

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11158	Date: December 16, 2021
	Change Request 12526

SUBJECT: National Coverage Determination (NCD) 220.6.19, Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer- Manual Update Only

I. SUMMARY OF CHANGES: The purpose for this change request is to update the NCD manual language to reflect that effective December 15, 2017, following the 24-month extension and absent any published, peer-reviewed journals regarding PET NaF-18 to identify bone metastases of cancer, NCD 220.6.19 reverted to a non-coverage determination.

EFFECTIVE DATE: December 15, 2017

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 17, 2022

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/220/6/19/ Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

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EFFECTIVE DATE: December 15, 2017

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 17, 2022

I. GENERAL INFORMATION

A. Background: On February 26, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a final decision regarding coverage of the radiopharmaceutical NaF-18 (sodium fluoride-18) to be utilized with positron emission tomography (PET) to identify bone metastases of cancer. CMS determined it not reasonable and necessary under 1862(a)(1)(A) of the Social Security Act (the Act) UNLESS it was used to inform initial anti-tumor treatment strategy OR to guide subsequent anti-tumor treatment strategy after completion of initial treatment, and then, ONLY under section 1862(a)(1)(E) of the Act under Coverage with Evidence Development (CED). All other uses and clinical indications of PET NaF-18 were deemed nationally non-covered. This national coverage determination (NCD) appeared at section 220.6.19 of Publication 100-03 of the NCD Manual.

In relation to the above decision, CMS issued an implementing Change Request (CR) 6861 dated March 26, 2010, that provided associated claims processing instructions and the official NCD 220.6.19 language. CMS created HCPCS code A9580, sodium fluoride F-18, diagnostic, per study dose, up to 30 millicuries, effective January 1, 2009, and instructed it be used for all PET NaF-18 claims under CED.

On March 16, 2015, CMS accepted a formal request to reconsider NCD 220.6.19 to end the prospective data collection requirements for use of PET NaF-18 in identifying bone metastasis of cancer. On December 15, 2015, CMS issued a final decision that reiterated its initial 2010 decision that PET NaF-18 to identify bone metastasis of cancer was not reasonable and necessary, and, therefore, not covered under section 1862(a)(1)(A) of the Act. In this final decision, CMS indicated it would continue the requirement for CED under §1862(a)(1)(E) of the Act for NaF-18 PET to identify bone metastasis of cancer for an additional 24 months from the final date of the decision to allow confirmatory analyses to be performed and resulting evidence to be published to definitively answer specific questions. All other uses and clinical indications for NaF-18 PET continued to be nationally non-covered. CMS indicated it would reconsider the NCD at such time when the evidence had been published in a peer-reviewed journal. That 2015 decision included draft verbiage of the prospective NCD 220.6.19.

B. Policy: Effective December 15, 2017, following the 24-month extension and absent any published, peer-reviewed journals regarding PET NaF-18 to identify bone metastases of cancer, NCD 220.6.19 reverted to a non-coverage determination. All MACs were informed in internal communications that all edits were to be deactivated as of December 15, 2017, until further notice. Following through, CMS issued CR 11655 dated June 19, 2020, and CR 12124 dated May 17, 2021, officially deactivating any edits relative to NCD 220.6.19.

This update to the NCD Manual is for conforming and clarifying purposes only. No further action is planned at this time.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12526.1	Contractors shall be aware that NCD 220.6.19, PET NaF-18 to Identify Bone Metastasis of Cancer, is being revised to comport with the final decision dated December 15, 2017. Following the 24-month extension and absent any published, peer-reviewed journals on the topic, NCD 220.6.19 reverted to a non-coverage determination. All related edits are deactivated. No action necessary. Manual update only.	X	X							
12526.2	Contractors shall adjust claims brought to their attention that were processed in error prior to the implementation date of this CR.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 4107860261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis Group) , Wanda Belle, 14107867491 or wanda.belle@cms.hhs.gov (Coverage and Analysis Group)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

220.6.19 – Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer (Effective December 15, 2017)

(Rev. 11158, Issued: 12-16-21, Effective:12-15-2017, Implementation: 01-27-22)

A. General

Positron Emission Tomography (PET) is a minimally-invasive, diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron-emitting radioactive tracer substances (radiopharmaceuticals) such as F-18 sodium fluoride (NaF-18).

B. Nationally Covered Indications

The confirmatory analyses were not published during the 24-month time period. Therefore, effective December 15, 2017, CMS determines that there are no nationally covered indications for PET NaF-18.

C. Nationally Non-Covered Indications

Effective December 15, 2017, CMS determines that PET NaF-18 PET is nationally non-covered.

D. Other

Other PET radiopharmaceutical tracers for cancer can be covered at local Medicare Administrative Contractor discretion when used according to their FDA-approved indication(s).

(This NCD last reviewed *December 2017.*)