

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12227	Date: August 31, 2023
	Change Request 13340

SUBJECT: October 2023 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to describe changes to and billing instructions for various payment policies implemented in the October 2023 Outpatient Prospective Payment System (OPPS) update. The October 2023 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 50.8 (Annual Updates to the OPPS Pricer for Calendar Year (CY) 2007 and Later).

EFFECTIVE DATE: October 1, 2023

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 2, 2023

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
N/A	N/A

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

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EFFECTIVE DATE: October 1, 2023

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IMPLEMENTATION DATE: October 2, 2023

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions on coding changes and policy updates that are effective October 1, 2023 for the Hospital OPPS. The updates include coding and policy changes for new services, pass-through drug and devices, Covid-19 treatments, PLA codes and other items and services. The October 2023 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2023 I/OCE CR.

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

The American Medical Association (AMA) has been issuing unique Current Procedural Terminology (CPT) Category I codes which are developed based on collaboration with the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) for each coronavirus vaccine as well as administration codes unique to each such vaccine and dose. These codes are effective upon receiving Emergency Use Authorization (EUA) or approval from the Food and Drug Administration (FDA).

Based on the Food and Drug Administration's (FDA's) recent changes for the administration of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) messenger ribonucleic acid (mRNA) vaccines, the Current Procedural Terminology (CPT®) Editorial Panel has approved new vaccine administration codes 0171A and 0172A for the administration of a first and second dose of the Pfizer bivalent vaccine product (91317) for patients aged 6 months through 4 years; vaccine administration code 0151A for the administration of a single dose of the Pfizer bivalent vaccine product (91315) for patients aged 5 through 11 years; vaccine administration code 0121A for the administration of a single dose of the Pfizer bivalent vaccine product (91312); and vaccine administration codes 0141A and 0142A for the administration of a first and second dose of the Moderna bivalent vaccine product (91314). The Centers for Medicare & Medicaid Services (CMS) identify an effective date of April 18, 2023 for these codes, following the FDA's announced changes.

Therefore, effective April 18, 2023, CPT codes: 0171A and 0141A are assigned to status indicator S, APC 9397 (Covid-19 Vaccine Admin Dose 1 of 2) and CPT codes: 0172A, 0142A, 0121A, 0151A are assigned to status indicator S, APC 9398 in the October 2023 I/OCE Update.

The original monovalent vaccines' emergency use authorization (EUA) has been rescinded and the following vaccine and vaccine administration codes are no longer recommended for use in the United States effective April 18, 2023: (0001A, 0002A, 0003A, 0004A, 0011A, 0012A, 0013A, 0051A, 0052A, 0053A, 0054A, 0064A, 0071A, 0072A, 0073A, 0074A, 0081A, 0082A, 0083A, 0091A, 0092A, 0093A, 0094A, 0111A, 0112A, 0113A, 91300, 91301, 91305, 91306, 91307, 91308, 91309, 91311). Therefore, effective April 18, 2023, these codes are assigned to status indicator "E1" in the October 2023 I/OCE update.

In addition, the term "booster" will no longer be used and has been replaced with "additional dose." Table 1, attachment A, contains revised long descriptors for CPT codes: 0124A, 0134A, 0144A, 0154A, 0164A, 0173A, and 0174A. Revised short descriptors are listed in the October 2023 OPPS Addendum B that is posted on the CMS website.

Effective June 1, 2023, the Janssen COVID-19 vaccine (0031A, 0034A, 91303) is no longer authorized for use in the United States. Therefore, effective June 1, 2023, these codes are assigned to status indicator “E1” in the October 2023 I/OCE update.

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 October 2023 OPSS Addendum B that is posted on the CMS website. For information on the OPSS status indicators, refer to OPSS Addendum D1 of the CY 2023 Outpatient Prospective Payment System (OPSS)/Ambulatory Surgical Center (ASC) final rule for the latest definitions.

2. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective October 1, 2023

The AMA CPT Editorial Panel established 18 new PLA codes, specifically, CPT codes 0402U through 0419U, effective October 1, 2023.

Table 2, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the October 2023 I/OCE with an effective date of October 1, 2023. In addition, the codes, along with their short descriptors and status indicators, are listed in the October 2023 OPSS Addendum B that is posted on the CMS website. For more information on OPSS status indicators, refer to OPSS Addendum D1 of the Calendar Year 2023 OPSS/ASC final rule for the latest definitions.

3. Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Change Effective October 1, 2023

The AMA CPT Editorial Panel established one new MAAA code, specifically, 0019M, effective October 1, 2023. Table 3, attachment A, lists the long descriptor and SI for CPT code 0019M. The code has been added to the October 2023 I/OCE with an effective date of October 1, 2023. In addition, the code, along with its short descriptor and status indicator, is listed in the October 2023 OPSS Addendum B that is posted on the CMS website. For more information on OPSS status indicators, refer to OPSS Addendum D1 of the Calendar Year 2023 OPSS/ASC final rule for the latest definitions.

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

On June 30, 2023, CMS announced the approval of one laboratory test as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502. We note that, under the OPSS, tests that receive ADLT status under section 1834A(d)(5)(A) of the Act are assigned to status indicator “A”. The laboratory test is listed in Table 4, attachment A.

Based on the ADLT designation, we revised the OPSS status indicator for HCPCS codes 0360U to “A” (Not paid under OPSS. Paid by MACs under a fee schedule or payment system other than OPSS) effective June 30, 2023. However, because the ADLT designation was made in June 2023, it was too late to include this change in the July 2023 I/OCE Release and the July 2023 OPSS update; therefore, we are including this change in the October 2023 I/OCE Release with an effective date of July 1, 2023.

For the latest list of ADLT approved tests under the CLFS, refer to this CMS website:

<https://www.cms.gov/files/document/advanced-diagnostic-laboratory-tests-under-medicare-clfs.pdf>. For more information on the OPSS status indicator “A”, refer to OPSS Addendum D1 of the CY 2023 OPSS/ASC final rule for the latest definitions.

5. New HCPCS code for Breast Imaging Service Using Opto-Acoustic Imaging

CMS is establishing a new HCPCS code, C9788, to describe the breast imaging service using opto-acoustic imaging. Table 5, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9788. For information on OPSS status indicators, please refer to OPSS Addendum D1 of the CY 2023 OPSS/ASC final rule for the latest definitions. This code, along with its short descriptor, status

indicator, and payment rate, is also listed in the October 2023 Update of the OPPS Addendum B.

6. New HCPCS code Describing the Instillation of an Anti-neoplastic Pharmacologic / Biologic Agent into the Renal Pelvis

CMS is establishing a new HCPCS code, C9789, to describe the instillation of an anti-neoplastic pharmacologic / biologic agent into the renal pelvis. Table 6, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9789. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2023 OPPS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the October 2023 Update of the OPPS Addendum B.

7. New HCPCS Code for Renal/Kidney Histotripsy

The clinical study associated with HistoSonic's Edison Histotripsy System for kidney histotripsy was approved by CMS for Medicare coverage on June 15, 2023, as a Category B IDE study. Currently, there is no specific HCPCS code to describe the service. Because the clinical study will be conducted in the hospital outpatient setting, we are establishing HCPCS code C9790 to enable Medicare to track and pay appropriately for this IDE study effective October 1, 2023.

Table 7, attachment A, lists the information associated with the clinical study, which is also posted on the CMS approved IDE studies website, specifically, at <https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies>.

Table 8, attachment A, lists the long descriptor and APC assignment for HCPCS code C9790. The code, along with its short descriptor, status indicator, and payment rate is also listed in the October 2023 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 2023 OPPS/Ambulatory Surgical Center (ASC) final rule for the latest definitions.

8. New HCPCS code Describing Magnetic Resonance Imaging with Inhaled Hyperpolarized Xenon-129 Contrast Agent of the Chest

CMS is establishing a new HCPCS code, C9791, to describe the magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent of the chest. Table 9, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9791. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2023 OPPS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the October 2023 Update of the OPPS Addendum B. Please note that HCPCS code C9791 cannot be reported with the imaging procedure CPT code 71551 (Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); with contrast material(s)).

9. New HCPCS code for Transcatheter Atrial Shunt System Clinical Trial

CMS is establishing a new HCPCS code, C9792, to describe the Transcatheter Atrial Shunt System clinical trial. Table 10, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9792. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2023 OPPS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the October 2023 Update of the OPPS Addendum B.

10. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2023 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

Eight (8) 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 October 1, 2023. These drugs and biologicals will receive drug pass-through status starting October 1, 2023. These HCPCS codes are listed in Table 11, attachment A.

b. Existing HCPCS Code for Certain Drug, Biological, and Radiopharmaceutical Starting Pass-Through Status as of October 1, 2023

There is one (1) existing HCPCS code for certain drug, biological, and radiopharmaceutical in the outpatient setting that will have its pass-through status start on October 1, 2023. This code is listed in Table 12, attachment A. Therefore, effective October 1, 2023, the status indicator for this code is changing to status indicator = “G”.

c. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on September 30, 2023

There are eleven (11) HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on September 30, 2023. These codes are listed in Table 13, attachment A. Therefore, effective October 1, 2023, the status indicator for these codes is changing from “G” to either “K” or “N.” For more information on OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year 2023 OPPS/ASC final rule for the latest definition. These codes, along with their short descriptors and status indicators are also listed in the October 2023 Update of the OPPS Addendum B.

d. HCPCS Code for Drug, Biological, and Radiopharmaceutical Previously Established Retroactive to July 6, 2023

HCPCS code J0174 (Injection, lecanemab-irmb, 1 mg) was established retroactive to July 6, 2023. The information for HCPCS code J0174 is listed in Table 14, attachment A.

e. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2023

Thirty-one (31) new drug, biological, and radiopharmaceutical HCPCS codes will be established on October 1, 2023. These HCPCS codes are listed in Table 15, attachment A.

f. HCPCS Code for Drug, Biological, and Radiopharmaceutical Deleted as of September 30, 2023

One (1) drug, biological, and radiopharmaceutical HCPCS code will be deleted on September 30, 2023. This HCPCS code is listed in Table 16, attachment A.

g. HCPCS Code for Drug, Biological, and Radiopharmaceutical with Descriptor Change as of October 1, 2023

One (1) drug, biological, and radiopharmaceutical HCPCS code has a descriptor change as of October 1, 2023. This HCPCS code is listed in Table 17, attachment A.

h. HCPCS Code for Drug, Biological, and Radiopharmaceutical with Descriptor Change as of July 1, 2023

One (1) drug, biological, and radiopharmaceutical HCPCS code has a descriptor change as of July 1, 2023. This HCPCS code is listed in Table 18, attachment A.

i. Vaccine that Will Retroactively Change from Non-Payable Status to Status Indicator “M” (Not Billable to the MAC) Effective May 31, 2023 in the October 2023 I/OCE Update

The status indicator for CPT code 90678 (Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use) effective May 31, 2023, will be changed retroactively from status indicator = “E1” to status indicator = “M” in the October 2023 I/OCE Update. This drug/biological is reported in Table 19, attachment A.

j. Vaccine that Will Retroactively be Assigned to Status Indicator “M” (Not Billable to the MAC) Effective May 3, 2023

CPT code, 90679 (Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use) was approved by Food and Drug Administration (FDA) on May 3, 2023 and will be assigned to status indicator “M” effective May 3, 2023 in the October 2023 I/OCE Update. This drug/biological is reported in Table 20, attachment A.

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

For CY 2023, payment for the majority of pass-through and nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals is generally made at a single rate of ASP plus 6 percent (or ASP plus 6 or 8 percent of the reference product for biosimilars), which provides payment for both the acquisition cost and pharmacy overhead costs of these items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective October 1, 2023, payment rates for many drugs and biologicals have changed from the values published in the CY 2023 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the second quarter of CY 2023. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the October 2023 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the October 2023 update of the OPPS. However, the updated payment rates effective October 1, 2023, can be found in the October 2023 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>.

l. 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 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 affected by adjustments to a previous quarter’s payment files.

11. 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 \$47 or the per day cost of \$837 for CY 2023.

a. Additional New Skin Substitute Products as of October 1, 2023

There are four (4) new skin substitute HCPCS codes that will be active as of October 1, 2023. These codes are listed in Table 21, attachment A.

b. Skin Substitute Products Reassigned to the High Cost Skin Substitute Group as of October 1, 2023

There is one (1) skin substitute HCPCS code that will be reassigned from the low cost skin substitute group to the high cost skin substitute group as of October 1, 2023. The code is listed in Table 22, attachment A.

12. 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 OPSS 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		D M E	Shared- System Maintainers				Other
		A	B		H H H	F M V C	M C M S	C M W F	
13340.1	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of the October 2023 OPSS I/OCE.	X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E	C M E D I	I
		A	B	H H H			
13340.2	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN	X		X			

Number	Requirement	Responsibility			
		A/B MAC			D M E
		A	B	H H H	M A C
	content releases when you distribute MLN Connects newsletter content per the manual section referenced above.				

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

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	Note
91300	Vaccine/ Product Code	Pfizer-BioNTech	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	No Longer Authorized for Use in the United States
0001A	Administration/ Immunization Code	Pfizer-BioNTech	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	No Longer Authorized for Use in the United States
0002A	Administration/ Immunization Code	Pfizer-BioNTech	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	No Longer Authorized for Use in the United States

			reconstituted; second dose	
0003A	Administration/ Immunization Code	Pfizer-BioNTech	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/0.3 mL dosage, diluent reconstituted; third dose	No Longer Authorized for Use in the United States
0004A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; booster dose	No Longer Authorized for Use in the United States
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	No Longer Authorized for Use in the United States
0011A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory	No Longer Authorized for Use in the United States

			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	No Longer Authorized for Use in the United States
0013A	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/0.5 mL dosage; third dose	No Longer Authorized for Use in the United States
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	No Longer Authorized for Use in the United States
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	No Longer Authorized for Use in the United States
0034A	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	No Longer Authorized for Use in the United States

			(Ad26) vector, preservative free, 5x10 ¹⁰ viral particles/0.5mL dosage; booster 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	
0044A	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; booster dose	
91305	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, trissucrose	No Longer Authorized for Use in the United States

			formulation, for intramuscular use	
0051A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; first dose	No Longer Authorized for Use in the United States
0052A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; second dose	No Longer Authorized for Use in the United States
0053A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease	No Longer Authorized for Use in the United States

			[COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; third dose	
0054A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; booster dose	No Longer Authorized for Use in the United States
91306	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use	No Longer Authorized for Use in the United States
0064A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2)	No Longer Authorized for Use in the United States

			(coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, booster dose	
91307	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	No Longer Authorized for Use in the United States
0071A	Administration/ Immunization Code	Pfizer-BioNTech	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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose	No Longer Authorized for Use in the United States
0072A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe	No Longer Authorized for Use in the United States

			acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose	
0073A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; third dose	No Longer Authorized for Use in the United States
0074A	Administration/ Immunization Code	Pfizer-BioNTech	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, 10 mcg/0.2 mL	No Longer Authorized for Use in the United States

			dosage, diluent reconstituted, tris-sucrose formulation; booster dose	
91308	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	No Longer Authorized for Use in the United States
0081A	Administration/ Immunization Code	Pfizer-BioNTech	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, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose	No Longer Authorized for Use in the United States
0082A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus	No Longer Authorized for Use in the United States

			2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose	
0083A	Administration/ Immunization Code	Pfizer-BioNTech	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, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; third dose	No Longer Authorized for Use in the United States
91309	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use	No Longer Authorized for Use in the United States

0091A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage; first dose, when administered to individuals 6 through 11 years	No Longer Authorized for Use in the United States
0092A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage; second dose, when administered to individuals 6 through 11 years	No Longer Authorized for Use in the United States
0093A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease	No Longer Authorized for Use in the United States

			[COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5mL dosage; third dose, when administered to individuals 6 through 11 years	
0094A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage; booster dose, when administered to individuals 18 years and over	No Longer Authorized for Use in the United States
91310	Vaccine/ Product Code	Sanofi Pasteur	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, for intramuscular use	
0104A	Administration/	Sanofi Pasteur	Immunization administration by intramuscular	

	Immunization Code		injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, booster dose	
91311	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use	No Longer Authorized for Use in the United States
0111A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; first dose	No Longer Authorized for Use in the United States

0112A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; second dose	No Longer Authorized for Use in the United States
0113A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; third dose	No Longer Authorized for Use in the United States
91312	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose	

			formulation, for intramuscular use	
0121A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; single dose	
0124A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, additional dose	
91313	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])	

			vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use	
0134A	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, bivalent, preservative free, 50 mcg/0.5 mL dosage, additional dose	
91314	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use	
0141A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike	

			protein, bivalent, preservative free, 25 mcg/0.25 mL dosage; first dose	
0142A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage; second dose	
0144A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRN-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, additional dose	
91315	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein,	

			preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	
0151A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; single dose	
0154A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose	

			formulation, additional dose	
91316	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 10 mcg/0.2 mL dosage, for intramuscular use	
0164A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, bivalent, preservative free, 10 mcg/0.2 mL dosage, additional dose	
91317	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose	

			formulation, for intramuscular use	
0171A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose	
0172A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose	
0173A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe	

			acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, third dose	
0174A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; additional dose	

Table 2. – PLA Coding Changes Effective October 1, 2023

CPT Code	Long Descriptor	OPPS SI
0402U	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal,	Q4

	endocervical, or male urine, each pathogen reported as detected or not detected	
0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed first-catch urine), algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer	A
0404U	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression	Q4
0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected	A
0406U	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer	Q4
0407U	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function	Q4
0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])	A
0409U	Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability	A

0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected	A
0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	A
0412U	Beta amyloid, A β 42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology	Q4
0413U	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations	A
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker	Q4
0415U	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS	Q4
0416U	Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine	Q4
0417U	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and	A

	categorization of mitochondrial disorder–associated genetic variants	
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	Q4
0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype	A

Table 3. – MAAA CPT Coding Change Effective October 1, 2023

CPT Code	Long Descriptor	OPPS SI
0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations	Q4

Table 4. – Advanced Diagnostic Laboratory Tests (ADLT) Under the Clinical Lab Fee Schedule (CLFS)

Lab Name	Test Name	CPT Code	CPT Long Descriptor
Biodesix, Inc.	Nodify CDT®	0360U	Oncology (lung), enzyme-linked immunosorbent assay (elisa) of 7 autoantibodies (p53, ny-eso-1, cage, gbu4-5, sox2, mage a4, and hud), plasma, algorithm reported as a categorical result for risk of malignancy

Table 5. – CY 2023 OPPS New Technology APC and Status Indicator Assignments for Opto-Acoustic Breast Imaging Service Effective October 1, 2023

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9788	Uni breas optoacoustic imag	Opto-acoustic imaging, breast (including axilla when performed), unilateral, with image documentation, analysis and report, obtained with ultrasound examination	S	5521

Table 6. – CY 2023 OPPS Status Indicator and New Technology APC Assignments for the Instillation of an Anti-neoplastic Pharmacologic / Biologic Agent into the Renal Pelvis Effective October 1, 2023

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9789	Instill pharm renal pelvis	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1559

Table 7. – Kidney Histotripsy Category B Investigational Device Exemption (IDE) Study

Study Title	Sponsor Name	NCT Number	IDE Number	CMS Approval Date	Category
The HistoSonics Edison System for Treatment of Primary Solid Renal Tumors Using Histotripsy (#HOPE4KIDNEY US)	HistoSonics, Inc.	NCT05820087	G230008	6/15/2023	B

Table 8. – New Kidney Histotripsy HCPCS Code Effective October 1, 2023

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9790	Kidney histotripsy w/image	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	S	1575

Table 9. – CY 2023 OPPS Status Indicator and New Technology APC Assignments for Magnetic Resonance Imaging with Inhaled Hyperpolarized Xenon-129 Contrast Agent of the Chest, Including Preparation and Administration of Agent Effective October 1, 2023

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9791	MRI hyperpolarized xenon129	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551

Table 10. — CY 2023 OPPS New Technology APC and Status Indicator Assignments for Transcatheter Atrial Shunt System Effective October 1, 2023

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9792	Blind/nonblind trans atrial	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study)	S	1537

Table 11. — New CY 2023 HCPCS Codes Effective October 1, 2023, for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

CY 2023 HCPCS Code	CY 2023 Long Descriptor	CY 2023 SI	CY 2023 APC
C9152	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246
C9153	Injection, amisulpride, 1 mg	G	9247
C9154	Injection, buprenorphine extended-release (brixadi), 1 mg	G	9249
C9155	Injection, epcoritamab-bysp, 0.16 mg	G	9250
C9156	Flotufolastat F 18, diagnostic, 1 millicurie	G	9254
C9157	Injection, tofersen, 1 mg	G	9262
C9158	Injection, risperidone, (uzedy), 1 mg	G	9266
J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviio), per factor viii i.u.	G	9277

Table 12. — Existing HCPCS Code for Certain Drug, Biological, and Radiopharmaceutical Starting Pass-Through Status as of October 1, 2023

CY 2023 HCPCS Code	CY 2023 Long Descriptor	July 2023 SI	October 2023 SI	October 2023 APC
J9058	Injection, bendamustine hydrochloride (apotex), 1 mg	K	G	9151

Table 13. – HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending Effective September 30, 2023

CY 2023 HCPCS Code	CY 2023 Long Descriptor	July 2023 SI	October 2023 SI	October 2023 APC
A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	N	N/A
C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	N	N/A
J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	K	9351
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	K	9378
J9227	Injection, isatuximab-irfc, 10 mg	G	K	9377
J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	K	9374
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	K	9376
J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	K	9428
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	G	K	9382
Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg	G	K	9349
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg	G	K	9381

Table 14. – HCPCS Code for Drug, Biological, and Radiopharmaceutical Previously Established Retroactive to July 6, 2023

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
J0174		Injection, lecanemab-irmb, 1 mg	K	9157

Table 15. – Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2023

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
90380		Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use	E1	
90381		Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use	E1	
A2022		Innovaburn or innovamatrix xl, per square centimeter	N	
A2023		Innovamatrix pd, 1 mg	N	
A2024		Resolve matrix, per square centimeter	N	
A2025		Miro3d, per cubic centimeter	N	
A9573		Injection, gadopiclesol, 1 ml	N	
A9603		Injection, pafolacianine, 0.1 mg	N	
A9697		Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose	N	
C9152		Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246
C9153		Injection, amisulpride, 1 mg	G	9247
C9154		Injection, buprenorphine extended-release (brixadi), 1 mg	G	9249
C9155		Injection, epcoritamab-bysp, 0.16 mg	G	9250
C9156		Flotufolastat F 18, diagnostic, 1 millicurie	G	9254
C9157		Injection, tofersen, 1 mg	G	9262
C9158		Injection, risperidone, (uzedy), 1 mg	G	9266
J0349		Injection, rezafungin, 1 mg	K	9267
J0801		Injection, corticotropin (acthar gel), up to 40 units	K	9268
J0802		Injection, corticotropin (ani), up to 40 units	K	9275
J0874		Injection, daptomycin (baxter), not therapeutically equivalent to j0878, 1 mg	E2	
J0889		Daprodustat, oral, 1 mg, (for esrd on dialysis)	E2	
J2359		Injection, olanzapine, 0.5 mg	N	
J2781	C9151	Injection, pegcetacoplan, intravitreal, 1 mg	G	9158
J7214		Injection, factor viii/von willebrand factor complex, recombinant (altuviio), per factor viii i.u.	G	9277
J7353		Anacaulase-bcdb, 8.8% gel, 1 gram	N	
J7519		Injection, mycophenolate mofetil, 10 mg	K	9279
J9051		Injection, bortezomib (maia), not therapeutically equivalent to j9041, 0.1 mg	E2	
J9064		Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg	E2	
J9345		Injection, retifanlimab-dlwr, 1 mg	K	9280
Q4285		Nudyn dl or nudyn dl mesh, per square centimeter	N	
Q4286		Nudyn sl or nudyn slw, per square centimeter	N	

Table 16. – HCPCS Code for Drug, Biological, and Radiopharmaceutical Deleted as of September 30, 2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 SI	APC
J0800	Injection, corticotropin, up to 40 units	K	9040

Table 17. – HCPCS Code for Drug, Biological, and Radiopharmaceutical with Descriptor Changes as of October 1, 2023

CY 2023 HCPCS Code	July 2023 Long Descriptor	October 2023 Long Descriptor
J1921	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1820, 5 mg	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1920, 5 mg

Table 18. – HCPCS Code for Drug, Biological, and Radiopharmaceutical with Descriptor Change as of July 1, 2023

CY 2023 HCPCS Code	April 2023 Long Descriptor	July 2023 Long Descriptor
J2426	Injection, paliperidone palmitate extended release, 1 mg	Injection, paliperidone palmitate extended release (invega sustenna), 1 mg

Table 19. – Vaccine that Will Retroactively Change from Non-Payable Status to Status Indicator “M” (Not Billable to the MAC) Effective May 31, 2023 in the October 2023 I/OCE Update

HCPCS Code	Long Descriptor	Old SI	New SI	Effective Date
90678	Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use	E1	M	5/31/2023

**Table 20. – Vaccine that Will Retroactively be Assigned to Status Indicator “M”
(Not Billable to the MAC) Effective May 3, 2023**

HCPCS Code	Long Descriptor	SI	Effective Date
90679	Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use	M	5/03/2023

Table 21. – New Skin Substitute Products Low-Cost Group/High-Cost Group Assignment Effective October 1, 2023

CY 2023 HCPCS Code	Short Descriptor	CY 2023 SI	Low/High-Cost Skin Substitute
A2022	Innovabr/innovamatx xl sqcm	N	High
A2024	Resolve matrix per sq cm	N	High
Q4285	Nudyn dl or dl mesh pr sq cm	N	Low
Q4286	Nudyn sl or slw, per sq cm	N	Low

Table 22. – Skin Substitute Products Reassigned to the High-Cost Skin Substitute Group as of October 1, 2023

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2023 SI	Prior Low/High-Cost Skin Substitute Group	October 2023 Low/High-Cost Skin Substitute Group
Q4282	Cygnus dual per sq cm	N	Low	High