March 24, 2021

PARA Weekly eJOURNAL

NEWS FOR HEALTHCARE DECISION MAKERS

Respiratory Panel Coding

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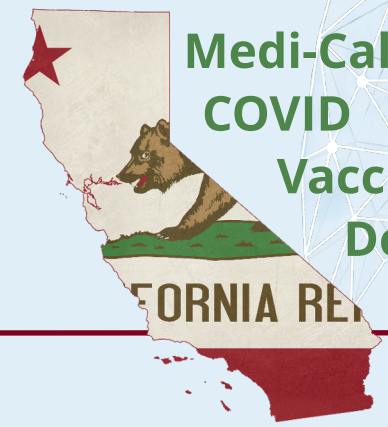

Medi-Cal COVID Vaccine Details

Pages 33 and 36

- **Same C Code**
- Home Health Providers: Billing Osteoporosis Drugs
- **2021 Appropriations No Surprises Act**
- April 1, 2021 OPPS Updates
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- Roadmap To A Strong Financial Comeback
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Billing And Coding Advice For Toxassure Lab Test

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labcorp

FAST LINKS

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SAME C CODE

Q. This questions refers to two products from a manufacturer that used to come as a kit, but are now individually pieced out, and we use the same C1813 HCPC. There are now issues with billing when multiple implants are used within the same encounter and have a shared C code. We looked at the MUE for C1813 and it shows "1". Is there a modifier that can be used in this scenario?

A. **Answer:** Even if there are components to the C1813 penile prosthesis, report only one unit of C1813. The C-code is required on the claim reporting the surgical procedure 54401, which is a "device dependent" procedure under Medicare OPPS.

The charges for the other components may be reported without a C-code in revenue code 0278, or the hospital may roll the charges for all the components parts into one line reporting C1813 under revenue code 0278. There is no need to report the C-code multiple times to account for each component of the implant.

Here's a link and an excerpt from the Boston Scientific webpage regarding billing for their products: [Penile Prosthesis (amsmenshealth.com)]

What C-Code is most commonly billed for an AMS 700™ Inflatable Penile Prosthesis or a Spectra™ Concealable Penile Prosthesis?

AMS 700 Inflatable Penile Prosthesis
C1813 Prosthesis, Penile, Inflatable

Spectra Conceable Penile Prosthesis
C2622 Prosthesis, Penile, Non-Inflatable

C-Codes are required for reporting devices when utilizing device-dependent APCs in the hospital outpatient setting. The American Hospital Association suggests that you "Report one unit of HCPCS code C1813, Prosthesis, penile, inflatable, for the penile implant" (versus line item billing all components). There are multiple components inserted during an inflatable penile implant surgery including the cylinders, reservoir, and pump. All three of these items can be lined itemed as one penile implant on the claim form as it is only one implant. (Benjamin D. Oden, CCS, January 18, 2012)

PRESUMPTIVE AND DEFINITIVE DRUG TEST CODING FOR MEDICARE

Q. Can you please provide some guidance on how to bill Toxassure for LabCorp?

A. **Answer:** The test results from LabCorp reflect their "Toxassure Comp Drug Analysis, UR". I googled Toxassure Comprehensive Profile and found the following LabCorp website listing the CPT® codes included:

790600: ToxASSURE® Comprehensive Profile (LabCorp MedWatch®) | Labcorp

We then checked the CPT®s listed. CPT® 80307 can be reported only once per day:

80307 - DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES; BY INSTRUMENT CHEMISTRY ANALYZERS (EG, UTILIZING IMMUNOASSAY [EG, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), CHROMATOGRAPHY (EG, GC, HPLC), AND MASS SPECTROMETRY EITHER WITH OR WITHOUT CHROMATOGRAPHY, (EG, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE

The majority of the other codes represent definitive drug test codes which are status B, not billable to Medicare on an outpatient hospital claim (83992 is status E1, excluded from coverage.)

PRESUMPTIVE AND DEFINITIVE DRUG TEST CODING FOR MEDICARE

HCPCS/CPT®	Status
80326 - AMPHETAMINES; 5 OR MORE	B
80331 - ANALGESICS, NON-OPIOID; 6 OR MORE	B
80334 - ANTIDEPRESSANTS, SEROTONERGIC CLASS; 6 OR MORE	B
80337 - ANTIDEPRESSANTS, TRICYCLIC AND OTHER CYCLICALS; 6 OR MORE	B
80338 - ANTIDEPRESSANTS, NOT OTHERWISE SPECIFIED	B
80341 - ANTIEPILEPTICS, NOT OTHERWISE SPECIFIED; 7 OR MORE	B
80344 - ANTIPSYCHOTICS, NOT OTHERWISE SPECIFIED; 7 OR MORE	B
80347 - BENZODIAZEPINES; 13 OR MORE	B
80348 - BUPRENORPHINE	B
80353 - COCAINE	B
80354 - FENTANYL	B
80355 - GABAPENTIN, NON-BLOOD	B
80357 - KETAMINE AND NORKETAMINE	B
80358 - METHADONE	B
80359 - METHYLENEDIOXYAMPHETAMINES (MDA, MDEA, MDMA)	B
80360 - METHYLPHENIDATE	B
80361 - OPIATES, 1 OR MORE	B
80364 - OPIOIDS AND OPIATE ANALOGS; 5 OR MORE	B
80365 - OXYCODONE	B
80366 - PREGABALIN	B
80367 - PROPOXYPHENE	B
80368 - SEDATIVE HYPNOTICS (NON-BENZODIAZEPINES)	B
80370 - SKELETAL MUSCLE RELAXANTS; 3 OR MORE	B
80371 - STIMULANTS, SYNTHETIC	B
80372 - TAPENTADOL	B
80373 - TRAMADOL	B
80377 - DRUG(S) OR SUBSTANCE(S), DEFINITIVE, QUALITATIVE OR QUANTITATIVE, NOT OTHERWISE SPECIFIED; 7 OR MORE	B
83992 - PHENCYCLIDINE (PCP)	E1

PRESUMPTIVE AND DEFINITIVE DRUG TEST CODING FOR MEDICARE

When billing definitive drug testing, as these codes represent, Medicare requires OPPS facilities to report one of the HCPCS G0480-G0483, one of which can be billed only once per day. The count of definitive drugs is per drug class, not per drug.

G0480 – Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to gc/ms (any type, single or tandem) and lc/ms (any type, single or tandem and excluding immunoassays (e.g., ia, eia, elisa, emit, fpia) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed

G0481 – Drug test(s), definitive, … per day; 8-14 drug class(es), including metabolite(s) if performed

G0482 – Drug test(s), definitive, … per day; 15-21 drug class(es), including metabolite(s) if performed

G0483 – Drug test(s), definitive, … per day; 22 or more drug class(es), including metabolite(s) if performed

PRESUMPTIVE AND DEFINITIVE DRUG TEST CODING FOR MEDICARE

The Toxassure test covers over 22 drug classes among the CPT® codes listed, therefore we recommend reporting one unit of G0483 for the definitive testing. This may be reported together with 80307 for the presumptive testing, it should not cause a CCI edit:

CCI Edits OPPS (v27.0, Jan-Mar 2021)

Codes and/or Descriptions: **G0483,80307**

Remove 'OK To Bill' Results | Export to PDF | Export to Excel | Copy to Clipboar

PRIME CPT	SECOND CPT	Edit Type	GB Modifier Indicato
G0483 - DRUG TEST(S), DEFINITIVE, UTILIZING (1) DRUG IDENTIFICATION METHODS ABLE TO IDENTIFY INDIVIDUAL DRUGS AND DISTINGUISH BETWEEN STRUCTURAL ISOMERS (BUT NOT NECESSARILY STEREOISOMERS), INCLUDING, BUT NOT LIMITED TO GC/MS (ANY TYPE, SINGLE OR TANDEM) AND LC/MS (ANY TYPE, SINGLE OR TANDEM AND EXCLUDING IMMUNOASSAYS (E.G., IA, EIA, ELISA, EMIT, FPIA) AND ENZYMATIC METHODS (E.G., ALCOHOL DEHYDROGENASE)), (2) STABLE ISOTOPE OR OTHER UNIVERSALLY RECOGNIZED INTERNAL STANDARDS IN ALL SAMPLES (E.G., TO CONTROL FOR MATRIX EFFECTS, INTERFERENCES AND VARIATIONS IN SIGNAL STRENGTH), AND (3) METHOD OR DRUG-SPECIFIC CALIBRATION AND MATRIX-MATCHED QUALITY CONTROL MATERIAL (E.G., TO CONTROL FOR INSTRUMENT VARIATIONS AND MASS SPECTRAL DRIFT); QUALITATIVE OR QUANTITATIVE, ALL SOURCES, INCLUDES SPECIMEN VALIDITY TESTING, PER DAY; 22 OR MORE DRUG CLASS(ES), INCLUDING METABOLITE(S) IF PERFORMED	80307 - DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES; BY INSTRUMENT CHEMISTRY ANALYZERS (EG, UTILIZING IMMUNOASSAY [EG, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), CHROMATOGRAPHY (EG, GC, HPLC), AND MASS SPECTROMETRY EITHER WITH OR WITHOUT CHROMATOGRAPHY, (EG, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE		OK to bil

Attached our paper on billing Medicare for drug tests.

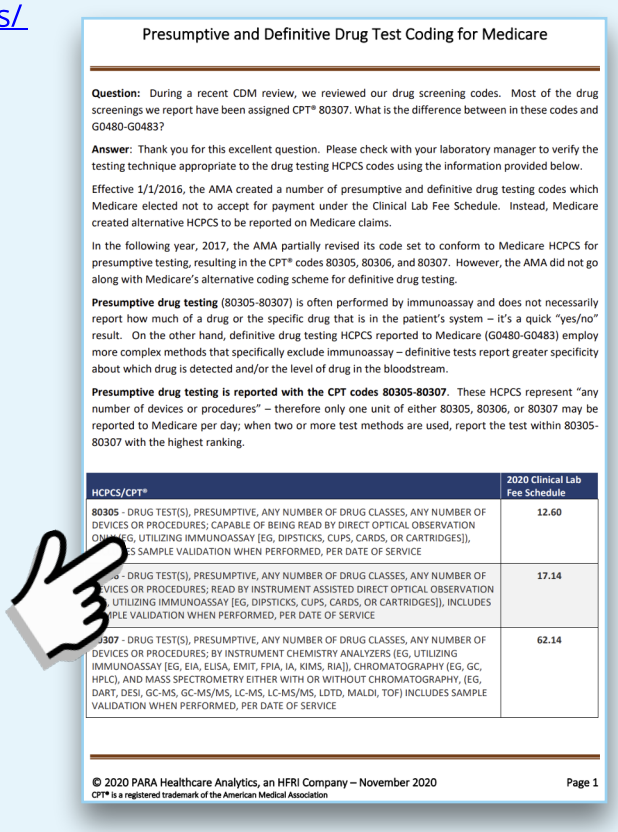
Incidentally, the MAC in your region has published a Local Coverage Determination on this code, which is accompanied by a Local Coverage Article that identifies the ICD10 codes that will support medical necessity. The LCD and LCA are found here:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35006&ContrTypeId=12&ver=119&ContrNum=04111&ContrId=331&ContrVer=1&SearchType=Advanced&CoverageSelection=Local&ArticleType=Ed|Key|SAD|FAQ&PolicyType=Both&s=---&Cntrctr=331&ICD=&CptHcpcsCodeG0483&kq=true&bc=IAAAACAAAAAA&

Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)

https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56645&ver=23&LCDId=35006&ContrId=331&ContrVer=1&SearchType=Advanced&CoverageSelection=Local&ArticleType=Ed%7cKey%7cSAD%7cFAQ&PolicyType=Both&s=%26mdash%3b-&Cntrctr=331&ICD=&kq=true&bc=IAAAACAAIAAA&

Local Coverage Article: Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing (A56645)



Presumptive and Definitive Drug Test Coding for Medicare

Question: During a recent CDM review, we reviewed our drug screening codes. Most of the drug screenings we report have been assigned CPT® 80307. What is the difference between in these codes and G0480-G0483?

Answer: Thank you for this excellent question. Please check with your laboratory manager to verify the testing technique appropriate to the drug testing HCPCS codes using the information provided below.

Effective 1/1/2016, the AMA created a number of presumptive and definitive drug testing codes which Medicare elected not to accept for payment under the Clinical Lab Fee Schedule. Instead, Medicare created alternative HCPCS to be reported on Medicare claims.

In the following year, 2017, the AMA partially revised its code set to conform to Medicare HCPCS for presumptive testing, resulting in the CPT® codes 80305, 80306, and 80307. However, the AMA did not go along with Medicare's alternative coding scheme for definitive drug testing.

Presumptive drug testing (80305-80307) is often performed by immunoassay and does not necessarily report how much of a drug or the specific drug that is in the patient's system – it's a quick "yes/no" result. On the other hand, definitive drug testing HCPCS reported to Medicare (G0480-G0483) employ more complex methods that specifically exclude immunoassay – definitive tests report greater specificity about which drug is detected and/or the level of drug in the bloodstream.

Presumptive drug testing is reported with the CPT codes 80305-80307. These HCPCS represent "any number of devices or procedures" – therefore only one unit of either 80305, 80306, or 80307 may be reported to Medicare per day; when two or more test methods are used, report the test within 80305-80307 with the highest ranking.

HCPCS/CPT®	2020 Clinical Lab Fee Schedule
80305 - DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES; CAPABLE OF BEING READ BY DIRECT OPTICAL OBSERVATION ONLY [EG, UTILIZING IMMUNOASSAY [EG, DIPSTICKS, CUPS, CARDS, OR CARTRIDGES]), INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE	12.60
80306 - DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES; READ BY INSTRUMENT ASSISTED DIRECT OPTICAL OBSERVATION [EG, UTILIZING IMMUNOASSAY [EG, DIPSTICKS, CUPS, CARDS, OR CARTRIDGES]), INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE	17.14
80307 - DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES; BY INSTRUMENT CHEMISTRY ANALYZERS (EG, UTILIZING IMMUNOASSAY [EG, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), CHROMATOGRAPHY (EG, GC, HPLC), AND MASS SPECTROMETRY EITHER WITH OR WITHOUT CHROMATOGRAPHY, (EG, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE	62.14

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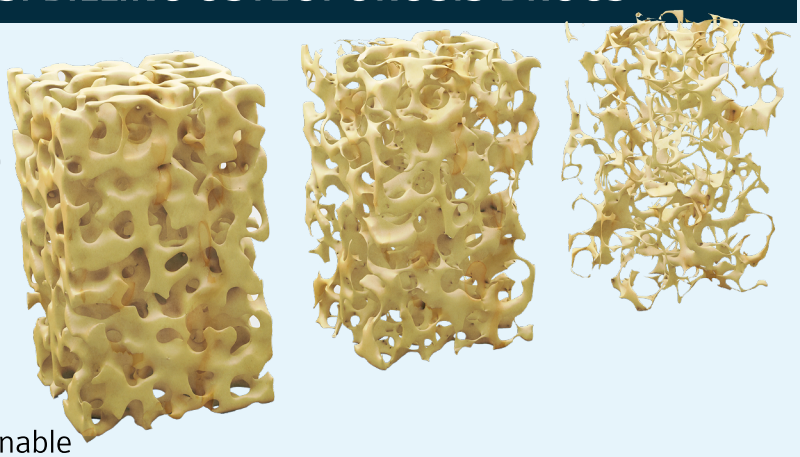
HOME HEALTH PROVIDERS: BILLING OSTEOPOROSIS DRUGS



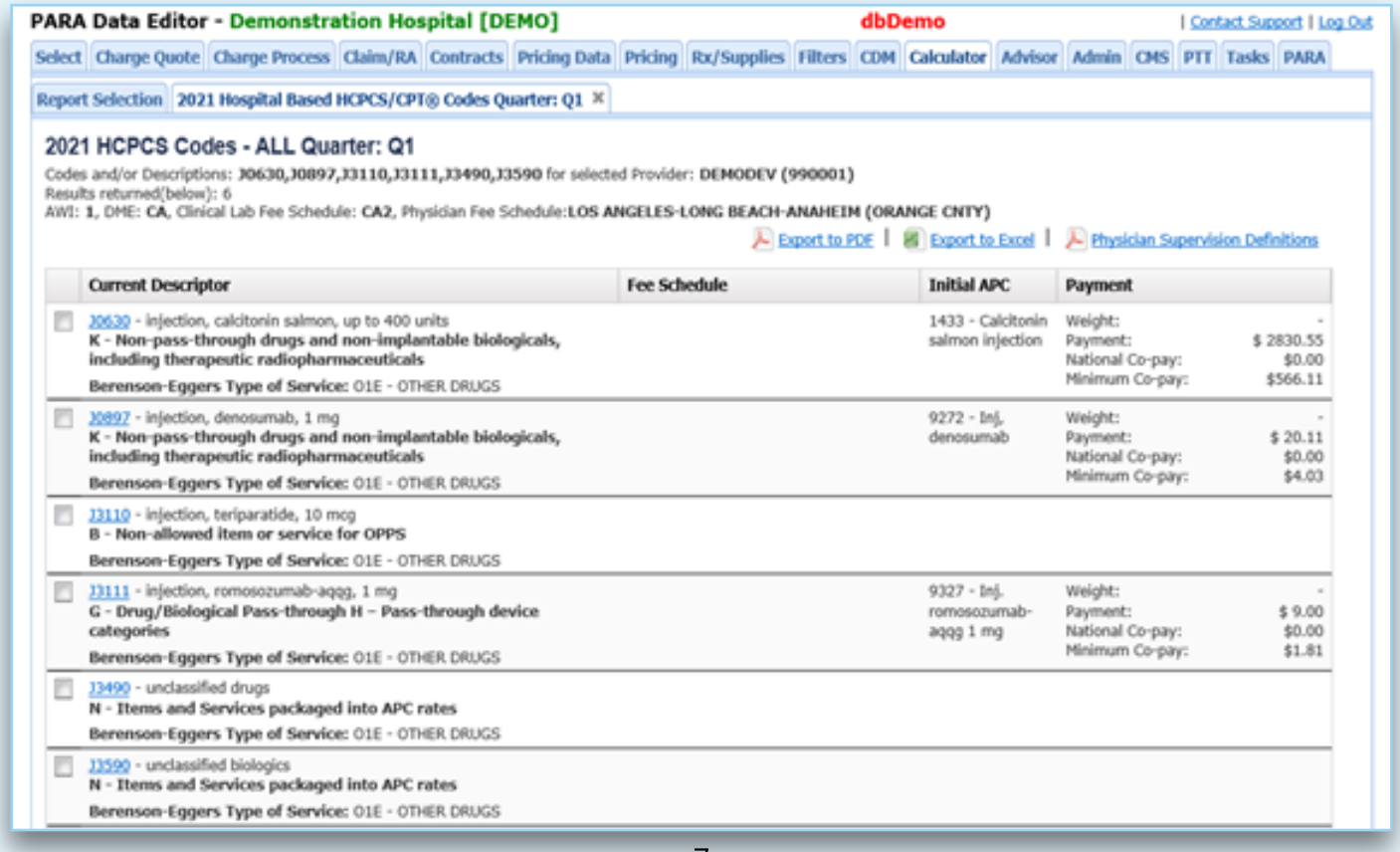
In Home Health, consolidated billing rules require the primary home health agency (HHA) to bill osteoporosis drugs for beneficiaries meeting the coverage requirements for these drugs, if the patient is under a certified HHA-PPS episode.

The actual Osteoporosis drug (s) are excluded from reimbursement under the Home Health Prospective Payment System (HHA-PPS) and are instead reimbursed to providers on a reasonable cost basis.

Reimbursement for administering the drug is included in the HH-PPS episode payment. The primary HHA should submit these charges with other skilled nursing visits on the HH-PPS claim using type of bill (TOB) 329, along with all other applicable home health related services provided by the HHA during the episode.

Providers seeking reimbursement for this service should:

- Ensure the beneficiary is entitled to Medicare Part B
- The date of service for the covered osteoporosis drug(s) must fall within the start and end-dates of an existing HHA PPS episode
- The provider number on the claim for osteoporosis drug(s) must also match the provider number that established the home health episode during which the drug(s) were administered
- Of note: HHAs should be aware if Medicare denies the skilled nursing visit during which the osteoporosis drug was administered, the charges for the drug will not be paid as well by Medicare.



HOME HEALTH PROVIDERS: BILLING OSTEOPOROSIS DRUGS

In addition to the usual information that is required on an HHA -PPS Medicare claim, the following table will identify the specific data that is required for osteoporosis drug(s) reporting:

Field Name	Description
Type of bill (TOB)	34X – HHA visit(s) provided on an outpatient basis
Statement dates from/To	Enter the dates of service for the billing period. NOTE: these dates should fall within the "FROM" and "TO" dates for the HH-PPS episode of care being provided by the primary HHA
Revenue Code	Enter the revenue code 0636 - Pharmacy
HCPCS	Enter the appropriate HCPCS code: J0630 – Drugs containing calcitonin J3110 – Drugs containing teriparatide (Forteo) J0897 - Drugs containing denosumab (Xgeva, Prolia) J3111 - Drugs containing romosozumab-aqqg (Evenity) J3490 – Drugs that are FDA approved and awaiting a specific HCPCS assignment J3590 - Drugs that are FDA approved and awaiting a specific HCPCS assignment (Tymlos)
Total Unit/Covered Unit	Enter units as defined by HCPCS code: **J0630** – 1 unit for every 100-400 units furnished during billing period 2 units for every 401-800 units furnished during billing period 3 units for every 801 -1200 units furnished during billing period 4 units for every 1201 -1600 units furnished during billing period 5 units for every 1601 -2000 units furnished during billing period 6 units for every 2001- 2400 units furnished during billing period **J3110** – Report 1 units for every 10mcg furnished during billing period J0897 - Report 1 unit for each 1mg dose provided during the billing period J3111 – Report 1 unit for each 1mg does provided during the billing period **J3490** – Report units as defined by the HCPCS code
Total Charges	Enter the charge per revenue code for the osteoporosis drug
Service date	Enter the line item **date of service** the drug was provided
Diagnosis Codes	Enter the ICD-9 code 733.01 (for DOS on or before October 01, 2015), or the ICD-10 code M810 (for DOS on or after October 01, 2015)

HOME HEALTH PROVIDERS: BILLING OSTEOPOROSIS DRUGS

References for this article:

https://www.cms.gov/files/document/r10670otn.pdf

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10670	**Date: March 12, 2021**
	Change Request 12016

Transmittal 10552, dated January 5, 2021, is being rescinded and replaced by Transmittal 10670, dated, March 12, 2021 to update the effective date from date of service to receipt date. All other information remains the same.

SUBJECT: Modification to Existing Common Working File (CWF) Edits for Osteoporosis Drug Codes Billable on Home Health Claims

I. SUMMARY OF CHANGES: This change request adds instructions to modify the existing CWF edits '5384' and '7283' for billing and paying additional codes for osteoporosis drugs under the home health benefit.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf

Chapter 7, Section 50.4.3

50.4.3 – Covered Osteoporosis Drugs

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Sections 1861(m) and 1861(kk) of the Act provide for coverage of FDA approved injectable drugs for the treatment of osteoporosis. These drugs are expected to be provided by an HHA to female beneficiaries who are currently receiving services under an open home health plan of care, who meet existing coverage criteria for the home health benefit and who meet the criteria listed below. These drugs are covered on a cost basis when provided by an HHA under the circumstances listed below.

The home health visit (i.e., the skilled nurse's visit) to administer the drug is covered under all fee-for-service Medicare (Part A or Part B) home health coverage rules (see section 30 above). Coverage of the drug is limited to female beneficiaries who meet each of the following criteria:

HOME HEALTH PROVIDERS: BILLING OSTEOPOROSIS DRUGS

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf
Chapter 10 Sections: 10, 20 and 90.1

Medicare Claims Processing Manual
Chapter 10 - Home Health Agency Billing

Table of Contents
(Rev. 10254, 07-31-20)
(Rev. 10274, 08-07-20)

https://www.cms.gov/files/document/r10274cp.pdf

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10274	**Date: August 7, 2020**
	Change Request 11846

SUBJECT: Update to Osteoporosis Drug Codes Billable on Home Health Claims

I. SUMMARY OF CHANGES: This change request adds instructions for billing and payment of additional codes for osteoporosis drugs under the home health benefit.

EFFECTIVE DATE: January 1, 2021 - Claims received on and after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2021

BIOFIRE® RESPIRATORY PANEL CODING AND COVERAGE UPDATE

Effective April 1, 2021, three proprietary CPT® codes for Biofire® respiratory panel lab tests will be deleted – 0098U, 0099U, and 0100U. The change was listed in the November 2020 CPT® Panel meeting agenda:

https://www.ama-assn.org/system/files/2021-01/cpt-pla-codes-short.pdf

AMA AMERICAN MEDICAL ASSOCIATION

CPT® Proprietary Laboratory Analyses (PLA) Codes: Short Descriptors

It is important to note that further CPT Editorial Panel (Panel) or Executive Committee actions may affect these codes and/or descriptors. For this reason, code numbers and/or descriptor language in the CPT code set may differ at the time of publication. In addition, further Panel actions may result in gaps in code number sequencing.

Most recent changes to the CPT® Proprietary Laboratory Analyses (PLA) Short Descriptor document

- Addition of 6 PLA codes (0242U-0247U) and deletion of 3 PLA codes (0098U-0100U) accepted by the CPT Editorial Panel.
- Deleted codes in this document appear with a ~~strikethrough~~.

Some have speculated that since COVID-19 was not among the targets tested in these three CPT®s, Biofire® withdrew the codes from active use.

0202U Deemed Non-Covered. Meanwhile, hospitals and laboratories across the US have found that the 22-target Biofire® respiratory panel HCPCS 0202U is non-covered by most MAC's through Local Coverage Determinations. This has confounded some purchasers of the test since the national Clinical Lab Fee Schedule rate was hefty $416.78.

In its response to comments received in the course of adopting LCD L37764, WPS offers the following rationale to a commenter who attempted to persuade the MAC that multiplex testing for more than five targets should be covered:

Local Coverage Article for Response to Comments: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (DL37764) (cms.gov)

BIOFIRE® BY BIOMÉRIEUX

BIOFIRE® RESPIRATORY PANEL CODING AND COVERAGE UPDATE

"The commenter makes a hypothetical argument pointing out that there potentially exists a clinical application for a respiratory viral panel in some patients so as to lead to a better outcome.

However, the commenter does not provide evidence that any particular panel (where a panel is a specified group of tests which must be ordered together) or any group of panels has clinical utility for a particular population or for beneficiaries with well identified indications. For coverage purposes Palmetto GBA must make coverage decisions regarding specific panels or specific selections of pathogens for specific indications. As such, while we agree that it is conceivable that there exists a patient population who might benefit from a particular group of multiple respiratory viral tests, at this point no evidence has been brought to our attention regarding how a clinician is to identify such a population for any specific available test. Moreover, the only virus group in the core set of pathogens for which treatment is widely (but still not universally) appropriate is influenza.

For those cases in which more than one causative virus could be related to the observed signs or symptoms (either due to overlap of typical symptoms or the presence of atypical symptoms), and diagnosis of a specific causative agent is expected to alter treatment in a way that improves the outcome, the clinician could order individual viral tests for which a result would be expected to lead to clinically actionable information.

If new evidence develops demonstrating that a particular panel or the use of a particular set of respiratory viral tests, which match the components of a panel, leads to enhanced patient outcomes we would be willing to reconsider this coverage determination. Draft LCDs and established LCDs limiting coverage of multiplex testing have been adopted by most MACs. Multiplex PCR respiratory viral panels of 6 or more pathogens are deemed not medically necessary and therefore non-covered.

Here are links to a few LCDs from MACs across the country

Novita

Proposed Local Coverage Determination for Respiratory Pathogen Panel Testing (DL38916) (cms.gov)

WPS

Local Coverage Determination for MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37764) (cms.gov)

Noridian

Local Coverage Determination for MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37315) (cms.gov)

CGS

Local Coverage Determination for MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37348) (cms.gov)

Palmetto

Local Coverage Article for Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (cms.gov)

First Coast

Proposed Local Coverage Determination for Respiratory Pathogen Panel Testing (DL38918) (cms.gov)

BIOFIRE® RESPIRATORY PANEL CODING AND COVERAGE UPDATE

PARA inquired of CMS whether hospitals which had purchased the 0202U test could report a lower target-count CPT®, such as 87631, in lieu of 0202U in order to receive some reimbursement for the spent expense of the 22-target respiratory panel.CMS responded by referring the question to local MACs for guidance.

MACs tend to limit interaction to identified provider representatives within each jurisdiction; therefore, PARA recommends that hospitals and laboratories reach out to its regional MAC for this coding guidance.

A copy of the email from CMS appears here.

Tue 3/16/2021 3:18 AM

CMS MCD Feedback <MCDFeedback@cms.hhs.gov>

RE: 0202U vs 87631

To

Thank you for your question. While we aren't able to provide you with guidance regarding the possible coding scenario you describe below we do recommend reaching out directly to each MAC representing the geographic area of your clients. At least some of the MACs may have previously encountered similar situations.

From: Monica Lelevich <mlelevich@para-hcfs.com>
Sent: Thursday, March 11, 2021 1:32 PM
To: CMS MCD Feedback <MCDFeedback@cms.hhs.gov>
Subject: 0202U vs 87631 - JOANNA

Greetings,

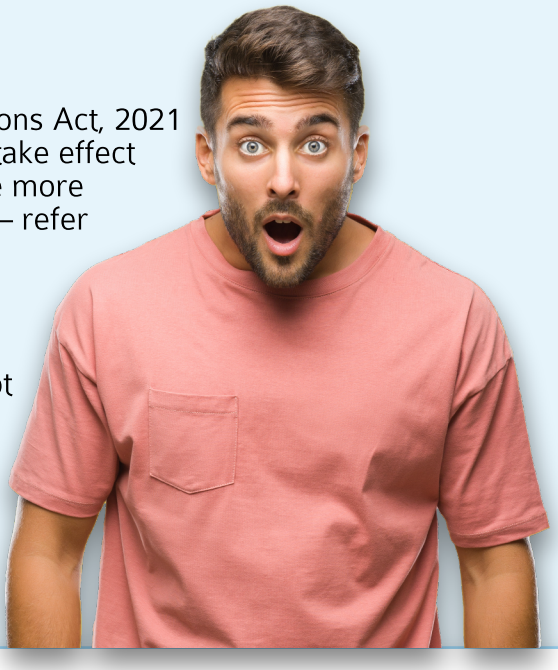
I represent a revenue cycle consulting firm with hospital clients across the US. Several of our clients have purchased Biofire laboratory equipment in order to perform multiplex testing, such as HCPCS 0202U, which tests a single specimen for 22 target organisms which may have caused a respiratory infection.

Most MAC's have adopted an LCD which does not deem multiplex testing for more than 5 targets to be supported by Medical Necessity, so our clients cannot be paid for testing done on the new equipment.

Since our clients have already invested in the technology to report 22 targets in one test, and since the test methodology is the same as that described by the HCPCS 87631, would it be acceptable for hospitals to report 87631 if the hospital agrees to accept that code as payment in full, even though more than 5 targets were evaluated?

HCPCS/CPT®	OPPS Status	Clinical Lab Fee Schedule
0202U - INFECTIOUS DISEASE (BACTERIAL OR VIRAL RESPIRATORY TRACT INFECTION), PATHOGEN-SPECIFIC NUCLEIC ACID (DNA OR RNA), 22 TARGETS INCLUDING SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2), QUALITATIVE RT-PCR, NASOPHARYNGEAL SWAB, EACH PATHOGEN REPORTED AS DETECTED OR NOT DETECTED	A	$416.78
87631 - INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); RESPIRATORY VIRUS (EG, ADENOVIRUS, INFLUENZA VIRUS, CORONAVIRUS, METAPNEUMOVIRUS, PARAINFLUENZA VIRUS, RESPIRATORY SYNCYTIAL VIRUS, RHINOVIRUS), INCLUDES MULTIPLEX REVERSE TRANSCRIPTION, WHEN PERFORMED, AND MULTIPLEX AMPLIFIED PROBE TECHNIQUE, MULTIPLE TYPES OR SUBTYPES, 3-5 TARGETS	Q4	$142.63

CONSOLIDATED APPROPRIATIONS ACT, 2021 -- NO SURPRISES ACT



Background and Overview

The No Surprises Act was part of the Consolidated Appropriations Act, 2021 signed into law on December 27, 2020.The provisions will not take effect until 1/1/2022, and agency rulemaking during 2021 will provide more specific guidance.The full text is published at the following link – refer to Division BB:

https://www.govtrack.us/congress/bills/116/hr133/text/enr

Surprise billing is the unexpectedly high financial liability that can be incurred by an insured patient when the patient does not know that a healthcare provider or facility is out-of-network, learning that the insurance benefits for medical expenses are minimal only after the services have been performed.

Surprise bills can arise in an emergency when the patient has no ability to select the facility or provider rendering the services. Surprise bills are also a commonplace when a patient receives planned care, for example when a patient receives care at an in-network facility but finds out after the fact that a provider who treated the patient is out-of-network, such as pathologists, radiologists, and anesthesiologists.

Division BB

Private Health Insurance and Public Health Provisions

Sec. 1. Table of contents

The table of contents of the division is as follows:

Division BB—Private Health Insurance and Public Health Provisions

Sec. 1. Table of contents.

Title I—No Surprises Act

The new law establishes a required process to resolve payment disputes between plans and providers, so that patient liability is not used as leverage between the provider and the plan.The legislation allows negotiation between the parties and imposes a prescribed arbitration process if negotiations fail. The arbitration methodology is applicable to providers and payers, with the most notable provider being air ambulances. The new law does not include a minimum negotiated payment rate to trigger arbitration.

The arbitration process, as outlined in the law, can be described as a baseball-style; meaning each party submits an offer and basis for that offer, and the mediator selects one of the offers. The decision is final, and payment must be made within thirty (30) days. Providers and payers cannot initiate a new arbitration process for ninety (90) days for the same items or services.

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The table below indicates the key takeaways of the new law:

Issue	Provision
Covered Services	Emergency services (including certain stabilization), air ambulances, and non-emergency services provided at an in-network facility by an out-of-network provider are covered.
Patient Responsibility	The patient is only responsible for the cost-sharing amount that would apply if the services had been provided at in-network facility or provider.
Minimum Payment	There is no minimum or median rate.
Notice and Consent	For non-emergency services, if providers meet specified notice and consent requirements, they may balance bill the patient.
Treatment of Ancillary Services	Providers may not balance bill for ancillary services (as defined in the CAA).
Independent Dispute Resolution (or arbitration)	After a 30-day negotiating period, if no agreement reached, an independent dispute resolution entity is selected and has thirty (30) days to determine payment amount. Payment must be one of the amounts submitted by either party. The party has thirty (30) days to make the payment.

While the framework is now law, many of the requirements will require additional agency rulemaking. Detailed regulations will be promulgated to establish the independent dispute resolution process. With the changes to the Presidential Administration and the implementation date of January 01, 2022, this leaves room for stakeholder input.Proposed regulations are expected to be published by mid-year.

Highlights of the prohibitions contained within the "no surprises" billing rules and dispute resolution process are provided below.Additional details contained within regulations to be promulgated during 2021 will be reported when they are finalized.

Prohibition on Balance Billing: Emergency Situations

The CAA prohibits providers and plans from balance billing patients for emergency services, regardless of the in-network or out-of-network status of the facility or provider treating the patient. The patient is only responsible for the cost-sharing amount, such as; co-payments and deductibles, that would apply if the services had been provided at in-network facility and in-network provider.

Patient cost-sharing cannot be greater than the recognized amount and will count toward any in-network deductible or out-of-pocket maximums. This recognized amount may either be

- Determined by existing state law or state regulations, or
- *If no state law is in place, the qualifying payment amount (defined in the CAA as "the median contracted rate recognized by the plan as the total maximum payment provided on January 31, 2019, for the same or similar item or service, by a similar provider, in the same geographic region") and,

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- The qualifying payment amount will be increased annually by the consumer price index

The plan will be required to send a payment or notice of denial to the provider within thirty (30) days following the receipt of the initial bill from the provider.

*HHS will establish a methodology to determine this amount.

HHS, in conjunction with US Department of Labor and Treasury, must issue regulations by July 01, 2021, to establish the following:

- Methodology the plan will use to determine the qualifying payment amount differentiating by individual market, large group market and same group market
- Any information the plan must share with the out-of-network facility or provider when determining the payment amount
- Geographic regions, taking into account access to items and services in rural and underserved areas, including health professional shortage areas
- Process to receive complaints of violations of the requirements

In addition, HHS in conjunction with US Department of Labor and Treasury, must issue regulations by October 01, 2021, to establish an audit process to ensure that plans are applying the qualifying payment amount for emergency services.

HHS in conjunction with US Department of Labor and Treasury would also need to issue regulations that would apply to

- Balance Billing Non-Emergency Situations, and
- Air Ambulances

Notice and Consent

HHS, is working in conjunction with the Departments of Labor and Treasury, to issue guidance on Notice and Consents by July 01, 2021. The guidance will consist of the consent format and details of the requirements.

In the scenario of non-emergency services, the law lays out specific notice and consent requirements that, if met, permit balance billing. This exception does not apply to certain ancillary services outlined below:

Providers who are eligible to request a consent waiver must include a written notice to the patient no later than 72 hours before the date on which the items or services are provided. This notice must include the following information:

- Notification that the provider or facility is out-of-network
- Clear statement that consent is optional and the patient can seek care from an in-network provider
- Good faith estimates of the amount the patient may be charged
- If the service is to be furnished by an out-of-network provider in an in-network facility, a list of in-network providers who are able to provide the service
- Information on whether prior authorization is needed

Once the patient received the notice, the patient has the option to consent. The notice must be signed by the patient where the patient acknowledges that they were provided with written notice and informed about the payment, indicating how it may affect cost-sharing. The consent must include the date on which the patient received the notice and the date on which the patient signed the consent.

The plan must retain the consent for seven (7) years.

Ancillary Services

If the out-of-network provider meets certain notice and consent requirements, the patient may be balanced billed. This, however, does not apply for specified ancillary services.

The specific ancillary services outlined below, may not be balance billed regardless of whether they are provided by a physician or non-physician practitioner, and items and services provided by assistant surgeons, hospitalists and intensivists

1. Services provided at an in-network facility related to
    - Emergency Medicine
    - Anesthesiology
    - Pathology
    - Radiology
    - Laboratory and Neonatology
2. Diagnostic services
    - Including radiology and laboratory services
3. Items and services provided by a non-participating provider if there is no participating provider who can furnish such item or service at the facility
4. Other items and services provided by other specialty practitioners as HHS specifies through future rulemaking.

HHS may, through rulemaking, establish and periodically update a list of advanced diagnostic laboratory tests that would not be subject to this prohibition and thus would be eligible for the balance billing notice and consent exception rule.

Independent Dispute Resolution (IDR) Process

To assist with payment disputes between providers and plans, the law will enable the use of an arbitration process, which is known as independent dispute resolution (IDR). This process will be utilized to settle disputed emergency and non-emergency services that fall within the definitions of surprised billing prohibitions.

This process must be initiated within thirty (30) days of the provider receiving an initial payment or notice of denial of payment from the plan. The provider and plan then have up to thirty (30) days for open negotiation. During this allotted time period, the provider and plan can attempt to come to agreement without formally initiating the IDR process. The provider and plan do not have to use all thirty (30) days if either party wishes to go to arbitration.

However, following the end of the thirty (30) days, the provider or plan have four (4) days to initiate the IDR process. The initiating party must notify the other party and HHS. The parties can continue to negotiate after one (1) party initiates the IDR process.

Providers and plans can consolidate (or batch) similar items and services in the IDR process. However, payment for the items and services must be made by the same plan, and the items and services must be furnished by the same provider or facility, be related to the treatment of a similar condition and be furnished within a thirty (30) day window. HHS has discretion to determine an alternative window for use in limited situations.

The law requires HHS, in conjunction with the Department of Labor and Treasury to issue regulations detailing the IDR resolution process and required documentation within one (1) year of enactment, or December 27, 2021.

For each calendar quarter beginning in CY 2022, HHA must publish specified performance metrics on the IDR process.

Independent Dispute Resolution (IDR) Entities

Entities must have medical, legal or other expertise to make the required determinations. Entities may not be a health plan or provider, or affiliated with plans or providers. The certification period lasts for five (5) years.

In addition, while the law does not speak to the ideal number of certified IDR entities, it does state that the process should allow for a sufficient number of entities. HHS may issue other requirements in forthcoming regulations..

The law requires HHS, in conjunction with the Department of Labor and Treasury, to establish a process to certify and re-certify IDR entities.

In addition, HHS is also tasked with providing a method by which the parties involved in the arbitration can choose from the available certified IDR entities. The parties have three (3) days to choose. If no agreement is made, HHS will choose the IDR entity with six (6) days.

Payment Determination

Once the IDR entity is chosen, the arbiter has thirty (30) days to issue a payment determination. Within ten (10) days of the IDR entity selection, the two parties must submit a payment offer and other information requested by the IDR entity. The IDR entity has been granted the flexibility to consider other factors, such as:

- Similar payment amounts in the same geographic region (which will be defined by HHS)
- The training level, experience, quality and outcomes measurements of the provider or facility
- The market share held by the out-of-network provider or plan in the geographic region
- The condition and complexity of the care needed
- Teaching status, case mix and scope of services of the out-of-network facility
- Demonstration of good faith efforts by the provider or plan to enter into network agreements, and if available and relevant, contracted rates for the previous four (4) years

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The CAA includes separate factors for IDR entity consideration for air ambulances. These include:

- Quality and outcomes measurements of the provider that furnished such services;
- Acuity of the individual receiving such services or the complexity of the services;
- Training, experience and quality of the medical personnel
- Ambulance, vehicle type
- Population density of the pick-up location
- Demonstrations of good faith efforts (or lack thereof) by the participating provider or facility, or the plan, or issuer, to enter into network agreements
- If applicable, contracted rates between provider and the plan, or issuer, as applicable, during the previous four (4) plan years

The IDR entity may NOT consider such factors as usual and customary charges or the payment amount for the same item or service by a public payer, for example, Medicare or Medicaid.

The final payment amount must be one of the amounts submitted by either party. Once the payment determination is made, it is final and binding, and is not subject to further judicial review, except in specific circumstances. The party that initially submitted the request for the IDR process may not initiate another IDR process with the same party for the same item or service for a 90-day period. The final payment must be made within 30 days of the final determination.

HHS has discretion to modify any of these deadlines under extenuating circumstances (which HHS also can define), with the exception of the date required to establish the IDR process (one year from enactment) and the 30-day deadline for final payment.

Further, within two (2) years of enactment, HHS, in conjunction with Departments of Labor and Treasury, will issue a report examining plans' pattern or practice of routine denial, low payment or down-coding of claims, or other abuse of the 90-day period.

Cost of Independent Dispute Resolution Process

The party whose offer is not chosen must pay all fees charged by the IDR entity. If the parties reach an agreement independently, but within the IDR process period, the IDR fees will be split between the parties.

In addition to the cost of the IDR entity, HHS may prescribe fees for parties that participate in the IDR process to offset expenditures by HHS in carrying out the IDR process.

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Patient Protections

The CAA allows for some flexibility for patients when choosing certain providers. The following requirements are in effect for plan years on or after January 01, 2022.

- If a plan requires the patient to identify a primary care provider, the patient can choose a participating primary care provider
- If a plan requires the patient to identify a pediatric primary care provider, the patient can choose any in-network physician (including allopathic or osteopathic) who specializes in pediatrics
- A plan cannot require a referral or authorization for women who seek obstetrical or gynecological care from an in-network provider who specializes in obstetrics or gynecology

Also, beginning January 01, 2022, providers will be required to make a one-page notice available to insured patients with information regarding surprise billing prohibitions, including state requirements, as well as contact information for state and federal entities to report surprise billing violations.

Plans will be required to include deductible information, out-of-pocket maximum limitations and customer assistance information on electronic or physical beneficiary insurance cards.

Treatment of Uninsured under CAA

The law establishes a separate provider-patient dispute resolution process for uninsured individuals. The patient must have been billed "substantially in excess of" a good faith estimates of the expected charges from a provider or plan. Similar to the arbitration process for insured patients, HHS is tasked with establishing a process for certifying IDR entities and a method for selecting a certified IDR entity. These entities will determine a payment amount. There are similar administration fees that must be established by HHS.

This section of the law is not as descriptive as other provisions, and there are no set time frames associated with the resolution process. HHS is required to issue regulations by January 01, 2022 for all of the components outlined in this section of the law.

Enforcement

Both states and HHS are permitted to enforce provisions of the law. Violations are subject to civil money penalties up to $10,000. HHS has the ability to establish a hardship exemption for these penalties and waive the penalties for providers and facilities that did not knowingly violate the requirements laid out in the law.

Interaction with state laws

Several states have already enacted comprehensive surprise billing laws. The new federal law defers to **existing state requirements with respect to state-established payment amounts, meaning the CAA does not fully preempt or otherwise displace state payment standards.**

States can continue to pass surprise billing laws and regulations in the future.

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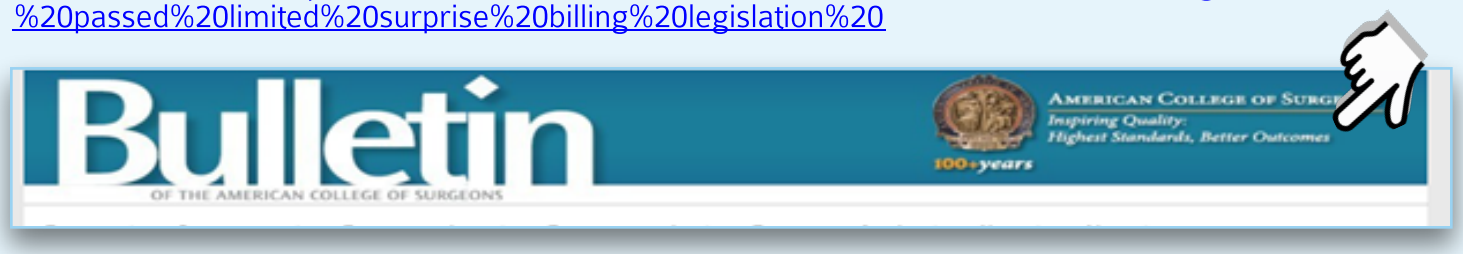
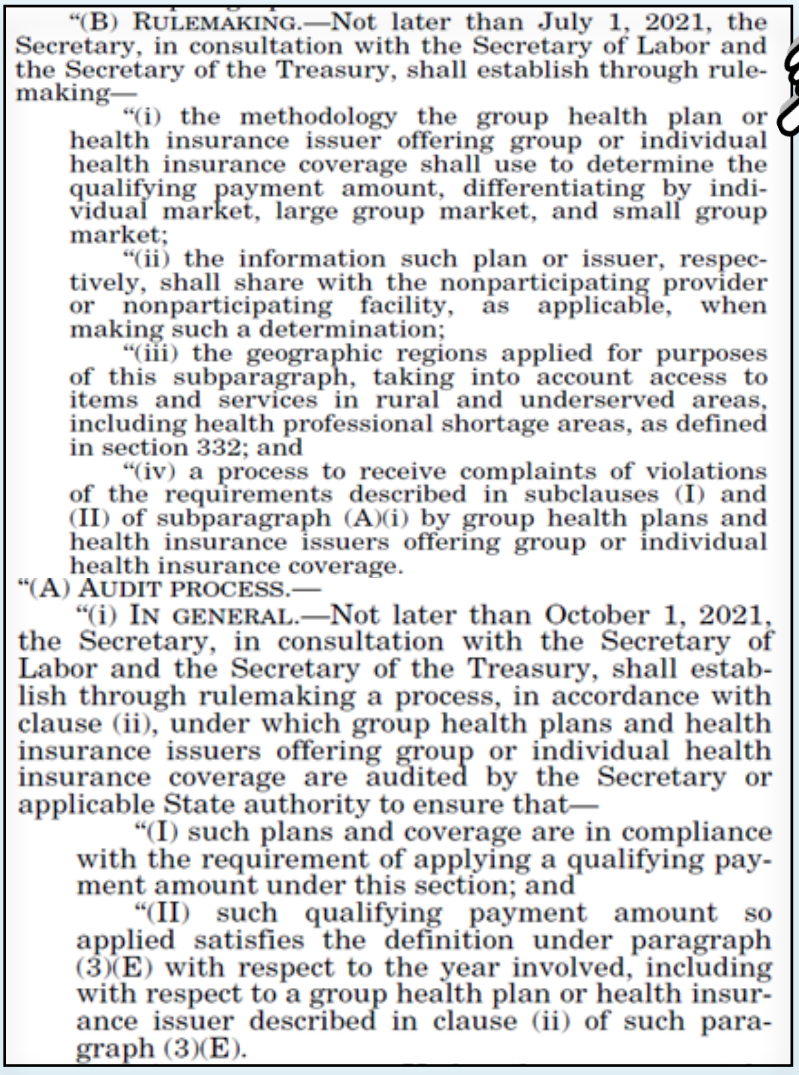
https://bulletin.facs.org/2019/11/state-legislatures-consider-surprise-billing-legislation-in-2019/#:~:text=As%20of%20January%202019%2C%20the%20Commonwealth%20Fund%20noted,Virginia%29%20had%20passed%20limited%20surprise%20billing%20legislation%20



In conclusion, surprise billing provisions in CAA means that opportunities for advocacy have shifted from Congress to the Administration. The surprise billing law has drawn criticism and praise, with providers, plans and patient groups sometimes advocating for differing positions. With the details of many important policies subject to agency rule making, stakeholders should be prepared to advocate for favorable definitions, processes and time frames.

References for this article:

https://www.govtrack.us/congress/bills/116/hr133/text



"(B) RULEMAKING.—Not later than July 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking—

"(i) the methodology the group health plan or health insurance issuer offering group or individual health insurance coverage shall use to determine the qualifying payment amount, differentiating by individual market, large group market, and small group market;

"(ii) the information such plan or issuer, respectively, shall share with the nonparticipating provider or nonparticipating facility, as applicable, when making such a determination;

"(iii) the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined in section 332; and

"(iv) a process to receive complaints of violations of the requirements described in subclauses (I) and (II) of subparagraph (A)(i) by group health plans and health insurance issuers offering group or individual health insurance coverage.

"(A) AUDIT PROCESS.—

"(i) IN GENERAL.—Not later than October 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking a process, in accordance with clause (ii), under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the Secretary or applicable State authority to ensure that—

"(I) such plans and coverage are in compliance with the requirement of applying a qualifying payment amount under this section; and

"(II) such qualifying payment amount so applied satisfies the definition under paragraph (3)(E) with respect to the year involved, including with respect to a group health plan or health insurance issuer described in clause (ii) of such paragraph (3)(E).

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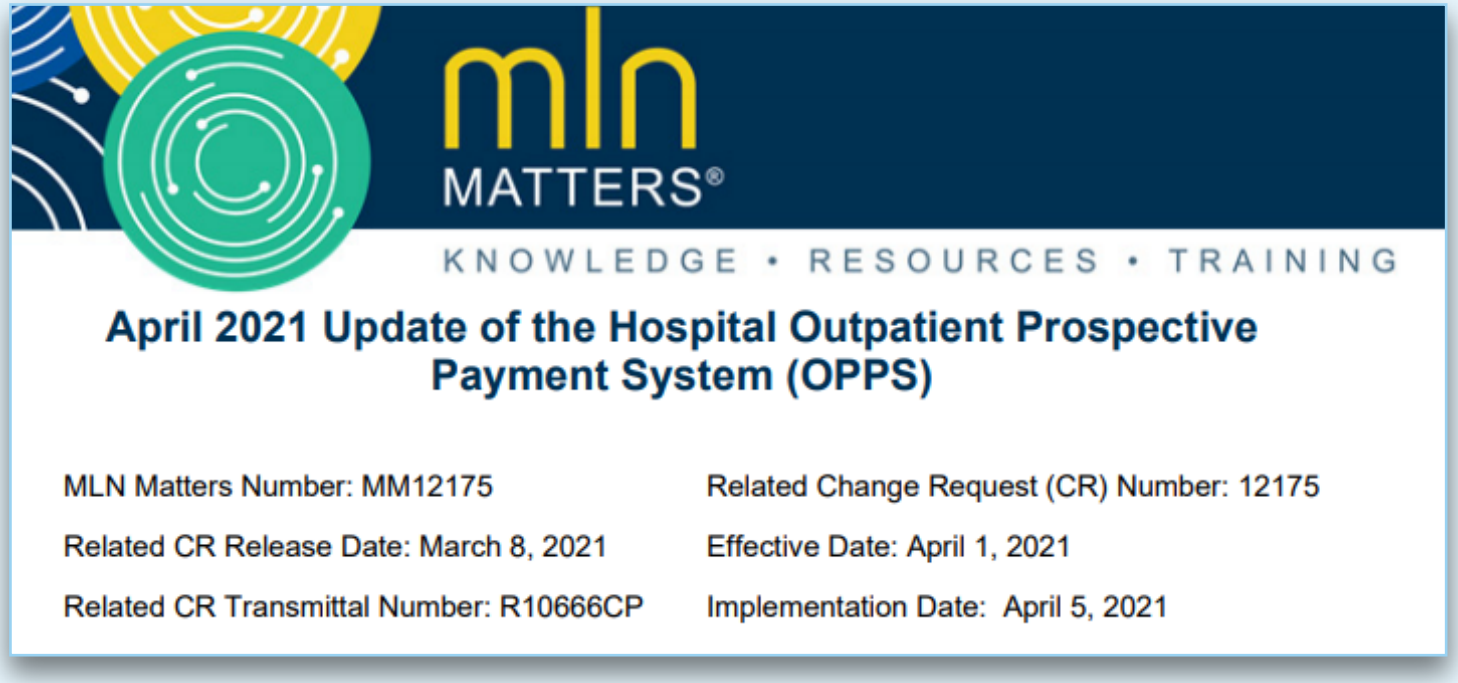
CMS issued Transmittal R1066CP with an MLN article "April 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)" on March 8, 2021.Eighteen HCPCS were deleted effective 4/1/2021, some of the deleted codes have been replaced with new HCPCS codes.Most of the newly added HCPCS were for proprietary laboratory testing and new pharmaceuticals.

https://www.cms.gov/files/document/mm12175.pdf



PARA will advise chargemaster clients by email of any line items in the hospital CDM require update as a result of a deleted HCPCS code; we will also provide a replacement HCPCS where available.(To take full advantage of **PARA** chargemaster support, clients are encouraged to upload a current CDM at least quarterly.)

The following summarizes the OPPS updates effective April 1, 2021.

- **Revised APC assignment:** Effective April 1, 2021, CMS reassigned OPPS APCs to Pfizer and Moderna COVID-19 administration codes. (The HCPCS are unchanged, only the payment APC changed.)

Old APC	APC Desciption	New APC	APC Description
1492	New Technology – Level 1B ($11-$20)	**9397**	Covid-19 Vaccine Administration Dose 1 of 2
1493	New Technology – Level 1C ($21-$30)	**9398**	Covid-19 Vaccine Administration Dose 2 of 2 or Single Dose Product

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Administration codes assigned rates from Addendum B will be available at the following webpage:

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

*Note:At time of print, the Addendum A and B updates were not yet published on the CMS.gov website

Addendum A and Addendum B Updates

Updates of Addendum A and B are posted quarterly to the OPPS website. These addenda are a "snapshot" of HCPCS codes and their status indicators, APC groups, and OPPS payment rates, that are in effect at the beginning of each quarter. The quarterly updates of Addendum A and Addendum B reflect the OPPS Pricer changes that are part of the quarterly OPPS recurring update notification transmittals.

The COVID vaccine codes with updated APC assignments are below:

Labeler	HCPCS	Type	Long Description
Pfizer	91300	Vaccine Product	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use
Pfizer	0001A	Administration Code	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/0.3mL dosage, diluent reconstituted; **first dose**
Pfizer	0002A	Administration Code	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/0.3mL dosage, diluent reconstituted; **second dose**
Moderna	91301	Vaccine Product	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use
Moderna	0011A	Administration Code	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/0.5mL dosage; **first dose**
Moderna	0012B	Administration Code	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/0.5mL dosage; **second dose**

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- **Johnson & Johnson COVID-19 Vaccine:** Effective February 27, 2021, under the FDA Emergency Use Authorization (EUA) of the Johnson & Johnson (Janssen) COVID-19 vaccine, providers may report HCPCS91303 for the vaccine product and 0031A for its single-dose administration. The payment rates will be published in the April Addendum B

- **Monoclonal AB Therapy for COVID-19:** CMS establish new HCPCS codes for Monoclonal Antibody Therapy treatments for COVID-19 effective on the date the FDA provided an EUA for each. Medicare covers these treatments during the Public Health Emergency (PHE) in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Medicare covers and pays for the monoclonal therapy through the COVID-19 vaccine program. Medicare expects that, at least initially, providers will receive the drug products free of charge.When the provider receives the product at no cost, Medicare will reimburse the administration of the monoclonal antibody drugs when reported with the unique M-code, it is not necessary to report the drug itself on claims to Medicare.

The following chart lists the effective dates and payment rates for each monoclonal antibody therapy code.

Monoclonal Drug	Effective Date	HCPCS	Description	Payment
Bamlanivimab	11/9/2020	M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring	$309.60
		Q0239	Injection, bamlanivimab-xxxx, 700 mg	$ 0.01
Casirivimab / Imdevimab	11/21/2020	M0243	intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	$309.60
		Q0243	Injection, casirivimab and imdevimab, 2400 mg	$ 0.01
Bamlanivimab / Etesevimab	02/09/2021	M0245	Bamlan and etesev infusion	$309.60
		Q0245	Injection, bamlanivimab and etesevimab, 2100 mg	$ 0.01

- New PLA Codes:Effective April 1, 2021, the AMA established the six following Proprietory Lab Analyses (PLA) codes; these have been assigned OPPS status A (paid under fee schedule) or Q4 (conditionally packaged laboratory services): (See following page.)

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CPT®	Description	OPPS SI
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	A
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	Q4
0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffinembedded tumor tissue	A
0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	A
0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens	A
0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone–binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth	Q4

- **New HCPCS Code C9776:** Effective April 1, 2021, report add-on code HCPCSC9776for intra-operative near-infrared fluorescence imaging of major extra hepatic bile duct(s) with intravenous administration of indocyanine green. This laser technique, which uses indocyanine (ICG) green, provides enhanced real-time visualization of cystic, common bile, or common hepatic ducts during open or laparoscopic cholecystectomy procedures.

HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI	OPPS APC
C9776	Fluo bile duct imaging w/icg	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	N	N/A

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- **New HCPCS Code C9777:** Effective April 1, 2021, report C9777 for Esophageal Mucosal Integrity Testing by Electrical Impedance.This procedure is used to detect esophageal mucosal changes that result from chronic Gastroesophageal Reflux Disease (GERD) or Eosinophilc Esophagitis (EoE.)

HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI	OPPS APC
C9777	Esophag mucosal integ add-on	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)	N	N/A

- **Change of Long Descriptor for HCPCS C9761:** Effective October 1, 2020, the long descriptor for HCPCS code C9761 as shown below

HCPCS Code	Old Long Descriptor	New Long Descriptor	OPPS SI	OPPS APC
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable.	J1	5375

- **Change of Long Descriptor for HCPCS C9761:** Effective October 1, 2020, the long descriptor for HCPCS code C9761 as shown below

HCPCS Code	Old Long Descriptor	New Long Descriptor	OPPS SI	OPPS APC
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable.	J1	5375

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- **Status Indicator Corrections:** In the January 1, 2021 Addendum B, CMS incorrectly listed G2061, G2062 and G2063 with a status indicator of A (paid by MACs under a fee schedule or payment system other than OPPS.) These codes were deleted effective December 31, 2020 and were replaced with CPT® codes 98970, 98971 and 97972 which CMS incorrectly assigned to status indicator B (Not paid under OPPS.) To correct these errors, CMS made the following changes with a retroactive effective date of January 1, 2021.

HCPCS Code	Long Descriptor	OPPS SI	OPPS APC
G2061	Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	D	N/A
G2062	Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	D	N/A
G2063	Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	D	N/A
98970	Qualified nonphysician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	A	N/A
98971	Qualified nonphysician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	A	N/A
98972	Qualified nonphysician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	A	N/A

- **Additional Status Indicator Changes:** In the January 2021 OPPS, CMS incorrectly assigned G2010 and G2012 with status indicator of A (Paid by MACs under a fee schedule or payment system other than OPPS.)G2211 was incorrectly assigned status indicator of N (payment is packaged into payment for other services.) To correct these errors, each of these codes are assigned status indicator B (Not paid under OPPS) with an effective date of January 1, 2021.

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HCPCS Code	Long Descriptor	OPPS SI	OPPS APC
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment	B	N/A

Status Indicator Corrections: In the January 1, 2021 Addendum B, CMS incorrectly listed G2061, G2062 and G2063 with a status indicator of A (paid by MACs under a fee schedule or payment system other than OPPS.) These codes were deleted effective December 31, 2020 and were replaced with CPT® codes 98970, 98971 and 97972 which CMS incorrectly assigned to status indicator B (Not paid under OPPS.) To correct these errors, CMS made the following changes with a retroactive effective date of January 1, 2021.

HCPCS Code	Long Descriptor	OPPS SI	OPPS APC
G2011	Brief communication technologybased service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	B	N/A
G2211	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established	B	N/A

APRIL 1, 2021 OPPS UPDATES

- **Change of HCPCS for DecisionDx-Melanoma test:** When DecisionDx-Melanoma test was approved as an ADLT on May 17, 2019, there was no CPT® code assigned to the test .In the October 2019 Update to OPPS labs were instructed to report this test with an unlisted code,81599(unlisted multianalyte assay with algorithmic analysis) with identifier ZB1D4.

  Effective January 1, 2021,DecisionDx-Melanomatest was assigned CPT® code81529(Oncology (cutaneous melanoma), mrna, gene expression profiling by real-time rt-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis).CPT® code 81529 was assignedstatus indicator A (Paid by MACs under a fee schedule or payment system other than OPPS.)

  Also, effective January 1, 2021, the status indicator for the unlisted code81599was returned to E1 (Not paid by Medicare when submitted on outpatient claims - any outpatient bill type.)

- **TIVUS™:** A treatment for pulmonary arterial hypertension (PAH),Therapeutic Intravascular Ultrasound (TIVUS) employs a catheter in an intravascular technology that interrupts nerve conduction surrounding blood vessels and other structures.The ultrasound waves heat the nerves to necrosis which interrupts nerve conduction.This ablation results in decreasing sympathetic hormones from the nerves, which, in turn, relaxes and reduces resistance and pressure in the vessels.

  Effective April 1, 2021, the OPPS status of the TIVUS procedure HCPCS code0632T(percutaneous transcatheter ultrasound ablation of nerves innervating thepulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imagingguidance) from E1 (excluded from coverage) to toJ1(hospital Part B services paid through a comprehensive APC.)-

  Additional information on TIVUS is available through the following webpage: https://sonivie.com/tivus

- **Drugs, Biologicals and Radiopharmaceuticals**
  - **New Pass-through Status:** The following HCPCS codes will be assigned Pass-Through Status indicator G effective April 1, 2021:

HCPCS Code	Long Descriptor	OPPS SI	OPPS APC
C9704	Injection, lumasiran, 0.5 mg	G	9407
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406

APRIL 1, 2021 OPPS UPDATES

- **Expiring Pass-through Status:** Effective April 1, 2021, pass-through status on the following HCPCS codes will change from a status indicator G to K (Paid under OPPS by APC.)

HCPCS Code	Long Descriptor	Jan 2021 OPPS SI	Apr 2021 OPPS SI	Apr 2021 APC
C9462	Injection, delafloxacin, 1 mg	G	K	9462
J0185	Injection, aprepitant, 1 mg	G	K	9463
J0517	Injection, benralizumab, 1 mg	G	K	9466
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	K	9469
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	K	9468
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	K	9174
J9311	Injection, rituximab 10 mg and hyaluronidase	G	K	9467
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	K	9035
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	K	9194
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	K	9036

APRIL 1, 2021 OPPS UPDATES

- **Newly Established HCPCS Codes for Drugs, Biologicals and Radiopharmaceuticals:** The following seven new codes will replace current HCPCS codes beginning April 1, 2021

New HCPCS	Old HCPCS	Long Descriptor	OPPS SI	APC
A9592	C9068	Copper cu-64, dotatate, diagnostic, 1 millicurie	G	9383
J1427	C9071	Injection, viltolarsen, 10 mg	G	9386
J1554	C9072c	Injection, immune globulin (asceniv), 500 mg	G	9392
J7402	C9122	Mometasone furoate sinus implant, (sinuva), 10 micrograms	G	9346
J9037	C9069	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384
J9349	C9070	Injection, tafasitamab-cxix, 2 mg	G	9385
Q2053	C9073	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391

- **Two HCPCS are deleted effective April 1, 2021:**

New HCPCS	Long Descriptor	OPPS SI	APC
J7333	Hyaluronan or derivative, visco-3, for intra-articular injection, per dose	N	N/A
J7401	Mometasone furoate sinus implant, 10 micrograms	N	N/A

- **Retroactive Status Indicator Changes:** The following drug status indicator change is retroactive from January 1, 2021, through March 31, 2021:

HCPCS Code	Long Descriptor	Old OPPS SI	New OPPS SI	APC
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	E2	K	9406

APRIL 1, 2021 OPPS UPDATES

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

  - Most nonpass-through, Non 340B Program = ASP +6 percent of reference product for biosimilars)
  - Nonpass-through, acquired through 340B Program = ASP – 22.5 percent of 340B acquired biosimilar
  - Single payment of ASP + 6 percent for pass-through to provide payment for the acquisition cost and pharmacy overhead
  - Based on OPPS/ASC final rule comments, values for many drugs and biologicals changed based on sales price from third quarter CY 2020.The full updated list will be available at the April 2021 update of OPPS Addendum A and B :

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

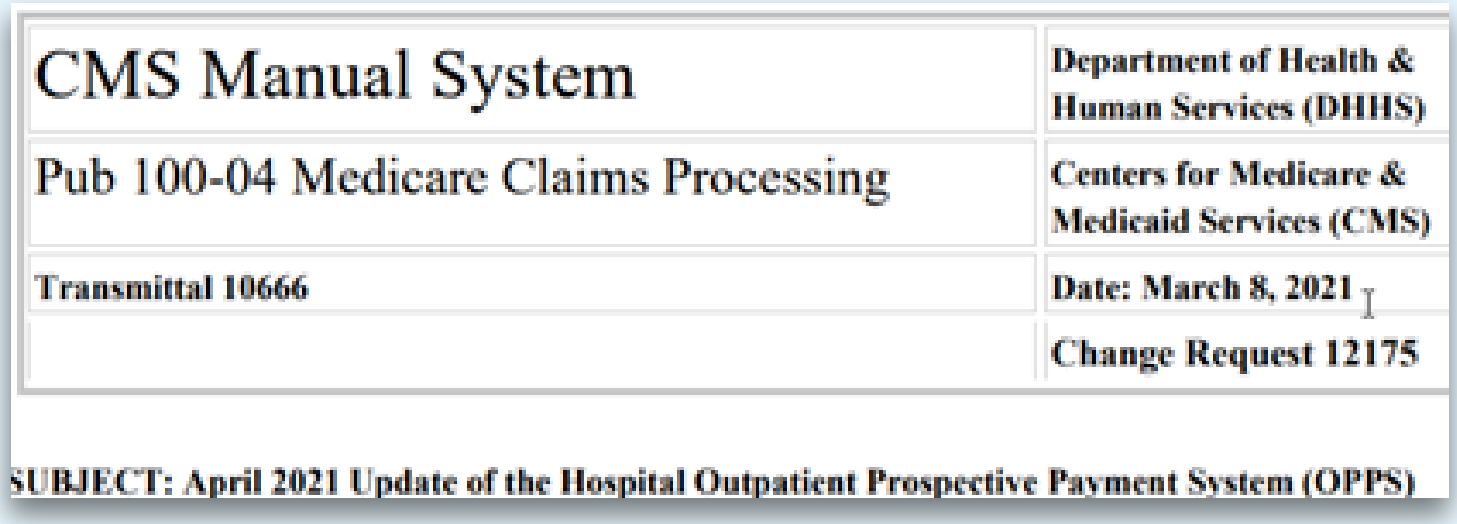
- **Restated ASP Methodology Payment Rates:** quarterly retroactive correction to some drugs and biological payment rates will be available on the first date of the quarter at the following CMS website:

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

- **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) 12175/ Medicare Claim Processing Transmittal 10666:https://www.cms.gov/files/document/r10666cp.pdf



CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10666	Date: March 8, 2021
	Change Request 12175

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

Addendum A and Addendum B Updates:*

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

***Not available at time of this print (3/15/2021)**

MARCH MEDI-CAL UPDATE: NEW COVID VACCINE BENEFIT

Medi-Cal has announced that the new Janssen COVID-19 vaccine recently released by Johnson & Johnson will be a payable benefit effective for dates of service on or after February 27, 2021. This vaccine can only be administered to patients 18 years of age and older.

When billed appropriately, the vaccine will be reimbursed at $28.39 for a 0.5mL dose.

It is important to note that providers shouldnotreport CPT Code 91303(severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [coronavirus disease (COVID-19)] vaccine, DNA, spike protein, adenovirus type 26 [Ad26] vector, preservative free, 5x1010viral particles/0.5 mL dosage, for intramuscular use)for the Janssen vaccine; this CPT Code is not currently a Medi-Cal benefit and providers are reminded that at this time, only the administration of the vaccine is reimbursable, not the vaccine itself.

The billing guidelines listed below must be followed for claims to be reimbursed:
https://files.medi-cal.ca.gov/pubsdoco/Janssen_COVID19_Vaccine.aspx

Pharmacy Claims:

- Use NDC 59676058005
- Claim quantity dispensed must be submitted as 0.5mL per administered vaccine
- Use Submission Clarification Code (SCC) 2 (Other Override) to indicate that a COVID-19 vaccine is being administered and billed
    - Since the Janssen COVID-19 vaccine is a one-dose vaccine, providers do not need to submit SCC 6 (Starter Dose)

Electronic Submissions:

Electronic claims should also adhere to the updated Medi-CalNCPDP Payer Sheet. Notable NCPDP D.0 submission details providers should be aware of include:

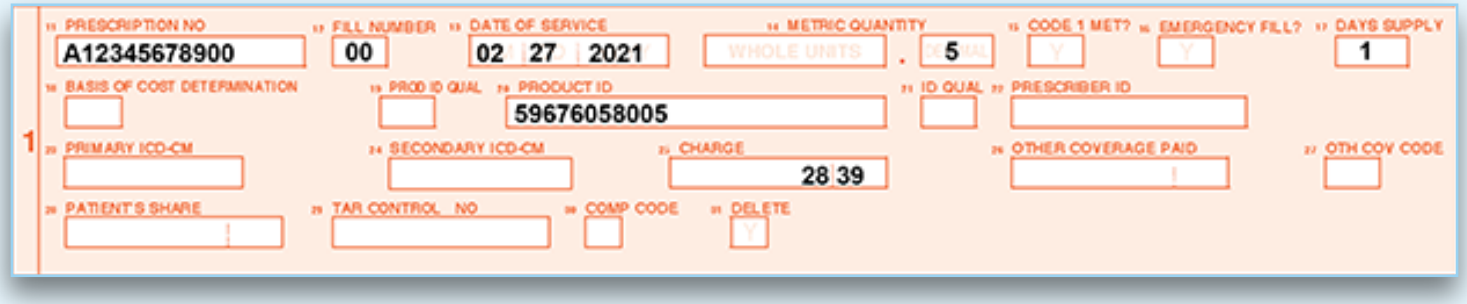
- Use of the value "MA" (Medication Administered) in the Professional Service Code (440-E5) field is not supported in Medi-Cal and submission of that code may result in a claim denial
- Use of the value "PH" (Preventive Health Care) in the Reason for Service Code (439-E4) field is not supportedin Medi-Cal and submission of that code may result in a claim denial
- Use of the value "3N" (Medication Administered) in the Result of Service Code (441-E6) field is not supported in Medi-Cal and submission of that code may result in a claim denial
- Use of the value "15" in the Basis of Cost Determination (423-DN) field is not supported in Medi-Cal and submission of that code may result in a claim denial. Providers are instructed to submit the value "01" instead.

- The Quantity Dispensed (field 442-E7) should be submitted with the value that represents the quantity of drug product administered.Submission Clarification Code (field 420-DK) should be submitted with a SCC code value of 2

MARCH MEDI-CAL UPDATE: NEW COVID VACCINE BENEFIT

The examples below are included for reference only. Providers should note that these are merely an example, and should adjust to their billing situation as would be appropriate.

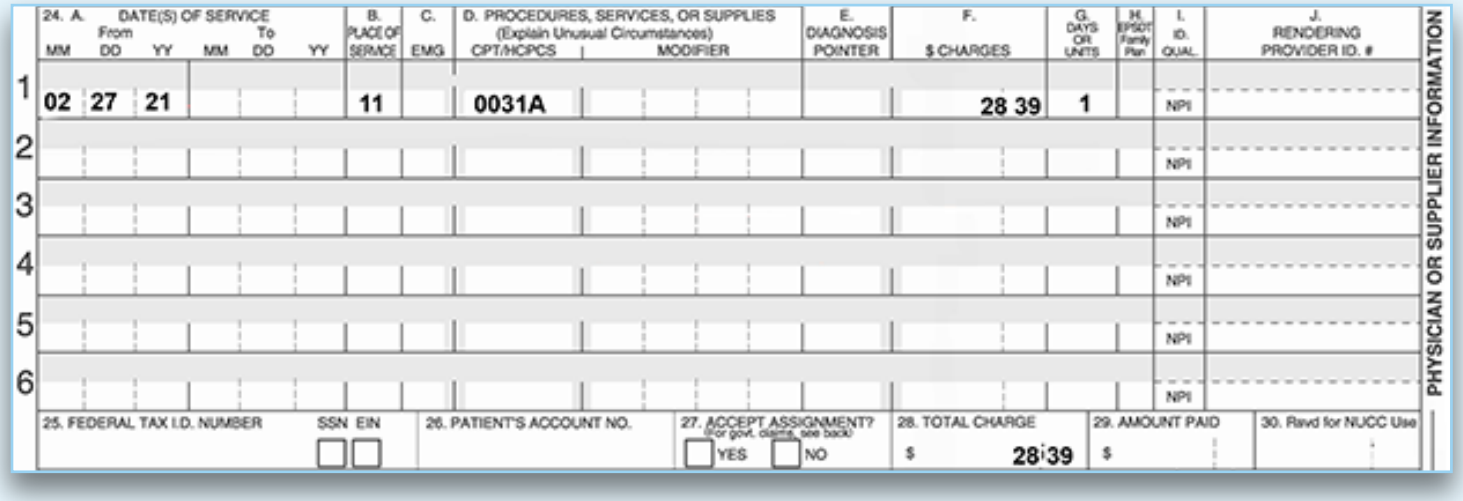
Hard Copy Submissions:



Medical and Outpatient Claims:

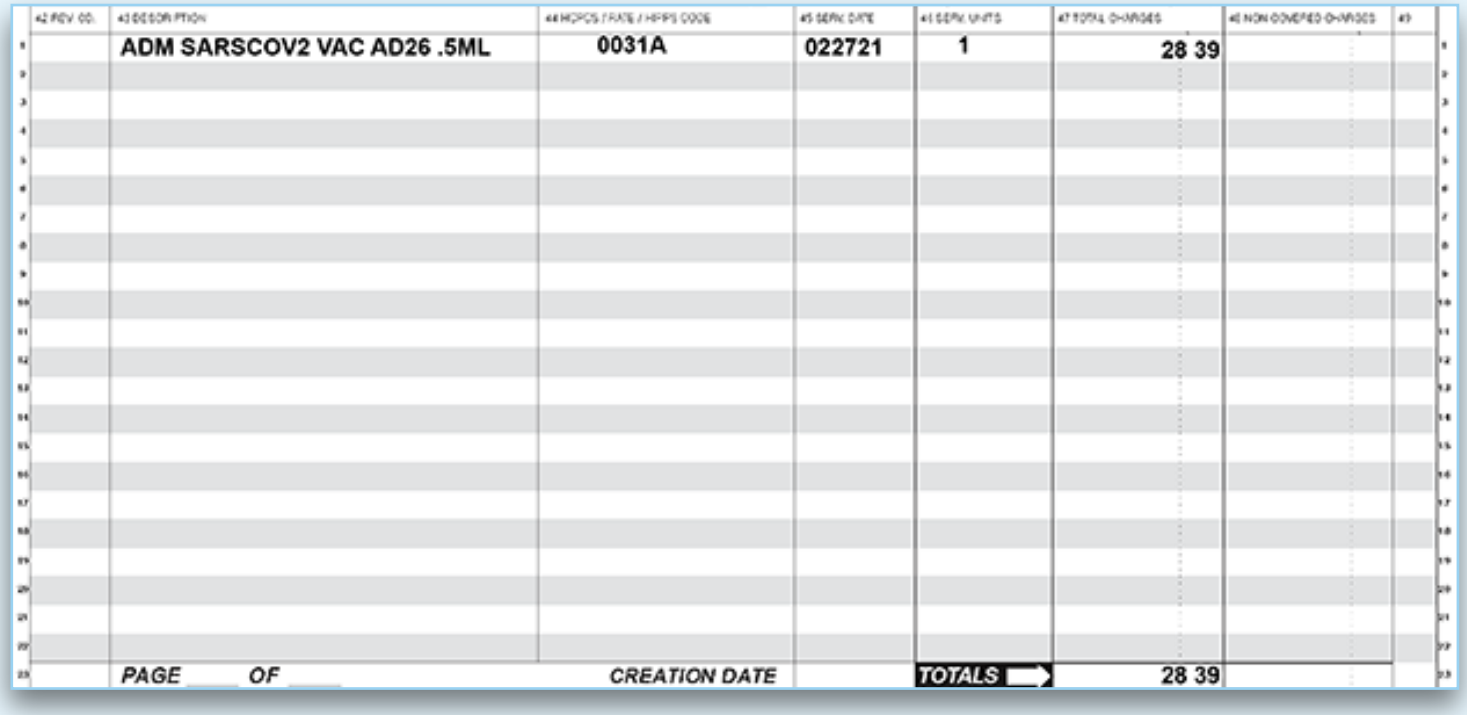
- Bill using Administration Code 0031A
- There are no special instructions for hard copy or electronic Medical or Outpatient submissions

1) Janssen vaccine administration on a CMS-1500



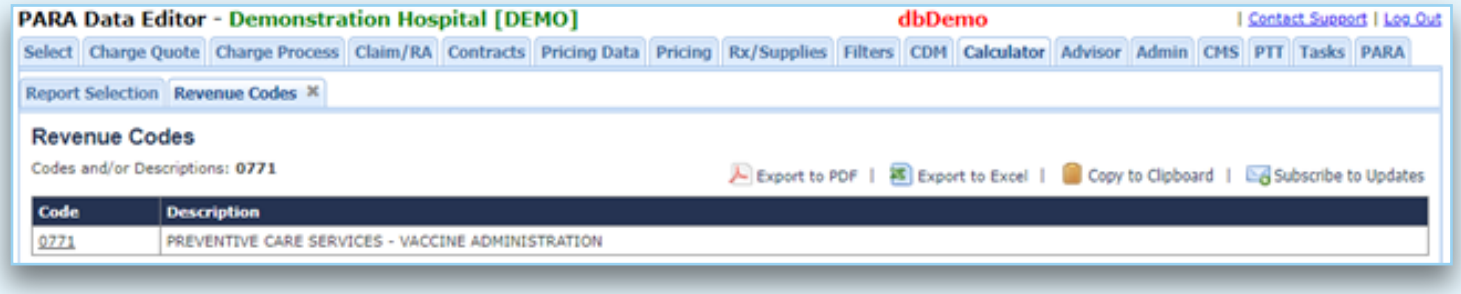
MARCH MEDI-CAL UPDATE: NEW COVID VACCINE BENEFIT

2) Janssen vaccine administration on a UB-04:



42 REV CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
	ADM SARSCOV2 VAC AD26 .5ML	0031A	022721	1	28 39		
	PAGE ___ OF ___	CREATION DATE		TOTALS	28 39		

Medi-Cal has not made a revenue code recommendation at this time. However, Medicare is requiring 0771.



MEDI-CAL COVID VACCINE CLAIM SUBMISSION

The Department of Health Care Service (DHCS) submitted a federal waiver request in December to the Centers for Medicare and Medicaid Services (CMS) seeking federal approval to cover the cost of vaccine administration for beneficiaries that have restricted scope coverage. The waiver includes vaccine coverage for beneficiaries who are enrolled in the Family Planning, Access, Care and Treatment (Family PACT) program as well as the Uninsured Group Program for COVID-19.

DHCS has also submitted a State Plan Amendment to request approval from CMS to reimburse Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) a fee-for-service rate for vaccine administration when the encounter does not meet all of the requirements of a billable visit (i.e. vaccine-only administration).

Providers who have administered the COVID-19 vaccines to Medi-Cal beneficiaries who are included in:

- The Family PACT program
- The COVID-19 Uninsured Group program

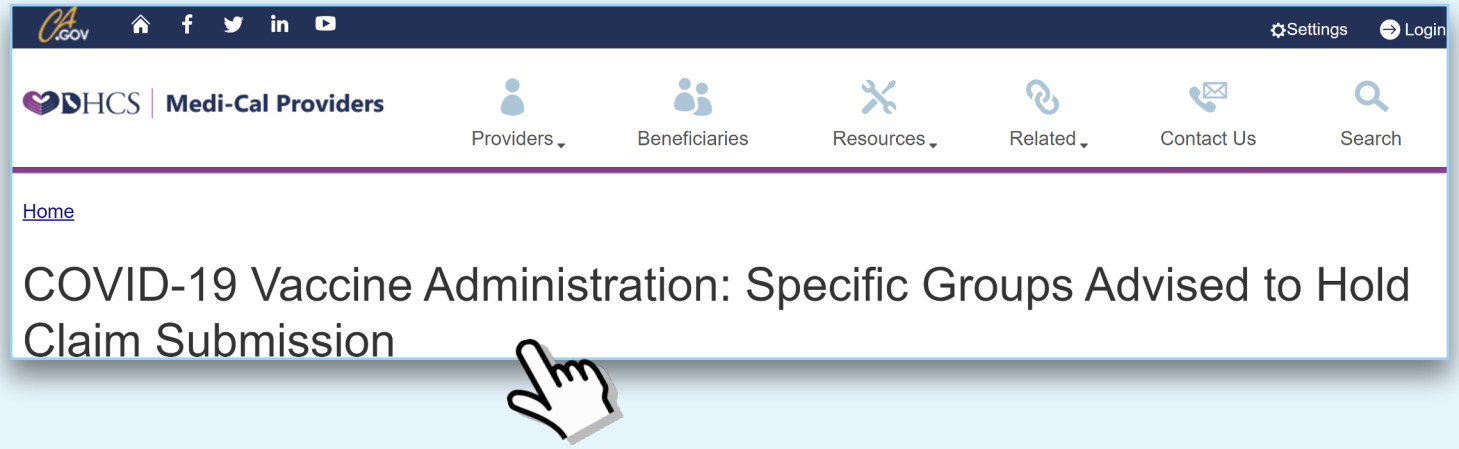
are advised to hold submission of claims pending further guidance from DHCS.

Similarly, FQHCs and RHCs should hold claims for vaccine-only administration to the extent the encounter does not meet the requirements of a billable visit or the beneficiary being served is in one of the identified populations above. Policy and reimbursement guidance will be updated upon additional CMS guidance and/or approvals of the requested waiver/State Plan Amendment.

Updates regarding IHS-MOA 638 clinics are forthcoming.

Providers with questions should contact the Telephone Service Center (TSC) at1-800-541-5555. The TSC is available 8 a.m. to 5 p.m., Monday through Friday, except holidays. Border providers and Out-of-State billers billing for in-state providers should call(916) 636-1200.

https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_30717_71.aspx?_cldee=bW1jbWlsbGFuQHBhcmEtaGNmcy5jb20%3d&recipientid=contact-9212cfb6eaf5ea11a815000d3a5bf119-ad7e1d690b2442a98883aeee6869497e&esid=6fabf100-4888-eb11-a812-00224809d41c



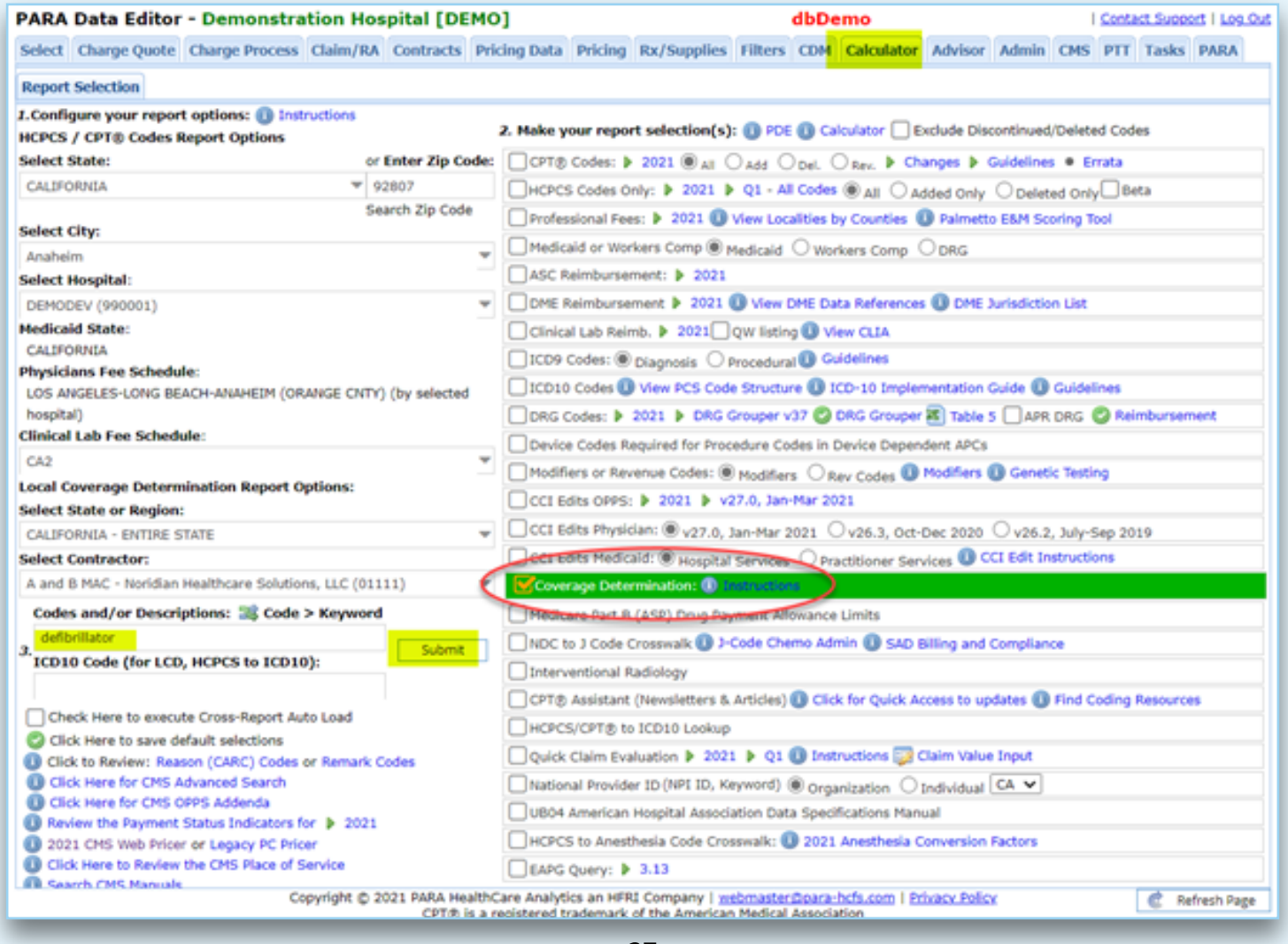
CAPTURING UPSTREAM MEDICAL NECESSITY DOCUMENTATION

Medicare's National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) began as a fairly straightforward matching game.

A particular service must report one of the covered diagnoses to support medical necessity. The most common medical necessity requirements apply to lab tests--most major EHR systems offer a built-in medical necessity evaluator to determine if the referring physician provided a covered ICD10 diagnosis code and assist in generating an ABN if the diagnosis is insufficient.

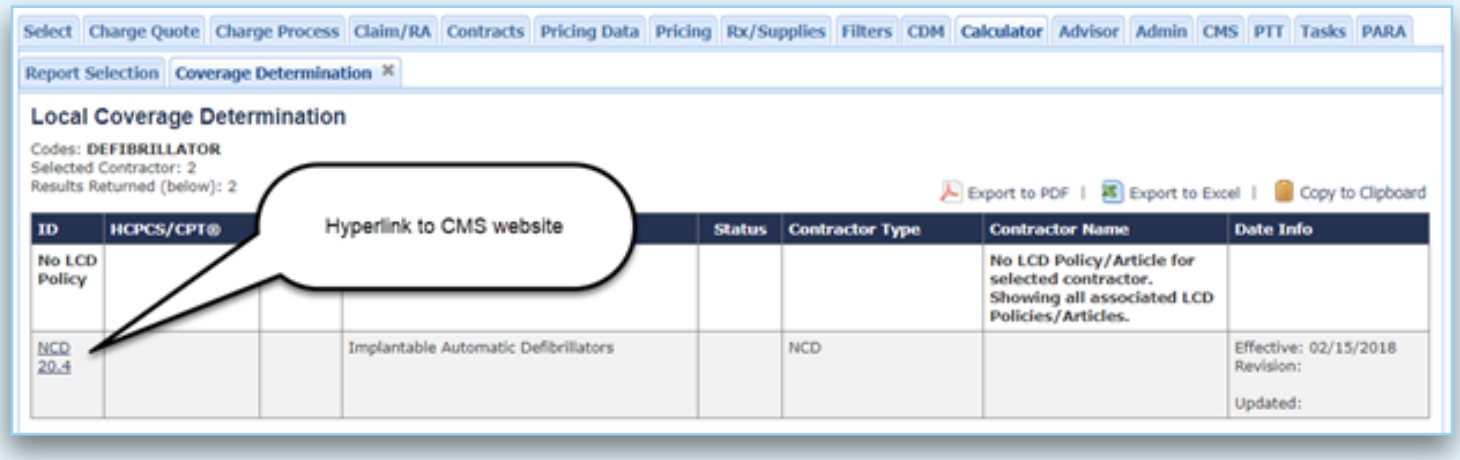
However, over the years, medical necessity requirements have become more complex, particularly for high-dollar procedures such as Implantable Cardiac Defibrillators and PET scans.

Many hospitals have no effective process to check more complex medical necessity requirements. **PARA recommends adopting processes that add documentation to support medical necessity to the hospital medical record prior to billing Medicare for services subject to an NCD or LCD.** This may be accomplished through documenting an attestation from the performing or ordering provider as a precondition of providing expensive surgical services.We provide a few examples on the last two pages of this paper. Medicare coverage information (NCDs and LCDs) is available on the **PARA Data Editor Calculator** feature – enter a HCPCS or a keyword into the "Codes and/or Descriptions" field, and select the report "Medicare Coverage" on the right, as illustrated:



CAPTURING UPSTREAM MEDICAL NECESSITY DOCUMENTATION

The resulting report will offer a hyperlink to the NCD or LCD or Local Coverage Article with details on the requirements to establish medical necessity (screenshot on the following page.)



Since October 2020, Medicare's Recovery Audit Contractors (RAC's) have been auditing whether hospital medical records support the medical necessity requirements for automatic implantable cardio defibrillators (AICD's.) Here's a link to Medicare's Approved Recovery Audit Contractor Issues List:

[0195-Implantable Automatic Defibrillator- Inpatient Procedure: Medical Necessity and Documentation Requirements | CMS]

Issue Name	0195-Implantable Automatic Defibrillator- Inpatient Procedure: Medical Necessity and Documentation Requirements
Date	2020-10-06
Review Type	Complex
Provider Type	Inpatient Hospital
MAC Jurisdiction	All A/B MACs

Description

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. Medical documentation will be reviewed for medical necessity to validate that implantable automatic cardiac defibrillators are used only for covered indications.

CAPTURING UPSTREAM MEDICAL NECESSITY DOCUMENTATION

The requirements of NCD 20.4, which apply to most AICD patients, include evidence of the physician's *"formal shared decision making visit"* with the patient before undergoing an AICD procedure. In most cases, the hospital medical record will not contain information on a physician visit performed outside the hospital. The RACs have seized upon this weakness in documentation – and have identified an easy and rewarding target for high-dollar RAC recoveries.

Within a few minutes of receiving the hospital medical records for an AICD case, RAC auditors can determine whether the hospital's AICD procedure documentation includes evidence of the"formal shared decision making visit." Claims without the documentation are identified as non-covered, and the RAC promptly sends a recoupment request.The recoupment of an inpatient AICD case is generally between $30,000 and $80,000 – a big payday for light work at the expense of hapless hospitals which didn't comprehend the need to obtain evidence of the shared decision making visit for the hospital record.

While it may seem unfair to hold hospitals responsible for physician activities, the Medicare Program Integrity Manual explains that when an entity responds to an additional documentation request, the entity audited is responsible for submitting documentation that meets medical necessity requirements, even if that documentation exists in the records of another entity:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf

Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

3.2.3.3 - Third-party Additional Documentation Request

(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

...

Unless otherwise specified, the MAC, RAC and UPIC shall request information from the billing provider/supplier. The treating physician, another clinician, provider, or supplier should submit the requested documentation. However, because the provider selected for review is the one whose payment is at risk, it is this provider who is ultimately responsible for submitting, within the established timelines, the documentation requested by the MAC, CERT, RAC and UPIC.

Hospitals should carefully evaluate whether complex medical necessity requirements have been met before performing expensive procedures, rather than finding out at a later date that payments will be recouped due to a RAC audit.

PARA advises hospitals to prepare brief physician attestations such as those found on the following pages and incorporate this documentation into the hospital medical record prior to performing services subjected to complex medical necessity standards.

Please note that the attestations must offer both medically necessary rationale and the opportunity to report a non-qualifying rationale – hospitals should not "drive" physicians to select only the options that support medical necessity.

CAPTURING UPSTREAM MEDICAL NECESSITY DOCUMENTATION

However, suppose a physician's response indicates that a Medicare beneficiary service does not meet Medicare medical necessity standards. In that case, the hospital should decline to schedule or perform the procedure unless and until the patient has signed an Advance Beneficiary Notice indicating that the patient accepts full financial liability.

Additional information about Medicare's Advance Beneficiary Notice can be found at:

https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN

Pre-Scheduling Information from Ordering Physician

(Medicare beneficiary AICD Implant Procedures)

Patient Name/MRN: _____

I, the ordering provider, attest that on (date) _____

☐ **A formal "Shared Decision Making Visit" with the patient occurred prior to implantation of the AICD as detailed below:**

a. **Utilizing an "Evidence Based decision tool" obtained from:**

☐ **Colorado Program for Patient Centered Decisions (https://patientdecisionaid.org/wp-content/uploads/2016/06/ICD-tool-shortened-V1-3-20-2019.pdf)**

☐ **Other Source (identify):** _____

☐ **A shared decision making visit with the patient occurred, without the use of an evidence-based decision tool.**

☐ **No shared decision making visit occurred because the patient:**

☐ **Has a personal history of sustained VT which episode was either spontaneous or induced by an electrophysiology (EP) study, was not associated with an acute myocardial infarction (MI), and was not due to a transient or reversible cause; or**

☐ **Had an episode of cardiac arrest due to VF, not due to a transient or reversible cause; or**

☐ **Is scheduled to receive an ICD replacement due to the end of battery life, elective replacement indicator, or device/lead malfunction.**

☐ **Other:** _____

I attest that medical documentation supporting the attestation above will be made available from our practice in response to an "Additional Documentation Request" from the hospital or CMS.

Signed: _____

Date: _____

Physicians:Your attestation will add required documentation to the hospital medical record to ensure that Medicare's medical necessity requirements have been met.For more information, review the requirements at
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10865.pdf

CAPTURING UPSTREAM MEDICAL NECESSITY DOCUMENTATION

Supporting Information from Ordering Physician

(Required for Medicare beneficiary FDG PET imaging orders)

I, the ordering provider, attest that this order for an FDG PET study is reasonable and necessary for the following reasons (check all that apply.)

The study will:

- ☐ **Inform an initial treatment strategy**
- ☐ **Inform Subsequent treatment strategy**
- ☐ **Avoid an invasive diagnostic procedure that may be unnecessary**
- ☐ **Determine the optimal location to perform an invasive procedure that is necessary**
- ☐ **Guide clinical management of the patient depending on the staging of the cancer identified**
- ☐ **Identify the stage of cancer after a standard diagnostic workup been completed, but the stage of cancer remains in doubt**
- ☐ **Confirm the stage of cancer following a conventional imaging study which was deemed insufficient for clinical management of the patient**
- ☐ **Other (explain):** _____

_____

I attest that I have provided, and will provide upon request, medical documentation supporting the rationale provided above in support of this PET study order.

Signed: _____

Date: _____

Physicians: Your attestation will inform the hospital which modifier to report, and will serve to document the hospital medical record that Medicare's medical necessity requirements have been met.

The modifiers required by Medicare are:

PI - PET or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing.

PS - PET or PET/CT to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treatment physician determines that the PET study is needed to inform subsequent anti-tumor strategy.

RCM IN 2021: ROADMAP TO A STRONG FINANCIAL COMEBACK

Throughout 2020, the COVID-19 pandemic threw hospitals an array of unprecedented challenges, but 2021 is the ultimate opportunity for your organization to bounce back.

The changing environments, staffing shortages and new regulations weren't easy for any organization, but you can ensure the best possible financial outcomes in 2021 by:

- Optimizing staff efficiency
- Staying on top of current inventory changes
- Identifying where and how to maximize revenue

How prepared is your organization to bounce back from the COVID-19 financial challenges?

Download this recorded webinar and listen to Daniel Low, Director of Operations at Healthcare Financial Resources, detail how to implement an action plan that will help your organization improve its bottom line.

Click here: https://www.hfri.net/resources/download-our-webinar-rcm-in-2021-roadmap-to-a-strong-financial-comeback/

DEVICE-INTENSIVE PROCEDURE BILLING -- BYPASS EDIT 92

Since breast biopsy procedures 19081, 19083, and 19085 were added to Medicare's "Device-Intensive" list of codes on 1/1/2021, numerous clients have inquired what HCPCS code should be used to report for the device when reporting these procedures.These procedures are new to Medicare's list of "Device-intensive" codes, which must be billed with a device code on the same claim – but not all cases actually result in the implantation of a tissue marker or a brachytherapy source.

PARA previously advised clients to report the following device codes, as appropriate to the case:

- If a brachytherapy source was implanted, report C2638
- If a tissue marker is implanted, report A4648
- If only a needle is used for localization, report C1889

2021 HCPCS Codes - ALL Quarter: Q1

Codes and/or Descriptions: **C2638,A4648,C1889** for selected Provider: **DEMODEV (990001)**
Results returned(below): 3
AWI: **1**, DME: **CA**, Clinical Lab Fee Schedule: **CA2**, Physician Fee Schedule:**LOS ANGELES-LONG**

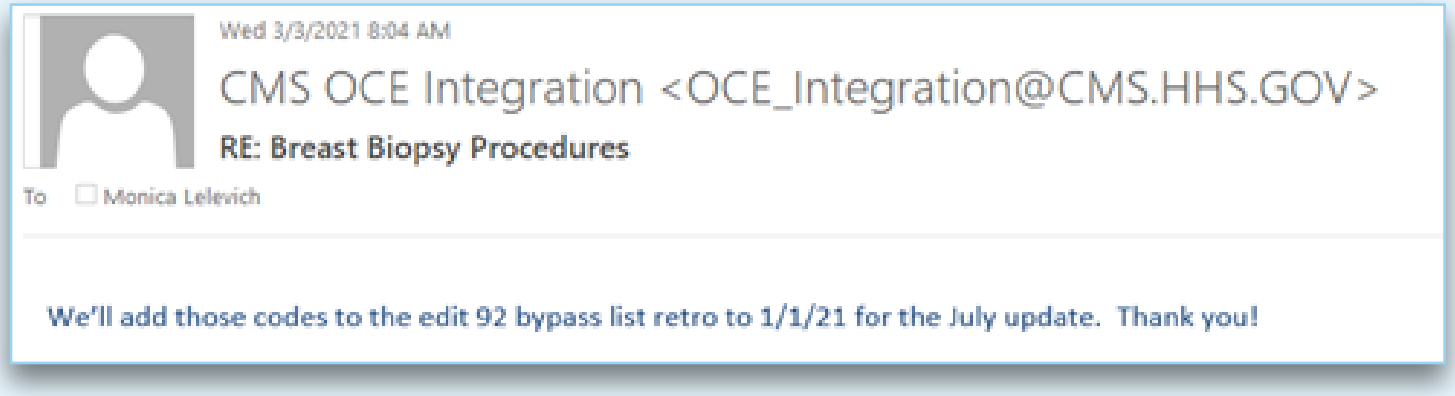
Current Descriptor	Fee Schedule
A4648 - tissue marker, implantable, any type, each **N - Items and Services packaged into APC rates** **Berenson-Eggers Type of Service:** I1E - STANDARD IMAGING - NUCLEAR MEDICINE	
C1889 - implantable/insertable device, not otherwise classified **N - Items and Services packaged into APC rates** **Berenson-Eggers Type of Service:** D1A - MEDICAL/SURGICAL SUPPLIES	
C2638 - brachytherapy source, stranded, iodine-125, per source **U - Brachytherapy sources** **Berenson-Eggers Type of Service:** I4B - IMAGING/PROCEDURE - OTHER	

We also suggested that modifier CG might be used to bypass the CMS edit that requires a device code; however, a sharp-eyed reader of the PARA Weekly pointed out that 19081-19083 are not among the HCPCS that are eligible for the CG modifier.Codes which are not on the "Edit 92 Bypass list" cannot resolve Edit 92 with modifier CG.

(We thank the reader for his prompt observation, permitting us to correct our advice in this article.)

DEVICE-INTENSIVE PROCEDURE BILLING -- BYPASS EDIT 92

We wrote to the Medicare Integrated Outpatient Code Editor team to suggest that CMS add the breast biopsy procedures to the "Edit 92 bypass" list of codes; they responded that they have agreed to do so, and will make that change retroactive to 1/1/2021, but not until the July 1, 2021 update.



Wed 3/3/2021 8:04 AM

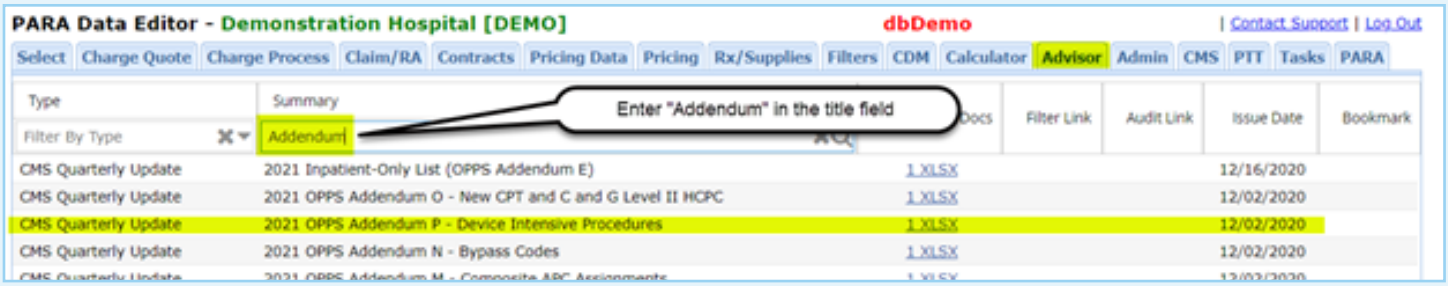
CMS OCE Integration <OCE_Integration@CMS.HHS.GOV>

RE: Breast Biopsy Procedures

To Monica Lelevich

We'll add those codes to the edit 92 bypass list retro to 1/1/21 for the July update. Thank you!

Medicare identifies the list of "device-intensive" HCPCS in the annual OPPS addendum P.



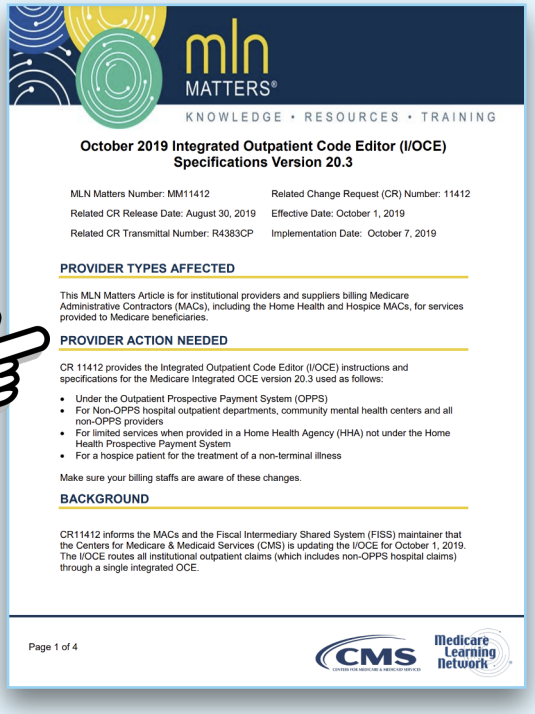
However, the "Edit 92 Bypass" indicator is maintained in a completely separate location, well out of view for all but the most determined researchers– under column DC of the "Data_HCPCS" file published under the Integrated Outpatient Code Editor quarterly release files.A zero ("0") in column DC indicates that the device-intensive procedure is not eligible for modifier CG to resolve the edit:

https://www.cms.gov/apps/aha/license.asp?file=/files/zip/iocev220r0quarterlydatafiles.zip

	A	D	E	DC
1	HCPCS	DESCRIPTION	APC	BYPASS_E92_MODIFIER
3073	19081	Bx breast 1st lesion	00005	0
3074	19081	Bx breast 1st lesion	05073	0
3075	19081	Bx breast 1st lesion	05072	0
3076	19082	Bx breast add lesion	00000	0
3077	19082	Bx breast add lesion	00000	0
3078	19083	Bx breast 1st lesion	00005	0
3079	19083	Bx breast 1st lesion	05073	0
3080	19083	Bx breast 1st lesion	05072	0

DEVICE-INTENSIVE PROCEDURE BILLING -- BYPASS EDIT 92

The list of the "Bypass Edit 92" -eligible codes as published in the January 2021 IOCE quarterly update file is provided at the end of this paper.



mln MATTERS®

KNOWLEDGE • RESOURCES • TRAINING

October 2019 Integrated Outpatient Code Editor (I/OCE) Specifications Version 20.3

MLN Matters Number: MM11412 | Related Change Request (CR) Number: 11412

Related CR Release Date: August 30, 2019 | Effective Date: October 1, 2019

Related CR Transmittal Number: R4383CP | Implementation Date: October 7, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is for institutional providers and suppliers billing Medicare Administrative Contractors (MACs), including the Home Health and Hospice MACs, for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11412 provides the Integrated Outpatient Code Editor (I/OCE) instructions and specifications for the Medicare Integrated OCE version 20.3 used as follows:

- Under the Outpatient Prospective Payment System (OPPS)
- For Non-OPPS hospital outpatient departments, community mental health centers and all non-OPPS providers
- For limited services when provided in a Home Health Agency (HHA) not under the Home Health Prospective Payment System
- For a hospice patient for the treatment of a non-terminal illness

Make sure your billing staffs are aware of these changes.

BACKGROUND

CR11412 informs the MACs and the Fiscal Intermediary Shared System (FISS) maintainer that the Centers for Medicare & Medicaid Services (CMS) is updating the I/OCE for October 1, 2019. The I/OCE routes all institutional outpatient claims (which includes non-OPPS hospital claims) through a single integrated OCE.

Page 1 of 4

CMS Medicare Learning Network

The 2021 OPPS Final Rule explains that HCPCS C1889 is available for procedures which may not use an implant, but consume a device not assigned a device HCPCS.Here are pertinent excerpts:

https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf (page 48865)

> "For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code.
>
> Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is "Implantable/insertable device, not otherwise classified".

DEVICE-INTENSIVE PROCEDURE BILLING -- BYPASS EDIT 92

"In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is "Implantable/insertable device, not otherwise classified".The current list of device-dependent HCPCS which are eligible to be reported to Medicare without a device code if modifier CG is appended appears on the following pages.In July of 2021, we expect the breast biopsy procedures to be added to this list."

Device-intensive procedures which allow an Edit 92 bypass (modifier CG-eligible)

HCPCS	DESCRIPTION
0200T	Perq sacral augmt unilat inj
23473	Revis reconst shoulder joint
23515	Treat clavicle fracture
23615	Treat humerus fracture
23616	Treat humerus fracture
23630	Treat humerus fracture
23680	Treat dislocation/fracture
24370	Revise reconst elbow joint
24371	Revise reconst elbow joint
24545	Treat humerus fracture
24546	Treat humerus fracture
24575	Treat humerus fracture
24579	Treat humerus fracture
24635	Treat elbow fracture
24666	Treat radius fracture
24685	Treat ulnar fracture
25515	Treat fracture of radius
25525	Treat fracture of radius
25526	Treat fracture of radius
25545	Treat fracture of ulna
25574	Treat fracture radius & ulna
25575	Treat fracture radius/ulna
27696	Repair of ankle ligaments
27792	Treatment of ankle fracture
27814	Treatment of ankle fracture
27822	Treatment of ankle fracture
27823	Treatment of ankle fracture
27826	Treat lower leg fracture
27827	Treat lower leg fracture
27828	Treat lower leg fracture
27832	Treat lower leg dislocation

48772 Federal Register / Vol. 85, No. 156 / Wednesday, August 12, 202 Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 414, 416, and 419

[CMS–1736–P]

RIN 0938–AU12

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2021 based on our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this proposed rule would establish and update the Overall Hospital Quality Star Rating beginning with the CY 2021; remove certain restrictions on the expansion of physician-owned hospitals that qualify as "high Medicaid facilities," and clarify that certain beds are counted toward a hospital's baseline number of operating rooms, procedure rooms, and beds; and add two new service categories to the OPD Prior Authorization Process.

DATES: To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on October 5, 2020.

ADDRESSES: In commenting, please refer to file code CMS–1736–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the "submit a comment" tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1736–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1736–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

h. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Nicole Hewitt via email *Nicole.Hewitt@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck

Br... il *Chuck.Braver@cms.hhs.gov*.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email *AuSha.Washington@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Nicole Hewitt via email *Nicole.Hewitt@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

Hospital Quality Star Rating Methodology, contact Annese Abdullah-Mclaughlin via email *Annese.Abdullah-Mclaughlin@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email *Ausha.Washington@cms.hhs.gov*, or Allison Bramlett via email *Allison.Bramlett@cms.hhs.gov*, or Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov*, or Scott Talaga via email *Scott.Talaga@cms.hhs.gov*, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*, or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov* or, or Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology

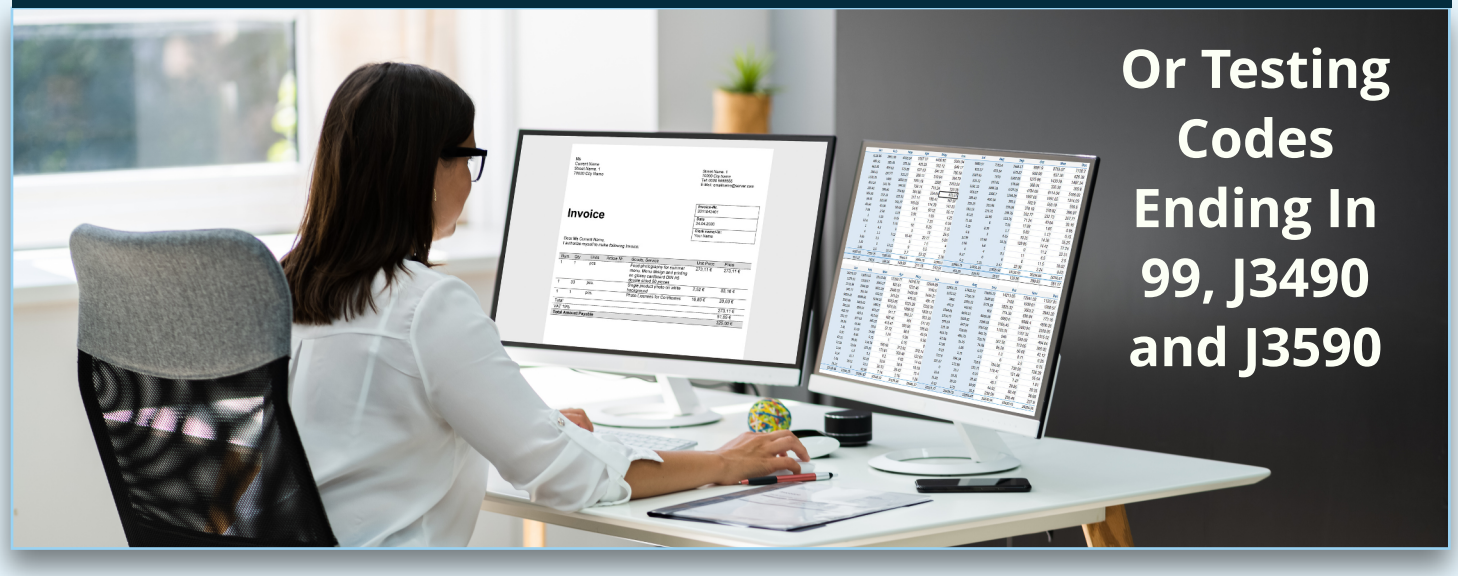
DEVICE-INTENSIVE PROCEDURE BILLING -- BYPASS EDIT 92

Device-intensive procedures which allow an Edit 92 bypass (modifier CG-eligible), continued.

HCPCS	DESCRIPTION
28300	Incision of heel bone
28415	Treat heel fracture
28420	Treat/graft heel fracture
28445	Treat ankle fracture
28465	Treat midfoot fracture each
28485	Treat metatarsal fracture
28555	Repair foot dislocation
28585	Repair foot dislocation
28615	Repair foot dislocation
29855	Tibial arthroscopy/surgery
29856	Tibial arthroscopy/surgery
33220	Repair lead pace-defib dual
33226	Reposition l ventric lead
33233	Removal of pm generator
33235	Removal pacemaker electrode
36261	Revision of infusion pump
36904	Thrmbc/nfs dialysis circuit
37192	Redo endovas vena cava filtr
37244	Vasc embolize/occlude bleed
43773	Lap replace gastr adj device
45327	Proctosigmoidoscopy w/stent
57288	Repair bladder defect
59072	Umbilical cord occlud w/us
61888	Revise/remove neuroreceiver
61888	Revise/remove neuroreceiver
62350	Implant spinal canal cath
63663	Revise spine eltrd perq aray
63664	Revise spine eltrd plate
64448	Njx aa&/strd fem nerve nfs
64569	Revise/repl vagus n eltrd
64569	Revise/repl vagus n eltrd

HCPCS	DESCRIPTION
64595	Revise/rmv pn/gastr stimul
64910	Nerve repair w/allograft
64912	Nrv rpr w/nrv algrft 1st
65779	Cover eye w/membrane suture

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS



All medical billers and AR follow-up teams have experienced billing or claim denials because there is a "miscellaneous" HCPCS on a claim. The reason is because miscellaneous codes do not provide adequate information for the item being billed.

Unlike established HCPCS for standard procedures and testing, most payers will manually calculate the reimbursement for the claim line reporting the miscellaneous item or testing. To do this process, however, the provider is expected to supply the additional information on the claim upon submission.

The type of information required however, varies on the type of miscellaneous service or item that is being reported on the claim. For example:

- If the service is a surgery, an operative report will be required to be submitted with the claim submission. This allows the payer to review the procedure and adjudicate the claim correctly
- If the service is a diagnostic test, clinical notes should be included. The clinical notes should clearly and precisely describe the patient's diagnosis, the full name of the test performed and the results of the test
- If the item is a DME item, the name of the item, a full description of the item, the name of the manufacturer, the product code/number and a copy of the invoice should be included with the claim submission
- If the miscellaneous item is a drug, the claim should contain the full name of the drug, the manufacturer, strength and dosage, NDC code for the drug and route of administration. This would apply to anesthesia agents
- **Special note for 80299: The name of the drug being tested must be indicated in Box 19 of the CMS 1500 claim form (remarks field) or in Box 80 of the UB04 claim

In the tables on the follow pages of this article, are examples of various procedures and items for which this article is applicable.

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS

Anesthesia	
Code	**Description**
01999	Unlisted anesthesia procedure(s)
Surgery	
15999	Unlisted procedure, excision pressure ulcer
17999	Skin, mucous membrane and subcutaneous tissue
19499	Breast
20999	Musculoskeletal system, general
21089	Unlisted maxillofacial prosthetic procedure
21299	Unlisted craniofacial and maxillofacial procedure
21499	Unlisted musculoskeletal procedure, head
21899	Unlisted procedure, neck or thorax
22899	Spine
22999	Abdomen, musculoskeletal system
23929	Shoulder
24999	Humerus or Elbow
25999	Forearm or Wrist
26989	Hands or Fingers
27299	Pelvis or Hip Joint
27599	Femur or Knee
27899	Leg or Ankle
28899	Foot or Toes
29799	Casting or Strapping
29999	Arthroscopy
30999	Nose
31299	Accessory Sinuses
31599	Larynx
31899	Trachea, Bronchi
32999	Cardiac Surgery
36299	Vascular Injection

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS

Surgery, continued	
Code	**Description**
37501	Unlisted vascular endoscopy procedure
37799	Unlisted procedure, vascular surgery
38129	Unlisted laparoscopy procedure, spleen
38589	Lymphatic System
38999	Unlisted procedure, hemic or lymphatic system
39499	Mediastinum
39599	Diaphragm
40799	Lips
40899	Vestibule of Mouth
41599	Tongue, floor of mouth
41899	Dentoalveolar structures
42299	Palate, uvula
42699	Salivary glands or ducts
43289	Unlisted Laparoscopy procedure, esophagus
43499	Unlisted procedure, esophagus
43659	Unlisted Laparoscopy procedure, stomach
43999	Unlisted procedure, stomach
44238	Unlisted Laparoscopy procedure, intestine, except rectum
44799	Unlisted procedure, intestine
44899	Merckel's diverticulum and the mesentery
44979	Unlisted laparoscopy procedure, appendix
45499	rectum
45999	Unlisted procedure, rectum
46999	anus
47379	Unlisted laparoscopy procedure, liver
47399	Unlisted procedure, liver
47579	Unlisted laparoscopy procedure, biliary tract
47999	Unlisted procedure, biliary tract
48999	Pancreas
49329	Unlisted laparoscopy procedure, abdomen, peritoneum and omentum
49659	Hernioplasty, herniorrhaphy, herniotomy
49999	Unlisted procedure, abdomen, peritoneum and omentum
50549	Unlisted laparoscopy procedure, renal
50949	ureter
51999	bladder
53899	Urinary system
54699	testis
55559	Spermatic cord
55899	Unlisted procedure, male genital system
58578	Unlisted Laparoscopy procedure, uterus

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS

Surgery, Continued	
Code	**Description**
58579	Unlisted hysteroscopy procedure, uterus
58679	Unlisted Laparoscopy Procedure, oviduct, ovary
58999	Unlisted procedure, female genital system (non-obstetrical)
59897	Unlisted fetal invasive procedure, including ultrasound guidance
59898	Unlisted laparoscopy procedure, maternity care and delivery
59899	Unlisted procedure, maternity care and delivery
60659	Unlisted laparoscopy procedure, endocrine system
60699	Unlisted procedure, endocrine system
64999	Nervous system
66999	Anterior segment of eye
67299	Posterior segment
67399	Ocular muscle
67599	Orbit
67999	Eyelids
68399	Conjunctiva
68899	Lacrimal system
69399	External ear
69799	Middle ear
69949	Inner ear
69979	Temporal bone, middle fossa approach
Radiology	
76496	Unlisted fluoroscopic procedure (e.g., diagnostic, interventional)
76497	Unlisted computed tomography procedure (e.g., diagnostic, interventional)
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
76499	Unlisted diagnostic radiographic procedure
76999	Unlisted ultrasound procedure (e.g., diagnostic, interventional)
77299	Unlisted procedure, therapeutic radiology clinical treatment planning
77399	Medical radiation physics, dosimetry and treatment devices, and special services
77499	Therapeutic radiology treatment management
77799	Clinical brachytherapy
78099	Unlisted endocrine procedure, diagnostic nuclear medicine
78199	Unlisted hematopoietic, reticuloendothelial and lymphatic procedure, diagnostic nuclear medicine
78299	Unlisted gastrointestinal procedure, diagnostic nuclear medicine
78399	Unlisted musculoskeletal procedure, diagnostic nuclear medicine
78499	Unlisted cardiovascular procedure, diagnostic nuclear medicine
78599	Unlisted respiratory procedure, diagnostic nuclear medicine
78699	Unlisted nervous system procedure, diagnostic nuclear medicine
78799	Unlisted genitourinary procedure, diagnostic nuclear medicine
78999	Unlisted miscellaneous procedure, diagnostic nuclear medicine
79999	Radiopharmaceutical therapy, unlisted procedure

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS

Pathology – Laboratory	
Code	**Description**
80299	Quantitation of drug, not elsewhere classified
81099	Unlisted urinalysis procedure
84999	Unlisted chemistry procedure
85999	Unlisted hematology and coagulation procedure
86849	Unlisted immunology procedure
86999	Unlisted transfusion medicine procedure
87999	Unlisted microbiology procedure
88099	Unlisted necropsy (autopsy) procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure
89240	Unlisted miscellaneous pathology test
89398	Unlisted reproductive medicine laboratory procedure
Medicine	
Code	**Description**
90399	Unlisted immune globulin
90749	Unlisted vaccine/toxoid
90779	Unlisted therapeutic, prophylactic or diagnostic intravenous or intra-arterial injection or infusion
90899	Unlisted psychiatric service or procedure
90999	Unlisted dialysis procedure, inpatient or outpatient
91299	Unlisted diagnostic gastroenterology procedure
92499	Unlisted ophthalmological service or procedure
92700	Unlisted otorhinolaryngological service or procedure
93799	Unlisted cardiovascular service or procedure
94799	Unlisted pulmonary service or procedure
95199	Unlisted allergy/clinical immunologic service or procedure
95999	Unlisted neurological or neuromuscular service or procedure
96549	Unlisted chemotherapy service or procedure
96999	Unlisted special dermatological service or procedure
97039	Unlisted modality service or procedure (specify type and time if constant attendance)
97139	Unlisted therapeutic service or procedure (specify)
97799	Unlisted physical medicine/rehabilitation service or procedure
99199	Unlisted special service, procedure, or report
99600	Unlisted home visit service or procedure
Evaluation and Management	
Code	**Description**
99429	Unlisted preventive medicine service
99499	Unlisted evaluations and management service

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS

Miscellaneous A Codes	
Code	**Description**
A4335	Incontinence supply, miscellaneous
A4421	Ostomy supply, miscellaneous
A4913	Miscellaneous dialysis supplies, NOS
A9698	Non-radioactive contrast imaging material, not otherwise classified, per study
A9699	Radiopharmaceutical, therapeutic, not otherwise classified
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
A9999	Miscellaneous DME supply or accessory, not otherwise specified
Miscellaneous E Codes	
Code	**Description**
E1399	Durable Medical Equipment, miscellaneous
Miscellaneous G Codes	
Code	**Description**
G0235	PET Imaging, any site NOS
Miscellaneous J Codes	
Code	**Description**
J3490	Unclassified drugs
J3590	Unclassified biologics
J7599	Immunosuppressive drug, NOC
J7699	NOC drugs, inhalation solutions, administered through DME
J7799	NOC drugs, other than inhalation drugs, administered through DME
J8498	Antiemetic drug, rectal suppository, NEC
J8499	Prescription drug, oral, non-chemotherapeutic, NOS
J8597	Antiemetic drug, oral, NOS
J8999	Prescription drug, oral, chemotherapeutic, NOS
J9999	NOC, antineoplastic drug
Miscellaneous L Codes	
Code	**Description**
L8499	Unlisted procedure for miscellaneous prosthetic services
L8699	Unlisted procedure for miscellaneous implant services
Miscellaneous Q Codes	
Code	**Description**
Q4050	Cast supplies for unlisted types and material of casts
Q4051	Splint supplies, misc. (includes thermoplastics, strapping, fasteners, padding and other supplies
Q4082	Drug or biological NEC, Part B drug competitive acquisition program

CLAIM TIPS FOR BILLING MISCELLANEOUS ITEMS

Miscellaneous S Codes	
Code	**Description**
S8189	Tracheostomy supply NOS
S3870	Comparative Genomic Hybrization (CGH)
Miscellaneous V Codes	
Code	**Description**
V2199	Not otherwise classified – single vision lens
V2797	Vision supply, accessory or component of another HCPCS vision code
V2799	Vision service, miscellaneous
V5299	Hearing service, miscellaneous

COVID-19 UPDATE

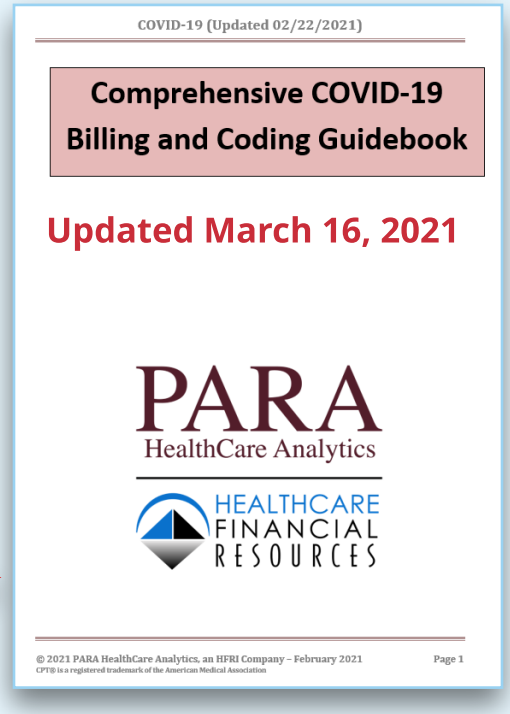
PARA HealthCare Analytics *continues to update COVID-19 coding and billing information based on frequently changing guidelines and regulations from CMS and payers. All coding must be supported by medical documentation.*

What you will find in this important update:

- New link to the CDC ICD-10 tool
- Updated information on Remdesivir, the FDA-approved COVID-19 treatment for most adults
- New MAC payment link and table for pricing of COVID-19 lab tests
- Updated language for RHCs and FQHCs regarding billing of MABs and vaccines
- Easier to read sections for Condition Codes and Modifiers
- New information on the CR/DR

https://apps.para-hcfs.com/para/Documents/COVID-19%20(Updated%2003-16-2021).pdf

Download the updated Comprehensive COVID-19 Billing and Coding Guidebook by clicking the link above or the document to the right.


COVID-19 (Updated 02/22/2021)

Comprehensive COVID-19 Billing and Coding Guidebook

Updated March 16, 2021

PARA HealthCare Analytics

HEALTHCARE FINANCIAL RESOURCES

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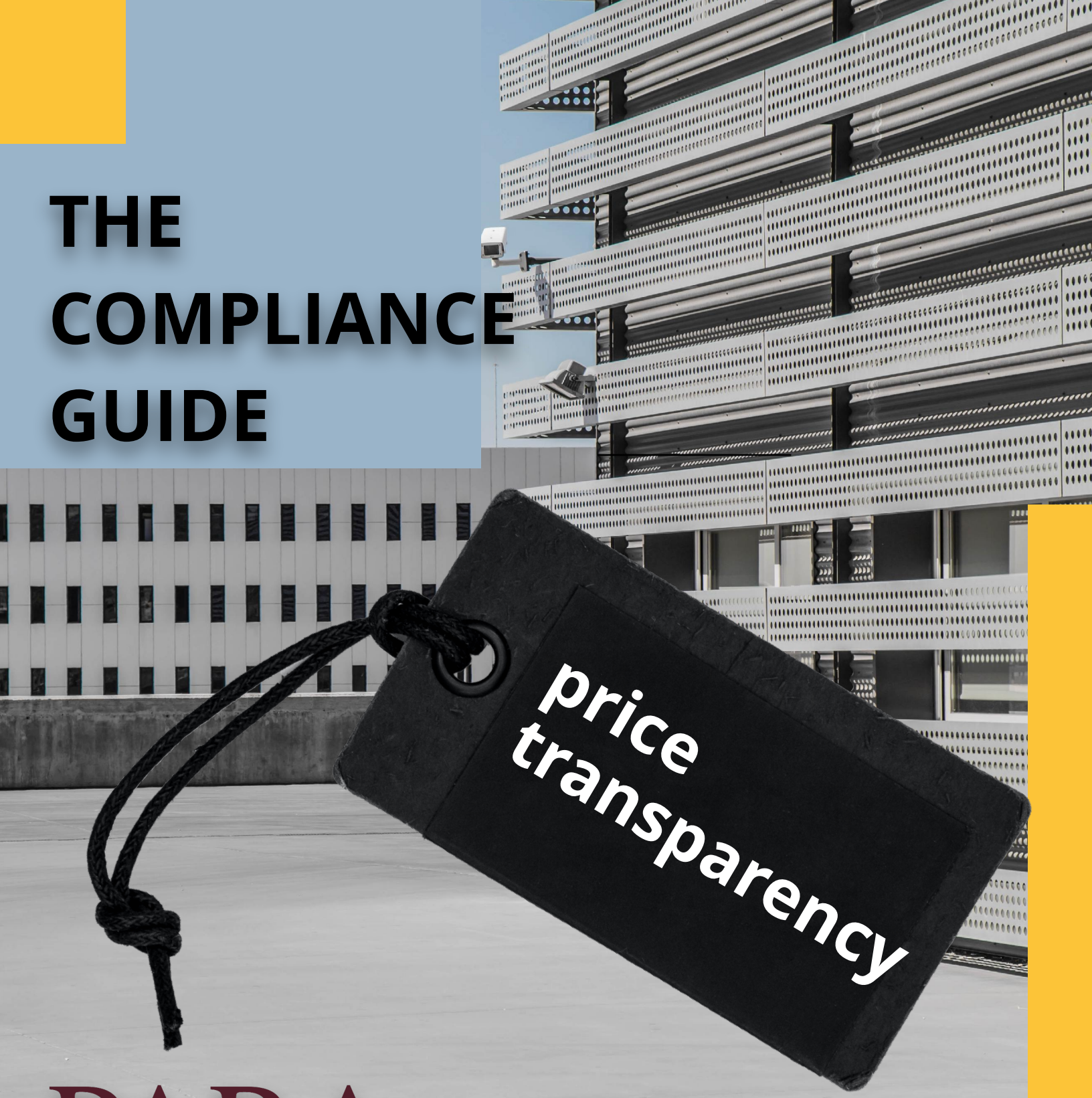
THE COMPLIANCE GUIDE



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2021

There is still time to achieve readiness for the critical Price Transparency Rule.

PARA can help.

THE CLOCK IS TICKING

DATES, RULES & REGS

The CMS final rule (CMS-1717-F2) aims to make hospital price information readily available to patients, so they can compare costs and make more informed healthcare decisions. Meeting the deadline and maintaining compliance will be no small endeavor for providers. Complying with the mandate will be a large undertaking that requires multi-disciplinary coordination. ***PARA HealthCare Analytics and HFRI can help navigate the dates, the rules and the regulations****.*

REQUIREMENT #1

By January 1, 2021, hospitals are required to be in compliance with the Hospital Price Transparency requirements set forth in the CY 2020 Hospital Outpatient PPS Policy Changes (CMS-1717-FS).

REQUIREMENT #2

A comprehensive machine-readable file that includes the specific standard charges for all hospital items and services.

REQUIREMENT #3

A consumer-friendly display that includes the standard charges for at least 300 "shoppable" services that are grouped with charges for ancillary services that ar customarily provided by the hospital.

SOLUTIONS FOR HOSPITALS

THE PARA PTT

In speaking with hospital associations, clients, and business vendor groups, we are finding that we are one of the only vendors who can completely satisfy, to the letter of the law, both CMS requirements in a fully customizable manner.

Providers will need to publish both machine-readable format files and the patient facing price estimator is a value-add service for enhancing price transparency.

PARA will use the CMS Extract file embedded in the Price Transparency Tool tab via the **PARA Data Editor** to build the shoppable items/bundles. This can be done by the hospital, coupled with **PARA's** guidance to ensure all primary procedures are linked to its customarily paired ancillary services.

Turnaround time for the **Price Transparency Tool** is 60 days from submission of completed data.

There is no limit at this time on how many clients **PARA** can assist with the CMS' 2021 price transparency requirements as we are constantly monitoring workload and innovating our automation to support the data mining need for this initiative.

FROM <THIS, TO THIS>

TAKING CONSUMERS FROM THE STONE AGE TO THE DIGITAL AGE

MEET THE TEAM

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CAPABILITIES AND SERVICES

To ensure consumers will be able to browse for healthcare services in the same way they shop for other goods and services online, hospitals partner with **PARA HealthCare Analytics**, an HFRI company that has been providing hospitals and health systems with pricing, reimbursement, coding, and contract management services since 1985.

PARA works closely with clients to deploy robust and accurate pricing capabilities for area healthcare consumers. The **PARA** solution includes a patient-facing estimator engineered to deliver user-friendly, procedure-level estimates reflecting patients' specific coverage limits.

Providing consumers with the ability to effectively shop for healthcare services is essential as more employers transition to high-deductible health plans.

Peter Ripper, CEO of **PARA HealthCare Analytics**, has led his team to design a solution that will provide meaningful, easy-to-understand information for healthcare consumers.

With the healthcare providers facing a range of new financial pressures due to the COVID-19 pandemic, **PARA** has pushed to ensure that the critical but complex transparency rule can be implemented in a timely, cost-effective and consumer-friendly manner. We look forward to helping other systems who may be struggling to achieve price transparency.

WATCH YOUR HOSPITAL'S BRIGHT FUTURE UNFOLD

With The Help Of Our Price Transparency Tool

PRESS HERE

DEMO

REPORTING MANUFACTURER CREDITS FOR MEDICAL DEVICES

NOTE: This update removes advice regarding modifiers FB and FC, which are not required on outpatient claims for no-cost or reduced-cost implantable devices effective January 1, 2014.

The Health and Human Services Office of the Inspector General (OIG) released a new audit report in November of 2020 advising Medicare to recoup payments from hospitals that improperly claimed reimbursement for medical devices supplied at a reduced cost for specific patients.Both inpatient (IPPS) and outpatient (OPPS) claims with billing deficiencies related to credited medical devices were found.

Hospitals Did Not Comply With Medicare Requirements for Reporting Cardiac Device Credits A-01-18-00502 11-16-2020 (hhs.gov)

Hospitals Did Not Comply With Medicare Requirements for Reporting Cardiac Device Credits

11-16-2020 | A-01-18-00502 | Complete Report | Report in Brief

Why OIG Did This Audit

Prior OIG audits with audit periods ranging from 2005 through 2016 found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for medical devices that were replaced. Specifically, hospitals did not always report to CMS device manufacturer credits that they received. One prior review estimated that services related to the replacement of seven recalled and prematurely failed cardiac medical devices cost Medicare $1.5 billion during calendar years 2005 through 2014.

How OIG Did This Audit

We obtained a list of warranty credits from the device manufacturers and matched the device recipients to the Medicare enrollment database to determine which recipients were Medicare beneficiaries. Next, we matched the beneficiaries to the Medicare National Claims History to identify claims that had a cardiac device replacement procedure for which the date of service matched to the device replacement procedure date on the credit listing. We evaluated compliance with selected billing requirements.

When an implanted device is eligible for a free or discounted replacement due to a manufacturer’s defect or risk management policy, hospitals are required to report the discounts on their claims for the device's implantation. Under both Medicare reimbursement systems (Outpatient Prospective Payment System (OPPS) and Inpatient Prospective Payment System (IPPS)), facility reimbursement rates are calculated to compensate the hospital for both the cost of the surgical procedure and the cost of the device itself.

PRICE TRANSPARENCY: CLARIFYING THE UNKNOWN

Let us clarify the facts, the questions and uncertainties about Price Transparency.

Click on the video clip below and watch how **PARA HealthCare Analytics** and **HFRI** can ease the anxieties of hospital compliance executives.

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!**

News

- Clinical Laboratory Data Reporting Delayed Until 2022: Reminder
- Comprehensive Eye Examinations: Comparative Billing Report in March

Compliance

- Polysomnography Services: Bill Correctly

Events

- Long-Term Care: Dementia-related Psychosis Call — March 23
- Open Payments & You Call — March 25
- SNF Quality Reporting Program: Achieving a Full APU Webinar-March 30

MLN Matters® Articles

- April 2021 Update to the Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS)
- April Quarterly Update for 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
- Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens
- Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2021 Update
- Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) & PC Print Update

Publications

- Medicare Quarterly Provider Compliance Newsletter

- View this edition as PDF (PDF)

There were 4 new or revised
MedLearns released this week.

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

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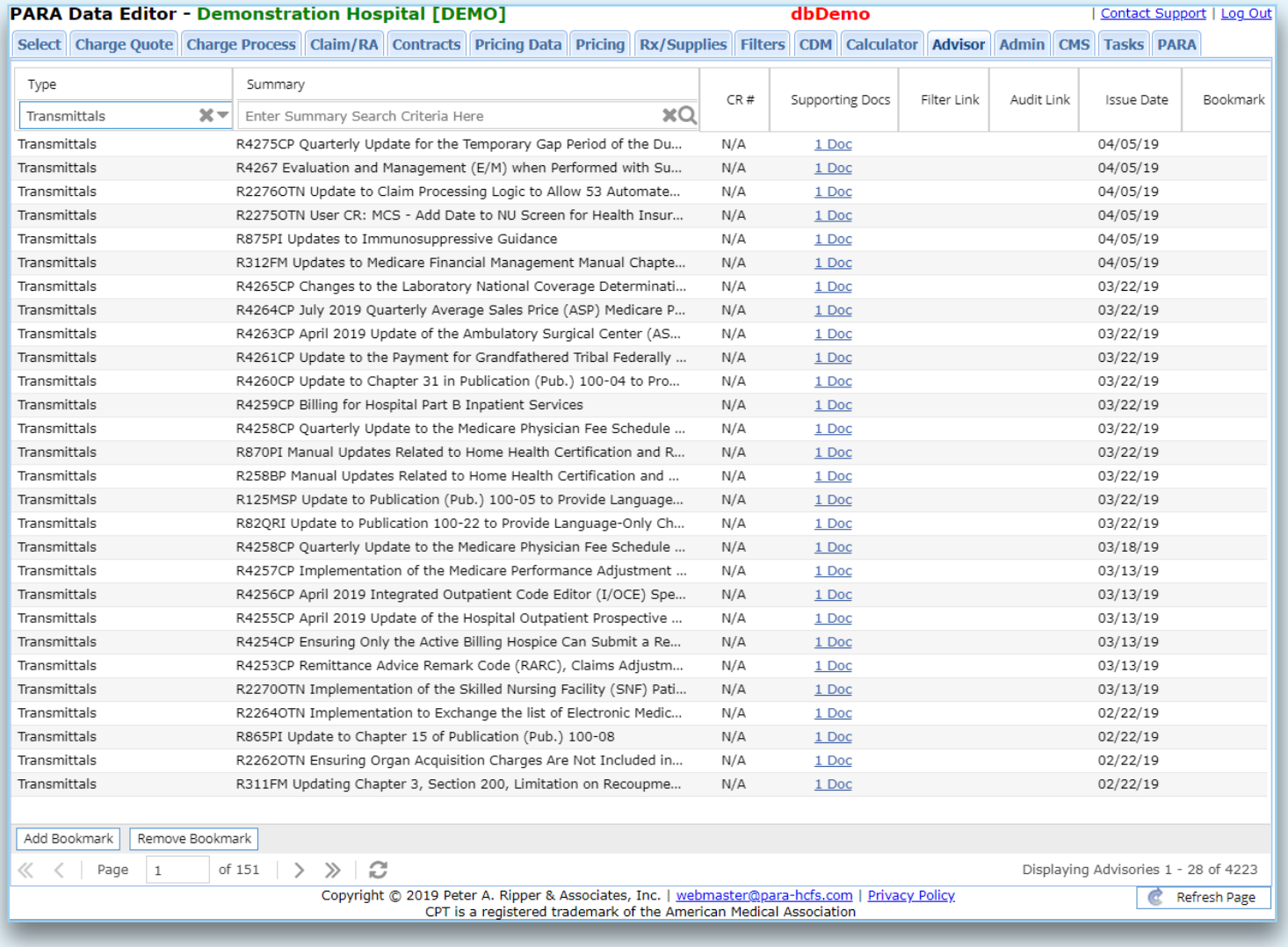

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KNOWLEDGE • RESOURCES • TRAINING

The Intravenous Immune Globulin (IVIG) Demonstration: Demonstration is ending on December 31, 2023

MLN Matters Number: MM11877 Replaced

Related CR Release Date: March 17, 2021

Related CR Transmittal Number: R10660DEMO

Related Change Request (CR) Number: 11877

Effective Date: January 1, 2021 – Demonstration ends December 31, 2023

Implementation Date: January 4, 2021

Note: We replaced this article and several other articles on the IVIG demonstration with a fact sheet. The Intravenous Immune Globulin Demonstration (Demonstration Ends on December 31, 2023) fact sheet gives a complete and current overview of this effort.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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KNOWLEDGE • RESOURCES • TRAINING

Correction to Period Sequence Edits on Home Health Claims

MLN Matters Number: MM12085

Related Change Request (CR) Number: 12085

Related CR Release Date: March 16, 2021

Effective Date: January 1, 2020

Related CR Transmittal Number: R10596OTN

Implementation Date: July 6, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for Home Health Agencies (HHAs) submitting Home Health (HH) claims to MACs for services they provide to Medicare patients.

PROVIDER ACTION NEEDED

This article informs you about revisions to Medicare's Common Working File (CWF) HH period sequence edits to no longer exclude Low-Utilization Payment Adjustment (LUPA) claims. Make sure your billing staffs are aware of these changes.

BACKGROUND

The CWF contains edits that ensure that Medicare pays HH claims in the correct episode or period of care sequence. Currently, these edits bypass LUPA claims. Before the implementation of the Patient-Driven Groupings Model (PDGM), this bypass was correct. If the claim had 4 or fewer visits, it would correctly receive a LUPA payment regardless of whether it was an early or late episode.

Under the PDGM, the early or late Health Insurance Prospective Payment System (HIPPS) codes for a period of care can have different LUPA thresholds, ranging from 1 to 6 visits. The correct early or late HIPPS code must be assigned before Medicare systems can correctly determine whether a LUPA payment should apply. In some cases, incorrect payments result if Medicare systems bypass period of care sequence edits for LUPA claims.

When HHAs bring such claims to their attention, MACs manually recode affected claims to correct payment. CR 12085 corrects CWF editing to remove the LUPA bypass for HH claims with from dates on or after January 1, 2020. Once the CR 12085 correction is in effect, manual recoding will no longer be necessary.

CR 12085 contains no new policy, but corrects the implementation of existing policy.

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KNOWLEDGE • RESOURCES • TRAINING

Common Working File (CWF) Edits for Medicare Telehealth Services and Manual Update

MLN Matters Number: MM12068 | Related Change Request (CR) Number: 12068

Related CR Release Date: March 16, 2021 | Effective Date: January 1, 2021

Related CR Transmittal Number: R10168CP | Implementation Date: July 6, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, non-physician practitioners, nursing facilities, and other providers submitting telehealth claims to Medicare Administrative Contractors (MACs) for nursing facility services provided to Medicare patients.

PROVIDER ACTION NEEDED

This article tells you about claims frequency editing changes that Medicare's Common Working File (CWF) performs based on relevant policy limitations for subsequent nursing facility care services. The article also tells you of updates to the Medicare Claims Processing Manual to reflect these changes. Make sure that your billing staffs are aware of these changes.

BACKGROUND

For subsequent nursing facility care services, Medicare had limited the patient's admitting physician or non-physician practitioner to one telehealth visit every 30 days. CMS is changing this limitation to once every 14 days. Also, you may not furnish or report subsequent nursing facility care services for a Federally-mandated periodic visit under 42 CFR 483.40(c) through telehealth. The frequency limit of the benefit doesn't apply to consulting physicians or practitioners, who should continue to report initial or follow-up inpatient telehealth consultations using the applicable HCPCS G-codes.

For this edit change, CWF revises the current line level edits from once every 30 days to allow a frequency of once every 14 days for the following codes when billed with the GT or GQ modifier or Place of Service (POS) code 02, effective for claims with dates of service on or after January 1, 2021, that are processed on or after July 6, 2021:

- 99307
- 99308

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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The link to this MedLearn MM12188

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KNOWLEDGE • RESOURCES • TRAINING

Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021

MLN Matters Number: MM12188	Related Change Request (CR) Number: 12188
Related CR Release Date: March 16, 2021	Effective Date: January 1, 2021
Related CR Transmittal Number: R10671bp	Implementation Date: April 5, 2021

PROVIDER TYPES AFFECTED

This MLN Matters article is for End Stage Renal Disease (ESRD) facilities that bill Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

PROVIDER ACTION NEEDED

This article tells you of the Calendar Year (CY) 2021 rate updates and policies for the ESRD Prospective Payment System (PPS) and implements payment for renal dialysis services you furnish to Medicare patients with Acute Kidney Injury (AKI) in ESRD facilities. Make sure your billings staffs are aware of these updates.

BACKGROUND

Effective January 1, 2011, CMS implemented the ESRD PPS based on requirements in Section 1881(b)(14) of the Social Security Act (the Act). The ESRD PPS provides a single, per-treatment payment to ESRD facilities that covers all the resources they use in providing an outpatient dialysis treatment. CMS adjusts the ESRD PPS base rate to reflect patient and facility characteristics that contribute to higher per-treatment costs. Section 1881(b)(14)(F) of the Act requires an annual increase to the ESRD PPS base rate by an ESRD market basket increase factor, reduced by the productivity adjustment described in Section 1886(b)(3)(B)(xi)(II) of the Act. That is, the ESRD bundled (ESRDB) market basket increase factor minus the productivity adjustment will update the ESRD PPS base rate.

In accordance with Section 1834(r) of the Act, as added by Section 808(b) of the Trade Preferences Extension Act of 2015 (TPEA), we pay ESRD facilities for providing renal dialysis services to Medicare beneficiaries with AKI. CR 9598 implemented payment for renal dialysis services and provides detailed information regarding payment policies.

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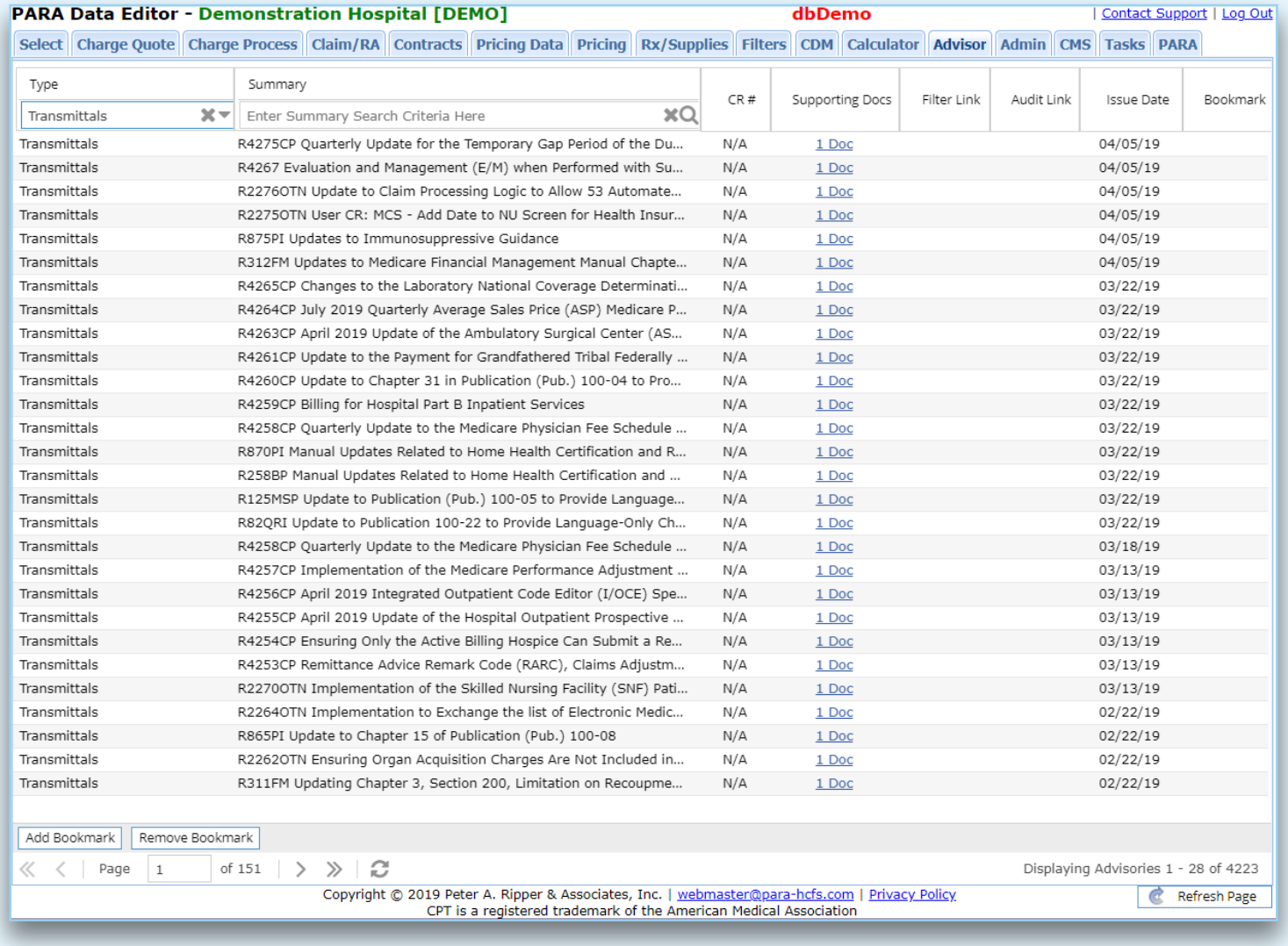

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The link to this Transmittal R10635CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10635	**Date: March 23, 2021**
	Change Request 12104

SUBJECT: Claims Processing Instructions for National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform the MACs of the follow-on instructions incorporating shared system changes for claims processing for Implantable Cardiac Defibrillators with dates of service on or after February 15, 2018.

EFFECTIVE DATE: February 15, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2021

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/Table of Contents
R	32/270/Implantable Cardiac Defibrillators (ICDs)
R	32/270/270.1/Coding Requirements for ICDs
R	32/270/270.2/Special Editing for Inpatient Claims
N	32/270/270.3/Denial Messaging

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 R10658CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10658	**Date: March 23, 2021**
	Change Request 12171

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2021

I. SUMMARY OF CHANGES: This Change Request (CR) announces the changes that will be included in the July 2021quarterly release of the edit module for clinical diagnostic laboratory services. This Recurring Update Notification applies to Chapter 16, Section 120.2, Publication 100-04.

EFFECTIVE DATE: July 1, 2021 - Unless noted differently in requirements.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 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.

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

III. FUNDING:

For Medicare Administrative Contractors (MACs):
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IV. ATTACHMENTS:

Recurring Update Notification

The link to this Transmittal R10601CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10601	**Date: March 23, 2021**
	Change Request 12091

SUBJECT: Modifications to the National Coordination of Benefits Agreement (COBA) Claims Crossover Process

I. SUMMARY OF CHANGES: Through this instruction, CMS is directing the Common Working File (CWF) maintainer to discontinue the practice of sending Beneficiary Other Insurance (BOI) auxiliary file data to the Next Generation Desktop (NGD) and the Medicare Beneficiary Database (MBD) **only** for COBA ID ranges 79000-79999 and for 89000-89999. Additionally, through this instruction, CMS is modifying one aspect of the CWF logic used as part of Recovery Audit Contractor (RAC)-initiated COBA crossover claims process, associated with COBA ID range 88000--88999.

EFFECTIVE DATE: July 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 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.

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	27/ 80.8- Inclusion and Exclusion of Specified Categories of Adjustment Claims for Coordination of Benefits Agreement (COBA) Crossover Purposes

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 R10629MSP

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-05 Medicare Secondary Payer	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10629	**Date: March 23, 2021**
	Change Request 11332

SUBJECT: Update Internet Only Manual (IOM) Chapter 7 Medicare Secondary Payer (MSP) Recovery Manual

I. SUMMARY OF CHANGES: Several years ago, Medicare Secondary Payer (MSP) Internet Only Manual (IOM) 100-05, Chapter 7 was removed from the IOM for MSP recovery processing revisions. The Centers for Medicare & Medicaid Services (CMS) has completed the updates to the manual and is sending the IOM out to the A/B MACs and DME MACs for review and comments. Certain references have been removed because either the law has been repealed, such as the Internal Revenue Service (IRS)/Social Security Administration (SSA)/CMS Data Match or the system no longer exists, such as the Recovery Management System (ReMAS). Overall, the IOM is smaller than previously due to the fact that many of the recoveries are now performed by the Coordination of Benefits & Recovery Contractors and are no longer required to be in the IOM.

EFFECTIVE DATE: April 19, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 19, 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.*

The link to this Transmittal R10614FM

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-06 Medicare Financial Management	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10614	**Date: March 23, 2021**
	Change Request 12028

SUBJECT: The Fiscal Year 2021 Updates for the CMS Internet Only Manual (IOM) Publication (Pub.) 100-06, Medicare Financial Management Manual, Chapter 7 - Internal Control Requirements

I. SUMMARY OF CHANGES: This Change Request (CR) contains the upcoming Fiscal Year 2021 annual document updates, and provides clarification for the Office of Management & Budget (OMB) A-123 and Internal Controls over Financial Reporting (ICOFR).

EFFECTIVE DATE: October 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 22, 2021

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II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
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The link to this Transmittal R10672PI

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10672	**Date: March 18, 2021**
	Change Request 12149

SUBJECT: First General Update to Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to: (1) Incorporate technical and editorial changes into parts of Chapter 10 of Pub. 100-08, PIM; and (2) Address any outstanding policy issues in the Chapter 10 sections included in this CR.

EFFECTIVE DATE: March 12, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 22, 2021

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.1/Introduction to Medicare Provider Enrollment
R	10/10.1/10.1.1/Definitions
R	10/10.1/10.1.2/Enrolling to Receive Medicare Payment
R	10/10.1/10.1.3/General Summary of Process to Enroll in Medicare
R	10/10.1/10.1.4/General Overview of Medicare Enrollment Application Forms
R	10/10.2/Provider and Supplier Types/Services
R	10/10.2/10.2.1/Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A
N	10/10.7/10.7.19/Model Approval Letter for Federally Qualified Health Centers (FQHCs)

III. FUNDING:
For Medicare Administrative Contractors (MACs):

The link to this Transmittal R10641PI

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10641	**Date: March 18, 2021**
	Change Request 12135

SUBJECT: Updates to Chapter 4 of Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update various sections within Chapter 4 in Pub. 100-08.

EFFECTIVE DATE: April 19, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 19, 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.*

The link to this Transmittal R10660DEMO

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10660	**Date: March 17, 2021**
	Change Request 11877

Transmittal 10307, dated August 21, 2020, is being rescinded and replaced by Transmittal 10660, dated, March 17, 2021, to extend the Demonstration end date to December 31, 2023 by revising the title and effective date, updating the background and policy sections, and by removing the note in business requirement 11877.1. All other information remains the same.

SUBJECT: The Intravenous Immune Globulin (IVIG) Demonstration: Demonstration is ending on December 31, 2023

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to notify those interested, that the IVIG Demonstration is ending on December 31, 2023.

EFFECTIVE DATE: January 1, 2021 - Demonstration ends on December 31, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 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	

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:
Demonstrations

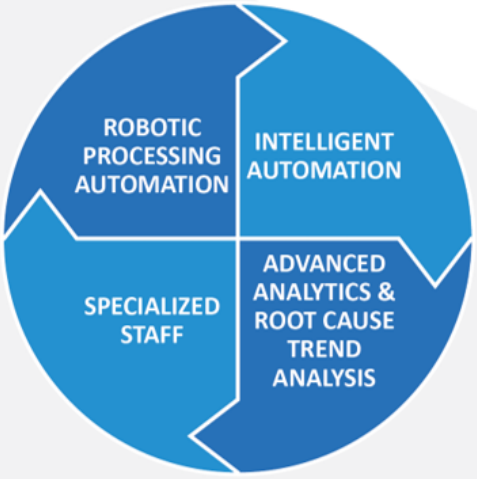
Creating results through our experience and automated processes.

30%+
INCREASE IN COLLECTIONS
IN SOME CASES UP TO 100% OR MORE

25%+
REDUCTION IN AN ACCOUNT'S LIFE CYCLE
LOWERING YOUR AR DAYS

20%+
DECREASE IN FUTURE DENIALS
INCREASING CASHFLOW & LOWERING WRITE-OFFS

Our Approach Uses:



HFRI Automation Process

- CATEGORIZE WORK INTO SIMILAR ISSUES
- IDENTIFY HIDDEN CAUSES OF DELAYED PAYMENTS
- TRAIN BOTS TO DO TEDIOUS FOLLOW-UP ACTIVITIES
- RESULT IN INCREASED PRODUCTION & COLLECTIONS

Additional Benefits Include:

AR FEES ARE CONTINGENCY BASED
PAY ONLY WHEN WE DELIVER CASH TO YOU

OUR SERVICE SITS ON THE BACKEND
AND DOESN'T DISRUPT ANY OTHER VENDOR OR INTERNAL EFFORTS ON AR

CANCEL AT ANY TIME FOR ANY REASON
WHETHER YOU WANT SHORT-TERM ASSISTANCE OR ARE EVER UNSATISFIED

PARA HealthCare Analytics | HEALTHCARE FINANCIAL RESOURCES

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