

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10927</b>	<b>Date: August 2, 2021</b>
	<b>Change Request 12254</b>

**Transmittal 10888, dated July 19, 2021, is being rescinded and replaced by Transmittal 10927, dated, August 2, 2021 to revise the attached spreadsheets for NCD 20.5 and NCD 220.6.16. All other information remains the same.**

**SUBJECT: National Coverage Determination (NCD) Removal**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors that CMS has removed six National Coverage Determinations (NCDs) from the Medicare Publication (Pub.) 100-03, NCD Manual as a result of an NCD removal process through rulemaking in the Calendar Year 2021 Medicare Physician Fee Schedule (85 FR 84472, December 28, 2020).

**EFFECTIVE DATE: January 1, 2021**

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

**IMPLEMENTATION DATE: June 22, 2021; October 4, 2021**

*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/revise 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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/20.5/Extracorporeal Immunoabsorption (ECI) Using Protein A Columns
R	1/30.4/Electrosleep Therapy
R	1/100/9/Implantation of Gastrointestinal Reflux Devices
R	1/110/19/Abarelix for the Treatment of Prostate Cancer
R	220/2/1/Magnetic Resonance Spectroscopy
R	220/6/Positron Emission Tomography (PET) Scans
R	220/6/16/FDG PET for Inflammation and Infection

**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

Pub. 100-03	Transmittal: 10927	Date: August 2, 2021	Change Request: 12254
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**SUBJECT: National Coverage Determination (NCD) Removal**

**EFFECTIVE DATE: January 1, 2021**

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

**IMPLEMENTATION DATE: June 22, 2021; October 4, 2021**

## I. GENERAL INFORMATION

**A. Background:** The purpose of this Change Request (CR) is to remove six National Coverage Determinations (NCDs) from the Medicare Publication (Pub.) 100-03, NCD Manual as a result of an NCD removal process through rulemaking in the Calendar Year 2021 Medicare Physician Fee Schedule (85 FR 84472, December 28, 2020). The text of the final rule is available at <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeeschedpfs-federal-regulation-notices/cms-1734-f>

**B. Policy:** The final rule contains a summary of the NCD removal process and explicitly removes the following six NCDs from the NCD Manual:

NCD 20.5 Extracorporeal Immunoabsorption (ECI) Using Protein A Columns

NCD 30.4 Electrosleep Therapy

NCD 100.9 Implantation of Gastrointestinal Reflux Devices

NCD 110.19 Abarelix for the Treatment of Prostate Cancer

NCD 220.2.1 Magnetic Resonance Spectroscopy

NCD 220.6.16 FDG PET for Inflammation and Infection

The final rule also makes a non-substantive conforming change to NCD 220.6 Positron Emission Tomography (PET) Scans, which will be reflected in the NCD Manual.

In the absence of an NCD, contractors and adjudicators should consider whether any Medicare claims for these items/services are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act consistent with the existing guidance for making such decisions when there is no NCD. Therefore, coverage of the above six NCDs revert to Medicare Administrative Contractor (MAC) discretion effective for claims with dates of service on and after January 1, 2021.

## 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	
12254.1	<p>The local A/B MAC contractors shall determine coverage for the following six NCDs effective for claims with dates of service on and after January 1, 2021:</p> <p>NCD 20.5 Extracorporeal Immunoabsorption (ECI) Using Protein A Columns</p> <p>NCD 30.4 Electrosleep Therapy</p> <p>NCD 100.9 Implantation of Gastrointestinal Reflux Devices</p> <p>NCD 110.19 Abarelix for the Treatment of Prostate Cancer</p> <p>NCD 220.2.1 Magnetic Resonance Spectroscopy</p> <p>NCD 220.6.16 FDG PET for Inflammation and Infection</p>	X	X							
12254.2	The local A/B MAC shall be aware of the conforming changes in the NCD Manual at section 220.6.	X	X							
12254.3	<p>NCD 20.5 - Extracorporeal Immunoabsorption (ECI) Using Protein A Columns - Effective for claims with dates of service on and after January 1, 2021, all shared system edits shall be end-dated December 31, 2020. This is FISS RC 59001, 59002, 59003, 59004, MCS edit 128D.</p> <p>CPT 36516 shall be deleted from NCD 20.5 back to December 31, 2017, as it was added in error effective January 1, 2018.</p> <p>See revised spreadsheet.</p>	X	X			X	X			
12254.4	NCD 220.6.16 PET for Inflammation/Infection -	X	X			X	X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Effective for claims with dates of service on and after January 1, 2021, all shared system edits shall be end-dated December 31, 2020. This is FISS RC 59174, 59175, MCS edit 052L. See revised spreadsheet.									

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12254.5	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X			

**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:

**Section B: All other recommendations and supporting information: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis Group) , Heather Hostetler, 410-786-7515 or Heather.Hostetler@cms.hhs.gov (Coverage and Analysis Group) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@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: 2**

# Medicare National Coverage Determination Manual

## Chapter 1 – Coverage Determinations

### **20.5 Extracorporeal Immunoabsorption (ECI) Using Protein A Columns**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

*Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Extracorporeal Immunoabsorption (ECI) Using Protein A Columns. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.*

### **30.4 Electrosleep Therapy**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

*Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Electrosleep Therapy. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.*

### **100.9 Implantation of Gastrointestinal Reflux Devices**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

*Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Implantation of Gastrointestinal Reflux Devices. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.*

### **110.19 Abarelix for the Treatment of Prostate Cancer**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

*Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Abarelix for the Treatment of Prostate Cancer. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.*

### **220.2.1 Magnetic Resonance Spectroscopy**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

*Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Magnetic Resonance Spectroscopy. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.*

### **220.6 Positron Emission Tomography (PET) Scans**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

Positron Emission Tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissues as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. A radiopharmaceutical is injected into the patient that gives off sub-atomic particles, known as positrons, as it decays. PET uses a positron camera (tomograph) to measure the decay of the radiopharmaceutical. The rate of decay provides biochemical information to on the metabolism of the tissue being studied.

**NOTE:** This manual section, 220.6 lists all Medicare-covered uses of PET scans. Except as set forth below in cancer indications listed as “Coverage with Evidence Development,” a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section, 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all noncovered uses.

*Effective for dates of service on or after January 1, 2021, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for Fluorodeoxyglucose (FDG) PET for Infection and Inflammation (formerly National Coverage Determination (NCD) 220.6.16).*

Effective for dates of service on or after March 7, 2013, MACs may determine coverage within their respective jurisdictions for PET using radiopharmaceuticals for their Food and Drug Administration (FDA)-approved labeled indications for oncologic imaging.

We emphasize each of the following points:

1. Changing the ‘restrictive’ language of prior PET decisions will not by itself suffice to expand Medicare coverage to new PET radiopharmaceuticals.
2. The scope of this change extends only to FDA-approved indications for oncologic uses of PET tracers.
3. This change does not include screening uses of PET scanning.

The Centers for Medicare & Medicaid Services (CMS) acknowledges the advances relating to the assessment of diagnostic performance and patient safety, as pioneered by the FDA in its regulatory policies and guidelines for diagnostic PET imaging agents and systems during the past decade. We note for completeness that local coverage cannot be in conflict with NCDs or other national policies. Finally, we note that future CMS NCDs, if any, regarding diagnostic PET imaging would not be precluded by this NCD.

### **220.6.16 FDG PET for Inflammation and Infection**

*(Rev. 10927, Issued: 08-02-21, Effective: 01-01-2021, Implementation: 06-22-21)*

*Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Inflammation and Infection. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.*