New IDEAS Coinsurance Reimbursement Program Policy

Version 1: December 15, 2021 - Effective Immediately

Updated: May 4, 2022 - Added clarifying coinsurance and deductible definitions

Updated: December 3, 2024 - Added program end date



Broad participation of dementia care and imaging providers in the New IDEAS Study is imperative for increased generalizability of the study findings to underrepresented populations. The Coinsurance Reimbursement Program aims to minimize participant financial burden associated with the study, which is a common recruitment barrier to study participation in Alzheimer's and dementia research.

The New IDEAS Study team has instituted the following 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. All PET imaging facilities and dementia practices that choose to participate in the study must adhere to this Policy. Additional Program details can be found in the Coinsurance Reimbursement Training Module. Sites and Facilities are highly encouraged to review the list of Frequently Asked Questions compiled by the study operations team.

Policy Statement:

The New IDEAS Study will now pay the coinsurance amounts that Medicare beneficiaries participating in the study would otherwise owe for Medicare-reimbursable amyloid PET scans provided during the study. Study participants who receive their amyloid PET scan on or after **January 1, 2022 through April 30, 2024** are eligible to have their amyloid PET scan coinsurance obligations submitted to the study sponsor for reimbursement, regardless of financial need; payments will be made directly to the PET facility through electronic funds transfer. Pursuant to guidance issued by the Department of Health and Human Services Office of Inspector General (HHS OIG), the New IDEAS Coinsurance Reimbursement Program will apply the following policies:

- Reimbursement is not provided for patients who have supplemental insurance, such as Medigap, that covers 100% of any coinsurance obligations unmet by their primary insurer.
- 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.
- Allowable components of the coinsurance amounts, to be reimbursed by the study include technical, professional, or global charges.
- Fixed co-payments are also permissible for reimbursement; however, the study will not provide reimbursement for any unmet beneficiary deductibles.
- 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.
- For the purposes of this program, coinsurance and deductible amounts are defined by the primary Medicare plan's Evidence of Benefits (EOB).

Obligations of Participating PET Imaging Facilities:

 Fully execute the New IDEAS Study Clinical Data and Image Access Agreement, and Addendum #1, if applicable, with the study's sponsor, the American College of Radiology.

- Delegate the role of 'Facility Finance User' to an employee of the participating organization. Detailed user responsibilities and operational information can be reviewed via the Coinsurance Reimbursement Training Module.
- Submit the necessary banking and tax information to the study sponsor via the secure and encrypted New IDEAS Study portal. Reimbursement will only be remitted via electronic funds transfer.
 - If the PET imaging facility requires separate payment for the technical and professional components of coinsurance, two separate bank accounts and tax information must be provided within the study portal.
- Properly bill all active insurances that the study participant has (primary and secondary, if applicable) before submitting final coinsurance obligations to the study for reimbursement.
 - Imaging Facilities are required to work through any claim denials received by the patient's insurance provider. Detailed guidance for proper billing procedures is provided on the Medicare reimbursement page of the <u>study's</u> website.
- Patients scanned on or after January 1, 2022 through April 30, 2024 must not receive
 a bill for coinsurance or copayment associated with their amyloid PET scans. The PET
 facility is responsible for implementing facility-level operational changes to ensure
 patients eligible for coinsurance reimbursement do not receive bills from the PET
 facility.
- Do not collect any co-payments or coinsurances at time of service.
- Submit the <u>Coinsurance Reimbursement Form</u> 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). Detailed operational information and training can be found with the <u>Coinsurance Reimbursement Training Module</u>.
- Manage and resolve any incorrect patient billing situations (i.e., if a bill is accidently issued to and/or paid for by a study participant).

Obligations of Participating Dementia Practices:

- Receive site-level approval from Advarra IRB for the updated informed consent document containing coinsurance reimbursement language. Upon receipt of IRB approval of the updated ICF, all prospective study participants must be consented 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.
- 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.

Termination Clause:

All PET imaging facilities and dementia practices that choose to participate in the study must adhere to this Policy. 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. The program will be terminated on **June 1, 2025** At this time, no additional requests for reimbursement will be considered.