Version 1.2, January 2022



PET Imaging Facility Information and Training



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Module Overview

- Protocol Introduction: Slides 3-12
 - Including Medicare Reimbursement
- Facility and Physician Registration: Slides 13-27
- Case Specific Data Entry: Slides 28-46
 - Including Image Transmission via TRIAD
- Additional Resources: Slide 47



Important New IDEAS Information

- PET imaging facilities are not considered as participating in research, so Institutional Review Board (IRB) approval is not needed.
- Medicare will reimburse for scans based on coverage plans (typically 80% coverage provided). This study is the only way Medicare covers beneficiaries for these scans.
- As part of the New IDEAS Coinsurance Reimbursement Program, the study sponsor will pay for the unmet coinsurance associated with the amyloid PET scan for patients who receive a scan on or after January 1, 2022.
- No escrow account is needed for patient scans.
- PET image transfer will be conducted via the American College of Radiology[®] TRIAD platform.
- Emphasis on balancing racial and ethnic make-up of study population.
 - At least 4,000 of the planned 7,000 New IDEAS participants will be Black or Hispanic which may allow better understanding of amyloid PET's impact on change in management and health outcomes in diverse dementia cases.



New IDEAS Site Selection Process

- <u>Reminder</u>: Dementia Specialists and PET Imaging Facilities will be selected on a rolling basis.
 - PET Imaging facility must be <u>within 3-4</u> <u>hours</u> of an amyloid tracer supplier.
- Site Locator for Enrolled Dementia Specialists and PET Imaging Facilities: <u>https://www.ideas-study.org/Find-a-Site</u>
- Interested sites start the application by completing the New IDEAS questionnaire: <u>https://www.ideas-study.org/Getting-</u><u>Started</u>





PET Facility Requirements

- Free standing PET facilities must be PET accredited by one of the following:
 The ACR
 - The Intersocietal Accreditation Commission (IAC)
 - RadSite
- Hospital based facilities must be accredited by the Joint Commission (or another Medicare-approved hospital-based accrediting organization).
 - Not required, but recommended: PET accreditation by ACR, IAC or RadSite.
- The PET facility must document that it has experience performing brain PET, PET/CT or PET/MRI with one of the FDA-approved amyloid imaging agents or with F-18 fluorodeoxyglucose or with both in the last 12 months.
- Complete and execute a Clinical Data and Image Access Agreement with ACR.



Scanner and Tracer Requirements

- PET facilities may only participate if they have full-ring BGO, GSO, LSO or LYSO PET, PET/CT or PET/MRI scanners.
 - Partial-ring systems and dedicated NaI systems are <u>not</u> <u>eligible</u> for use in the New IDEAS Study.
- Scans must be conducted using one of the following tracers:
 - Neuraceq[™] (F-18 florbetaben)
 - Amyvid[™] (F-18 florbetapir)
 - Vizamyl[™] (F-18 flutemetamol)



Interpreting Radiologist Requirements

- Board certified by one or more of the following:
 - American Board of Radiology (Diagnostic Radiology)
 - American Board of Radiology (Nuclear Radiology)
 - American Osteopathic Board of Radiology (Diagnostic Radiology)
 - American Board of Nuclear Medicine
 - American Osteopathic Board of Nuclear Medicine
- Completed Vendor Specific Training for interpretation of amyloid images.
 - Trainings guidance available at: <u>https://www.ideas-study.org/-/media/Ideas/Files/PET-</u> <u>Facilities/Amyloid-Radiotracer-Reader-Training-Guidance.pdf</u>
- Eligible to bill Medicare for PET services.



Medicare Reimbursement

- PET imaging facility may <u>not</u> perform a New IDEAS Study PET scan until the referring physician has submitted a pre-PET clinical assessment form to the New IDEAS Study database.
- Once the PET scan has been completed and the appropriate data uploaded to the New IDEAS Study database, a system-generated notification is sent from the email address <u>NewIDEAS@acr.org</u> to the PET imaging facility administrator indicating that the case data are complete.
- These notifications should be maintained as documentation in the event that CMS opts to audit the PET imaging facility.
- After receiving the notification, the PET facility (and the interpreting physician, if technical and professional component billing are performed separately) may submit the claim for the service to the local Medicare Administrative Contractor (MAC) or MA plan as appropriate.



Medicare Reimbursement (continued)

Hospital-based PET Facilities:

The National 2021 OPPS payment for CPT code 78811 or 78814 (limited body PET or PET/CT, respectively) is \$1,305.94 - \$1,480.34, respectively (rates are adjusted by local wage indexes, so the exact payment will vary slightly based on region).

Payment for the diagnostic radiopharmaceutical is packaged into the OPPS payment amount. For hospital-based PET facilities, there is a co-payment or co-insurance associated with the procedure.

Physician Offices
and Independent
Diagnostic
Testing Facilities
(IDTFs):

For physician offices and IDTFs, payment is determined by the Medicare Physician Fee Schedule (MPFS). The technical component payment for the procedure is carrier priced but is often capped at the OPPS technical component rate (For CPT 78811 at \$1,305.94 and 78814 at \$1,480.34).

Payment for the diagnostic radiopharmaceutical is based on the invoice cost (approximately \$3,000, depending on the product used).

In the MPFS setting, all rates are subject to co-payment, co-insurance and any deductibles that the patient's Medicare plan requires. The co-payment policies for the diagnostic radiopharmaceutical differ in the MPFS setting versus the OPPS.



Coinsurance Reimbursement Program

- Review the <u>Operational Training: New IDEAS</u> <u>Coinsurance Reimbursement Program Training Module</u> for in depth training on the Coinsurance Reimbursement Program.
- All PET imaging facilities and dementia practices that choose to participate in the New IDEAS study must adhere to the <u>Coinsurance Reimbursement Program</u> <u>Policy.</u>
 - Failure to comply with this policy or requirements specified by the New IDEAS Study will result in termination of the participating PET imaging facility or dementia practice as detailed in the study's executed legal agreement.
- Additional Resources:
 - <u>Frequency Asked Questions</u>





Participant Study Timeline



Study team reviews patient Medicare claims for 12 months and up to 3 years



Training Materials

• Updated New IDEAS training materials for PET Imaging Facilities can be found at <u>https://www.ideas-study.org/During-Study/Resources</u>.

PET Imaging Facilities

- Case Report Form Packet PET Facility Version 1, December 2020
- Nuts & Bolts of Medicare Reimbursement for New IDEAS January 22, 2021
- New IDEAS Sample Claim Forms January 21, 2021
- New IDEAS Claim Denial Check List January 13, 2021
- PET Imaging of the Brain for Technologists
- Optimal Patient Prep Amyloid Brain PET (video)
- Working with Patients Being Evaluated (video)
- Patient Positioning for PET (video)
- Dose Uptake Time Scan for Amyloid Brain PET (video)



Important Portal Information

Processed via a secure, role-based online application with a two-factor authentication system (Okta)

- Each user is required to have his/her own username/password and current e-mail address for access and receipt of notifications/alerts.
- Passwords must be changed every 90 days.
- Physicians must complete their <u>own</u> data entry





Registration Overview

- Registration should only be completed if your facility was invited to the New IDEAS study by ACR staff.
- PET Facility registration is a one time event to be completed by the facility administrator (overall access).
- Each user is required to have his/her own username/password and current e-mail address for access and receipt of notifications/alerts.



Facility User Roles in the New IDEAS Portal

• To access your Facility's account in the New IDEAS Portal, your facility administrator needs to assign you a user role. (Note: a single user can have more than one role in the database).

Facility	Interpreting	Facility	Facility
Administrator	Radiologist	User	Finance User
 Automatically assigned to the person who initially submits the facility pre-registration form (next slide) Has complete administrative functionality in the New IDEAS portal Responsible for administrative duties associated with facility registration and addition of staff profile accounts Has view access to all forms and edit/submission access to all forms except Amyloid PET Assessment Form Has edit/submission access to the Coinsurance Reimbursement Form, but NOT Banking/Tax information for Facility 	 Has view, edit	 Has view access	 New role for Coinsurance
	and submission	to all forms	Reimbursement Program Only user role that has access
	access to all case	and edit/submission	to facility finance portal Responsible
	report forms Only user role that	access to all	for submitting facility banking
	has edit and	forms except	and tax information Has edit/submission access to
	submission access to	Amyloid	the Coinsurance
	Amyloid	PET Assessment	Reimbursement Form Has view only access to
	PET Assessment Form	Form	Case Registration Form
	an't accors your facilit		

IDEAS-Study.org

Can't access your facility's account? Email newideas@acr.org



Facility Registration Tutorial

Link to portal:

https://app.ideas-study.org/

I do not have an ACR ID specifically for New IDEAS

I already registered for New IDEAS

Create your ACR ID

Click here to create your ACR ID

Create

- Create your ACR ID profile.
- You will receive an email link.
- Follow slides for Administrator Login Instructions

Log in with your ACR ID

Click here to log in with your ACR ID





Facility Administrator Login Instructions



- 1. Create your account and click "Register."
- 2. Locate the 'Welcome to ACR ID' email in the email inbox you used to register and follow the one-time link to activate your account. Simply clicking on this link will activate your account (Note: check spam folder).
- 3. Return to the application's <u>home</u> page and click "Login with your ACR ID" (purple Login button).
- 4. Type in your username (email address used to create ACR ID).
- 5. Set up Okta (two-factor authentication).
- 6. Return to the login portal and login with username and two-factor authentication.

Note: You will have to utilize a 'multifactor authentication' mechanism to log in each time. This is for security purposes.



Facility Administrator Login Instructions (cont.)

Under PET Facilities Select "Register"





Pre-Registration Form

Fill out the Pre-Registration Form and click "Next"

iO	EAS		Andrew March +
New	IDEAS Study PE	T Facility Pre-registration Form	
	Thank you for your interest in parti-	ipating in the New IDEAS Study.	
	Each PET Facility participating in the Facility Number and to set up a Facilit Registration Form. The entity applying charges for PET studies. In the case o separate Facility ID number will be an	iew IDEAS Study must complete this web-based Facility Pre-Registration Form to receive a unique Administrator User ID. The Facility Administrator will then be able to log in and complete the full Fac as a FET Facility should be the entity that bits Medicare for either the technical charges or the globul f a mobile PET provider that bits Medicare directly, a separate application form must be completed a signed for each location of service.	4-digit sitty id a
	Name of PET Facility		
	PET Facility	Contact Person	
	This person will become	the PET Facility Administrator, and the official conflact person for the New ICEAS Study	
	First name	Johns	
	Last name	March	
	Email Address	amarch@aoz.org	
	HUMAN SUBJECT PROTECTION CO	URSE COMPLETION CERTIFICATE (return here when ready to upload)	
	Each user will be required to receive H link to the Human Subject Protection o subjects-research-Post	uman Subject Protection course certificate. If a user does not already have a certificate ready for up nume is available on the Human Subjects Research site https://about.ottprogram.org/en/heries/hama	oad, a
	Upload Human Subject Protection of	ourse certificate (allowed file extension: pdf, max file size: 10Mb)	
	Upload Human Subject Protection co	sane certificate 😂 Browne	
		Next	



Registration Form Overview

- After a Pre-Registration Form is completed, a PET Facility Registration Form will be generated. Complete the PET Facility Registration Form.
- Overview:
 - PET Facility Administrator Information
 - PET Facility Information
 - PET Facility Accreditation Information
 - Scanner Information
 - Staff Information
 - Interpreting Radiologists/Nuclear Medicine Physician Information



Registration Form Example

After a Pre-Registration Form is completed, a PET Registration Form will be generated. Complete the PET Facility Registration Form.

10702 - Test for powerpoint facility

PET Facility Registration Form



PET Facility Administrator



Add Physicians and Facility Staff

- 1. Select the type of user you want to add (e.g. Radiologist, Registrar, etc.)
- 2. Enter personal information for the new user.
- 3. An automated email will be sent to the email address entered for that user.
- 4. Instruct your team member to click on the link they receive in their email to activate their account (Note: Check SPAM folders).

Demonda oper					
Upon submission of thi the physician.	is form, an account will be created	for each Dementia Specialist at your si	e. The login credentials will be emailed to	Interpreting Radiologist	
PLEASE NOTE: THE	PHYSICIAN IS REQUIRED TO LO	GIN AND CREATE AN ACCOUNT PR	OR TO SITE APPROVAL	1 5 5	
	E	Add Physician		Personal Inform	nation
Registrars				First Name	
A dementia specialist (j below.	physician) may delegate the conse	ent and registration of the subject to a c	oordinator or similar person. Please list	Lost Name	
Last Name	First Name	E-mail	User Type	Last Name	
Specialist	Dementia	bux39899@cuoly.com	Practice Administrator	NPI	
		Add Registrar		E-mail	Unique email address for every user
To which PET fail imaging? *	acilities does your Prac	tice plan to refer patients	or brain amyloid-PET	Confirm e-mail	
					NEW

IDEAS-Study.org

Dementia Specialists *

Automated Email Example

Subject Line: New IDEAS-Study Interpreting Radiologist/Nuclear Medicine Physician Registration Confirmation

PET Facility Name: Name of PET facility entered on Pre-Registration Form PET Facility ID#: 4-digit ID number

Your Facility Administrator has registered you as a Radiologist/Nuclear Medicine Physician for the New IDEAS Study.

The New IDEAS (Imaging Dementia—Evidence for Amyloid Scanning) Study is managed by the American College of Radiology and thus requires an ACR ID (username) to access the recently upgraded database.

Please read the following instructions before clicking on the study link below.

All users, including users with existing ACR IDs, need to sign up for a new ACR account to access the New IDEAS portal. Existing IDs do not work for the New IDEAS study. Click on "Sign up", then fill out the necessary information. Upon submission, you will be sent another automatic email to 'verify' your ACR ID. Do so by clicking the link in that email and login to the New IDEAS portal. To access the study portal at any time, navigate to the <u>study website</u> and click "Login" in the top right-hand corner.

Once logged in you should see your name in the top right corner. **Do Not re-register your facility**. This has already been done. Instead, click on your name then click 'physician profile'. You will be prompted to confirm your Board and Subspecialty certification(s) and verify completion of vendor specific training. Click submit and wait to be approved by the ACR.

To access your facility's registration page, click 'Facility Management' along the top.

Note: the link below must be used in order to connect your account to the correct site. This link expires after 10 days. Once expired, your site administrator will have to re-issue the link from their account.

To log in to New IDEAS please access the following secure New IDEAS link and complete the steps outlined above: CLICK ON LINK TO LOGIN

We look forward to working with your facility on the New IDEAS Study!

Best Regards, The New IDEAS-Study Team





Physician Profiles

Every Interpreting Radiologist added to the portal will need to:

- 1. Click on the login link in the automatically generated email from the New IDEAS portal.
- 2. Create a New ACR ID with a unique email address and set up two-factor authentication.
- 3. Login to the New IDEAS portal at <u>https://app.ideas-study.org/</u>
- 4. Use the site selection drop-down menu to the facility.
- 5. Click on his/her name in the top right-hand corner and select "Physician Profile"
- 6. Complete the following sections:
 - Personal information
 - ✓ Upload Human Subject Protection Course Completion Certificate *optional
 - ✓ Vendor-Specific Training for interpretation of amyloid images
 - ✓ Board and Subspecialty Certification(s)
 - ✓ Eligibility to bill Medicare for services
- 7. Review responses and Click "Submit."
- 8. A member of the ACR New IDEAS Team will review and approve each Interpreting Radiologist.



Physician Profile Status





Facility Activation Requirements

The New IDEAS Operations Team at ACR will activate your facility when you complete the following tasks:

- Complete the New IDEAS Referring Physician Site Agreement and BAA fully executed.
- ✓ Interpreting Radiologists are approved by the New IDEAS Operations Team.
- ✓ Accreditation status is added to the portal and approved by the New IDEAS Operations Team.

ACR Staff Only

- New IDEAS PET Facility agreement and BAA fully executed
- Radiologist Approved
- Accreditation Approval

	Facility Active	Yes	No
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Protocol Reminder for Facility Activation

Your facility is only active for scanning patients for New IDEAS **AFTER** you receive approval from the New IDEAS Study Team.

• Your facility administrator will receive an email notification when an ACR New IDEAS study staff member has activated your facility.



Study Forms Overview

Form/Assessment:	Must be completed by:	Requirements:
Amyloid PET Scan	PET Imaging Facility	Must be completed <u>within 60 Days after</u> Pre-PET electronic Case Report Form Completion.
Amyloid PET Completion Form	Facility Administrator, Registrar or Interpreting Radiologist	Must be completed by the PET Facility via Web-based data entry within 7 days after completing the Amyloid PET scan.
Amyloid PET Report	Facility Administrator, Registrar or Interpreting Radiologist	Must be completed by the PET facility via Web-based data entry within 7 days after completing the Amyloid PET scan.
Amyloid PET Assessment	Interpreting Radiologist ONLY	Must be completed via Web-based data entry <u>within 7 days</u> of the scan.
Coinsurance Reimbursement Form	Facility Administrator or Finance User	Must be completed via Web-based data entry for patients who have an outstanding balance for their amyloid PET scan. For step-by-step training, reference <u>Operational</u> <u>Training: New IDEAS Coinsurance Reimbursement Program</u>



Study Flow Overview:

- The dementia specialist practice will consent the patient, schedule the scan and register the patient.
- A patient case ID number will be generated to link all electronic case report forms.





Case Status Overview

View list of registered cases under "Data Collection." Select "Case Registration."

Unique 5-digit study case identifier. Click on this Case # to see patient form status.



NEW

For Amyloid Scanning

Facility Management -

Data Collection -

Case Registration

PET Completion

PET Assessment

PET Report

My Requests

Amyloid PET Scan

- The PET facility will receive an e-mail notification when the Pre-PET eCRF has been completed by the Referring Dementia Specialist.
- The Amyloid PET Scan must be completed **within 60 Days** <u>after</u> Pre-PET electronic Case Report Form Completion.

Example Case: Patient 50011 has been registered, a Socio-Demographic form has been completed and the Pre-PET form has been completed. Patient is awaiting scan.





Study Timeline Overview



*Image Upload to TRIAD should only be completed for patients that consented to Image Archive. If patient OPTS OUT, TRIAD will block ability to upload.



Amyloid PET Completion Form

• This form is completed by the PET Facility via Web-based data entry **7 days from the date the scan was performed.**

Overview of Form:

- PET Completion Visit Status
- Identification Data
- Scan Type
- Radiopharmaceutical Tracer Information
- Name of Person Submitting Form



Amyloid PET Completion Form Example

Click on the Case ID # of interest.

Select "PET Completion" Tab.

Complete the form and click "Submit"

Must be completed within 7 days from the day the scan was performed.

	Case Registration	PET Completion	PET Report	PET	Assessment	Comments (0)	Protocol Violations			
Case Registration										
PET Completion	This record has been	submitted.								
PET Report	Amyloid PET C	completion Form								
PET Assessment										
My Requests	This form is completed by the PET Facility via Web-based data entry by midnight on the day the scan was performed.									
Submit Data Change	PET Completion Visit Status: Was the PET Completion visit completed?									
		Yes, I certify that the PET Completed. The PET Completed. submitted.	ompletion visit was etion form can be		 No, the PET Cor I confirm that the be submitted. 	npletion visit was not c PET Completion form	ompleted. cannot			
	Identification Data									
	PET Facility ID#:	10697								
	New IDEAS Study Case#:	50014								

Case #50014 John Doe, 11/07/1955



Amyloid PET Report

- Must be completed by the PET facility via Web-based data entry within 7 days after completing the Amyloid PET scan.
- This form is used to transmit the Amyloid PET Report.

Overview of Form:

- Identification Data
- Interpreting Physician Information
- PET Report (entered as free text- copy and paste from Microsoft Word or Other text document)
- Name of Person Submitting Form



Amyloid PET Report Example



IDEAS-Study.org

Tab.

Amyloid PET Assessment

• The radiologist/nuclear medicine physician who interprets the amyloid PET will be required to complete the online Amyloid PET Assessment Form within 7 days of the scan.

Overview of Form:

- Identification Data
- Radiopharmaceutical
- Scan Type
- Image quantification question
- Comparison of imaging question
- Scan Quality Assessment
- Global scan result
- Name of Person submitting form



Amyloid PET Assessment Example

......

Click on the Case ID # of interest.

Select "PET Assessment" Tab.

Complete the form and click "Submit"

Must be completed by Interpreting **Radiologist within 7** days of scan.

	Case #50014 John Doe, 11/07/1955									
	Case Registration	PET Completion	PET Report	PET Assessment	Comments (0)	Protocol Violations				
Case Registration										
PET Completion	This record has been	submitted.								
PET Report	Amyloid PET Assessment Form									
PET Assessment										
My Requests	The radiologist/nuclear medicine physician who interprets the amyloid PET will be required to complete the online Amyloid PET Assessment Form within 7 days of the scan.									
Submit Data Change	Identification data									
	Subject Name:	John Doe								
	Subject ID:	50014								
	DOB:	11/07/1955								
	Site ID:	10697								
	Reader ID:	Facility Radiologist								
	1. Radiopharma	ceutical								
	F-18 florbetaben	(Neuraceq™)								
	F-18 florbetapir ((Amyvid™)								
	F-18 flutametam	ol (VizamyI™)								



Coinsurance Reimbursement Form

For patient's who owe a balance for the amyloid PET scan after all insurances have been billed, the Financer User or Facility Administrator will need to:

- 1. Verify patient's general information and confirm pre-populated fields:
 - PET facility provider type (Hospital-based/Not hospital-based)
 - Patient's Medicare type (Traditional/Medicare Advantage Plan)
 - Supplemental insurance (Yes/No)
 - Scan Date
 - Radiopharmaceutical administered
- 2. Upload required documentation for reimbursement
 - Upload patient's Explanation of Benefits (EOB) documents for all insurances
 - PDF document only; max file size 10Mb)
 - Multiple documents can be uploaded
 - Multiple documents <u>must be</u> uploaded before submission if technical and professional components are billed separately. Requests for partial payments will not be accepted.
- 3. Provide an attestation of coverage
 - Confirm that ALL insurances have been billed appropriately and all appeals have been pursued and resolved with Medicare and any supplemental insurer.
- 4. Indicate the total amounts requested for reimbursement
 - Entered amounts must match the coinsurance amounts shown on provided EOBs.



Data Change Request Form

- Click on the Case # of interest.
- Select the completed form you have a data change request for.
- Detail your requested data changes in the comment box.
- Click "Send." An email will be sent to ACR New IDEAS staff for review.

	Case Registrat		РЕТ Кероп н	Please sub	mit your requested data change for this form	PET Completion
Case Registration				Site #:	10697	PET Report
PET Completion	This record has t	been submitted.		Case #:	50018	
PET Report	Amyloid PE	T Completion Form		Form:	PET Completion	PETASSessment
PET Assessment		r completion Form		User:	Facility Radiologist (00uup1jrguD0FaMVx0h7)	My Requests
My Requests	This form is comple	eted by the PET Facility via Web-	based data entry by midnigh	Detail your r	equested data change(s) below. You will be contacted if clarification of your eeded:	
Submit Data Change	PET Comple Was the F	etion Visit Status: PET Completion visit completed?	,			
		Yes, I certify that the PET Completed. The PET Comp submitted.	Completion visit was eletion form can be			View All requests by clicking "My
	Identification	Data				Requests"

IDEAS-Study.org



Close

Send

Case Registration

Protocol Violation Form

- Protocol Violations can be viewed by clicking on the Case ID # of interest and clicking on the "Protocol Violations" tab.
- Protocol Violations are initiated by the New IDEAS Study Team (ACR staff) and must be acknowledged by the Facility.

	Case #50018							
	Case Registration	PET Completion	PET Report	PET Asse	essment	Comments (0)	Protocol Violations	
Case Registration								
PET Completion	Id	Date of Violation	Submiss	ion Date	Туре		Status	
PET Report	There are no items to displa	ay						
PET Assessment								
My Requests								
						NE		

Case Comments Section

- Communication about patient cases should only be communicated through the New IDEAS portal, <u>never</u> by email.
 - Select "Case Registration"
 - Click on the Case # of interest.
 - Select "Comments" tab.
 - Write patient comment and submit by selecting "Comment for everyone."



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Will Subjects Endure Any Costs?

- **Best Practice:** Determine and discuss any potential out-of-pocket costs with the patient/family as part of the shared decision making <u>prior</u> to conducting the scan.
- As a New IDEAS Study participant, the amyloid PET scan is a covered procedure by Medicare.
 - However, co-payments may apply for clinical services.
 - E.g. deductible or copay for the PET scan visit and/or the copay of the follow-up visit with the referring Dementia Specialist.
 - Patients with Medicare supplemental insurance (Medicaid):
 - Most co-payments will be covered
 - Patients with Medicare Advantage Plans:
 - Most will have no deductible or co-pay (some MA plans have co-share requirements).
 - Patients who <u>do not</u> have supplemental insurance:
 - Responsible for the usual patient co-share portion of the imaging (20% co-payment).
 - Amyloid PET scan estimate: \$250-\$700 (depending on the imaging facility setting and patient insurance plan).



TRIAD Overview



- TRIADTM (**Tr**ansfer of Images and **D**ata)
- Cloud based image and data exchange platform to support image and data sharing for Clinical Trials.
- TRIAD meets FDA regulatory requirements for use in Clinical Trials; it is Title 21 CFR Part 11 compliant.
 - Sends images and data files securely.
 - Anonymizes the DICOM headers locally before submission based on flexible and profile-based algorithm.
 - A straight-forward software download to get started.
 - Images are submitted with a click of a button.
 - More info: <u>http://triadhelp.acr.org/</u>



Digital Image Submission



- Except for subjects who have specifically opted out of image collection during the study consent process, all brain amyloid PET scans will be submitted to the American College of Radiology (ACR) archive within 7 days of scan acquisition using the TRIADTM application.
 - If patient OPTS OUT of Image Archive, TRIAD will automatically block access to transmit images.
- Site staff (e.g., Nuclear Medicine Technologists) who submit images will need to be registered by the PET Facility Administrator as users, which will automatically enable them as TRIAD users.
- Site staff who submit images through TRIAD will need to be registered in the New IDEAS Database and have a valid account.



Digital Image Submission (Continued)

- Training on image transmission can be found at: https://www.ideas-study.org/Getting-Started/TRIAD
- All PET scans are required to be submitted using TRIAD.
- Can be installed on one or several computers of choice within the institutional 'firewall' and on institutional network.
- TRIAD application can be used to submit images located on CDs/DVDs or network drives.
- TRIAD application can also be configured as a DICOM destination on either scanner and/or PACS system for direct network transfer.



Additional Study Information

- New IDEAS resources for PET Facilities:
 - <u>https://www.ideas-study.org/PET-Facility</u>
- For protocol specific information visit:
 - <u>https://www.ideas-study.org/Getting-Started/Protocol</u>
- Official study details and results reporting can be found at ClincalTrials.gov:
 - <u>https://clinicaltrials.gov/ct2/show/NCT04426539</u>





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