CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10825	**Date: June 11, 2021**
	Change Request 12316

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

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the July 2021 OPPS update. The July 2021 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.7.

The July 2021 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2021 I/OCE CR.

EFFECTIVE DATE: July 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2021

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/Table of Contents
N	4/160.2 - Clinic Visits

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 10825	Date: June 11, 2021	Change Request: 12316

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EFFECTIVE DATE: July 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2021

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the July 2021 OPPS update. The July 2021 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.7.

The July 2021 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2021 I/OCE CR.

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

On May 4, 2021, the AMA released three new CPT codes associated with the Novavax COVID-19 vaccine.

The codes, specifically, CPT codes 91304, 0041A, and 0042A, will be available for use once the vaccine receives Emergency Use Authorization (EUA) or approval from the Food and Drug Administration.

Table 1, attachment A, 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 July 2021 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

For more information on the payment and effective dates for the COVID-19 vaccines and their administration during the Public Health Emergency (PHE), refer to the following CMS website:

https:/www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

2. a. Revocation of Emergency Use Authorization (EUA) for the Covid-19 Monoclonal Antibody Therapy

Bamlanivimab and Deletion of HCPCS codes M0239 and Q0239 from the July 2021 I/OCE

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 (Transmittal 10541, Change Request 12120 dated December 31, 2020), 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. The codes were added to the January 2021 I/OCE with their effective dates set to the dates they were authorized by the FDA.

Effective April 16, 2021, the U.S. Food and Drug Administration revoked the emergency use authorization (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. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA.

Therefore, effective April 16, 2021, HCPCS codes M0239 and Q0239 were deleted from the July 2021 I/OCE. Table 2, attachment A lists the deleted HCPCS codes along with their long descriptors.

b. Revised APC Assignment for the Covid-19 Monoclonal Antibody 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 (Transmittal 10541, Change Request 12120 dated December 31, 2020), CMS 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. The codes were added to the January 2021 I/OCE with their effective dates set to the dates they were authorized by the FDA.

In section I.B.3 (Monoclonal Antibody Therapy Product and Administration Codes) of the April 2021 OPPS Update of the Hospital Oupatient Prospective Payment System (Transmittal 10666, Change Request 12175 dated March 8, 2021), CMS listed new HCPCS codes M0245 and Q0245 effective February 9, 2021, for bamlanivimab and etesevimab. The codes have been added to the April 2021 I/OCE with their effective dates set to the same date as the FDA authorization.

HCPCS codes describing the administration of Covid-19 mononclonal antibodies: M0243, and M0245 were assigned to APC 5694 (Level 4 Drug Administration) with a payment rate of $310.75.

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

For the July 2021 IOCE 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, attachment A, 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 listed in the July 2021 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

For more information on the Medicare Monoclonal Antibody COVID-19 Infusion Program during the Public Health Emergency, refer to the following CMS websites:

https:/www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

https:/www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion#Payment

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

Effective May 6, 2021, CMS is establishing two new HCPCS codes M0244 and M0246 to describe the service to administer COVID-19 monoclonal antibodies in the home or residence. These two new codes

were assigned to APC 1509 (New Technology - Level 9 ($701 - $800)) with status indicator “S” in the July 2021 I/OCE. Table 4, attachment A, lists the new HCPCS codes, long descriptors and their APC assignments.

The Covid-19 monoclonal antibody administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates are listed in the July 2021 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

For more information on the Medicare Monoclonal Antibody COVID-19 Infusion Program during the Public Health Emergency, refer to the following CMS websites:

https:/www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

https:/www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion#Payment

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

The AMA CPT Editorial Panel established seven new PLA codes, specifically, CPT codes 0248U through 0254U, effective July 1, 2021. Table 5, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the July 2021 I/OCE with an effective date of July 1. In addition, the codes, along with their short descriptors, status indicators, and payment rates (where applicable) are listed in the July 2021 OPPS Addendum B that is posted on the CMS website. 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 American Medical Association (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 that the AMA released in January 2021 for implementation on July 1, 2021. The status indicators and APC assignments for these codes are shown in Table 6, attachment A. CPT codes 0640T through 0670T have been added to the July 2021 I/OCE with an effective date of July 1, 2021. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the July 2021 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

5. a. New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that we 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 one new device pass-through categories as of July 1, 2021. Table 7, attachment A, provides a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

b. Device Offset from Payment:

Section 1833(t)(6)(D)(ii) of the Act requires that we 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.

i. We have determined that the costs associated with HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) are not already reflected in APC 5193. Therefore, we are not applying a device offset to C1761. The device(s) in the category described by HCPCS code C1761 should always be billed with one of the following Current Procedural Terminology (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 Calendar Year (CY) 2021

c. Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned 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. All related payment calculations will be returned on the same APC line and identified as a designated new device. We refer readers to Addendum P of the CY 2021 final rule with comment period for the most current OPPS HCPCS Offset file. Addendum P is available via the Internet on the CMS website.

d. Alternative Pathway for Devices That Have a Food and Drug Administration (FDA) Breakthrough Designation

For devices that have received FDA marketing authorization and a Breakthrough Device designation from the FDA, CMS provided an alternative pathway to qualify for device pass-through payment status, under which devices would not 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 Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, section 160, to reflect the information found in Policy section I.B.4 of the Transmittal 2845, CR 8572, published on December 27, 2013 related to clinic visits.

7. Drugs, Biologicals, and Radiopharmaceuticals

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

Eleven (11) new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available starting on July 1, 2021. These drugs and biologicals will receive drug pass-through status starting July 1, 2021. These HCPCS codes are listed in Table 8, attachment A.

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

There are six (6) HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on June 30, 2021. These codes are listed in Table 9, attachment A. Therefore, effective July 1, 2021, the status indicator for these codes is changing from "G" to "K". For more information on OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year 2021 OPPS/ASC final rule for the latest definition. These codes, along with the short descriptor and status indicators are also listed in the July 2021 Update of the OPPS Addendum B.

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

Five (5) new drug, biological, and radiopharmaceutical HCPCS codes will be established on July 1, 2021. These HCPCS codes are listed in Table 10, attachment A.

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, a zero dollar payment amount will be assigned to these two HCPCS codes for the period of July 1, 2021 through September 30, 2021. In the October 2021 Quarterly OPPS Update, a retroactive change will be made 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

The status indicator for HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes) will be changed from status indicator = "K" to status indicator = "A" beginning on July 1, 2021. This drug/biological is reported in Table 11, attachment A.

e. Drugs and Biologicals with Payments Based on Average Sales 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 percent (or ASP + 6 percent 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 – 22.5 percent (or ASP - 22.5 percent 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 percent 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 percent of the reference product for biosimilars). Payments for drugs and biologicals based on ASPs will be updated 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 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. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the July 2021 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the July 2021 update of the OPPS. However, the updated payment rates effective July 1, 2021 can be found in the July 2021 update of the OPPS Addendum A and Addendum B on the CMS website at https:/www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS

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 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 CMS website on the first date of the quarter at https:/www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html

Providers may resubmit claims that were impacted by adjustments to previous quarter's payment files.

8. Skin Substitutes

The payment for skin substitute products that do not 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 divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products. New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless CMS has 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

There is one (1) skin substitute HCPCS codes that will be reassigned from the low cost skin substitute group to the high cost skin substitute group as of July 1, 2021. These codes are listed in Table 12, attachment A.

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

CMS is establishing HCPCS code C9778, effective July 1, 2021, to describe the technology associated with vaginal colpopexy by sacrospinous ligament fixation. Table 13 attachment A, lists the long descriptor, status indicator, and APC assignment for HCPCS code C9778. For more information on OPPS status indicator "J1", refer to OPPS Addendum D1 of the Calendar Year 2021 OPPS/ASC final rule for the latest definition. This code, along with the short descriptor, status indicator, and payment rate is also listed in the July 1, 2021 OPPS Addendum B.

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 Integrated Outpatient Code Editor.

11. 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 does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (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 beneficiary's condition and whether it is excluded from payment.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12316.1	Medicare contractors shall install the July 2021 OPPS Pricer.	X		X		X				
12316.2	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of July 2021 Pricer.	X		X						
12316.3	Medicare contractors shall update the HCPCS file indicators to make J3399 contractor priced. When a contractor receives a claim with J3399, contact CMS at: OutpatientPPS@cms.hhs.gov for pricing instructions.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12316.4	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X		X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova, marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Attachment A − Tables for the Policy Section

Table 1. ─ Covid-19 Vaccine Product and Administration CPT Codes

CPT Code	Type	Labeler	Long Descriptor
91300	Vaccine/ Product Code	Pfizer	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use
0001A	Administration/ Immunization Code	Pfizer	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose
0002A	Administration/ Immunization Code	Pfizer	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose
91301	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use
0011A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose
0012A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose

91302	Vaccine/ Product Code	AstraZeneca/ University of Oxford	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, $5x10^{10}$ viral particles/0.5mL dosage, for intramuscular use
0021A	Administration/ Immunization Code	AstraZeneca/ University of Oxford	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, $5x10^{10}$ viral particles/0.5mL dosage; first dose
0022A	Administration/ Immunization Code	AstraZeneca/ University of Oxford	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, $5x10^{10}$ viral particles/0.5mL dosage; second dose
91303	Vaccine/ Product Code	Janssen/Johnson&Johnson	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, $5x10^{10}$ viral particles/0.5mL dosage, for intramuscular use
0031A	Administration/ Immunization Code	Janssen/Johnson&Johnson	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free,

			$5x10^{10}$ viral particles/0.5mL dosage, single dose
91304	Vaccine/ Product Code	Novavax	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use
0041A	Administration/ Immunization Code	Novavax	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; first dose
0042A	Administration/ Immunization Code	Novavax	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; second dose

Table 2.– HCPCS codes for the the Covid-19 Monoclonal Antibody Therapy Bamlanivimab that were Deleted Effective April 16, 2021

HCPCS Code	Long Descriptor
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring
Q0239	Injection, bamlanivimab-xxxx, 700 mg

Table 3.– Updated APC Assignments for Administration of Covid-19 Monoclonal Antibodies Effective May 6, 2021

HCPCS Codes	Long Descriptors	Old APC	New APC
M0243	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	5694	1506
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring	5694	1506

Table 4.– New HCPCS Codes for Administering Covid -19 Monoclonal Antibodies in the Home or Residence and their APC Assignments Effective May 6, 2021

HCPCS Codes	Long Descriptors	APC
M0244	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid 19 public health emergency	1509
M0246	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid 19 public health emergency	1509

Table 5. – PLA Coding Changes Effective July 1, 2021

CPT Code	Long Descriptor	OPPS SI
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	A
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	Q4
0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	A
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	Q4
0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	A
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)	A
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested	A

Table 6. – CPT Category III Codes Effective July 1, 2021

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound	M	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	T	5732
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound	M	N/A
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	E1	N/A
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	J1	5192
0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed	E1	N/A
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	E1	N/A
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	J1	5302

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	5523
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	N	N/A
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional	Q1	5741
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	T	5301
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	T	5301
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	T	5301
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	J1	5302
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	J1	5374

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	C	N/A
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	C	N/A
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	S	5733
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	C	N/A
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	E1	N/A
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	E1	N/A
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	5732
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)	N	N/A
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	E1	N/A
0665T	Donor hysterectomy (including cold preservation); open, from living donor	E1	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	E1	N/A
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	E1	N/A
0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	E1	N/A
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	E1	N/A
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	E1	N/A

Table 7. ─ New Device Code Effective July 1, 2021

HCPCS code	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Device Offset Amount(s)
C1761	7/1/2021	H	2033	Cath, trans intra litho/coro	Catheter, transluminal intravascular lithotripsy, coronary	CPT code 92928 - $0.00 CPT C9600 - $0.00

Table 8. ─ New CY 2021 HCPCS Codes Effective July 1, 2021 for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 SI	CY 2021 APC
C9075	Injection, casimersen, 10 mg	G	9412
C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413
C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414
C9078	Injection, trilaciclib, 1mg	G	9415
C9079	Injection, evinacumab-dgnb, 5mg	G	9416
C9080	Injection, melphalan flufenamide hydrochloride, 1 mg	G	9417
J9348	Injection, naxitamab-gqgk, 1mg	G	9408
J9353	Injection, margetuximab-cmkb, 5 mg	G	9418
Q5123	Injection, rituximab-arrx, biosimilar (riabni), 10 mg	G	9411

Table 9. ─ HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending Effective June 30, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	April 2021 SI	July 2021 SI	July 2021 APC
A9513	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	G	K	9067
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	K	9070
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	K	9257
J9057	Injection, copanlisib, 1 mg	G	K	9030
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	K	9073
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	K	9239

Table 10. ─ Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of July 1, 2021

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
A9593	N/A	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	N	N/A
A9594	N/A	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	N	N/A
J0224	C9074	Injection, lumasiran, 0.5 mg	G	9407
J1951	N/A	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg	K	9419
J7168	C9132	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	G	9132

Table 11. ─ Drugs and Biologicals that Will Change from a Payable Status to Manual Adjudication Status on July 1, 2021

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes	K	A	N/A	07/01/2021

Table 12. ─ Skin Substitute Products Reassigned to the High Cost Skin Substitute Group as of July 1, 2021

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2021 SI	April 2021 Low/High Cost Skin Substitute Group	July 2021 Low/High Cost Skin Substitute Group
Q4201	Matrion 1 sq cm	N	Low Cost Group	High Cost Group

Table 13. ─ New Vaginal Colpopexy By Sacrospinous Ligament Fixation HCPCS Code Effective July 1, 2021

HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI	OPPS APC

C9778	Colpopexy, min/inv, ex-perit	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	J1	5414

Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)

Table of Contents

(Rev.10825; Issued: 06-11-21)

Transmittals for Chapter 4

160.2 - Clinic Visits

160.2 - Clinic Visits

(Rev.10825; Issued: 06-11-21; Effective: 07-01-21; Implementation: 07-06-21)

Effective January 1, 2014, CMS will recognize HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) for payment under the OPPS for outpatient hospital clinic visits. Effective January 1, 2014, CPT codes 99201-99205 and 99211-99215 will no longer be recognized for payment under the OPPS.