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

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Related Change Request (CR) Number: 12316
Related CR Release Date: June 11, 2021
Effective Date: July 1, 2021
Related CR Transmittal Number: R10825CP
Implementation Date: July 6, 2021

Provider Types Affected

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

Provider Action Needed

This Article tells you about changes to and billing instructions for various payment policies CMS is implementing in the July 2021 OPPS update. The July 2021 Integrated Outpatient Code Editor (I/OCE) will reflect the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions in CR 12316. Be sure your billing staffs are aware of these updates.

Background

Here is a summary of the main topics covered by CR 12316.

1. New COVID-19 Vaccines and Administration CPT Codes

On May 4, 2021, the American Medical Association (AMA) released 3 new CPT codes for the Novavax COVID-19 vaccine. CPT codes 91304, 0041A, and 0042A, will be available for use once the vaccine receives FDA's Emergency Use Authorization (EUA) or approval.

Table 1 of CR 12316 lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates (where applicable), are also in the July 2021 OPPS Addendum B. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/Ambulatory Surgical Center (ASC) final rule for the latest definitions.

COVID-19 vaccines and their administration has more information on payment and effective dates for during the Public Health Emergency (PHE).

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2. a. Revocation of EUA for the COVID-19 Monoclonal Antibody Therapy Bamlanivimab and Deletion of HCPCS codes M0239 and Q0239 from the July 2021 I/OCE

CMS listed new HCPCS codes M0239 and Q0239 that were established effective November 9, 2020, for bamlanivimab to track and pay appropriately for monoclonal antibodies used to treat COVID-19. We added the codes to the January 2021 I/OCE with effective dates set to the dates the FDA authorized their use.

Effective April 16, 2021, the FDA revoked the EUA that allowed for the investigational monoclonal antibody therapy bamlanivimab, *when administered alone*, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Effective April 16, 2021, we deleted HCPCS codes M0239 and Q0239 from the July 2021 I/OCE. Table 2 of CR 12316 lists the deleted HCPCS codes along with their long descriptors.

b. Revised APC Assignment for the COVID-19 Monoclonal Antibody Administration Codes

In CR 12120, we listed new HCPCS codes M0243 and Q0243 that were established effective November 21, 2020, for casirivimab and imdevimab to track and pay appropriately for monoclonal antibodies used to treat COVID-19. We added the codes to the January 2021 I/OCE with effective dates set to the dates the FDA authorized them.

In CR 12175, we listed new HCPCS codes M0245 and Q0245, effective February 9, 2021, for bamlanivimab and etesevimab. We added the codes to the April 2021 I/OCE with effective dates set to the same date the FDA authorized them.

We assigned HCPCS codes describing the administration of COVID-19 monoclonal antibodies M0243 and M0245 to APC 5694 (Level 4 Drug Administration) with a payment rate of $310.75.

We assigned HCPCS codes describing monoclonal antibody therapy products Q0243 and Q0245 to status indicator L (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance).

For the July 2021 I/OCE update, we are updating the APC assignment for the monoclonal antibody administration codes. Specifically, we are reassigning HCPCS codes M0243 and M0245 from APC 5694 to APC 1506 (New Technology - Level 6 ($401 - $500)), effective May 6, 2021. The status indicator will remain S (Procedure or Service, Not Discounted When Multiple, separate APC assignment).

Table 3 of CR 12316 lists the HCPCS codes, their long descriptors, and updated APC assignments for the administration of COVID-19 monoclonal antibodies.

The COVID-19 monoclonal antibody administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates, are in the July 2021 OPPS Addendum B. For information on the OPPS status indicators, see OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

Visit the CMS website for more information on the Medicare Monoclonal Antibody COVID-19 Infusion Program and Infusion payments during the PHE.

c. New HCPCS Codes for Administering COVID-19 Monoclonal Antibodies in the Home or Residence

Effective May 6, 2021, we are establishing 2 new HCPCS codes (M0244 and M0246) to describe the service to administer COVID-19 monoclonal antibodies in the home or residence. We assigned these 2 new codes to APC 1509 (New Technology - Level 9 ($701 - $800)) with status indicator S in the July 2021 I/OCE. Table 4 of CR 12316 lists the new HCPCS codes, long descriptors, and their APC assignments.

3. CPT Proprietary Laboratory Analyses (PLA) Coding Changes, Effective July 1, 2021

The AMA CPT Editorial Panel established 7 new PLA codes, including CPT codes 0248U through 0254U, effective July 1, 2021. Table 5 of CR 12316 lists the long descriptors and status indicators for the codes, which have been added to the July 2021 I/OCE with an effective date of July 1. Also, the codes, along with their short descriptors, status indicators, and payment rates (where applicable), are in the July 2021 OPPS Addendum B. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

4. New CPT Category III Codes Effective July 1, 2021

The AMA releases CPT Category III codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January.

For the July 2021 update, CMS is implementing 31 CPT Category III codes the AMA released in January 2021 for implementation on July 1, 2021. The status indicators and APC assignments for these codes are in Table 6 of CR 12316. We added these codes (0640T through 0670T) to the July 2021 I/OCE, with an effective date of July 1, 2021.

5. a. New Device Pass-Through Categories

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. Section 1833(t)(6)(B)(ii)(IV) of the Act requires us to create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

We are establishing 1 new device pass-through categories as of July 1, 2021. Table 7 of CR 12316 provides a listing of new coding and payment information regarding the new device categories for transitional pass-through payment.

b. Device Offset from Payment:

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.

We have determined that the costs associated with HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) aren't already reflected in APC 5193. Therefore, we aren't applying a device offset to C1761. Always bill the device(s) in the category described by C1761 with 1 of the following CPT codes:

- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5193 for Calendar Year (CY) 2021
- CPT code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5193 for CY 2021

c. Transitional Pass-Through Payments for Designated Devices

We assigned certain designated new devices to APCs and the I/OCE identifies 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. 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 provided an alternative pathway to qualify for device pass-through payment status. Under this pathway, 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 receive pass-through payment status effective on or after January 1, 2020.

6. Clinic Visits

We are updating Chapter 4, Section 160 of the Medicare Claims Processing Manual to reflect information related to clinic visits. We attached the updated manual content to CR 12316.

7. Drugs, Biologicals, and Radiopharmaceuticals

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

There are 9 new HCPCS codes (C9075 – C9080, J9348, J9353, and Q5123) reporting drugs and biologicals in the hospital outpatient setting, where there haven't previously been specific codes available, starting on July 1, 2021. These drugs and biologicals will receive drug pass-through status starting July 1, 2021. We list these HCPCS codes in Table 8 of CR 12316.

b. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on June 30, 2021

There are 6 HCPCS codes (A9513, J3398, J7170, J9057, Q9991, and Q9992) for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on June 30, 2021. We list these codes in Table 9 of CR 12316. Effective July 1, 2021, the status indicator for these codes is changing from G to K.

c. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of July 1, 2021

There are 5 (J0224, J1951, J7168, A9593, and A9594) new drug, biological, and radiopharmaceutical HCPCS codes for July 1, 2021. We list these HCPCS codes in Table 10 of CR 12316.

Due to a late correction, HCPCS codes A9593 (Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie) and A9594 (Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie) will appear in the I/OCE with a status indicator of "G" (Pass-Through Drugs and Biologicals. Paid separately under OPPS). Since diagnostic radiopharmaceuticals are packaged in the OPPS when not receiving pass-through status, we will assign a zero-dollar payment amount to these 2 HCPCS codes for the period of July 1, 2021 through September 30, 2021. In the October 2021 Quarterly OPPS Update, we will make a retroactive change to change the status indicators of A9593 and A9594 to SI = "N" (Packaged under OPPS) in the I/OCE for the period of July 1, 2021 through September 30, 2021.

d. Drugs and Biologicals that Will Change from a Payable Status to Manual Adjudication Status on July 1, 2021

We are changing the status indicator for HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes) from status indicator = K to status indicator = A beginning on July 1, 2021. We show this drug/biological in Table 11 of CR 12316.

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

For CY 2021, payment for most non-pass-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 non-pass-through drugs, biologicals, and therapeutic 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 2021, 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 will update payments for drugs and biologicals based on ASPs on a quarterly basis as later quarter ASP submissions become available. Effective July 1, 2021, payment rates for many drugs and biologicals have changed from the values we 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 the third quarter of CY 2020.

In cases where adjustments to payment rates are necessary, changes to payment rates will be incorporated in the July 2021 Fiscal Intermediary Standard System (FISS) release. We aren't publishing the updated payment rates in CR 12316. However, the updated payment rates, effective July 1, 2021, are in the July 2021 update of the OPPS Addendum A and Addendum B.

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

Some drugs and biologicals based on ASP methodology will have payment rates that we correct retroactively. These retroactive corrections typically occur on a quarterly basis. See the list of drugs and biologicals with corrected payment rates. You may resubmit claims impacted by adjustments to previous quarter's payment files.

8. Skin Substitutes

We package 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, we divide the skin substitute products into 2 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

have pricing data that demonstrates that the cost of the product is above either the mean unit cost of $48 or per-day cost of $949 for CY 2021.

Skin Substitute Products Reassigned to the High-Cost Skin Substitute Group as of July 1, 2021

We are reassigning 1 skin substitute HCPCS code (Q4201) from the low-cost skin substitute group to the high-cost skin substitute group as of July 1, 2021. We list this code in Table 12 of CR 12316.

9. New HCPCS Code Describing Vaginal Colpopexy by Sacrospinous Ligament Fixation

We are establishing HCPCS code C9778, effective July 1, 2021, to describe technology associated with vaginal colpopexy by sacrospinous ligament fixation. Table 13 of CR 12316 lists the long descriptor, status indicator, and APC assignment for C9778.

10. Changes to OPPS Pricer

a. Added APC 2033 to OPPS Pricer.

b. Added Payment Adjustment Flag 2 to the OPPS Pricer fields received from the I/OCE.

11. Coverage Determinations

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate under the OPPS doesn't imply Medicare Program coverage. It indicates only how we pay for the product, procedure, or service if Medicare covers it. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the patient's condition and whether it is excluded from payment.

More Information

We issued CR 12316 to your MAC as the official instruction for this change.

For more information, contact your MAC.

Document History

Date of Change	Description
June 14, 2021	Initial article released.

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