



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

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Related CR Transmittal Number: R11305CP	Implementation Date: April 4, 2022	

Provider Types Affected

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

Provider Action Needed

Make sure your billing staff knows about:

- The April 2022 Integrated Outpatient Code Editor (I/OCE)
- New COVID-19 CPT codes
- The latest changes to HCPCS codes

Background

This Article describes changes to and billing instructions for various payment policies in the April 2022 OPPS update. The April 2022 I/OCE will show the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions. Visit <u>CR 12468</u> for details in the April 2022 I/OCE.

Key Points

1. New Covid-19 CPT Vaccines and Administration Codes:

The American Medical Association (AMA) issues unique CPT Category I codes which are developed in collaboration with the CMS and CDC for each coronavirus vaccine as well as administration codes unique to each vaccine and dose. These codes are effective upon receiving Emergency Use Authorization (EUA) or approval from the FDA.

On September 3, 2021, the AMA released new CPT Category I codes for reporting SARS-CoV-2 vaccines and their administration. These codes include:



- A new code describing a new tris-sucrose formulation of the Pfizer BioNTech COVID-19 vaccine (91305).
- An affiliated set of codes that describe the services to administer the first dose, second dose, third dose and booster dose (0051A, 0052A, 0053A, 0054A, respectively).

The FDA authorized the tris-sucrose formulation of the Pfizer BioNTech COVID-19 vaccine on October 29, 2021. The effective date has been revised to January 3, 2022. CMS identifies an effective date of January 3, 2022, for this formulation and its administration. This effective date corresponds with when the product was first made available to Medicare providers and suppliers. So, vaccine product HCPCS code 91305 and administration HCPCS codes 0051A, 0052A, 0053A, and 0054A are effective on January 3, 2022.

We assigned:

- CPT code 91305 to status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the April 2022 I/OCE
- CPT code 0051A to status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 9397 (Covid-19 Vaccine Admin Dose 1 of 2) in the April 2022 I/OCE
- CPT codes 0052A, 0053A and 0054A to status indicator "S", APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the April 2022 I/OCE

On January 12, 2022, the AMA released new CPT Category I code which describes the service to administer the third pediatric dose of Pfizer BioNTech's COVID-19 vaccine.

CMS identifies an effective date of January 3, 2022, for CPT code 0073A. This effective date corresponds with updates to FDA EUAs and or approvals. We assigned CPT code 0073A to status indicator "S" and APC 9398 in the April 2022 I/OCE.

On February 1, 2022, the AMA released new CPT Category I codes to report immunization administration for Pfizer First and Second Dose SARS-CoV-2 vaccine for pediatric patients ages 6 months through up to 5 years of age (0081A and 0082A) and the new Pfizer pediatric vaccine product (91308). These codes will be available for use once the vaccine gets EUA or approval from the FDA.

<u>Table 1 of CR 12666</u> lists the long descriptors for the codes. These codes with their short descriptors, status indicators, and payment rates (where applicable) are also in the <u>April 2022</u> <u>OPPS Addendum B</u>. For information on the OPPS status indicators, visit <u>OPPS Addendum D1</u> <u>of the CY 2022 OPPS/ASC final rule</u> for the latest definitions.



2. Changes for COVID-19 Monoclonal Antibody Therapy Product and Administration Codes:

a. New COVID-19 Monoclonal Antibody Product Code and Administration Codes for EVUSHELD™ (Tixagevimab Co-packaged with Cilgavimab)

On December 8, 2021 (and updated on December 10, 2021), the FDA released an EUA "… for the emergency use of EVUSHELD[™] (tixagevimab co-packaged with cilgavimab) for the preexposure prophylaxis of coronavirus disease 2019 (COVID-19) in certain adults and pediatric individuals."

In response to the COVID-19 Public Health Emergency (PHE), CMS is creating new HCPCS Level II codes for EVUSHELD[™] and its affiliated injections. That is, EVUSHELD[™] is to be administered as 2 separate consecutive intramuscular injections (one injection per monoclonal antibody, given in immediate succession).

These HCPCS codes are Q0220, M0220 and M0221. The codes and their long descriptors are in <u>Table 2 of CR 12666</u>.

The HCPCS code describing EVUSHELD[™] (tixagevimab co-packaged with cilgavimab), is Q0220. It is assigned to status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) effective December 8, 2021, in the April 2022 I/OCE.

The HCPCS code describing the service to administer EVUSHELD[™] in healthcare settings is M0220. We assign the code to status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 1503 (New Technology - Level 3 (\$101 - \$200)) effective December 8, 2021, in the April 2022 I/OCE.

The HCPCS code describing the service to administer EVUSHELD[™] in the home is M0221. It is assigned to status indicator "S", APC 1504 (New Technology - Level 4 (\$201 - \$300)) effective December 8, 2021, in the April 2022 I/OCE.

The COVID-19 monoclonal antibody products and administration HCPCS codes, and their short descriptors, status indicators, APCs, and payment rates (where applicable) are in the <u>April 2022</u> <u>OPPS Addendum B</u>. For information on the OPPS status indicators, visit the <u>OPPS Addendum D1 of the CY 2022 OPPS/ASC final rule</u>.

For more information on the Medicare Monoclonal Antibody COVID-19 Infusion Program during the PHE, visit:

- https://www.cms.gov/monoclonal
- <u>https://www.cms.gov/monoclonal#Payment</u>

b. Revisions to EVUSHELD™ Dosing

On February 24, 2022, the FDA released a revised EUA for AstraZeneca's EVUSHELD™



(tixagevimab co-packaged with cilgavimab). With this EUA revision, FDA has increased the initial authorized dose to 300 mg of tixagevimab and 300 mg of cilgavimab. FDA stated that patients who already got the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) should get an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise their monoclonal antibody levels to those expected for patients getting the higher dose. We're creating a new HCPCS Level II code (Q0221) to show an updated dosing regimen for EVUSHELDTM as the FDA authorized in the February 24, 2022, EUA.

The HCPCS code describing the dose of 300 mg of tixagevimab and 300 mg of cilgavimab for EVUSHELD[™] is Q0221, and we assigned it to status indicator "L" effective February 24, 2022, in the April 2022 I/OCE. The code with its long descriptor is in <u>Table 2 of CR 12666</u>.

The COVID-19 monoclonal antibody product and administration HCPCS codes with their short descriptors, status indicators, APCs, and payment rates (where applicable) are in the <u>April 2022</u> <u>OPPS Addendum B</u>. For information on the OPPS status indicators, visit <u>OPPS Addendum D1</u> <u>of the CY 2022 OPPS/ASC final rule</u> for the latest definitions.

For more information on payment and coverage of COVID-19 Monoclonal Antibodies under Medicare during the PHE, visit:

- <u>https://www.cms.gov/monoclonal</u>
- <u>https://www.cms.gov/monoclonal#Payment</u>

c. New COVID-19 Monoclonal Antibody Therapy Product Code and Administration Codes for Bebtelovimab

On February 11, 2022, the FD) released an EUA "... for the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients. We're creating new HCPCS Level II codes for bebtelovimab and its affiliated administration. You administer bebtelovimab as a single intravenous injection over at least 30 seconds. These HCPCS codes are: Q0222, M0222 and M0223. The codes, with their long descriptors, are in Table 2 of CR 12666.

The HCPCS code describing bebtelovimab, is Q0222. We assign it to status indicator "L" effective February 11, 2022, in the April 2022 I/OCE.

The HCPCS code describing the service to administer bebtelovimab in healthcare settings is M0222. We assign it to status indicator "S", APC 1505, (New Technology - Level 5 (\$301 - \$400)), effective February 11, 2022, in the April 2022 I/OCE.

The HCPCS code describing the service to administer bebtelovimab in the home is M0223 and it is assigned to status indicator "S", APC 1507 (New Technology - Level 7 (\$501 - \$600)) effective February 11, 2022, in the April 2022 I/OCE.

The COVID-19 monoclonal antibody product and administration HCPCS codes with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the <u>April</u>



<u>2022 OPPS Addendum B</u>. For information on the OPPS status indicators, visit the <u>OPPS</u> <u>Addendum D1 of the CY 2022 OPPS/ASC final rule</u> for the latest definitions.

For more information on payment and coverage of COVID-19 Monoclonal Antibodies under Medicare during the PHE, visit:

- <u>https://www.cms.gov/monoclonal</u>
- <u>https://www.cms.gov/monoclonal#Payment</u>

3. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective April 1, 2022:

The AMA CPT Editorial Panel established 17 new PLA codes, specifically, CPT codes 0306U through 0322U, effective April 1, 2022.

Table 3 of CR 12666 lists the long descriptors and status indicators for the codes. We added the codes to the April 2022 I/OCE, effective April 1, 2022. The codes, with their short descriptor and status indicators, are in the <u>April 2022 OPPS Addendum B</u>. For more information on OPPS status indicators, visit the <u>OPPS Addendum D1 of the Calendar Year 2022 OPPS/ASC final rule</u>.

4. Device Offset from Payment for HCPCS Codes C1748:

<u>Section 1833(t)(6)(D)(ii) of the Social Security Act</u> requires that we 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 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.

In the January 2021 OPPS quarterly update CR (<u>Transmittal 10541, Change Request 12120</u>, dated December 31, 2020), we listed the procedure codes reportable with device category HCPCS code C1748 (Endoscope, single-use (i.e. disposable), Upper GI, imaging/illumination device (insertable)). The long descriptors for the codes are in the same transmittal. We note that we specified the device offset amounts for the procedure codes associated with HCPCS code C1748. That is, we stated that CPT codes 43260 through 43265 and CPT codes 43274, and 43276-43278 have an offset amount of \$0.00.

Effective April 1, 2022, we're updating the list of procedure codes associated with HCPCS code C1748. You may bill the device described by device category HCPCS code C1748 with 1 of the following CPT codes: 0652T, 0653T, 0654T, 43197, and 43198. We list the long descriptors for the CPT code below. The offset amounts for the CPT codes are in <u>Table 4 of CR 12666</u>. We assigned the codes to APC 5301 (Level 1 Upper GI Procedures) and APC 5302 (Level 2 Upper GI Procedures).

 CPT code 0652T- Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)



- CPT code 0653T Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple
- CPT code 0654T Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter
- CPT code 43197 Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
- CPT code 43198 Esophagoscopy, flexible, transnasal; with biopsy, single or multiple

5. New HCPCS Code Describing the InSpace Subacromial Tissue Spacer System Procedure

CMS is establishing a new HCPCS code, C9781, to describe the implantation of a saline-filled balloon for the shoulder to treat irreparably torn rotator cuff tendons. <u>Table 5 of CR 12666</u> lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9781. For information on OPPS status indicators, visit to <u>OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule</u> for the latest definitions. This code with its short descriptor, status indicator, and payment rate, is in the <u>April 2022 Update of the OPPS Addendum B</u>.

6. Medical Procedures Effective April 1, 2022, New HCPCS codes C9782 and C9783:

<u>Table 6 of CR 12666</u> describes new separately payable procedure codes for medical procedures that are effective April 1, 2022.

7. Status Indicator and APC Corrections for CPT codes 66989 and 66991 Effective January 1, 2022:

When we published the <u>CY 2022 OPPS/ASC final rule</u> in the Federal Register on November 16, 2021, we inadvertently assigned CPT codes 66989 and 66991 to APC 1526 (New Technology - Level 26 (\$4001-\$4500)) with status indicator "S" (<u>86 FR 63544</u>). We corrected these errors in the <u>2022 Correction Notice (87 FR 2058) that was published in the Federal Register on January</u> <u>13, 2022</u>, but it was too late to include these corrections in the January 2022 I/OCE Update. We're including them in the April 2022 I/OCE by re-assigning CPT codes 66989 and 66991 to APC 1563 (New Technology - Level 26 (\$4001-\$4500)) with status indicator "T" (Procedure or Service, Multiple Procedure Reduction Applies. Paid under OPPS; separate APC payment) retroactive to January 1, 2022. <u>Table 7 of CR 12666</u> lists long descriptors, status indicator, APC, and APC title for these codes. The payment rates for these codes can be found in <u>Addendum B of the April 2022 OPPS Update</u>.

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 April 1, 2022

We created 5 new HCPCS codes for reporting drugs and biologicals in the hospital outpatient setting, where there haven't previously been specific codes available starting on April 1, 2022. These drugs and biologicals will get drug pass-through status. These HCPCS codes are in



Table 8 of CR 12666.

b. Existing CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting April 1, 2022

Three drugs and biologicals with existing HCPCS codes will get drug pass-through status starting April 1, 2022. These HCPCS codes are in <u>Table 9 of CR 12666</u>.

c. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of April 1, 2022:

We're establishing 12 new drug, biological, and radiopharmaceutical HCPCS codes on April 1, 2022. These HCPCS codes are listed in <u>Table 10 of CR 12666</u>.

d. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals Deleted, Retroactive to January 1, 2022

In the <u>CY 2022 OPPS/ASC final rule Addendum B</u>, we inadvertently assigned new HCPCS code A2003 (Bio-connekt wound matrix, per square centimeter) to status indicator "A". Since this code was created in error, we deleted this code through the <u>2022 Correction Notice (87 FR 2060</u>) in the Federal Register on January 13, 2022, but it was too late to include this correction in the January 2022 I/OCE Update. So, we're including it in the April 2022 I/OCE Update. We're deleting HCPCS code A2003 retroactive to January 1, 2022, in April 2022 I/OCE Update. HCPCS code A2003 is listed in <u>Table 11 of CR 12666</u>.

e. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals Deleted, Retroactive to February 28, 2022

We're deleting HCPCS code M1145 (Most Favored Nation (MFN) model drug add-on amount, per dose, (do not bill with line items that have the JW modifier)) retroactive to February 28, 2022 in April 2022 I/OCE Update. HCPCS code M1145 is in <u>Table 12 of CR 12666</u>.

f. Rabies Vaccine that Will Retroactively Change from Non-Payable Status to Payable Status Effective January 1, 2021

We're changing the status indicator for CPT code 90377 (Rabies immune globulin, heat- and solvent/detergent-treated (rig-ht s/d), human, for intramuscular and/or subcutaneous use) effective January 1, 2021, retroactively from status indicator = "E2" to status indicator = "K" in the April 2022 I/OCE Update. We show this vaccine in <u>Table 13 of CR 12666</u>.

g. Hepatitis-B Vaccine that Is Retroactively Is Payable at Reasonable Cost, Effective January 11, 2022

CPT code 90759 (Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule, for intramuscular use) is retroactively payable at reasonable cost (SI = F) effective January 11, 2022 in the April 2022 I/OCE Update. This vaccine is <u>Table 14 of CR 12666</u>.



h. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Is Separately Payable Retroactively, Effective December 23, 2021, until March 31, 2022, in the April I/OCE

HCPCS code J0248 (Injection, remdesivir, 1 mg) will be separately payable with SI=K, retroactive to December 23, 2021, until March 31, 2022, in the April 2022 I/OCE Update. HCPCS code J0248 is reported in <u>Table 15 of CR 12666</u>.

i. Update on the Payment Rate for HCPCS code J3399

HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes) is a separately paid drug under the OPPS with a payment rate of the drug's Average Sales Price (ASP) plus 6%. Due to technical reasons, we assign HCPCS code J3399 to status indicator = "A" which allows MACs to manually pay claims appropriately reporting the drug at the ASP plus 6% rate.

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

For CY 2022, payment for the majority of non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals that weren't acquired through the 340B Program is made at a single rate of ASP plus 6% (or ASP plus 6% of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP minus 22.5% (or ASP minus 22.5% of the biosimilar's ASP if a biosimilar is acquired under the 340B Program), which provides 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 plus 6% for passthrough 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 plus 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 April 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 the third quarter of CY 2021. In cases where adjustments to payment rates are necessary, we'll make changes to the payment rates in the April 2022 Fiscal Intermediary Standard System (FISS) release. We aren't publishing the updated payment rates in CR 12666 implementing the April 2022 update of the OPPS. The updated payment rates effective April 1, 2022, are in the April 2022 update of the OPPS Addendum A and Addendum B.

k. 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 corrected payments rates will be accessible on the <u>CMS</u> website on the first date of the quarter. You may resubmit claims that were affected by adjustments to a previous quarter's payment files.



9. Skin Substitutes

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

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

We assign new skin substitute HCPCS codes into the low-cost skin substitute group unless we've pricing data that shows 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 April 1, 2022

There are 9 new skin substitute HCPCS codes that will be active as of April 1, 2022. These codes are listed in <u>Table 16 of CR 12666</u>.

b. Skin Substitute Products Reassigned to the High-Cost Skin Substitute Group as of April 1, 2022

We're reassigning 1 skin substitute HCPCS code that from the low-cost skin substitute group to the high-cost skin substitute group as of April 1, 2022. The code is listed in <u>Table 17 of CR 12666</u>.

c. Skin Substitute Products with Individual HCPCS Codes Reassigned to Be Payable and Packaged as of April 1, 2022

There are 9 skin substitute products assign HCPCS codes in the range of A2001-A2010 that have a status indicator = "A" (Not paid under OPPS. MACs pay these codes under a fee schedule or payment system other than OPPS.) that will be reassigned to status indicator = "N" (Paid under OPPS; payment is packaged into payment for other services.) as of April 1, 2022. Since these codes are now payable in the OPPS, they're assigned to either the high-cost or low-cost skin substitute group as of April 1, 2022. The codes are listed in <u>Table 18 of CR 12666</u>.

10. Blood Products

a. New Blood Product Effective April 1, 2022 in the April I/OCE

There's 1 new blood product HCPCS code effective April 1, 2022, in the April I/OCE. We assign it to status indicator "R" (Blood and Blood products. Separate APC payment under OPPS). The code is listed in <u>Table 19 of CR 12666</u>.

b. Retroactive Payment of a Blood Product HCPCS Code Effective December 28, 2021, until March 31, 2022, in the April I/OCE

HCPCS code C9507 (Plasma, high titer COVID-19 convalescent, each unit) will be separately payable with SI=S retroactive to December 28, 2021, until March 31, 2022, in the April 2022 I/OCE Update. HCPCS code C9057 is reported in <u>Table 20 of CR 12666</u>.



11. Billing for Devices Under OPPS:

We are revising <u>Medicare Claims Processing Manual, Chapter 4, Section 61.1</u> to clarify to hospitals for reporting devices that aren't described by a specific HCPCS code.

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 OPPS doesn't imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it's reasonable and necessary to treat the patient's condition and whether it's excluded from payment.

More Information

We issued <u>CR 12666</u> to your MAC as the official instruction for this change.

For more information, find your MAC's website.

Document History

Date of Change		Description	
March 28, 2022	Initial article released.		

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