



January 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)

MLN Matters Number: MM12552

Related Change Request (CR) Number: 12552

Related CR Release Date: December 10, 2021 Effective Date: January 1, 2022

Related CR Transmittal Number: R11150CP Implementation Date: January 3, 2022

Provider Types Affected

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

Provider Action Needed

In this Article, you'll learn about:

- New Covid-19 CPT vaccines and administration codes
- OPPS updates for January 2022
- New Drugs, Biologicals, and Radiopharmaceuticals

Make sure your billing staff knows about these changes.

Background

CR 12552 describes changes to and billing instructions for various payment policies implemented in the January 2022 OPPS update. The January 2022 Integrated Outpatient Code Editor (I/OCE) will show the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions that CR 12552 identifies. The January 2022 revisions to I/OCE data files, instructions, and specifications are in [CR 12533](#).

The key points of CR 12552 are:

1. New Covid-19 CPT Vaccines and Administration Codes

On September 3, 2021, the American Medical Association (AMA) released the following 8 new CPT Category I codes for reporting SARS-CoV-2 vaccines and their administration:

- 91305, 0051A, 0052A and 0053A for reporting Pfizer-BioNTech COVID-19 vaccine and its administration for the tris-sucrose formulation
- 0004A and 0054A for reporting administration of Pfizer-BioNTech COVID-19 booster doses for both available formulations

- 91306 and 0064A for reporting the Moderna COVID-19 booster dose and its administration, respectively

On September 22, 2021, FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine (CPT 91300) to allow for use of a single booster dose, to be administered at least 6 months after completion of the primary series for certain populations. Effective September 22, 2021, CMS assigned CPT 0004A to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose).

On October 6, 2021, AMA released new CPT Category I codes 91307, 0071A, and 0072A for reporting Pfizer-BioNTech COVID-19 vaccine and its administration for the tris-sucrose formulation for children 5 through 11 years of age. Recently, the AMA released the new CPT Category I code 0034A for reporting the administration of the Janssen COVID-19 vaccine booster for patients who had previously gotten the Janssen single-dose primary vaccine.

On October 20, 2021, FDA amended the EUA for COVID-19 vaccines to allow for the use of a single booster dose, including:

- The use of a single booster dose of the Moderna COVID-19 Vaccine (CPT 91306) that you may administer at least 6 months after completion of the primary series to certain populations.
- The use of a single booster dose of the Janssen COVID-19 Vaccine (CPT 91303) that you may administer at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.

Effective October 20, 2021, we assigned CPT codes 0034A and 0064A to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) and 91306 was assigned to status indicator “L” (Not paid under OPSS. Paid at reasonable cost; not subject to deductible or coinsurance).

On October 29, 2021, FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age. Effective October 29, 2021, we assigned CPT code 0071A to status indicator “S”, APC 9397 (Covid-19 Vaccine Admin Dose 1 of 2). We assigned CPT code 0072A to status indicator “S”, APC 9398 and CPT code 91307 was assigned to status indicator “L”

[Table 1, Attachment A in CR12552](#) lists the long descriptors for the codes

2. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective January 1, 2022

The AMA CPT Editorial Panel established 21 new PLA codes, specifically, CPT codes 0285U through 0305U, effective January 1, 2022. [Table 2, Attachment A in CR12552](#), lists the long descriptors and status indicators for the codes. We added CPT codes 0285U through 0305U to the January 2022 I/OCE with an effective date of January 1, 2022.

3. Device Pass-Through Category Codes

Effective January 1, 2022, the revised Medicare Claims Processing Manual, Chapter 4, [Section 60.4](#) gives the explanations of certain items and descriptions for the [complete list of device pass-through category codes](#).

4. a New Device Pass-Through Categories

[Section 1833\(t\)\(6\)\(B\)](#) of the Social Security Act (the Act) requires that, under the OPPTS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. It also requires us to create more categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices. We are establishing 2 new device pass-through categories effective January 1, 2021:

- HCPCS code C1833 (Cardiac monitor sys)
- HCPCS code C1832 (Auto cell process).

We are also updating the device offset CPT code information for the device category described by HCPCS codes C1833, C1832, and C1831. [Table 3, Attachment A in CR 12552](#), gives a listing of new coding information concerning the new device categories for transitional pass-through payment. Device offset amounts for these CPT codes will be available in the January 2022 I/OCE update.

b. Device Offset from Payment for HCPCS codes C1832 and C1833, and An Update for HCPCS Code C1831

[Section 1833\(t\)\(6\)\(D\)\(ii\)](#) of the Act requires us to deduct from pass-through payments for devices an amount that reflects the device portion of the APC payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-through payments for the applicable pass-through device.

(1) Device Offset for HCPCS Code C1833

The device offset amounts for APC 5223 (Level 3 Pacemaker and Similar Procedures), APC 5222 (Level 2 Pacemaker and Similar Procedures), APC 5741 (Level 1 Electronic Analysis of Devices), and APC 5221 (Level 1 Pacemaker and Similar Procedures) are associated with the costs of the device category described by HCPCS code C1833 (Cardiac monitor). Always bill the device in the category described by HCPCS code C1833 with 1 of the following CPT codes:

- CPT code 0525T – Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor), which is assigned to APC 5223 for Calendar Year (CY) 2022
- CPT code 0526T – Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only, which is assigned to APC 5222 for CY 2022

- CPT code 0527T – Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only, which is assigned to APC 5222 for CY 2022

(2) Device Offset for HCPCS Code C1832

The device offset amounts for APC 5053 (Level 3 Skin Procedures), APC 5054 (Level 4 Skin Procedures), and APC 5055 (Level 5 Skin Procedures) are associated with the cost of the device category described by HCPCS code C1832 (Auto cell process). Always bill device in the category described by HCPCS code C1832 with 1 of the following CPT codes:

- CPT code 15110 (Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children), which is assigned to APC 5054 for Calendar Year (CY) 2022
- CPT code 15115 (Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children), which is assigned to APC 5054 for CY 2022

You may bill the device in the category described by HCPCS code C1832 with 1 of the following CPT codes but must also be accompanied by 1 of the preceding codes:

- CPT code 15100 (Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)), which is assigned to APC 5054 for CY 2022
- CPT code 15120 (Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)), which is assigned to APC 5055 for CY 2022

(3) Device Update for HCPCS Code C1831

Hospitals can no longer bill C1831 when performing 22558 and 22586 as these procedures have been added to the Inpatient Only List effective January 1, 2022. See the [most current device pass-through information](#).

c. Transitional Pass-Through Payments for Designated Devices

We assign certain designated new devices to APCs and the I/OCE shows these are eligible for payment based on the reasonable cost of the new device reduced by the amount included in the APC for the procedure that shows the packaged payment for device(s) used in the procedure. The I/OCE will decide the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. All related payment calculations will be returned on the same APC line and identified as a designated new device.

See [Addendum P](#) of the CY 2021 final rule with comment period for the most current OPPS HCPCS Offset file.

d. Alternative Pathway for Devices That Have an FDA Breakthrough Designation

For devices that have FDA marketing authorization and a Breakthrough Device designation from the FDA, we give an alternative pathway to qualify for device pass-through payment status. Under this, devices wouldn't be evaluated in terms of the current substantial clinical improvement criterion for the purposes of deciding device pass-through payment status. The devices would still need to meet the other criteria for pass-through status. This applies to devices that get pass-through payment status effective on or after January 1, 2020.

5. Billing for Allogeneic Stem Cell Transplant

[Section 108 of the Further Consolidated Appropriations Act, 2020](#) affects the cost reporting and payment of inpatient acquisition costs of allogeneic hematopoietic stem cells, beginning in Fiscal Year (FY) 2021. The outpatient payment methodology for allogeneic hematopoietic stem cell acquisition costs remains unchanged. We're updating [Chapter 4](#) of the manual to give instructions for outpatient cost reporting.

6. Changes to the Inpatient-Only (IPO) List for CY 2022

The Medicare IPO list includes procedures provided in the inpatient setting and therefore aren't paid under the OPPS. For CY 2022, 293 of the 298 services removed from the IPO list in CY 2021 are returning to the IPO list. The changes to the IPO list for CY 2022 are in [Table 4, Attachment A in CR 12552](#).

7. Payment Adjustment for Certain Cancer Hospitals Beginning CY 2022

For certain cancer hospitals that gets interim monthly payments associated with the cancer hospital adjustment at 42 Code of Federal Regulation (CFR) 419.43(i), Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent CYs, the target Payment-to-Cost Ratio (PCR) that should be used in the calculation of the interim monthly payments and at final cost report settlement is reduced by 0.01. For CY 2022, the target PCR, after including the reduction required by Section 16002(b), is 0.89.

8. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

Five new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there haven't previously been specific codes available starting on January 1, 2022. These drugs and biologicals will get drug pass-through status starting January 1, 2022. These HCPCS codes are in [Table 5, Attachment A in CR12552](#).

b. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of January 1, 2022

Fifteen new drug, biological, and radiopharmaceutical HCPCS codes will be established on January 1, 2022. These HCPCS codes are in [Table 6, Attachment A in CR 12552](#).

c. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted as of January 1, 2022

Four drug, biological, and radiopharmaceutical HCPCS codes will be deleted on January 1, 2022. These HCPCS codes are in [Table 7, Attachment A in CR 12552 in CR 12552](#).

d. Vaccines that Will Retroactively Change from Non-Payable Status to Payable Status in the January 2022 I/OCE Update

The status indicator for CPT code 90671 (Pneumococcal conjugate vaccine, 15 valent (PCV15), for intramuscular use) effective July 16, 2021, will change retroactively from status indicator = “E1” to status indicator = “L” in the January 2022 I/OCE Update. The status indicator for CPT code 90677 (Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use) effective July 1, 2021, will change retroactively from status indicator = “E1” to status indicator = “L” in the January 2022 I/OCE Update. We show these drugs/biologicals in [Table 8, Attachment A in CR 12552](#).

e. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)

For CY 2022, payment for most non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals that weren’t acquired through the 340B Program is at a single rate of ASP + 6% (or ASP + 6% of the reference product for biosimilars).

Payment for non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program is at the single rate of ASP – 22.5% (or ASP - 22.5% of the biosimilar’s ASP if a biosimilar is acquired under the 340B Program), which gives payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical. In CY 2022, a single payment of ASP + 6% for pass-through drugs, biologicals, and radiopharmaceuticals is made to give payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP + 6% of the reference product for biosimilars).

We’ll update payments for drugs and biologicals based on ASPs on a quarterly basis as later quarter ASP submissions become available. Effective January 1, 2022, payment rates for many drugs and biologicals have changed from the values published in the CY 2022 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from fourth quarter of CY 2020. In cases where adjustments to payment rates are necessary, changes to the payment rates are in the January 2022 Fiscal Intermediary Standard System (FISS) release. We aren’t publishing the updated payment rates in CR 12552. However, the updated payment rates effective January 1, 2022, are in the January 2022 update of the [OPPS Addendum A and Addendum B](#).

f. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

We retroactively correct payment rates for some drugs and biologicals paid based on ASP methodology. These retroactive corrections typically occur on a quarterly basis. The [list](#) of drugs and biologicals with corrected payments rates is available on the first date of the quarter. You may resubmit claims that affected by adjustments to a previous quarter’s payment files

9. Skin Substitutes

We package the payment for skin substitute products that don't qualify for pass-through status into the payment for the associated skin substitute application procedure. For payment packaging purposes, the skin substitute products are divided into two groups: 1) high-cost skin substitute products and 2) low-cost skin substitute products.

We assign new skin substitute HCPCS codes into the low-cost skin substitute group unless we've pricing data showing the cost of the product is above either the mean unit cost of \$48 or the per day cost of \$949 for CY 2022.

a. New Skin Substitute Products as of January 1, 2022

- There's 1 new skin substitute HCPCS code that will be active as of January 1, 2022. This code is in [Table 9, Attachment A in CR 12552](#).

b. Skin Substitute Assignments to High Cost and Low Costs Groups for CY 2022

- [Table 10, Attachment A in CR 12552](#), lists the skin substitute products and their assignment as either a high-cost or a low-cost skin substitute product, when applicable.

10. Method to Control for Unnecessary Increases in Utilization of Outpatient Services/G0463 with Modifier PO

In CY 2020, we finalized a policy to use our authority to apply an amount equal to the site-specific Physician Fee Schedule (PFS) payment rate for nonexcepted items and services provided by a nonexcepted off-campus Provider-Based Department (PBD). We completed the phase-in of the policy in CY 2020. The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40% of OPPS payment (that is, 60% less than the OPPS rate) for CY 2022.

Specifically, the total 60% payment reduction will apply in CY 2022. These departments will be paid 40% of the OPPS rate (100% of the OPPS rate minus the 60% payment reduction for the clinic visit service in CY 2022

11. Changes to OPPS Pricer Logic

- Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACHs) will continue to get a 7.1% payment increase for most services in CY 2022. The rural SCH and EACH payment adjustment excludes drugs, biologicals, items and services paid at charges reduced to cost, and items paid under the pass-through payment policy.
- New OPPS payment rates and copayment amounts will be effective January 1, 2022. All copayment amounts will be limited to a maximum of 40% of the APC payment rate. Copayment amounts for each service can't exceed the CY 2022 inpatient deductible of \$1,556. For most OPPS services, copayments are set at 20% of the APC payment rate.
- For hospital outlier payments under OPPS, there's no change in the multiple threshold of 1.75 for 2022. This threshold of 1.75 is multiplied by the total line-item APC payment to decide eligibility for outlier payments. We also use this factor to decide the outlier payment, which is 50% of estimated cost less 1.75 times the APC payment amount. The

- payment formula is $(\text{cost} - (\text{APC payment} \times 1.75)) / 2$.
- The fixed-dollar threshold for OPSS outlier payments increases in CY 2022 relative to CY 2021. The estimated cost of a service must be greater than the APC payment amount plus \$6,175 in order to qualify for outlier payments.
 - For outliers for Community Mental Health Centers (bill type 76x), there's no change in the multiple threshold of 3.4 for 2022. This threshold of 3.4 is multiplied by the total line-item APC payment for APC 5853 to decide eligibility for outlier payments. We also use this multiple amount to decide the outlier payment, which is 50% of estimated costs less 3.4 times the APC payment amount. The payment formula is $(\text{cost} - (\text{APC 5853 payment} \times 3.4)) / 2$.
 - The OPSS Pricer will apply a reduced update ratio of 0.9804 to the payment and copayment for hospitals that fail to meet their hospital outpatient quality data reporting requirements or that fail to meet our validation edits. We'll use the reduced payment amount to calculate outlier payments.
 - Effective January 1, 2022, we're adopting the Fiscal Year (FY) 2022 Inpatient Prospective Payment System (IPPS) post-reclassification wage index values with application of the CY 2022 out-commuting adjustment.
 - Effective January 1, 2022, for claims with APCs, which require implantable devices and have significant device offsets (greater than 30%), we'll apply a device offset cap based on the credit amount listed in the "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) value code. The credit amount in value code "FD" which reduces the APC payment for the applicable procedure, will be capped by the device offset amount for that APC.

12. Coverage Determinations

As a reminder, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPSS, doesn't imply coverage by the Medicare Program, but shows only how the product, procedure, or service may be paid if covered by the program. MACs decide whether a drug, device, procedure, or other service meets all program requirements for coverage.

More Information

We issued [CR 12552](#) to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
December 13, 2021	Initial article released.

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