September 29, 2021

PARA Weekly eJOURNAL

NEWS FOR HEALTHCARE DECISION MAKERS

The Q & A Edition

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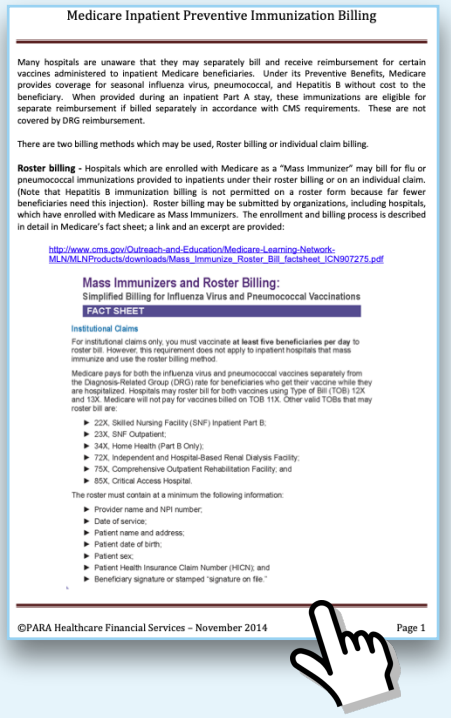
FAST LINKS

ADMIN CODE FOR 90672

Q. Is there an admin fee code for intranasal flu vaccine?



Medicare Inpatient Preventive Immunization Billing

Many hospitals are unaware that they may separately bill and receive reimbursement for certain vaccines administered to inpatient Medicare beneficiaries. Under its Preventive Benefits, Medicare provides coverage for seasonal influenza virus, pneumococcal, and Hepatitis B without cost to the beneficiary. When provided during an inpatient Part A stay, these immunizations are eligible for separate reimbursement if billed separately in accordance with CMS requirements. These are not covered by DRG reimbursement.

There are two billing methods which may be used, Roster billing or individual claim billing.

Roster billing - Hospitals which are enrolled with Medicare as a "Mass Immunizer" may bill for flu or pneumococcal immunizations provided to inpatients under their roster billing or on an individual claim. (Note that Hepatitis B immunization billing is not permitted on a roster form because far fewer beneficiaries need this injection). Roster billing may be submitted by organizations, including hospitals, which have enrolled with Medicare as Mass Immunizers. The enrollment and billing process is described in detail in Medicare's fact sheet; a link and an excerpt are provided:

http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Mass_Immunize_Roster_Bill_factsheet_ICN907275.pdf

Mass Immunizers and Roster Billing:
Simplified Billing for Influenza Virus and Pneumococcal Vaccinations
FACT SHEET

Institutional Claims

For institutional claims only, you must vaccinate **at least five beneficiaries per day** to roster bill. However, this requirement does not apply to inpatient hospitals that mass immunize and use the roster billing method.

Medicare pays for both the influenza virus and pneumococcal vaccines separately from the Diagnosis-Related Group (DRG) rate for beneficiaries who get their vaccine while they are hospitalized. Hospitals may roster bill for both vaccines using Type of Bill (TOB) 12X and 13X. Medicare will not pay for vaccines billed on TOB 11X. Other valid TOBs that may roster bill are:

- 22X, Skilled Nursing Facility (SNF) Inpatient Part B;
- 23X, SNF Outpatient;
- 34X, Home Health (Part B Only);
- 72X, Independent and Hospital-Based Renal Dialysis Facility;
- 75X, Comprehensive Outpatient Rehabilitation Facility; and
- 85X, Critical Access Hospital.

The roster must contain at a minimum the following information:

- Provider name and NPI number;
- Date of service;
- Patient name and address;
- Patient date of birth;
- Patient sex;
- Patient Health Insurance Claim Number (HICN); and
- Beneficiary signature or stamped "signature on file."

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A. **Answer:** HCPCS 90672, INFLUENZA VIRUS VACCINE, QUADRIVALENT, LIVE (LAIV4), FOR INTRANASAL USE is labeled for use for the immunization of individuals 2 to 49 years of age, so the administration codes are dependent upon age:

- 90460 is used for administration through 18 years of age
- 90473 is used for administration to those over 18 years of age
- G0008 is used for Medicare beneficiaries
- When administering the intranasal vaccine with any other vaccines, report the influenza vaccine with 90461 or 90474 in addition to the primary code for the other vaccine administration.

Select | Charge Quote | Charge Process | Claim/RA | Contracts | Pricing Data | Pricing | Rx/Supplies | PTT | Tasks | PARA

Report Selection | 2021 Hospital Based HCPCS/CPT® Codes Quarter: Q3

2021 HCPCS Codes - ALL Quarter: Q3

Codes and/or Descriptions: **G0008, 90471, 90472, 90473, 90474, 90460, 90461** for selected Provider:
Results returned(below): 7
AWI: **1**, DME: **CO**, Clinical Lab Fee Schedule: **CO**, Physician Fee Schedule:**CO STATEWIDE**

Export to PDF | Physician Supervision Definitions | Export to Excel

Current Descriptor	Fee Schedule		Initial APC	Payment	
90460 - immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered **B - Non-allowed item or service for OPPS**	GB (Physician Facility): GB (Physician Non-Facility):	$17.53 $17.53			
90461 - immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered (list separately in addition to code for primary procedure) **B - Non-allowed item or service for OPPS**	GB (Physician Facility): GB (Physician Non-Facility):	$13.18 $13.18			
90471 - immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid) **Q1 - STV-Packaged codes**	GB (Physician Facility): GB (Physician Non-Facility):	$17.53 $17.53	5692 - Level 2 Drug Administration	Weight: Payment: National Co-pay: Minimum Co-pay:	0.7485 $ 61.97 $0.00 $12.40
90472 - immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (list separately in addition to code for primary procedure) **N - Items and Services packaged into APC rates**	GB (Physician Facility): GB (Physician Non-Facility):	$13.18 $13.18			
90473 - immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid) **Q1 - STV-Packaged codes**	GB (Physician Facility): GB (Physician Non-Facility):	$17.53 $17.53	5692 - Level 2 Drug Administration	Weight: Payment: National Co-pay: Minimum Co-pay:	0.7485 $ 61.97 $0.00 $12.40
90474 - immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid) (list separately in addition to code for primary procedure) **N - Items and Services packaged into APC rates**	GB (Physician Facility): GB (Physician Non-Facility):	$13.18 $13.18			
G0008 - administration of influenza virus vaccine **S - Procedure or service, not discounted when multiple** **Berenson-Eggers Type of Service:** O1G - INFLUENZA IMMUNIZATION			5691 - Level 1 Drug Administration	Weight: Payment: National Co-pay: Minimum Co-pay:	0.4831 $ 40.00 $0.00 $8.00

ADMIN CODE FOR 90672

Attached is **PARA's** paper about Medicare inpatient immunization billing that indicates HCPCS 90672 is billed with G0008.

See the excerpt below:

2015 Flu Vaccine Codes – bill with G0008 Administration Code (Medicare)

HCPCS/CPT®	2014-2015 Payment Allowance
90654 - INFLUENZA VIRUS VACCINE, SPLIT VIRUS, PRESERVATIVE-FREE, FOR INTRADERMAL USE	18.918
90655 - INFLUENZA VIRUS VACCINE, TRIVALENT, SPLIT VIRUS, PRESERVATIVE FREE, WHEN ADMINISTERED TO CHILDREN 6-35 MONTHS OF AGE, FOR INTRAMUSCULAR USE	(pending)
90656 - INFLUENZA VIRUS VACCINE, TRIVALENT, SPLIT VIRUS, PRESERVATIVE FREE, WHEN ADMINISTERED TO INDIVIDUALS 3 YEARS AND OLDER, FOR INTRAMUSCULAR USE	14.096
90657 - INFLUENZA VIRUS VACCINE, TRIVALENT, SPLIT VIRUS, WHEN ADMINISTERED TO CHILDREN 6-35 MONTHS OF AGE, FOR INTRAMUSCULAR USE	6.022
90660 - INFLUENZA VIRUS VACCINE, TRIVALENT, LIVE, FOR INTRANASAL USE	(not listed)
90661 - INFLUENZA VIRUS VACCINE, DERIVED FROM CELL CULTURES, SUBUNIT, PRESERVATIVE AND ANTIBIOTIC FREE, FOR INTRAMUSCULAR USE	21.666
90662 - INFLUENZA VIRUS VACCINE, SPLIT VIRUS, PRESERVATIVE FREE, ENHANCED IMMUNOGENICITY VIA INCREASED ANTIGEN CONTENT, FOR INTRAMUSCULAR USE	33.374
90672 - INFLUENZA VIRUS VACCINE, QUADRIVALENT, LIVE, FOR INTRANASAL USE	25.736
90673 - INFLUENZA VIRUS VACCINE, TRIVALENT, DERIVED FROM RECOMBINANT DNA (RIV3),	37.193

IMPLANTABLE CARDIAC DEVICE MONITORING

Q. We have a question about cardiac device monitoring services. The visits are in-person at the cardiology office with a device representative (e.g. Medtronic/Boston Scientific). The progress note is created only by the cardiac nurse and is not signed by the doctor.

The doctor is in the building, but is not seeing the patient in person. The doctor is reviewing the device report prepared by the device rep and charging professional fees for the interpretation of the report. The concern of our cardiology coder is that the doctor is only signing the report prepared by the device rep and not preparing their own separate report of the interpretation.

There are also no interpretation notes written by the physician on the device rep report, only a signature by the physician. Should we have the doctor prepare a separate report of the interpretation, or is the signature alone sufficient documentation for the professional charges? Should the doctor be adding their own comments stating that they have reviewed the device report report and agree with the findings?

A. **Answer:** The service is billable when the physician personally reviews and analyzes the data, generates a report, and signs it, as stated in this LCD.

Article - Surveillance of Implantable or Wearable Cardioverter Defibrillators (ICDs): Office, Hospital, Web, or Non-Web Based – Medical Policy Article (A53018) (cms.gov)

Surveillance of Implantable or Wearable Cardioverter Defibrillators (ICDs): Office, Hospital, Web, or Non-Web Based – Medical Policy Article

A53018 Expand All | Collapse All

For physician billing, each interrogation, with/without reprogramming must be provided under **direct** supervision of the physician in a hospital or other facility setting and also direct supervision in the office or private clinic setting. The physician must personally review and analyze the data, generate a report **and sign it**.

For hospital billing, the technical component of these tests, each interrogation, with/without reprogramming must be provided under direct supervision of a qualified physician in the hospital. A qualified physician must personally review and analyze the data, generate a report **and sign it if a professional component (-26) is billed. If performed in the hospital, a physician cannot bill for the technical component.**

Since the device representative is generating the report, the physician documentation would best support the professional fee if the progress note indicated the physician reviewed and analyzed the data. That note can look something like this:

"I, John Smith, MD, directly supervised the interrogation services described in this report. I personally reviewed and analyzed the data in this report and concur with the results."

The Medicare Benefit Policy Manual, Chapter 5, Section 80, defines "direct supervision" as present in the office suite and immediately available to assist.

Medicare Benefit Policy Manual (cms.gov)

80 - Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests
(Rev. 251, Issued: 11-30-18, Effective: 01-01- 19, Implementation: 01-02-19)

This section describes the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is not a hospital inpatient. For hospital outpatient diagnostic services, the supervision levels assigned to each CPT or Level II HCPCS code in the Medicare Physician Fee Schedule Relative Value File that is updated quarterly, apply as described below. For more information, see Chapter 6 (Hospital Services Covered Under Part B), §20.4 (Outpatient Diagnostic Services).

Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare. The regulation defines these levels of physician supervision for diagnostic tests as follows:

General Supervision - means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

Direct Supervision - in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Personal Supervision - means a physician must be in attendance in the room during the performance of the procedure.

AMBULANCE BILLING: DEATH BEFORE TRANSPORT

Q. Is there was any billable code that would generate reimbursement, under Medicare guidelines, when the ambulance has been dispatched, but the patient is pronounced dead before transport?There are many runs where the paramedic(s) have conducted a code for 20 to 30 minutes, used expensive supplies and drugs, but no transport resulted because the patient was declared dead prior to transport.

A. **Answer:** The Medicare Claims Policy Manual and the Medicare Benefits Policy Manual both indicate that if the patient diesafterthe ambulance has been dispatched, butbeforetransport, the ambulance may be paid for the BLS response, without mileage.Report A0428 (AMBULANCE SERVICE, BASIC LIFE SUPPORT, NON-EMERGENCY TRANSPORT, (BLS)) with modifier QL (Patient pronounced dead after ambulance called).

Here's some detail from our 2020 Medicare claims database reporting payments on claims submitted by another hospital-owned ambulance service which reported the QL modifier:

Claim Headers For: - Count of all claims matching criteria: 2 - Date Range: 2020 Q1 through 2020 Q4

	PARA ID	Payment	Charges	Diag ICD10	Diag ICD10 Description	Diag ICD10 2	Diag ICD10 3	Diag ICD...	Dischar...	Codes	Status
1	20090051	$189.80	$1,559.00	I469	Cardiac arrest, cause unspecified				20200226	, QL	01
2	110413431	$193.67	$1,558.30	I469	Cardiac arrest, cause unspecified	I10	E039		20201028	, QL	01

Claim Details

	PARA ID	Rev Code	HCPCS	HCPCS Desc	Mod 1	Mod 2	Units	Payment	Charges
1	20090051	0540	A0425	GROUND MILEAGE, PER STATUTE MILE	QL	QN	0		$3.00
2	20090051	0540	A0428	AMBULANCE SERVICE, BASIC LIFE SUPPORT, NON-EMERGENCY TRANSPORT, (BLS)	QL	QN	1	$189.80	$1,556.00

Here's a link and an excerpt from the Medicare Claims Processing Manual which provides this instruction:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c15.pdf#

Medicare Claims Processing Manual, Chapter 15 - Ambulance

30.2 - Fiscal Intermediary Shared System (FISS) Guidelines

(Rev. 3076, Issued: 09-24-14, Effective: Upon Implementation of ICD-10 ASC X12: 01-01-

12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-16-14)

...

"For claims with dates of service on or after January 1, 2001, providers must report revenue code 540 and one of the following HCPCS codes for each ambulance trip provided during the billing period:

A0426; A0427; A0428; A0429; A0430; A0431; A0432; A0433; or A0434."Providers using an ALS vehicle to furnish a BLS level of service report HCPCS code, A0426 (ALS1) or A0427 (ALS1 emergency), and are paid accordingly. In addition, all providers report one of the following mileage HCPCS codes: A0380; A0390; A0435; or A0436. Since billing requirements do not allow for more than one HCPCS code to be reported for per revenue code line, providers must report revenue code 0540 (ambulance) on two

AMBULANCE BILLING: DEATH BEFORE TRANSPORT

separate and consecutive lines to accommodate both the Part B ambulance service and the mileage HCPCS codes for each ambulance trip provided during the billing period. Each loaded (e.g., a patient is onboard) 1-way ambulance trip must be reported with a unique pair of revenue code lines on the claim. Unloaded trips and mileage are NOT reported.

"However, in the case where the beneficiary was pronounced dead after the ambulance is called but before the ambulance arrives at the scene: Payment may be made for a BLS service if a ground vehicle is dispatched or at the fixed wing or rotary wing base rate, as applicable, if an air ambulance is dispatched. Neither mileage nor a rural adjustment would be paid. The blended rate amount will otherwise apply. Providers report theA0428 (BLS) HCPCS code. Providers report modifier QL(Patient pronounced dead after ambulance called) in "HCPCS/Rates" instead of the origin and destination modifier. In addition to the QL modifier, providers report modifier QM or QN.

The Medicare Benefits Policy Manual repeats that same instruction:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c10.pdf#

10.2.6 - Effect of Beneficiary Death on Medicare Payment for Ground Ambulance Transports

(Rev. 103; Issued: 02-20-09; Effective Date: 01-05-09; Implementation Date: 03-20-09)

Because the Medicare ambulance benefit is a transport benefit, if no transport of a Medicare beneficiary occurs, then there is no Medicare-covered service. In general, if the beneficiary dies before being transported, then no Medicare payment may be made. Thus, in a situation where the beneficiary dies, whether any payment under the Medicare ambulance benefit may be made depends on the time at which the beneficiary is pronounced dead by an individual authorized by the State to make such pronouncements.

The chart below shows the Medicare payment determination for various ground ambulance scenarios in which the beneficiary dies. In each case, the assumption is that the ambulance transport would have otherwise been medically necessary.

Ground Ambulance Scenarios: Beneficiary Death	
Time of Death Pronouncement	**Medicare Payment Determination**
Before dispatch.	None.
After dispatch, before beneficiary is loaded onboard ambulance (before or after arrival at the point-of-pickup).	The provider's/supplier's BLS base rate, no mileage or rural adjustment; use the QL modifier when submitting the claim.
After pickup, prior to or upon arrival at the receiving facility.	Medically necessary level of service furnished.

CARDIAC STRESS TEST WITH NP

Q. Can a nurse practitioner observe cardiac stress tests? If so, is this billable under the nurse practitioner. In some of the research we found that we may have to bill incident to under a supervising physician's NP?

A. **Answer:** The nurse practitioner (NP) may supervise the cardiac stress test if it is within the State scope of practice laws and under applicable State requirements for physician supervision or collaboration and bill for the supervision of the stress test with CPT® 93016. Attached is **PARA's** paper which includes the table and explanation below, as well an article from the American Heart Association -Supervision of Exercise Testing by Non-physicians– which has a table that summarizes guideline recommendation for non-physician supervision of exercise tests

The code set for stress test performance, supervision, and interpretation and report are as follows:

CPT/HCPCS	Type	Description
93015 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; WITH SUPERVISION, INTERPRETATION AND REPORT	Pro fee, non-hospital setting	All 3 components: Testing, supervision, and interp/report
93016 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; SUPERVISION ONLY, WITHOUT INTERPRETATION AND REPORT	Pro Fee (hospital or non-hospital setting)	Supervision only
93017 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; TRACING ONLY, WITHOUT INTERPRETATION AND REPORT	Facility Fee	Facility Fee-performance of test
93018 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; INTERPRETATION AND REPORT ONLY	Pro Fee (hospital or non-hospital setting	Interp/report only

Hospitals typically charge 93017 for conducting the stress test. The supervising physician charges 93016 on a pro fee claim, and the interpreting physician charges 93018. Note that APC reimbursement under OPPS is indicated for only 93017; the other codes are for professional fee reporting, not facility charges.

CARDIAC STRESS TEST WITH NP

An LCD concerning cardiac stress testing defines the provider qualifications as a provider who is capable of recognizing signs and symptoms of cardiac disease and can interpret the stress test findings.

[LCD - Cardiology Non-emergent Outpatient Stress Testing (L35083) (cms.gov)]

Provider Qualifications

Exercise testing must be supervised consistent with the CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80. The appropriately trained provider in exercise testing must be capable of recognizing signs and symptoms of cardiac disease and capable of interpreting the exercise test findings. Exercise testing in selected patients may be conducted by a healthcare professional that has training in a related health area, has appropriate training in the supervision of exercise stress tests, and is capable of performing cardio-pulmonary resuscitation.[3,50]

The Physician Fee Schedule lists the level of Physician Supervision of a Diagnostic Procedure as "02" and when opening the description, it defines "02" as "direct supervision."

2021 Physician Fee Schedule - Query: 93015 — Export Query Results to Excel

Schedule

Code - Description:	93015 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIO
Modifier:	« Select/toggle between Modifiers for this code
Locality:	CO STATEWIDE

Pricing Information

	Facility	Non Facility	OPPS Cap Facility	OPPS Cap Non Facility
Participating Amount:	73.57	73.57	N/A	N/A
Limiting Charge Amount:	80.38	80.38	N/A	N/A

Surgery Information (Show Descriptions)

Status Code	A
Multiple Surgery	
Bilateral Surgery	0
Assistant at Surgery	0
Team Surgeons	0
Co-Surgeons	0
Physician Supervision of Diagnostic Procedures	02

Relative Value Units

Non-Facility Practice Expense	1.26
Non-Facility NA Indicator	
Facility NA Indicator	NA
Facility Practice Expense	1.26
Total Non-Facility (Transitioned)	2.06
Total Non-Facility (Implemented)	2.06
Work	0.75
Malpractice	0.05

Physician Supervision of Diagnostic Procedures

02 - Procedure must be performed under the direct supervision of a physician.

CARDIAC STRESS TEST WITH NP

The Medicare Benefit Policy Manual, Chapter 5, Section 80, defines "direct supervision" as present in the office suite and immediately available to assist.

Medicare Benefit Policy Manual (cms.gov)

80 - Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests
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Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare. The regulation defines these levels of physician supervision for diagnostic tests as follows:

General Supervision - means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

Direct Supervision - in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Personal Supervision - means a physician must be in attendance in the room during the performance of the procedure.

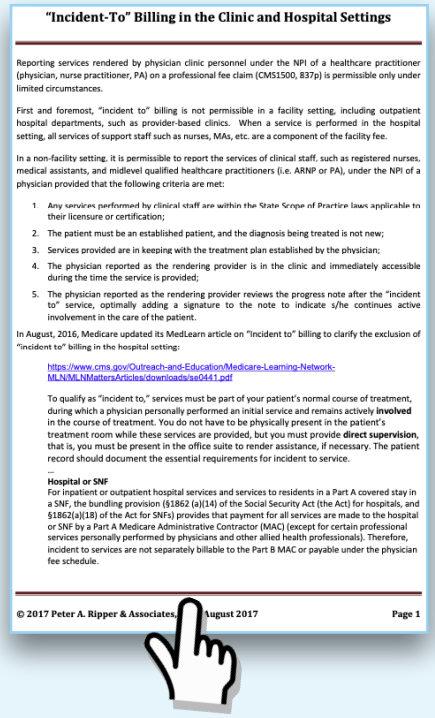
CARDIAC STRESS TEST WITH NP

While CMS has not defined the word "immediate" there is a transmittal which gives an example of a physician performing another procedure or service that cannot be interrupted.

R169BP.pdf (cms.gov)

Immediate availability requires the immediate physical presence of the supervisory physician or nonphysician practitioner. CMS has not specifically defined the word "immediate" in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician or nonphysician practitioner is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician or nonphysician practitioner may not be so physically distant on-campus from the location where hospital/CAH outpatient services are being furnished that he or she could not intervene right away. The hospital or supervisory practitioner must judge the supervisory practitioner's relative location to ensure that he or she is immediately available.

The "incident to" rule is not permissible in a facility setting, including outpatient hospital departments, such as provider-based clinics. Attached is **PARA's** paper which discusses "incident to" billing in the clinic and hospital settings.



"Incident-To" Billing in the Clinic and Hospital Settings

Reporting services rendered by physician clinic personnel under the NPI of a healthcare practitioner (physician, nurse practitioner, PA) on a professional fee claim (CMS1500, 837p) is permissible only under limited circumstances.

First and foremost, "incident to" billing is not permissible in a facility setting, including outpatient hospital departments, such as provider-based clinics. When a service is performed in the hospital setting, all services of support staff such as nurses, MAs, etc. are a component of the facility fee.

In a non-facility setting, it is permissible to report the services of clinical staff, such as registered nurses, medical assistants, and midlevel qualified healthcare practitioners (i.e. ARNP or PA), under the NPI of a physician provided that the following criteria are met:

1. Any services performed by clinical staff are within the State Scope of Practice laws applicable to their licensure or certification;
2. The patient must be an established patient, and the diagnosis being treated is not new;
3. Services provided are in keeping with the treatment plan established by the physician;
4. The physician reported as the rendering provider is in the clinic and immediately accessible during the time the service is provided;
5. The physician reported as the rendering provider reviews the progress note after the "incident to" service, optimally adding a signature to the note to indicate s/he continues active involvement in the care of the patient.

In August, 2016, Medicare updated its MedLearn article on "Incident to" billing to clarify the exclusion of "incident to" billing in the hospital setting:

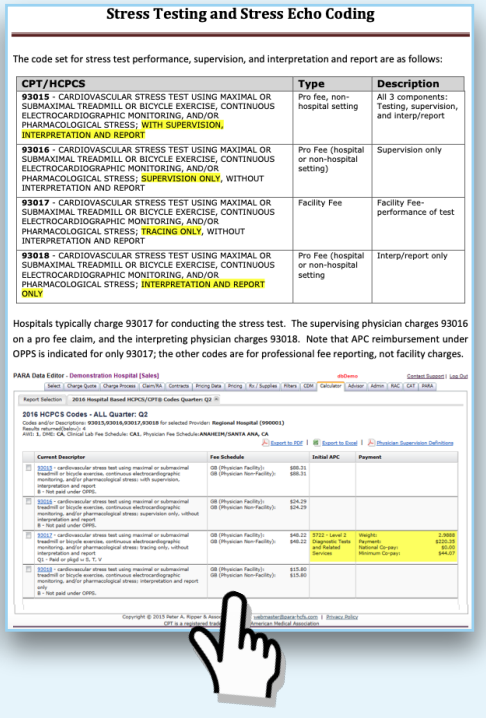
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf

To qualify as "incident to," services must be part of your patient's normal course of treatment, during which a physician personally performed an initial service and remains actively **involved** in the course of treatment. You do not have to be physically present in the patient's treatment room while these services are provided, but you must provide **direct supervision**, that is, you must be present in the office suite to render assistance, if necessary. The patient record should document the essential requirements for incident to service.

...

Hospital or SNF

For inpatient or outpatient hospital services and services to residents in a Part A covered stay in a SNF, the bundling provision (§1862 (a)(14) of the Social Security Act (the Act) for hospitals, and §1862(a)(18) of the Act for SNFs) provides that payment for all services are made to the hospital or SNF by a Part A Medicare Administrative Contractor (MAC) (except for certain professional services personally performed by physicians and other allied health professionals). Therefore, incident to services are not separately billable to the Part B MAC or payable under the physician fee schedule.



Stress Testing and Stress Echo Coding

The code set for stress test performance, supervision, and interpretation and report are as follows:

CPT/HCPCS	Type	Description
93015 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; WITH SUPERVISION, INTERPRETATION AND REPORT	Pro fee, non-hospital setting	All 3 components: Testing, supervision, and interp/report
93016 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; SUPERVISION ONLY, WITHOUT INTERPRETATION AND REPORT	Pro Fee (hospital or non-hospital setting)	Supervision only
93017 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; TRACING ONLY, WITHOUT INTERPRETATION AND REPORT	Facility Fee	Facility Fee-performance of test
93018 - CARDIOVASCULAR STRESS TEST USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/OR PHARMACOLOGICAL STRESS; INTERPRETATION AND REPORT ONLY	Pro Fee (hospital or non-hospital setting	Interp/report only

Hospitals typically charge 93017 for conducting the stress test. The supervising physician charges 93016 on a pro fee claim, and the interpreting physician charges 93018. Note that APC reimbursement under OPPS is indicated for only 93017; the other codes are for professional fee reporting, not facility charges.

AHA Scientific Statement

Supervision of Exercise Testing by Nonphysicians
A Scientific Statement From the American Heart Association

Jonathan Myers, PhD, FAHA, Chair; Daniel E. Forman, MD, FAHA; Gary J. Balady, MD, FAHA; Barry A. Franklin, PhD, FAHA; Jane Nelson-Worel, MS, APNP, Billie-Jean Martin, MD; William G. Herbert, PhD; Marco Guazzi, MD, PhD; Ross Arena, PhD, PT, FAHA; on behalf of the American Heart Association Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention of the Council on Clinical Cardiology, Council on Lifestyle and Cardiometabolic Health, Council on Epidemiology and Prevention, and Council on Cardiovascular and Stroke Nursing

The standard exercise test is a well-established procedure that has been widely used in cardiovascular medicine for many decades, with staffing issues that have changed over time. The test is frequently considered the "gatekeeper" to more expensive and/or invasive procedures since it is often the first diagnostic evaluation when coronary artery disease (CAD) is suspected. Thus, it is used to help guide decisions regarding diagnosis and/or medical and interventional management. Moreover, the prognostic value of aerobic capacity and other variables obtained during exercise is firmly established in those who are apparently healthy and in virtually all patient populations.[1,2] Generally, peak or symptom-limited exercise testing is used to detect signs or symptoms of myocardial ischemia and to discern fundamental information on exercise capacity, exercise hemodynamics, dysrhythmias, oxygenation, neurovasomotonic health, symptoms, and other physiological responses. In most instances, peak effort entails at least brief periods of high-intensity exercise, and evidence suggests that such vigorous physical exertion may cause a transient increase in the risk of cardiovascular events in high-risk individuals.[3,4] Because the exercise test is typically performed in patients with known or suspected cardiovascular disease, guidelines and scientific statements on exercise testing have historically recommended physician presence for supervision as a means both to optimize functional and diagnostic testing decisions and safety and to administer emergency treatment should complications occur. However, systematic surveys of multiple centers and reports from individual clinical exercise laboratories have shown that contemporary exercise tests are often conducted and supervised by nonphysicians (eg, exercise physiologists, nurses, physical therapists [PTs], physician assistants [PAs]). These reports and empirical evidence suggest that testing efficacy and safety are similar in laboratories where tests are directly supervised by physicians and those where nonphysicians administer testing under the egis of a physician supervisor.[5–8] This issue has been the topic of significant debate in the past, and there are currently no consistent or widely accepted standards on exercise test supervision.

To some extent, staffing shifts in exercise testing laboratories have been motivated by growing priorities for cost containment and greater efficiencies of medical care. Nonphysician care providers often now conduct the mechanics of exercise testing under a physician's supervision at less cost than testing performed directly by physicians. Although the details of supervision and physician proximity vary between individuals and institutions, the key point is that direct physician contact with the patient has diminished[9–11] while involvement by allied healthcare providers has expanded. A premise of this scientific statement is to characterize testing strategies that center attention on quality compared with cost. Nonphysicians may even provide some advantages in regard to patient care but not as surrogates for physicians' clinical skills and medical knowledge.

Previous statements are related to physician qualifications for the supervision of exercise testing from the American

Circulation is available at http://circ.ahajournals.org DOI: 10.1161/CIR.0000000000000101

CMS PROPOSES RESCINDING MOST FAVORED NATION MODEL

On August 6, 2021, CMS proposed rescinding the November 2020 Most Favored Nations Innovation Model (MFN). Public comment period ends on October 12, 2021.

Several states challenged this Medicare drug payment rule which had an implementation date of January 1, 2021. Injunctions and court orders in the U.S. District Courts delayed the start date based on the need for further rulemaking.

The rule, which was intended to reduce drug prescription costs, significantly cut reimbursement to hospitals and physician practices for 50 of the highest expenditure Medicare Part B drugs, as selected by CMS.The regulations bypassed usual regulatory processes by including it in a Final Rule with Comment Period.

Under the MFN model, OPPS hospitals and physician reimbursement would be phased into the MFN price, which is the lowest price paid for that drug among certain other developed nations, such as Canada, Germany, France, United Kingdom, Italy, and Japan (among others).

The Background, Regulation and Notice for the August 2021 MFN are available through the following link:

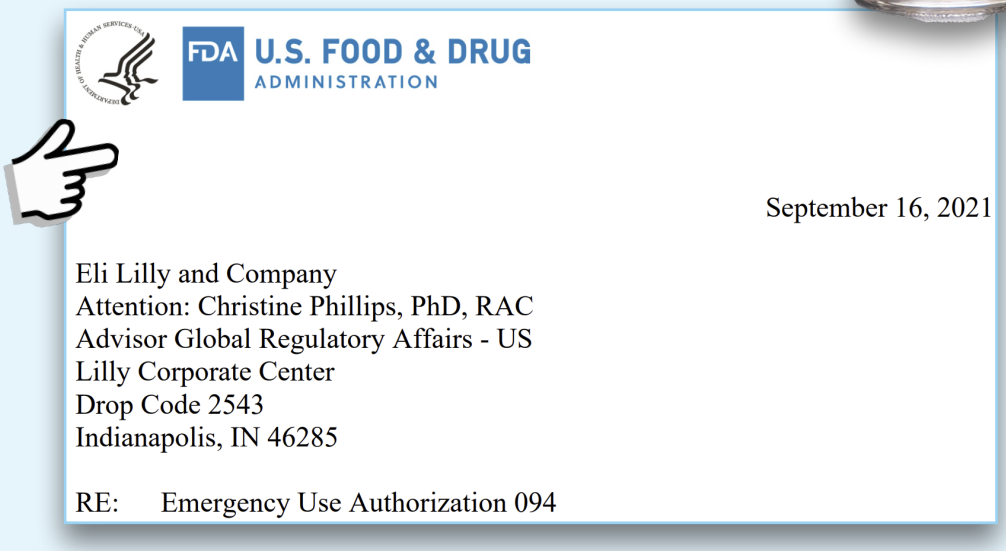
https://innovation.cms.gov/innovation-models/most-favored-nation-model

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.

WEBINAR: ZERO BALANCE INSURANCE AR

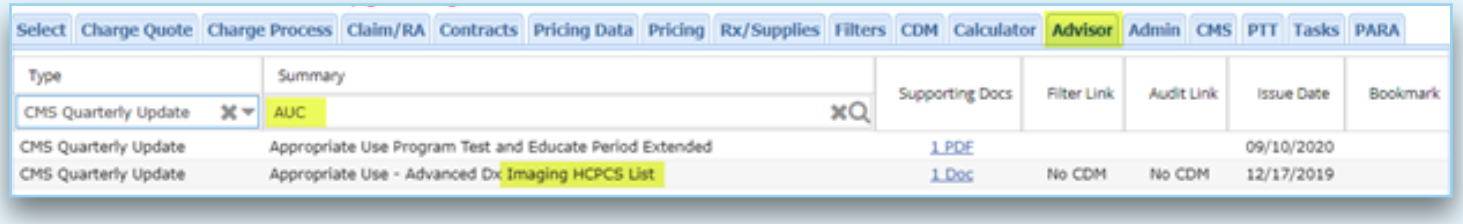
Watch this free webinar to learn why hospitals may be leaving money on the table.

Click the webinar icon.

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.

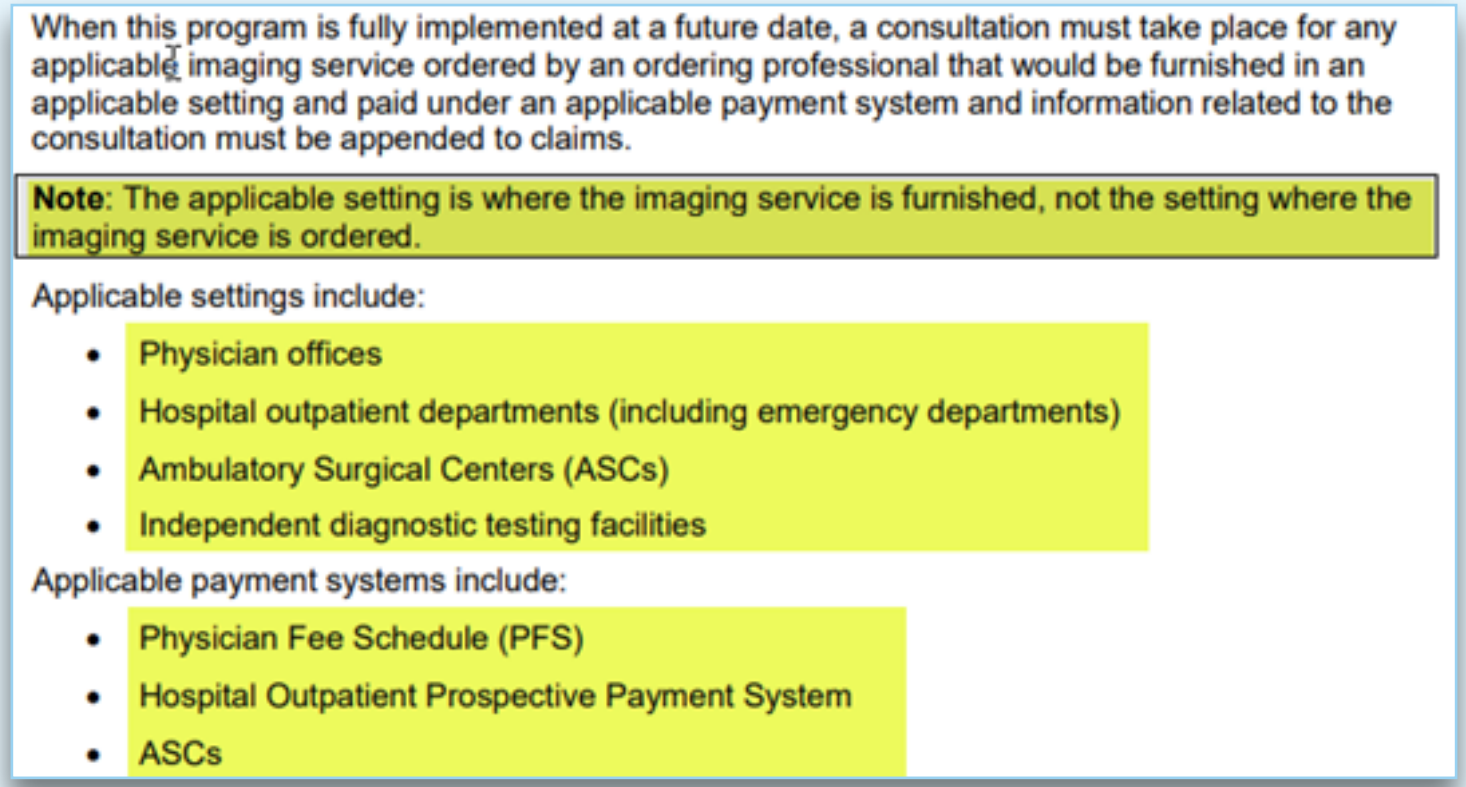
APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

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

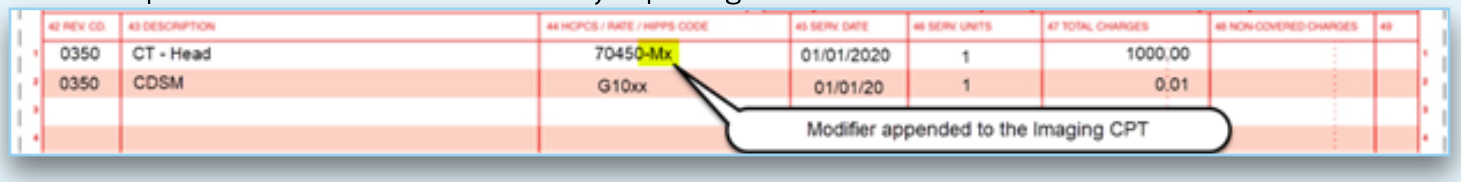
APPROPRIATE USE COMPLIANCE DEADLINE DELAYED

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

NEW COVID-19 VACCINE PRODUCT AND ADMINISTRATION CODES

In a Special Edition September 2021 CPT® Assistant Guide, 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	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**	Upon FDA approval

NEW COVID-19 VACCINE PRODUCT AND 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	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

NEW COVID-19 VACCINE PRODUCT AND 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	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	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

CMS REPORTS 2021 FOURTH QUARTER MUE CHANGES

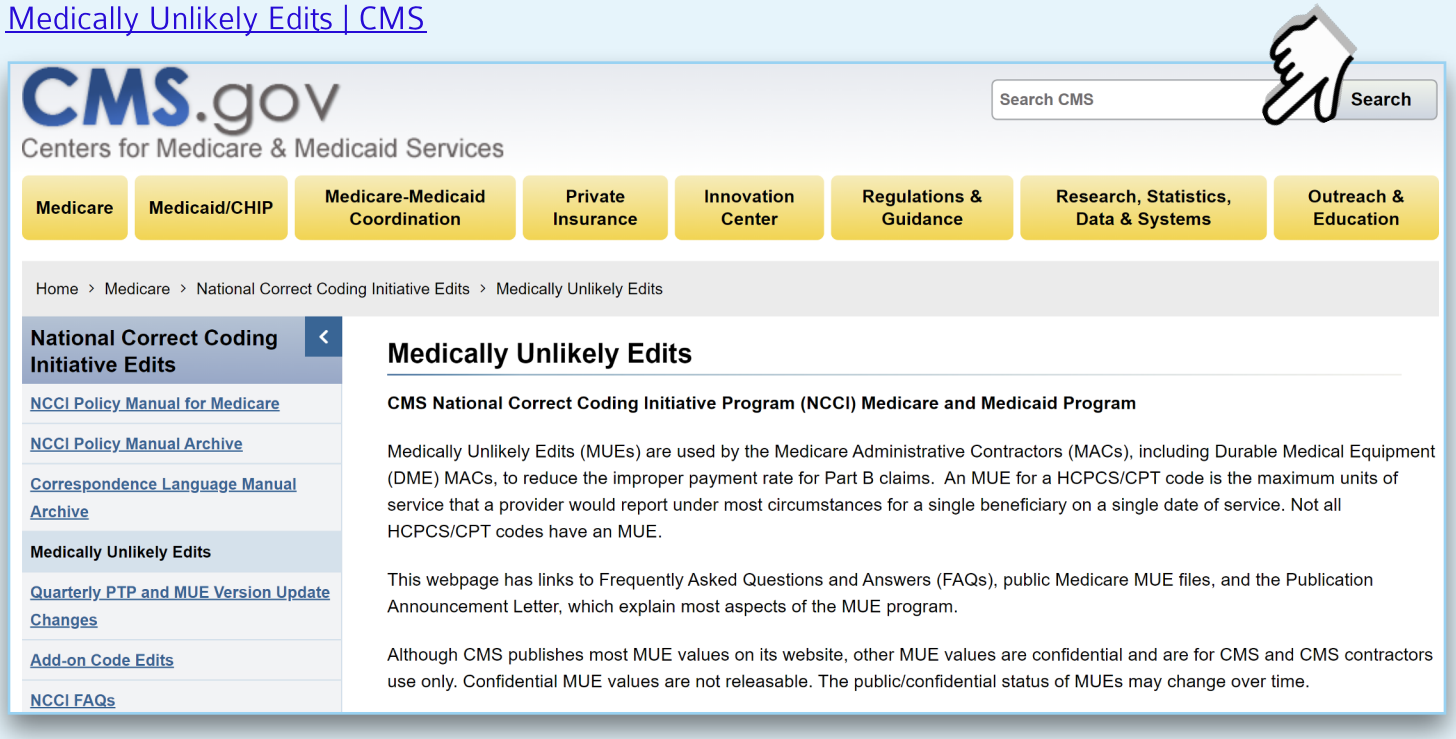
CMS posted the quarterly changes to Medically Unlikely Edits (MUE) effective October 10, 2021. These changes reflect additions, deletions, and revisions to published MUEs for Practitioner Services, Outpatient Hospital Services, and DME Supplier Services.

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

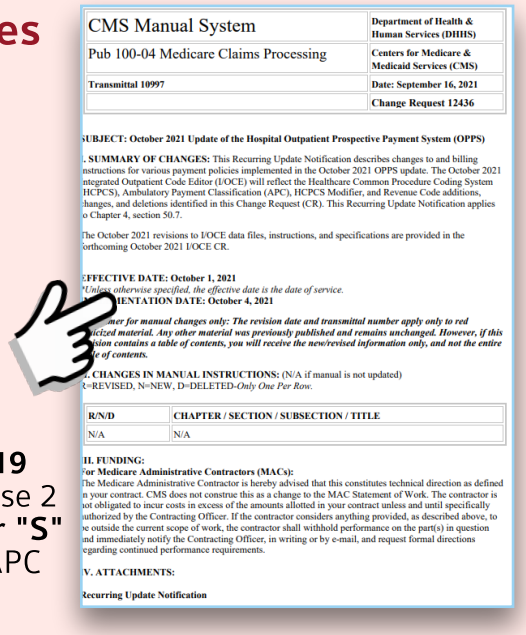
Medically Unlikely Edits | CMS



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:

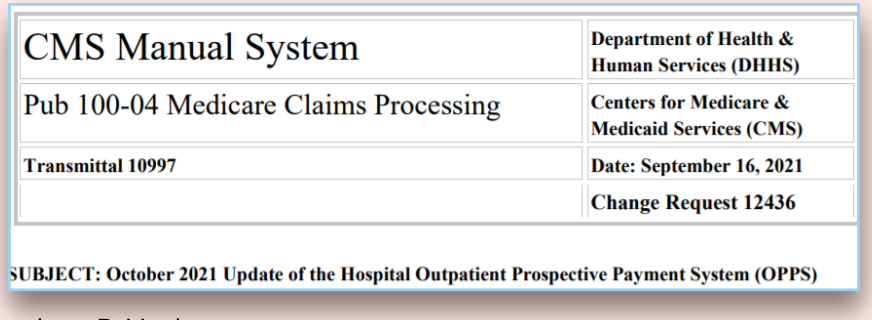
HCPCS	Description	SI	APC
P9025	Plasma, cryoprecipitate reduced, pathogen reduced, each unit	R	9538
P9026	Cryoprecipitated fibrinogen complex, pathogen reduced, each unit	R	9539

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)

ddendum A and Addendum B Updates

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

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."

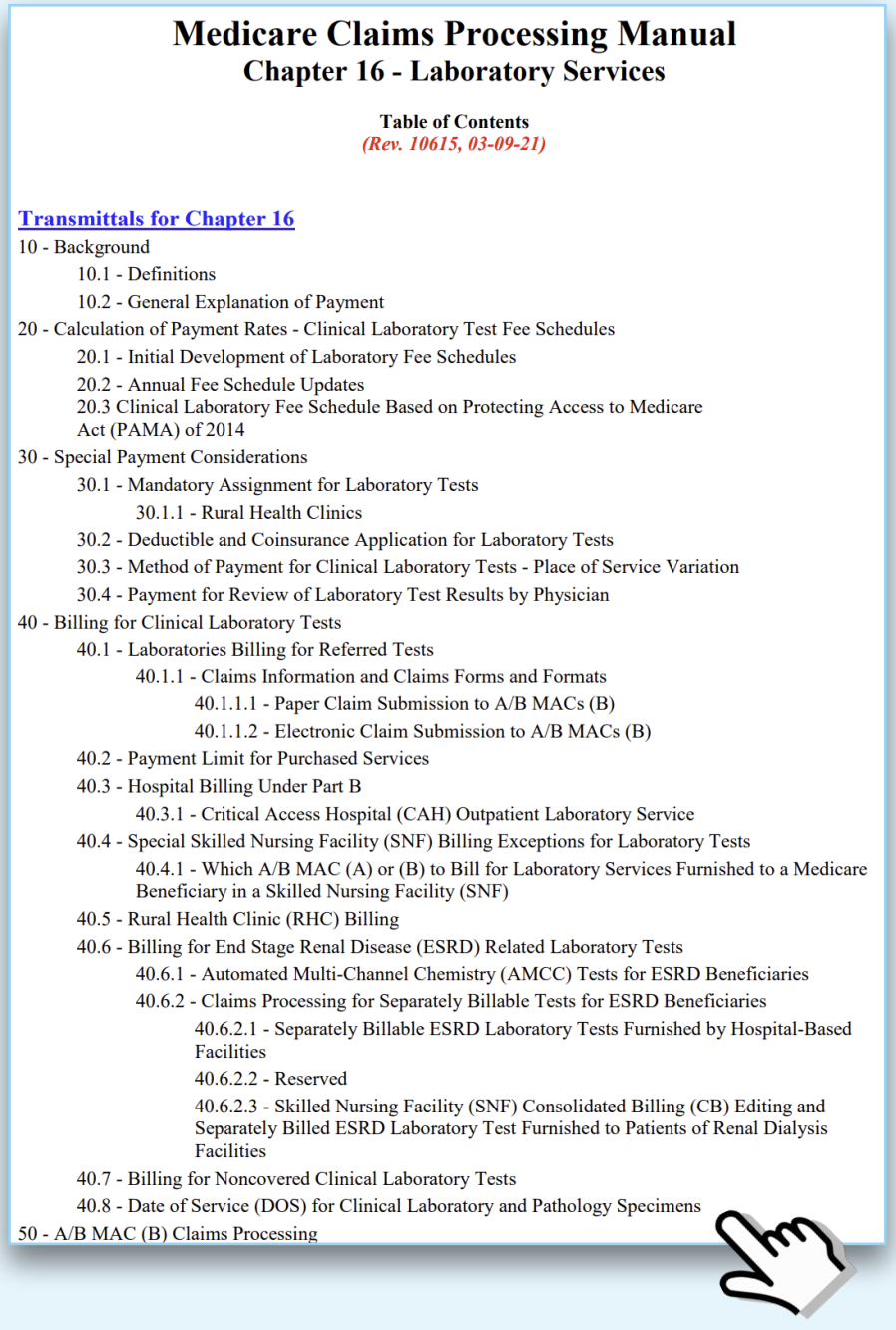
PARA interprets this reply to mean that CMS expects hospitals to report private payer lab rates for non-patient specimen testing whether or not the claim was submitted on TOB 14x, so long as the hospital can affirm that the testing qualified as a non-patient service. In other words, only the specimen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

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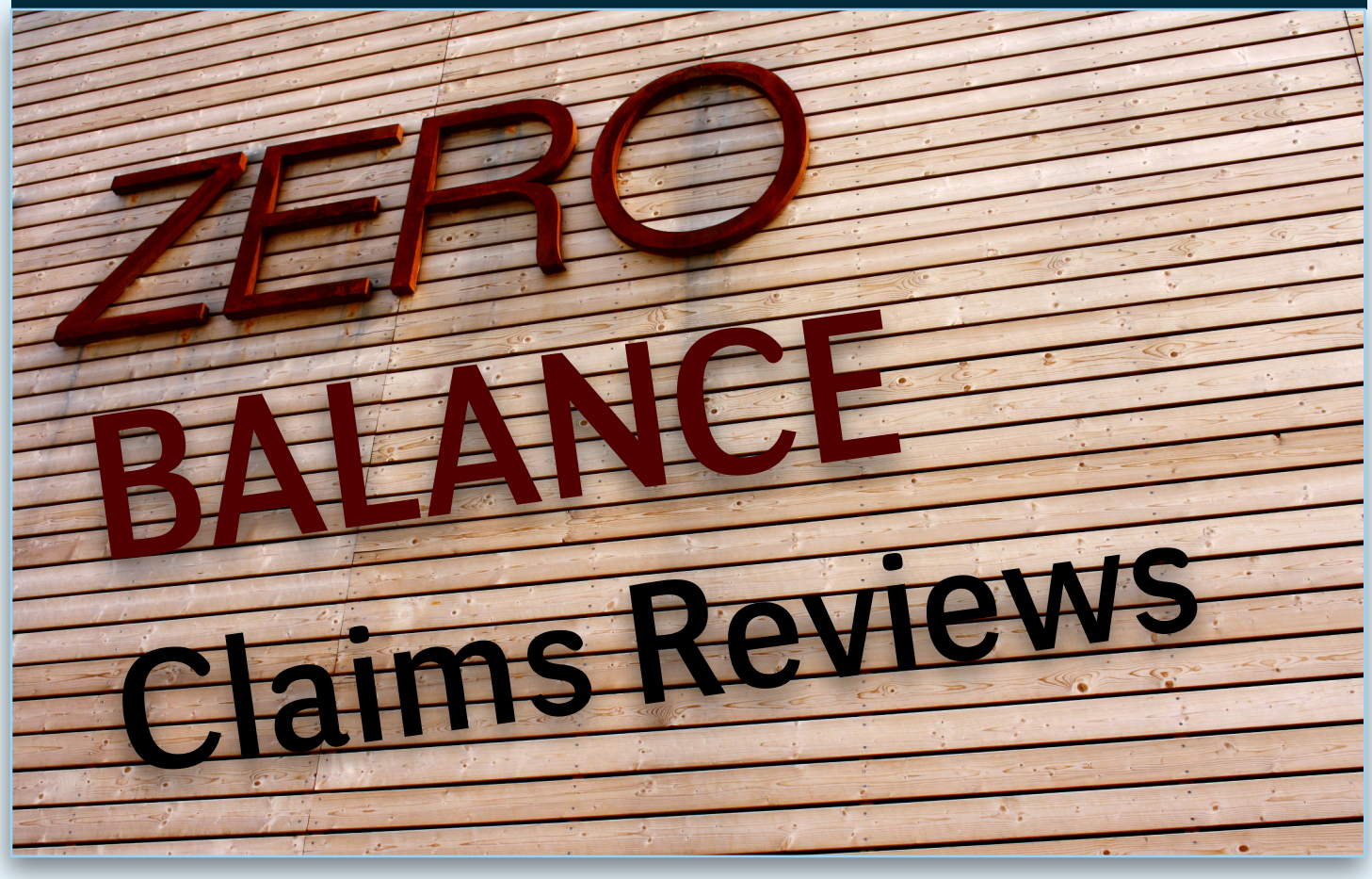
ZERO-BALANCE CLAIMS REVIEW -- A WHITE PAPER FROM HFRI



A CRITICAL BACKSTOP FOR AR MANAGEMENT STRATEGIES

As payer rules and coding have become more complex and internal pressures mount to keep accounts receivable (AR) days low, denial rates and resulting write-offs have continued to climb for most hospitals. Between 2011 and 2017, denial volume soared by nearly 80 percent for the average hospital.[1] The financial impact of these late or foregone collections is significant. Even though 90 percent of denials are preventable, and two-thirds are recoverable, 65 percent of claim denials are never corrected and resubmitted for reimbursement.[2] A recent survey of hospital executives found that 30 percent of facilities had bad debt of between $10 million and $50 million.[3]

AR STRATEGIES FOR AGED ACCOUNTS

Today, in the wake of often-severe cash flow problems triggered by the COVID-19 pandemic and other operational and regulatory challenges, a growing number of hospitals are partnering with third parties to implement comprehensive AR management strategies that can help reduce denials and ensure facilities collect every dollar they're entitled to.

These integrated approaches typically incorporate both internal and external elements: Hospital billing staff focus exclusively on the newest claims, then turn over unpaid balances to specialists at specific aging intervals.

Relying on external experts to pursue low-dollar, high-volume claims is often the most cost-effective way to optimize collections and minimize write-offs, since it frees up staff to concentrate on fresher, higher-dollar claims.

Pre-write-off insurance collection experts well-versed in health plan policies can provide an additional safeguard to help prevent legitimate claims, regardless of age or size, from going uncollected. A comprehensive approach will help organizations obtain hard collectible dollars from the full spectrum of aged accounts, including pre-write off claims and even from closed balance accounts.

BOOSTING CASH FLOW WITH ZERO-BALANCE REVIEWS OF CLOSED BALANCE ACCOUNTS

One critical element in a comprehensive AR management strategy is a zero-balance claims review. Zero-balance reviews are essentially forensic audits of written-off claims. Thorough, closed-balance reviews can validate claims integrity and maximize contractual revenue for all payers. They are designed to assess whether the factors that initially caused a payer's denial can be mitigated to secure retroactive reimbursement.

While some may assume that pursuing old write-offs isn't likely to be productive, experts skilled at identifying common mistakes that frequently result in denials can recover up to one percent of a hospitals total net patient revenue. For large hospitals and health systems that may generate hundreds of millions of dollars annually, this can translate into a significant amount of found revenue.

FOUR STEPS TO IMPROVING COLLECTIONS THROUGH AN EXTERNAL ZERO-BALANCE REVIEW

Most healthcare systems or organizations typically don't have the time, resources or expertise to conduct in-depth reviews of denied or unpaid aged claims. External reviews consequently can provide the extra scrutiny needed to potentially capture revenue from denied, underpaid and unpaid claims. Zero-balance reviews of closed balance accounts performed by an experienced partner represent a final safety net at the end of the revenue cycle management process, again freeing up staff to concentrate on fresher, higher-dollar claims.

Here are the four primary steps that should be included in a zero-balance review:

1. Scrutinize contracts

Specialists review all payer contractual agreements to identify areas of underpayment risk. This process is conducted in conjunction with hospital contracting staff and attorneys to help clarify the facility's expectations or intent with respect to specific contract provisions. Not infrequently, specialists identify ambiguous language that leaves the facility vulnerable to underpayments or common reimbursement methodologies that can be exploited by payers to reduce reimbursement.

Not infrequently, specialists identify ambiguous language that leaves the facility vulnerable to underpayments or common reimbursement methodologies that can be exploited by payers to reduce reimbursement. Contract problems sometimes can be as simple as a grammatical error or word choice: A clause that should have included 'and' instead of 'or,' or vice versa, depending on the anticipated scenario, can lead to reoccurring underpayments. Language like this may be causing significant underpaid revenue unbeknownst to revenue cycle staff.

Experts also flag any coding changes that may have occurred since the contract was executed to ensure updates have been made and reimbursements continue to be paid at appropriate levels.

2. Evaluate discharge files

After the contract review is completed, zero-balance specialists download a full set of discharge files for a specific timeframe, usually two full years of data for all payers, including Medicare, Medicare Advantage, Medicaid, Medicaid HMO, and commercial carriers. **STAT Revenue**, the zero-balance division of **HFRI**, processes the data files through a proprietary application that has been custom-programed with each payer's contract specifications. This process produces an independent payment analysis that isn't reliant on the hospital's contractual expected amounts to identify both underpayments and areas where the hospital's model may be deficient or inaccurate. Given the inherent limitations of existing billing platforms in calculating complex reimbursements—such as payments due from a secondary payer or more accurate outpatient coding—greater accuracy is usually achieved.

3. Perform an in-depth, 360-degree review

Once the subset of closed accounts is identified for potential additional revenue, an in-depth review is performed to pressure-test the integrity of the claim and the subsequent reimbursement. This step relies on the external team's collective experience to research each claim and maximize the revenue potential unique to that claim and payer, focusing on industry changes, coding best practices, and the contractual intent for each hospital. When accounts are verified through this review as underpaid, STAT Revenue's experts work with the payers to deliver the additional revenue to the hospital's bottom line.

4. Recommend improvements

From this extensive review process and subsequent trend analysis, recommendations can be made about how hospitals can optimize collections through implementation of coding best practices for specific procedures or drugs. One example: a hospital may not be billing properly for expensive new drugs that are FDA-approved but do not have an HCPCS code assigned.

Medicare and most commercial payers have specific, often complex requirements for reimbursing for unclassified drugs, and external experts can help in resubmitting claims with this correct coding to achieve proper reimbursement.

In addition to flagging coding mistakes, the zero-balance claims analysis also identifies payer deficiencies, whether they're one-off events or reoccurring, systemic issues. Working withing appropriate contractual claim and appeal submission timeframes, **STAT Revenue** will work with the hospital staff to resubmit corrected claims to the payer, and, in instances when the payer is at fault, bring the problem to the attention of provider relations and help prepare for arbitration if necessary

ZERO-BALANCE CLAIMS REVIEW -- A WHITE PAPER FROM HFRI

A SECOND SET OF EYES

The zero-balance review can produce immediate benefits, in terms of recovered reimbursement on written-off claims, as well as longer-term reductions in inaccurate coding, denials and write-offs. Working in partnership with hospital staff, experts identify process improvements and help implement staff training to reduce and eliminate denial root causes.

Ultimately, zero-balance reviews provide expert oversight to scrutinize the all-important denial arena. This can help produce lasting solutions that improve collections while ensuring optimal compliance. Amid the current challenges in healthcare, this capability helps hospitals not only collect every dollar they are owed, but also allows them to focus on other, equally pressing areas of operations. **HFRI** can help you progress toward the goal of zero-percent write-offs through our comprehensive AR solutions. We're able to resolve all claims, regardless of size or age quickly, and conduct zero-balance claims reviews and root cause analysis to ensure you're collecting every dollar you deserve.

Contact us today to learn more.

For more information, be sure to watch the recorded webinar "Zero Balance Insurance AR: Learn how most hospitals are leaving money on the table."

1 Kelly Gooch, "4 ways hospitals can lower claim denial rates," Becker's Hospital CFO Report, Jan. 5, 2018.

2 Chris Wyatt, "Optimizing the Revenue Cycle Requires a Financially Integrated Network," HFMA, July 7, 2015.

3 "Bad Debt Exceeds $10M at a Third of Organizations, But Lack of Confidence Exists in How Much is Recoverable," Cision PR Newswire. June 19, 2018.

EUA AMENDED TO ADD ANOTHER DOSE OF COVID VACCINES

On August 12, 2021, the FDA announced in a press release that they amended the EUA for the Pfizer and Moderna COVID-19 vaccines.The amendment allows solid organ transplant recipients and individuals diagnosed with conditions considered immunocompromised to receive an additional dose of the vaccines. The FDA also states that, at this time, fully vaccinated people do not need an additional dose.

People with immunocompromised conditions are more vulnerable to COVID-19 and other infections.The FDA evaluated data and determined that an additional COVID-19 vaccine may protect this small, vulnerable group of people.

The announcement also recommends that if an immunocompromised person is exposed to or contracts COVID-19, they should consult a healthcare provider to determine if they may need monoclonal antibody therapy.

The AMA provided the following HCPCS codes in response to the amended EUA:

https://www.ama-assn.org/press-center/press-releases/ama-announces-cpt-code-set-ready-third-doses-covid-19-vaccines

Description	Product	CPT®
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**	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, 100 mcg/0.5 mL dosage; third dose	**Moderna**	0013A

Medicare will cover the additional doses with approximately $40 administration fee as they have the first and second COVID-19 vaccine doses.

https://www.cms.gov/newsroom/news-alert/people-medicare-who-are-immunocompromised-would-be-able-receive-additional-covid-19-dose-no-cost

EUA AMENDED TO ADD ANOTHER DOSE OF COVID VACCINES

CMS.gov | Centers for Medicare & Medicaid Services

Newsroom Press Kit Data Contact Blog Podcast

News alert

People With Medicare Who Are Immunocompromised Would be Able to Receive an Additional COVID-19 Dose At No Cost

Aug 13, 2021 | Coverage, Medicare Parts A & B

The August 12, 2021 FDA announcement is available through the following link:

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals

Other fully vaccinated individuals do not need an additional vaccine dose right now

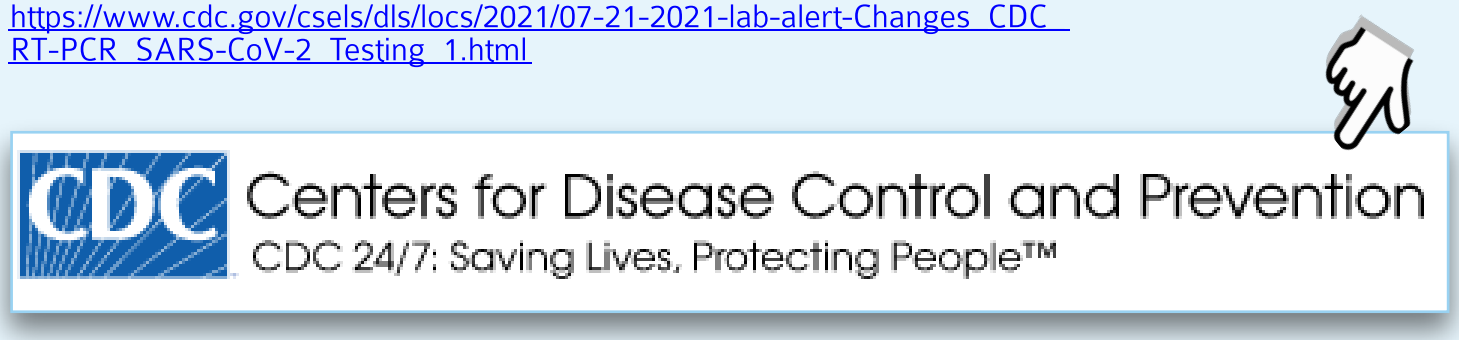
FDA TO WITHDRAW EUA ON COVID PCR TEST DECEMBER 31, 2021

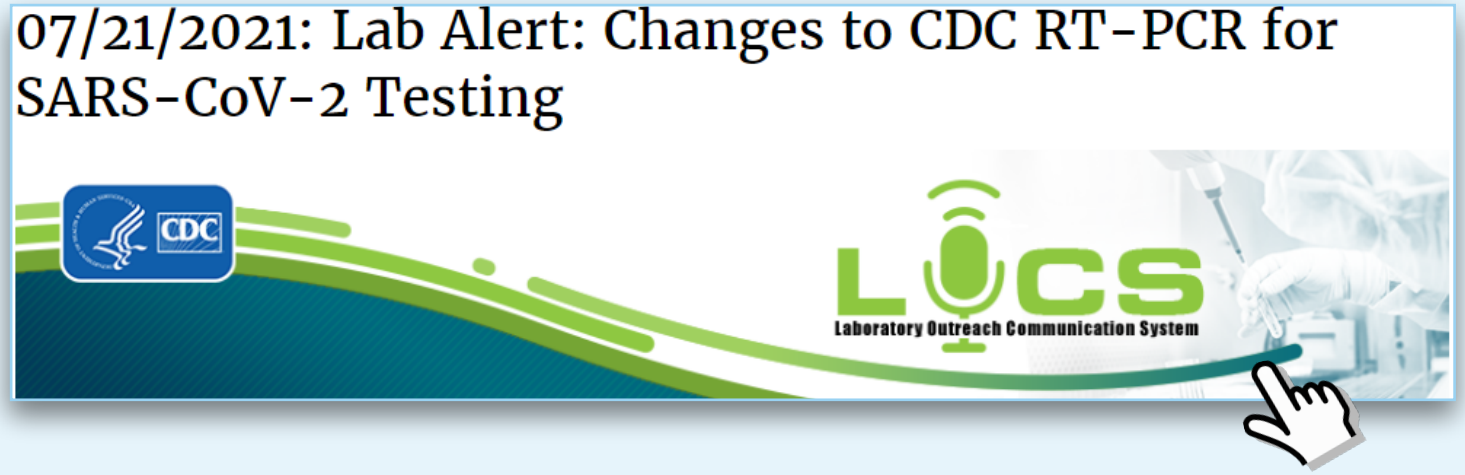
On July 21, 2021, the CDC announced it will withdraw its Emergency Use Authorization (EUA) request for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel after December 31, 2021.

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





CHECK PHYSICIAN ORDER ON OBSERVATION CLAIMS

The Health and Human Services Office of the Inspector General (OIG) recently publicized a self-disclosed recoupment from a Virginia facility which had charged for observation care when there was no physician order to support the service, and/or when the service was not supported as medically necessary:

https://oig.hhs.gov/fraud/enforcement/sentara-healthcare-agreed-to-pay-43-million-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-improper-claims-for-observation-services/

Sentara Healthcare Agreed to Pay $4.3 Million for Allegedly Violating the Civil Monetary Penalties Law by Submitting Improper Claims for Observation Services

After it self-disclosed conduct to OIG, Sentara Healthcare (Sentara), Virginia, agreed to pay $4,330,218 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that Sentara submitted, or caused the submission of, improper claims for observation services provided to patients discharged from the emergency departments of Sentara's hospitals when there was inadequate support for the medical necessity or reasonableness or for the amount of units, or when there was no physician order for the observation services provided.

PARA reminds facilities that observation may be reported only if:

- ·There is a physician order for observation care in the medical record
- ·The service is medically necessary
- ·Observation begins on the date and time of the physician order
- ·All units of observation care should be reported on only one line on the claim (not by DOS)
- ·Observation time must be reduced for the period of time a patient is undergoing another closely monitored, billable service (such as an imaging procedure)
- ·Observation may not be charged retroactively

PARA offers a comprehensive paper on billing for observation at the following link:

https://apps.para-hcfs.com/para/Documents/Observation_Charging_Billing_Compliance_and_Reimbursement_January_2016_Update_edited.pdf

Observation – Charging, Billing, Compliance and Reimbursement

CMS REMOVES CERTAIN NCDs -- DEFERS COVERAGE TO MACs

In an MLN dated August 2, 2021, CMS announced that effective January 1, 2021, it has removed several older National Coverage Determinations (NCDs) that may have become obsolete or unnecessary.The agency has deferred coverage decisions on the services previously addressed in these NCDs to the judgement of the MACs.

MACs may decide to cover services previously covered, or to continue non-coverage as previously established in the NCD.

https://www.cms.gov/files/document/mm12254.pdf

Background

The final rule contains a summary of the NCD removal process and explicitly removes the following 6 NCDs from the NCD Manual:

- NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns
- NCD 30.4 Electrosleep Therapy
- NCD 100.9 Implantation of Gastrointestinal Reflux Devices
- NCD 110.19 Abarelix for the Treatment of Prostate Cancer
- NCD 220.2.1 Magnetic Resonance Spectroscopy
- NCD 220.6.16 FDG PET for Inflammation and Infection

The 2021 Payment Policies under the Medicare Physician Fee Schedule and other Part B services were published in the Federal Register on December 28, 2021 – a pertinent excerpt is provided:

https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf#page=326

J. Removal of Selected National Coverage Determinations

In the CY 2021 PFS proposed rule (85 FR at 50255), we proposed to use the notice and comment rulemaking to identify and remove older NCDs that we believed no longer contained clinically pertinent and current information or no longer reflected current medical practice. ...Instead, in the absence of an NCD, the coverage determinations for those items and services would be made by Medicare Administrative Contractors (MACs).

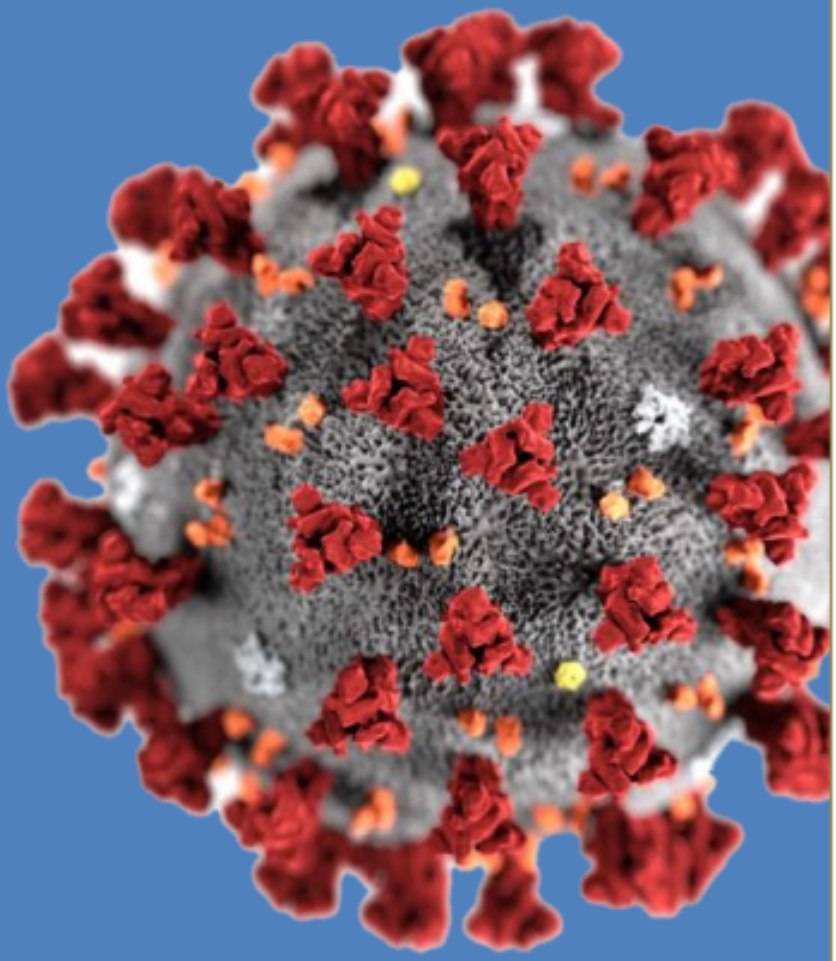
We also noted that if the previous NCD barred coverage for an item or service under title XVIII (that is, national noncoverage NCD), a MAC would now be able to cover the item or service if the MAC determined that such action was appropriate under the statute. Removing a national non-coverage NCD may permit access to technologies that may be beneficial for some uses.

We explained that as the scientific community continues to conduct research producing new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions. In the proposed rule, we also described the circumstances that we had used in determining whether an older NCD should be removed.

COVID-19 UPDATE

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 August 22, 2021

Comprehensive COVID-19 Billing and Coding Guide

PARA HealthCare Analytics

HEALTHCARE FINANCIAL RESOURCES

Download the updated Guidebook by clicking here.

Expanded PDE Training Sessions Available

PARA offers nationwide overview training on the PARA Data Editor each week. And, due to increased demand, we are expanding the training schedule to include sessions that focus on the two most frequently used modules with the PDE.

Sessions on Charge Quote and the Calculator will now be offered on Tuesdays (Charge Quote) and Thursdays (Calculator) at the following times:

Tuesdays:
11:00 am Pacific Daylight Time

Thursdays:
8:00 am Pacific Daylight Time

Regular PDE Training Sessions:
Wednesdays at 11:00 am PDT and Fridays at 8:00 am PDT

Interested?

Please contact one of the following experts for a session key.

Mary McDonnell: 800.999.3332, ext 216
mmcdonnell@para-hcs.com

Violet Archuleta-Chiu: 800.999.3332, ext 219
varchuleta@para-hcfs.com

Sandra LaPlace: 800.999.3332, ext 225
slaplace@para-hcfs.com

Gail Langord: 800.999.3332, ext 426
glangford@para-hcs.com

Randi Brantner: 800.999.3332, ext 215
rbrantner@para-hcfs.com

If you can't make any of these sessions, but would still like to attend, please contact Mary McDonnell for options.

PARA HealthCare Analytics

HEALTHCARE FINANCIAL RESOURCES

MLN CONNECTS

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, September 23, 2021

News

- CMS Launches New Medicare.gov Feature to Compare Nursing Homes by Vaccination Rate
- Drugs of Abuse Testing: Comparative Billing Report in September
- Cardiovascular Disease: Talk to your Patients about Screening

Compliance

- DMEPOS Items: Ordering or Referring Practitioner Requirements

Claims, Pricers, & Codes

- ESRD Facilities: Bill Correctly for Cinacalcet Oral Drug

MLN Matters® Articles

- Claims Processing Instructions for National Coverage Determination 20.33 – Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation
- National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds
- October 2021 Update of the Ambulatory Surgical Center (ASC) Payment System
- Medicare Clarifies Recognition of Interstate License Compact Pathways — Revised

Publications

- Medicare Vision Services — Revised
- Power Mobility Devices — Revised
- Transitional Care Management Services — Revised

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Friday, September 24, 2021

SPECIAL EDITION

CMS Will Pay for COVID-19 Booster Shots, Eligible Consumers Can Receive at No Cost

Coverage without cost-sharing available for eligible people with Medicare, Medicaid, CHIP, and Most Commercial Health Insurance Coverage

Following the FDA's recent action that authorized a booster dose of the Pfizer COVID-19 vaccine for certain high-risk populations and a recommendation from the CDC, CMS will continue to provide coverage for this critical protection from the virus, including booster doses, without cost sharing.

Beneficiaries with Medicare pay nothing for COVID-19 vaccines or their administration, and there is no applicable copayment, coinsurance, or deductible. In addition, thanks to the American Rescue Plan Act of 2021, nearly all Medicaid and CHIP beneficiaries must receive coverage of COVID-19 vaccines and their administration, without cost-sharing. COVID-19 vaccines and their administration, including boosters, will also be covered without cost-sharing for eligible consumers of most issuers of health insurance in the commercial market. People can visit vaccines.gov (English) or vacunas.gov (Spanish) to search for vaccines nearby.

"The Biden-Harris Administration has made the safe and effective COVID-19 vaccines accessible and free to people across the country. CMS is ensuring that cost is not a barrier to access, including for boosters," said CMS Administrator Chiquita Brooks-LaSure. "CMS will pay Medicare vaccine providers who administer approved COVID-19 boosters, enabling people to access these vaccines at no cost."

CMS continues to explore ways to ensure maximum access to COVID-19 vaccinations. More information regarding the CDC COVID-19 Vaccination Program Provider Requirements and how the COVID-19 vaccine is provided through that program at no cost to recipients is available on the CDC COVID-19 Vaccination Program Provider Requirements and Support webpage and through the CMS COVID-19 Provider Toolkit.View this edition as PDF (PDF)

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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!**

Monday, September 27, 2021

SPECIAL EDITION

Flu & Pneumococcal Vaccines: Expanded SNF Enforcement Discretion for Certain Pharmacy Billing

Effective September 20, 2021, CMS exercised enforcement discretion for Skilled Nursing Facility (SNF) consolidated billing provisions related to flu and pneumococcal vaccines. This allows Medicare-enrolled immunizers, including pharmacies, to bill directly and get direct reimbursement from the Medicare program (including vaccine administration and product), whether these vaccines are administered at the same time (co-administered) with a COVID-19 vaccine or at different times.

Visit the SNF: Enforcement Discretion Relating to Certain Pharmacy Billing webpage.

Vaccinations for respiratory illnesses reduce the impact and resulting burdens on the health care system during the COVID-19 PHE.

The CDC recommends that patients in post-acute care facilities get the flu vaccine during the COVID-19 pandemic.View this edition as a PDF (PDF)

There were 2 new or revised
MedLearns released this week.

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

FIND ALL THESE MEDLEARNS
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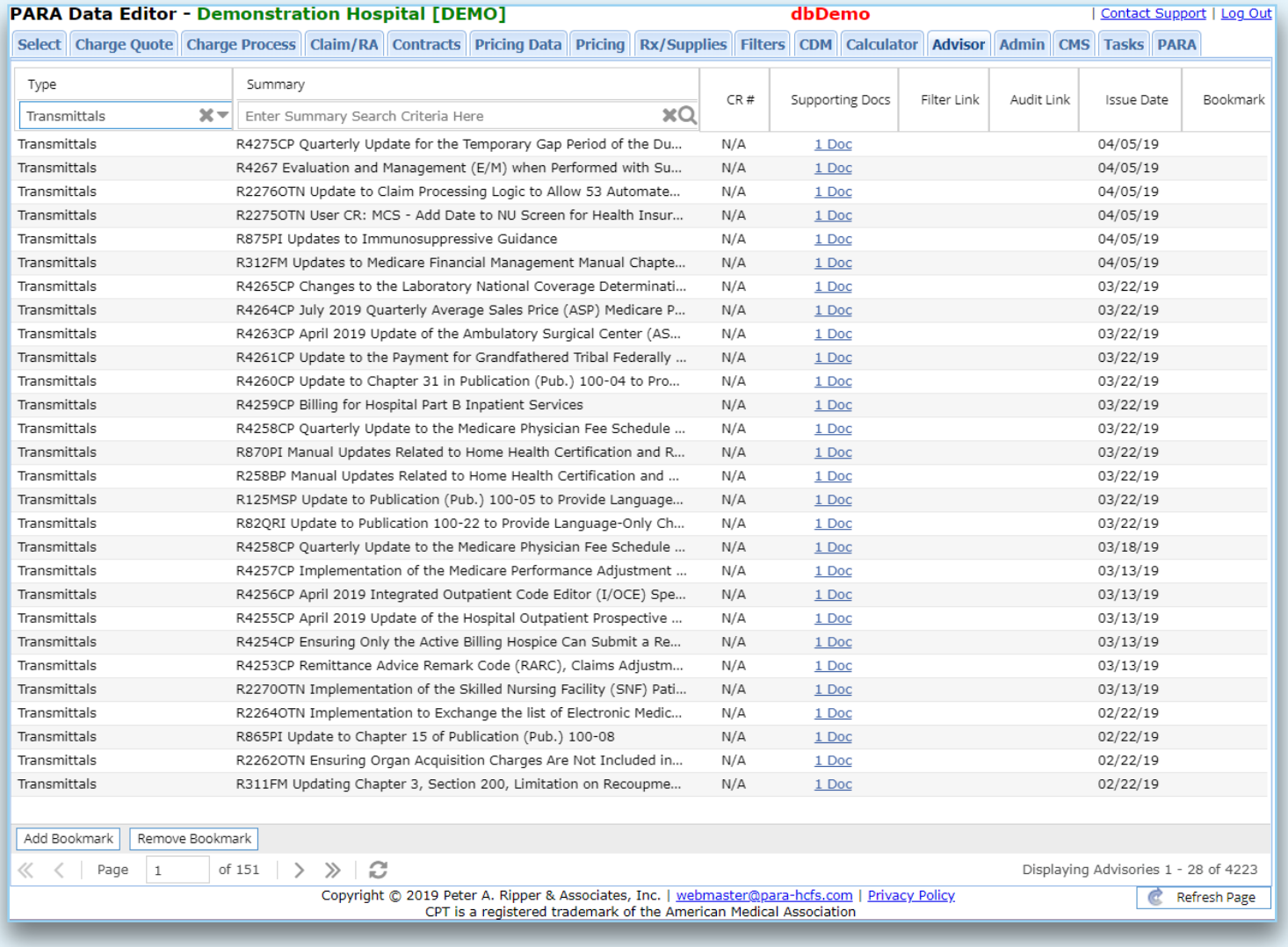

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Transmittals	R4267 Evaluation and Management (E/M) when Performed with Su...	N/A	1 Doc			04/05/19	
Transmittals	R2276OTN Update to Claim Processing Logic to Allow 53 Automate...	N/A	1 Doc			04/05/19	
Transmittals	R2275OTN User CR: MCS - Add Date to 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	
Transmittals	R4258CP Quarterly Update to the Medicare Physician Fee Schedule ...	N/A	1 Doc			03/22/19	
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	
Transmittals	R4258CP Quarterly Update to the Medicare Physician Fee Schedule ...	N/A	1 Doc			03/18/19	
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	
Transmittals	R865PI Update to Chapter 15 of Publication (Pub.) 100-08	N/A	1 Doc			02/22/19	
Transmittals	R2262OTN Ensuring Organ Acquisition Charges Are Not Included in...	N/A	1 Doc			02/22/19	
Transmittals	R311FM Updating Chapter 3, Section 200, Limitation on Recoupme...	N/A	1 Doc			02/22/19	

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

MLN Matters Number: MM12399 Revised

Related Change Request (CR) Number: 12399

Related CR Release Date: September 28, 2021

Effective Date: January 1, 2022

Related CR Transmittal Number: R11025CP

Implementation Date: September 10, 2021 – MACs, January 3, 2022 - SSMs

Note: We revised this Article to reflect a revised CR 12399. The CR revision didn't impact the substance of the Article. We did change the CR release date, transmittal number, and the web address of the CR. All other information is the same.

Provider Types Affected

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

Provider Action Needed

This article tells you about updates of ICD-10 conversions and other coding updates specific to NCDs. These changes result from:

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

CMS isn't including any policy changes this ICD-10 quarterly update. We cover NCD policy changes using the current, longstanding NCD process. Make sure your billing staff knows of these changes.

Background

Previous NCD coding changes appear in ICD10 Quarterly Updates along with other CRs implementing new NCD policy.

Relevant NCD coding changes in CR 12399 include:

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The link to this MedLearn MM12417

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

MLN Matters Number: MM12417 Revised | Related Change Request (CR) Number: 12417

Related CR Release Date: September 27, 2021 | Effective Date: October 1, 2021

Related CR Transmittal Number: R11019CP | Implementation Date: October 4, 2021

Note: We revised this Article due to a revised CR 12417, which corrected the fixed dollar loss threshold amount to $16,040. We changed the CR release date, transmittal number, and the web address of the CR. We show the revised fixed dollar loss threshold amount in dark red font on page 3. All other information remains the same.

Provider Type Affected

This MLN Matters Article is for IPFs submitting claims to Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

Provider Action Needed

Make sure that your billing staff knows about the changes that apply to discharges occurring from October 1, 2021, through September 30, 2022.

Background

CMS must make annual updates to the IPF PPS. This Article discusses the changes for FY 2022. We base the changes on the 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).

Under 42 CFR 412.428, the annual update includes revisions to:

- The federal per diem base rate
- The hospital wage index
- ICD-10-CM Coding and Diagnosis-Related Groups (DRGs) classification changes discussed in the annual update to the hospital Inpatient Prospective Payment System (IPPS) regulations
- Electroconvulsive therapy (ECT) payment per treatment
- The fixed dollar loss threshold amount
- The national urban and rural cost-to-charge medians and ceilings.

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There were FIVE new or revised Transmittals released this week.

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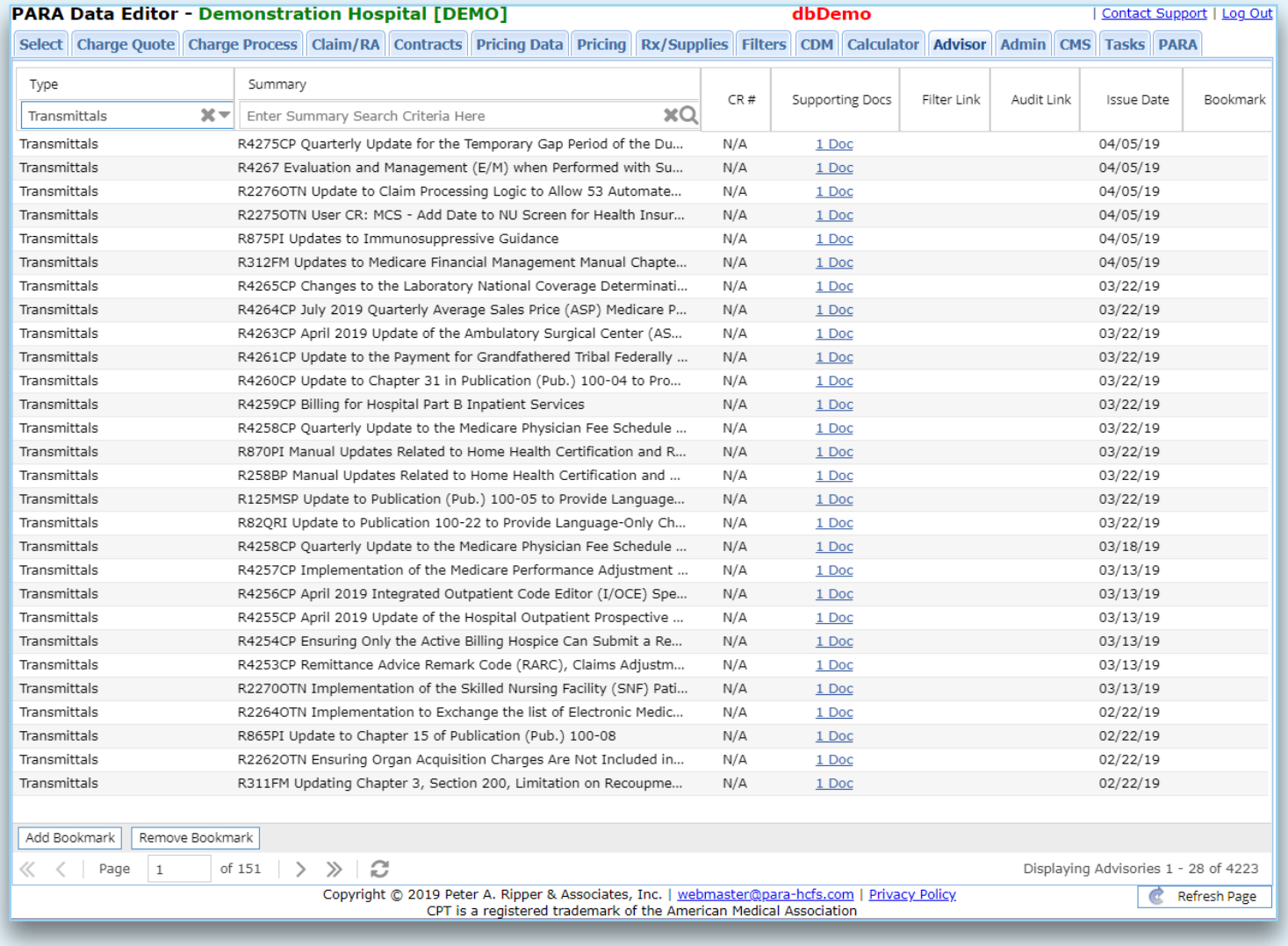

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Transmittals	R312FM Updates to Medicare Financial Management Manual Chapte...	N/A	1 Doc			04/05/19	
Transmittals	R4265CP Changes to the Laboratory National Coverage Determinati...	N/A	1 Doc			03/22/19	
Transmittals	R4264CP July 2019 Quarterly Average 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	
Transmittals	R4258CP Quarterly Update to the Medicare Physician Fee Schedule ...	N/A	1 Doc			03/22/19	
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	
Transmittals	R4258CP Quarterly Update to the Medicare Physician Fee Schedule ...	N/A	1 Doc			03/18/19	
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	
Transmittals	R865PI Update to Chapter 15 of Publication (Pub.) 100-08	N/A	1 Doc			02/22/19	
Transmittals	R2262OTN Ensuring Organ Acquisition Charges Are Not Included in...	N/A	1 Doc			02/22/19	
Transmittals	R311FM Updating Chapter 3, Section 200, Limitation on Recoupme...	N/A	1 Doc			02/22/19	

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The link to this Transmittal R11026DEMO

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11026	**Date: September 28, 2021**
	Change Request 11914

Transmittal 10993, dated September 2, 2021, is being rescinded and replaced by Transmittal 11026, dated, September 28, 2021 to remove business requirement 11914.65, the provider education instruction. All other information remains the same.

SUBJECT: Kidney Care Choices (KCC) Kidney Care First (KCF) - Payment Mechanism (PM) and Benefit Enhancements (BEs) - Implementation

I. SUMMARY OF CHANGES: This Change Request (CR) is the implementation of payment mechanisms and Benefit Enhancements for the Kidney Care Choices (KCC) Kidney Care First (KCF) (Demo 97) Model. This CR focuses on the implementation of the Chronic Kidney Disease Quarterly Capitation Payment (CKD QCP) payment mechanism. Additionally, the following Benefit Enhancements will be implemented with this CR: Telehealth Benefit Enhancement, Post-Discharge Home Visits Benefit Enhancement, Kidney Disease Education Benefit Enhancement, and Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit.

EFFECTIVE DATE: April 1, 2021; July 1, 2021 - BRs 11914.45 through 11914.64
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 5, 2021; July 6, 2021 - BRs 11914.45 through 11914.64

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

The link to this Transmittal R11027DEMO

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11027	**Date: September 28, 2021**
	Change Request 11915

Transmittal 10715, dated August 19, 2021, is being rescinded and replaced by Transmittal 11027, dated, September 28, 2021 to remove business requirement 11915.74, the provider education instruction and to add the NCH to BRs 11915.27.3.5 and 11915.35. All other information remains the same.

SUBJECT: Kidney Care Choices (KCC) Comprehensive Kidney Care Contracting (CKCC) - Payment and Benefit Enhancements - Implementation

I. SUMMARY OF CHANGES: This Change Request (CR) is the implementation of a payment mechanism and benefit enhancements for the Kidney Care Choices (KCC) Comprehensive Kidney Care Contracting (CKCC) (demonstration code 93) Model. This CR focuses on the implementation of the Chronic Kidney Disease Quarterly Capitation Payment (CKD QCP) mechanism. Additionally, the following Benefit Enhancements and waiver will be implemented with this CR: Telehealth Benefit Enhancement, Post-Discharge Home Visits Benefit Enhancement, 3-Day Skilled Nursing Facility Rule waiver, Kidney Disease Education Benefit Enhancement, Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit, and Home Health Benefit Enhancement.

EFFECTIVE DATE: April 1, 2021; July 1, 2021 - BRs 11915.36 through 11915.71
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 5, 2021; July 6, 2021 - BRs 11915.36 through 11915.71

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)
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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

The link to this Transmittal R11029CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11029	**Date: September 28, 2021**
	Change Request 12357

Transmittal 10907, dated August 10, 2021, is being rescinded and replaced by Transmittal 11029, dated, September 28, 2021 to revise business requirement 12357.1 removing the CG modifier. All other information remains the same.

SUBJECT: Implementation of the GV Modifier for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for Billing Hospice Attending Physician Services

I. SUMMARY OF CHANGES: This change request implements the GV modifier for both RHCs and FQHCs to report on claims when billing for hospice attending physician services furnished by certain RHCs or FQHC practitioners during a patient's hospice election.

EFFECTIVE DATE: January 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 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)
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R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	9/Table of Contents
N	9/60/60.6/RHCs and FQHCs for Billing Hospice Attending Physician Services

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

The link to this Transmittal R11025OTN

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11025	**Date: September 28, 2021**
	Change Request 12399

Transmittal 10963, dated August 19, 2021, is being rescinded and replaced by Transmittal 11025, dated, September 28, 2021 to: (1) revise spreadsheet 110.23, Stem Cell Transplants, to add back 30 diagnosis codes to the diagnosis tab removed in error, (2) add override notes to business requirements (BRs) 12399.2, NCD 110.23, Stem Cell Transplants, and 12399.5.1, NCD 160.18 VNS, (3) add updated coding to BR 12399.3, NCD 110.24, CAR-T, and its associated spreadsheet, and, update BRs 5 and 5.1, NCD 160.18, VNS, and its associated spreadsheet, to reflect accurate code edits. All other information remains the same.

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

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.

EFFECTIVE DATE: January 1, 2022 - Unless otherwise noted in requirements
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 4, 2021 - MACs; January 3, 2022 - shared system maintainers

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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:

The link to this Transmittal R11019CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11019	**Date: September 27, 2021**
	Change Request 12417

Transmittal 10944, dated August 12, 2021, is being rescinded and replaced by Transmittal 11019, dated, September 27, 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 published in the Federal Register on Month Day, Year. 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

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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 regarding continued performance requirements.