

New IDEAS Study Coinsurance Reimbursement Program Frequently Asked Questions

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General Questions

What is the New IDEAS Coinsurance Reimbursement Program?

The New IDEAS Coinsurance Reimbursement Program will allow the study sponsor to pay for the coinsurance amounts that Medicare beneficiaries participating in the study would otherwise owe for Medicare-reimbursable amyloid PET scans provided during the study, regardless of financial need.

What is the New IDEAS Coinsurance Reimbursement Policy?

The New IDEAS Study team has instituted a policy which is intended to outline the study's Coinsurance Reimbursement Program and the obligations set forth for participating PET imaging facilities and dementia practices. Read the full policy <u>here</u>.

When does the Program start?

Study participants who have not received their amyloid PET scan as of January 1st, 2022 are eligible to have their amyloid PET scan coinsurance obligations submitted to the study sponsor for reimbursement.

What costs are reimbursed under this Program?

Coinsurance amounts associated with the amyloid PET scan (including technical, professional or global charges) and/or fixed copayments not covered by patient's supplemental insurance are reimbursed under this Program.

What costs are not reimbursed under this Program?

Unmet beneficiary deductibles and coinsurance or copayments associated with dementia expert visits are <u>not</u> reimbursed under this Program.

Who is being reimbursed?

Participating imaging facilities will receive a direct payment from the study sponsor (American College of Radiology) for coinsurance amounts related to the amyloid PET scan, that a study participant would otherwise owe.

To Which Patients Does this Program Apply?

Not every patient enrolled in New IDEAS will require and/or be eligible for coinsurance reimbursement through this Program. To be eligible for coinsurance reimbursement, a patient <u>must</u>

- Be enrolled in the New IDEAS Study;
- Have Medicare as their primary insurance;
- Receive their amyloid PET scan on or after January 1st, 2022; and
- Owe a remaining coinsurance amount for the PET scan after all insurances (primary and supplemental, if applicable) have been appropriately billed by the PET facility.

Is my patient eligible for this Program if they received a scan before January 1st, 2022?

No. Patients who received a scan prior to January 1st, 2022 are not eligible for amyloid PET scan coinsurance reimbursement.

Is amyloid PET scan reimbursement associated with patient financial need?

No. The study sponsor will reimburse PET facilities for outstanding amyloid PET scan coinsurance costs regardless of patient financial need as long as the patient meets the eligibility criteria for the Program.

My patient has supplemental insurance that covers only a part of the PET scan. Are they eligible for the Program?

Yes. Patients who do not have supplemental insurance or have supplemental insurance that only covers a part of the PET scan are eligible for the Program. However, patients must meet all other eligibility criteria for the Program.

What are the benefits of this Program?

This Program may 1) minimize patient costs associated with the Study, 2) ensure broad participation of patients and/or 3) increase the generalizability of the study findings.

What if my site or facility does not want to take part in this Program?

All PET imaging facilities and dementia practices that choose to participate in the New IDEAS study must adhere to the <u>New IDEAS Coinsurance Reimbursement 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.

Who manages the Program?

The study sponsor, the American College of Radiology (ACR), is responsible for overseeing and managing the operations of the Program.

I have general questions about the New IDEAS Study and/or technical problems in the New IDEAS Portal. Who should I contact for support?

Practices and PET facilities should contact the New IDEAS Operations Team with any general study questions or IT questions regarding the New IDEAS portal (Email: <u>newideas@acr.org</u>, Phone: 215-574-3150 ext. 4156)

Common PET Facility Questions

What are the PET Facility responsibilities associated with the Program?

PET facilities must adhere to the New IDEAS <u>Coinsurance Reimbursement Program Policy</u> and the terms and conditions listed in the Agreement that was executed with the study sponsor prior to facility activation.

What does my facility need to do to be ready for the Program?

Facility Readiness Checklist:

- ✓ Fully execute the New IDEAS Study Clinical Data and Image Access Agreement, and Addendum #1, which is required if your facility already has a signed agreement in place.
- ✓ Delegate the role of 'Facility Finance User' to an employee at your facility.
- ✓ Submit the necessary banking and tax information via the New IDEAS Study portal.
- Continue to properly bill all active insurances that the study participant has (primary and supplemental, if applicable) before submitting final coinsurance obligations to the study for reimbursement.
- ✓ Implement facility-level operational changes to ensure patients eligible for coinsurance reimbursement do not receive bills from the PET facility or professional component entity.
- ✓ Implement facility-level operational changes to ensure that co-payments or coinsurances are not collected at time of service for patients eligible for the Program.
- ✓ Facility Finance User or Facility Administrator must submit the Coinsurance Reimbursement Form via the New IDEAS Study portal for each patient that has a coinsurance obligation that is not covered by his/her health insurance plan(s).
- ✓ Manage and resolve any incorrect patient billing situations (i.e. if a bill is accidentally issued to and/or paid for by a study participant).
- ✓ Review the Coinsurance Reimbursement Program: Operational Training Module.

Who should I contact if I have contract-related questions about this Program?

Please email all contracts related questions and template requests to the New IDEAS Operations Team at newideas@acr.org. All facilities must fully execute the New IDEAS study Clinical Data and Image Access Agreement, and Addendum #1, if applicable, with the study sponsor, the American College of Radiology.

My PET facility is currently active. Can I submit Coinsurance Reimbursement Forms before my Agreement Amendment is fully executed?

Yes. PET facilities may submit the Coinsurance Reimbursement Forms prior to executing the agreement amendment. However, payment for approved Coinsurance Reimbursement Forms will not be provided until the facility has a fully executed agreement with the study sponsor.

Who has access to the Facility Finance Page of the New IDEAS Portal?

Each PET facility will be responsible for adding a Facility Finance User Role to their Facility Registration Page. The facility administrator must add the Finance User to the registration page for the Finance User to gain access to the facility's registration page to update banking and tax information.

Who should serve as the Facility Finance User?

The Facility Finance User is responsible for submitting facility banking and tax information for the facility to receive reimbursement. This individual may also be responsible for completing the Coinsurance Reimbursement Form, which includes verifying general patient information and uploading required documentation for reimbursement [e.g. patient's Explanation of Benefits document(s)]. The Finance User may be someone that has additional roles already established in the study portal (i.e. Facility Administrator, Facility User, and/or Physician).

Who should I contact if I need access to the Facility Finance Portal?

Your facility administrator will need to add you as a Facility Financer User before you access the portal. When the facility administrator adds your information to the portal, an automatic email will be sent to your email address with instructions for activating your account.

Can I have more than one Facility Finance User?

Yes. Your facility administrator may assign more than one individual the role of Facility Finance User.

Can my facility administrator submit the Coinsurance Reimbursement Form?

Yes. In addition to the Facility Finance User, the Facility Administrator role also has edit/submission access to the Coinsurance Reimbursement Form. However, this role does not have access to the Facility Finance Portal to submit facility banking and tax information for the facility payments.

Can I include more than one bank account for facility reimbursement?

Yes. If a PET imaging facility requires separate payment for professional and technical components of coinsurance, two separate bank accounts and tax information must be provided within the study portal.

What information will I need to submit a Coinsurance Reimbursement Form?

The user submitting the Coinsurance Reimbursement Form will be responsible for verifying patient's general information and confirm pre-populated fields including PET facility provider type (Hospital-based/Not hospital-based), patient's Medicare type (Traditional/Medicare Advantage Plan, Supplemental insurance (Yes/No), Scan Date and Radiopharmaceutical administered.

Users will also need PDF copies (max file size 10mb) of the patients Explanation of Benefits (EOB) documents for all insurances. Multiple documents must be uploaded before submission if technical and professional components are billed separately.

My facility bills technical and professional components separately, and I only have the Explanation of Benefit documents for one component. Can I submit the Coinsurance Reimbursement Form for partial reimbursement payment?

No. Requests for partial payments will not be accepted. Multiple documents must be uploaded before submission if technical and professional components are billed separately.

My patient's insurance claims were submitted to Medicare, and their PET scan coverage was denied. Can I submit a Coinsurance Reimbursement Form to cover the full cost of the scan?

No. Facilities must continue to properly bill all active insurances that the study participant has (primary and supplemental, if applicable) before submitting final coinsurance obligations to the study for reimbursement. A facility should appeal a denial and, if the first appeal is denied, the facility should appeal once again and provide additional documentation to support the request. For Medicare Reimbursement guidance, visit the <u>New IDEAS Medicare Reimbursement</u> <u>Resources webpage</u> or contact <u>newideas@acr.org.</u>

What happens if a patient incorrectly receives a bill for a PET scan that should be covered under this Program?

Per the Program <u>policy</u>, PET facilities are responsible for implementing facility-level operational changes to ensure patients eligible for coinsurance reimbursement do not receive bills from the PET facility or professional component entity. PET facilities are responsible for managing and resolving any incorrect patient billing situations (i.e. if a bill is accidentally issued to and/or paid for by a study participant).

My facility collects copayments or coinsurance payments at the time of PET scan service. Can we still collect copayments at time of service?

No. Facilities are responsible for implementing facility-level operational changes to ensure that co-payments or coinsurances are <u>not</u> collected at time of service for patients eligible for the Program. Request for unpaid coinsurance/copayment reimbursement must be submitted via Coinsurance Reimbursement Form in the New IDEAS portal.

When will my facility be reimbursed?

PET facilities will receive reimbursement payment for sponsor-approved Coinsurance Reimbursement Forms after all banking and tax information for the facility is added to the New IDEAS portal and after the facility has a fully executed agreement in place with the study sponsor. Payments are disbursed on a monthly basis for reimbursement requests that were approved by the study sponsor in the prior month.

Who should I contact to schedule a PET Facility training to discuss the study and the Coinsurance Reimbursement Program?

The New IDEAS Operations Team is available to schedule training sessions to review the study and the new Coinsurance Reimbursement Program (Email: <u>newideas@acr.org</u>, Phone: 215-574-3150 ext. 4156).

Common Dementia Practice Questions

What are the Dementia Practice responsibilities associated with the Program?

Dementia practices must adhere to the New IDEAS <u>Coinsurance Reimbursement Program</u> <u>Policy</u> and terms and conditions listed in the Agreement that was executed with the study sponsor prior to site activation.

What does my practice need to do to be ready for the Program?

Practice Readiness Checklist:

- ✓ Download your 1) site-level amendment approval letter and 2) approved informed consent form from Advarra IRB that contains coinsurance reimbursement language.
- Practice Administrators or Regulatory Users need to upload 1) site-level approval letter and 2) approved ICF document to the New IDEAS portal under section IRB approval documents.
- ✓ Consent all prospective study participants on the most recently approved version of the ICF document.
 - Per the IRB of record's determination, currently enrolled study participants do not need to be reconsented with the updated and IRB approved ICF.
- ✓ Inform site team members that coinsurance assistance must not be part of any advertisement or solicitation relating to participation in the study.
 - Study participants are made aware of their cost obligations during the informed consent process.
- ✓ Review the Coinsurance Reimbursement Program: Operational Training Module.

Which Informed Consent Form should I use?

All prospective study participants must be consented on the site's most recently approved version of the Informed Consent Form. Per the Advarra IRB's determination, the IRB of record for New IDEAS, currently enrolled study participants do not need to be reconsented with the updated and IRB approved ICF containing coinsurance reimbursement language.

Where can I find a copy of my up-to-date site-level Advarra IRB approval letter and approved Informed Consent Form?

Copies of your Advarra IRB approved documents can be found in your CIRBI portal.

My patient was registered before January 1st, 2022 and has a scan date scheduled on or after January 1st, 2022. Do they need to be reconsented to be eligible for this Program?

No. Practices are responsible for consenting study participants on their most recently approved version of the ICF document. Per the IRB of record's determination, currently enrolled study participants do not need to be reconsented with the updated and IRB approved ICF.

My patient was registered and scanned before January 1st, 2022. Can I reconsent my patient with the new ICF containing Coinsurance Reimbursement Language so they are eligible for the scan?

No. Patients scanned prior to the Program's go-live date, January 1st, 2022 are <u>not</u> eligible for the Program, even if they are reconsented on updated IRB approved ICF containing Coinsurance Reimbursement Program language.

What are my patient's out-of-pocket costs associated with the New IDEAS study?

As a New IDEAS Study participant, the amyloid PET scan is a covered procedure by Medicare. However, patients are responsible for unmet beneficiary deductibles, coinsurance or copayments associated with dementia expert visits, and coinsurance or copayments associated with the amyloid PET scan (if scanned before January 1st, 2022).

Patients who received a scan on or after January 1st, 2022 are <u>not</u> responsible for coinsurance amounts associated with the amyloid PET scan (including fixed copayments and technical, professional or global charges) not covered by patient's supplemental insurance.

With whom should a participant talk to if they receive a bill?

The participant's PET facility is obligated to handle incorrect patient billing situations (i.e. if a bill is accidentally received and/or paid for).

Who should I contact to schedule a dementia practice training to discuss the study and the Coinsurance Reimbursement Program?

The New IDEAS Operations Team is available to schedule training sessions to review the study and the new Coinsurance Reimbursement Program (Email: <u>newideas@acr.org</u>, Phone: 215-574-3150 ext. 4156).