referral to non-pharmacological interventions</b>		
Other specialist (e.g. psychiatrist, sleep medicine)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Surgical intervention (e.g. shunting for hydrocephalus)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Substance abuse treatment/support programs	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Physical, occupational or speech therapy rehabilitation	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Cognitive rehabilitation	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Clinical trial referral</b>		
Drug therapy or other therapeutic trial for AD (includes amyloid (+) MCI)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>NON-PHARMACEUTICAL INTERVENTIONS</b>	<i>7a. Status of interventions</i>	<i>7b. Did the amyloid PET results contribute significantly to this decision?</i>
Drug therapy or other therapeutic trial for non-AD disorder (please specify)	<input type="checkbox"/> Recommended  <i>Status</i> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Specify other type of clinical trial		

**PART 4: STATUS OF PHARMACEUTICAL INTERVENTIONS SELECTED ON THE PRE-PET FORM**

**Instructions:** Report the status of the pharmaceutical interventions you included in this patient's Pre-PET management plan. Complete EVERY ROW of this table, as each of the drugs shown is one you selected on the Pre-PET form.

*These are the items you selected on the Pre-PET form for  
Pharmaceutical Interventions*

*Your Pre-PET response is shown in the left-most column. Status options in the middle column will vary depending upon your Pre-PET selection. Respond the the right-most column regardless of your answer in the middle column.*

<b>PHARMACEUTICAL INTERVENTIONS</b>	<i>8a. Status of Drug</i>	<i>8b. Did the amyloid PET results contribute significantly to this decision?</i>
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<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>8a. Status of Drug</b>	<b>8b. Did the amyloid PET results contribute significantly to this decision?</b>
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine) <ul style="list-style-type: none"> <li>○ Patient already on drug; recommended continuing</li> <li>○ Patient already on drug; recommended adjusting</li> <li>○ Patient already on drug; recommended stopping</li> <li>○ Recommended starting this drug</li> </ul>	<ul style="list-style-type: none"> <li>○ Patient [<i>action from pre-PET</i>] this drug as recommended on the Pre-PET form               <p>Actions from Pre-PET are these:</p> <ul style="list-style-type: none"> <li>○ Continued</li> <li>○ Adjusted</li> <li>○ Stopped</li> <li>○ Started</li> </ul> </li> <li>○ Management varied from Pre-PET [<i>Action options available will depend upon your responses on the pre-PET form.</i>]               <ul style="list-style-type: none"> <li>○ Continued</li> <li>○ Adjusted</li> <li>○ Stopped</li> <li>○ Started</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
Memantine	<i>Options are as described above for each item in the table.</i>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
<b>Neuropsychiatric drugs impacting cognition</b>		
Anti-depressants, mood stabilizers	<i>Options are as described above for each item in the table.</i>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
Anti-psychotics	<i>Options are as described above for each item in the table.</i>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
Sedatives/sleep aids	<i>Options are as described above for each item in the table.</i>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
<b>Non-neuropsychiatric drugs impacting cognition</b>		
Anti-cholinergic drugs, opiates, muscle relaxants, etc.	<i>Options are as described above for each item in the table.</i>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
<b>Non-neurology/psychiatric pharmacologic therapies*</b>		
Medical/vascular risk factors (e.g. anti-platelets, anti-hypertensives, diabetes medications, lipid lowering, etc.)	<i>Options are as described above for each item in the table.</i>	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>

<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>8a. Status of Drug</b>	<b>8b. Did the amyloid PET results contribute significantly to this decision?</b>
<b>Other neurologic condition</b>		
Treatment for Parkinson’s Disease (e.g. carbidopa/levodopa, dopamine agonists, MAO-B inhibitors, others)	<i>Options are as described above for each item in the table.</i>	<input type="radio"/> Yes <input type="radio"/> No
Treatment for Epilepsy (i.e. anti-epileptics)	<i>Options are as described above for each item in the table.</i>	<input type="radio"/> Yes <input type="radio"/> No
<b>Targeted therapies</b>		
Immunosuppressant (auto-immune/inflammatory encephalopathy)	<i>Options are as described above for each item in the table.</i>	<input type="radio"/> Yes <input type="radio"/> No
Vitamin repletion (nutritional deficiency)	<i>Options are as described above for each item in the table.</i>	<input type="radio"/> Yes <input type="radio"/> No
Antimicrobials (infectious encephalopathy)	<i>Options are as described above for each item in the table.</i>	<input type="radio"/> Yes <input type="radio"/> No

**PART 5: NEW PHARMACEUTICAL INTERVENTIONS RECOMMENDED AFTER THE Aβ PET SCAN**

**Instructions:** Complete only the rows of this table for interventions you **recommended** since the PET scan. Items that were part of your pre-PET management plan are not shown here. List **all recommended interventions**, even if they have not yet been implemented.

<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>8a. Status of Drug</b>	<b>8b. Did the amyloid PET results contribute significantly to this decision?</b>
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>8a. Status of Drug</b>	<b>8b. Did the amyloid PET results contribute significantly to this decision?</b>
Memantine	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Neuropsychiatric drugs impacting cognition</b>		
Anti-depressants, mood stabilizers	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Anti-psychotics	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Sedatives/sleep aids	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Non-neuropsychiatric drugs impacting cognition</b>		
Anti-cholinergic drugs, opiates, muscle relaxants, etc.	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Non-neurology/psychiatric pharmacologic therapies*</b>		
Medical/vascular risk factors (e.g. anti-platelets, anti-hypertensives, diabetes medications, lipid lowering, etc.)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
<b>Other neurologic condition</b>		
Treatment for Parkinson’s Disease (e.g. carbidopa/levodopa, dopamine agonists, MAO-B inhibitors, others)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Treatment for Epilepsy (i.e. anti-epileptics)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

<b>PHARMACEUTICAL INTERVENTIONS</b>	<b>8a. Status of Drug</b>	<b>8b. Did the amyloid PET results contribute significantly to this decision?</b>
<b>Targeted therapies</b>		
Immunosuppressant (auto-immune/inflammatory encephalopathy)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Vitamin repletion (nutritional deficiency)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No
Antimicrobials (infectious encephalopathy)	<input type="checkbox"/> Recommended  <u>Status</u> <input type="radio"/> Implemented <input type="radio"/> Not implemented	<input type="radio"/> Yes <input type="radio"/> No

9. *A list of the non-pharmaceutical and pharmaceutical interventions you selected on the Pre-PET form, the status of those actions as indicated above, and additional interventions selected above appear in the boxes below. Please certify that these represent your complete management plan for your patient.*

<b>Pre-PET Management Plan</b>	<b>Status of Pre-PET Plan</b>	<b>New Interventions</b>
Non-Pharmaceutical Interventions	Non-Pharmaceutical Interventions	Non-Pharmaceutical Interventions
1. 2. 3. 4. ...	1. 2. 3. 4. ...	1. 2. ...
Pharmaceutical Interventions	Pharmaceutical Interventions	Pharmaceutical Interventions
5. 6. 7. 8. ...	1. 2. 3. 4. ...	1. 2. ...

I certify that the list above is my complete management plan for this patient, and that the status of items I had selected on the Pre-PET form are accurate.

I wish to make changes to my selections.  
Return to question 7.

**PRA Disclosure Statement**  
 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1305. The time required to complete this information collection is estimated to average thirty (30) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

## Incomplete Study Form

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- This form is to be completed when the patient is unable to complete the study.
- 

### **1. Reason this patient was unable to complete the study**

- Patient died prior to PET scan
- Patient died after PET scan  
*(Please complete first part of the Post-PET Clinical Assessment Form)*
- Patient withdrew study consent
- Patient lost to follow-up
- Further care of patient will be handled by physician not in study
- Other \_\_\_\_\_

#### **PRA Disclosure Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1305. The time required to complete this information collection is estimated to average thirty (30) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.