

8 Digit Registry Number Required on Clinical Trials and NOPR NaF-18 Claims

Effective January 1, 2014, the Centers for Medicare and Medicaid Services (CMS) made it mandatory to report a clinical trial number when submitting claims for items and services provided in a clinical trial that are qualified for coverage as specified in the National Coverage Determination (NCD) Manual, Publication 100-03, Section 310.1. Previously, the clinical trial number was reported on a voluntary basis.

When a new study is listed in the National Library of Medicine (NLM) Clinical Trials data base, a clinical trial number is assigned by the NLM Clinical Trials.gov website. This number is prominently displayed on each specific study's page and is preceded by the letters "NCT." This number is used by CMS to identify all items and services provided to a beneficiary during their participation in a clinical trial, clinical study, or registry including studies covered under coverage with evidence development (CED), the Medicare Clinical Trial Policy, or a CMS-approved investigational device exemption (IDE).

The use of this number helps CMS to track Medicare payments, ensure research information is used to inform coverage decisions, and to verify that the study targets issues that are relevant to the Medicare population. Please check CMS' clinical trials registry website: <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html> to verify the validity of a clinical trial, study or registry. Also, you can search for studies and the associated NCT Identifier on the National Library of Medicine (NLM) website: <http://clinicaltrials.gov/>

The Clinical Trails.gov Identifier associated with National Oncologic PET Registry (NOPR) is NCT00868582 and can be verified at:

<https://clinicaltrials.gov/ct2/show/NCT00868582?term=nopr&rank=1>

Please note the above National Clinical Trials identifier is the same NCT identifier that was used to report both F-18 FDG-PET and NaF-18 studies. The FDG-PET registry was closed effective June 11, 2013 when CMS issued a final decision memorandum which called for the end of the prospective data collection requirements under Coverage with Evidence Development (CED) for all oncologic indications for FDG-PET. This decision applied only to the FDG-PET registry; the

NaF-PET registry remains open. Claims reporting items and services for NaF-PET studies must continue to report NCT00868582 on the claim. See below for details.

For **facility/institutional claims**, submitted on Form UB-04 (CMS 1450), enter value code “D4” and “00868582” in Form Locators 39-41. For claims submitted on the electronic claim 837I, the 8-digit number should be placed in Loop 2300 REF02 (REF01=P4) when a clinical trial claim includes condition code 30; ICD-9 code V70.71/ICD-10 code Z00.6 in either the primary or secondary positions; and, modifier Q0 and/or Q1, as appropriate (outpatient claims only).

For **professional claims**, the 8-digit clinical trial number preceded by “CT” (**use “CT” only on paper claims**) must be placed in Item No. 19 on paper claim Form CMS-1500 (e.g., CT00868582) or the electronic equivalent 837P in Loop 2300 REF02 (REF01=P4). Note: **Do not use “CT” on the electronic claim**, e.g., 00868582 when a clinical trial claim includes: ICD-9 code of V70.7/ICD-10 code Z00.6 (in the primary or secondary positions); and, modifier Q0 and/or Q1, as appropriate (outpatient claims only).

Note: Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing an 8 digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number. Please see the following reference for copies of the MLM Matters Number: MM8401 Revised June 9, 2014 and CR Transmittal #: R2955CP released May 13, 2014 by clicking on the following link:

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R2955CP.html>

An example of a NaF-18 NOPR PET/CT whole body study is provided below that demonstrates the format and claim form location involved with reporting the clinical trial number. Also, the following link to the NOPR Educational Materials webpage provides links to complete examples of NaF-18 claim forms for both PI (initial treatment strategy) and PS (subsequent treatment strategy) in the hospital/facility and physician/IDTF provider settings.

<https://www.cancerpetregistry.org/ed.htm>

Sample Hospital Billing
Medicare / Managed Medicare
Hospital Outpatient Setting

NaF-PET/CT Study - skull vertex to feet
Initial Treatment Strategy (Breast Cancer)

1 Any Hospital One Hospital Place Any City Any State 00000		2		3a PAT. CNTL. # XXXXXXXXXX		4 TYPE OF BILL 131	
8 PATIENT NAME a Doe, Jane		9 PATIENT ADDRESS a 123 Any Street, A					
10 BIRTHDATE 01/17/1934		11 SEX F		12 DATE		13 ADMISSION	
31 OCCURRENCE DATE		32 OCCURRENCE CODE		33 OCCURRENCE DATE		34 OCCURRENCE CODE	
38		39 VALUE CODES a D4 00868582					
42 REV. CD 0404		43 DESCRIPTION NOPR PET/CT Whole Body		44 HCPCS / RATE / HIPPS CODE 78816 Q0 PI		45 SERV. DATE 01/14/2014	
42 REV. CD 0343		43 DESCRIPTION Sodium Fluoride F-18 per study dose		44 HCPCS / RATE / HIPPS CODE A9580		45 SERV. DATE 01/14/2014	
46 SERV. UNITS 1		47 TOTAL CHARGES XXXX : XX		48 NON-COVERED CHARGES		49	
46 SERV. UNITS 1		47 TOTAL CHARGES XXX : XX		48 NON-COVERED CHARGES		49	
58 INSURED'S NAME Jane Doe		59 P.REL		60 INSURED'S UNIQUE ID 123-45-6789		61 GROUP NAME Medicare	
63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME			
66 DX 1749 V707		67		68		69	
74 PRINCIPAL PROCEDURE CODE DATE		a. OTHER PROCEDURE CODE DATE		b. OTHER PROCEDURE CODE DATE		75	
76 ATTENDING LAST		NPI		QUAL		FIRST	
77 OPERATING LAST		NPI		QUAL		FIRST	
78 OTHER LAST		NPI		QUAL		FIRST	
79 OTHER LAST		NPI		QUAL		FIRST	
80 REMARKS		81CC a		b		c	

Form Locator 18-28:
 Enter the condition "30" *Qualifying Clinical Trials Non-research services provided to all patients, including managed care enrollees enrolled in a Qualified Clinical Trial.*

Managed Medicare
 Submit NaF claim to Medicare Administrative Contractor (MAC) for payment instead of Managed Medicare Contractor for all NaF NOPR claims

Form Locators 39-41:
 Enter Code D4 & Clinical Trials No. 00868582

Form Locator 42:
 Enter revenue codes.
0404 PET Procedures
0343 Diagnostic Radiopharmaceutical

Form Locator 46:
 Enter the number of units based on the CPT or HCPCS code description

Form Locator 44:
 Enter CPT or HCPCS code for procedures and radiopharmaceuticals or drug.
78816 PET/CT Whole Body
A9580 NaF, diagnostic, per study dose, up to 30 millicuries
Q0 (zero) Investigational clinical service provided in a clinical research study that is in an approved clinical research study
PI PET or PET/CT to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing

Form Locator 67 & 67A:
 Enter ICD-9-CM code for principle diagnosis in FL 67.
174.9 Breast (female), unspecified
 Enter NOPR Identifier in FL 67A
V70.7 Exam of Participants in Clinical Trials