



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

MLN Matters Number: MM12761 **Revised**

Related Change Request (CR) Number: 12761

Related CR Release Date: **June 15, 2022**

Effective Date: July 1, 2022

Related CR Transmittal Number: **R11457CP**

Implementation Date: July 5, 2022

**Note: We revised this Article due to a revised CR 12761. The CR revision added some codes to table 1. The link to table 1 in this Article takes you to the revised table 1. Also, we revised the CR release date, transmittal number, and the CR web address. All other information is the same.**

### Provider Types Affected

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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

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Make sure your billing staff knows about these changes:

- New COVID-19 CPT vaccines and administration codes
- CPT proprietary laboratory analyses (PLA) coding changes effective July 1, 2022
- New CPT Category III codes effective July 1, 2022

### Background

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CR 12761 describes changes to and billing instructions for various payment policies in the July 2022 OPPS update. The July 2022 Integrated Outpatient Code Editor (I/OCE) will show the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in CR 12761.

**Note:** The July 2022 I/OCE data files, instructions, and specifications are in [CR 12759](#).

**The July 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. Those codes and their OPPS status indicators are listed in [Table 1 of CR 12761](#). The codes, short descriptors, and status indicators are also in the [July 2022 OPPS Addendum B](#).

## 2. Over the Counter (OTC) COVID-19 Test Demonstration

In response to the COVID-19 Public Health Emergency (PHE), we're implementing the Medicare Payment for OTC COVID-19 Tests Demonstration (the demonstration) to cover and pay for OTC COVID-19 tests for eligible Medicare patients.

We established the Level II HCPCS code K1034 as payable for all eligible providers under the demonstration. This code represents a quantity of 1 single test and is inclusive of all types of FDA-approved, authorized, or cleared COVID-19 tests intended for self-administration and where the specimen is self-collected. K1034 was effective on April 4, 2022, and will remain effective for dates of service (DOS) through the end of the COVID-19 PHE.

K1034 is listed in [Table 2 of CR 12761](#) along with its OPPS status indicator.

## 3. New COVID-19 CPT Vaccines and Administration Codes

The American Medical Association (AMA) has been issuing unique CPT Category I codes which are developed based on collaboration between us and the CDC, for which the COVID-19 vaccine as well as administration codes are unique to each such vaccine and dose. These codes are effective upon getting Emergency Use Authorization (EUA) or FDA approval.

On March 7, 2022, the AMA released 2 new CPT Category I codes, including 91309, which describes an additional presentation of the Moderna COVID-19 vaccine for booster vaccination doses; and 0094A, an affiliated code for administration of the booster dose.

We identify an effective date of March 29, 2022, for code 0094A, which corresponds to FDA EUAs and approvals. Code 91309 is also effective March 29, 2022.

Effective March 29, 2022, CPT code 0094A is assigned 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 July 2022 I/OCE update. Also, effective March 29, 2022, CPT code 91309 is assigned to status indicator L (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the July 2022 I/OCE update.

Patient cost sharing doesn't apply to the new vaccine and administration code.

On April 26, 2022, the AMA released 3 new CPT Category I codes: Sanofi Pasteur booster vaccine for adults 18 years of age and older (91310) and its associated administration code (0104A), as well as Pfizer booster code 0074A for patients 5 to 11 years old. These codes will be available for use once they get an EUA or FDA approval.

[Table 3 of CR 12761](#) lists the long descriptors for these codes. Their short descriptors, status indicators, and payment rates (where applicable) are in the [July 2022 OPPS Addendum B](#).

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

The AMA CPT Editorial Panel established 9 new PLA codes, including CPT codes 0323U through 0331U, effective July 1, 2022. [Table 4 of CR 12761](#) lists the long descriptors and status indicators for these codes, which have been added to the July 2022 I/OCE with an effective date of July 1, 2022. These 9 codes, along with their short descriptors and status indicators, are in the [July 2022 OPPS Addendum B](#).

#### 5. Advanced Diagnostic Laboratory Tests (ADLTs) Under the Clinical Laboratory Fee Schedule (CLFS)

On March 24, 2022, we announced the approval of 1 laboratory test as an ADLT under paragraph (1) of the definition of an ADLT in [42 CFR 414.502](#). This laboratory test is in [Table 5 of CR 12761](#).

Based on the ADLT designation, we revised the OPPS status indicator for HCPCS code 0108U to A (Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS), effective July 1, 2022. However, because the ADLT designation was made in March 2022, it was too late to include this change in the April 2022 I/OCE release and the April 2022 OPPS update. So, it's included in the July 2022 I/OCE release with an effective date of March 24, 2022.

For the latest list of ADLT-approved tests under the CLFS, view [the ADLT page](#).

#### 6. New CPT Category III Codes Effective July 1, 2022

The AMA releases CPT Category III codes twice per year:

- In January, for implementation beginning the following July
- In July, for implementation beginning the following January

For the July 2022 update, we're implementing 24 new CPT Category III codes released by the AMA in January 2022 for implementation on July 1, 2022. The status indicators and APC assignments for these codes are listed in [Table 6 of CR 12761](#). CPT codes 0714T through 0737T have been added to the July 2022 I/OCE with an effective date of July 1, 2022. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also in the [July 2022 OPPS Addendum B](#).

#### 7. Procedures Assigned to New Technology APCs

##### a. The Optellum Lung Cancer Prediction (LCP) Procedure

The AMA is establishing the new CPT code 0721T to describe the Optellum LCP service, which applies an algorithm to a patient's Computed Tomography (CT) scan to produce a raw risk

score for a patient's pulmonary module. The physician uses the risk score to quantify the risk of lung cancer and to help determine whether to refer the patient to a pulmonologist. We assigned this service to status indicator S (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 1508 (New Technology – Level 8 (\$600-\$700)), effective July 1, 2022.

**b. The Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) Procedure**

The AMA is establishing the new CPT code 0723T to describe the QMRCP service, which performs a quantitative assessment of the biliary tree and gallbladder to produce a 3-Dimensional reconstruction of the biliary tree and pancreatic duct. It also provides precise quantitative information of biliary tree volume and duct metrics. We assign this service to status indicator S (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 1508 (New Technology – Level 11 (\$900-\$1,000)), effective July 1, 2022.

[Table 7 of CR 12761](#) lists the official long descriptors, status indicators, and APC assignments for CPT codes 0721T and 0723T. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also in the [July 2022 update of OPSS Addendum B](#).

**c. Retinal Prosthesis Implant Procedure – Status Indicators and APC Assignments for the Argus® II Device, the Argus® II Implantation Procedure, and the Argus® II Programming Procedures**

We've determined that the Argus® II device, which is implanted for the retinal prosthesis implant procedure, is no longer available in the marketplace. We also understand that outpatient hospital providers are no longer performing the Argus® II implantation procedure, and we understand that providers are no longer providing programming services for the Argus® II. So, we're changing the status indicators and APC assignments for CPT codes 0100T, 0472T, 0473T, and C1841. We show these in [Table 8 of CR 12761](#), and the changes are effective July 1, 2022.

**d. CardiAMP Cell Therapy IDE Descriptor Change and APC Reassignment Retroactive to April 1, 2022**

HCPCS code C9782 (CardiAMP cell therapy IDE study) was established April 1, 2022, and assigned to APC 1574 with a status indicator T. We've revised the descriptor for HCPCS code C9782 to specify the inclusion of the device. Additionally, we determined that APC 1590 most accurately accounts for the resources associated with providing CardiAMP cell therapy IDE. The revised descriptor and APC assignment are shown in [Table 9 of CR 12761](#).

**8. Comprehensive APC (C-APC) Exclusion List Changes**

We're revising Chapter 4, [section 10.2.3 of the Medicare Claims Processing Manual](#) to add OTC COVID-19 tests to the C-APC exclusion list.

## 9. Drugs, Biologicals, and Radiopharmaceuticals

### a. New Calendar Year (CY) 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting July 1, 2022

We've created 9 new HCPCS codes for reporting drugs and biologicals in the hospital outpatient setting, where there haven't previously been specific codes available, starting July 1, 2022. These drugs and biologicals will receive drug pass-through status starting July 1, 2022. These codes are in [Table 10 of CR 12761](#).

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

We're adding 16 new drug, biological, and radiopharmaceutical HCPCS codes, effective July 1, 2022. These codes are listed in [Table 11 of CR 12761](#).

### c. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Will Retroactively Change from Non-Payable Status to Payable Status Effective April 1, 2022

The status indicator for HCPCS code J0879 (Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)) effective April 1, 2022, will be changed retroactively from status indicator E2 to K in the July 2022 update. This code is in [Table 12 of CR 12761](#).

### d. 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 acquired through the 340B Program is made at a single rate of ASP + 6% (or ASP + 6% of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals, and radiopharmaceuticals that were acquired under the 340B Program is made 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 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 + 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 update payments for drugs and biologicals based on ASPs quarterly as later quarter ASP submissions become available.

Effective July 1, 2022, payment rates for many drugs and biologicals will change from the values published in the CY 2022 OPPTS/ASC final rule with comment period, due to new ASP calculations based on sales price submissions from the 4<sup>th</sup> quarter of CY 2021. In cases where

adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the July 2022 Fiscal Intermediary Standard System (FISS) release. We aren't publishing the updated payment rates in CR 12761. However, the updated payment rates effective July 1, 2022, are in the July 2022 update of the [OPPS Addendums A & B](#).

#### **e. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates**

Some drugs and biologicals paid based on ASP methodology will have payment rates corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The [list of drugs and biologicals with corrected payment rates](#) will be accessible on the first day of the quarter.

You may resubmit claims affected by adjustments to a previous quarter's payment files.

### **10. Skin Substitutes**

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 in 2 groups:

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

New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless we've pricing data demonstrating 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.

#### **a. New Skin Substitute Products as of July 1, 2022**

There are 3 new skin substitute HCPCS codes that will be active as of July 1, 2022. These codes are listed in [Table 13 of CR 12761](#).

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

There are 4 skin substitute HCPCS codes reassigned from the low-cost skin substitute group to the high-cost skin substitute group as of July 1, 2022. The codes are in [Table 14 of CR 12761](#).

#### **c. Skin Substitute Product Defined as a Powdered Skin Substitute Retroactive to January 1, 2022**

We revised HCPCS code A2004's descriptor retroactive to January 1, 2022, as we show in [Table 15 of CR 12761](#). Since A2004 is no longer described as a graft skin substitute product for the period of January 1, 2022-June 30, 2022, the code isn't assigned to either skin substitute group retroactive to January 1, 2022, as we show in [Table 16 of CR 12761](#).

#### d. Skin Substitute Product Reassigned to the High-Cost Skin Substitute Group Retroactive to April 1, 2022

The manufacturer of skin substitute product HCPCS code A2001 (Innovamatrix ac, per square centimeter) submitted a request before the development of the April 2022 OPPS quarterly update to have A2001 assigned to the high-cost skin substitute group. Because of an error, the request wasn't considered for the April 2022 OPPS quarterly update, even though we determined that skin substitute products assigned to codes A2001-A2013 could be payable in the OPPS starting April 1, 2022. So, we're retroactively assigning A2001 to the high-cost skin substitute group effective April 1, 2022, as we show in [Table 17 of CR 12761](#).

#### 11. Coverage Determinations

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 Medicare. 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 [CR 12761](#) to your MAC as the official instruction for this change.

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

#### Document History

Date of Change	Description
June 16, 2022	We revised this Article due to a revised CR 12761. The CR revision added some codes to table 1. The link to table 1 in this Article takes you to the revised table 1. Also, we revised the CR release date, transmittal number, and the CR web address. All other information is the same.
May 31, 2022	Initial article released.

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