

Code and Bill the Big IDEAS Behind Amyloid Imaging



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Amyloid PET imaging helps to diagnose and treat dementia patients.

Amyloid imaging in the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study is a Medicare-approved coverage with evidence development (CED) procedure. This nuclear medicine procedure uses positron emission tomography (PET) imaging to examine how amyloid plaques (a core feature of Alzheimer’s disease) in the brain help to guide doctors in patient treatment, and whether these changes in treatment lead to better medical outcomes. The IDEAS Study (activated Feb. 8, 2016) provides access to amyloid imaging for more than 18,000 patients for whom the cause of cognitive decline/dementia is ambiguous, and who may benefit from an early and accurate diagnosis.

Who Can Participate in the IDEAS Study

A PET imaging facility may not perform an IDEAS Study PET scan unless they are enrolled in the IDEAS program, and until the referring physician has submitted a pre-PET clinical assessment form for the patient to the IDEAS Study database. After the PET scan is completed and the appropriate data uploaded to the IDEAS Study

database, a system-generated notification is sent from the email address IDEAS-Study@acr.org to the PET imaging facility, indicating the case data are complete. Only after the email notification is received may the PET facility and the reading physicians begin to bill Medicare for the study and the radiopharmaceutical.

Reading physicians should coordinate with the PET imaging facility to obtain a copy of the system-generated notification prior to billing for PET studies reading. Both the PET imaging centers and the reading physician should maintain the email notification for each patient study as documentation, in case the Centers for Medicare & Medicaid Services (CMS) opts to audit the PET imaging facility.

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 Medicare Advantage (MA) plan, as appropriate.

Note: Amyloid imaging services are currently not covered by any third-party payers.

IDEAS Coding

Providers report the procedure and radiopharmaceutical codes in **Table 1** and **Table 2**. CED studies for IDEAS also require other important elements for claim processing, and the details of these instructions are found in the Medicare Claims Processing Manuals, which are referenced in the **Definitions and Resources** section of this article.

For instance, append modifier Q0 *Investigational clinical service provided in a clinical research study that is in an approved clinical research study* to both the CPT® procedure code and the HCPCS Level II radiopharmaceutical code. This modifier is important because it signifies to the payer that this procedure is a CED study. By appending this modifier, the provider attests they participated in a CMS-approved study (e.g., IDEAS).

The National Coverage Determination (NCD) for Amyloid imaging approved a short list of ICD-10-CM codes that MACs or MA plans may accept (see **Table 3**). All claims submitted must contain one of these CMS-approved ICD-10-CM codes in the primary position for claims processing.

For CMS-1500 claims that have modifier Q0, the payer then looks for the national clinical trial number. For IDEAS, that number is CT02420756, placed in box 19 on the CMS-1500 claim form for

Table 3: CMS-approved ICD-10 Codes for IDEAS Study

Code	Description
F03.90	Unspecified dementia without behavioral disturbance
F03.91	Unspecified dementia with behavioral disturbance
F01.50	Vascular dementia without behavioral disturbance
F01.51	Vascular dementia with behavioral disturbance
F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance
F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance
G31.01	Pick's disease
G31.83	Dementia with Lewy bodies
G31.84	Mild cognitive impairment, so stated
G31.85	Corticobasal degeneration
G31.09	Other frontotemporal dementia
R41.1	Anterograde amnesia
R41.2	Retrograde amnesia
R41.3	Other amnesia [applicable to amnesia not otherwise specified (NOS), memory loss NOS]

paper submissions. For electronic submissions, drop the CT and enter the number in loop 2300 with the qualifier P4=02420756. Institutional claims billing on the 1450 form require condition code 30 *Qualifying clinical trial* and ICD-10-CM code Z00.6 *Encounter for examination for normal comparison and control in clinical research* in the secondary diagnosis position.

CODING TIP: Do not use 78608 *Brain imaging, positron emission tomography (PET); metabolic evaluation* because this CPT® code is not appropriate for amyloid imaging. Amyloid is not a metabolic evaluation.

CODING TIP: Report CPT® 78811 with magnetic resonance imaging (MRI) codes for studies ordered and performed with PET/MRI, as there are no PET/MRI CPT® codes.

Table 1: Diagnostic Nuclear Medicine Procedure for IDEAS Study

CPT® Code	Description
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

Table 2: Diagnostic Radiopharmaceuticals for IDEAS Study

Radiopharmaceutical/ Vendor	Setting	HCPCS Level II Code Before July 1, 2016	HCPCS Level II Code On or after July 1, 2016	Description
Neuraceq™ Piramal NDC # 54828-001-30	Hospital	C9458	Q9983	Florbetaben F-18, diagnostic, per study dose, up to 8.1 millicuries
	MPFS	A9599		
Vizamyl™ G.E. NDC # 17156-067-01	Hospital	C9459	Q9982	Flutemetamol F-18, diagnostic, per study dose, up to 5 millicuries
	MPFS	A9599		
Amyvid™ Lilly NDC # 0002-1200-01	Hospital	A9586		Florbetapir F-18, diagnostic, per study dose, up to 10 millicuries
	MPFS			

Both the PET imaging centers and the reading physician should maintain the email notification for each patient study as documentation, in case the Centers for Medicare & Medicaid Services (CMS) opts to audit the PET imaging facility.

Top 5 IDEAS Study Coding Tips

Follow these top tips to avoid common omissions/errors on IDEAS claim submissions:

TIP 1: Providers should append modifier Q0 to the HCPCS Level II radiopharmaceutical codes. This is in addition to appending modifier Q0 to the CPT® procedure code for the PET study. MACs say this is the main issue that causes IDEAS claim denials.

TIP 2: Providers should include the appropriate clinical trial number following CMS Transmittal 2955 (CR 8401, May 13, 2014). Examples are also provided by IDEAS in the Sample Medicare Claims on the IDEAS website.

TIP 3: Independent diagnostic testing facilities (IDTF) should verify that the CPT® and HCPCS Level II codes to be used for IDEAS scans are on their CMS-855B form and accepted by the MAC for use prior to billing for IDEAS studies. This issue is the No. 1 issue for IDTF claim denials in IDEAS.

TIP 4: If a payer instructs you to append modifier PI *Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing* or modifier PS *Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy* to either the CPT® or HCPCS Level II codes on the claim, be aware that this is not a CMS billing requirement of IDEAS claims. Please notify Denise Merlino or the IDEAS team immediately with sample claims using the Claim Denial Form process noted.

TIP 5: If an MA plan denies prior authorization for an IDEAS patient, it's recommended you appeal all denials. Specifically, follow up with additional documentation to support your request, "This patient is enrolled in the CMS approved CED program IDEAS and provide the MA plan," with the three references below:

1. A copy of the link to the CMS communication to MA plans.
2. A copy of the link to the IDEAS FAQ, specifically guiding them to the question:

Will managed Medicare plans (Medicare Advantage) reimburse for scans done as part of the IDEAS Study?

Yes, Medicare Advantage (MA) beneficiaries are eligible to be included in the IDEAS Study. The MA plans will make payments for MA enrollees. IDEAS Study claims should be billed to the MA plan. This policy is located in Publication 100-16, Chapter 4: Managed Care Manual 10.7.3 – Benefits and Beneficiary Protections – Payment for Clinical Studies Approved Under Coverage with Evidence.

3. A copy of the CMS letter, dated August 23, 2016, specifically directing MA plans to item 3 in this letter. For a copy of the letter, visit www.ideas-study.org/wp-content/uploads/2015/06/CMS-Memo_23August2016.pdf.

There are many important elements to a CMS CED-approved study. If any element is not performed or not on the claim, the claim will likely deny for payment, or be considered by Medicare as not covered. Merlino Healthcare Consulting Corp. has been working with MACs regarding some claims processing issues to resolve them as quickly as possible. At the time this article was written, Noridian was updating the list of ICD-10 codes payable with only modifier Q0 for claims processing.

Need Support?

As part of the IDEAS team, I am happy to support participating IDEAS facilities, physician offices, and IDTFs with reimbursement assistance. If your coding and billing questions are not answered in these materials, or if you continue to receive denials from a payer,

Common Questions About IDEAS Billing

Q: Can we bill Medicare for the IDEAS study or reading as soon as it is performed?

A: No. As noted earlier, providers must meet the elements of IDEAS and receive the e-mail from IDEAS as this is the indication and documentation required to bill Medicare. We caution PET facilities, especially those with automated billing systems, to set up in advance internal mechanisms to hold these claims until all the required case data for the IDEAS Study is entered and this has been acknowledged by the IDEAS Study database with a system-generated e-mail to the PET facility administrator. Only after receipt of this automatically generated notification from IDEAS may a provider bill Medicare for an IDEAS study.

Q: Will patients need to pay the Medicare co-pay?

A: Yes. Excerpted from the IDEAS patient consent form:

Your amyloid PET scan will be paid for by Medicare as a covered benefit as part of the Coverage with Evidence Development program. As with any medical service covered by Medicare, you will still be responsible for any deductible or co-payment required for the service. The amount you would have to pay will depend on if you have supplemental insurance or other coverage for your deductible and co-payments.

There is no mechanism in place to allow for coverage of the co-pay for CED studies in general.

complete the Claim Denial Form and send it to IDEAS-Study@acr.org or fax it to 888-606-4223.

Definitions and Resources

CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of a CMS-approved clinical studies, or with the collection of additional clinical data. "A CED cycle is considered 'completed' when CMS removes a requirement for study participation as a condition of coverage for one or more indications of an item or service."

The IDEAS Study will provide additional data allowing CMS to complete the CED cycle, which may result in Medicare coverage for a brain amyloid PET scan for all eligible Medicare beneficiaries. For more information about CED, go to: www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.

For more about the Medicare NCD for Beta Amyloid PET in dementia and neurodegenerative disease, see:

- CMS Transmittal 164 updates the NCD Manual
- CMS Transmittal 2915 CR 8526, March 27, 2014

For references of the mandatory reporting of an eight-digit clinical trial number on claims currently in use for all CED programs, including the IDEAS Study, see:

- Transmittal 2955 CR 8401, May 13, 2014
- *MLN Matters* article SE1344

For more information on the IDEAS Study go to: [ClinicalTrials.gov NCT02420756](http://ClinicalTrials.gov/NCT02420756).

For more information on IDEAS Medicare Reimbursement information go to: www.ideas-study.org/medicare-reimbursement/

References for IDEAS codes in different settings of care:

- Transmittal 3518 CR 9636, May 6, 2016, and *MLN Matters* MM9636 add HCPCS Level II codes Q9982 and Q9983,

effective for claims with dates of service July 1, 2016, and beyond.

- Transmittal 3528 CR 9633, May 20, 2016, and *MLN Matters* MM9633 update the Medicare Physician Fee Schedule with HCPCS Level II codes Q9982 and Q9983, effective for claims with dates of service July 1, 2016, and beyond.
- Transmittal 3523 CR 9658, May 13, 2016, and *MLN Matters* MM9658 update the Hospital Outpatient Prospective Payment System with HCPCS Level II codes Q9982 and Q9983, with dates of service July 1, 2016, and beyond.

IDEAS reimbursement educational materials

IDEAS coding and billing educational items with links to the IDEAS website:

- The Nuts and Bolts of Medicare Reimbursement for the IDEAS Study (Webinar slides, May 24, 2016)
- The Nuts and Bolts of Medicare Reimbursement for the IDEAS Study (PowerPoint slides, updated Oct. 5, 2016)

Sample Medicare Claims

Claims Denial Checklist to report claims issues

Frequently Asked Questions

CMS IDEAS-Study Reimbursement Letter



Denise A. Merlino, MBA, CPC, CNMT, is president of Merlino Healthcare Consulting Corp., which provides consulting for AMA CPT® and the Relative Value Update Committee, development and implementation of new coding structures, new and innovative payment policy initiatives, and educational and health policy strategy for several professional medical specialties. Merlino is a member of the Boston, Mass., local chapter.