October 13, 2021

PARA Weekly eJOURNAL

NEWS FOR HEALTHCARE DECISION MAKERS

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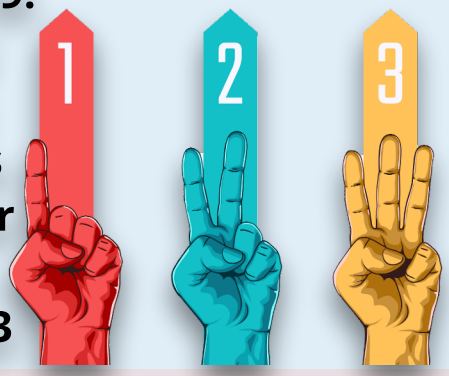


FAST LINKS

MOLECULAR TESTING

Q. We are thinking about bringing Molecular Testing in-house, instead of sending these tests out to a reference lab. Our only issue is with reimbursement. Here are the tests we would like to bring in-house and start performing. Do you have any suggestions on how we can maximize reimbursement when performing these tests?

TestName
BCR-ABL Standard p190
BCR-ABL1 Standard p210
BCR-ABL1 Standard p210, p190
BRAF Mutation Analysis
EGFR Mutation Analysis
IgVH Hypermutation Analysis
JAK2 V617F Mutation Analysis - Qualitative
KIT (c-KIT) Mutation Analysis
KRAS Mutation Analysis by Sanger
MGMT Gene Promoter Methylation Analysis
MLH1 Promoter Methylation Analysis
MSI by PCR
MYD88 Mutation Analysis
NRAS Mutation Analysis
STAT3 Mutation Analysis
T-Cell Receptor Beta Gene Rearrangement
T-Cell Receptor Gamma Gene Rearrangement
FII&FV
AML / MDS FISH
High Grade B Cell Lymphoma

A. **Answer:** Molecular testing does not meet the definition of a statutory benefit category. The Molecular Diagnostic Services (MolDX®) Program was developed to identify and establish coverage and reimbursement for molecular diagnostic tests, and is managed by Palmetto GBA.

[MolDX - Coding and Billing Guidelines (palmettogba.com)]

Coding and Billing Guidelines

Medicare is a defined benefit program. In order to be considered for Medicare coverage, an item or service must fall within a statutory benefit category. Although IOM 100-2, Ch. 15, Sec 10 identifies "Diagnostic X-Ray tests, laboratory tests, and other diagnostic tests" as a benefit category, Sec. 1862 (1)(A) Statutory Exclusion "except for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" must also be applied. In order to be paid under this benefit category, a diagnostic test must be ordered by a physician who is treating the beneficiary and the results used in the management of a beneficiary's specific medical problem. Although many molecular diagnostic tests may provide valid and useful information, they do not meet this definition.

Does the test fall within a Medicare benefit category?

Based on the Medicare Benefit requirements, the following test types are examples of services that may not be considered a benefit (statutory excluded) and therefore would be denied as Medicare Excluded tests:

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law
- Tests that confirm a diagnosis or known information
- Tests to determine risk for developing a disease or condition
- Tests performed to measure the quality of a process
- Tests without diagnosis specific indications
- Tests identified as investigational by available literature and/or the literature supplied by the developer, and are not a part of a clinical trial
- Tests typically performed on patients younger than 65 years of age and outside of the Medicare population
    - Tests performed on patients receiving Medicare benefits younger than 65 years will be reviewed on a case-by-case basis

MolDX reviews test registration applications and technical assessments (TA) to confirm that each test meets Medicare reasonable and necessary criteria. Covered tests reviewed through the TA process are identified in the Molecular Diagnostic Test policy found in the LCD section. Coding and Billing guidelines are available to facilitate reimbursement.

MOLECULAR TESTING

Palmetto GBA determines coverage, coding, and pricing for molecular diagnostic testing and other molecular pathology services administered through the Molecular Diagnostic Services (MolDX®) Program.Palmetto GBA website contains a manual which outlines its process in maintaining a weekly Master Edit File (MEF) which is provided to MACs to adjudicate claims. Laboratory providers who bill MDT services must obtain a test-specific identifier – a DEX Z-Code. That process is detailed in the manual which can be found at this link -MolDX Manual (palmettogba.com)

Local Coverage Article, A56853, contains a list of diagnostic services that fall within the scope of MolDX®. It also outlines how to submit a clean claim for reimbursement of Molecular Diagnostic Tests (MDT). An excerpt of the claim process is provided below.

Article - Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A56853) (cms.gov)

Article Text

The information in this article contains billing, coding, or other guidelines that complement the Local Coverage Determination (LCD) for MolDX: Molecular Diagnostic Tests (MDT) L35025.

To report a Molecular Diagnostic Test service, please submit the following claim information:

- Select appropriate CPT® code
- Enter 1 unit of service (UOS)
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following Part B claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Box 19 for paper claim
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following Part A claim field/types:
  - Line SV202-7 for 837I electronic claim
  - Block 80 for the UB04 claim form

The above Article relates to LCD L35025 which talks about coverage indications, limitations, and/or medical necessity and refers back to the Palmetto GBA website.

LCD - MolDX: Molecular Diagnostic Tests (MDT) (L35025) (cms.gov)

Payment Rules

MolDX will reimburse:

- approved tests covered for dates of service consistent with the effective date of the coverage determination.

Covered Tests

Please refer to the MolDX website www.palmettogba.com/MolDX for covered and excluded tests' specific coding and billing information.

For additional MolDX Program information, go to the Medicare home page www.PalmettoGBA.com/MolDX.

MolDX expects laboratory providers to follow test indications published by the developer.

The first step, if not already completed, is to register at https://app.dexzcodes.com/login and complete information about each lab test to receive a DEX Z-code.

Attached is **PARA's** paper discussing the MolDx® Program.There is a FAQ website that may answer any other questions we may not have covered in this response:
MolDX - Frequently Asked Questions (M00086, V23) (palmettogba.com)

Advanced Diagnostic Lab Tests – July 1 2019 Billing Change

PARA YEAR-END HCPCS UPDATE PROCESS

PARA clients will be fully supported with information and assistance on the annual CPT® HCPCS coding updates for calendar year 2022.

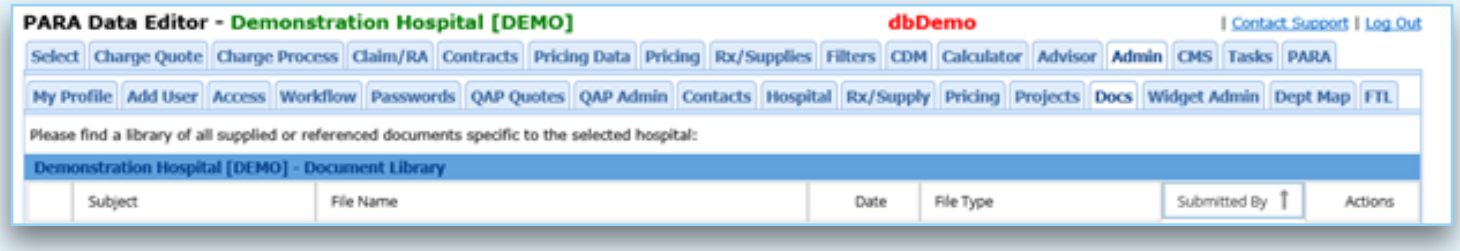
The **PARA Data Editor** (PDE) contains a copy of each client chargemaster. We use the powerful features of the PDE to identify any line item in the chargemaster which has a HCPCS code assigned that will be deleted as of December 31, 2021. It is important that clients check to ensure that a recent copy of the chargemaster has been supplied to **PARA** for use in the year-end update.

PARA will produce excel spreadsheets of each CDM line item, as well as our recommendation for alternate codes, in three waves as information is released from the following sources:

- The American Medical Association's publication of new, changed, and deleted CPT® codes. This information is released in September of each year. **PARA** will produce the first spreadsheet of CPT® updates for client review in October 2021.
- Following the release of Medicare's 2022 OPPS Final Rule, typically in early November; **PARA** will perform an analysis and produce the second spreadsheet to include both the CPT® information previously supplied, as well as alpha-numeric HCPCS updates (J-codes, G-codes, C-codes, etc.) from the Final Rule. Clients may expect this spreadsheet to be available in November 2021.
- Following the publication of Medicare's 2022 Clinical Lab Fee Schedule (CLFS), typically released in late November, **PARA** will prepare a final spreadsheet to be available in December 2021. This final spreadsheet ensures that **PARA** shares any late-breaking news or coding information, although we expect the December spreadsheet to be very similar to the November edition.

Clients will be notified by email as spreadsheets are produced and recorded on the **PARA Data Editor** "Admin" tab, under the "Docs" sub tab.

The spreadsheet will appear as shown below:



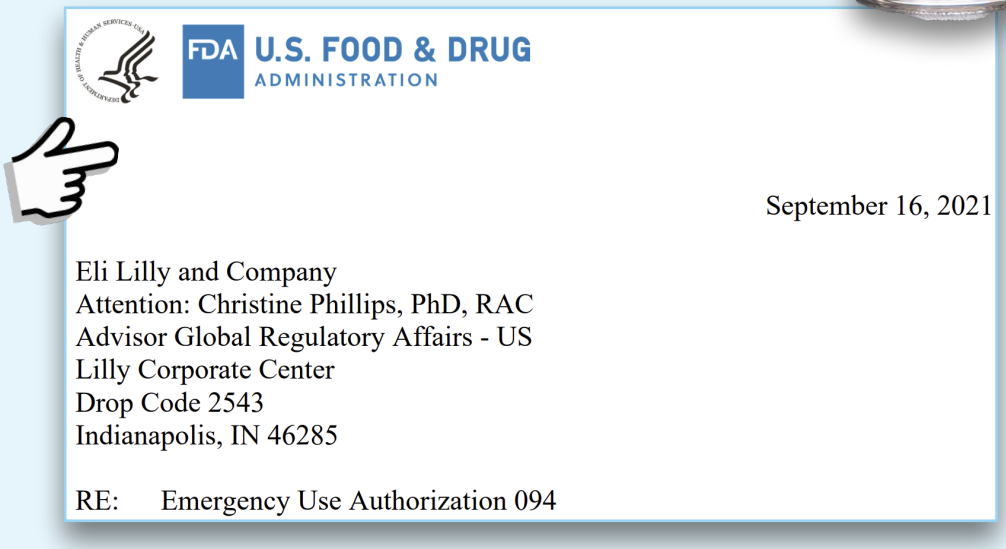
In addition, **PARA** consultants will publish concise papers on coding update topics to ensure that topical information is available in a manner that is organized and easy to understand. **PARA** clients may rest assured that they will have full support for year-end HCPCS coding updates to the chargemaster.

BAMLANIVIMAB AND ETESEVIMAB FOR COVID-19 RESUMES

In a letter dated September 16, 2021, the FDA announced a revision to the Emergency Use Authorization (EUA) on the COVID-19 monoclonal antibody drug combination bamlanivimab and etesevimab.Distribution and use of this therapy, was paused on June 25, 2021 while additional clinical trials were conducted.After collecting and evaluating data, the FDA declares all states may resume the administration to patients being treated for COVID-19 in accordance with EUA 094.

This letter may be downloaded from the following site:

https://www.fda.gov/media/145801/download



U.S. FOOD & DRUG ADMINISTRATION

September 16, 2021

Eli Lilly and Company
Attention: Christine Phillips, PhD, RAC
Advisor Global Regulatory Affairs - US
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

RE: Emergency Use Authorization 094

Medicare will cover monoclonal drugs, when not provided free of cost, at reasonable costs in an outpatient hospital and may base physician office payments on average wholesale price.Medicare will pay for the monoclonal infusions, when administered in accordance with the EUA, under the vaccine program.

HCPCS	Description	Labeler	Payment Allowance	Effective Date(s)
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg	Eli Lilly	$ 0.01	02/09/2021
M0245	Bamlan and etesev infusion	Eli Lilly	$ 309.60 $ 450.00	11/21/2020* 05/06/2021**

**For Claims with Dates of Service 11/21/2020 – 05/05/2021. ** For Claims with Dates of Service on or after 05/06/2021.* → → → → → → →

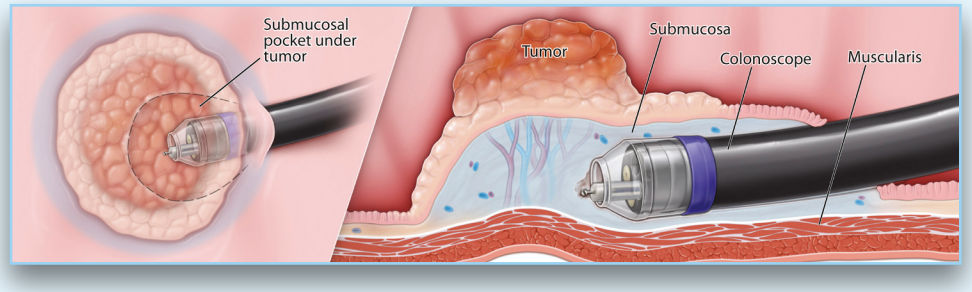
PARA offers additional COVID-19 billing and coding guidance through our "COVID-19 Comprehensive Billing & Coding" publication.

NEW C-CODE FOR ENDOSCOPIC SUBMUCOSAL DISSECTION

Effective October 1, 2021, CMS established a new HCPCS C9779 to be used when coding an endoscopic submucosal dissection performed during an endoscopy or colonoscopy. The new code has been assigned OPPS status indicator of J1, and APC assignment 5313:

Current Descriptor	Fee Schedule	Initial APC	Payment
C9779 - endoscopic submucosal dissection (esd), including endoscopy or colonoscopy, mucosal closure, when performed **J1 - Hospital Part B services paid through a comprehensive APC**		5313 - Level 3 Lower GI Procedures	Weight: 29.5106 Payment: $ 2443.39 National Co-pay: $0.00 Minimum Co-pay: $488.68

Courtesy ScienceDirect.com



Endoscopic submucosal dissection (ESD) is a procedure in which a substance is injected under a targeted lesion to act as a cushion before the submucosa is dissected under the lesion with a specialized knife. As an established effective treatment option for premalignant and early-stage malignant lesions of the GI tract, it is associated with higher success rates than other endoscopic resection techniques and outcomes are comparable to open or laparoscopic surgical procedures.

The procedure requires a high degree of expertise and is time-consuming yet was poorly reimbursed with the use of unlisted codes, such as 43499, 43999, 44799, 45299, 45999. The claim process was also more time-consuming when a payer requested documentation to justify use, coverage and payment of the unlisted code.

Medicare reimbursement for the new code at $2443.39 (National rate) under APC 5313 offers increased reimbursement as compared to the unlisted codes, which were the only means of reporting the procedure previously. The unlisted codes have an APC of 5301 and 5311, with reimbursement of $809.60 and $793.65, respectively.

Current Descriptor	Fee Schedule	Initial APC	Payment
43499 - unlisted procedure, esophagus **T - Procedure or service, multiple reduction applies**	Contractor Priced	5301 - Level 1 Upper GI Procedures	Weight: 9.7781 Payment: $ 809.60 National Co-pay: $0.00 Minimum Co-pay: $161.92
43999 - unlisted procedure, stomach **T - Procedure or service, multiple reduction applies**	Contractor Priced	5301 - Level 1 Upper GI Procedures	Weight: 9.7781 Payment: $ 809.60 National Co-pay: $0.00 Minimum Co-pay: $161.92
44799 - unlisted procedure, small intestine **T - Procedure or service, multiple reduction applies**	Contractor Priced	5301 - Level 1 Upper GI Procedures	Weight: 9.7781 Payment: $ 809.60 National Co-pay: $0.00 Minimum Co-pay: $161.92
45399 - unlisted procedure, colon **T - Procedure or service, multiple reduction applies**	Contractor Priced	5311 - Level 1 Lower GI Procedures	Weight: 9.5855 Payment: $ 793.65 National Co-pay: $0.00 Minimum Co-pay: $158.74
45999 - unlisted procedure, rectum **T - Procedure or service, multiple reduction applies**	Contractor Priced	5311 - Level 1 Lower GI Procedures	Weight: 9.5855 Payment: $ 793.65 National Co-pay: $0.00 Minimum Co-pay: $158.74

Professional fees must continue to be reported with an unlisted code, as there is no Medicare Physician Fee Schedule reimbursement listed for HCPCS C9779.

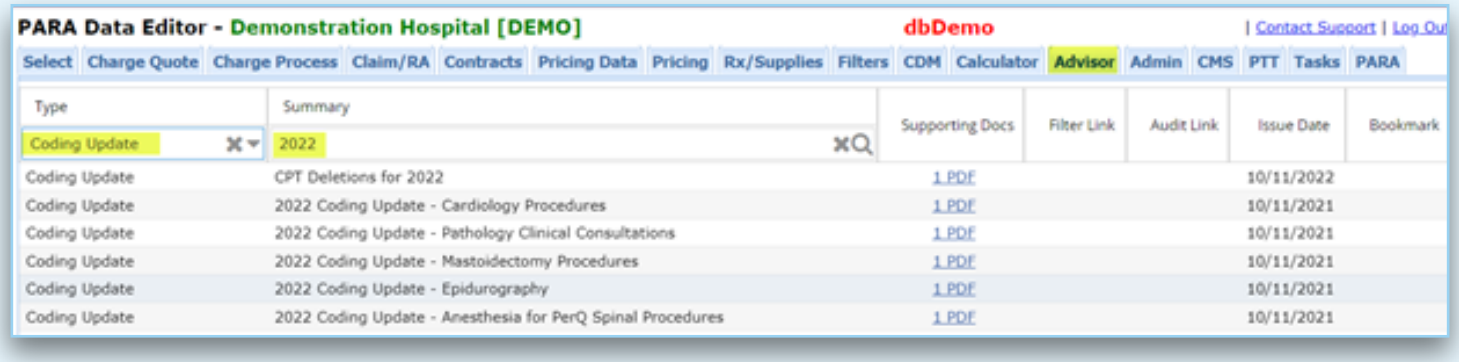
2022 CODING UPDATE DOCUMENTS AVAILABLE

In preparation for the year-end CPT®/HCPCS update, **PARA** has prepared several brief "2022 Coding Update" documents listing deleted codes and possible replacement codes within a particular clinical area or procedure group. The documents are available on the **PARA Data Editor** "Advisor" tab.

The individual coding topics addressed do not encompass all CPT® updates, only those which are most likely to be "hard-coded" to a line item in a facility chargemaster. Topics are divided into immediately related areas, and more than one paper may contain information useful to a service line manager.

In addition, the list of all CPT® codes that will be deleted in 2022 is also available.

Due to CPT® licensing restrictions, these documents cannot be published within the **PARA Weekly eJournal**. **PARA Data Editor** users may access the information on the Advisor tab; search "Coding Update" in the type field, and/or 2022 in the subject field, as illustrated below:



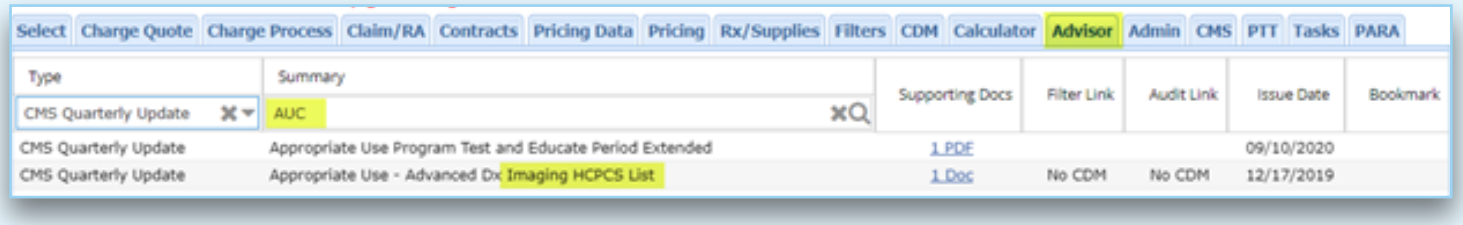
Provisional Medicare reimbursement information is offered in keeping with the 2022 OPPS Proposed Rule.

Following the release of the OPPS Final Rule (typically published in early November), coding update papers will be revised to indicate with certainty whether Medicare will accept/cover the new codes.If changes are made to the coding update papers, readers can identify new versions the word "Revised" in the title, and the date issued will be updated – the hyperlink to the paper will remain identical to the original hyperlink, when an updated version is produced.

APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

In consideration of the impact that COVID-19 has on practitioners, providers and beneficiaries, CMS is proposing to delay the payment penalty phase of the appropriate use criteria (AUC) program until January 1, 2023, or the January 1 following the end of the PHE for COVID-19.

The list of imaging HCPCS services affected by the AUC, which will require the use of a Clinical Decision Support Mechanism (CDSM) tool, is available on the **PARA Data Editor**; search the Advisor tab with the keyword "AUC" in the summary field, then click on the hyperlink to the right of that Advisor:



In 2019, CMS announced that calendar year 2020 would serve as a "test and educate" period during which providers billing for advanced imaging studies are required to report whether the ordering physician consulted a clinical decision support mechanism. The requirement to report the informational codes is currently in effect, but Medicare will not yet impose penalties for failure to report, or for incorrect reporting. (The requirement does not apply to Critical Access Hospitals).

The AUC program was authorized by the Protecting Access to Medicare Act of 2014 (PAMA) to promote the use of AUC and decrease the number of inappropriate advanced diagnostic imaging services provided to Medicare beneficiaries.

Ordering physicians (or clinical staff acting at the physician's direction) will consult the AUC using a clinical decision support mechanism (CDSM). The CDSM is an interactive, electronic tool that is either stand-alone or integrated into an electronic health record (EHR).

When queried, it provides a response indicating that the advanced diagnostic imaging service is appropriate, not appropriate or not applicable for the patient. The AUC requirements apply to advanced diagnostic imaging services (CT, PET, MRI, and Nuclear Medicine) provided in physician offices, hospital outpatient departments (including emergency departments), ambulatory surgical centers, and independent diagnostic testing facilities.

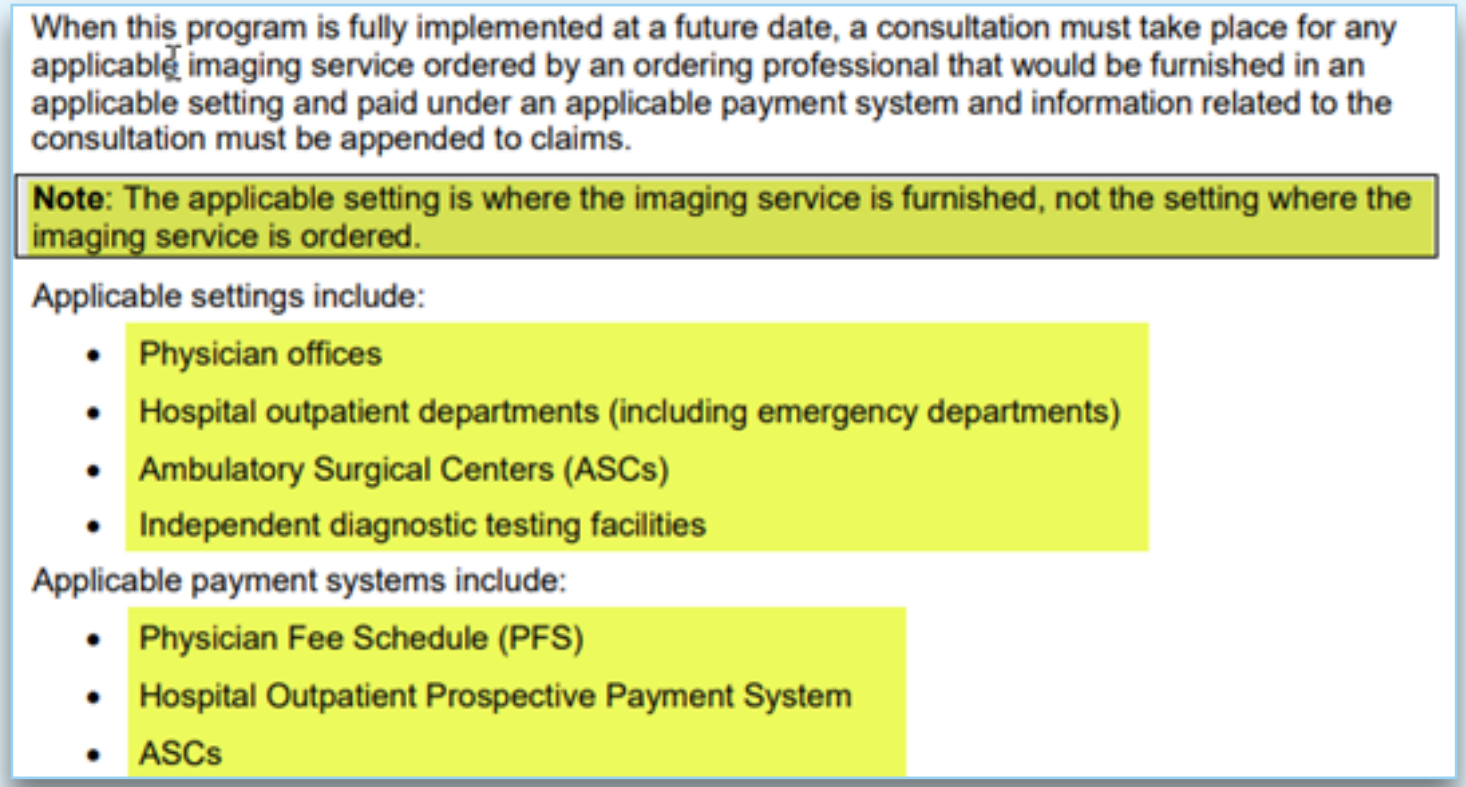
APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

CMS released an MLN Matters article in July 2019 that includes the imaging HCPCS codes, the G-codes for the CDSMs, and AUC modifiers. mm11268 (cms.gov)

There are a few exceptions to the requirement to consult the CDSM, which are:

- Emergencies
- Inpatient advanced diagnostic imaging services
- Ordering physician meets hardship exception
    - Hardship exceptions include:
        - Insufficient internet access
        - EHR or CDSM vendor issues
        - Extreme and uncontrollable circumstances

If an exception exists, the physician will include it with the order and the furnishing physician will report the corresponding modifier on the claim.



When this program is fully implemented at a future date, a consultation must take place for any applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid under an applicable payment system and information related to the consultation must be appended to claims.

Note: The applicable setting is where the imaging service is furnished, not the setting where the imaging service is ordered.

Applicable settings include:

- Physician offices
- Hospital outpatient departments (including emergency departments)
- Ambulatory Surgical Centers (ASCs)
- Independent diagnostic testing facilities

Applicable payment systems include:

- Physician Fee Schedule (PFS)
- Hospital Outpatient Prospective Payment System
- ASCs

After the physician has consulted the CDSM and ordered the advanced diagnostic imaging service, the following data will be sent, with the order, to the provider completing the imaging service:

- The CDSM consulted by the ordering physician.
- Whether the service adhered to the applicable AUC, did not adhere to the applicable AUC, or whether no criteria in the CDSM were applicable to the patient's clinical scenario.
- The National Provider Identifier (NPI) of the ordering physician.

CMS maintains a list of qualified CDSMs on its website at Clinical Decision Support Mechanisms | CMS.

APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

The following list was posted on August 30, 2021:

Mechanism Name	Code
eviCore healthcare's Clinical Decision Support Mechanism	G1001
MedCurrent OrderWise™	G1002
Medicalis Clinical Decision Support Mechanism	G1003
National Decision Support Company CareSelect™*	G1004
AIM Specialty Health ProviderPortal®*	G1007
Cranberry Peak ezCDS	G1008
Sage Health Management Solutions Inc. RadWise®	G1009
Stanson Health's Stanson CDS	G1010
AgileMD's Clinical Decision Support Mechanism	G1012
EvidenceCare's Imaging Advisor	G1013
InveniQA's Semantic Answers in Medicine™	G1014
Reliant Medical Group CDSM	G1015
Mechanism Name	Code
Speed of Care CDSM	G1016
HealthHelp's Clinical Decision Support Mechanism	G1017
INFINX CDSM	G1018
LogicNets AUC Solution	G1019
Curbside Clinical Augmented Workflow	G1020
E*HealthLine Clinical Decision Support Mechanism	G1021
Intermountain Clinical Decision Support Mechanism	G1022
Persivia Clinical Decision Support	G1023
Radrite*	G1011

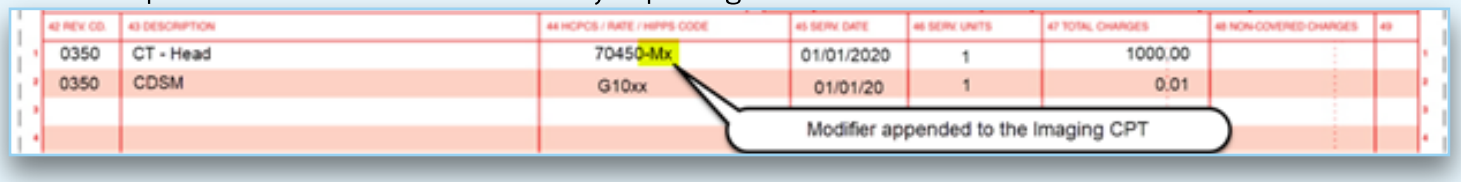
APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

Medicare also released eight new modifiers to be appended to the imaging HCPCS when an advanced diagnostic imaging is billed. The modifiers indicate the clinician's use (or non-use) and compliance with a CDSM when ordering advanced diagnostic images.

Modifiers to be appended to Advanced Diagnostic Imaging HCPCS on Medicare Outpatient Claims		
Modifier	**Short Descriptor**	**Long Descriptor**
MA	Emer med cond susp/confirm	Ordering professional is not required to consult a clinical decision support mechanism due to service being rendered to a patient with a suspected or confirmed emergency medical condition
MB	AUC hardship, insuf internet	Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of insufficient internet access
MC	AUC hardship, vendor issues	Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of electronic health record or clinical decision support mechanism vendor issues
MD	AUC hardship, extreme circ	Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of extreme and uncontrollable circumstances
ME	Order adheres to AUC	The order for this service adheres to appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
MF	Order does not adhere to AUC	The order for this service does not adhere to the appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
MG	AUC not applicable to order	The order for this service does not have applicable appropriate use criteria in the qualified clinical decision support mechanism consulted by the ordering professional
MH	AUC consult not provided	Unknown if ordering professional consulted a clinical decision support mechanism for this service, related information was not provided to the furnishing professional or provider

APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

The excerpt below illustrates the mandatory reporting for a CT of the head billed to Medicare on a UB04:



The following is the workflow for meeting the AUC requirements:

- The physician sees a Medicare beneficiary and plans to order an advanced diagnostic imaging service
- The physician (or clinical staff under the direction of the physician) consults the AUC for the proposed advanced diagnostic imaging service through a CDSM. The CDSM can be integrated into the EHR or a separate portal
    - If a hardship exception exists, the physician will include it with the order
- The CDSM will search for and present the AUC relevant to the patient's condition
- The CDSM response will indicate if the proposed advanced diagnostic imaging service:
    - adheres to the AUC, or
    - does not adhere to the AUC, or
    - if there is no applicable AUC
- If it adheres to the AUC, the physician will proceed with the order
- If it does not adhere, the physician must decide to order a different imaging service or proceed with the proposed service despite it not adhering to the AUC
- The physician orders the advanced diagnostic imaging service and includes with the order:
    - the CDSM queried, and
    - the AUC response, and
    - the physician's NPI
- The rendering provider furnishes the imaging service to the patient
- The rendering provider reports in the professional and institutional claims:
    - HCPCS G-code associated with the CDSM, and
    - The applicable AUC modifier, and
    - the ordering physician's NPI

The outcome of this program will be to analyze the ordering practices of the physicians and determine any outliers. PAMA calls for identification on an annual basis of no more than five percent of the total number of ordering physicians who are outliers. The use of two years of data is required for this analysis. Data collected during the education and testing period will not be used when identifying outliers.

Outliers will be determined based on low adherence to applicable AUC or comparison to other ordering physicians. Physicians who are found to be outliers will be required to complete prior authorizations for advanced diagnostic imaging services.

The following clinical areas will be the focus of the analysis of outliers:

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Cervical or neck pain

CMS RELEASES NO SURPRISES ACT -- PART II

On September 30, 2021, the Department of Health and Human Services (HHS), the Department of Labor and the Department of Treasury released Part II of the No Surprises Act. The Act, which goes into effect on January 1, 2022, aims to protect patients from unexpected out of pocket costs resulting from surprise and balance billing.

Part II of the Act addresses plan coverage requirements, independent dispute resolution processes between the payers and providers, and details for how payers will determine patient cost-sharing responsibilities.

The unpublished rule, which will be published on October 7, 2021, can be accessed through the Federal Register website:

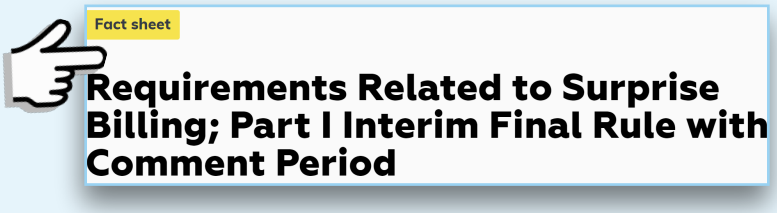
https://www.federalregister.gov/public-inspection/2021-21441/requirements-related-to-surprise-billing-part-ii

CMS devotes a website to the No Surprises Act:

https://www.cms.gov/nosurprises

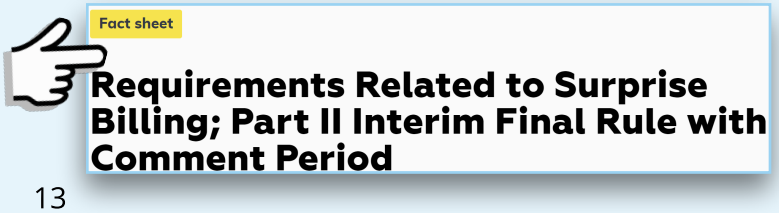
CMS Fact Sheet – No Surprises Act, Part I:

https://www.cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-i-interim-final-rule-comment-period



CMS Fact Sheet – No Surprises Act, Part II:

https://www.cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-ii-interim-final-rule-comment-period



MEDICARE LIFETIME RESERVE DAYS

What are Medicare Lifetime Reserve Days?

Medicare Part A covers eligible inpatient costs for a hospital admission that lasts between one and ninety (90) days. Medicare provides additional coverage for hospital stays that go beyond ninety days. This extra coverage is known as lifetime reserve days.

Medicare beneficiaries receive sixty lifetime reserve days that begin on day ninety-one (91) of hospitalization. Each beneficiary has a lifetime reserve of 60 days of inpatient hospital services to draw upon after having used 90 days of inpatient hospital services in a benefit period.

The lifetime reserve days are available to beneficiaries that have Part A, but co-payments still apply.

For CY2021, Medicare Part A has the following co-payments:

- Day one to day sixty: $0.00 co-payment
- Day sixty-one (61) to ninety (90): $371.00 per day co-payment
- **Day ninety-one (91) and beyond: $742.00 per day co-payment when using lifetime reserve days**
- After lifetime reserve days are exhausted, the Medicare Beneficiary is financially responsible to pay all costs

Exclusions to lifetime reserve days: This benefit does not apply to stays at Skilled Nursing Facilities or stays at Psychiatric Hospitals.

https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles

Part A Deductible and Coinsurance Amounts for Calendar Years 2020 and 2021
by Type of Cost Sharing

	2020	2021
Inpatient hospital deductible	$1,408	$1,484
Daily coinsurance for 61st–90th Day	$352	$371
Daily coinsurance for lifetime reserve days	$704	$742
Skilled Nursing Facility coinsurance	$176.00	$185.50

MEDICARE LIFETIME RESERVE DAYS

When a Medicare beneficiary receives inpatient service after all of their ninety (90) regular days (60 full/30 co-insurance) have been exhausted during a benefit period, the lifetime reserve days are used unless:

- The beneficiary, or medical power of attorney, indicates in writing they elect NOT TO USE lifetime reserve days;
- The beneficiary is "deemed" to have elected NOT TO USE lifetime reserve days when the average daily charge for covered services is equal to or less than the co-insurance amount for the lifetime reserve days.

Election NOT TO USE lifetime reserve days:As indicated in the paragraph above, the Medicare Beneficiary has the option to elect whether they want to use their Medicare lifetime reserve benefit.

- This election may be made by the beneficiary (or by someone acting on his/her behalf) at the time of admission to the hospital or at any time thereafter, subject to the limitations on retro-active elections
- Hospitals are required to notify patients who have already used or will use ninety (90) days of benefits in a benefit period that they can elect NOT TO USE their lifetime reserve days for all or part of the hospital stay
- The hospital notice should be given when the beneficiary has five (5) regular co-insurance days left and is expected to be hospitalized beyond that period
- If a patient elects NOT TO USE reserve days, covered Part B services are billed on a UB Outpatient type of bill (TOB)

Once the beneficiary is deemed to have elected NOT TO USE lifetime reserve days:

- The average daily charge for covered services furnished during a lifetime reserve billing period is equal to or less than the co-insurance amount for lifetime reserve days; and
    - The hospital is reimbursed on a cost reimbursement basis; or
    - The hospital is reimbursed under the prospective payment system and lifetime reserve days are needed to pay for all or part of the outlier days
- If the beneficiary has one or more regular benefit days remaining in the benefit period upon admission to a prospective payment system (PPS) hospital
- The beneficiary has no regular days available at the time of admission to a PPS hospital and the total charges for which the beneficiary would be liable, if lifetime reserve days are not used, is equal to or less than the charges for which the beneficiary would be liable if he/she used lifetime reserve days

Under ordinary circumstances, an election NOT TO USE lifetime reserve days will apply prospectively. If the election is filed at the time of admission to a hospital, it may be made effective beginning with the first day of hospitalization or with any day thereafter.

MEDICARE LIFETIME RESERVE DAYS

If the election is filed later, it may be made effective beginning with any day after the day it is filed.

A Medicare beneficiary may retroactively elect NOT TO USE lifetime reserve days provided when:

- The beneficiary (or some other source) offers to pay the hospital for the services not payable under Part B; and
- The hospital agrees to accept the retroactive election
- In this scenario, the hospital will correct any claims already submitted

A retroactive election NOT TO USE lifetime reserve days must be filed within ninety days following the beneficiary's discharge from the hospital, unless benefits are available from a third-party payer to pay for the services and the hospital agrees to the retroactive election.

In this scenario, the beneficiary may file an election NOT TO USE lifetime reserve days later than ninety days following discharge.

What period is covered by election? Is dependent upon whether the hospital is reimbursed under the Prospective Payment System (PPS) or not.

Hospitals NOT reimbursed by PPS: A beneficiary election NOT TO USE lifetime reserve days for a particular hospital stay may apply to the entire stay or to a single period of consecutive days in the stay but cannot apply to selected days in a stay.

If an election, made prospectively or retroactively, NOT TO USE lifetime reserve days is made effective with the first day in which lifetime reserve days are available, it may be terminated at any time. After termination of an election, all hospital days would be covered to the extent that lifetime reserve days are available.

Further, if an election NOT TO USE lifetime reserve days is made effective beginning with any day after the first day in which lifetime reserve days are available, it must remain in effect until the end of that stay unless the entire election is revoked.

Hospitals reimbursed under PPS: The rules outlined above apply to PPS hospitals. In addition, for PPS discharges on and after October 01, 1997, involving cost outlier status, a beneficiary whose ninety (90) days of benefits are exhausted before cost outlier status is reached MUST ELECT TO USE lifetime reserve days for the hospital to be paid cost outlier payments.

Cost outlier status is reached on the day that charges reach the cost outlier status for the applicable diagnosis related groups (DRGs) for inpatient PPS or case-mix group (RUG) for inpatient rehabilitation facility PPS. Use of reserve days must begin on the day following that day, to permit payment for outlier charges.

If the beneficiary elects NOT TO USE lifetime reserve days where benefits are exhausted, the hospital may bill the beneficiary for charges that would have been paid as cost outlier.

A beneficiary's election NOT TO USE lifetime reserve days should specify the name of the hospital and the starting date of the election.

MEDICARE LIFETIME RESERVE DAYS

For model language/format of the election notice, please visit:
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c05.pdf

40.1 - Election Format
(Rev. 257, Issued: 03-01-19, Effective: 04- 01-19 Implementation: 04- 01-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The following model election language may be used:

Election Not To Use Lifetime Reserve Days

I do not wish to have Medicare benefits paid on my behalf under the lifetime reserve provisions of section 1812 (b) of the Social Security Act for services furnished me by (name of hospital) beginning (date).

WHERE THE ELECTION MAY TERMINATE BEFORE THE END OF THE STAY IN ACCORDANCE WITH §40, THE FOLLOWING MAY BE INCLUDED:

The last day to which this election applies is (date).

I understand that I will be responsible for all of the hospital's charges not reimbursed by Medicare because of this election, except those covered under Medicare Part B. Where Medicare Part B payments may be made for services furnished during the period covered by the election, I will be responsible for the deductible and 20 percent coinsurance amounts.

(Signature) (Date)
(*Medicare beneficiary identifier*)

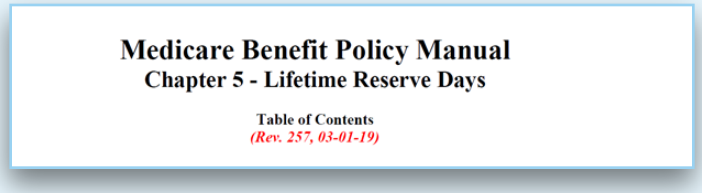
MEDICARE LIFETIME RESERVE DAYS

What is a revocation of election? An election NOT TO USE lifetime reserve days may be revoked in whole or in part, provided a claim has NOT BEEN filed for Part B ancillary services furnished on the hospital days in question.

- The revocation must be submitted to the hospital, in writing, and should be made part of the patient's hospital record
- If a beneficiary is incapacitated, any of the individuals who are permitted to sign the Request for Payment may file the revocation on the beneficiary's behalf
- Of note: An election NOT TO USE lifetime reserve days may NOT be revoked after the beneficiary dies
- A revocation of election NOT TO USE lifetime reserve days must be made within ninety (90) days following the beneficiary's discharge from the hospital
- EXCEPTION: The election may be revoked later than ninety (90) days after discharge if benefits are available from a private insurer to pay the lifetime reservedays co-insurance amounts and the insurer requires as a condition of payment that lifetime reserve days be used
- The revocation notice of an election NOT TO USE lifetime reserve days should specify:
  - The name of the hospital, and
  - The admission date of the stay to which it applies, and
  - If appropriate, the effective date of revocation

References for this article:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c05.pdf



Medicare Benefit Policy Manual
Chapter 5 - Lifetime Reserve Days

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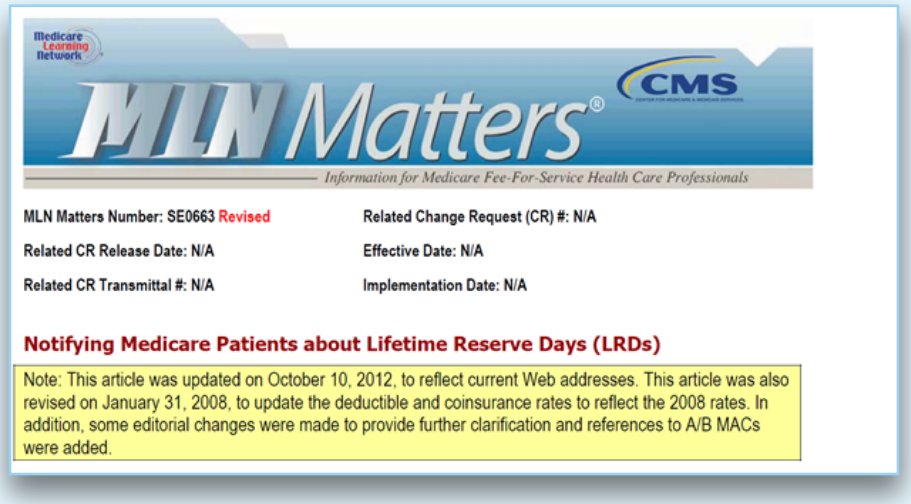
(Rev. 257, 03-01-19)

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0663.pdf



Medicare Learning Network

MLN Matters® CMS

Information for Medicare Fee-For-Service Health Care Professionals

MLN Matters Number: SE0663 Revised | Related Change Request (CR) #: N/A
Related CR Release Date: N/A | Effective Date: N/A
Related CR Transmittal #: N/A | Implementation Date: N/A

Notifying Medicare Patients about Lifetime Reserve Days (LRDs)

Note: This article was updated on October 10, 2012, to reflect current Web addresses. This article was also revised on January 31, 2008, to update the deductible and coinsurance rates to reflect the 2008 rates. In addition, some editorial changes were made to provide further clarification and references to A/B MACs were added.

NEW COVID-19 VACCINE PRODUCT & ADMINISTRATION CODES

The AMA announced in Special Edition 2021 CPT® Assistant Guides in September and October, the AMA CPT® Editorial Panel approved COVID-19 vaccine product and administration codes. Some codes assigned will become effective upon receiving FDA approval. The AMA website offers COVID-19 coding updates:

https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes
(New codes are in red font)

Pfizer COVID-19 Vaccine (original phosphate buffer) and Administration Codes

Code	CPT Long Descriptor	Mfr Vaccine Product / Procedure Name	Effective Date
91300	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted, for intramuscular use *(Report with administration codes 0001A, 0002A, 0003A, or 0004A)*	**Pfizer**-Biontech Covid-19 Vaccine NDC: 59267-1000-01	12/11/2020
0001A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; **first dose**	**Pfizer**-Biontech Covid-19 Vaccine Administration – **1st Dose**	12/11/2020
0002A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; **second dose**	**Pfizer**-Biontech Covid-19 Vaccine Administration – **2nd Dose**	12/11/2020
0003A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; **third dose**	**Pfizer**-Biontech Covid-19 Vaccine Administration – **3rd Dose**	08/12/2021
0004A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; **booster dose**	**Pfizer**-Biontech Covid-19 Vaccine Administration – **Booster Dose**	9/22/2021

UPDATE

NEW COVID-19 VACCINE PRODUCT & ADMINISTRATION CODES

Pfizer COVID-19 Tris-sucrose Buffer (Ready-To-Use) Vaccine And Administration Codes

Code	CPT Long Descriptor	Mfr Vaccine Product / Procedure Name	Effective Date
91305	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use *(Report with administration codes 0051A, 0052A, 0053A, 0054A)*	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation NDC: 59267-1000-01	Upon FDA approval
0051A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; **first dose**	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation administration – **1st dose**	Upon FDA approval
0052A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; **second dose**	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation administration – **2nd dose**	Upon FDA approval
0053A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; **third dose**	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation administration – **3rd dose**	Upon FDA approval
0054A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; **booster dose**	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation administration – **booster dose**	Upon FDA approval

UPDATE NEW COVID-19 VACCINE PRODUCT & ADMINISTRATION CODES

Moderna Vaccines

Code	CPT Long Descriptor	Mfr Vaccine Product / Procedure Name	Effective Date
91301	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 100 mcg/0.5 mL dosage, for intramuscular use *(Report with administration codes 0011A, 0012A, 0013A)*	**Moderna**-Covid-19 Vaccine NDC: 80777-0273-10	08/16/2021
91306	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use *(Report with administration codes 0064A)*	**Moderna**-lower dose Covid-19 Vaccine NDC: 80777-0273-10	Upon FDA approval
0011A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage; **first dose** *(Report with vaccine product 91301)*	**Moderna** Covid-19 Vaccine Administration – **1st Dose**	12/18/2020
0012A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage; **second dose** *(Report with vaccine product 91301)*	**Moderna** Covid-19 Vaccine Administration – **2nd Dose**	12/18/2020
0013A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage; **third dose** *(Report with vaccine product 91301)*	**Moderna** Covid-19 Vaccine Administration – **3rd Dose**	08/12/2021
0064A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, **booster dose** *(Report with vaccine product 91306)*	**Moderna** Covid-19 lower dose Vaccine Administration – **Booster Dose**	Upon FDA approval

NEW COVID-19 VACCINE PRODUCT & ADMINISTRATION CODES

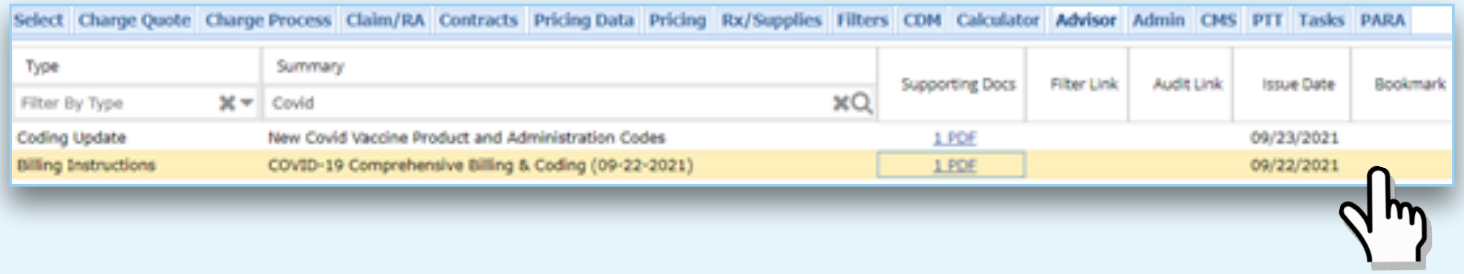
Reformulated Pfizer Vaccine For Pediatric Use*

*For patients ages 5 through 11. Requires reconstition using a diluent to administer the appropriate dosage. The second dose should be administered at least 21 days following the first dose.

Code	CPT Long Descriptor	Mfr Vaccine Product / Procedure Name	Effective Date
91307	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, trissucrose formulation, for intramuscular use *(Report with administration codes 0071A, 0072A)*	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation NDC: 59267-1000-01	Upon FDA approval
0071A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; **first dose** *(Report with vaccine product 91307)*	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation administration – **1st dose**	Upon FDA approval
0072A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; **second dose** *(Report with vaccine product 91307)*	**Pfizer**- Covid-19 Vaccine tris-sucrose formulation administration – **2nd dose**	Upon FDA approval

COVID-19 VACCINES, THIRD DOSE VERSUS BOOSTER DOSE

The three COVID-19 vaccines currently offered come in a "series" of one, two, or three doses, based on an individual's age and chronic illnesses. This paper is intended to clear up the confusion about the difference between a third dose and a booster. For proper administration coding, please reference the two **PARA** papers relating to vaccine coding -Comprehensive COVID-19 Billing and Coding Guide, and New Covid Vaccine Product and Administration Codes.



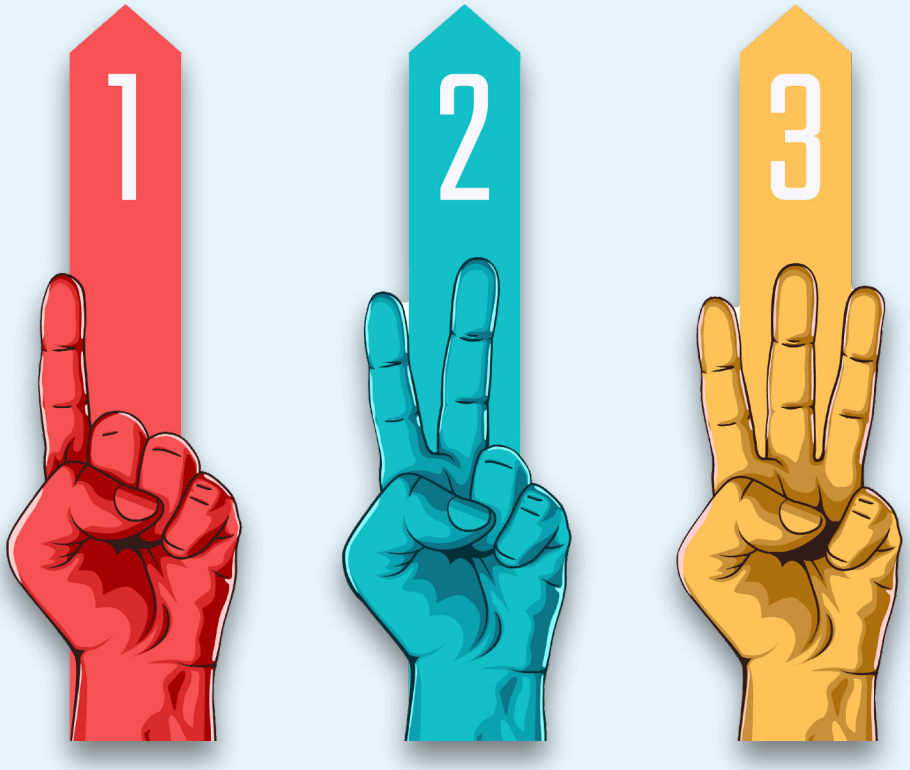
Janssen has an FDA EUA for one dose in the vaccine series, while Moderna and Pfizer have an FDA EUA for a series of two doses for all individuals over the age of 12, and a series of three doses for immunocompromised individuals. We are now hearing about a booster dose for the Pfizer vaccine.

What is the difference between the third in a series versus a booster?

The third dose is intended to improve immunocompromised people's response to their initial two doses and is given 28 days after the initial two doses. Alternatively, a booster dose is being recommended at least six months after the initial series of two or three doses when the immune response to the primary vaccine series is likely to have decreased over time.

The people receiving a booster dose do not have to be immunocompromised; they need to be at a high risk of exposure and serious illness.

To put it more simply, a third dose in the series is intended to be given 28 days after the initial series of two doses to immunocompromised individuals, and a booster dose is given six months after the initial series of two or three doses.



COVID-19 VACCINES, THIRD DOSE VERSUS BOOSTER DOSE

According to the CDC, the following individuals should get a Pfizer booster dose:

- People 65 years and older and residents in long-term care settings
- People ages 50-64 years with underlying medical conditions

A booster dose is also available to the following individuals based on their own benefits and risks:

- People aged 18-49 years with underlying medical conditions
- People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting

More information about the timing of each vaccine can be found on the CDC website at the following links.

An excerpt is provided for each manufacturer:

Moderna COVID-19 Vaccine Fact Sheet for Health Care Providers (fda.gov)

Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (fda.gov)

Primary Series:

The Pfizer-BioNTech COVID-19 Vaccine is administered as a primary series of two doses (0.3 mL each) 3 weeks apart in individuals 12 years of age or older.

A third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

CMS REPORTS 2021 FOURTH QUARTER MUE CHANGES

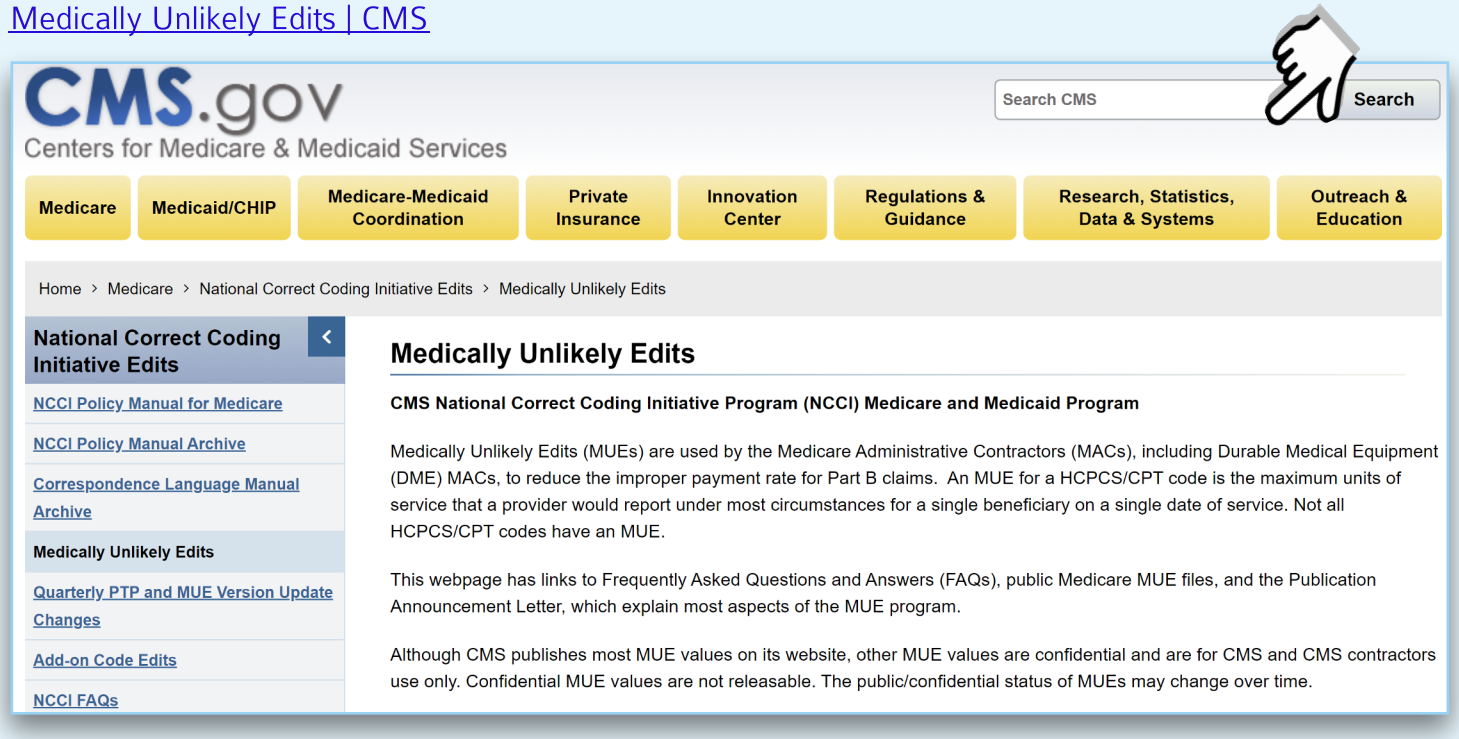
CMS posted the quarterly changes to Medically Unlikely Edits (MUE) effective October 10, 2021. These changes reflect additions, deletions, and revisions to published MUEs for Practitioner Services, Outpatient Hospital Services, and DME Supplier Services.

The table below summarizes the MUE changes to two J-codes and the addition of MUEs to ten J-codes. There were no deletions of MUEs this quarter.

HCPCS/CPT Code	HCPCS description	Current MUE Values	Revised or New MUE Values effective 10-01-2021
J2357	INJECTION, OMALIZUMAB, 5 MG	90	120
J9055	INJECTION, CETUXIMAB, 10 MG	120	150
J0693	INJECTION, CEFIDEROCOL, 5 MG	0	1600
J1554	INJECTION, IMMUNE GLOBULIN (ASCENIV), 500 MG	0	240
J1823	INJECTION, INEBILIZUMAB-CDON, 1 MG	0	300
J7212	FACTOR VIIA (ANTIHEMOPHILIC FACTOR, RECOMBINANT)-JNCW (SEVENFACT), 1 MICROGRAM	0	90000
J7352	AFAMELANOTIDE IMPLANT, 1 MG	0	16
J9144	INJECTION, DARATUMUMAB, 10 MG AND HYALURONIDASE-FIHJ	0	180
J9223	INJECTION, LURBINECTEDIN, 0.1 MG	0	120
J9281	MITOMYCIN PYELOCALYCEAL INSTILLATION, 1 MG	0	80
J9316	INJECTION, PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF, PER 10 MG	0	120
J9317	INJECTION, SACITUZUMAB GOVITECAN-HZIY, 2.5 MG	0	648

Click the link below to access the CMS home page related to MUEs. On this webpage, providers can access quarterly updates, Frequently Asked Questions (FAQs) and NCCI FAQs

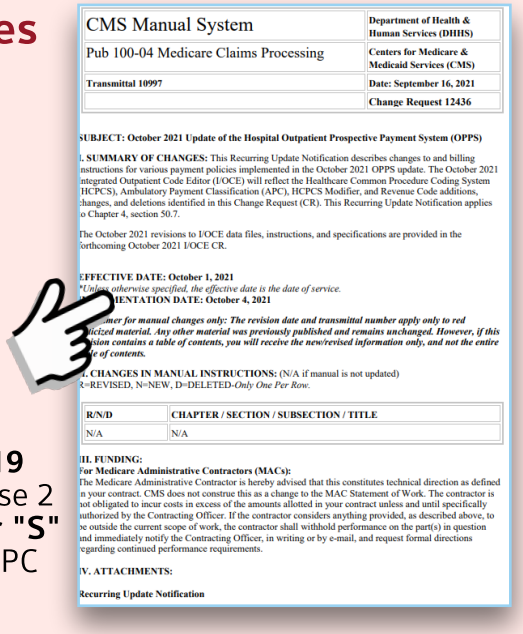
Medically Unlikely Edits | CMS



OCTOBER 1, 2021 OPPS UPDATES

This provides a summary of the OPPS updates effective October 1, 2021. The transmittal, dated September 16, 2021, includes OPPS payment policy and Outpatient Code Editor (I/OCE) updates available through the link below.

https://www.cms.gov/files/document/r10997cp.pdf



CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10997	Date: September 16, 2021
	Change Request 12436

SUBJECT: October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the October 2021 OPPS update. The October 2021 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.7.

The October 2021 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2021 I/OCE CR.

EFFECTIVE DATE: October 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 4, 2021

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

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

IV. ATTACHMENTS:

Recurring Update Notification

1. New COVID-19 Administration codes for 3rd Dose COVID-19 vaccine assigned **APC 9398** (COVID-19 Vaccine Administration Dose 2 of 2, Single Dose Product or Additional Dose) with **Status Indicator "S"** – (Procedure or Service, Not Discounted When Multiple, separate APC assignment)

Code	CPT Long Descriptor	Mfr Vaccine/ Procedure Name	APC / SI	Effective Date	Payment Allowance
0003A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; third dose	**Pfizer-** BioNTech Covid-19 Vaccine Administration **– Third Dose**	9398/S	08/12/2021	$40.00
0013A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage; **third dose**	**Moderna** Covid-19 Vaccine Administration **– Third Dose**	9398/S	08/12/2021	$40.00

OCTOBER 1, 2021 OPPS UPDATES

2. New HCPCS code assigned for administering a COVID-19 vaccine to a beneficiary in their home assigned **APC 1494** (New Technology - Level 1D ($31-$40)).This code, covered under the vaccine benefit, may be billed along with the COVID-19 vaccine administration code (0001A, 0001A, 0002A, 0003A, 0011A, 0012A, 0013A and 0031A).

Code	CPT Long Descriptor	APC / SI	Effective Date	Payment Allowance
M0201	COVID-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID-19 vaccine administration is performed at the patient's home.	1494/S	06/08/2021	$40.00

3. COVID-19 Monoclonal Antibody Therapy Updates include drug and infusion codes for Sotrovimab administered in a health care setting or home.

Code	CPT Long Descriptor	APC / SI	Effective Date	Payment Allowance
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring	1506/S	05/26/2021	$450
M0248	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring **in the home or residence**; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency	1509/S	05/26/2021	$750
Q0247	Injection, sotrovimab, 500 mg	L	05/26/2021	$2,394

Descriptor changes for new potential administration route for Casirivimab/Imdevimab (Regeneron) drug combination.

Code	CPT Long Descriptor
M0243	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes **infusion or injection**, and post administration monitoring
M0244	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab **includes infusion or injection**, and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider- based to the hospital during the covid-19 public health emergency

OCTOBER 1, 2021 OPPS UPDATES

Codes assigned for the updated FDA (EUA) COVID-19 dosing regimen for Casirivimab/Imdevimab (Regeneron) drug combination and repeat administration.

Code	CPT Long Descriptor	APC / SI	Effective Date	Payment Allowance
M0240	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses	1506/S	07/30/2021	$450
M0241	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring **in the home or residence**; this includes a beneficiary's home that has been made provider based to the hospital during the covid-19 public health emergency, subsequent repeat doses	1509/S	07/30/2021	$750
Q0244	Injection, casirivimab and imdevimab, 1200 mg	L	07/30/2021	$0.01

New codes were assigned in accordance with the June 24, 2021, EUA for Tocilizumab when infused to treat COVID-19.

Code	CPT Long Descriptor	APC / SI	Effective Date	Payment Allowance
M0249	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, **first dose**	1506/S	06/24/2021	$450
M0250	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, **second dose**	1506/S	06/24/2021	$450
Q0249	Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg	L	06/24/2021	$6.572

OCTOBER 1, 2021 OPPS UPDATES

4. Proprietary Laboratory Analyses (PLA) coding changes effective October 1, 2021:

Deleted:

- **0139U** neurology (autism spectrum disorder [asd]), quantitative measurements of 6 central carbon metabolites (ie, a-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), lc-ms/ms, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of asd)
- **0168U** fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy

Revised:

- **0051U** Prescription drug monitoring, evaluation of drugs present by liquid chromatography tandem mass spectrometry (LC-MS/MS), urine or blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service (Status Indicator Q4)

30 New PLA Codes:

CPT®	Long Descriptor	OPPS SI
0139U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LCMS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	D
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	D
0255U	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score	Q4
0256U	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report	Q4
0257U	Very long chain acyl- coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood	Q4
0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin- surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics	A
0259U	Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative	Q4
0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	A
0261U	Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score	Q4
0262U	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalinfixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score	A
0263U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	Q4

OCTOBER 1, 2021 OPPS UPDATES

New PLA Codes, con't.

CPT®	Long Descriptor	OPPS SI
0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	A
0265U	Rare constitutional and other heritable disorders, whole- genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants	A
0266U	Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and nextgeneration sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes	A
0267U	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole-genome sequencing	A
0268U	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	A
0269U	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	A
0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid	A
0271U	Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	A
0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood, buccal swab, or amniotic fluid, comprehensive	A
0273U	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU) blood, buccal swab, or amniotic fluid	A
0274U	Hematology (genetic platelet disorders), genomic sequence analysis of 43 genes, blood, buccal swab, or amniotic fluid	A
0275U	Hematology (heparin-induced thrombocytopenia) platelet antibody reactivity by flow cytometry, serum	Q4
0276U	Hematology (inherited thrombocytopenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	A
0277U	Hematology (genetic platelet function disorder), genomic sequence analysis of 31 genes, blood, buccal swab, or amniotic fluid	A
0278U	Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid	A
0279U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen III binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen III binding	Q4
0280U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen IV binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen IV binding	Q4
0281U	Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level	Q4
0282U	Red blood cell antigen typing, DNA, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes	A
0283U	von Willebrand factor (VWF), type 2B, platelet binding evaluation, radioimmunoassay, plasma	Q4
0284U	von Willebrand factor (VWD), type 2N, factor VIII and VWF binding evaluation, enzyme-linked immunosorbent assays (ELISA), plasma	Q4

OCTOBER 1, 2021 OPPS UPDATES

5. New Multianalyte Assays with Algorithmic Analysis (MAAA) code effective October 1, 2021, with a Status Indicator of Q4:

0018M Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+Tcytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score

6. New HCPCS Procedure Codes:

Code	CPT Long Descriptor	OPPS SI	APC
C9779	Endoscopic submucosal dissection (ESD), including endoscopy or colonoscopy, mucosal closure, when performed	J1	5313
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

7. APC 5115 (Level 5 Musculoskeletal Procedures) and APC 5116 (Level 6 Musculoskeletal Procedures) associated with device category HCPCS C1831 (Personalized, anterior and lateral interbody cage (implantable)). CMS states C1831 should always be reported with one of the codes in the following table:

CPT® Codes Billed with C1831

CPT®	Description	SI	APC
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (list separately in addition to code for primary procedure)	N	
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure)	N	
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	J1	5116
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	J1	5115
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar	J1	5115

OCTOBER 1, 2021 OPPS UPDATES

8. OPPS retroactively (to July 1, 2021) updates: The July 2021 OPPS update stated C1761 (Catheter, transluminal intravascular lithotripsy, coronary) should always be reported with 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch) or HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch). The October 2021 OPPS retroactively updates this list to include additional procedures.

New Device Pass-Through Codes with Device Offset Amounts:

HCPCS	Description	Effective Date	SI	APC	Device Offset Amount(s) w/CPT
C1761	Catheter, transluminal intravascular lithotripsy, coronary	07/1/20201	H	2033	92933 - $8,778.98 92943 - $4,278.29 C9602 - $9,129.17 C9607 - $8,677.77
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/01/2021	H	2034	22558 - $7,662.72 22586 - $4,919.12 22612 - $5,301.50 22630 - $7,837.27 22633 - $6,851.93

9. Drugs, Biologicals and Radiopharmaceuticals

New Pass-Through Status Drugs, Biologicals and Radiopharmaceuticals effective October 1, 2021:

HCPCS	Description	SI	APC
J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427
C9081	Idecabtagene vicleucel, up to 460 million autologous anti-BCMA car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422
C9082	Injection, dostarlimab-gxly, 100 mg	G	9423
C9083	Injection, amivantamab-vmjw, 10 mg	G	9424
C9804	Injection, loncastuximab tesirine-lpyl, 0.1 mg	G	9425

Existing Pass-Through Status Drugs, Biologicals and Radiopharmaceuticals effective October 1, 2021:

HCPCS	Description	SI	APC
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410
J1823	Injection, inebilizumab-cdon, 1 mg	G	9394

OCTOBER 1, 2021 OPPS UPDATES

Pass-Through Status Drugs, Biologicals and Radiopharmaceuticals Ending on September 30, 2021:

HCPCS	Description	July 2021 SI	Oct 2021 SI	Oct 2021 APC
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	K	9099
Q5105	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units	G	N	N/A
Q5106	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for non-esrd use), 1000 units	G	K	9097

Newly Established HCPCS for Drugs, Biologicals and Radiopharmaceuticals effective October 1, 2021:

New HCPCS	Old HCPCS	Description	SI	APC
C9081	N/A	Idecabtagene vicleucel, up to 460 million autologous anti-BCMA car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422
C9082	N/A	Injection, dostarlimab-gxly, 100 mg	G	9423
C9083	N/A	Injection, amivantamab-vmjw, 10 mg	G	9424
C9084	N/A	Injection, loncastuximab tesirine-lpyl, 0.1 mg	G	9425
J0699	N/A	Injection, cefiderocol, 10 mg	G	9426
J0741	C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414
J1305	C9079	Injection, evinacumab-dgnb, 5mg	G	9416
J1426	C9075	Injection, casimersen, 10 mg	G	9412
J1445	N/A	Injection, ferric pyrophosphate citrate solution (triferic avnu), 0.1 mg of iron	E2	N/A
J1448	C9078	Injection, trilaciclib, 1mg	G	9415
J2406	N/A	Injection, oritavancin (kimyrsa), 10 mg	G	9427
J7294	N/A	Segesterone acetate and ethinyl estradiol 0.15mg, 0.013mg per 24 hours; yearly vaginal system, each	E1	N/A
J7295	J7303	Ethinyl estradiol and etonogestrel 0.015mg, 0.12mg per 24 hours; monthly vaginal ring, each	E1	N/A
J9247	C9080	Injection, melphalan flufenamide, 1mg	G	9417
J9318	C9065	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428
J9319	J9315	Injection, romidepsin, lyophilized, 0.1 mg	K	9429
Q2054	C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413
Q4251	N/A	Vim, per square centimeter	N	N/A
Q4252	N/A	Vendaje, per square centimeter	N	N/A
Q4253	N/A	Zenith amniotic membrane, per square centimeter	N	N/A

Revised Descriptors for Drugs, Biologicals and Radiopharmaceuticals:

HCPCS	Description	SI	APC
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410
J1823	Injection, inebilizumab-cdon, 1 mg	G	9394

OCTOBER 1, 2021 OPPS UPDATES

Deleted HCPCS Drugs, Biologicals and Radiopharmaceuticals Ending on September 30, 2021:

HCPCS	Description	Old SI	New SI	APC
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	N	G	9409
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	N	G	9410

Updates on Drugs and Biologicals with payments based on Average Sales Price (ASP):

- Most nonpass-through, Non 340B Program = ASP + 6 percent (or ASP + 6 percent of reference product for biosimilars)
- Nonpass-through, acquired through 340B Program = ASP – 22.5 percent (or ASP – 22.5 percent of 340B acquired biosimilar)
- Single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals
- CMS states retroactive payment rates occur on a quarterly basis and will be published on the first date of the quarter at the following website (not active at time of print):

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPSRestated-Payment-Rates

10. Skin Substitutes: Payments for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the skin substitute application procedure.Skin substitutes are assigned either high cost or low cost skin substitute.New skin substitute drugs with a mean unit cost of under $48 or $949 per day will be assigned low-cost status.

New Skin Substitute Products effective October 1, 2021:

HCPCS	Description	CY 2021 SI	Low/High Cost Skin Substitute
Q4251	Vim, per square centimeter	N	Low
Q4252	Vendaje, per square centimet	N	Low
Q4253	Zenith amniotic membrane psc	N	Low

OCTOBER 1, 2021 OPPS UPDATES

Deleted Skin Substitute Products effective October 1, 2021:

HCPCS	Description	CY 2021 SI
Q4228	Bionextpatch, per sq cm	N
Q4236	Carepatch per sq cm	N

11. Vaccine Status indicator Change for 90677 (Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use) will change from OPPS status indicator E1 (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to status indicator L (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) effective October 1, 2021.

12. Two New Blood Product HCPCS codes, assigned Status indicator R (Paid under OPPS; separate APC payment) effective October 1, 2021:

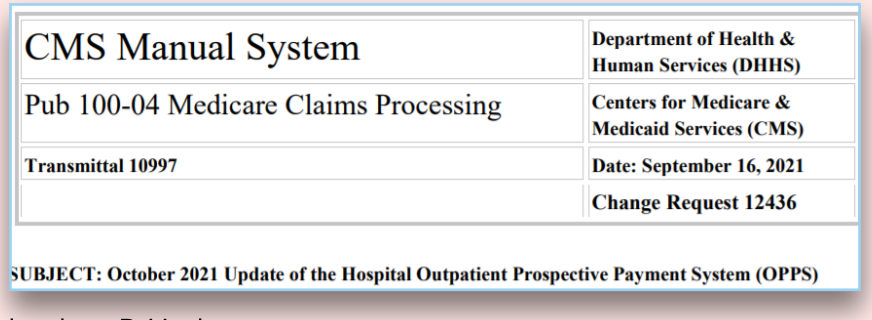
HCPCS	Description	SI	APC
P9025	Plasma, cryoprecipitate reduced, pathogen reduced, each unit	R	9538
P9026	Cryoprecipitated fibrinogen complex, pathogen reduced, each unit	R	9539

13. Coverage Determination: CMS reminds us that HCPCS codes and payment rates demonstrate how services, products, or procedures may pay if covered by Medicare. To determine coverage, consult the local MAC for HCPCS code coverage limitations.

CMS References

Change Request (CR) 12436, /Medicare Claim Processing Transmittal 10997:

https://www.cms.gov/files/document/r10997cp.pdf



CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10997	Date: September 16, 2021
	Change Request 12436

SUBJECT: October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Addendum A and Addendum B Updates

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates

USE THE PARA DATA EDITOR CALCULATOR FOR DRUG NDC CODES

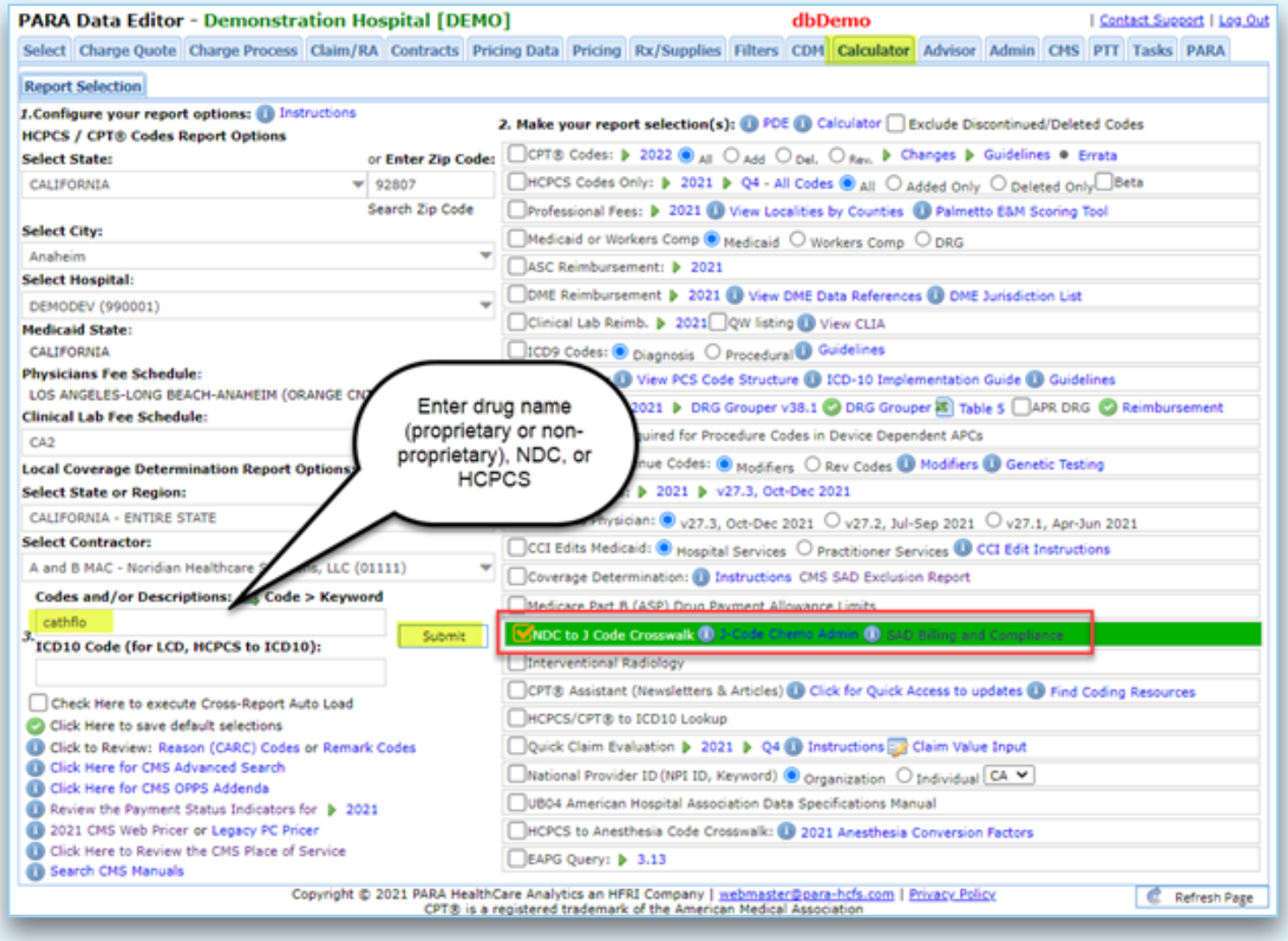
Billers know that NDC numbers are required for reporting most drugs to state Medicaid payers. They may not know that the states then use the NDC data submitted by providers to claim a rebate from drug manufacturers. Accuracy in reporting NDC codes to Medicaid is important to ensure the accuracy of state programs claim rebates from pharmaceutical manufacturers.

Reporting an NDC code on claims can be problematic because the NDC reported on a drug package may not match the 11-digit NDC code required on a claim. A 9- or 10-digit NDC format need to be converted into the 11 digit format for reporting on a Medicaid claim.

The **PARA Data Editor** offers an NDC to J-code Lookup feature which provides the full 11-digit NDC number for drugs by searching any of the following references:

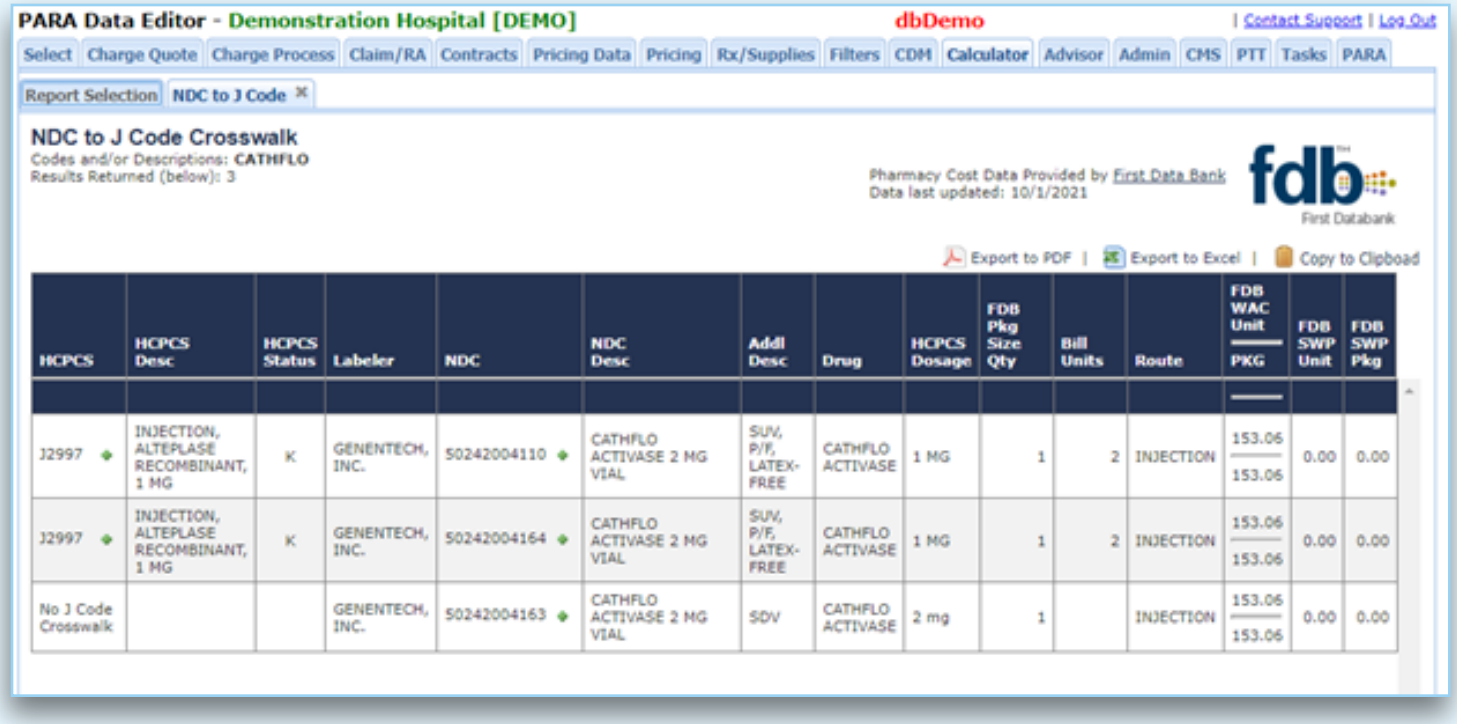
- The HCPCS (whether a J-code, a C-code, or a Q-code)
- The proprietary name of the drug
- The non-proprietary/generic drug name
- The NDC, or even a partial NDC

The NDC to J-Code crosswalk is found on the **PARA Data Editor** Calculator tab – it combines the NDC data from the drug manufacturer with HCPCS coding supplied by Medicare's NDC to HCPCS crosswalks:



USE THE PARA DATA EDITOR CALCULATOR FOR DRUG NDC CODES

The resulting report will offer the NDC, a HCPCS code (if and as assigned by Medicare), and the bill units in the vial, according to the manufacturer data collected by PARA's pharmacy data vendor, First Data Bank:



HCPCS	HCPCS Desc	HCPCS Status	Labeler	NDC	NDC Desc	Addl Desc	Drug	HCPCS Dosage	FDB Pkg Size Qty	Bill Units	Route	FDB WAC Unit / PKG	FDB SWP Unit	FDB SWP Pkg
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG	K	GENENTECH, INC.	50242004110	CATHFLO ACTIVASE 2 MG VIAL	SUV, P/F, LATEX-FREE	CATHFLO ACTIVASE	1 MG	1	2	INJECTION	153.06 / 153.06	0.00	0.00
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG	K	GENENTECH, INC.	50242004164	CATHFLO ACTIVASE 2 MG VIAL	SUV, P/F, LATEX-FREE	CATHFLO ACTIVASE	1 MG	1	2	INJECTION	153.06 / 153.06	0.00	0.00
No J Code Crosswalk			GENENTECH, INC.	50242004163	CATHFLO ACTIVASE 2 MG VIAL	SDV	CATHFLO ACTIVASE	2 mg	1		INJECTION	153.06 / 153.06	0.00	0.00

In the United States, medication listed under the Federal Food, Drug, and Cosmetic Act is assigned a unique 11-digit, three-segment number, known as the National Drug Code (NDC.) An NDC consist of three sections of numbers, known as a 5-4-2 format:

- **The first 5 digits represent the labeler code.** This code is assigned by the Food and Drug Administration (FDA) to a firm that manufactures, repacks, or distributes a drug product. Although this segment must contain five numbers, some labeler codes have leading zero's that might be dropped
- **The next 4 digits are the product code.** These identify a specific drug, strength, and dosage form of that drug. This segment must contain four numbers. Leading zeroes are sometimes dropped from this segment
- **The last 2 digits are the package code.** This identifies the package size. This segment must contain two numbers – usually 01 or 02.

Billers may use the **PARA Data Editor** to verify the 11-digit NDC number for the drug to be reported by matching the drug name (proprietary or non-proprietary) to the NDC or partial NDC provided.

PARA chargemaster reviews verify that the HCPCS is appropriate to the NDC, and the bill units are calculated correctly (when bill units are provided by the client.)

USE THE PARA DATA EDITOR CALCULATOR FOR DRUG NDC CODES

Medicare updates HCPCS codes, particularly for expensive drugs, on a quarterly basis. A newly approved drug may or may be assigned a HCPCS code at any time, and HCPCS should be reported when the HCPCS accurately describes the drug provided.

An expensive new drug may be reported to Medicare with HCPCS C9399 – Unclassified Drugs or Biologicals, provided that the remarks section on the claim includes information on the NDC and quantity required.

CMS will examine the remarks field to determine whether the drug should be separately reimbursed under OPPS. The Average Sales Price cost threshold for determining whether a drug should be separately paid or reimbursed is in 2022 will be $130 per administration, as it was in 2021, per the 2022 OPPS Proposed Rule.

On the other hand, many low-cost drugs are not assigned to any HCPCS, and should be reported by hospitals under revenue code 0250 "General pharmacy" without a HCPCS code, unless a payer (such as state Medicaid) requires an unclassified drug HCPCS such as J3490.(Bear in mind that J3490 should not be billed indiscriminately to commercial payers, as they may deny that HCPCS code for failure of prior authorization when no authorization is truly required.)

The state of Maryland offers a handy guide to converting a 10-digit NDC to an 11-digit number:

How do you convert a 10-digit NDC to an 11-digit NDC?

Increasingly payers are requiring an 11-digit NDC code for billing purposes. Therefore, proper billing may require a specially-placed zero to create a 5-4-2 format depending upon the drug product's 10-digit NDC. See Table 1 for conversion examples. Note that hyphens for the 11-digit NDC (in the last column below) are for illustration purposes only, and should not be used when submitting data for a claim.

Table 1: 10-Digit to 11-Digit NDC Conversion

10-Digit Format on package	10-Digit Format on package	Converted 11-Digit Format	Actual 10-digit example	11-digit conversion example
4-4-2	9999-9999-99	5-4-2	0777-3105-02 (Prozac)	00777-3105-02
5-3-2	99999-999-99	5-4-2	43063-609-30 (alprazolam)	43063-0609-30
5-4-1	99999-9999-9	5-4-2	11822-0544-1 (acetaminophen)	11822-0544-01

Table 1: Adapted from Maryland Dept. of Health (www.maryland.gov)

PAMA REPORTING CLARIFIED FOR "NON-PATIENT SPECIMEN" CLAIMS

PARA received clarification on whether hospitals must report payment rates and volumes for lab tests that were performed on a non-patient basis, but billed on a 13X or 85X Type of Bill.

For the first time, Medicare will require certain hospitals which meet the definition of an "Applicable Laboratory" to report payments made by commercial insurers for non-patient laboratory services.The reports are due in the first quarter of 2022.

The central qualifying criteria for hospitals is whether the entity was paid more than $12,500 by Medicare in the period January 1 through June 30, 2019.The data that must be reported are allowable payment rates made by commercial payers per lab CPT® code, and the frequency of times each hospital has been paid each separate rate.

The rates of commercial payments to be reported are limited to those paid for "non-patient services", which should be reported on the 14X Type of Bill (TOB.) However, several hospitals have asked **PARA** whether payments made for non-patient services, but which were billed on another TOB (such as 13X or 85X), should be reported.

We turned to Medicare's Clinical Fee Schedule Inquiries email address (CLFS_Inquiries@cms.hhs.gov) for clarification on this point.

PAMA REPORTING CLARIFIED FOR "NON-PATIENT SPECIMEN" CLAIMS

In an email sent on August 12, 2021, the CLFS Fee Schedule Inquiries email responded:

> "We apologize for the delay in responding. If a CLIA-certified hospital outreach laboratory that bills Medicare Part B under the hospital's NPI meets the requirements of an applicable laboratory, the reporting entity reports identifiable applicable information attributed to non-hospital patients. That is, for a hospital outreach laboratory that bills under the hospital's NPI, the reporting entity reports private payor data that can be distinguished from testing performed for hospital patients."

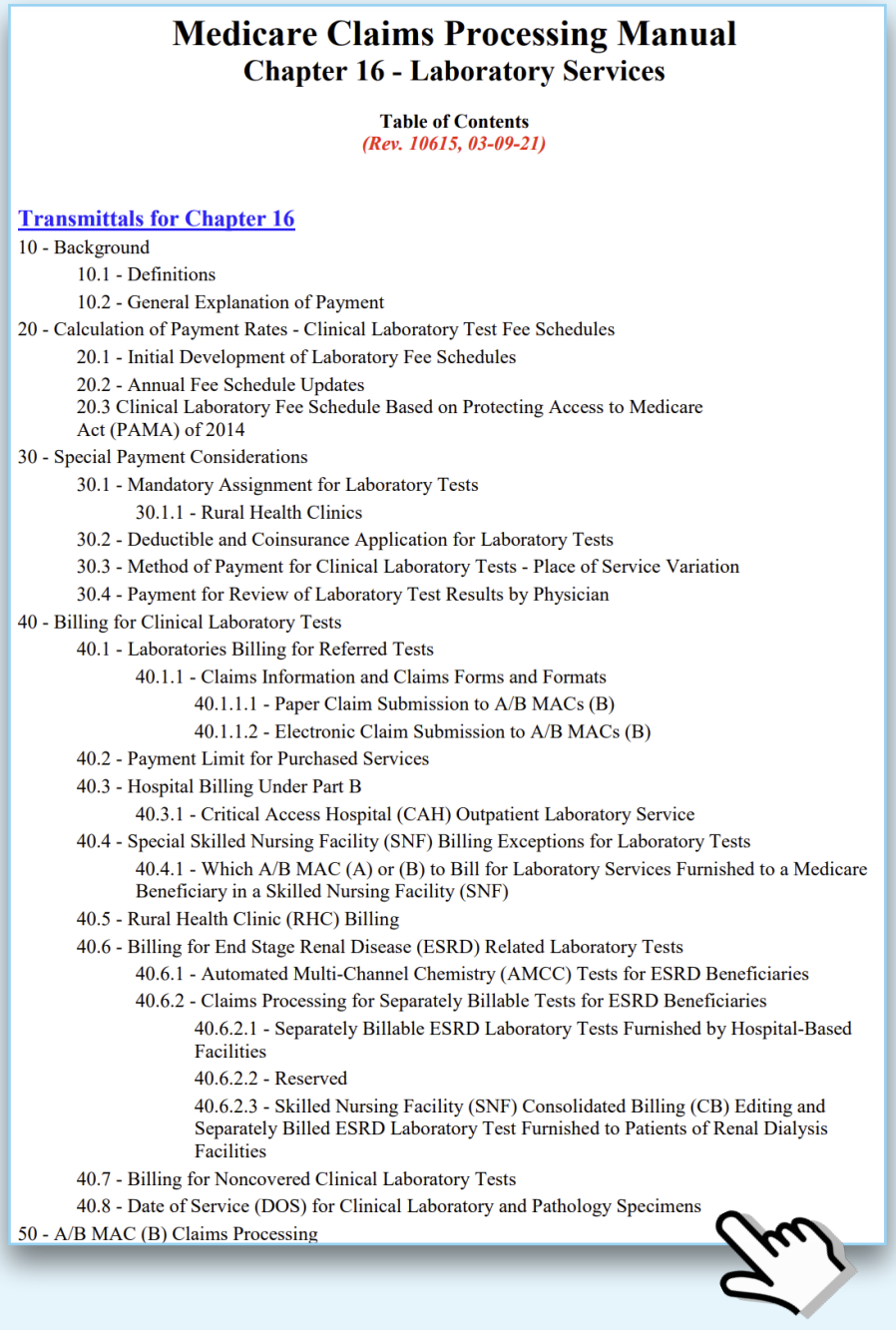
PARA interprets this reply to mean that CMS expects hospitals to report private payer lab rates for non-patient specimen testing whether or not the claim was submitted on TOB 14x, so long as the hospital can affirm that the testing qualified as a non-patient service. In other words, only the specimen was registered.

CMS offers a description of a "non-patient" service in Chapter 16 of the Medicare Claims Processing Manual:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf#

Non-Patient (Referred) Laboratory Specimen- A non-patient is defined as a beneficiary that is neither an inpatient nor an outpatient of a hospital, but that has a specimen that is submitted for analysis to a hospital and the beneficiary is not physically present at the hospital.

All hospitals (including Maryland waiver hospitals and CAHs) bill non-patient lab tests on TOB 14X. They are paid under the clinical laboratory fee schedule at the lesser of the actual charge, the fee schedule amount, or the NLA (including CAH and MD Waiver hospitals). Part B deductible and coinsurance do not apply.



Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

Table of Contents
(Rev. 10615, 03-09-21)

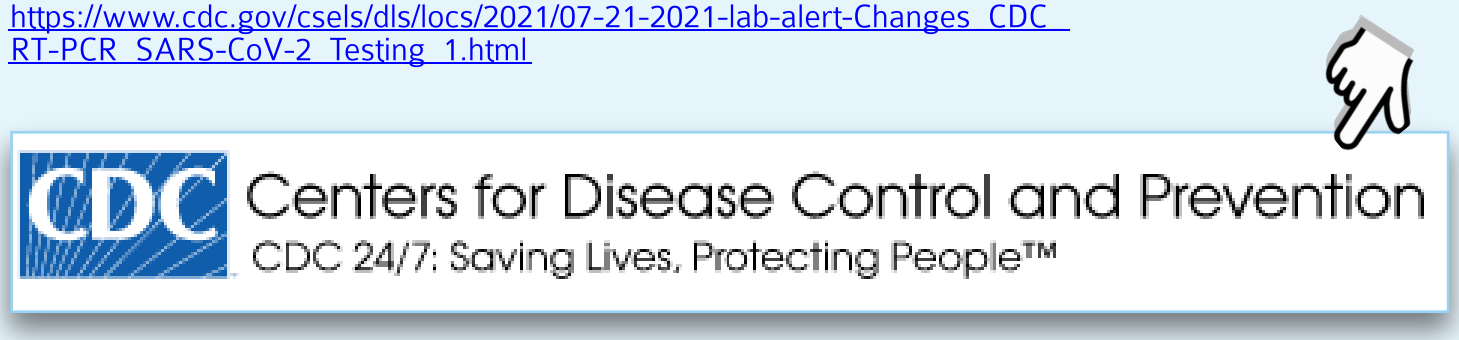
FDA TO WITHDRAW EUA ON COVID PCR TEST DECEMBER 31, 2021

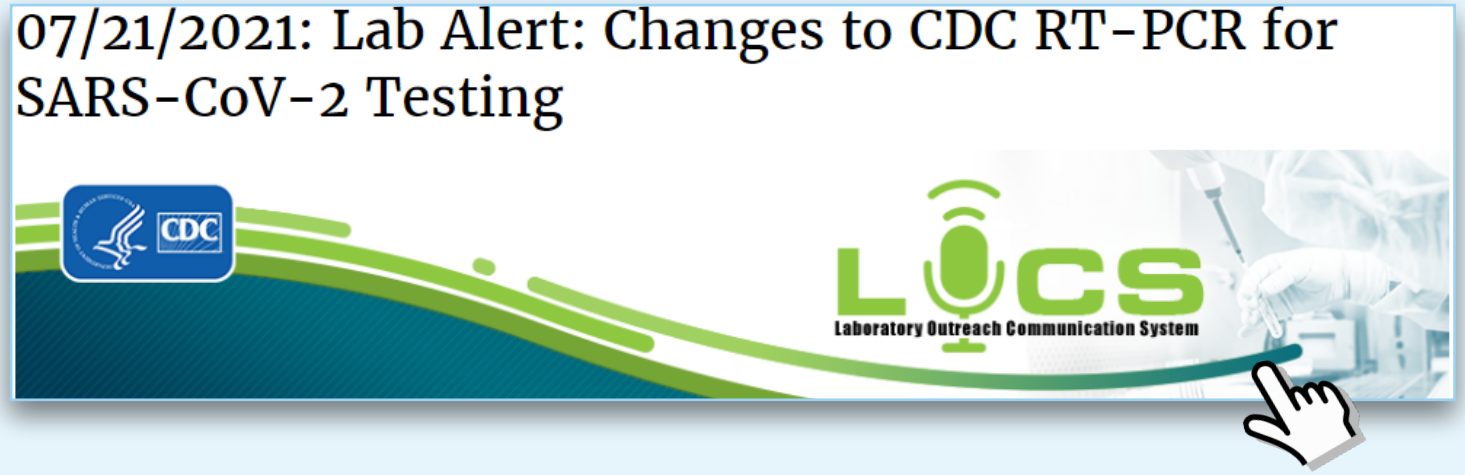
On July 21, 2021, the CDC announced it will withdraw its Emergency Use Authorization (EUA) request for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel after December 31, 2021.

The advanced notice allows laboratories to adopt and prepare to use an alternative FDA approved test.

The 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel detects only COVID-19.The CDC suggests laboratories begin using a multiplex assay that can detect both COVID-19 and influenza, which will be save time and laboratory resources as we enter flu season.

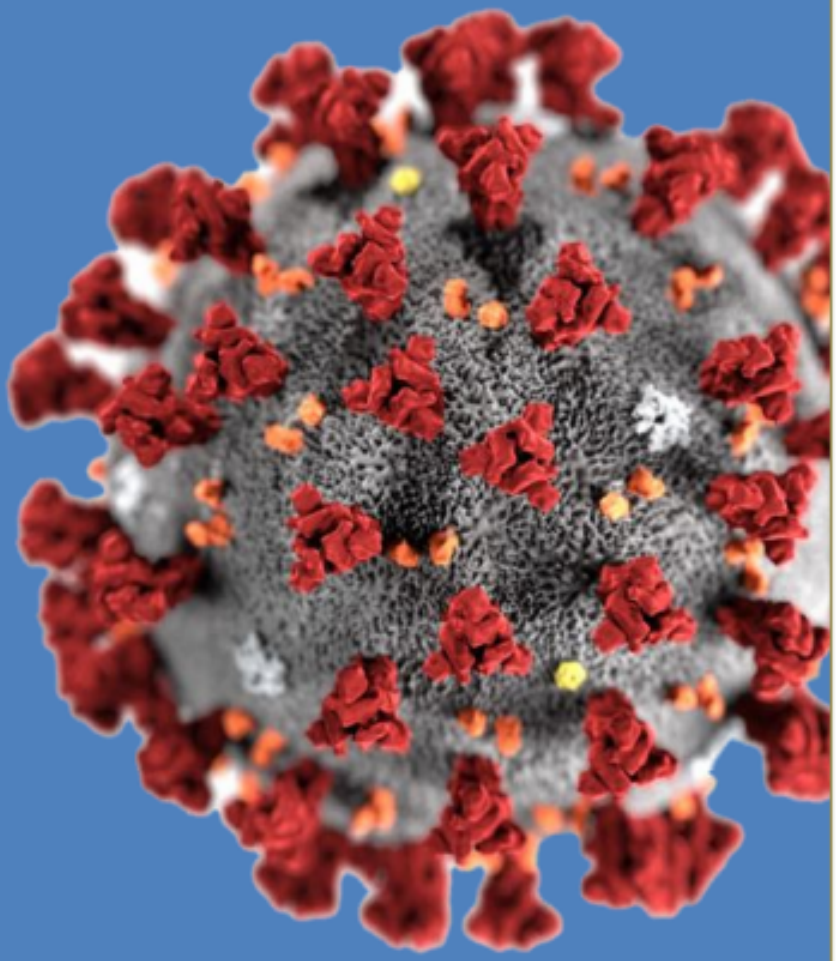
https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html





PARA HealthCare Analytics *continues to update COVID-19 coding and billing information based on frequently changing guidelines and regulations from CMS and payers. All coding must be supported by medical documentation.*

NEW UPDATE



Updated And Revised September 22, 2021

Comprehensive COVID-19 Billing and Coding Guide

PARA HealthCare Analytics

HEALTHCARE FINANCIAL RESOURCES

Download the updated Guidebook by clicking here.

PARA invites you to check out the **mlnconnects** page available from the Centers For Medicare and Medicaid (CMS). It's chock full of news and information, training opportunities, events and more! Each week **PARA** will bring you the latest news and links to available resources. **Click each link for the PDF!**

Thursday, October 7, 2021

News

- Medicare-Dependent Hospital COVID-19 Waiver: Modification
- Organ Procurement Organization Performance Report
- NPPES: Add Digital Contact Information
- Hospice QRP Claims-Based Measures: FAQs
- Breast Cancer: Talk to Your Patients about Screening

Claims, Pricers, & Codes

- Drugs & Biologics: HCPCS Level II Application Summaries & Coding Decisions

Events

- Medicare Ground Ambulance Data Collection System Webinar: Labor Costs — October 7
- Medicare Ground Ambulance Data Collection System: Q&A Session — October 12
- Hospice Quality Reporting Program Forum — October 19

MLN Matters® Articles

- Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)
- Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2022 — Revised

Publications

- Medicare DMEPOS Payments While Inpatient — Revised

Multimedia

- Modernizing Health Care to Improve Physical Accessibility

View this edition as PDF (PDF)

There were 0 new or revised
MedLearns released this week.

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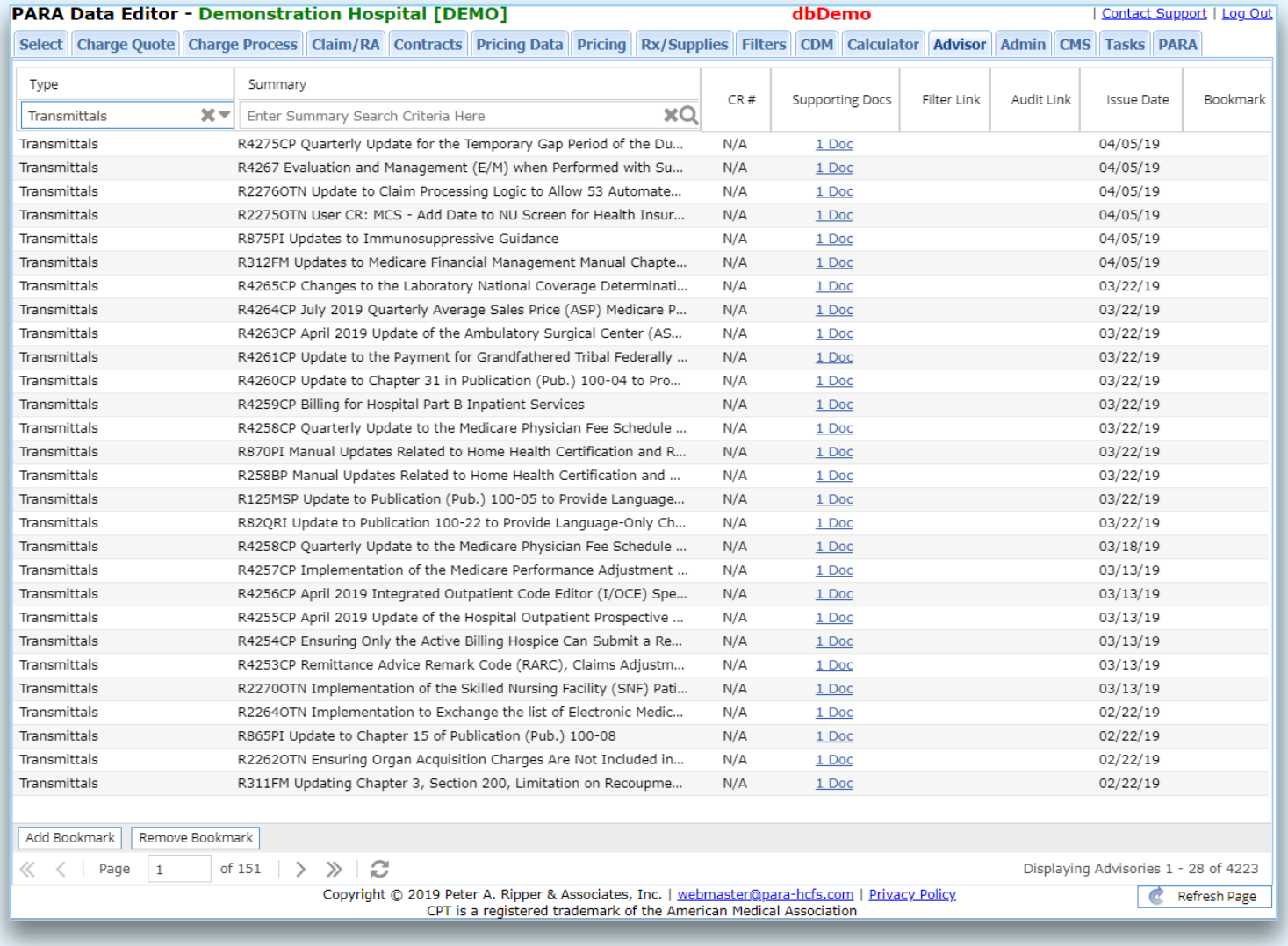

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Select | Charge Quote | Charge Process | Claim/RA | Contracts | Pricing Data | Pricing | Rx/Supplies | Filters | CDM | Calculator | **Advisor** | Admin | CMS | Tasks | PARA

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Transmittals	Enter Summary Search Criteria Here						
Transmittals	R4275CP Quarterly Update for the Temporary Gap Period of the Du...	N/A	1 Doc			04/05/19	
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Transmittals	R2276OTN Update to Claim Processing Logic to Allow 53 Automate...	N/A	1 Doc			04/05/19	
Transmittals	R2275OTN User CR: MCS - Add Date to NU Screen for Health Insur...	N/A	1 Doc			04/05/19	
Transmittals	R875PI Updates to Immunosuppressive Guidance	N/A	1 Doc			04/05/19	
Transmittals	R312FM Updates to Medicare Financial Management Manual Chapte...	N/A	1 Doc			04/05/19	
Transmittals	R4265CP Changes to the Laboratory National Coverage Determinati...	N/A	1 Doc			03/22/19	
Transmittals	R4264CP July 2019 Quarterly Average Sales Price (ASP) Medicare P...	N/A	1 Doc			03/22/19	
Transmittals	R4263CP April 2019 Update of the Ambulatory Surgical Center (AS...	N/A	1 Doc			03/22/19	
Transmittals	R4261CP Update to the Payment for Grandfathered Tribal Federally ...	N/A	1 Doc			03/22/19	
Transmittals	R4260CP Update to Chapter 31 in Publication (Pub.) 100-04 to Pro...	N/A	1 Doc			03/22/19	
Transmittals	R4259CP Billing for Hospital Part B Inpatient Services	N/A	1 Doc			03/22/19	
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Transmittals	R870PI Manual Updates Related to Home Health Certification and R...	N/A	1 Doc			03/22/19	
Transmittals	R258BP Manual Updates Related to Home Health Certification and ...	N/A	1 Doc			03/22/19	
Transmittals	R125MSP Update to Publication (Pub.) 100-05 to Provide Language...	N/A	1 Doc			03/22/19	
Transmittals	R82QRI Update to Publication 100-22 to Provide Language-Only Ch...	N/A	1 Doc			03/22/19	
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Transmittals	R4257CP Implementation of the Medicare Performance Adjustment ...	N/A	1 Doc			03/13/19	
Transmittals	R4256CP April 2019 Integrated Outpatient Code Editor (I/OCE) Spe...	N/A	1 Doc			03/13/19	
Transmittals	R4255CP April 2019 Update of the Hospital Outpatient Prospective ...	N/A	1 Doc			03/13/19	
Transmittals	R4254CP Ensuring Only the Active Billing Hospice Can Submit a Re...	N/A	1 Doc			03/13/19	
Transmittals	R4253CP Remittance Advice Remark Code (RARC), Claims Adjustm...	N/A	1 Doc			03/13/19	
Transmittals	R2270OTN Implementation of the Skilled Nursing Facility (SNF) Pati...	N/A	1 Doc			03/13/19	
Transmittals	R2264OTN Implementation to Exchange the list of Electronic Medic...	N/A	1 Doc			02/22/19	
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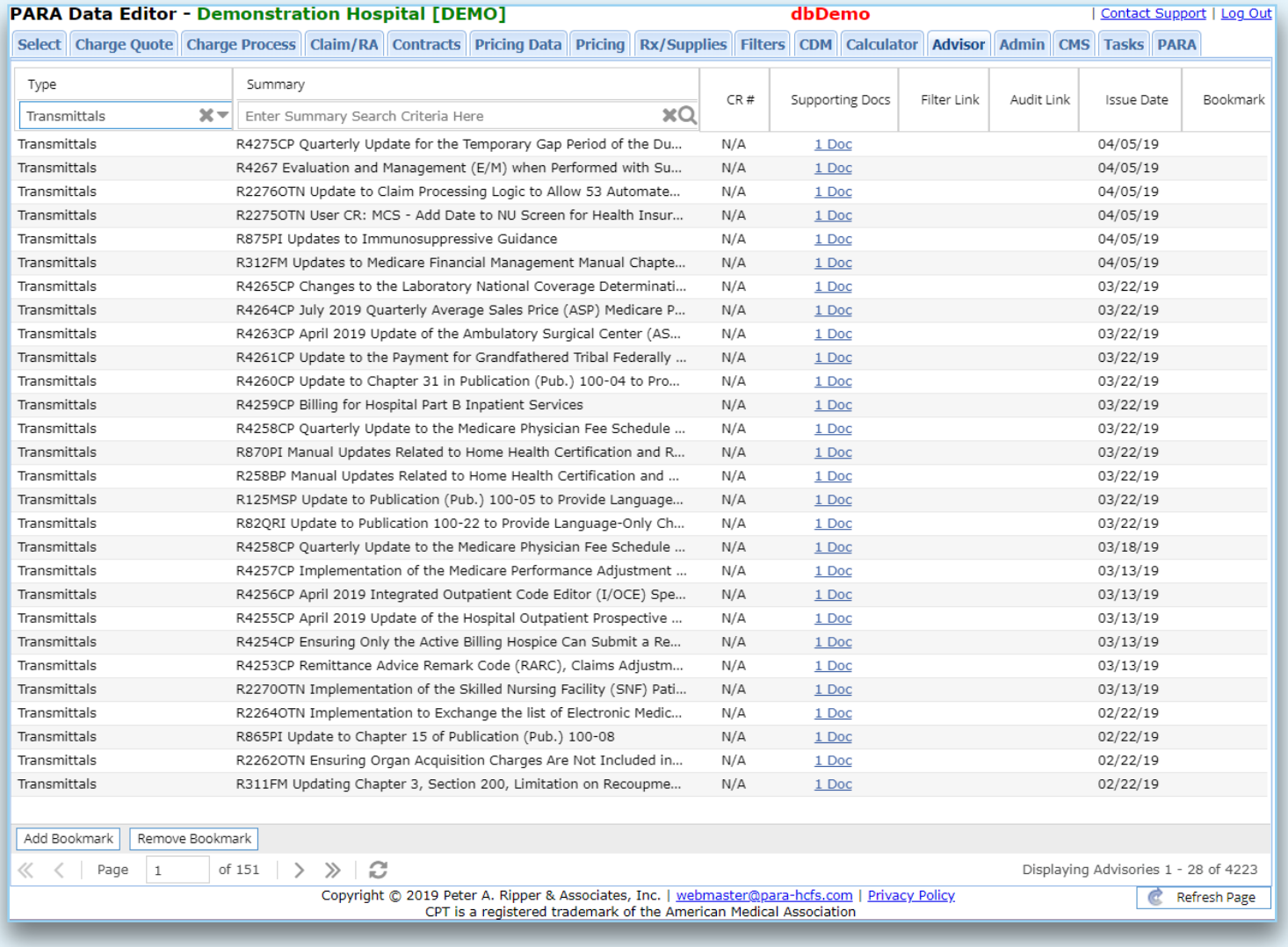

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The link to this Transmittal R11039CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11039	**Date: October 5, 2021**
	Change Request 12417

Transmittal 11019, dated September 27, 2021, is being rescinded and replaced by Transmittal 11039, dated, October 5, 2021 to correct the outlier fixed dollar loss threshold amount, as discussed in the correction notice entitled "Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022); Correction", which was displayed in the Federal Register on September 30, 2021. All other information remains the same.

SUBJECT: Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2022

I. SUMMARY OF CHANGES: This Change Request (CR) identifies changes that are required as part of the annual IPF PPS update established in IPF Final Rule entitled "**Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022)"**. These changes are applicable to discharges occurring from October 1, 2021 through September 30, 2022 (FY 2022). This Recurring CR applies to the Claims Processing Manual (CLM), chapter 3, section 190.4.3 and section 190.6.5.

EFFECTIVE DATE: October 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 4, 2021

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/190/4.3/Annual Update
R	3/190/6.5/Cost-of-Living Adjustment (COLA) for Alaska and Hawaii

III. FUNDING:

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