



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9125-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances -

April through June 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (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 2020, 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 Number
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 Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 17, 2020.

Trenesha Fultz-Mimms,
Federal Register Liaison,
Department of Health and Human Services.

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 9, 2019 (84 FR 39323), November 6, 2019 (84 FR 59815), February 13, 2020 (85 FR 8282), and April 24, 2020 (85 FR 23030). 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 2020)

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 National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM), use (CMS-Pub. 100-03) Transmittal No. 10073.

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

Please Note: 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)	
10050	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10133	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Medicare Benefit Policy (CMS-Pub. 100-02)	
	None
Medicare National Coverage Determination (CMS-Pub. 100-03)	
10073	National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM)
10128	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP) Acupuncture ACUPUNCTURE for Chronic Lower Back Pain (cLBP) Acupuncture for Fibromyalgia ACUPUNCTURE FOR OSTEOARTHRITIS
10145	National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS) Vagus Nerve Stimulation
10179	NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR)
10199	National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS) Vagus Nerve Stimulation
Medicare Claims Processing (CMS-Pub. 100-04)	
10026	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10027	April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.1
10028	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP) Acupuncture for Chronic Low Back Pain (cLBP) Claims Processing General Information 32/410/3/Institutional Claims Bill Type and Revenue Coding Information Messaging Common Working File (CWF) Editing
10030	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10031	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10033	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10036	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10037	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
10038	Quarterly Update to the Fiscal Year 2020 Inpatient Psychiatric Facilities Pricer
10039	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update
10041	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

10042	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Schedule and Laboratory Services Subject to Reasonable Charge Payment
10044	Claim Status Category and Claim Status Codes Update
10045	Claim Status Category and Claim Status Codes Update
10046	April 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
10048	New Waived Tests
10052	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10053	April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.1
10054	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10058	July 2020 Quarterly Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2020 Pricer
10059	Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2020 - Recurring July File Update
10060	Quarterly Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2020 Pricer
10064	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Code from Council for Affordable Quality Healthcare (CAQH) CORE
10067	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10069	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10070	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10071	Modify Edits in the Fee for Service (FFS) System When a Beneficiary has a Medicare Advantage (MA) Plan National Coverage Determination (NCDs) services that are considered a Significant cost for Medicare Advantage Institutional Billing for National Coverage Determination (NCDs) Services that are considered a significant cost for Medicare Advantage Services Identified as having Significant Cost for Medicare Advantage
10072	Removal of Signature Line from Appeals Page of the Medicare Summary Notice (MSN) and MSN Envelope Correction Specifications for Section 4 (Last Page): Denials and Appeals
10073	National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM) Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements
10074	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10075	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

10079	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10081	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10082	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10084	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10085	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10086	New Codes for Therapist Assistants Providing Maintenance Programs in the Home Health Setting Adjustments of Episode Payment - Low Utilization Payment Adjustments (LUPAs) Adjustments of Episode Payment - Early or Later Episodes Adjustments of Episode Payment – Validation of HIPPS Codes Glossary and Acronym List HH PPS Claim
10087	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10088	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10090	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10093	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10096	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10097	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10098	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update
10107	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10120	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2020 Update
10121	Combined Common Edits/Enhancements Modules (CEM) Code Set Update
10122	July 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10123	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10124	New Physician Specialty Code for Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD) and a New Supplier Specialty Code for Home Infusion Therapy Services
10125	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10126	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

10128	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP) Acupuncture for Chronic Low Back Pain (cLBP) Claims Processing General Information Institutional Claims Bill Type and Revenue Coding Information Messaging Common Working File (CWF) Editing
10129	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10135	Manual Update to Pub. 100-04, Chapter 38, to Remove Identification of Items or Services Related to the 2010 Oil Spill in the Gulf of Mexico Section
10136	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
10137	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2020
10140	Updates in the Fiscal Intermediary Shared System (FISS) Inpatient Inputs/Outputs to PRICER Input/Output Record Layout Provider Specific Files (PSF)
10142	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10148	Claim Status Category Codes and Claim Status Codes Update
10149	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10150	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
10151	Combined Common Edits/Enhancements Modules (CEM) Code Set Update
10152	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10153	October 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10154	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
10165	July 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.2
10166	July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10167	Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2020
10168	July Quarterly Update for 2020 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10173	Internet Only Manual Update, Pub. 100-04, Chapter 11 Notice of Termination/Revocation (NOTR) Data Required on the Institutional Claim to A/B MAC (HHH) Processing Professional Claims for Hospice Beneficiaries

10174	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10175	Instructions for Downloading the Medicare ZIP Code Files for October 2020
10176	Quarterly Update to Home Health (HH) Grouper
10177	Annual (2021) Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
10179	Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR) Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012 Coding Requirements for TAVR Services Furnished on or After January 1, 2013 Claims Processing Requirements for TAVR Services on Professional Claims
10180	Removal of Signature Line from Appeals Page of the Medicare Summary Notice (MSN) and MSN Envelope Correction Specifications for Section 4 (Last Page): Denials and Appeals
10183	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10186	Updates to Chapter 1, Payer Only Codes in the Medicare Claims Processing Manual
10187	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10188	July 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
10189	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 26.3, Effective October 1, 2020
10191	Quarterly Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2020 Pricer
10192	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10196	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Secondary Payer (CMS-Pub. 100-05)	
10040	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10101	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10147	Update the International Classification of Diseases, Tenth Revision (ICD- 10) 2021 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)	
10035	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
10049	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2020
10124	New Physician Specialty Code for Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD) and a New Supplier Specialty Code for Home Infusion Therapy Services Claims Processing Timeliness - All Claims

	Part E - Interest Payment Data Classification of Claims for Counting Physician/Limited License Physician Specialty Codes Non-Physician Practitioner/Supplier Specialty Codes Exhibit
10164	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare State Operations Manual (CMS-Pub. 100-07)	
201	State Operations Manual (SOM) Chapter 2, The Certification Process
202	State Operations Manual (SOM) Chapter 3, Additional Program Activities
Medicare Program Integrity (CMS-Pub. 100-08)	
10047	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10056	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10057	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10062	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10063	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10099	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10100	Revision to Language in Chapter 3, Section 3.7.5 (Corrective Action Reporting Requirements) of Publication (Pub.) 100-08
10111	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10117	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10130	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10131	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10132	Revising Subsection 3.2.5, Targeted Probe and Educate (TPE), in Chapter 3 of Publication (Pub.) 100-08
10134	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10138	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment)
10146	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
10156	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10157	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10159	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

10169	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10171	Updates to Durable Medical Equipment, Prosthetics, Orthotics & Supplies
10182	Update to Chapter 10 of Publication (Pub.) 100-08 - Model Letter Templates Model Letters Approval Letters DME Approval Letter Templates Part A/B Certified Provider Approval Letter Templates Part B Non-Certified Supplier Approval Letter Templates
10184	Updates to Chapters 4, 6, and 8 of Publication (Pub.) 100-0
10190	Suppliers Documentation for DMEPOS Repair Claims Suppliers Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP) and Respiratory Assist Devices (RADs) Evidence of Medical Necessity Evidence of Medical Necessity for the Oxygen Claims Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims Period of Medical Necessity - Home Dialysis Equipment Safeguards in Making Monthly Payments Reserved for Future Use Pick-up Slips Incurred Expenses for DMEPOS Reserved for Future Use Definitions of Customized DMEPOS - Advance Determination of Medical Coverage (ADMC) of Customized DMEPOS Items Eligible for ADMC Instructions for Submitting ADMC Requests Instructions for Processing ADMC Requests Affirmative ADMC Decisions Negative ADMC Decisions DME MAC Tracking Recent Final Rule CMS-1713-F
10194	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10197	Publication (Pub.) 100-08 Chapter 3 Updates to Section 3.2.3.2 (Timeframes for Submission) and Section 3.2.3.8 (No Response or Insufficient Response to Additional Documentation Requests (ADRs) Timeframes for Submission No Response or Insufficient Response to Additional Documentation Requests
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
10144	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10195	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None

Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
10185	Update to Chapter 1 of Publication (Pub.) 100-15 Fraud Referrals
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
10051	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10113	Remove/Archive Demonstration Code 58 - Inactive Medicare Demonstration Projects within the Multi Carrier System (MCS) and Common Working File (CWF) System
10114	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10127	Value-Based Insurance Design (VBID) Model – Implementation
10141	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 1: Provider, Beneficiary and Procedure Code Files to Support Model Implementation
10170	Value-Based Insurance Design (VBID) Model – Implementation
10181	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
One Time Notification (CMS-Pub. 100-20)	
10023	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10024	Second Update to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
10025	Update to the Home Health Grouper for New Diagnosis Codes for Vaping Related Disorder and COVID-19.
10029	Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder and 2019 Novel Coronavirus (COVID-19)
10032	User CR: ViPS Medicare System (VMS) Report Daily Edit Receipts
10034	Fiscal Intermediary Shared System (FISS) Enhancement of PC Print Billing Software
10043	Implementation of Additional Requirement to add Healthcare Common Procedure Coding System (HCPC) and Current Procedural Terminology (CPT) - HCPC/CPT as Paired Items of Service for Prior Authorization and Medicare Claims Processing for Part A and Home Health and Hospice
10055	Implementation of the Award for the Jurisdiction 5 Part A and Part B Medicare Administrative Contractor (J-5 A/B MAC)
10061	Provider Education for Required Prior Authorization (PA) of Hospital Outpatient Department (OPD) Services
10065	Fiscal Intermediary Shared System (FISS) Enhancement of PC Print Billing Software
10066	Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) code U0002 and 87635
10068	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity

	of Instructions
10076	COBOL Version 6.2 Upgrade - Additional Analysis and Phase I Implementation
10077	Coding Support for Secure Destruction Program Implemented in Change Request (CR)
10078	Additional Coordination of Benefits (COB) Workload Numbers Added to the Medicare Part B Contractor Reporting Operational Workload Data (CROWD) Table for Purposes of Identifying Medicare Secondary Payer (MSP) Part B Recovery Savings for the Benefits Coordination and Recovery Center (BCRC) and the Commercial Repayment Center (CRC) Contractors
10080	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10083	Update to Medicare Shared Savings Program (SSP) Skilled Nursing Facility (SNF) Affiliates' Requirement to Include Demonstration Code 77 on SNF Waiver Claims
10089	Implementation of the Error Scenario for the Document Code File (DCF) and Data Element Format Revisions for Providers Participating in the Electronic Medical Documentation Requests (eMDR) via the Electronic Submission of Medical Documentation (esMD) System
10091	Systematic Updating of the Spanish Medicare Summary Notice (MSN) Short Descriptors
10092	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—October 2020 Update
10094	Implementation for First Coast Service Options (FCSO) and Novitas for the CMS Enterprise Identity Management OKTA/Saviynt Migration
10095	Updates to Ensure the Original 1-Day and 3-Day Payment Window Edits are Consistent With Current Policy
10102	User Change Request (CR): Fiscal Intermediary Shared System (FISS) – Operator Control File Enhancement for Online Parm Access
10103	Editing Update for Abdominal Aortic Aneurism and Screening Pap Smears and Pelvic Examinations
10104	Expand Retention of Claims History for Outpatient, Part B, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to 5 Years
10105	User CR: ViPS Medicare System (VMS) - Update Waiver of Liability Claim Edits 6142 and 6143
10106	User Change Request (UCR): Implementation Requirements for Analysis UCR 10766 - Reduce Unmailable Medicare Summary Notices (uMSNs) Created in the Fiscal Intermediary Shared System
10108	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10109	Updates to Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) to Correct the Adjustment Process
10110	Implement Error Tracking into the Recovery Audit Contractor (RAC) Data Warehouse (RACDW) Non-RAC Prepayment File Layout
10112	Common Working File (CWF) to Medicare Beneficiary Database (MBD) Extract File Changes to send Hospice DOEBA, DOLBA dates and days used to support HIPAA Eligibility Transaction System (HETS)

10115	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10116	Extension of Payment for Section 3712 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
10118	User CR: ViPS Medicare System (VMS) - Contractor Options Screen Contractor Options Screen (VMAP/1/1) Automation
10119	User Change Request (CR): Fiscal Intermediary Shared System (FISS) – Invalid User IDs on the Operator Control File
10139	Therapy Codes Update
10143	Editing Update for Abdominal Aortic Aneurism and Screening Pap Smears and Pelvic Examinations
10155	Provider Education for Required Prior Authorization (PA) of Hospital Outpatient Department (OPD) Services
10158	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10160	Summary of Policies in the Calendar Year (CY) 2020 Medicare Physician Fee Schedule (MPFS) Public Health Emergency (PHE) Interim Final Rules
10161	Therapy Codes Update
10162	COBOL Version 6.2 Upgrade - Additional Analysis and Phase I Implementation
10163	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10172	Medicare Appeals System (MAS) Enhanced Web Services for Part A Medicare Administrative Contractors
10178	New Point of Origin Code for Transfer From a Designated Disaster Alternate Care Site
10193	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--July 2020 Update
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2020)

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 GPO Access. 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/regs1q20qpu.pdf>

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

**Addendum III: CMS Rulings
(April through June 2020)**

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 <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

**Addendum IV: Medicare National Coverage Determinations
(April through June 2020)**

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
Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD)	NCD 20.32	10199	06/23/2020	02/15/2019
National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM)	NCD 10.19	10073	05/01/2020	07/02/2019
National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)	NCD 30.3.3	10128	05/18/2020	01/21/2020

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2020)
(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information
(April through June 2020)**

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 2020)**

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/MedicareApprovedFacilities/CASF/list.asp#TopOfPage> For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
St. John's Regional Medical Center 1600 N. Rose Avenue Oxnard, CA 93030	1073665360	05/19/2020	CA
Tidelands Georgetown Memorial Hospital 606 Back River Road Georgetown, SC 29442 <u>Other Information:</u> P.O. Box 421718	420020	06/09/2020	SC
HCA Houston Healthcare Conroe 504 Medical Center Boulevard Conroe, TX 77304	1962455816	02/10/2020	TX
Monongalia County General Hospital Company 1200 JD Anderson Drive Morgantown, WV 26505 <u>Other Information:</u> d/b/a Mon Health Medical Center	510024	06/23/2020	WV
The following facilities have editorial changes (in bold).			
Baptist Health Regionals (Ft. Smith) 1001 Towson Avenue Fort Smith AR 72901-4921	040055	09/22/2005	AR
Jackson Madison County General 620 Skyline Drive Jackson, TN 38301	440002	08/23/2005	TN
Springhill Medical Center 3719 Dauphine Street Mobile, AL 36608	010144	08/22/2005	AL

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2020)

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 2020)

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 2020)

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 2020)**

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 2020)

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
The following facilities have editorial changes (in bold).				
Morristown Medical Center 100 Madison Avenue Morristown, NJ 07960 Other information: Joint Commission ID # 5958 Previous Re-certification Dates: 06/16/2009; 09/28/2011; 10/31/2013; 11/17/2015; 12/12/2017	310015	06/16/2009	01/25/2020	NJ
Piedmont Hospital, Inc. 1968 Peachtree Rd NW Atlanta, GA 30309 Other information: Certificate ID # 502231-2020-VAD Previous Re-certification Dates: 6/9/2011; 2/8/17	110083	06/09/2011	03/19/2020	GA
FROM: Florida Hospital TO: Adventist Health System/Sunbelt Inc. 601 East Rollins Street Orlando, FL 32803 Other information: Joint Commission ID # 6873 Previous Re-certification Dates: 10/24/2012; 10/07/2014; 11/15/2016	100007	10/24/2012	01/30/2019	FL

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Lancaster General Hospital 555 North Duke Street Lancaster, PA 17602 Other information: Joint Commission ID # 6086 Previous Re-Certification Dates: 05/19/2009; 09/23/2011; 09/06/2013; 09/22/2015; 10/03/2017	390100	05/19/2009	02/05/2020	PA
WellSpan York Hospital 1001 South George Street York, PA 17405 Other information: Joint Commission ID # 6228 Previous Re-certification Dates: 11/19/2013; 12/15/2015; 01/23/2018	390046	11/19/2013	03/14/2020	PA
FROM: Aurora St. Luke's Medical Center of Aurora Health Care Metro, Inc. TO: Aurora Health Care Metro, Inc. Aurora Health Care Metro, Inc. 2900 West Oklahoma Avenue Milwaukee, WI 53201-2901 Other information: Joint Commission ID # 7675 Previous Re-certification Dates: 02/03/2009; 08/09/2011; 07/17/2013; 07/21/2015; 11/14/2017	520138	02/03/2009	02/12/2020	WI

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Lehigh Valley Hospital 1200 S. Cedar Crest Boulevard Allentown, PA 18105 Other information: Joint Commission ID # 4880 Previous Re-certification Dates: 10/29/2013; 11/10/2015; 12/12/2017	390133	10/29/2013	03/04/2020	PA
FROM: CHI St. Vincent Heart Clinic; TO: St. Vincent Infirmiry Medical Center dba CHI St. Vincent 2 St. Vincent Circle Little Rock, AR 72205 Other information: Joint Commission ID # 8661 Previous Re-certification Dates: 11/21/2017	040007	11/21/2017	02/05/2020	AR
Scott & White Medical Center 2401 South 31st Street Temple, TX 76508 Other information: Joint Commission ID # 9241 Previous Re-certification Dates: 12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017	45-0054	12/07/2011	03/05/2020	TX
Ochsner Medical Center 1516 Jefferson Highway New Orleans, LA 70121 Other information: Joint Commission ID # 8777 Previous Re-certification Dates: 05/28/2009; 11/09/2011; 12/12/2013; 01/05/2016; 12/12/2017	19-0036	05/28/2009	03/12/2020	LA

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Baptist Health Medical Center - Little Rock 9601 Baptist Health Drive Little Rock, AR 72205-7299 Other information: Joint Commission ID # 8656 Previous Re-certification Dates: 11/10/2009; 11/08/2011; 12/11/2013; 01/12/2016; 12/15/2017	04-0114	11/10/2009	02/12/2020	AR
Westchester Health Care Corporation 100 Woods Road Valhalla, NY 10595 Other information: Joint Commission ID # 2518 Previous Re-certification Dates: 11/19/2009; 11/15/2011; 12/03/2013; 12/08/2015; 12/19/2017	330234	11/19/2009	03/07/2020	NY

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(April through June 2020)**

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 2020)**

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 2020)

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).

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