

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

MLN Matters Number: MM12885 Related Change Request (CR) Number: 12885

Related CR Release Date: September 9, 2022 Effective Date: October 1, 2022

Related CR Transmittal Number: R11594CP Implementation Date: October 3, 2022

Provider Types Affected

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

Provider Action Needed

Make sure your billing staff knows about:

- New COVID-19 CPT vaccine and administration codes
- Redosing update for EVUSHELD™
- New procedure to assess coronary disease severity using computed tomography angiography

Background

This Article describes changes to and billing instructions for various payment policies implemented in the October 2022 OPPS update. <u>CR 12875</u> for the October 2022 Integrated Outpatient Code Editor (I/OCE) shows the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions.

The October 2022 OPPS changes are:

1. COVID-19 Laboratory Tests and Services and Other Laboratory Tests Coding Update

Since February 2020, CMS has recognized several COVID-19 laboratory tests and related services. We list the codes in <u>Table1</u> of CR 12885, along with their OPPS status indicators. The codes, along with their short descriptors and status indicators, are also listed in the October 2022 OPPS Addendum B.

2. New COVID-19 CPT Vaccines and Administration Codes

The American Medical Association (AMA) issues CPT Category I codes they develop in





collaboration with CMS and the CDC for each COVID-19 vaccine, as well as administration codes unique to each such vaccine and dose. These codes are effective upon receiving an Emergency Use Authorization (EUA) or approval from the FDA.

On April 26, 2022, the AMA released a new code describing the service to administer the booster dose of Pfizer BioNTech COVID-19 vaccine for patients ages 5-11 years old (0074A).

We identified an effective date of May 17, 2022, for CPT code 0074A. This effective date corresponds with updates to FDA EUAs and approvals. Effective May 17, 2022, we assign CPT code 0074A to status indicator S (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 9398 (COVID-19 vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the October 2022 I/OCE update.

Note: Patient cost-sharing won't apply to 0074A.

On June 7, 2022, the AMA released a new vaccine administration code (0083A) for the third dose of the Pfizer vaccine product to address COVID-19 in pediatric patients aged 6 months through 4 years.

We identified an effective date of June 17, 2022, for the Pfizer BioNTech COVID-19 vaccine administration CPT codes 0081A, 0082A, and 0083A, which describe the service to administer the first, second, and third doses of the vaccine, respectively, for pediatric patients aged 6 months through 4 years. This effective date corresponds to updates of FDA EUAs and approvals for Pfizer BioNTech COVID-19 vaccine product CPT code 91308, effective June 17, 2022.

Effective June 17, 2022, we assigned:

- CPT code 91308 to status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the October 2022 I/OCE update
- CPT code 0081A to status indicator "S", APC 9397 (COVID-19 vaccine Admin Dose 1 of 2)
- CPT codes 0082A and 0083A to status indicator "S", APC 9398 in the October 2022 I/OCE update

Note: Patient cost-sharing won't apply to CPT codes 0081A, 0082A, and 0083A.

On May 19, 2022, the AMA released a new vaccine product code (91311) and its associated vaccine administration codes (0111A, 0112A) for the new Moderna vaccine product to address severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) in pediatric patients ages 6 months through 5 years.

On July 6, 2022, the AMA released 3 new vaccine administration codes (0091A, 0092A, 0093A) for the Moderna vaccine product to address severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) in pediatric patients ages 6 through 11 years. Report these codes with previously established Moderna vaccine product code 91309. Table 2 of CR 12885 lists a revised descriptor for 0094A.





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We identify an effective date of June 17, 2022, for codes 0091A, 0092A, and 0093A, which describe the service to administer the Moderna COVID-19 vaccine's first, second, and third doses, respectively, for pediatric patients ages 6-11 years. This effective date corresponds with the June 17, 2022, update to the FDA EUA for the Moderna COVID-19 vaccine product code 91309.

We identified an effective date of June 17, 2022, for Moderna COVID-19 vaccine administration codes 0111A, 0112A, and 0113A, which describe the service to administer the vaccine's first, second, and third doses, respectively, for pediatric patients ages 6 months through 5 years. This effective date corresponds with updates to FDA EUAs and approvals for the Moderna vaccine product code 91311.

Effective June 17, 2022, we assigned:

- CPT code 0091A to status indicator S and APC 9397
- CPT codes 0092A and 0093A to status indicator S and APC 9398
- CPT code 91311 to status indicator L
- CPT code 0111A to status indicator S and APC 9397
- CPT codes 0112A and 0113A to status indicator S, APC 9398

Note: Patient cost sharing won't be applied to the new vaccine product code or new administration codes.

In MLN Matters Article MM12316, we listed 3 new CPT codes (0041A, 0042A, and 91304) associated with the Novavax COVID-19 vaccine and its administration for patients ages 18 or older. We identified an effective date of July 13, 2022, for codes 0041A and 0042A, which describe the service to administer the vaccine's first and second dose, respectively. This effective date corresponds with updates to FDA EUAs and approvals for the Novavax COVID-19 vaccine product (91304).

Effective July 13, 2022, we assigned:

- CPT code 0041A to status indicator S and APC 9397
- CPT code 0042A to status indicator S and APC 9398
- CPT code 91304 to status indicator L

<u>Table 2</u> of CR 12885 lists the long descriptors for these codes which, along with their short descriptors, status indicators, and payment rates (where applicable). These are also in the October 2022 OPPS <u>Addendum B</u>.

Note: Patient cost-sharing won't apply to CPT codes 0041A and 0042A.

3. Updates for COVID-19 Monoclonal Antibody Therapy Product and Administration Codes - Redosing Update for EVUSHELD™

On June 29, 2022, the FDA revised the EVUSHELD™ (tixagevimab co-packaged with





cilgavimab) Fact Sheet for Health Care Providers to recommend repeat dosing every 6 months with a dose of 300mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection.

You may bill HCPCS code Q0221 which describes the 300-mg dose of tixagevimab and 300-mg dose of cilgavimab and M0220 and M0221, which describe the service to administer EVUSHELD™ in health care settings or in the home, respectively, every 6 months for the repeat dosing for patients needing ongoing protection.

4. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective October 1, 2022

The AMA CPT Editorial Panel established 23 new PLA codes (CPT codes 0332U through 0354U), effective October 1, 2022. <u>Table 3</u> of CR 12885 lists the long descriptors and status indicators for these codes, which are in to the October 2022 I/OCE with an effective date of October 1, 2022. These codes, along with their short descriptor and status indicators, are also in the October 2022 OPPS Addendum B.

5. Status Indicator Revisions for Bone (Mineral) Density Studies Described by CPT Codes 0554T, 055T, 0556T, 0557T, and 0558T

For the October 2022 update, we're revising the status indicator for CPT codes 0554T through 0558T to E1, indicating that these codes are non-covered because the services they describe don't meet Medicare's definition of bone mass measurements (BMMs). The conditions for coverage of BMMs are in Chapter 15, section 80.5 of the Medicare Benefit Policy Manual As specified in section 80.5.3 of that chapter, BMMs mean a radiologic, radioisotopic, or other procedure that meets these 3 conditions:

- Is performed to identify bone mass, detect bone loss, or decide bone quality
- Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that's been cleared for marketing for BMM by the FDA under 21 CFR 807, or approved for marketing under 21 CFR 814
- Includes a physician's interpretation of the results

We include the status indicator change in the October 2022 I/OCE, retroactive to July 1, 2019, which is the effective date of the CPT codes. These codes, along with their short descriptors and status indicators, are also listed in the October 2022 OPPS Addendum B on CMS website.

Note: Use the MLN Educational Tool for the latest HCPCS codes for all Medicare preventive services, including BMMs.

6. a. New Device Pass-Through Category Effective October 1, 2022

Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. In addition, section 1833(t)(6)(B)(ii)(IV) of the Act requires that we create





additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

For the October 2022 update, we approved a new device for pass-through status under the OPPS. We're establishing a new device category, HCPCS code C1834 (Pressure sensor system, includes all components (for example, introducer, sensor), intramuscular (implantable), excludes mobile (wireless) software application), effective October 1, 2022. See <u>Table 4</u> of CR 12885 for the long descriptor, status indicator, APC, and offset amount for C1834.

We're also including the pass-through expiration dates for several device category codes. See <u>Table 5</u> of CR 12885 for the complete list of device category HCPCS Codes and Definitions used for present and previous transitional pass-through payment.

b. Device Offset from Payment for HCPCS Code C1834

Section 1833(t)(6)(D)(ii) of the Act requires us to deduct from pass-through payments for devices an amount that shows 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's 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.

You should always bill new device category C1834 with CPT code 20950 (Monitoring of interstitial fluid pressure (includes insertion of device, eg, wick catheter technique, needle manometer technique) in detection of muscle compartment syndrome), which is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage) for CY 2022. See <u>Table 4</u> of CR 12885 for the offset amount.

c. Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned to APCs and identified by the I/OCE as 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. We'll return all related payment calculations on the same APC line and identified as a designated new device.

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

For devices that got a marketing authorization and a Breakthrough Device designation from the FDA, we provide an alternative pathway to qualify for device pass-through payment status, under which devices wouldn't be evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining 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.





7. New Procedure to Assess Coronary Disease Severity Using Computed Tomography Angiography

We assigned CPT code 0625T (Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography), which was effective January 1, 2021, to OPPS status indicator E1, indicating that the code isn't payable by Medicare because the device associated with the code didn't have FDA clearance. CPT code 0625T describes the procedure to assess coronary disease severity using computed tomographic angiography.

The device associated with the procedure described by 0625T got FDA clearance in October 2020. We're reassigning 0625T from status indicator E1 to S (Procedure of Service; Not Discounted When Multiple, separate APC assignment), and assigning it to APC 1511 (New Technology – Level 11 (\$900 - \$1000) effective October 1, 2022. Table 6 of CR 12885 lists the official long descriptor, status indicator, and APC assignment for 0625T. The payment rate for 0625T is in Addendum B of the October 2022 OPPS Update.

- 8. Drugs, Biologicals, and Radiopharmaceuticals
- a. New CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting October 1, 2022

Six new drugs, biologicals, and radiopharmaceuticals receiving pass-through status HCPCS codes will be established on October 1, 2022. These codes are <u>Table 7</u> of CR 12885.

There's 1 new drug, biological, and radiopharmaceutical receiving a pass-through status HCPCS code with a status indicator change for October 1, 2022. This code is listed in <u>Table 8</u>.

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

We're establishing 12 new drug, biological, and radiopharmaceutical HCPCS codes on October 1, 2022. These codes are in <u>Table 9</u> of CR 12885.

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

For CY 2022, payment for most nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that weren't required through the 340B Program is made at a single rate of ASP + 6% (or ASP + 6% of the reference product for biosimilars). In CY 2022, a single payment of ASP + 6% for pass-through drugs, biologicals, and radiopharmaceuticals is made to provide 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 are available.





Effective October 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 because of the new ASP calculations based on sales price submissions from the fourth quarter of CY 2021. In cases where adjustments to payment rates are necessary, we'll add changes to the payment rates in the October 2022 Fiscal Intermediary Standard System (FISS) release. We're not publishing the updated payment rates in this Article. However, the updated payment rates effective October 1, 2022, are in the October 2022 update of the OPPS <u>Addendums A and B</u>.

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

Some drugs and biologicals paid based on ASP methodology will have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with <u>corrected payment rates</u> will be accessible on the first date of the quarter. You may resubmit claims that were affected by adjustments to a previous quarter's payment files.

e. CPT Codes Approved for Smallpox & Monkeypox Immunizations

The CPT Editorial Panel has approved code 90622 to identify vaccine (smallpox) virus shot product and code 90611 to identify monkeypox and smallpox virus shot product. The new shot product codes are in <u>Table 10</u> of CR 12885, along with their OPPS status indicators. These codes, along with their short descriptors and status indicators are also in the October 2022 OPPS <u>Addendum B</u>.

f. Skin Substitutes

The payment for skin substitute products that don't qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. For payment packaging purposes, the skin substitute products are divided into 2 groups:

- High-cost skin substitute products
- Low-cost skin substitute products

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

g. Skin Substitute Products with Descriptor Changes as of October 1, 2022

There's 1 skin substitute HCPCS code with a descriptor change for October 1, 2022. The code is listed in <u>Table 11</u> of CR 12885.

h. New Skin Substitute Products as of October 1, 2022

There are 5 new skin substitute HCPCS codes that will be active as of October 1, 2022. These codes are listed in Table 12 of CR 12885.





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10. Payment Change for Q0222 Injection, Bebtelovimab, 175 mg effective August 15, 2022

We're changing how we process OPPS claims for Eli Lilly's monoclonal antibody treatment, bebtelovimab (HCPCS Q0222), to align with the commercial distribution. Effective for OPPS claims with dates of service on or after August 15, 2022, when gotten commercially, we began paying, bebtelovimab (HCPCS Q0222) at 95% average wholesale price (AWP).

Effective August 15, 2022, the revised status indicator assigned to HCPCS Q0222 is "K" [Paid under OPPS; separate APC payment.] The revised APC is 9401. HCPCS code Q0222 has no associated co-insurance or deductible. If you got bebtelovimab (HCPCS Q0222) free, continue to bill with a token charge. If you believe that you were paid improperly for Q0222, you may request an adjustment from your MAC.

11. 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 OPPS doesn't imply coverage by the Medicare Program but show s 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. For example, MACs decide that it's reasonable and necessary to treat the patient's condition and whether it's excluded from payment.

Note: As appropriate, MACs will adjust claims you bring to their attention with any retroactive changes that they get from you prior to implementation of the October 2022 OPPS I/OCE.

More Information

We issued CR 12885 to your MAC as the official instruction for this change.

For more information, <u>find your MAC's website</u>.

Document History

Date of Change		Description	
September 13 2022	Initial article released.		

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