and dollars, and improve Americans' quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the CPSTF. During its meetings, the CPSTF considers the findings of systematic reviews of existing research and practice-based evidence and issues recommendations. CPSTF recommendations are not mandates for compliance or spending. Instead, they provide information about evidence-based options that decision makers and stakeholders can consider when they are determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The CPSTF's recommendations, along with the systematic reviews of the evidence on which they are based, are compiled in the The Community Guide.

Matters proposed for discussion: The agenda will consist of deliberation on systematic reviews of literature and is open to the public. Topics will include Cancer Screening; HIV Prevention; Nutrition, Physical Activity, and Obesity; Social Determinants of Health, and Violence Prevention. Information

regarding the start and end times for each day, and any updates to agenda topics, will be available on the Community Guide website (www.thecommunityguide.org) closer to the date of the meeting.

The meeting agenda is subject to change without notice.

Dated: August 11, 2021.

### Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021-17556 Filed 8-16-21; 8:45 am]

BILLING CODE 4163-18-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Centers for Medicare & Medicaid Services** 

[CMS-9131-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2021

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from April through June 2021, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	William Parham	(410) 786–4669
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786–3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

### SUPPLEMENTARY INFORMATION:

### I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that

process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

#### II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a

more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

#### III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at http://www.cms.gov/manuals.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Lynette Willson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 11, 2021.

### Lynette Wilson,

Federal Register Liaison, Centers for Medicare and Medicaid Services.

BILLING CODE 4120-01-P

### **Publication Dates for the Previous Four Quarterly Notices**

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 12, 2020 (85 FR 48691), November 4, 2020 (85 FR 70168), March 17, 2021 (86 FR 14629) and May 3, 2021 (86 FR 23373). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

# Addendum I: Medicare and Medicaid Manual Instructions (April through June 2021)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

### How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

### How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government

publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for 2021 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List, use (CMS-Pub. 100-04) Transmittal No. 10737.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

#### Fee-For Service Transmittal Numbers

<u>Please Note</u>: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100-01)
10757	Physician Certification and Recertification of Services Manual Update to
	Incorporate Allowed Practitioners into Home Health Policy Certification and
	Recertification by Physicians and Allowed Practitioners for Home Health
	Services Content of the Physician's or Allowed Practitioner's Certification
10783	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10784	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
	Medicare Benefit Policy (CMS-Pub. 100-02)
10729	Updates to Medicare Benefit Policy Manual for Rural Health Clinic (RHC)
	and Federally Qualified Health Center (FQHC) Services (Manual Updates
	Only) of Aeronyms
	Care Management Services General
	Care Management Services – Chronic Care
10738	Home Health Manual Update to Implement Calendar Year 2021 Request for
	Anticipated Payment Policies and Corrections to Certification and Split

Federal
deral Register/
ster/Vol.
86,
No.
156/
86, No. 156/Tuesday, August 17, 2021/Notice
August
17,
2021/
Notices

Percentage Payment Approach to the 30-Day Period Unit of Payment
Requirements for Submission of "No-Pay" RAPs
Who May Sign the Certification or Recertification? Recertification for Home Health Beneficiaries
ledicare National Coverage Determination (CMS-Pub. 100-03)
National Coverage Determination (CVIS-Pub. 100-03)  National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor
(CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.
Chimeric Antigen Receptor (CAR) T-cell therapy
National Coverage Determination (NCD) Removal
Extracorporeal Immunoadsorption (ECI) Using Protein A Columns
Electrosleep Therapy
Implantation of Gastrointestinal Reflux Devices Abarclix for the Treatment of Prostate Cancer
Magnetic Resonance Spectroscopy
Positron Emission Tomography (PET) Scans
FDG PET for Inflammation and Infection
National Coverage Determination (NCD) 210.3 - Screening for Colorectal
Cancer (CRC)-Blood-Based Biomarker Tests
Colorectal Cancer Screening Tests
National Coverage Determination (NCD) Removal
Extracorporeal Immunoadsorption (ECI) Using Protein A Columns
Electrosleep Therapy
Implantation of Gastrointestinal Reflux Devices
Abarelix for the Treatment of Prostate Cancer
Magnetic Resonance Spectroscopy
Positron Emission Tomography (PET) Scans
FDG PET for Inflammation and Infection
Medicare Claims Processing (CMS-Pub. 100-04)
April 2021 Update of the Ambulatory Surgical Center (ASC) Payment
System
Issued to a specific audience, not posted to Internet/Intranet due to a
Sensitivity of Instruction
Issued to a specific audience, not posted to Internet/Intranet due to
Confidentiality of Instructions
Issued to a specific audience, not posted to Internet/Intranet due to
Confidentiality of Instructions
Common Working File (CWF) Edits for Medicare Telehealth Services and
Manual Update
Telehealth Consultation Services, Emergency Department or Initial Inpatient
versus Inpatient Evaluation and Management (E/M) Visits
Payment for Subsequent Hospital Care Services and Subsequent Nursing
Facility Care Services as Telehealth Services
New Waived Tests
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Issued to a specific audience, not posted to Internet/Intranet due to a
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
New Waived Tests Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction File Conversions Related to the Spanish Translation of the Healthcare
New Waived Tests  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
New Waived Tests  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
New Waived Tests  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  2021 Durable Medical Equipment Prosthetics, Orthotics, and Supplies
New Waived Tests  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  2021 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction
New Waived Tests  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  2021 Durable Medical Equipment Prosthetics, Orthotics, and Supplies

	and Neonatal Intensive Care (Codes 99291 - 99292) Nursing Facility Services
10756	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10758	Replacing Home Health Requests for Anticipated Payment (RAPs) with a
	Notice of Admission (NOA) Manual Instructions
10760	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10762	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10766	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10768	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10771	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10773.	Issued to a specific audience, not posted to Internet/Intranet due to a
10775.	Confidentiality of Instruction
10775	Issued to a specific audience, not posted to Internet/Intranet due to a
10773	Confidentiality of Instruction
10782	Issued to a specific audience, not posted to Internet/Intranet due to a
10762	Confidentiality of Instruction
10788	
10788	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10702	
10793	Quarterly Update to the Medicare Physician Fee Schedule Database
10501	(MPFSDB) - July 2021 Update
10794	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10796	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor
	(CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.
	Chimeric Antigen Receptor (CAR) T-cell therapy
	Coverage Requirements
	Billing Requirements
	Medicare Administrative Contractor (MAC) (A) Bill Types
	Revenue Codes
	Billing Healthcare Common Procedural Coding System (HCPCS) Codes
	Diagnosis Requirements
	Payment Requirements
	Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark
	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN)
	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing
10803	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a
	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10803	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal
10809	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and
10809	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
10809	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and
10809	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
10809	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment October 2021 Healthcare Common Procedure Coding System (HCPCS)
10809 10810 10811	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment October 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10809 10810 10811	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment October 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10809 10810 10811 10812	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment October 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code
10809 10810 10811 10812 10814	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment October 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10809 10810 10811 10812	Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment October 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code

	Confidentiality of Instruction
10818	National Coverage Determination (NCD) 210.3 - Screening for Colorectal
	Cancer (CRC)-Blood-Based Biomarker Tests
	Preventive and Screening Services
	Colorectal Cancer (CRC) Screening Payment Deductible and Coinsurance
	HCPCS Codes, Frequency Requirements, and Age Requirements
	CWF Edits
	Ambulatory Surgical Center (ASC) Facility Fee
	Determining High Risk for Developing CRC Non-Covered Services
	Billing Requirements for Claims Submitted to A/B MACs (A Medicare
	Summary Notice (MSN) Messages
	Remittance Advice Codes
10819	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10822	Issued to a specific audience, not posted to Internet/Intranet due to a
10000	Sensitivity of Instruction
10823	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
10824	July 2021 Integrated Outpatient Code Editor (I/OCE) Specifications Version
10825	22.2  July 2021 Update of the Hospital Outpatient Prospective Payment System
10023	(OPPS) Clinic Visits
10826	Shared System Support Hours for Application Programming Interfaces (APIs)
10831	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to
10031	and Excluded from Clinical Laboratory Improvement Amendments (CLIA)
	Edits
10833	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics,
10000	and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October
	2021
10834	Quarterly Update to Home Health (HH) Grouper
10836	July 2021 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing
	Files and Revisions to Prior Quarterly Pricing Files
10837	National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices
	(VADs)
	Artificial Hearts and Related Devices
	Ventricular Assist Devices (VADs
	Post-Cardiotomy
	VADs for Short-term or Long-term Mechanical Circulatory Support Other Replacement Accessories and Supplies for External VADs or Any
	VAD
10839	Replacing Home Health Requests for Anticipated Payment (RAPs) with a
10005	Notice of Admission (NOA) Manual Instructions
	Creation of HH PPS and Subsequent Refinements
	RESERVED
	The HH PPS Unit of Payment
	Number, Duration, and Claims Submission of HH PPS Periods of Care
	More Than One Agency Furnished Home Health Services
	Effect of Election of Medicare Advantage (MA) Organization and Eligibility
	Changes on HH PPS
	RESERVED
	Basis of Medicare Prospective Payment Systems and Case-Mix
	Coding of HH PPS Case-Mix Groups on HH PPS Claims: HHRGs and HIPPS Cod
	Composition of HIPPS Codes for HH PPS
	Grouper Links Assessment and Payment
	RESERVED
	Submission of the Notice of Admission (NOA)
	. ,

	Claim Submission and Processing
	Payment, Claim Adjustments and Cancellations
	RESERVED
	Transfer Situation - Payment Effects
	Discharge and Readmission Situation Under HH PPS - Payment Effects
	Payment Adjustments - Partial Period Payment Adjustment
	Payment When Death Occurs During an HH PPS Period
	Payment Adjustments - Low Utilization Payment Adjustments (LUPAs
	RESERVED
	Payment Adjustments – Applying OASIS Assessment Items to Determine
	HIPPS Codes
	Payment Adjustments - Outlier Payments
	RESERVED
	Changes in a Beneficiary's Payment Source
	Glossary and Acronym List
	Home Health Prospective Payment System (HH PPS) Consolidated Billing
	Responsibilities of Home Health Agencies
	Responsibilities of Providers/Suppliers of Services Subject to Consolidated
	Billing
	Home health Consolidated Billing Edits in Medicare Systems
	Therapy Editing
	Other Editing Related to Home Health Consolidated Billing
	Only Notice of Admission (NOA) Received and Services Fall Within
	Admission Period
	No NOA Received and Therapy Services Rendered in the Home
	Eligibility Query to Determine Status
	CWF Response to Inquiry
	Timeliness and Limitations of CWF Responses  National Home Health Prospective Payment Episode History File
	Opening and Length of HH PPS Periods of Care
	RESERVED
	RESERVED
	Exhibit: Chart Summarizing the Effects of NOA/Claim Actions on the HH
	PPS Episode File
	Notice of Admission (NOA
	HH PPS Claims
	Beneficiary-Driven Demand Billing Under HH PPS
	No Payment Billing
	General
	Input/Output Record Layout
	RESERVED
	Decision Logic Used by the Pricer on Claims
	Annual Updates to the HH Pricer
	Medical and Other Health Services Submitted Using Type of Bill 034x
	Temporary Suspension of Home Health Services
	Payment Procedures for Terminated HHAs
10840	Updates to the Internet Only Publication 100-04, Chapter 1, Section 10.1 and
	Chapter 20, Section 10
	A/B MACs [Part B] and DME MACs Jurisdiction of Requests for Payment
	Where to Bill DMEPOS and PEN Items and Services
10844	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
	Medicare Secondary Payer (CMS-Pub. 100-05)
10730	Electronic Correspondence Referral System (ECRS) Updates to the Revised
	Remote Identity Proofing, Implementation of a New ECRS Web Error Code,
	and Multi-Factor Authentication (MFA) Process and Requirements for the
	Transition from Connect Direct to the
	— <del>·</del>

Federal
deral Register/Vol.
Vol.
86,
86, No.
156/
156 / Tuesday, August 17, 2
August
17,
2021,
2021/Notices

	Attachment 2 - ECRS Web Quick Reference Card, Version 2021/5 April
	Attachment 1 - ECRS Web User Guide, Version 6.6 CMS Electronic File
	Transfer (EFT) System
10753	Update the Common Working File (CWF) to Accept a Group Health Plan
	(GHP) and non-GHP (NGHP) Medicare Secondary Payer (MSP) Effective
	Date 3 Months from the Current Date for Medicare Enrolled and Medicare
	Entitled Beneficiaries
10786	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10807	Update the International Classification of Diseases, Tenth Revision (ICD-10)
	2022 Tables in the Common Working File (CWF) for Purposes of Processing
	Non-Group Health Plan (NGHP) Medicare Secondary Payer (MSP) Records
	and Claims
	Medicare Financial Management (CMS-Pub. 100-06)
10710	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files
	to the Provider and Statistical Reimbursement (PS&R) System
10731	Notice of New Interest Rate for Medicare Overpayments and Underpayments
	-3rd Qtr Notification for FY 2021
10790	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
10806	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files
	to the Provider and Statistical Reimbursement (PS&R) System
10821	Pub. 100-06, Chapter 4, Section 10 Revision (New Accounts Receivable (AR)
	Status Codes for Undeliverable Initial Demand Letters and Terminated/Out of
	Business Providers) Requirements for Collecting Part A and B Provider Non-
	MSP Overpayments
10835	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
	Medicare State Operations Manual (CMS-Pub. 100-07)
204	Revisions to the State Operations Manual (SOM) Appendix Z - Emergency
	Preparedness
	Medicare Program Integrity (CMS-Pub. 100-08)
10709	Update to Chapter 12 (The Comprehensive Error Rate Testing (CERT)
	Program) of Publication (Pub.) 100-08 Handling Overpayments and
	Underpayments Resulting from the CERT Findings
10711	Updates to Chapter 4 of Publication (Pub.) 100-08 Organizational
	Requirements
	Procedural Requirements
	Program Integrity Security Requirements
	Requests for Information From Outside Organizations Screening Leads
	Vetting Leads with CMS
	Conducting Investigations
	Reversed Denials by Administrative Law Judges on Open Cases
	Production of Medical Records and Documentation for an Appeals Case File
	Guidelines for Incentive Reward Program Complaint Tracking Fraud Alerts
	Administrative Relief from Program Integrity Review in the Presence of a
	Disaster
	UPIC Hospice Cap Liability Process – Coordination with the MAC
	Referral of Cases to the OIG/OI
	Immediate Advisements to the OIG/OI
	Referral to Other Law Enforcement Agencies
	Reserved for Future Use
1	
	Referral to State Agencies or Other Organizations LIDICs and OLOs
	Referral to State Agencies or Other Organizations UPICs and QIOs
	Referral to State Agencies or Other Organizations UPICs and QIOs Discounts, Rebates, and Other Reductions in Price Identity Theft Investigations and Victimized Provider Waiver of Liability Procedure

10723	Implementation of Provider Enrollment Provisions in CMS-6058-FC – Phase 1 – Continued Removal/Moving of Instructions from Chapter 15 of
	Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08 Medicare Enrollment: Contractor Processing Duties
	Other Medicare Contractor Duties
	Development Letters
10727	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional
10727	Release of Chapter 10 of Pub. 100-08, Modification of the Timeliness
	Standards
10733	Issued to a specific audience, not posted to Internet/Intranet due to
10755	Confidentiality of Instructions
10735	Updates to Medicare Administrative Contractor (MAC) Appeals and
10,00	Rebuttals Reporting
10736	Issued to a specific audience, not posted to Internet/Intranet due to
10,00	Confidentiality of Instructions
10740	Voluntary Terminations of Enrollment Involving Certified Providers and
10710	Certified Suppliers
	Voluntary Terminations
	Model Letters for Voluntary Terminations Involving Certified Providers and
	Certified Suppliers
10741	Issued to a specific audience, not posted to Internet/Intranet due to
10,11	Confidentiality of Instructions
10743	Issued to a specific audience, not posted to Internet/Intranet due to
107.15	Confidentiality of Instructions
10744	Issued to a specific audience, not posted to Internet/Intranet due to
10,	Confidentiality of Instructions
10745	Issued to a specific audience, not posted to Internet/Intranet due to
10715	Confidentiality of Instructions
10749	Updates to Chapter 4 and Chapter 5 of Publication (Pub.) 100-08
	Identity Theft Investigations and Victimized Provider Waiver of Liability
	Certificates of Medical Necessity (CMNs) and DME Information Form
	(DIFs)
	Completing a CMN or DIF
	Cover Letters for CMNs
	DME MACs and UPICs Authority to Initiate an Overpayment and/or Civil
	Monetary Penalty (CMP) When Invalid CMNs or DIFs Are Identified
	Documentation in the Patient's Medical Record
	Supplier Documentation
	Evidence of Medical Necessity for the Oxygen Claims
	Period of Medical Necessity - Home Dialysis Equipment
	Safeguards in Making Monthly Payments
	Pick-up Slips
	Advance Determination of Medicare Coverage (ADMC) of Customized
1077	DMEPOS
10750	Issued to a specific audience, not posted to Internet/Intranet due to
L	Confidentiality of Instructions
10751	Issued to a specific audience, not posted to Internet/Intranet due to
4055	Confidentiality of Instructions
10752	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10776	Issued to a specific audience, not posted to Internet/Intranet due to
L	Confidentiality of Instructions
10777	Issued to a specific audience, not posted to Internet/Intranet due to
10	Confidentiality of Instructions
10779	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions

10799	Issued to a specific audience, not posted to Internet/Intranet due to
10799	Confidentiality of Instructions
10800	Second General Update to Chapter 10 of Publication (Pub.) 100-08, Program
10800	Integrity Manual
	Suppliers That Enroll Via the Form CMS-855B
	Ambulatory Surgical Centers (ASCs
	Home Infusion Therapy Suppliers
	Independent Clinical Laboratory Improvement Act Labs
	Independent Diagnostic Testing Facilities (IDTFs)
	Intensive Cardiac Rehabilitation (ICR)
	Mammography Screening Centers (MSCs)
	Pharmacies
	Portable X-Ray Suppliers (PXRSs)
	Radiation Therapy Centers (RTCs
	Suppliers of Ambulance Services
	Individual Practitioners Who Enroll Via the Form CMS-855I
	Anesthesiology Assistants
	Audiologists
	Certified Nurse-Midwives
	Certified Registered Nurse Anesthetists (CRNAs)
	Clinical Nurse Specialists
	Clinical Psychologists
	Clinical Social Workers
	Nurse Practitioners
	Occupational Therapists in Private Practice
	Physical Therapists in Private Practice
	Physician
	Physician Assistants
	Psychologists Practicing Independently
	Registered Dietitians/Nutrition Professionals
	Speech Language Pathologists in Private Practice
	Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or
	Implantable Durable Medical Equipment (DME) Surgically Inserted at an
	Ambulatory Surgical Center (ASC) Enrollment Form: Information and Processing
	CMS-20134 (Section 1 – Basic Information)
	CMS-20134 (Section 1 – Basic information) CMS-20134 (Section 2 – Identifying Information)
	CMS-20134 (Section 2 – Identifying information)  CMS-20134 (Section 3 – Final Adverse Legal Actions/Convictions)
	CMS-20134 (Section 4 – MDPP Location Information)
	CMS-20134 (Section 4 – MD11 Eccation Information) CMS-20134 (Sections 5 & 6 – Owning and Managing Organizations and
	Individuals)
	Reserved for Future Use
	CMS-20134 (Section 7 – Coach Roster)
	CMS-20134 (Section 8 – Billing Agency Information)
	CMS-20134 (Section 13 - Contact Person)
	CMS-20134 (Section 14 – Penalties for Falsifying Information)
	CMS-20134 (Section 15 – Certification Statement and Authorized
	Officials)
	CMS-20134 (Section 16 – Delegated Officials)
	CMS-20134 (Section 17 – Supporting Documents)
	Additional Form CMS-20134 Processing Information and Alternatives
10805	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10808	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10828	Provider Enrollment Rebuttal Process - Additional Instructions for Returning
	Applications and Deactivations

10829	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10830	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10841	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10843	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare C	ontractor Beneficiary and Provider Communications (CMS-Pub. 100-09)
10705	Issued to a specific audience, not posted to Internet/Intranet due to
10705	Confidentiality of Instructions
11772	Updates to Pub. 100-09, Chapter 6 Beneficiary and Provider Communications
	Manual, Chapter 6, Provider Customer Service Program
	Quality Assurance Monitoring (QAM)
	Remote Monitoring
	Disaster Recovery
	Guidelines for High Quality Responses to Provider Telephone Inquiries
	Telephone Response Quality Monitoring Program
	Telephone Responses to Provider Inquiries QCM Program Minimum
	Requirements
	Recording Calls
	QCM Calibration
	Provider Written Inquiries
	Controlling Provider Written Inquiries
	Provider Written Inquiry Storage
	Duplicate Inquiries Telephone Responses to Provider Written Inquiries
	Electronic Responses to Provider Written  Electronic Responses to Provider Written
	Check Off Letters
	Guidelines for High Quality Responses to Provider Written
	Stock Language/Form Letters
	Provider Written Response Quality Monitoring Program
	Written Responses to Provider Inquiries – QWCM Program Minimum
	Requirements
	QWCM Calibration
	Replying to Correspondence from Members of Congress
	Provider Walk-In Inquiries
	Guidelines for Provider Walk-In Service
	PRRS Operations
	Complex Provider Inquiries Complex Beneficiary Inquiries
	Provider Inquiry Tracking
	Updates to the CMS Standardized Provider Inquiry Chart
	MAC Inquiry Tracking Self-Data Review and Self-Validation Process
	Fraud and Abuse
	Provider Education Website Satisfaction Survey
	Staff Development and Education
	PCC Staff Development and Training
	Required Training for PCC Staff
	Provider Notifications of PCC Training Closures
	PCC Training Documentation
	Provider Self-Service Technology
	Interactive Voice Response System
	Provider Education Website
	General Requirements
	Webmaster and Attestation
	Website Governance

45993

CMS Feedback
Contents
Dissemination of Information from CMS to Providers
Frequently Asked Questions
Internet-based Provider Educational Offerings Provider Education Website Promotion
Electronic Mailing List (Listsery)
Targeted Electronic Mailing Lists (Listservs)
Electronic Mailing List (Listserv) Promotion
Social Media
Internet-based Provider Portal Service Interruptions Survey
Provider Satisfaction Survey
MAC Survey Participation Requirements
Continuous Improvement
Closed-Loop Ticketing
Survey Response Prohibition
MCE User Guide
Third-Party Contractor Platform System Users
MAC Satisfaction Score
PCSP Performance Management
POE - Electronic Mailing List (Listserv) Subscribership
Telephone Standards
Call Completion
Call Acknowledgment
Average Speed of Answer (ASA) Callback
QCM Performance Standards
QAM (Telephone) Performance Standard
Standards for Written Responses to Provider Inquiries
QWCM Performance Standards
Timeliness of Responses to Written Provider Inquiries
Timeliness of Responses to General Provider Inquiries
Timeliness of Responses to Complex Provider Inquiries (PRRS)
Timeliness of Responses to Complex Beneficiary Inquiries Timeliness of Responses to Congressional Inquiries
PCSP Data Reporting
PIE
Access to PIES
Due Date for Data Submission to PIES
Data to be Reported Monthly in PIES
PCID
Access to PCID
MAC Contract and PCSP Data to be Reported in PCID
Additional Data to be Reported Monthly in PCID and Reporting Due Dates
Inquiry Tracking Data to be Reported in PCID
PCC Training Closure Information to be Reported in PCID
POE Data to be Reported in PCID
Provider Electronic Mailing List (Listserv) Subscriber Data to be Reported
in PCID
Special Initiatives Activities to be Reported in PCID
Special Initiatives Activities to be Reported in PCID
Emergency and Similar PCC Closure Data to be Reported in PCID
Telecommunications Service Interruptions to be Reported in PCID
Provider Internet-based Portal Service Interruptions to be Reported in PCID
Provider Internet-based Portal Functionality to be Reported in PCID
Provider Education Website Analytic Data to be Reported in PCID
Direct Mailing Information to be Reported in PCID
QCM

	A 4- OCM
	Access to QCM OWCM
	Access to OWCM
	Disclosure of Information
10813	Issued to a specific audience, not posted to Internet/Intranet due to
10813	Confidentiality of Instructions
N.F	edicare Quality Improvement Organization (CMS- Pub. 100-10)
191	None
Modicar	re End Stage Renal Disease Network Organizations (CMS Pub 100-14)
.neurai	None
Modia	aid Program Integrity Disease Network Organizations (CMS Pub 100-15)
Mean	None
	Medicare Managed Care (CMS-Pub, 100-16)
	None
<b>X</b> /	edicare Business Partners Systems Security (CMS-Pub. 100-17)
- N	None
	Medicare Prescription Drug Benefit (CMS-Pub. 100-18)
	None
10704	Demonstrations (CMS-Pub. 100-19)
10704	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10715	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
10,10	of Instructions
10726	Issued to a specific audience, not posted to Internet/Intranet due to
10,20	Confidentiality of Instructions
10746	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 3:
	IURs and Edits for Non-Sequential Claims
10747	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instructions
10774	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10787	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instructions
10791	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10802	Direct Contracting (DC) Model - Professional and Global Options: Total Care
	Capitation (TCC), Primary Care Capitation (PCC), Advanced Payment
	Option (APO), Telehealth Expansion, 3-day SNF Rule Waiver, Post-
	Discharge and Care-Management Home Visits – Implementation
10820	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 3:
	IURs and Edits for Non-Sequential Claims
	One Time Notification (CMS-Pub. 100-20)
10712	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10717	MAC Participation in Change Requests Developed through Agile
	Methodology
10718	Cognitive Assessment & Care Plan Services
10732	Addition of the QW Modifier to Healthcare Common Procedure Coding
	System (HCPCS) Code 87636
10734	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
10739	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instructions
10748	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions

10780	Update to Rural Health Clinic (RHC) Payment Limits
10781	Initiative to Reduce Avoidable Hospitalizations among Nursing Facility
	Residents (NFI) - Updates and Clarifications
10785	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instructions
10789	The Fiscal Intermediary Shared System (FISS) Business Requirement for
	Rejected Claims Throwing Off the Provider and Statistical Reimbursement
	(PS&R) System Managed Care Days
10792	Mobile Personal Identity Verification (PIV) Station Installation
10795	Replacing Home Health Requests for Anticipated Payment (RAPs) with a
	Notice of Admission (NOA) – Implementation
10801	Additional Payment Edits for DMEPOS Suppliers of Custom Fabricated and
	Prefabricated (Custom Fitted) Orthotics. Update to Change Request (CR)
	3959, CR 8390, and CR 873
10804	International Classification of Diseases, 10th Revision (ICD-10) and Other
	Coding Revisions to National Coverage Determination (NCDs)July 2021
10817	International Classification of Diseases, 10th Revision (ICD-10) and Other
	Coding Revisions to National Coverage Determination (NCDs)October
	2021
10827	Addition of the QW Modifier to Healthcare Common Procedure Coding
	System (HCPCS) Codes 0240U, 0241U, 87637
10832	International Classification of Diseases, 10th Revision (ICD-10) and Other
	Coding Revisions to National Coverage Determination (NCDs)July 2021
10842	Implementation of the Hospital Outpatient Department (HOPD) Prior
	Authorization (PA) Paired Items of Service for the X12 278 PA Transactions
Med	licare Quality Reporting Incentive Programs (CMS- Pub. 100-22)
	None
	State Payment of Medicare Premiums (CMS-Pub.100-24)
	None
Info	rmation Security Acceptable Risk Safeguards (CMS-Pub. 100-25)
	None

# Addendum II: Regulation Documents Published in the Federal Register (April through June 2021)

# **Regulations and Notices**

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through <u>GPO Access.</u> The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: https://www.cms.gov/files/document/regs2q21qpu.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

# Addendum III: CMS Rulings (April through June 2021)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings">http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings</a>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

# Addendum IV: Medicare National Coverage Determinations (April through June 2021)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice. we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers	NCD 110.24	12177	05/21/2021	08/07/2019

Artificial Hearts/ Related Devices & VADs for Bridge to Transplant/Destination Therapy	NCD 20.9- 20.9.1	10837	06/22/2021	12/01/2020
Screening for Colorectal Cancer - Blood-Based Biomarker Tests	NCD 210.3	10818	05/21/2021	01/19/2021

### Addendum V: FDA-Approved Category B Investigational Device **Exemptions (IDEs) (April through June 2021)**

(Inclusion of this addenda is under discussion internally.)

### Addendum VI: Approval Numbers for Collections of Information (April through June 2021)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

### Addendum VII: Medicare-Approved Carotid Stent Facilities (April through June 2021)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	lity Provider Number		State
The following facilities	are new listings	for this quarter.	
New York Health + Hospitals 462 1st Street H-Building, Executive Administration New York, NY 10016	330204	03/30/2021	NY
Inova Fair Oaks Hospital	490101	04/26/2021	VA

Facility	Provider	Effective Date	State
	Number		
3600 Joseph Siewick Drive			
Fairfax, VA 22033			
UPMC Hanover	390233	04/13/2021	PA
300 Highland Avenue			
Hanover, PA 17331			
St. Joseph's Hospital - North	1881632818	05/18/2021	FL
4211 Van Dyke Road			
Lutz, FL 33558			
Kalispell Regional Medical Center	1417945627	05/18/2021	MT
310 Sunnyview Lane			
Kalispell, MT 59901			
Sierra Vista Regional Medical Center	050506	05/25/2021	CA
1010 Murray Avenue			
San Luis Obispo, CA 93405			
Emanate Health-Queen of the Valley	050382	06/08/2021	CA
Hospital			
1115 South Sunset Avenue			
West Covina, CA 91790			
Carilion New River Valley Medical	1295868792	06/15/2021	VA
Center			
2900 Lamb Circle			
Christianburg, VA 24073			
The following facilities			,
Orlando Health	100006	05/23/2005	FL
Old Address: 52 West Underwood			
Street Orlando, FL 32806			
New Address: 1414 Kuhl Avenue			
Orlando, FL 32806			
Previous Name: Gwinnett Medical	110087	08/31/2005	GA
Center			
New Name: Northside Hospital			
Gwinnett (For 1000 Medical Center			
Boulevard Lawrenceville, GA 30045			
Previous Name: Bay Medical Center	100026	05/23/2005	FL
New Name: Ascension Sacred Heart			
Bay 615 North Bonita Avenue			
Panama City, FL 32402			

### Addendum VIII:

# American College of Cardiology's National Cardiovascular Data **Registry Sites (April through June 2021)**

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

# Addendum IX: Active CMS Coverage-Related Guidance Documents

### (April through June 2021)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

#### Addendum X:

### List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2021)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at http://www.cms.gov . For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

# Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2021)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

# Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2021)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re- certification	State		
Th	The following are new facilities.					
HCA Houston Healthcare	450659	04/13/2021		TX		
Medical Center						
1313 Hermann Drive						
Houston, TX 77004						
Other information:						
DNV ID # 10000432549-						
MSC-VAD-USA						
Previous Re-certification						
Dates: n/a						
Kaiser Foundation Hospital -	050071	03/25/2021		CA		
Santa Clara						
700 Lawrence Expressway						
Santa Clara, CA 95051						
Other information						
Joint Commission ID # 10123						
Previous Re-certification						
Dates: n/a						
The following facilities have editorial changes (in bold).						
The University of Kansas	170040	03/08/2016	06/01/2021	KS		
Health System						
4000 Cambridge Street						
Kansas City, KS 66160-7200						

Facility	Provider Number	Date of Initial Certification	Date of Re- certification	State
Other information: Joint Commission ID # 8567				
Previous Re-certification				
Dates:				
03/08/2016; 03/06/2018				
Froedtert Memorial Lutheran Hospital, Inc	520177	07/31/2012	01/07/2021	WI
9200 West Wisconsin Avenue				
Milwaukee, WI 53226				
Other information:				
Joint Commission ID # 7718				
Previous Re-certification				
Dates:				
07/31/2012; 07/08/2014; 08/09/2016				
From: Saint Thomas West	440082	06/22/2010	01/14/2021	TN
Hospital				
To: Ascension Saint Thomas Hospital				
4220 Harding Road				
Nashville, TN 37205				
Other information:				
Joint Commission ID # 7891				
Previous Re-certification				
Dates:				
06/22/2010; 06/22/2012; 05/20/2014; 07/13/2016				
University Hospitals Cleveland	360137	02/09/2010	01/21/2021	ОН
Medical Center 11100 Euclid Avenue				
Cleveland, OH 44106				
Other information:				
Joint Commission ID # 7017				
Previous Re-certification				
Dates:				
02/09/2010; 01/24/2012;				
01/30/2014; 02/23/2016; 02/09/2018				
	l	I		

Facility	Provider Number	Date of Initial Certification	Date of Re- certification	State
University of North Carolina Hospitals 101 Manning Drive Chapel Hill, NC 27514	340061	10/26/2008	02/17/2021	NC
Other information: Joint Commission ID # 6478				
Previous Re-certification Dates: 10/16/2008; 10/19/2010;				
10/26/2012; 10/16/2014; 11/08/2016; 11/28/2018				
Mayo Clinic Hospital — Rochester 1216 Second Street SW Rochester, MN 55902-1906	240010	02/26/2008	03/20/2021	MN
Other information: Joint Commission ID # 8181				
Previous Re-certification Dates: 02/26/2008; 02/09/2010; 02/21/2012; 02/21/2014;				
04/05/2016; 03/23/2018 St. Francis Hospital 100 Port Washington Blvd Roslyn, NY 11576	330182	11/08/2016	05/08/2021	NY
Other information: Joint Commission ID # 5860				
Previous Re-certification Dates: 11/08/2016; 11/14/2018				
West Virginia University Hospitals, Inc. One Medical Center Drive Morgantown, WV 26506	510001	07/26/2018	02/25/2021	WV
Other information: Joint Commission ID # 6444				
Previous Re-certification Dates: 2018-07-26	260162	02/17/2012	02/27/2024	OII
Christ Hospital 2139 Auburn Avenue Cincinnati, OH 45219	360163	02/17/2012	02/26/2021	ОН
Other information: Joint Commission ID # 6987				
Previous Re-certification Dates:				

45997

Facility	Provider Number	Date of Initial Certification	Date of Re- certification	State
02/17/2012; 02/20/2014; 04/05/2016; 03/20/2018				
Northeast Georgia Medical Center 743 Spring Street Gainesville, GA 30501	110029	04/26/2018	05/05/2021	GA
Other information: DNV GL-USA ID # 10000464475-MSC-DNV GL- USA				
Previous Re-certification Dates: 04-26-2018				
University of Colorado Hospital Authority 12605 E 16th Ave Aurora, CO 80045	060024	07/22/2008	03/10/2021	СО
Other information: Joint Commission ID # 9384				
Previous Re-certification Dates: 07/22/2008; 08/17/2010; 08/10/2012; 07/22/2014; 07/26/2016				
From: California Pacific Medical Center-Van Ness Campus 1101 Van Ness Avenue San Francisco, CA 94109 To: California Pacific Medical Center-Pacific Campus;	050047	12/08/2009	02/20/2021	CA
Other information: Joint Commission ID # 5152				
Previous Re-certification Dates: 12/08/2009; 11/11/2011; 01/07/2014; 02/09/2016; 03/20/2018				
JFK Medical Center 5301 South Congress Avenue Atlantis, FL 33462	100080	01/24/2017	03/03/2021	FL
Other information: Joint Commission ID # 6836				
Previous Re-certification Dates: 01/24/2017; 3/6/2019				
Mission Hospital	340002	05/17/2016	04/14/2021	NC

Facility	Provider Number	Date of Initial Certification	Date of Re- certification	State
509 Biltmore Avenue Asheville, NC 28801-4690				
Other information: Joint Commission ID # 6468				
Previous Re-certification Dates: 05/17/2016; 6/27/2018				

# Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2021)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
  - Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

# Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2021)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric

Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

# Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2021)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2021–17602 Filed 8–16–21; 8:45 am]

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW,

Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: http://www.hrsa.gov/vaccinecompensation/index.html.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 et seq., provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register." Set forth below is a list of petitions received by HRSA on July 1, 2021, through July 31, 2021. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability,