# EDURNAL



Seeing Through Price Transparency

The Cost Of GFEs For Uninsured

CMS Corrections

Part-B Only CAH Claims Processing



#### IPPS TRANSFER TO SWING BED



■ Can you please tell me how an IPPS DRG would be reimbursed if their patient was admitted there for three days, and then transferred to our swing bed? Will the IPPS hospital have a reduced DRG reimbursement? Can you also please provide the CMS guideline?

A. It depends on the Geometric Mean Length of Stay (GMLOS) of the DRG reported by the discharging hospital. A three-day stay prior to discharge could very easily result in full DRG reimbursement if the GMLOS for that DRG was 4 or less.

The facility is paid a graduated per deim rate based on several factors as outlined in 42 Code of Federal Regulations. I've shared a link and some excerpts for your convenience.

#### 42 CFR § 412.4 Discharges and transfers - Code of Federal Regulations (ecfr.io)

#### 412.4 Discharges and transfers.

§ 412.4 Discharges and transfers.

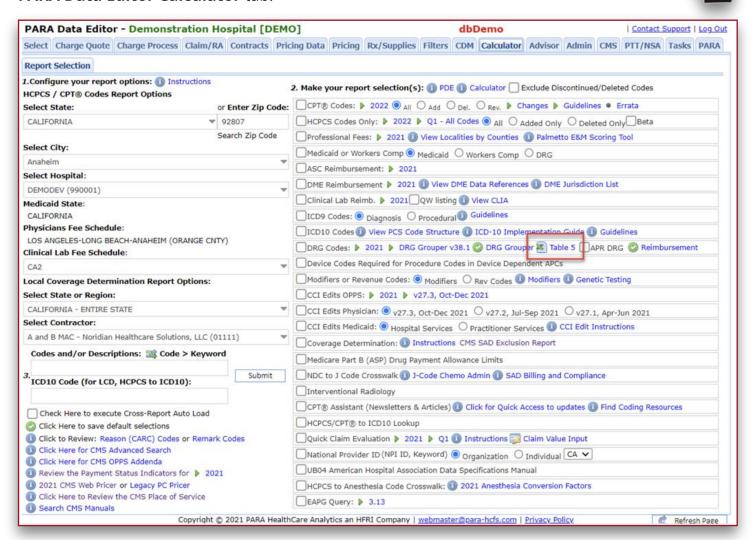
(a) Discharges. Subject to the provisions of paragraphs (b) and (c) of this section, a hospital inpatient is considered discharged from a hospital paid under the prospective payment system when

- (1) The patient is formally released from the hospital; or
- (2) The patient dies in the hospital.
- (b) Acute care transfers. A discharge of a hospital inpatient is considered to be a transfer for purposes of payment under this part if the patient is readmitted the same day (unless the readmission is unrelated to the initial discharge) to another hospital that is -
- (1) Paid under the prospective payment system described in subparts A through M of this part;
- (2) Excluded from being paid under the prospective payment system described in subparts A through M of this part because of participation in an approved statewide cost control program as described in subpart C of part 403 of this chapter;
- (3) An acute care hospital that would otherwise be eligible to be paid under the IPPS, but does not have an agreement to participate in the Medicare program; or
- (4) A critical access hospital.
- (c) Postacute care transfers. A discharge of a hospital inpatient is considered to be a transfer for purposes of this part when the patient's discharge is assigned, as described in § 412.60(c), to one of the qualifying diagnosis-related groups (DRGs) listed in paragraph (d) of this section and the discharge is made under any of the following circumstances:
- (1) To a hospital or distinct part hospital unit excluded from the prospective payment system described in subparts A through M of this part under subpart B of this part
- (2) To a skilled nursing facility.
- (3) To home under a written plan of care for the provision of home health services from a home health agency and those services begin within 3 days after the date of discharge
- (4) For discharges occurring on or after October 1, 2018, to hospice care provided by a hospice program.

#### IPPS TRANSFER TO SWING BED

(f) Payment for transfers - (1) General rule. Except as provided in paragraph (f)(2) or (f)(3) of this section, a hospital that transfers an inpatient under the circumstances described in paragraph (b) or (c) of this section, is paid a graduated per diem rate for each day of the patient's stay in that hospital, not to exceed the amount that would have been paid under subparts D and M of this part if the patient had been discharged to another setting. The per diem rate is determined by dividing the appropriate prospective payment rate (as determined under subparts D and M of this part) by the geometric mean length of stay for the specific DRG to which the case is assigned. Payment is graduated by paying twice the per diem amount for the first day of the stay, and the per diem amount for each subsequent day, up to the full DRG payment. (f) Payment for transfers - (1) General rule. Except as provided in paragraph (f)(2) or (f)(3) of this section, a hospital that transfers an inpatient under the circumstances described in paragraph (b) or (c) of this section, is paid a graduated per diem rate for each day of the patient's stay in that hospital, not to exceed the amount that would have been paid under subparts D and M of this part if the patient had been discharged to another setting. The per diem rate is determined by dividing the appropriate prospective payment rate (as determined under subparts D and M of this part) by the geometric mean length of stay for the specific DRG to which the case is assigned. Payment is graduated by paying twice the per diem amount for the first day of the stay, and the per diem amount for each subsequent day, up to the full DRG payment. (2) Special rule for DRGs 209, 210, and 211 for fiscal years prior to FY 2006. For fiscal years prior to FY 2006, a hospital that transfers an inpatient under the circumstances described in paragraph (c) of this section and the transfer is assigned to DRGs 209, 210, or 211 is paid as follows: (i) 50 percent of the appropriate prospective payment rate (as determined under subparts D and M of this part) for the first day of the stay; and (ii) 50 percent of the amount calculated under paragraph (f)(1) of this section for each day of the stay, up to the full DRG payment. (3) Transfer assigned to DRG for newborns that die or are transferred to another hospital. If a transfer is classified into CMS DRG 385 (Neonates, Died or Transferred) prior to October 1, 2007, or into MS-DRG 789 (Neonates, Died or Transferred to Another Acute Care Facility) on or after October 1, 2007, the transferring hospital is paid in accordance with § 412.2(b)

#### Table 5, which indicates whether the DRG is a post-acute DRG, is available on the **PARA Data Editor Calculator** tab:



#### **IPPS TRANSFER TO SWING BED**

Column D in Table 5 indicates whether the DRG is FY 2022 Post-Acute DRG, and column O shows FY 2022 GMLOS. The data in this screenshot is filtered to display only Post-Acute DRG's and sorted by the GMLOS from lowest to highest.



Attached is an MLN and an FAQ on this topic. Please let us know if you need additional information or support.

#### CMS ESTIMATES BURDEN OF PROVIDING GFE TO UNINSURED

WHETHER YOU'RE WITH A HEALTHCARE
FACILITY, A PROVIDER ASSOCIATED WITH
A HEALTHCARE FACILITY, AN INDIVIDUAL
PHYSICIAN PRACTITIONER, OR PART OF A
WHOLLY-PHYSICIAN-OWNED PRIVATE PRACTICE,
THE NO SURPRISES ACT WILL CREATE
UNBUDGETED COSTS IN 2022.



While some provisions of the NSA are not being enforced in 2022, the requirement to present a Good Faith Estimate (GFE) to an uninsured (or self-pay) individual is being enforced. HHS estimates that it will take an average of one hour for a business operations specialist to determine a patient's insurance status, inform uninsured (or self-pay) individuals of their right to receive a GFE of expected charges, and provide a GFE. CMS published a report on the estimated costs for providers.

The report can be found at this link: <a href="Mailto:CMS-10791">CMS-10791</a> | CMS-10791</a> | CMS-10791

Supporting Statement—Part A
Requirements Related to Surprise Billing; Part II
CMS-10791/OMB control number1210-0169

#### A. Background

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.

#### CMS ESTIMATES BURDEN OF PROVIDING GFE TO UNINSURED

Within the Supporting Statement, Medicare provides tables which offer an example of some of the costs and burdens associated with providing a GFE. Here are a couple of examples:

TABLE 2: Estimated One-Time and Hour Burden for Providers Associated with Facilities to Enter into Agreements to Provide Notice of Right to a Good Faith Estimate

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Burden (Hours)	Total Estimated Cost
2021	245,336	245,336	4	981,344	\$91,770,384

HHS assumes that the associated facility will draft the notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by

TABLE 5: Estimated One-Time Cost and Hour Burden for Individual Physician Practitioners to Draft and Post Notice of Good Faith Estimate Notice\*

	and rest Notice or Good rain Estimate Notice					
Year	Estimated Number of Respondents (Occupation Type)	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Printingand MaterialCosts	Total Estimated Cost
2021	145,887(All Physicians)	145,887	2.5	364,717	\$14,589*	\$61,797,674
2021	116,709** (Additional burden for Subset of Physicians with Websites)	116,709	1	116,709	-	\$13,278,038
Total	-	-	3.5	481,426	-	\$75,075,712***

<sup>\*</sup>HHS estimates that 80 percent (116,709) of individual physician practitioners have a website. Therefore, estimated cost includes computer programming cost to update individual physician practitioners' websites with right to good faith estimate notice to uninsured (or self-pay) individuals. HHS assumes that each individual physician practitioner will incur a printing cost of \$0.05 per page and materials for a total equivalent cost of \$0.10. Total printing and material costs of \$14,589 are included.

<sup>\*\*</sup>Note that the 116,709 computer programmers are accounted for in the total number of 145,887 individual physician practitioners that must comply with the requirement.

<sup>\*\*\*</sup> This is calculated as the sum of \$75,075,712(cost for individual physician practitioners to draft notice of right to GFE) + \$13,278,038 (cost for computer programmers to post notice of right to

#### CMS ESTIMATES BURDEN OF PROVIDING GFE TO UNINSURED

The **PARA Data Editor** offers a feature to enable **ParaRev** clients to create estimates and print the documents required for compliance with the new rules. The knowledgeable **ParaRev** team can get your staff educated and up-to-date on the provisions of the NSA which are being enforced in 2022 so you can be compliant.

**ParaRev** is developing further enhancements to assist clients with additional No Surprises Act requirements which will be enforced in 2023. Providers will be required to work with facilities to provide one consolidated GFE for scheduled services to the uninsured (or self-pay) individual.

In addition, new rules which require all health care providers (facilities and practitioners) to provide a GFE to the individual's health plan will be enforced in 2023. This will allow the plan to send an advanced EOB to the insured individual. The GFE and Advanced EOB will be provided to all insured individuals regardless of contract status between the plan and provider.

Contact one of **ParaRev's Account Executives** for more information about the NSA tool available to cut labor costs when providing estimates to individuals or health plans.



#### TOP THREE HOSPITAL DEPARTMENTS WITH HIGH DENIAL VOLUME

## MOST HOSPITAL LEADERS UNDERSTAND THE FINANCIAL DAMAGE DENIED CLAIMS CAN PRODUCE. YET ORGANIZATIONS CONTINUE TO STRUGGLE WHEN IT COMES TO ELIMINATING NEW DENIALS AND RESOLVING EXISTING ONES.

The complexity of revenue cycle management, coupled with frequent changes in payer policies and rules, can make it extremely difficult for providers to consistently identify and mitigate denial root causes. As a result, the problem of denials is becoming substantially worse. A recent study determined that write-offs triggered by denials for the average, 350-bed hospital jumped 79% between 2011 and 2017, from \$3.9 million to \$7 million. <sup>1</sup> Another report estimated that about 9% of \$3 trillion in U.S. hospital claims were denied in 2016. <sup>2</sup> And even with the administrative costs of resolving denials estimated at nearly \$9 billion a year, only about one-third of denials are actually reworked. Gaining control over denials to reduce chronic revenue loss and costly remediation requires accurate information about where, when and why denials are occurring. With more than 20 years' experience in helping hospitals identify and address rejected and aging accounts receivable, ParaRev has developed a clear understanding of areas within the hospital where denials are most prevalent, and why.

#### THE TOP THREE HOSPITAL DEPARTMENTS WITH HIGH DENIAL VOLUME

#### 1. EMERGENCY DEPARTMENT

Hospital emergency departments (ED) serve as the primary gateway for inpatient admissions, with two-thirds of all admissions coming through the ED. <sup>4</sup> That's why it is essential that patient information, especially insurance data, is captured accurately at the time of service.

Unfortunately, the hectic pace and critical nature of ED services frequently means that confirming coverage takes a back seat to more pressing concerns. But hospitals risk growing denials and write-offs if they can't effectively collect payment information at the outset of the care event.

Mistakes or omissions that occur during the initial encounter impact not only payment for emergent services but also can undermine reimbursement along the entire continuum of care.

#### TOP THREE HOSPITAL DEPARTMENTS WITH HIGH DENIAL VOLUME

Inaccurate or invalid insurance information is the most common cause of denials in the ED. Internal **ParaRev** analysis has indicated that around 40% of ED patients have invalid insurance or no insurance when they present for care. In one case, almost 75% of patients who presented at a hospital emergency room had expired or non-existent insurance.

Given the financial risks denials present for hospitals, it is imperative that systems be developed to ensure accurate information about that patient's coverage, or lack thereof, is obtained as soon as possible and before any claims are submitted.

Specifically, hospitals should implement edits in their intake systems that can block claim submissions if there is no active insurance. Staff also needs to be trained in the appropriate steps to take.

Too often, we've seen hospital personnel submit claims to the insurance company on record, even if an automated rejection has already indicated that the coverage is no longer in force.

Another important step is to create an intervention process that allows staff to discuss the issue of payment with patients who do not have appropriate insurance. This can be impractical and even ill-advised before care is provided. But it should be undertaken as soon as possible once the patient is stable or discharged. A brief post-care meeting allows hospital staff to inform the patient that their coverage isn't valid and to ask for their assistance in determining if another policy might be available. If no other coverage exists, a payment plan should be discussed.

#### 2. LABORATORY

Because clinical laboratory claims typically are low-dollar amounts generated in large volume, many hospitals have concluded it's not cost-effective to aggressively pursue laboratory denials, given the resources required to work them and the nominal returns resolution can produce. This results in an often-significant number of write-offs.

However, hospitals that shift their thinking and no longer view laboratories as simply cost centers can generate a substantial source of new or "found" revenue by taking a more aggressive and systematic approach to lab denials. Strong denial management programs are especially important for hospitals that seek to expand their outreach business and transform the lab into a profit center.

Comprehensive lab denial management includes intelligent automation processes that can resolve the simplest denials without human intervention while supporting detailed analysis and identification of denial root causes.

#### TOP THREE HOSPITAL DEPARTMENTS WITH HIGH DENIAL VOLUME

**ParaRev's** experience has shown that the failure to obtain prior authorizations and medical necessity confirmations, as well as inaccurate or incomplete documentation, represent the most common reasons for laboratory denials.

Because prior authorizations typically are the responsibility of either the referring physician practice, the emergency department or the hospital's pre-certification department, making sure authorizations are obtained is usually beyond the control of the pathology group and laboratory.

But unless the testing is conducted during emergent care, it is probable that the test is pre-scheduled. Therefore, pre-authorization can and should take place when the lab work is scheduled. It's true it can be difficult for the laboratory or hospital staff to keep track of the many and varied insurance company pre-authorization guidelines.

However, most carriers provide links on their websites that identify the procedures or tests requiring pre-authorization, and hospitals should be able to consolidate these links for easy access or create their own documents for internal use. In any case, laboratories should develop their own pre-authorization check systems to confirm decisions from the referring physicians and avoid simply relying on oral assurances from the referring doctors. This is particularly true if the physician practice has been a significant source of denials in the past.

Toxicology tests is another category that continues to generate significant numbers of denials. According to the Center for Medicare and Medicaid Services (CMS), the majority of the denials for the category of "Laboratory Tests – Other," which includes urine drug screenings, are due to insufficient documentation. S Specifically, denials in this category are triggered by: • Insufficient or no documentation to support the intent to order the test • Insufficient or no documentation to support the medical necessity for the test of the individual patient • Unsigned medical record documentation by the treating physician or non-physician practitioner LCD, NCD criteria A combination of local coverage determinations (LCDs) and national coverage determinations (NCDs) usually will enable staff to determine medical necessity criteria for specific diagnosis codes and tests. The most current information is available online and should be checked by referring staff before exams are ordered, especially for those tests that have historically high denial rates. Finally, providers should make sure all patients are provided with, and sign, an Advanced Beneficiary Notice of Non-Coverage (ABN) before treatment. This ensures that the pathology group or lab will be able to bill the patient directly if the service is not payable by Medicare

#### CMS CORRECTS PART-B ONLY CAH CLAIMS PROCESSING

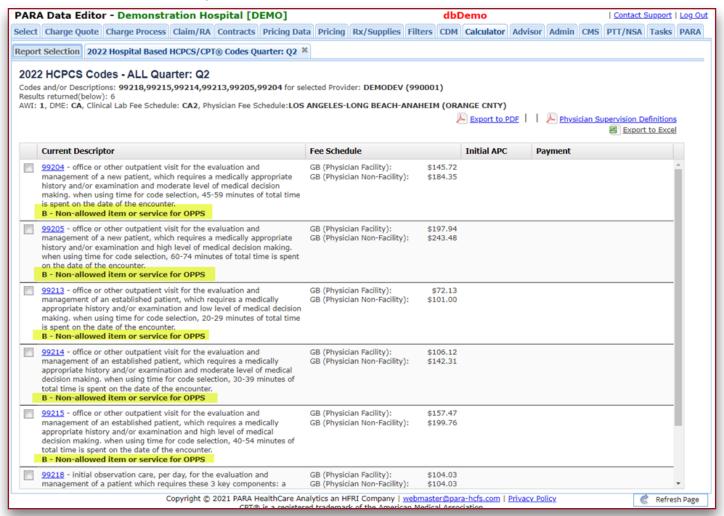
Medicare recently published Change Request 12636 directing Medicare Administrative Contractors to correct reimbursement processing for Critical Access Hospital (CAH) claims billed on Type of Bill (TOB) 12X for inpatient care provided to a beneficiary with Part B coverage only.

The MACs are not required to change claims processing, however, until October 1, 2022. The Change Request instructs contractors to allow payment for CAH ancillary services, including status B facility fees, using the reasonable cost (percent of charges) methodology.

The Change Request indicates that CAHs may have been improperly denied reimbursement for certain facility fee HCPCS billed on TOB 12X, specifically HCPCS which have been assigned OPPS Status Indicator B.

OPPS Status Indicator B codes can be valid for CAH claims, but are not recognized by OPPS when submitted on an outpatient OPPS hospital type of bill 12x or 13x. Typically, status B codes are not eligible for OPPS hospital claims because an alternate code may be reported (such as G0463 -HOSPITAL OUTPATIENT CLINIC VISIT FOR ASSESSMENT AND MANAGEMENT OF A PATIENT) for facility fees. Medicare permits CAHs to report OPPS status B HCPCS for facility fees.

Here are a few HCPCS examples:



#### CMS CORRECTS PART-B ONLY CAH CLAIMS PROCESSING

Medicare's Change Request instructs MACs to pay CAH claims for OPPS status B ancillary <u>facility</u> services at 101% of the reasonable cost of those service – in other words, on the percent-of-charges methodology otherwise applicable to most covered CAH outpatient facility fees.

(The instruction points out that professional fees billed by a CAH on the UB/837iunder revenue codes 096x, 097x, or 098x are paid under the Medicare Physician Fee Schedule – there is no change to claims processing for professional fees.)

Furthermore, Medicare stipulated that "Medicare contractors should not search their files to retroactively pay claims. However, contractors shall adjust claims brought to their attention."

The CAH ancillary service(s) TOB 12x must include the appropriate revenue codes to distinguish facility fees from professional fees. Most covered facility fees services on a CAH TOB 012X should be paid at 101 percent of the reasonable costs of the services. There are a few exceptions, such as mammography, which are paid under the Medicare Physician Fee Schedule when billed by a CAH or OPPS facility.

Consequently, this new guidance indicates that some Part-B only claims on TOB 012X may have been short paid due to improper line-item denials.

A link and an excerpt from the transmittal is provided below:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11339otn

Critical Access
Hospitals which
have submitted Part
B-Only inpatient
claims on TOB 12X
should keep an eye
on reimbursement
and resubmit the
claim for corrected
processing after
10/1/2022.

EFFECTIVE DATE: October 1, 2022 - Unless otherwise specified, the effective date is for claims processed on or after CR implementation.

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

**IMPLEMENTATION DATE: October 3, 2022** 

#### I. GENERAL INFORMATION

**A. Background:** Medicare allows for ancillary services when provided in a CAH. CAH ancillary services are submitted on a TOB 12X and based on 101 percent of reasonable costs like TOB 85x, excluding professional services that are separately billable by the performing clinician. It has been brought to CMS' attention when a CAH submits a TOB 12x no-reimbursement is being made for all ancillary services which have a pricing indicator 'B'.

This change request instructs contractors to allow for CAH ancillary services at reasonable cost when appropriate. The CAH ancillary service(s) TOB 12x should include the appropriate revenue codes. For facility services, not including physician or other practitioner services, payment will be based on 101 percent of the reasonable costs of the services. Services are paid based on the Medicare Physician Fee Schedule only when the physician or other practitioner has reassigned their benefits, and should be billed on TOB 85x with the appropriate Healthcare Common Procedure Coding System (HCPCS) code and revenue codes of 096x, 097x or 098x.

The Part A Medicare Administrative Contractor will not correct the claim payment unless brought to their attention:

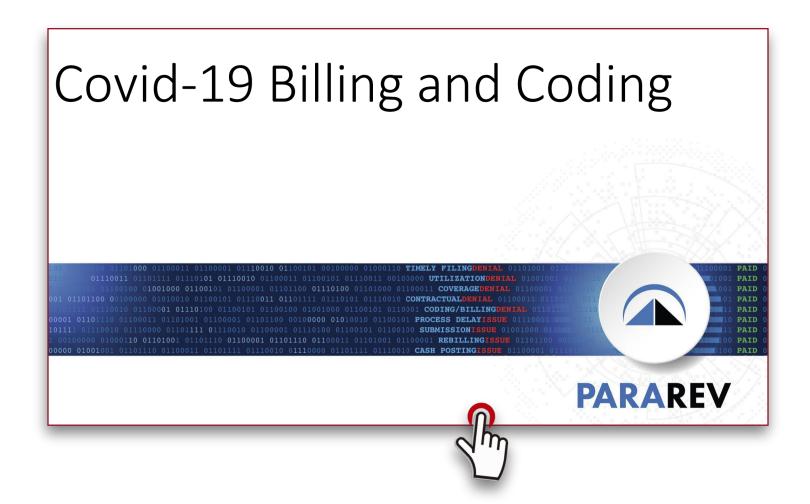
12636.2	Medicare contractors should not search their files to
	retroactively pay claims. However, contractors shall adjust claims brought to their attention.

#### **NEW PRESENTATION: COVID-19 BILLING AND CODING DETAILED GUIDANCE**

ParaRev has created a new, informative presention filled with details on the proper and effective COVID-19 billing and coding.

And, now it's here for you to download and review.

Then contact one of our Account Executives for more information and details on how ParaRev can help.





#### RARC CODES RELATED TO THE NO SURPRISES ACT

Under HIPAA, all payers, including Medicare, are required to use claims adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) approved by X12 recognized code set maintainers, instead of proprietary codes to explain any adjustment in the claim payment.

RARCs are used to provide additional explanation for an adjustment already described by a CARC or to convey information about remittance processing. The following RARCs related to the No Surprises Act have been approved by the RARC Committee and were effective as of March 1, 2022

The No St	urprises Act Provisions that Apply to the Claim
RARC#	RARC Text
N864	Alert: This claim is subject to the No Surprises Act provisions that apply to emergency services.
N865	Alert: This claim is subject to the No Surprises Act provisions that apply to nonemergency services furnished by nonparticipating providers during a patient visit to a participating facility.
N866	Alert: This claim is subject to the No Surprises Act provisions that apply to services furnished by nonparticipating providers of air ambulance services.
How Cost	Sharing Was Calculated under the No Surprises Act
RARC#	RARC Text
N862	Alert: Member cost share is in compliance with the No Surprises Act, and is calculated using the lesser of the QPA or billed charge.
N867	Alert: Cost sharing was calculated based on a specified state law, in accordance with the No Surprises Act.
N868	Alert: Cost sharing was calculated based on an All-Payer Model Agreement, in accordance with the No Surprises Act.
N869	Alert: Cost sharing was calculated based on the qualifying payment amount, in accordance with the No Surprises Act.
N870	Alert: In accordance with the No Surprises Act, cost sharing was based on the billed amount because the billed amount was lower than the qualifying payment amount.
Initial Pay	ment Amount
RARC#	RARC Text
N871	Alert: This initial payment was calculated based on a specified state law, in accordance with the No Surprises Act.
N877	Alert: This initial payment is provided in accordance with the No Surprises Act. The provider or facility may initiate open negotiation if they desire to negotiate a higher out-of-network rate.
Final Payı	ment Amount
RARC#	RARC Text
N863	Alert: This claim is subject to the No Surprises Act (NSA). The amount paid is the final out-of-network rate and was calculated based on an All Payer Model Agreement, in accordance with the NSA.

#### RARC CODES RELATED TO THE NO SURPRISES ACT

N872	Alert: This final payment was calculated based on a specified state law, in accordance with the No Surprises Act.
N873	Alert: This final payment was calculated based on an All-Payer Model Agreement, in accordance with the No Surprises Act.
N874	Alert: This final payment was determined through open negotiation, in accordance with the No Surprises Act.
N875	Alert: This final payment equals the amount selected as the out-ofnetwork rate by a Federal Independent Dispute Resolution Entity, in accordance with the No Surprises Act.
Denial of	Payment
RARC#	RARC Text
N876	Alert: This item or service is covered under the plan. This is a notice of denial of payment provided in accordance with the No Surprises Act. The provider or facility may initiate open negotiation if they desire to negotiate a higher out-of-network rate than the amount paid by the patient in cost sharing.
Notice ar	nd Consent
RARC#	RARC Text
N878	Alert: The provider or facility specified that notice was provided and consent to balance bill obtained, but notice and consent was not provided and obtained in a manner consistent with applicable Federal law. Thus, cost sharing and the total amount paid have been calculated based on the requirements under the No Surprises Act, and balance billing is prohibited.
N879	Alert: The notice and consent to balance bill, and to be charged out-ofnetwork cost sharing, that was obtained from the patient with regard to the billed services, is not permitted for these services. Thus, cost sharing and the total amount paid have been calculated based on the requirements under the No Surprises Act, and balance billing is prohibited.
Miscellar	
RARC#	RARC Text
N830	Alert: The charge[s] for this service was processed in accordance with Federal/ State, Balance Billing/ No Surprise Billing regulations. As such, any amount identified with OA, CO, or PI cannot be collected from the member and may be considered provider liability or be billable to a subsequent payer. Any amount the provider collected over the identified PR amount must be refunded to the patient within applicable Federal/State timeframes. Payment amounts are eligible for dispute pursuant to any Federal/State documented appeal/grievance process(es).
N859	Alert: The Federal No Surprise Billing Act was applied to the processing of this claim.  Payment amounts are eligible for dispute pursuant to any Federal documented appeal/ grievance/ dispute resolution process(es).



#### FDA PAUSES CERTAIN COVID-19 MONOCLONAL THERAPIES

On April 5, 2022, the FDA updated the Emergency Use Authorization (EUA) to add Sotrovimab to the list of monoclonal antibody therapies paused for the treatment of COVID-19. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-useauthorization?utm\_campaign=FDA+Roundup%3A+April+5%2C+2022&utm\_medium =email&utm\_sou\_rce=govdelivery

## FDA updates Sotrovimab emergency use authorization

On January 24, 2022, the FDA revised the EUA for the Regeneron drug combination (casirivamab and imdevimab and the Eli Lilly drug combination (bamlanivimab and etesevimab). Because studies indicate these therapies are less effective in targeting the most prevalent COVID-19 variant, Omicron, the FDA limits the use of these monoclonals to patients infected with or exposed to COVID-19 variants receptive to these therapies.

https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimabetesevimab/Pages/default.aspx



### Public Health Emergency

Public Health and Medical Emergency Support for a Nation Prepared

PHE Home > Emergency > Events > 2019 Novel Coronavirus > ASPR's Portfolio of COVID-19 MCMs > bamlanivimab-etesevimab

#### Bamlanivimab/etesevimab

#### **Important Updates**

January 24, 2022: The FDA today updated the Emergency Use Authorization (EUA) fact sheets for two COVID-19 monoclonal antibody treatments: Lilly's bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV). FDA now says these two treatments are not currently authorized for use anywhere in the U.S., due to the prevalence of Omicron. FDA is encouraging healthcare providers to choose authorized treatment options with activity against circulating variants in their state, territory, or U.S. jurisdiction. Learn More >>



#### FDA PAUSES CERTAIN COVID-19 MONOCLONAL THERAPIES

Other FDA-approved therapies to treat patients with mild to moderate COVID-19 and are at high risk for hospitalization, severe disease, or death include:

- ► Infusions of Veklury (remdesivir) or bebtelovimab (both deemed effective against Omicron, which currently accounts for most COVID-19 infections in the United States.)
- Convalescent plasma (blood product transfusion)
- Antiviral oral medications Pfizer's Paxlovid (12 and older) and Merck's molnupiravir (18 and older)

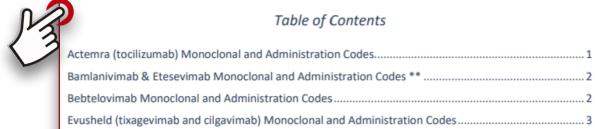
**ParaRev** offers papers with detailed information at the following links: https://apps.parahcfs.com/para/Documents/EUA%20Issued%20for%20Antiviral%20Pills%20to%20Treat%20Covid.pdf

#### FDA Issues EUAs for Antiviral Pills to Treat Covid-19 at Home

On December 23, 2021, the Food and Drug Administration approved emergency use authorization (EUA) for Merck **Molnupiravir** pill for the treatment of Covid-19. The drug is cleared for patients 18 and older who test positive for Covid-19 and are at high risk of hospitalization or death. The treatment course includes four capsules every 12 hours for 5 days beginning as soon as the patient tests positive for Covid-19 and within five days of exhibiting symptoms.

https://apps.para-hcfs.com/para/Documents/COVID19%20Monoclonal%20Product%20and %20Administration%20Codes.pdf

#### **COVID-19 Monoclonal Product and Administration Codes**



CMS Covid-19 Vaccines and Monoclonal Antibody website: .....

CMS ISSUED A DOCUMENT REPORTING HCPCS CODING DECISIONS IN RESPONSE TO MANUFACTURER APPLICATIONS FOR NEW CODE ASSIGNMENT EACH QUARTER. THE FIRST QUARTER 2022 REPORT INCLUDES A NUMBER OF HCPCS FOR DRUGS AND BIOLOGICS, WHICH WILL BECOME EFFECTIVE JULY 1, 2022.

https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-1-2022-drugs-and-biologicals.pdf

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations

First Quarter, 2022 HCPCS Coding Cycle

A summary of the decisions is provided below in three sections – Medicine, Wound Care, and Radiopharmaceuticals.

#### Medicine

- ► **FYARRO**® -- which is currently reported with temporary HCPCS C9091, will be assigned HCPCS J9331 "Injection, sirolimus protein-bound particles, 1 mg." This drug is used to treat advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)
- ▶ **LEQVIO**® -- will be assigned HCPCS J1306 Injection, inclisiran, 1 mg. LEQVIO® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH)] or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

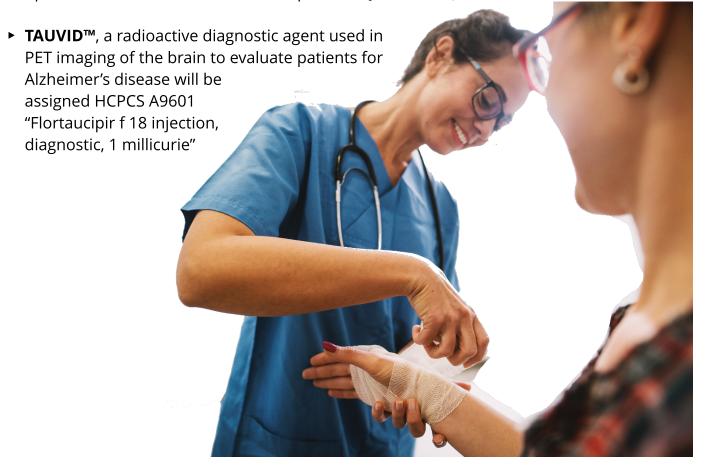
- ► **SUSVIMO**<sup>™</sup>, an intraocular injection used to treat patients with age-related macular degeneration, will be assigned two HCPCS, one for the injection, and another for the implant. The recommended dose of SUSVIMO<sup>™</sup> is 2 mg (0.02 mL of 100mg/mL solution) continuously delivered via the SUSVIMO<sup>™</sup> ocular implant with refills administered every 24 weeks (approximately 6 months). The new HCPCS are: J2779 "Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg", and C9093 "Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg"
- ▶ **RYPLAZIM**®, which is indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplaminogenemia), will be assigned HCPCS J2998 "Injection, plasminogen, human-tvmh, 1 mg". Apparently this medication is considered a self-administered drug unless delivered by IV infusion; modifier JA "administered intravenously" must be appended when delivered by IV infusion to qualify for Medicare coverage
- ➤ XIPERE™ (Triamcinolone acetonide) is a synthetic glucocorticoid (glucocorticoids are often referred to as corticosteroids) with immunosuppressive and anti-inflammatory activity. The newly assigned HCPCS will be J3299 "Injection, triamcinolone acetonide (xipere), 1 mg"
- ► VYVGART™, is indicated for the treatment of adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor antibody positive. This drug may have been reported with miscellaneous/unclassified codes previously. The newly assigned HCPCS is J9332 "Injection, efgartigomod alfa-fcab, 2 mg"
- **cutaquig®**, which prevents infections of a wide variety of bacterial and viral agents in immunodeficient adults by temporarily restoring IgG levels in circulating plasma, will be assigned HCPCS J1551, "Injection, immune globulin (cutaquig), 100 mg"
- ► **TEZSPIRE™** is an add-on maintenance treatment of adult and pediatric patients aged 12 years and older with uncontrolled asthma while receiving treatment with medium- or high-dose inhaled corticosteroids (ICS) plus at least one additional controller medication with or without oral corticosteroids (OCS). The newly assigned HCPCS will be J2356, "Injection, tezepelumab-ekko, 1 mg"
- ► **APRETUDE**, which reduces the risk of sexually acquired HIV-1 infection, is an intramuscular injection kit that must be administered by a healthcare provider. The new HCPCS assigned by CMS will be J0739, "Injection, cabotegravir, 1 mg".

#### **Skin Substitutes and Wound Care Products**

- ► Celera<sup>™</sup> Dual Membrane and Celera<sup>™</sup> Dual Layer skin substitutes will be assigned new HCPCS Q4259 "Celera dual layer or celera dual membrane, per square centimeter." Previously, this product may have been reported with Q4100 "Skin Substitute, Not Otherwise Specified."
- ► **Signature APatch**, a wound protection barrier/cover will be assigned HCPCS Q4260 "Signature APatch, per square centimeter"
- ► **TAG**, a wound protection barrier/cover, will be assigned HCPCS Q4261, "Tag, per square centimeter".

#### Radiopharmaceuticals

▶ Illucix®, a radioactive prostate cancer PET imaging product, will be assigned HCPCS A9596 "Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie". Providers using this agent in PET scans are hopeful that the new HCPCS will offer better reimbursement for this expensive radiopharmaceutical. (The payment status will be announced with the next update to the OPPS Addendum B, expected in June, 2022.)



The CMS document also listed the applications for which it declined to assign a HCPCS for various reasons:

- ► **RETHYMIC®** used only in inpatient settings
- ► **Lidocidex**<sup>™</sup> a compounded drug (CMS does not issue HCPCS for compounded drugs)
- ► Cocoon Dual-Layer and Single-Layer Membranes due to differences in the HCPCS application and information submitted to the FDA
- ► PalinGen® Dual Layer Membranes are dehydrated, human allografts derived from the placenta due to differences in the HCPCS application and information submitted to the FDA
- ► **Esano AAA**, a triple layer decellularized, dehydrated human amniotic membrane allograft for wound care, due to differences in the HCPCS application and information submitted to the FDA
- ► **Sanopellis** are dehydrated, human allografts derived from the placenta for wound care, due to differences in the HCPCS application and information submitted to the FDA
- ▶ 3L Biovance® Tri-Layer and 3L Biovance®, a human amniotic membrane allograft for wound care, due to differences in the HCPCS application and information submitted to the FDA
- ▶ **Pemetrexed**, a single agent in the treatment of locally advanced and metastatic non-squamous non-small cell lung cancer, due to an incomplete HCPCS application.

#### CMS ADDS HCPCS FOR NEW PNEUMOCOCCAL, HEP B VACCINES

The MLN article for the pneumococcal vaccines is available at the following link:

https://www.cms.gov/files/document/mm12439-claims-processing-instructions-new-pneumococcal-15-valent-conjugate-vaccine-code-90671-and.pdf



The transmittal which announced the hepatitis B vaccine is available at the following link (no MLN yet.)

https://www.cms.gov/files/document/r11322cp.pdf

Number	Requirement
12686.8	Contractors shall hold claims for Hepatitis B code 90759 with DOS January 11, 2022 thru July 4, 2022, received prior to July 5, 2022. Contractors shall release held claims within 10 business days of the implementation.

**UPDATED** 3/15/22

## COMPREHENSIVE COVID-19 Guide





Click
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on this
page to be
taken to
the full
online
document.



TUESDAY WEBINARS: COMPLYING WITH THE NO SURPRISES ACT

### TIME IS RUNNING OUT.

PARA experts are providing a free webinar each Tuesday designed to help hospitals understand and comply with the requirements under the No Surprises Act.



1st and 3rd Tuesdays 11:30 am PST



Sign Up By Clicking <u>HERE</u>,
Or Scan The QR Code



PARA invites you to check out the <u>mlnconnects</u> 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, May 5, 2022

#### News

- COVID-19: Patients Can Get Free Over-the-Counter Tests from Participating Providers
- Immunosuppressive Drug Coverage for Kidney Transplant Patients: Proposed Rule
- <u>Diabetic Testing Supplies Ordering Guide</u>
- Inpatient Rehabilitation Facilities: Care Compare March Preview Reports Reissued & April Refresh
- Long-Term Care Hospitals: Care Compare March Preview Reports Reissued & April Refresh
- Skilled Nursing Facilities: Care Compare April Preview Reports & Refresh
- May is National Asian American, Native Hawaiian, & Pacific Islander Heritage Month

#### Claims, Pricers, & Codes

- Outpatient Claims with Reason Code W7120 Returned in Error
- Eliminating Certificates of Medical Necessity & Durable Medical Equipment Information Forms January 1, 2023

#### **Events**

CMS National Provider Enrollment Conference in Boston — August 16 & 17

#### **MLN Matters®Articles**

- <u>Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 15 Ambulance</u>
- <u>Update to the Payment for Grandfathered Tribal Federally Qualified Health Centers (FQHCs) for Calendar Year (CY) 2022</u>
- Section 127 of the Consolidated Appropriations Act: Graduate Medical Education (GME) Payment for Rural Track Programs (RTPs)
- New Waived Tests Revised
- <u>Update to Chapter 7, "Home Health Services," of the Medicare Benefit Policy Manual (Pub 100-02) —</u> Revised

#### **Publications**

- Medical Record Maintenance & Access Requirements Revised
- Medicare Mental Health Revised

PARA Weekly eJournal: May 11, 2022

## RANSMITTALS

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There were SEVEN new or revised Transmittal released this week.

To go to the full Transmittal document simply click on the screen shot or the link.



#### **TRANSMITTAL R11398CP**

CMS Manual System	Department of Health & Human Services (DHHS)	
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)	
Transmittal 11398	Date: May 4, 2022	
	Change Request 12737	

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: The Purpose of this Change Request (CR) is a Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

#### EFFECTIVE DATE: July 1, 2022

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

IMPLEMENTATION DATE: July 5, 2022

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

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

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

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

#### **TRANSMITTAL R11397CP**

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11397	Date: May 4, 2022
	Change Request 12730

SUBJECT: Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2022

I. SUMMARY OF CHANGES: The Purpose of this Change Request (CR) is an annual update of Indian Health Services (IHS) payment rates for calendar year 2022. The attached Recurring Update Notification applies to Medicare Claims Processing Manual, IOM 100-04, Chapter 19, Section 100.3.4, 100.4.2, and 100.5.

#### EFFECTIVE DATE: January 1, 2022

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

IMPLEMENTATION DATE: August 4, 2022

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

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R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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#### III. FUNDING:

#### For Medicare Administrative Contractors (MACs):

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#### IV. ATTACHMENTS:

#### Recurring Update Notification

#### **TRANSMITTAL R11399BP**

CMS Manual System	Department of Health & Human Services (DHHS)	
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)	
Transmittal 11399	Date: May 4, 2022	
	Change Request 12723	

SUBJECT: Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to inform contractors that effective July 1, 2021, CMS updated the Medicare coverage requirements to align with the Advisory Committee on Immunization Practices (ACIP) recommendations for Coverage of Pneumococcal Vaccinations. This CR makes the necessary updates to the Benefit Policy Manual.

#### EFFECTIVE DATE: July 1, 2021

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

IMPLEMENTATION DATE: June 6, 2022

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

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

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

ı	R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
	R	15/50.4.4.2/Immunizations

#### III. FUNDING:

#### For Medicare Administrative Contractors (MACs):

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

#### IV. ATTACHMENTS:

Business Requirements Manual Instruction

#### **TRANSMITTAL R11396CP**

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11396	Date: May 4, 2022
	Change Request 12715

SUBJECT: Update to Chapters 3, 4, 27 and 37 of Publication (Pub.) 100-04 Medicare Claims Processing Manual to Remove Reference to the Term "OSCAR"

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the Internet Only Manual (IOM) Pub. 100-04, by removing reference to the term OSCAR for Chapters 3 (Sections 60, 150.3, 190.3, 190.17.1 and Addendum A), Chapter 4 (Section 50.1), Chapter 27 (Section 80.4), and Chapter 37 (Section 1.4).

#### EFFECTIVE DATE: October 1, 2022

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

IMPLEMENTATION DATE: October 3, 2022

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/60/Swing-Bed Services
R	3/150.3/Affected Medicare Providers
R	3/190.3/Affected Medicare Providers
R	3/190.17.1/Inputs/Outputs to PRICER
R	3/Addendum A - Provider Specific File
R	4/50.1/Outpatient Provider Specific File
R	27/80.4/Consolidated Claims Crossover Process
R	37/1.4/Use of Legacy Provider Numbers After National Provider Identifiers (NPIs) Are Fully Implemented

#### 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

#### TRANSMITTAL R11401CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-01 Medicare General Information, Eligibility, and Entitlement	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11395	Date: May 4, 2022
	Change Request 12714

SUBJECT: Updated Instructions for the Change Request Implementation Report (CRIR) and Technical Direction Letter (TDL) Compliance Report (TCR)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide updated instructions about reporting delayed Medicare Learning Network® (MLN) articles on the CRIR.

EFFECTIVE DATE: May 31, 2022 - Begin with Quarter 2 report in 2022

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

IMPLEMENTATION DATE: May 31, 2022 - Begin with Quarter 2 report in 2022

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

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R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	7/50 - Contractor Implementation of Change Requests and Compliance with Technical Direction Letters

#### III. FUNDING:

#### For Medicare Administrative Contractors (MACs):

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#### IV. ATTACHMENTS:

Business Requirements Manual Instruction

#### TRANSMITTAL R114000TN

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11401	Date: May 4, 2022
	Change Request 12741

SUBJECT: Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)

I. SUMMARY OF CHANGES: The purpose for this Change Request (CR) is to update the list of outlier services under the End Stage Renal Disease Prospective Payment System.

#### EFFECTIVE DATE: July 1, 2022

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

IMPLEMENTATION DATE: July 5, 2022

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

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

#### III. FUNDING:

#### For Medicare Administrative Contractors (MACs):

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#### IV. ATTACHMENTS:

#### Recurring Update Notification

#### **TRANSMITTAL R113740TN**

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11400	Date: May 4, 2022
	Change Request 12705

SUBJECT: International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--October 2022 Update

I. SUMMARY OF CHANGES: This Change Request (CR) constitutes a maintenance update of ICD-10 conversions and other coding updates specific to NCDs. These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received.

Previous NCD coding changes appear in ICD-10 quarterly updates that can be found at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html, along with other CRs implementing new policy NCDs. Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent quarterly releases and individual CRs as appropriate. No policy-related changes are included with the ICD-10 quarterly updates. Any policy-related changes to NCDs continue to be implemented via the current, longstanding NCD process.

EFFECTIVE DATE: October 1, 2022 - Or as indicated in individual business requirements \*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: October 3, 2022

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

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

#### III. FUNDING:

#### For Medicare Administrative Contractors (MACs):

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4

There were FOUR new or revised MedLearn released this week.

To go to the full Transmittal document simply click on the screen shot or the link.





### Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM12737 Related Change Request (CR) Number: 12737

Related CR Release Date: May 4, 2022 Effective Date: July 1, 2022

Related CR Transmittal Number: R11398CP Implementation Date: July 5, 2022

#### Provider Types Affected

This MLN Matters Article is for laboratory physicians, suppliers, and other providers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

#### Provider Action Needed

Make sure your billing staff knows about these changes:

- Where to find updates pertaining to Advanced Diagnostic Laboratory Tests (ADLTs)
- Delays in the next CLFS data reporting period for clinical diagnostic laboratory tests
- New codes, effective July 1, 2022

#### Background

CR 12737 provides instructions for the quarterly update of the CLFS.

#### **ADLTs**

Visit the ADLT page for more information regarding appropriate tests.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests (CDLTs) – DELAYED

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (S. 610) delayed the reporting requirement and the application of the 15% phase-in reduction.







### Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2

MLN Matters Number: MM12723 Related Change Request (CR) Number: 12723

Related CR Release Date: May 4, 2022 Effective Date: July 1, 2021

Related CR Transmittal Number: R11399BP Implementation Date: June 6, 2022

#### Provider Types Affected

This MLN Matters Article is for physicians, suppliers, and other providers billing Medicare Administrative Contractors (MACs) for vaccine services they provide to Medicare patients.

#### Provider Action Needed

Make sure your billing staff knows about these changes to the Benefit Policy Manual:

- CMS updated the Medicare coverage for pneumococcal vaccinations to align with the Advisory Committee on Immunization Practices (ACIP) recommendations
- . The ACIP recommendations vary based on patient age and risk factors

#### Background

Section 1861(s)(10)(A) of the Social Security Act and regulations at 42 CFR 410.57 authorize Medicare coverage under Medicare Part B for pneumococcal vaccine and its administration.

On October 20, 2021, the ACIP recommended 15-valent pneumococcal conjugate vaccine (PCV15) or 20-valent (PCV20) for PCV-naïve adults who are either age 65 years or older or aged 19–64 years with certain underlying conditions or other risk factors. When you give PCV15, you should follow it with a dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23), typically 1 year or more later.

Effective July 1, 2021, we updated the Medicare coverage requirements to align with the ACIP recommendations.

Adults aged 19–64 years with certain underlying medical conditions or other risk factors who haven't previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When you give PCV15, you should follow it with a dose of PPSV23.







#### Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)

MLN Matters Number: MM12741 Related Change Request (CR) Number: 12741

Related CR Release Date: May 4, 2022 Effective Date: July 1, 2022

Related CR Transmittal Number: R11401CP Implementation Date: July 5, 2022

#### **Provider Types Affected**

This MLN Matters Article is for ESRD facilities billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

#### **Provider Action Needed**

Make sure your billing staff knows about these CMS changes:

- Revised list of outlier services to include 27 National Drug Codes (NDCs), effective January 1, 2022
- Updated mean unit cost for renal dialysis drugs that are oral equivalents to injectable drugs, effective July 1, 2022
- Revised mean dispensing fee for NDCs qualifying for outlier to \$0.57 per NDC per month, effective July 1, 2022

#### Background

The ESRD PPS recognizes high-cost patients and CMS includes an outlier policy and the methodology for calculating outlier payments in <u>42 CFR 413.237</u>. The policy covers certain services and supplies that were or would've been separately billable under Medicare Part B (or Part D, as noted below) prior to January 1, 2011. These include:

- 1. Renal dialysis drugs and biological products
- 2. Renal dialysis laboratory tests
- Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products
- Renal dialysis drugs and biological products covered under Part D, including renal dialysis oral-only drugs
- Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in 42 CFR 413.236(a)(2)), that get the transitional add-on payment adjustment specified in 42 CFR 413.236 after the payment period has ended

CINTES FOR MEDICARE & MEDICARE SERVICE



Page 1 of 3



#### International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)--October 2022

MLN Matters Number: MM12705 Related Change Request (CR) Number: 12705

Related CR Release Date: May 4, 2022 Effective Date: October 1, 2022

Related CR Transmittal Number: R114000TN Implementation Date: October 3, 2022

#### **Provider Types Affected**

This MLN Matters Article is for physicians, providers and suppliers billing MACs for services they provide to Medicare patients.

#### Provider Action Needed

Make sure your staff knows about:

- Newly available codes
- Separate NCD coding revisions
- Coding feedback

Previous NCD coding changes are available. Also, see the NCD spreadsheets for CR 12705.

CMS isn't including any policy changes in this ICD-10 quarterly update. We cover NCD policy changes using the current, longstanding NCD process.

#### Background

CR 12705 is a maintenance update of ICD-10 conversions and other coding updates specific to NCDs. These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback.

The translations from ICD-9 to ICD-10 aren't consistent one-to-one matches, nor are all ICD-10 codes appearing in a complete General Equivalence Mappings (GEMs) mapping guide or other mapping guides proper when reviewed against individual NCD policies.

Relevant NCD coding changes in CR 12705 include:



