



Merlino

Healthcare
Consulting Corp.



**Nuts & Bolts of Medicare
Reimbursement; NEW IDEAS Study**
4-22-2021 Updated

Presented by:

Denise A. Merlino, MBA, CNMT, CPC, FSNMTS

Presenter & Disclosures

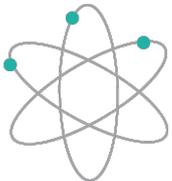
Consultant to:

SNMMI & ACNM & ASNC
Bracco & SunPharma
American Thoracic Society (ATS)
American College of Chest Physicians (CHEST)
American Geriatrics Society (AGS)
American Psychiatric Association (APA)



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Agenda for Today

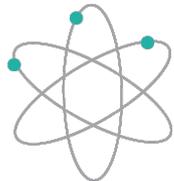
- Review the **Medicare billing guidance** for the study, including the basics of the **CPT and HCPCS codes** as well as **national payment rates** in the varying patient settings
- Review the **basic set up necessary to begin billing** New IDEAS studies as well as **the patient copayment and cost sharing**
- How to work with your local Medicare Administrative Contractors (MAC) or Medicare Advantage Plans to **resolve any denials**
- **Questions** will be taken at the end of the presentation





Transmittals, Change Requests, MLN Matters Articles

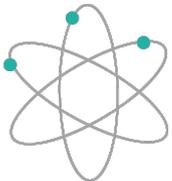
CMS GUIDANCE





Who is Eligible for NEW IDEAS?

- First, those Medicare patients that meet the NEW IDEAS study criteria
- Second, must have Medicare as “primary” not secondary insurance plan
- Third, must have Medicare “Part B” or Medicare Advantage plan as “primary”.
- Patients may have Medi-Gap plans that would generally be secondary to pick up co-payments and deductibles.





Important PET Transmittals

Beta Amyloid PET Imaging

CMS Transmittals for (CAG-00181R4)

CMS Manuals Pub 100-03 NCD 220.6.17

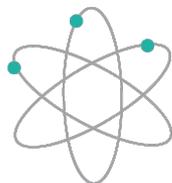
Claims Processing Chapter 13 Section 60.14-16

For information on **Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia & Neurodegenerative Disease;**

Transmittals 164 & 2915 (CR 8526, March 27, 2014)

The official instruction, CR 8526, is in two transmittals issued to the A/B MACs.

1. This transmittal updates the "National Coverage Determinations Manual" and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R164NCD.pdf>
2. This transmittal updates the "Medicare Claims Processing Manual" and it is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2915CP.pdf>





Important PET Transmittals

Beta Amyloid PET Imaging

HCPCS Updates and Clarification via MLN Matters:

MM8526 – 2915CP / 164 NCD updated July 7, 2014

MM8888 – R3097CP updated October 2014 A9586 changed status indicator from “N” not covered to “C” Carrier Priced

MM9636 – CR 9636, R3518CP issued May 6, 2016, updated & implemented July 5, 2016 **added Q9982 and Q9983 effective for DOS July 1, 2016.**

Transmittal 3524 – CR 9661, issued May 13, 2016 **deleted C9458 and C9459 while adding Q9982 and Q9983 to hospital OPPS claims, effective for DOS July 1, 2016, implemented July 5, 2016.**

Transmittal 1708 – CR 9751, issued August 19, 2016 added Q9982 and Q9983 to the national coverage updates, effective for DOS January 1, 2017, **implemented January 3, 2016**



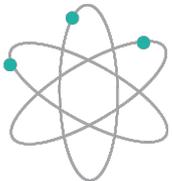


Medicare Advantage Plans Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence (CED)

(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

- In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. **MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service** (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET>).
- **Billing instructions are issued for each NCD.**

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>



cost-sharing would be based on similar services/coverage areas

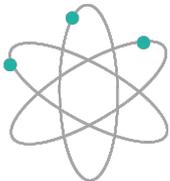


Reimbursement Policy

Medicare Advantage Plans

- Medicare Advantage (MA) beneficiaries are eligible to be included in the registry, and CMS will make payments to the MA plan for enrollees for covered routine clinical trial costs (including services provided under coverage with evidence development).
- Beneficiaries enrolled in Medicare Advantage (MA) plans are responsible for cost-share applicable to their MA plan, meaning that the co-payments and deductibles are **NOT** waived. The PET provider should bill the MA enrollee for any cost-sharing, including both co-payments and deductibles.

The complete requirements for payment may be found in the Medicare Claims Processing Manual, Transmittal 2955

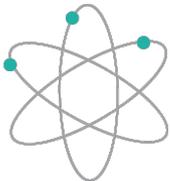




Important PET Transmittals

Clinical Trial Number on Claims

- For information on **Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims**, see Transmittal 2955 (CR 8401, May 13, 2014) at <http://www.cms.gov/transmittals/downloads/R2955CP.pdf>
 - Currently in use for all CED programs, including Beta Amyloid
 - <http://clinicaltrials.com/>
 - MM8401 or below.
 - MLN Matters Article SE1344 at <http://www.cms.gov/outreach-and-education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1344.pdf>
 - [Medicare Q&As](https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf)
<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf>



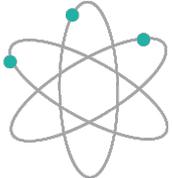


NEW IDEAS is a CMS Approved Clinical Trial

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html>

- Study Title: New IDEAS: Imaging Dementia-Evidence for Amyloid Scanning Study
Sponsor: American College of Radiology
ClinicalTrials.gov Number: [NCT04426539](https://clinicaltrials.gov/ct2/show/study/NCT04426539)
New IDEAS Study site: <https://www.ideas-study.org/>
CMS Approval Date: 04/21/2020

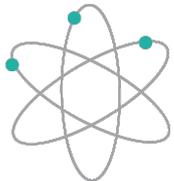
See sample claim forms for proper location and reporting of the clinical trials number on Medicare Claims.





CPT, HCPCS, Hospital Revenue Codes & ICD-10-CM

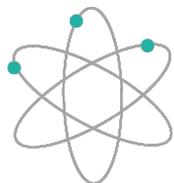
CODING & REIMBURSEMENT BY SETTING OF CARE



Abbreviations: APC, Ambulatory Payment Classifications; DRG, Diagnosis-Related Groups; HOPPS, Hospital Outpatient Prospective Payment System; IPPS, Inpatient Prospective Payment System; MPFS, Medicare Physician Fee Schedule; RBRVS, Resource-Based Relative Value System, POS, Place of Service IDTF, Independent Diagnostic Testing Facilities

	Hospital Inpatient IPPS/DRG	On Campus-Hospital Outpatient OPPS/APC	Off Campus-Hospital Outpatient OPPS/APC	Physician outpatient Services RBRVS/MPFS	Imaging outpatient Centers (IDTF) RBRVS/MPFS
POS	21	22	19	11	The setting the beneficiary received the technical component (TC) of the service.
Medicare program \$	Part A	Part B			
Local Medicare contractors/ administrators of the policies	Fiscal Intermediaries (old)			Carriers (old)	
	Medicare Administrative Contractors (MAC) (Current) www.cms.hhs.gov/medicarecontractingreform/				

POS 15 = Mobile Unit / Facility/ unit that moves from place-to-place equipment to provide diagnostic and/or treatment services.





Medicare Payment Systems

Basic Comparison of **MPFS** vs **OPPS**

- **MPFS** is a system that pays for covered physician & IDTF services furnished outside the hospital.
- Under the MPFS a relative value (RVU) is assigned to each service to capture the direct and indirect (overhead) practice expenses typically involved in furnishing the service. *AMA along with professional societies* develop inputs and values by survey not claims data.
- The higher the number of relative value units (RVUs) assigned to a service, the higher the payment.
- **Radiopharmaceuticals are paid at AWP or invoice cost.**
- Drugs are paid at ASP + 6%.
- All services under the **Hospital OPPS** are technical and are classified into groups called Ambulatory Payment Classifications (APCs) groups. Services in each APC are grouped by clinically similar services that require the use of similar resources.
- A payment rate is established for each APC using **two-year-old hospital claims data adjusted by individual hospital's cost to charge ratios.**
- Currently, diagnostic radiopharmaceuticals are bundled into the APC rate and considered supplies.



Both OPPS and MPFS have local wage adjustments, these slides list national rates.



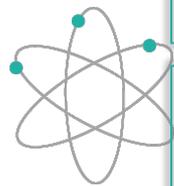
Procedure Coding – NEW IDEAS

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)

CODING TIP: Do **NOT** use CPT **78608**

Brain imaging, positron emission tomography (PET); **metabolic evaluation**

CODING TIP: Report CPT **78811** along with MRI codes for studies ordered & performed with PET/MRI



CODING TIP: Report CPT **78811** OR **78814**, **not both**, plus any required modifiers and HCPCS radiopharmaceutical codes supplied.

Diagnostic Radiopharmaceutical (Dx Rp) Packaged Payment or Contractor Priced

Must participate in CED Trial for Amyloid Agents

2021 HCPCS Level II Codes

HCPCS Level II	Trade Name Company	Description	2021 SI / APC 2020/2021 OPPS Payment	2021 MPFS Payment
Q9983	Neuraceq™ Life Molecular Imaging (formerly Piramal) NDC # 54828-001-30	Florbetaben F-18, diagnostic, <u>per study dose</u> , up to 8.1 millicuries	P a c k a g e d	Contractor Priced Most likely at Invoice Cost. * This setting typically does not accept C codes , use Q9983, Q9982 OR A9586
Q9982	Vizamyl™ G.E. NDC # 17156-067-30	Flutemetamol F-18, diagnostic, <u>per study dose</u> , up to 5 millicuries		
A9586	Amyvid™ Lily NDC # 0002-1200-01	Florbetapir F-18, diagnostic, <u>per study dose</u> , up to 10 millicuries		

**MPFS does have 20% co-payment
Patient deductibles apply to both HOPPS and MPFS
technical, professional and global rates**

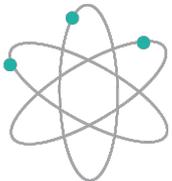


Procedure Coding – NEW IDEAS

National Payment Rates- Technical

CPT Code	Description	2021 OPPS National Rate	2021 MPFS NF National Rate
78811-Tc	PET imaging; limited area (eg, chest, head/neck)	\$1,272.05	Contractor Priced OPPS CAP \$1,272.05
78814-Tc	PET w/ CT for AC and anatomic localization imaging; limited area (eg, chest, head/neck)	\$1,443.00	Contractor Priced OPPS CAP \$1,443.00

MPFS NF= Non-Facility, Physician Office, Independent Diagnostic Testing Facility Setting (IDTF)
Co-Payment is 20% of the above national rates. Additionally, beneficiaries may have deductible responsibilities.



Rates will vary geographically. Figures are national rates.

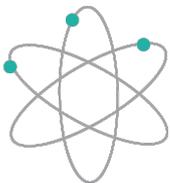


Procedure Coding – NEW IDEAS

National Payment Rates- Professional

CPT Code	Description	2021 MPFS NF National Rate	2021 20% Co- payment
78811-26	PET imaging; limited area (eg, chest, head/neck)	\$72.58	\$14.52
78814-26	PET w/ CT for AC and anatomic localization imaging; limited area (eg, chest, head/neck)	\$104.33	\$18.21

MPFS NF= Non-Facility, Physician Office, Independent Diagnostic Testing Facility Setting (IDTF)



Rates will vary geographically. Figures are national rates.

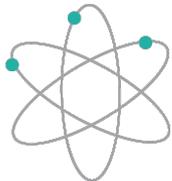


Co-Insurance – New IDEAS Medicare Patients

Co-Insurance includes co-payments & deductibles

Would apply as does any procedure or service. There is no added co-payment for participating in the NEW IDEAS study.

- Yes, co-insurance for **PET Procedure** (2021 ~\$254-~\$289.00)
- Yes, co-insurance for **PET Reading** (2021 ~\$15-\$18)
- Yes, MPFS-Physician office, IDTF, HCPCS Dx Rp co-insurance **would** apply (typically 20%, as with any other drug or Rp)
- Yes, co-insurance and deductibles apply for MA plans, each patient and each plan can have differing co-insurance, therefore check individually for each plan and each patient.



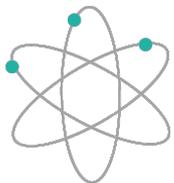
ICD-10-CM – CMS NCD identified

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
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 (Amnesia NOS, Memory loss NOS)



Resources, Tips, Sample Claim Forms, New IDEAS Billing Denial Form

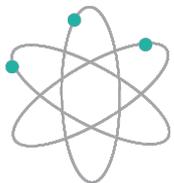
LOGISTICS





Logistics – CED - Claims

- Implement policies to **HOLD claims** until all elements of New IDEAS are met
 - applies to technical and professional
- Keep a copy of the e-mail from New IDEAS in your billing records in case of audit
 - Implement policies to notify and share with those billing professional component



If you participated in NOPR, treat similarly.

Amyloid PET Report Form

- This form becomes available when the Amyloid PET Completion form has been submitted.
- This form must be submitted within 7 days after the PET is completed.
- Following fields are required:
 - Date of PET report
 - Selection of interpreting physician
 - Entering **COMPLETE** text of PET report (copy/paste)

Interpreting physician will see available PET Assessment Forms for completion.

The screenshot displays the IDEAS web application interface. At the top left is the IDEAS logo with the tagline "Imaging Dementia—Evidence For Amyloid Scanning". Navigation options include "Data Collection" and "Facility Management", and the user "Robert Krasny" is logged in. The main heading is "Case Registration". Below this, there are filter buttons for "Patient Status: Eligible" and "Available Form: PET Assessment". A table lists case registrations, with one row for Case # 29, Stage "PET Scan Form Completed", Status "OPEN", Patient "Mary Poppins", and Registration date "12/29/2015". The "Forms" column for this case contains links for "Case", "Completion", "Report", and "Assessment". A large red arrow points to the "Assessment" link. On the left sidebar, there are buttons for "Case Registration", "PET Completion", "PET Report", and "PET Assessment" (which is highlighted with a notification icon).

Case #	Stage	Status	Patient	Registration	Forms
29	PET Scan Form Completed	OPEN	Mary Poppins	12/29/2015	Case Completion Report Assessment

When Amyloid PET Report form has been submitted, the PET Facility will receive the following email.

Practice ID#: 2005

Practice Name: Harvard

PET Facility ID#: 8006

PET Facility Name: Resolution Imaging

Patient SSN: *****111

Case #: 29

PET Scan Completed: 12/29/2015

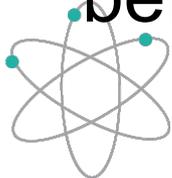
The Amyloid PET Report Form has been successfully submitted for the above referenced patient.



Independent Diagnostic Testing Facilities - IDTF

This is NOT a new policy rather a Reminder for IDTFs; IDTFs must notify CMS for any new service or equipment added to site:

- Complete an **855B form** and send to your Medicare Administrative Contractor, as required.
- Complete for any CPT or HCPCS codes (or equipment) if not already listed.
- Wait for the MAC to send you a confirmatory letter before you begin performing new services.





PET Resources – CMS, SNMMI & NEW IDEAS Websites

- **CMS Coverage Database:**

<https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

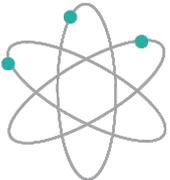
- **SNMMI PET PROS Referring/Interpreting Physician Resources – Elements of PET/CT Reporting & Q&As:**

<http://www.snmmi.org/Membership/Content.aspx?ItemNumber=5181>

- **New IDEAS: Imaging Dementia – Evidence For Amyloid Scanning**

<https://www.ideas-study.org/During-Study/Resources>

- **New IDEAS Claim Forms – <https://www.ideas-study.org/During-Study/Medicare-Reimbursement>**



Reimbursement Info New IDEAS web site

<https://www.ideas-study.org/>



Getting Started ▾ During Study ▾ For Patients Find a Site ▾



I need additional information ▾

News

New Research Study To Demonstrate Value Of Brain PET Scans In Diagnosing Alzheimer's In Diverse Populations
IDEAS Finds Small Drop in Hospitalizations
JAMA Study: Alzheimer's Diagnosis, Management Improved by Brain Scans

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Find a site



ZIP code finder
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[Request data from IDEAS Study »](#)

[Become a participating site »](#)

Contact Us

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newideas@acr.org

The New IDEAS Study

Sponsored and managed by
American College of Radiology®

Directed by
Alzheimer's Association

Advised by
Centers for Medicare and Medicaid Services

[Log In / Register](#)

[Become a participating site](#)



Reimbursement Info New IDEAS web site

<https://www.ideas-study.org/During-Study/Medicare-Reimbursement>

Medicare Reimbursement for Amyloid PET Scans

The Centers Medicare & Medicaid Services (CMS) issued a [National Coverage Determination \(NCD\)](#) on September 27, 2013, which allows conditional coverage of amyloid PET under Coverage with Evidence Development (CED).

Clinical Study Approval

Study Title: Imaging Dementia—Evidence for Amyloid Scanning (New IDEAS) Study

Sponsor: American College of Radiology

ClinicalTrials.gov Number: [NCT04426539](#)

CMS Approval Date: 04/21/2020

CMS Transmittals and MLN Matters Articles

- [Transmittal R1753OTN](#) and [MM9751](#) (Released November 17, 2016) - Coding Revisions to National Coverage Determination (NCDs)
- [Transmittal R2955CP](#) and [MM8401](#) (Released May 14, 2014) - Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims
- [Transmittal 2915CP](#), [Transmittal 164NCD](#), and [MM8526](#) (Released March 27, 2014) - Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease

Reimbursement FAQ

Can a participating physician other than the one who started it complete the post-PET clinical assessment form?





Medicare/Managed Medicare Hospital Outpatient Prospective Payment System (HOPPS) Setting HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 02/12



CARRIER

Form header section including PICA, Medicare/Medicaid/TRICARE/Champus/ChampVA/Group Health Plan/FECA/Other, Insured's ID Number (123-45-6789), Patient's Name (Smith, Stephen S.), Patient's Birth Date (01/17/1934), Patient's Address (123 Any Street, Any City), Patient Relationship (Self), and Reserved for NUCC Use.

Managed Medicare (e.g., Medicare MA Plan) Submit claim to MA Plan, NOT MAC. MA plans vary, however Typically require prior authorization and may dictate imaging site be part of their network, however out of network can be possible

Item No. 21 & 24E: Enter ICD-10-CM code for principle diagnosis in Item No. 21A. Enter CED identifier in Item No. 21B, check with payer for placement Enter ICD indicator 0 for ICD-10-CM Enter Dx Ref. letter(s) corresponding to the procedure in Item No. 24E F03.90 Unspecified dementia w/o behavioral disturbance Z006 Encounter for exam for normal comparison and control in clinical research program

Form section including Insured's Policy Group or FECA Number (9876543210), Insured's Date of Birth (01/17/1934), Sex (M), Insurance Plan Name (Medicare Or MA Plan), and Insured's or Authorized Person's Signature.

PATIENT AND INSURED INFORMATION

SIGNED Signature On File DATE 04 01 16

SIGNED Signature on File

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) 15. OTHER DATE 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. I.D. 999999999 17b. NPI 8888888888

Item No. 24G: Enter the number of units based on the CPT or HCPCS code description

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) CT04426539

Table with columns: A. DATE(S) OF SERVICE, B. PLACE OF SERVICE, C. PROCEDURE, SERVICES, OR SUPPLIES, D. DIAGNOSIS, E. POINTER, F. CHARGES, G. DAYS OF USE, H. EPSON Farm Plan, I. ID. QUAL, J. RENDERING PROVIDER ID. #

PHYSICIAN OR SUPPLIER INFORMATION

Item No. 19: Enter Clinical Trials Number CT04426539 (Mandatory requirement effective Jan. 1, 2014) if filing paper claim Use CT in front of 8 digit number. Item No. 24D: Enter CPT or HCPCS code for procedures interpreted by the physician in the hospital outpatient setting 78811 PET, limited 26 Modifier, Professional Component Q0 (zero) Investigational clinical service provided in a clinical research study that is in an approved clinical research study CHECK with payer for KX, may or may not be required, is required for NaF NOPR studies. KX Requirements specified in the medical policy have been met, proven or strongly suspected of being cancerous based on other diagnostic testing.

Sample Physician Office



Medicare/Managed Medicare

Non-Hospital Technical

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 02/12



CARRIER

PICA		PICA	
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE CHAMPUS (DoD) <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN (ID#) <input type="checkbox"/> FECA BENEFIT (IC#) <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Smith, Stephen S.		3. PATIENT'S BIRTH DATE MM DD YY 01 17 1934 M <input checked="" type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street) 123 Any Street		6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/>	
CITY Any City		8. RESERVED FOR NUCC USE	
9. ZIP CODE 00010		TELEPHONE (Include Area Code) 555 5555555	
11. INSURED'S POLICY GROUP OR FECA NUMBER 9876543210		a. INSURED'S DATE OF BIRTH MM DD YY 01 17 1934 M <input checked="" type="checkbox"/> F <input type="checkbox"/>	
b. OTHER CLAIM ID (Designated by NUCC)		c. INSURANCE PLAN NAME OR PROGRAM NAME Medicare Or MA Plan	
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete items 9, 9a, and 9d.		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
SIGNED Signature On File DATE 04 01 16		SIGNED Signature on File	
14. DATE OF CURRENT ILLNESS, INJURY OR PREGNANCY (LMP) MM DD YY QUAL. 1G 999999999		15. OTHER DATE MM DD YY 17a. 1G 999999999 17b. NPI 888888888	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE DK Dr. Neurologist		19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) CT04426539	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Route A-L to services line below (24E)) A. G3184 B. Z006		22. CHARGES FOR SAMPLE ONLY, PET SITE TO SET RATES.	
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE 04 05 2 04 05 2 11 78814 TC Q0 AB 3000 00 1 NPI 999999999		23. PRIOR AUTHORIZATION NUMBER	
04 05 2 04 05 2 11 A9599 Q0 AB 3135 00 1 NPI 999999999			
VIZAMYL (FLUTEMETAMOL) 5 MCI, IV, NDC 1715606701			

Item No. 21 & 24E:
Enter ICD-10-CM code for principle diagnosis in Item No. 21A.
Enter CED identifier in Item No. 21B, check with payer for placement
Enter ICD indicator 0 for ICD-10-CM
Enter Dx Ref. letter(s) corresponding to the procedure in Item No. 24E

F03.90 Unspecified dementia w/o behavioral disturbance

Z006 Encounter for exam for normal comparison and control in clinical research program

Managed Medicare (e.g., Medicare MA Plan)
Submit claim to MA Plan, NOT MAC. MA plans vary, however
Typically require prior authorization and may dictate imaging site
be part of their network, however out of network can be possible.

Item No. 24G:
Enter the number of units based on the CPT or HCPCS code description

Charges are for sample only, PET site to set rates.

Item No. 24B:
Enter Place of Service number.
11- Physician office

Item No. 19:
Enter Clinical Trials Number CT04426539 (Mandatory requirement effective Jan. 1, 2014) if filing paper claim
Use CT in front of 8 digit number. If filing electronic eliminate the CT and only list 8 digit number.
Item No. 24D:
Enter CPT or HCPCS code for procedure, radiopharmaceutical and modifier
(Chose only one procedure and HCPCS radiopharmaceutical code based on equipment PET or PET/CT and tracer administered.)
78811 PET limited or 78814 PET/CT limited
TC modifier, Technical Component
Q0 (zero) Investigational clinical service provided in a clinical research study in an approved clinical research study
Radiopharmaceuticals are contractor priced, may require invoice or additional information in box 19, 24 or other, check individual payer policy.
CHECK MAC and DOS for appropriate code that the payer may accept for payment.
Q9983 Florbetaben F-18, diagnostic, per study dose, up to 8.1 millicuries
Q9982 Flutemetamol F-18, diagnostic, per study dose, up to 5 millicuries
A9586 Florbetapir F-18, diagnostic, per study dose, up to 10 millicuries

Sample Physician Office



Medicare/Managed Medicare

Non-Hospital Global

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 02/12



CARRIER

1. MEDICARE (Medicare #) MEDICAID (Medicaid #) TRICARE (TRICARE #) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA (FECA #) OTHER 1a. INSURED'S NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Smith, Stephen S.

3. PATIENT'S BIRTH DATE
01 17 1934

6. PATIENT RELATIONSHIP TO INSURED
Self Spouse Child

5. PATIENT'S ADDRESS (No., Street)
123 Any Street

8. RESERVED FOR NUCC USE

Managed Medicare (e.g., Medicare MA Plan)
Submit claim to MA Plan, NOT MAC. MA plans vary, however typically require prior authorization and may dictate imaging site be part of their network, however out of network can be possible.

Item No. 21 & 24E:
Enter ICD-10-CM code for principal diagnosis in Item No. 21A.
Enter CED identifier in Item No. 21B, check with payer for placement
Enter ICD indicator 0 for ICD-10-CM
Enter Dx Ref. letter(s) corresponding to the procedure in Item No. 24E

F03.90 Unspecified dementia w/o behavioral disturbance

Z006 Encounter for exam for normal comparison and control in clinical research program

11. INSURED'S POLICY GROUP OR FECA NUMBER
9876543210

a. INSURED'S DATE OF BIRTH
01 17 1934 M F

b. OTHER CLAIM ID (Designated by NUCC)

c. INSURANCE PLAN NAME OR PROGRAM NAME
Medicare Or MA Plan

d. IS THERE ANOTHER HEALTH BENEFIT PLAN?
 YES NO If yes, complete items 9, 9a, and 9d.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED Signature on File

PATIENT AND INSURED INFORMATION

14. DATE OF CURRENT ILLNESS, INJURY OR PREGNANCY (LMP)
MM DD YY

15. OTHER DATE
MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
17a. I.D. 9999999999
17b. NPI 8888888888

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
CT04426539

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Route A-L to services line below (24E))
A. G3184 B. Z006 ICD Ind. 0

Item No. 24G:
Enter the number of units based on the CPT or HCPCS code description

Charges are for sample only, PET site to set rates.

Item No. 24B:
Enter Place of Service number.
11- Physician office

	A. DATE(S) OF SERVICE		B. PLACE OF SERVICE	C. PLIES	D. DIAGNOSIS POINTER	E. CHARGES	F. \$ CHARGES	G. DAYS OF SERVICE	H. EPSON FORM PLAN	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
	From MM DD YY	To MM DD YY									
1	04 07 2 1	04 07 2 1	11		78814 Q0		3200 00	1		NPI	9999999999
2	04 07 2 1	04 07 2 1	11		A9586 Q0		2756 00	1		NPI	9999999999

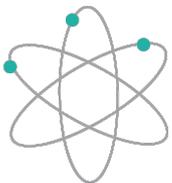
CLAIM INFORMATION

Item No. 19:
Enter Clinical Trials Number CT04426539 (Mandatory requirement effective Jan. 1, 2014) if filing paper claim
Use CT in front of 8 digit number. If filing electronic eliminate the CT and only list 8 digit number.

Item No. 24D:
Enter CPT or HCPCS code for procedure, radiopharmaceutical and modifier
(Chose only one procedure and HCPCS radiopharmaceutical code based on equipment PET or PET/CT and tracer administered).
78811 PET limited or 78814 PET/CT limited
No modifier, Global Billing includes Professional and Technical Component
Q0 (zero) Investigational clinical service provided in a clinical research study in an approved clinical research study
Radiopharmaceuticals are contractor priced, may require invoice or additional information in box 19, 24 or other, check individual payer policy.
Q9983 Flortbetaben F-18, diagnostic, per study dose, up to 8.1 millicuries
Q9982 Flutemetamol F-18, diagnostic, per study dose, up to 5 millicuries
A9586 Flortbetapir F-18, diagnostic, per study dose, up to 10 millicuries

Billing Specifics – CED- Amyloid

- Condition code 30 (for institutional claims only)
- Modifier Q0 (zero)
 - On both CPT and HCPCS codes
- Form Locator 39 (institutional claims) 1450 claim form
 - Clinical Trial Number D4 **CT04426539** *(paper claim)* or **04426539** *(electronic claim)*
- Form Locator 19 (physician office and/or IDTF claims) 1500 claim form
 - Clinical Trial Number P4 **CT04426539** *(paper claim)* or **04426539** *(electronic claim)*
- ICD-10-CM codes *(choose at least 1 from NCD list)* place in primary position, plus Z00.6 (in secondary position)



Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program



General Claims Processing Questions: Modifiers on Claims

Q: Do I append the Q0 (zero) modifier for Amyloid PET scans?

A: Yes, this is appended to the PET procedure code and may be applied to the Dx Rp depending on the Medicare Administrative contractor. Update, most MACs are requiring the Q0 on the HCPCS code in addition to the procedure code.

Q: Do I append the PI or PS modifier for Amyloid PET scans?

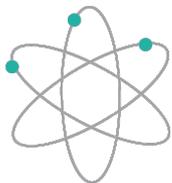
A: No, these are only for FDG and NaF PET studies at this point. *If a MAC requests this, notify NEW IDEAS immediately.*



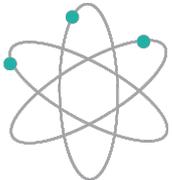
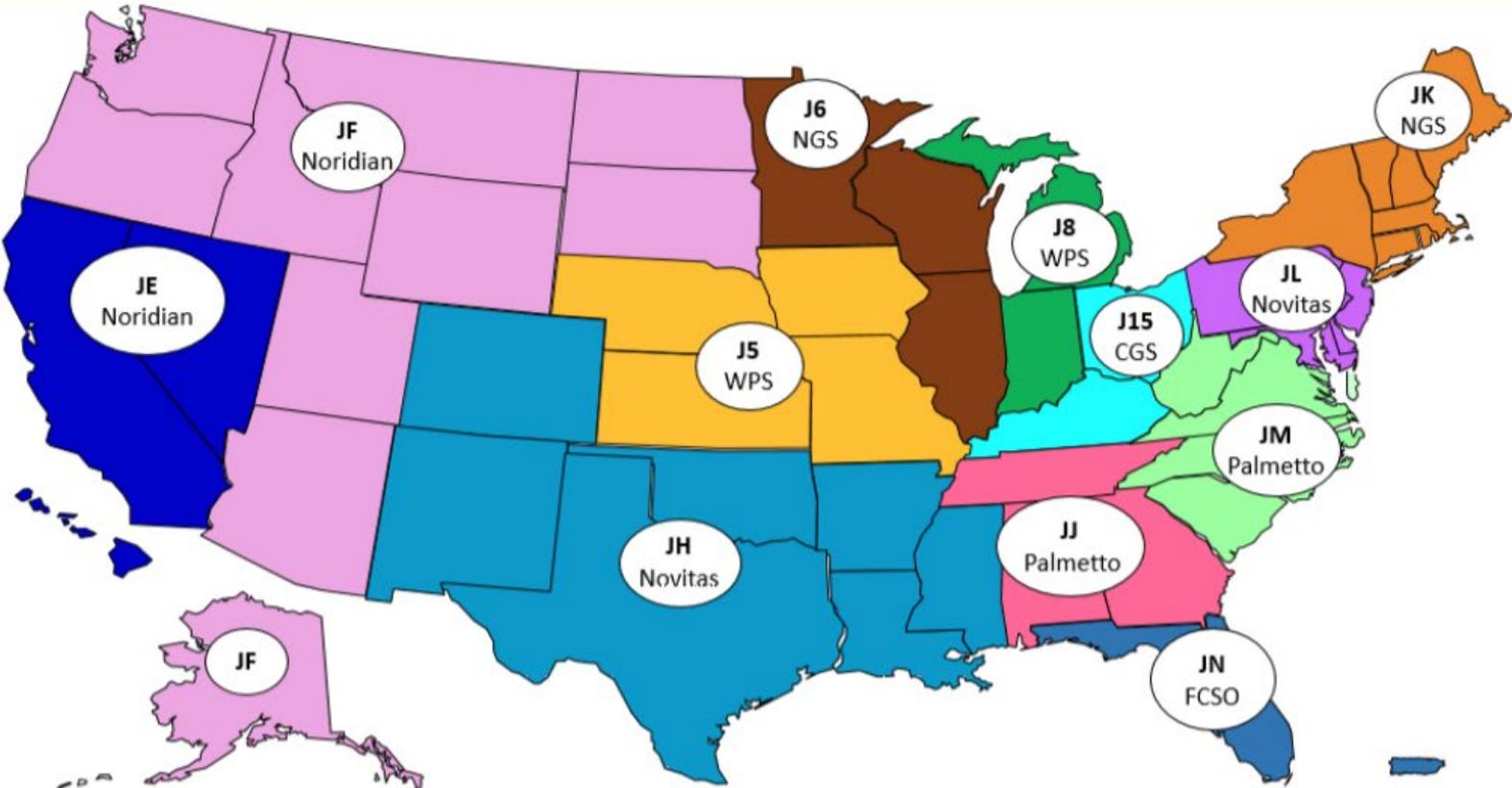


General Claims Processing Questions: Billing Limitations

- **Question:** Is the limit of 1 scan per year or per patient lifetime?
- **Answer:** The limits are per patient over the patient's lifetime (*with the count technically beginning at the start of the CMS approved CED trial*).



A/B MAC Jurisdictions as of December 2020



New IDEAS Claim Check List



NEW IDEAS Claim Check List

Request for NEW IDEAS Billing Assistance for Claim Denial

Ensure all the following items have been completed prior to submitting a request for assistance.

- Review sample claim forms for the site of service that applies to **your** claim. Verify all elements on the claim that are required or recommended are present on the submitted claim. Sample claims are located at the following URL: <https://www.ideas-study.org/During-Study/Medicare-Reimbursement>
- Check the New IDEAS Billing FAQ located at the following URL: <https://www.ideas-study.org/About-Us/FAQ>
- Locate your local Medicare Administrative Contractor (MAC), Local Coverage Policy or Article and Bulletins for PET services. Maintain this in your billing department and check for periodic changes. **Attach policy with request for assistance, if applicable.**
- If you are an Independent Diagnostic Testing Facility (IDTF), verify the CMS 855-B Application has been submitted adding both the procedure CPT and radiopharmaceutical HCPCS codes, if they are not already listed for your site. **Maintain this approval of listed codes in your billing department.**

*The below should be completed by the person requesting billing assistance. This should be submitted by the person that has the most knowledge of the billing, preferably the biller but may be others involved with New IDEAS. This form should **not** be completed by an industry representative. Send completed form and attachments to the New IDEAS-Study for routing: NewIdeas@ocr.org*

Check only one:

Provider type: MD Office IDTF Hospital Outpatient

Claim Information: Single Multiple "Like" Claim (complete attached sheet) number of claims: _____

Medicare type: Traditional Medicare Medicare Advantage (MA Plan)

Provider Name:		Contact at Provider Site:	
Provider Address:		Contact Position/Title:	
State Service Provided:		Contact Phone:	
MAC or MA Plan Name:		Contact E-Mail:	
MAC or MA Plan Phone and/or E-mail:		Date of Service (DOS) or Span of dates of issues:	
Date Last Communicated with payer:		Reason for Denial:	
Description of the billing issue and other pertinent information:			

Provider Request for IDEAS Claim Processing Assistance
(For use with multiple "LIKE" claims)

Number	MAC or MA Plan	ICN	DOS	Appeal Status
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

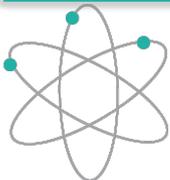
Page ____ of ____

Check here if additional information is attached.

This form and attachments may be sent to IDEAS-Study@ocr.org or Faxed to 888-606-4223.

TIP: Along with completing this form, use all your appeal rights, through to ALJ process. Do NOT rely only on New IDEAS to resolve.

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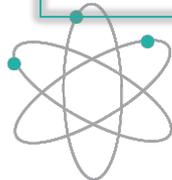




New IDEAS Denial Issues Status MA Plans

- Several **MA plans** don't know about **NEW IDEAS** – many resolved individually
- NEW IDEAS facilitating and obtaining a copy of a **communication to the MA plans**, when available, download the PDF from the NEW IDEAS web site.

Prior Authorization TIPS: Do **NOT** give up if MA plan denies on first or second call; continue to pursue all levels of an appeal of a denial. Be thoughtful and complete regarding supplying MA plans with New IDEAS and patient information.





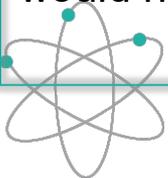
NEW IDEAS Denial Issues Status MA Plans- EXAMPLE

- Some **MA plans** don't know about NEW IDEAS

TIPS: I assisted a provider who was denied through Evicor; a radiology benefit manager (RBM), for some MA plans. Evicor **does** approve New IDEAS studies, however providers must give complete information in order to gain prior authorization.

The office that made the first call (likely the referring MD) to Evicor provided the following information, “**the pt. has mild cognitive impairment - G31.84** and no history or notes. Evicor then requested additional clinical information.

If the office would have stated the following, “**the pt. has mild cognitive impairment - G31.84 and meets the qualifications to participate in the NEW IDEAS study. We have enrolled the patient in the NEW IDEAS study a CMS approved CED trial 04426539, the patient New IDEAS case number is ___.** If additional clinical information is necessary, it would be the clinical items of the New IDEAS study that allowed the patient to qualify. In this case no peer to peer would have been needed if the clinical information had been provided.





Thank you!

QUESTIONS

