



## October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)

MLN Matters Number: MM12436

Related Change Request (CR) Number: 12436

Related CR Release Date: September 16, 2021 Effective Date: October 1, 2021

Related CR Transmittal Number: R10997CP Implementation Date: October 4, 2021

### Provider Types Affected

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

### Provider Action Needed

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Make sure your billing staffs know about these OPPS updates.

### Background

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Here's a summary of the main topics in related CR 12436:

#### 1. New Covid-19 CPT Administration Codes

On July 30, 2021, the American Medical Association (AMA) released new CPT code 0003A, which describes the service to administer the third dose of Pfizer-BioNTech vaccine. Effective August 12, 2021, the FDA updated the Emergency Use Authorization (EUA) for this product to allow a third dose in certain populations. CMS included CPT code 0003A in the October 2021 Integrated Outpatient Code Editor (I/OCE) with:

- Status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate Ambulatory Payment Classification (APC) assignment)
- APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose)

Note that we revised the APC title for APC 9398 from Covid-19 Vaccine Administration Dose 2 of 2 or Single Dose Product to Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose.

On August 16, 2021, the AMA released new CPT code, 0013A, for the administration of the third dose of Moderna vaccine. Effective August 12, 2021, the FDA updated the EUA for this

product to allow a third dose in certain populations. CPT code 0013A has a status indicator “S” and APC 9398.

[Table 1 of CR 12436](#) lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the October 2021 OPPS [Addendum B](#).

## **2. New COVID-19 HCPCS Vaccine Administration Code for Administering in the Patient’s Home**

Effective June 8, 2021, we created new HCPCS Level II code M0201. This code describes the additional payment you can bill when you give a COVID-19 vaccine in the patient’s home. You may bill M0201 in addition to the existing COVID-19 vaccine administration CPT codes: 0001A, 0002A, 0003A, 0011A, 0012A, 0013A and 0031A. Because it’s covered and paid for under the COVID-19 vaccine benefit, no patient cost-sharing applies.

HCPCS code M0201 is assigned to status indicator “S” and APC 1494 (New Technology - Level 1D (\$31-\$40)).

[Table 2 of CR 12436](#) lists the long descriptor for the code. The code, along with its short descriptor, status indicator, and payment rate is also listed in the October 2021 OPPS [Addendum B](#).

See [payment and effective dates for the COVID-19 vaccines](#) and their administration during the Public Health Emergency (PHE) for more information.

## **3. Changes for COVID-19 Monoclonal Antibody Therapy Product and Administration Codes**

### **a. New COVID-19 Monoclonal Antibody Therapy and Administration codes for Sotrovimab**

On May 26, 2021, the FDA released an EUA for Sotrovimab, a COVID-19 monoclonal antibody product. We’re creating new Category II HCPCS codes for Sotrovimab and the services to administer (infuse) it in a health care setting and the home. These HCPCS codes are: M0247, M0248, and Q0247. The codes, along with their long descriptors, are in [Table 3 of CR 12436](#).

Effective May 26, 2021, we assigned:

- HCPCS code M0247 status indicator “S” and APC 1506 (New Technology - Level 6 (\$401 - \$500))
- HCPCS code M0248 to status indicator “S” and APC 1509 (New Technology - Level 9 (\$701 - \$800))
- HCPCS code Q0247 to status indicator “L” (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance)

We list the COVID-19 monoclonal antibody therapy products and administration HCPCS codes,

along with their short descriptors, status indicators, APCs, and payment rates (where applicable) in the October 2021 OPPS [Addendum B](#).

The CMS website has more information on [monoclonal antibody COVID-19 infusion](#) and related [payment](#).

## **b. Changes for COVID-19 Monoclonal Antibody Combination Product Casirivimab and Imdevimab**

### **1) New HCPCS Code Q0244 for Monoclonal Antibody Combination Product Casirivimab and Imdevimab**

On June 3, 2021, the FDA released a revised EUA for Regeneron's COVID-19 monoclonal antibody combination product casirivimab and imdevimab. The updated EUA includes a new dosing regime (1200 mg vs. 2400 mg) and allows a new route of administration.

In response to the COVID-19 PHE, CMS is creating a new Category II HCPCS code Q0244 that reflects an updated dosing regime for casirivimab and imdevimab. Therefore, effective June 3, 2021, HCPCS code Q0244 is assigned to status indicator L in the October I/OCE. [Table 2 of CR 12436](#) contains the Long Descriptor for Q0244.

### **2) New HCPCS codes M0240 and M0241 Describing Repeat Administration for Casirivimab and Imdevimab and New HCPCS code Q0240 for New Product Code that Describes the New Dosing for Casirivimab and Imdevimab**

Due to the COVID-19 PHE, and the updated July 30, 2021 EUA for casirivimab and imdevimab, we're creating new HCPCS Level II codes:

- Q0240 to account for the new dosage (300 mg of casirivimab and 300 mg of imdevimab, for a total dose of 600 mg)
- M0240 and M0241 to account for repeat administrations of casirivimab and imdevimab

We assigned code:

- Q0240 to status indicator "L" effective July 30, 2021
- M0240 to status indicator "S" and APC 1506 (New Technology - Level 6 (\$401 - \$500)) effective July 30, 2021
- M0241 to status indicator "S" and APC 1509 (New Technology - Level 9 (\$701 - \$800)) effective July 30, 2021

[Table 3 of CR 12436](#) describes the long descriptors for the codes.

### **3) Updates to the Descriptors for the HCPCS Codes M0243 and M0244 that Describe Services to Administer Casirivimab and Imdevimab to Reflect the Addition of a New Potential Route of Administration**

We're updating the code descriptors for the HCPCS codes M0243 and M0244 that describe the services to administer (infuse) casirivimab and imdevimab. The revised descriptors show the

addition of a new potential route of administration. The effective date of the descriptor change for the HCPCS code M0243 is November 21, 2020, and the effective date of the descriptor change for the HCPCS code M0244 is May 6, 2021. We didn't change the APC assignments and payment rates for these codes in the October Update.

All the coding changes described above, specifically, the codes along with their long descriptors, are in [Table 3 of CR 12436](#). The COVID-19 monoclonal antibody therapy products and administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the October 2021 OPPS Addendum B

More information is available on the [Medicare Monoclonal Antibody COVID-19 Infusion Program](#) during the PHE, [including payment guidelines](#).

### **c. New COVID-19 Monoclonal Antibody Therapy and Administration codes for Tocilizumab**

On June 24, 2021, the FDA released an EUA for Tocilizumab, for its new COVID-19 indication monoclonal antibody product.

In response we are creating new Category II HCPCS codes for Tocilizumab and the services to administer (infuse) it. These codes are: M0249, M0250, and Q0249. The codes along with their long descriptors are identified in [Table 3 of CR 12436](#).

We assigned code:

- M0249 and M0250 to status indicator "S" and APC 1506 (New Technology - Level 6 (\$401 - \$500)) effective June 24, 2021
- New HCPCS code Q0249 is assigned to status indicator "L" effective June 24, 2021

More information is available on the [Medicare Monoclonal Antibody COVID-19 Infusion Program](#) during the PHE, [including payment guidelines](#).

### **4. CPT Proprietary Laboratory Analyses (PLA) Coding Changes, Effective October 1, 2021**

Effective October 1, 2021, the AMA CPT Editorial Panel:

- Deleted 2 PLA codes, 0139U and 0168U
- Revised 1 PLA code, 0051U
- Established 30 new PLA codes, CPT codes 0255U through 0284U, effective October 1, 2021

[Table 4 of CR 12436](#) lists the long descriptors and status indicators for the codes.

We list the codes, along with their short descriptor and status indicators in the October 2021 OPPS [Addendum B](#).

## 5. Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Change, Effective October 1, 2021

The AMA CPT Editorial Panel established 1 new MAAA code, 0018M, effective October 1, 2021. [Table 5 of CR 12436](#) lists the long descriptor and status indicator (Q4) for CPT code 0018M.

We list the codes, along with their short descriptor and status indicators in the October 2021 OPPS [Addendum B](#).

## 6. New HCPCS Code Describing the Endoscopic Submucosal Dissection (ESD) Procedure

We're establishing a new HCPCS code, C9779, to describe ESD you perform during an endoscopy or colonoscopy. [Table 6 of CR 12436](#) lists the official long descriptor, status indicator (J1), and APC assignment (5313) for HCPCS code C9779.

## 7. New HCPCS Code Describing a Procedure Utilizing the Surfacar Inside-Out Access Catheter System

We're establishing a new HCPCS code, C9780, to describe a procedure using the Surfacar Inside-Out Access Catheter System. [Table 7 of CR 12436](#) lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9780. We list this code, along with its short descriptor, status indicator, and payment rate in the October 2021 Update of the OPPS [Addendum B](#).

### 8. a. New Device Pass-Through Categories

We're establishing 1 new device pass-through category as of October 1, 2021. We're also updating the device offset from payment information for the device category described by HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary).

[Table 9 of CR 12436](#) gives a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

### b. Device Offset from Payment

We've determined that the offset amounts for APCs 5115 and 5116 are associated with costs of the device category described by HCPCS code C1831 (Personalized, anterior and lateral interbody cage (implantable)). Always bill the device(s) in the category described by HCPCS code C1831 with 1 of the primary CPT codes 22558, 22586, 22612, 22630, or 22633 and add-on code 22853 or 22854. See [Table 8 of CR 12436](#) for code long descriptors and APC assignments (if applicable). The codes, along with their short descriptors, status indicators, APC assignments, and payment rates are also listed in the October 2021 Update of the OPPS [Addendum B](#).

In the [July 2021 Update of the Hospital OPPS](#), we stated that you always bill the device in the category described by HCPCS C1761 with either CPT code 92928 or HCPCS code C9600.

We're updating this list to include the following codes:

- CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch)
- CPT code 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel)
- HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch)
- HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel)

This change is retroactive to July 1, 2021.

With this change always bill the device in the category described by HCPCS code C1761 with 1 of the following codes:

- CPT code 92933, which we assign to APC 5194 for CY 2021
- CPT code 92943, which we assign to APC 5193 for CY 2021
- HCPCS code C9602, which we assign to APC 5194 for CY 2021
- HCPCS code C9607, which we assign to APC 5194 for CY 2021
- CPT code 92928, which we assign to APC 5193 for CY 2021
- HCPCS code C9600, which we assign to APC 5193 for CY 2021

We've determined that the device offset amounts for APC 5193 - Level 3 Endovascular Procedures and APC 5194 - Level 4 Endovascular Procedures are associated with the costs of the device category described by HCPCS code C1761 when you bill this device with CPT codes 92933, 92943, C9602, or C9607. Therefore, we're applying a device offset to C1761 when you bill with these codes.

### **c. Transitional Pass-Through Payments for Designated Devices**

We assign certain designated new devices 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 reflects the packaged payment for device(s) used in the procedure. The I/OCE will determine the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. See [Addendum P](#) of the CY 2021 final rule with comment period for the most current OPFS HCPCS Offset file.

### **d. Alternative Pathway for Devices that have an FDA Breakthrough Designation**

For devices getting FDA marketing authorization and a Breakthrough Device designation from the FDA, we offered 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 receiving pass-through payment status, effective on or after January 1, 2020.

## **9. Drugs, Biologicals, and Radiopharmaceuticals**

### **a. New CY 2021 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status**

We've created 5 new HCPCS codes for reporting drugs and biologicals in the hospital outpatient setting, where there haven't been specific codes available. These drugs and biologicals will receive drug pass-through status starting October 1, 2021. See [Table 10 of CR 12436](#) for details on these codes.

### **b. Existing CY 2021 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status**

We've determined that 3 existing HCPCS codes used to report drugs, biologicals, and radiopharmaceuticals in the hospital outpatient setting will get drug pass-through status starting October 1, 2021. These HCPCS codes are in [Table 11 of CR 12436](#).

### **c. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on September 30, 2021**

The pass-through status of 3 HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting will end on September 30, 2021. These codes are in [Table 12 of CR 12436](#). Effective October 1, 2021, the status indicator for these codes is changing from G to either K or N. These codes, along with their short descriptors and status indicators are also listed in the October 2021 Update of the OPPS [Addendum B](#).

### **d. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2021**

We've established 20 new drug, biological, and radiopharmaceutical HCPCS codes as of October 1, 2021. These HCPCS codes are listed in [Table 13 of CR 12436](#).

### **e. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals with Revised Long Descriptors as of October 1, 2021**

The long descriptors for HCPCS codes J1443 and J2407 are changing on October 1, 2021. We show these changes are reported in [Table 14 of CR 12436](#).

### **f. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted as of October 1, 2021**

We're deleting 12 HCPCS codes on October 1, 2021, which we list in [Table 15 of CR 12436](#).

### **g. Radiopharmaceuticals that'll Retroactively Change from Packaged Status to Pass-Through Status, Effective July 1, 2021, in the October I/OCE Update**

We're changing the status indicators for HCPCS code A9593 (Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie) and for HCPCS code A9594 (Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie) effective July 1, 2021, retroactively from status indicator = "N" to status indicator = "G" in the October I/OCE Update. We list the details in [Table 16 of CR 12436](#).

### **h. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)**

For CY 2021, we make payment for most non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals that weren't acquired through the 340B Program at a single rate of ASP + 6% (or ASP + 6% of the reference product for biosimilars).

We pay for non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program 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). This gives payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical.

In CY 2021, we make a single payment of ASP + 6% for pass-through drugs, biologicals, and radiopharmaceuticals 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 October 1, 2021, payment rates for many drugs and biologicals have changed from the values published in the CY 2021 OPPS/ASC Final Rule with comment period, as a result of the new ASP calculations based on sales price submissions from third quarter of CY 2020.

We aren't publishing the updated payment rates in CR 12436 for the October 2021 update of the OPPS. However, the updated payment rates, effective October 1, 2021, are in the October 2021 update of the [OPPS Addendum A and Addendum B](#) website.

### **i. 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 we correct retroactively. 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 affected by adjustments to a previous quarter's payment files.

## **10. Skin Substitutes**

We'll 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 2 groups:

1. High-cost skin substitute products
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 that demonstrates the cost of the product is above either the mean unit cost of \$48 or the per-day cost of \$949 for CY 2021.

#### **a. New Skin Substitute Products as of October 1, 2021**

There are 3 new skin substitute HCPCS codes active as of October 1, 2021. These codes are in [Table 17 of CR 12436](#).

#### **b. Skin Substitute Products Deleted as of October 1, 2021**

There are 2 skin substitute HCPCS codes (Q4228 and Q4236) that we'll delete as of October 1, 2021. These codes are in [Table 18 of CR 12436](#).

#### **11. Vaccine CPT Code Status Indicator Change, Effective October 1, 2021**

The status indicator for CPT code 90677 (Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use) will change from status indicator "E1" to "L," effective October 1, 2021. We show this in [Table 19 of CR 12436](#).

#### **12. New Blood Product HCPCS Codes, Effective October 1, 2021**

We've established 2 new blood product HCPCS codes (P9025 and P9026) for October 1, 2021. We show these codes in [Table 20 of CR 12436](#). We assigned these codes to status indicator R (Paid under OPPS; separate APC payment.) and APC 9538 and APC 9539, respectively.

#### **13. Coverage Determinations**

Remember that the assignment of an HCPCS code to a drug, device, procedure, or service doesn't imply coverage by Medicare. It shows only how we pay for the product, procedure, or service if we cover it. Your MAC determines 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**

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We issued [CR 12436](#) to your MAC as the official instruction for this change.

See [OPPS Addendum D1](#) of the Calendar Year 2021 OPPS/ASC final rule for the latest definitions for more information on OPPS status indicators.

For more information, contact your [MAC](#).

## Document History

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Date of Change	Description
September 21, 2021	Initial article released.

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