

Pre-PET Clinical Assessment Form

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 <u>as if amyloid PET imaging were not available to your patient</u>. 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;

 \circ Yes \circ 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;

 \circ Yes \circ No

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

 \circ Yes \circ No

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

 \circ Yes \circ No



PATIENT DEMOGRAPHICS

2.	 Please specify marital status: Married or domestic partnership Widowed Divorced or separated Never Married 					
3.						
	With whom does patient live (check all that apply): □ Spouse or domestic partner □ Child(ren) □ Other relative □ Caregiver/Household worker/Assisted Living □ Friend/Roomate/Other					
4.	Please specify the highest level of education: O Doctoral or professional degree O Master's Degree O Bachelor's Degree O Some college or associate degree O High school graduate (including equivalency) O Some high school O Grade school O No formal education					
5.	 What is patient's primary language? English Spanish Other, specify					
6.	In what language was the consent form completed?EnglishSpanish					



PATIENT CHARACTERISTICS

7.	<i>Ple</i> o	ase specify the level of cognitive impairment: Mild cognitive impairment Amnestic (single domain or mixed) Non-amnestic (single domain or mixed) Dementia						
8.	a.	lease enter MMSE and/or MoCA score at last clinical evaluation: . MMSE: MoCA:						
9.		Confirm the patient's amyloid status is <u>not</u> 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 Aβ, or previous testing was equivocal						
10.	Yea	ar of onset of cognitive impairment: Year unknown:						
11.	Ind	licate 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 month (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 Apolipoprotiein 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 Aβ42, total tau, phosphorylated tau) FDG-PET SPECT- Dopamine transporter (DaTscan) SPECT- cerebral perfusion Polysomnogram Other brain imaging (Specify) Other, specify: 						
12.	(<i>Ch</i>	ase indicate whether the patient is currently taking the following AD medications neck all that apply): Cholinesterase inhibitor (e.g. donepezil, rivastigimine, galantamine) Memantine						



PATIENT MEDICAL HISTORY

13.			check all of the following items that are part of the patient's past or current medical history:
	0		clinically relevant medical history
	0	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:
			o Stroke or TIA occurred within past 24 months
			o 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:
			o TBI occurred within past 24 months
			o TBI occurred more than 24 months ago
			Tobacco use
			Please indicate timing of tobacco use:
			o Past
			o Current
			Family history of dementia
			o Family member diagnosed with Alzheimer's Disease
			o 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):

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

Non-AD neurodegenerative (please specify below):

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

Other CNS conditions:

- O Auto-immune encephalopathy (e.g. CNS lupus, cerebral vasculitis, limbic encephalitis, paraneoplastic syndrome, etc.)
- O Brain mass
- O Encephalopathy NOS
- O Epilepsy
- O Hydrocephalus (idiopathic or secondary)
- O Infectious encephalopathy (e.g. encephalitis or post-encephalitic encephalopathy, HIV, neurospyphilis, Lyme disease, etc.)

 Specify disease
- O Multiple sclerosis
- O Prion disease
- O Traumatic brain injury (static)
- O Other CNS condition (Specify in space provided below)

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

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

Primary psychiatric disease:

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

Toxic-metabolic encephalopathy:

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

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

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

Other Diagnosis

O Other diagnosis (Specify in space provided below)

Complete list will pop up



DIFFERENTIAL DIAGNOSIS.

14. <i>Pl</i> .	ease	enter the	MOST like	elv etinlogi	r cause of	coonitive	imnairmer	1 <i>t</i>	Com	plete list will pop up	
	lease enter the MOST likely etiologic cause of cognitive impairment If diagnosis listed above is among these, this question will appear: Other non-AD neurodegenerative disease, Other CNS condition, Other primary disease, Other toxic-metabolic encephalopathy, or Other diagnosis Specify your differential diagnosis:								nary psycl	y psychiatric	
b.	Inc	dicate you	r confiden	ce in your [primary di	agnosis:					
Not at										Cartain	
confide	eni	2	3	4	5	6	7	8	9	Certain 10	
0		0	0	0	0	0	0	0	0	0	
		enter at le erceived or		nd up to 3) elihood.	additiona	l items on	your curre	ent differ	ential dia	gnosis, <u>in</u>	
a.	Ad	ditional di	fferential	diagnosis					Com	plete 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? 									
		o Yes		o No							
<i>b</i> .	Ad	ditional di	fferential	diagnosis (optional)				Com	plete 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: 									
	;;	Do you w	sigh to add	l another di	iagnasis?						
	и.	o Yes	ish to aud	o No	ugnosis:						
		0 165		0 110					Com	plete list will pop up	
c.		If diagno Other not disease,	osis listed on the contract of	diagnosis (above is am codegenerat c-metabolic ential diagr	ong these, ive disease encephalo	, Other Cl	NS condition	on, Other			
		rate your ive sympto		likelihood i	that AD po	thology is	s present a	nd causin	g or con	tributing to	
Dei	finite	ly									
	not	2	2	A	Ē	6	7	0	0	Certain	
	1	2	3	4	5	6	7	8	9	10 o	
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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.)
 - o 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.)
 - o 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.)).
 - o 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 (See next table/questions for drug management)	17a. Would you recommend this action? For this question, you should assume that the patient DOES NOT HAVE ACCESS TO AMYLOID PET		
Counseling for safety, planning & social support			
Counseling about safety precautions (home safety, medication monitoring, driving)	☐ Recommend		
Counseling about financial/medical decision making, advanced directives	☐ Recommend		
Referral to community patient/caregiver support resources (e.g. social work, Alzheimer's Association, Family caregiver Alliance, etc.)	☐ Recommend		
Other (specify) – free text for pilot testing	☐ Recommend		
Specify other counseling:			
Additional diagnostic procedures			
Neuropsychological testing referral	☐ Recommend		
Imaging (brain/head)			
CT/CTA with/without contrast	☐ Recommend		
MRI/MRA with/without contrast	☐ Recommend		
Brain FDG-PET	☐ Recommend		
DaTscan (Parkinson's disease)	☐ Recommend		
SPECT for regional cerebral perfusion	☐ Recommend		
Other imaging (free text for pilot testing)	☐ Recommend		
Specify other imaging:			
Genetic tests			
ApoE genotyping	☐ Recommend		
Autosomal dominant mutations for AD	☐ Recommend		
Autosomal dominant mutations for other conditions	☐ Recommend		
Laboratory testing (non-imaging)			
Lumbar puncture:			
AD CSF biomarkers (CSF Aβ42, total tau, phosphorylated tau)	☐ Recommend		
Other CSF studies	☐ Recommend		
Serologic (RPR, HIV, auto-antibodies)	☐ Recommend		
Other Tests			
EEG	☐ Recommend		
Polysomnography	☐ Recommend		
Other Tests	☐ Recommend		
Specify other test:			



NON-PHARMACEUTICAL INTERVENTIONS (See next table/questions for drug management)	17a. Would you recommend this action? For this question, you should assume that the patient DOES NOT HAVE ACCESS TO AMYLOID PET						
Referral to non-pharmacological interventions	Referral to non-pharmacological interventions						
Other specialist (e.g. psychiatrist, sleep medicine)	☐ Recommend						
Surgical intervention (e.g. shunting for hydrocephalus)	☐ Recommend						
Substance abuse treatment/support programs	☐ Recommend						
Physical, occupational or speech therapy rehabilitation	☐ Recommend						
Cognitive rehabilitation	☐ Recommend						
Clinical trial referral							
Drug therapy or other therapeutic trial for AD (includes amyloid (+) MCI)	☐ Recommend						
Drug therapy or other therapeutic trial for non-AD disorder (please specify)	☐ 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 <u>currently taking</u> OR that you <u>recommend starting</u> at this time.
- b. For any drug your patient is <u>already taking</u>, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.

PHARMACEUTICAL INTERVENTIONS	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	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
AD Symptomatic Drugs		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop
Memantine	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop
Neuropsychiatric drugs impacting cognition		
Anti-depressants, mood stabilizers	Currently takingRecommend starting at this time	O Continue O Adjust O Stop
Anti-psychotics	Currently takingRecommend starting at this time	ContinueAdjustStop
Sedatives/sleep aids	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop
Non-neuropsychiatric drugs impacting cognition		
Anti-cholinergic drugs, opiates, muscle relaxants, etc.	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop
Non-neurology/psychiatric pharmacologic therapies*		
Treatment for medical/vascular risk factors (e.g. antiplatelets, anti-hypertensives, diabetes medications, lipid lowering, etc.)	Currently takingRecommend starting at this time	O Continue O Adjust O Stop



PHARMACEUTICAL INTERVENTIONS	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	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	
Other neurologic condition			
Treatment for Parkinson's Disease (e.g. carbidopa/levodopa, dopamine agonists, MAO-B inhibitors, others	Currently taking Recommend starting at this time	ContinueAdjustStop	
Treatment for Epilepsy (i.e. anti-epileptics)	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop	
Targeted therapies			
Immunosuppressant (auto-immune/inflammatory encephalopathy)	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop	
Vitamin repletion (nutritional deficiency)	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop	
Antimicrobials (infectious encephalopathy)	O Currently taking O Recommend starting at this time	O Continue O Adjust O Stop	

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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 $A\beta PET$ 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.

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.