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

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PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Related CR12175 describes changes to and billing instructions for various payment policies implemented in the April 2021 Outpatient Prospective Payment System (OPPS) update. The April 2021 Integrated Outpatient Code Editor (I/OCE) will reflect the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in CR 12175. Please make sure your billing staffs are aware of these updates.

BACKGROUND

1. Revised APC Assignments for Pfizer-BioNTech and Moderna COVID-19 CPT Administration Codes

CMS listed the CPT codes associated with the Pfizer and Moderna COVID-19 vaccines and their administration in Section I.B.4. (New COVID-19 CPT Vaccines and Administration Codes) of the January 2021 OPPS Update of the Hospital OPPS (Transmittal 10541, CR 12120, dated December 31, 2020). Because it was too late for us to establish new APCs for the January 2021 I/OCE update, we assigned COVID-19 vaccine administration CPT codes 0001A and 0011A to APC 1492 (New Technology – Level 1B ($11-$20)) with a payment rate of $15.50 and CPT codes 0002A and 0012A to APC 1493 (New Technology – Level 1C ($21-$30)) with a payment rate of $25.50.

To pay appropriately for the COVID-19 vaccine administration codes, for the April 2021 I/OCE update, we are updating the APC assignments for the administration codes. We are reassigning CPT codes 0001A and 0011A from APC 1492 to APC 9397 and codes 0002A and 0012A from APC 1493 to APC 9398.

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Note: In the April I/OCE, we assigned CPT code 0001A to APC 9397 and CPT code 0002A to APC 9398, effective April 1, 2021. CPT code 0011A is assigned to APC 9397 and CPT code 0012A is assigned to APC 9398, effective April 1, 2021. Table 1 of CR 12175 lists the APC titles for the two new COVID-19 vaccine administration APCs.

The COVID-19 vaccine and administration CPT codes, along with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the April 2021 OPPS Addendum B. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year (CY) 2021 OPPS/ASC final rule for the latest definitions.

The CMS website features payment and effective dates for the COVID-19 vaccines and their administration during the Public Health Emergency (PHE).

2. Janssen/Johnson & Johnson COVID-19 Vaccine and Vaccine Administration Code

On January 19, 2021, the American Medical Association (AMA) released 2 new CPT codes associated with the Janssen/Johnson & Johnson vaccine. CPT code 91303 refers to the specific vaccine product while CPT code 0031A describes the service to administer the vaccine. These 2 codes will be available for use once the vaccine receives Emergency Use Authorization (EUA) or approval from the FDA. Table 2 of CR 12175 lists the long descriptors for these codes.

Short descriptors, status indicators, and payment rates (where applicable) for these codes are in the April 2021 OPPS Addendum B. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year (CY) 2021 OPPS/ASC final rule for the latest definitions.

3. New Monoclonal Antibody Therapy Product and Administration Codes

In section I.B.3. (Monoclonal Antibody Therapy Product and Administration Codes) of the January 2021 OPPS Update of the Hospital Outpatient Prospective Payment System (CR12120), we listed new HCPCS codes

- M0239 and Q0239 that were established effective November 9, 2020 for bamlanivimab
- M0243 and Q0243 that were established effective November 21, 2020 for casirivimab and imdevimab

These codes help track and pay appropriately for monoclonal antibodies used to treat COVID-19. We added the codes to the January 2021 I/OCE with their effective dates set to the dates the FDA authorized them.

On February 9, 2021, FDA issued an EUA for two monoclonal antibodies, specifically, bamlanivimab and etesevimab, that are administered together, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19).

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To ensure access to these monoclonal antibody treatments during the COVID-19 PHE, Medicare covers and pays for the infusion of monoclonal antibody therapy in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). That is, as a result of the circumstances of the PHE, Medicare covers and pays for the infusion of monoclonal antibody therapy in the manner in which it will pay for COVID-19 vaccines and other statutory vaccines such as influenza.

CMS established new HCPCS codes M0245 and Q0245 effective February 9, 2021, for bamlanivimab and etesevimab. The codes are in the April 2021 I/OCE with their effective dates set to the same date as the FDA authorization. Table 3 of CR 12175 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 April 2021 OPPS Addendum B.

Similar to other vaccines, Medicare won't make a separate payment to you for a monoclonal antibody product when that product is given to you for free by the government. We anticipate much of the initial volume will be supplied to providers free of charge. Medicare established HCPCS code Q0245 for bamlanivimab and etesevimab, administered together. If you purchase bamlanivimab and etesevimab, they should report HCPCS code Q0245 to receive separate payment for the monoclonal antibody treatment.

Medicare will pay you for the administration of monoclonal antibodies even when whether the product is given to you for free. To receive separate payment for the infusion of bamlanivimab and etesevimab, report HCPCS code M0245.

For more information on the Medicare Monoclonal Antibody COVID-19 Infusion Program during the Public Health Emergency, refer https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion and https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion#Payment.

4. CPT Proprietary Laboratory Analyses (PLA) Coding Change Effective April 1, 2021

The AMA CPT Editorial Panel established 6 new PLA codes (CPT codes 0242U through 0247U), effective April 1, 2021. Table 4 of CR 12175 lists the long descriptors and status indicators for the codes, which have been added to the April 2021 I/OCE, with an effective date of April 1.

Short descriptors, status indicators, and payment rates (where applicable) for these codes are listed in the April 2021 OPPS Addendum B found on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year (CY) 2021 OPPS/ASC final rule for the latest definitions.

5. New HCPCS Code Describing the Application of Intraoperative Near-Infrared Fluorescence Imaging Using Indocyanine Green on the Extrahepatic Ducts

Effective April 1, 2021, we are establishing the new HCPCS code C9776 to describe the application of intraoperative near-infrared fluorescence imaging using indocyanine green on the

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extrahepatic ducts. The administration of the intravenous indocyanine green for the visualization of major extrahepatic biliary ducts (example, cystic duct, common bile duct, and common hepatic duct) is associated with laparoscopy cholecystectomy. Table 5 of CR 12175 lists the official long descriptor and status indicator for C9776.

The short descriptor and status indicator for C9776 are also listed in the April 2021 Update of the OPPS Addendum B. For information on OPPS status indicator N, please refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definition.

6. New HCPCS Code Describing Esophageal Mucosal Integrity Testing by Electrical Impedance

We are establishing HCPCS code C9777, effective April 1, 2021, to describe the technology associated with esophageal mucosal integrity testing by electrical impedance. Table 6 of CR 12175 lists the long descriptor and status indicator for C9777.

The short descriptor and status indicator for C9777 are also listed in the April 2021 Update of the OPPS Addendum B. For more information on OPPS status indicator N, please refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definition.

7. Change to the Long Descriptor for HCPCS Code Descriptor for C9761

Effective October 1, 2020, the long descriptor for HCPCS code C9761 has changed to (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable). Table 7 of CR 12175 lists the old and new long descriptor, status indicator, and APC assignment for C9761.

8. Status Indicator Corrections for HCPCS codes G2061-G2063 and CPT codes 98970-98972 Effective January 1, 2021

In the January 2021 I/OCE, HCPCS codes G2061, G2062, and G2063 were incorrectly listed as active codes with status indicator A to indicate that they should be paid under a fee schedule or payment system other than OPPS. These codes have been deleted effective December 31, 2020, and therefore, we changed their status indicator to D in the April 2021 I/OCE, retroactively to indicate that they are discontinued codes. These codes were replaced with CPT codes 98970, 98971, and 98972, respectively. These 3 codes were incorrectly assigned status indicator B in the January 2021 I/OCE to indicate that other more appropriate codes should be reported but because these codes replaced G2061, G2062, and G2063, we assigned them to status indicator A effective January 1, 2021, in the April 2021 I/OCE. Table 8 of CR 12175 lists the long descriptors and status indicators for these codes.

For more information on OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definition. The short descriptors and status indicators for these codes are also in the April 2021 update of the OPPS Addendum B.

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9. Status Indicator Corrections for HCPCS codes G2010, G2012, and G2211 Effective January 1, 2021

In the January 2021 I/OCE, HCPCS codes G2010 and G2012 were incorrectly assigned to status indicator A to indicate that they should be paid under a fee schedule or payment system other than OPPS. Because these codes were replaced with HCPCS codes G2250 and G2251 for certain non-physician practitioners, including rehabilitation therapists, effective January 1, 2021, we assigned them to status indicator B under OPPS to indicate that other more appropriate codes should be reported in the April 2021 I/OCE. Table 9 of CR 12175 lists the long descriptors and status indicators for these codes.

In the January 2021 I/OCE, HCPCS code G2211 was incorrectly assigned to status indicator N to indicate that it should be packaged under OPPS. We intended to assign this code to status indicator B to indicate that it shouldn't be payable under OPPS because this code is an add-on code to existing Evaluation and Management code(s) that are assigned to status indicator B. Therefore in the April 2021 I/OCE update, we assigned this code to status indicator B effective January 1, 2021. Table 9 of CR 12175 lists the long descriptor and status indicator for the codes.

10. Advanced Diagnostic Laboratory Tests (ADLT) Under the Clinical Lab Fee Schedule (CLFS)

Under the OPPS, tests that receive ADLT status under Section 1834A(d)(5)(A) of the Social Security Act (the Act) are assigned to status indicator A (Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS). In the October 2019 update to the OPPS (CR 11451, Transmittal 4411, dated October 4, 2019), we indicated that the DecisionDx-Melanoma test was approved for ADLT status on May 17, 2019. However, because there was no specific code to describe this test, we revised the status indicator for CPT code 81599 from E1 (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type.)) to A, so that this laboratory test would be paid separately under the CLFS when reported with identifier ZB1D4.

For the 2021 update, the CPT Editorial Panel established CPT code 81529 (Oncology (cutaneous melanoma), mrna, gene expression profiling by real-time rt-pcr of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis) to describe the DecisionDx-Melanoma test effective January 1, 2021. Because the DecisionDx-Melanoma test is now described by CPT code 81529, we are revising the status indicator for CPT code 81599 back to E1. We are also including this change in the April 2021 I/OCE Release with an effective date of January 1, 2021.

Note: CPT code 81529 is assigned to OPPS status indicator A, effective January 1, 2021.

For the latest list of ALDT approved tests under the CLFS, refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/List-of-Approved-ADLTs.pdf.

11. Therapeutic Intra-Vascular Ultrasound System (TIVUS™) for Pulmonary Artery Denervation in Patients with Pulmonary Arterial Hypertension

In the CY 2021 OPPS/ASC final rule that was published in the Federal Register on December 29, 2020, we stated that CPT code 0632T (Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance), which was effective January 1, 2021, would be assigned to OPPS status indicator E1 to indicate that the code is not payable by Medicare because the clinical trial associated with the code has not met Medicare's standards for coverage (85 FR 85975).

Note: CPT code 0632T describes the surgical procedure associated with the TIVUS system.

We approved the clinical study associated with the TIVUS system for Medicare coverage on November 19, 2020, as a Category B Investigational Device Exception (IDE) study. Based on the IDE approval, we are reassigning CPT code 0632T from status indicator E1 to status indicator J1 (Hospital Part B Services Paid Through a Comprehensive APC) and assigning it to APC 5194 (Level 4 Endovascular Procedures), effective April 1, 2021. The payment rate for 0632T is found in Addendum B of the 2021 OPPS Update.

12. Drugs, Biologicals, and Radiopharmaceuticals

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

Three new HCPCS codes have been created (effective April 1, 2021) for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available. These drugs and biologicals will receive drug pass-through status starting April 1, 2021. Table 10 of CR 12175 lists these codes.

b. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on March 31, 2021

There are 10 HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on March 31, 2021. Table 11 of CR 12175 lists these codes. Effective April 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 April 1, 2021

Seven new drug, biological, and radiopharmaceutical HCPCS codes will be established on April 1, 2021, and they are listed in Table 12 of CR 12175.

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d. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted as of April 1, 2021

Two drug, biological, and radiopharmaceutical HCPCS codes will be deleted on April 1, 2021. They are listed in Table 13 of CR 12175.

e. Drugs and Biologicals that Will Retroactively Change from Non-Payable Status to Separately Payable Status from January 1, 2021, to March 31, 2021

The status indicator for HCPCS code Q5122 (Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg) for the period of January 1, 2021, through March 31, 2021, will be changed retroactively from status indicator E2 to K in the April I/OCE. Table 14 of CR 12175 lists the code.

f. Drugs and Biologicals with Payments Based on Average Sale Price (ASP)

For CY 2021, payment for the majority of nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were not 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 therapeutic pharmaceuticals 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 settle payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP + 6% of the reference product for biosimilars). Payment for drugs and biologicals based on ASPs will be updated on a quarterly basis as later-quarter ASP submissions become available.

Effective April 1, 2021, payment rates for many drugs and biologicals will change 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 the third quarter of CY 2020. In cases where adjustments to payment rates are necessary, they will be incorporated into the April 2021 Fiscal Intermediary Shared System (FISS) release. We are not publishing updated payment rates in this CR implementing the April 2021 OPPS update. However, the updated payment rates effective April 1, 2021, are in the April 2021 update of the OPPS Addendums A and B.

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

Some drugs and biologicals based on ASP methodology will have payment rates corrected retroactively. These corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payment rates will be accessible on the CMS website on the first date of the quarter.

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Providers may resubmit claims impacted by adjustments to payment files from previous quarters.

13. Coverage Determination

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. Rather, it 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 coverage requirements. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

ADDITIONAL INFORMATION

The official instruction, CR 12175, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10666cp.pdf.

If you have questions, your MACs may have more information. The CMS website contains this list of MAC websites so you can find yours.

DOCUMENT HISTORY

Date of Change	Description
March 9, 2021	Initial article released.

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