CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11594	**Date: September 9, 2022**
	Change Request 12885

SUBJECT: October 2022 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 2022 OPPS update. The October 2022 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 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).

The October 2022 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2022 I/OCE CR.

EFFECTIVE DATE: October 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2022

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

Pub. 100-04	Transmittal: 11594	Date: September 9, 2022	Change Request: 12885

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EFFECTIVE DATE: October 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2022

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to describe changes to and billing instructions for various payment policies implemented in the October 2022 OPPS update. The October 2022 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 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).

The October 2022 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2022 I/OCE CR.

B. Policy: 1. Covid-19 Laboratory Tests and Services and Other Laboratory Tests Coding Update

Since February 2020, CMS has recognized several Covid-19 laboratory tests and related services. The codes are listed in Table 1, attachment A, along with their OPPS status indictors. The codes, along with their short descriptors and status indicators are also listed in the October 2022 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the CY 2022 OPPS/Ambulatory Surgical Center (ASC) final rule.

2. New Covid-19 CPT Vaccines and Administration Codes

American Medical Association (AMA) has been issuing unique Current Procedural Terminology (CPT) Category I codes which are developed based on collaboration with Centers for Medicare and Medicaid Services (CMS) and 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).

On April 26, 2022, the AMA released a new code describing the service to administer the booster dose of Pfizer BioNTech COVID-19 vaccine for patients 5-11 years old (0074A).

CMS identifies an effective date of 05/17/2022 for the Pfizer BioNTech COVID-19 vaccine administration CPT code 0074A, which describes the service to administer the booster dose for patients 5-11 years old. This effective date corresponds with updates to FDA EUAs and/or approvals. CMS will provide future direction to the contractors as EUAs and/or approvals become available.

Effective May 17, 2022, CPT code 0074A is assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the October 2022 I/OCE update.

Beneficiary cost-sharing shall not apply to CPT code 0074A.

On June 7, 2022, the AMA released a new vaccine administration code (0083A) for the third dose of the Pfizer vaccine product to address severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) in pediatric patents aged 6 months through 4 years.

CMS identifies an effective date of 06/17/2022 for the Pfizer BioNTech COVID-19 vaccine administration CPT codes 0081A, 0082A, and 0083A which describe the service to administer the vaccine’s first, second, and third dose, respectively, for pediatric patients ages 6 months through 4 years. This effective date corresponds with updates to FDA EUAs and/or approvals for Pfizer BioNTech COVID-19 vaccine product CPT 91308, effective 06/17/2022. CMS will provide future direction to the contractors as EUAs and/or approvals become available.

Effective June 17, 2022, CPT code 91308 is assigned to status indicator “L” (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the October 2022 I/OCE update.

Effective June 17, 2022, CPT code 0081A is assigned to status indicator “S”, APC 9397 (Covid-19 Vaccine Admin Dose 1 of 2). CPT codes 0082A and 0083A are assigned to status indicator "S", APC 9398 in the October 2022 I/OCE update.

Beneficiary cost-sharing shall not apply to CPT codes 0081A, 0082A, and 0083A.

On May 19, 2022, the AMA released a new vaccine product code (91311) and its associated vaccine administration codes (0111A, 0112A) for the new Moderna vaccine product to address severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) in pediatric patients aged 6 months through 5 years.

On July 6, 2022, the AMA released three new vaccine administration codes (0091A, 0092A, 0093A) for the Moderna vaccine product to address severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) in pediatric patients aged 6 through 11 years. These codes are to be reported with previously established Moderna vaccine product code 91309. The AMA has also approved an additional vaccine administration code (0113A) that is to be reported with the previously established Moderna vaccine product (91311) for pediatric patients aged 6 months through 5 years.

In addition, the descriptor for Moderna vaccine administration code 0094A has been revised to specify the appropriate age for its administration. Table 2, attachment A lists the descriptor for CPT code 0094A.

CMS identifies an effective date of 06/17/2022 for Moderna COVID-19 vaccine administration CPT codes 0091A, 0092A, and 0093A which describe the service to administer the vaccine’s first, second, and third dose, respectively, for pediatric patients ages 6 years through 11 years. This effective date corresponds with the 06/17/2022 update to the FDA EUA for the Moderna COVID-19 vaccine product CPT 91309 which authorizes the presentation described by this CPT code to provide primary series doses in individuals 6 years

through 11 years of age.

CMS identifies an effective date of 06/17/2022 for Moderna COVID-19 vaccine administration CPT codes 0111A, 0112A, and 0113A which describe the service to administer the vaccine's first, second, and third dose, respectively, for pediatric patients ages 6 months through 5 years. This effective date corresponds with updates to FDA EUAs and/or approvals for the Moderna COVID-19 vaccine product CPT 91311, effective 06/17/2022.

Effective June 17, 2022, CPT code 0091A is assigned to status indicator "S", APC 9397. CPT codes 0092A and 0093A are assigned to status indicator "S" and APC 9398 in the October 2022 I/OCE update.

Effective June 17, 2022, CPT code 91311 is assigned to status indicator "L" in the October 2022 I/OCE update.

CPT code 0111A is assigned to status indicator "S", APC 9397 and CPT codes 0112A and 0113A are assigned to status indicator "S", APC 9398 in the October 2022 I/OCE update.

Beneficiary cost sharing shall not be applied to the new vaccine product code or the new administration codes.

In section I.B.1. (New Covid-19 CPT Vaccines and Administration Codes) of the July 2021 OPPS Update of the Hospital Outpatient Prospective Payment System (Transmittal 10825, Change Request 12316 dated June 11, 2021), we listed 3 new CPT codes associated with the Novavax COVID-19 vaccine and its administration for patients ages 18 years and older. Specifically, CPT codes: 0041A, 0042A, and 91304.

The Centers for Medicare & Medicaid Services (CMS) identifies an effective date of 07/13/2022 for Novavax COVID-19 vaccine administration CPT codes 0041A and 0042A, which describe the service to administer the vaccine's first and second dose, respectively, for patients ages 18 years and older. This effective date corresponds with updates to FDA Emergency Use Authorizations (EUAs) and/or approvals for the Novavax COVID-19 vaccine product CPT 91304, effective 07/13/2022.

Effective July 13, 2022, CPT code 0041A is assigned to status indicator "S", APC 9397 and CPT code 0042A is assigned to status indicator "S", APC 9398 in the October 2022 IOCE.

Effective July 13, 2022, CPT code 91304 is assigned to status indicator "L" in the October 2022 IOCE.

Beneficiary cost-sharing shall not apply to CPT codes 0041A and 0042A.

Table 2, 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 2022 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 2022 OPPS/ASC final rule for the latest definitions.

3. Updates for COVID-19 Monoclonal Antibody Therapy Product and Administration Codes

a. Redosing Update for EVUSHELD™

On June 29, 2022, the FDA revised the EVUSHELD™ (tixagevimab co-packaged with cilgavimab) Fact Sheet for Healthcare Providers to recommend repeat dosing every six months with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection.

The HCPCS code Q0221 describing the dose of 300 mg of tixagevimab and 300 mg of cilgavimab and the HCPCS codes describing the service to administer EVUSHELD™ in healthcare settings or in the home (M0220 and M0221, respectively) can be billed for the repeat dosing every six months for patients that need ongoing protection.

4. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective October 1, 2022

The AMA CPT Editorial Panel established 23 new PLA codes, specifically, CPT codes 0332U through 0354U, effective October 1, 2022.

Table 3, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the October 2022 I/OCE with an effective date of October 1, 2022. In addition, the codes, along with their short descriptor and status indicators, are listed in the October 2022 OPPS Addendum B that is posted on the CMS website. For more information on OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year 2022 OPPS/ASC final rule for the latest definitions.

5. Status Indicator Revision for Bone (Mineral) Density Studies Described by CPT Codes 0554T, 0555T, 0556T, 0557T, and 0558T

For the October 2022 update, we are revising the status indicator for CPT codes 0554T through 0558T to "E1" to indicate that the codes are non-covered because the services described by the codes do not meet Medicare's definition of bone mass measurements (BMMs). The conditions for coverage of bone mass measurements can be found in chapter 15, section 80.5 of Pub.100-02, Medicare Benefit Policy Manual (MBPM). As specified in section 80.5.3 of the MBPM, bone mass measurements means a radiologic, radioisotopic, or other procedure that meets all of the following conditions:

- Is performed to identify bone mass, detect bone loss, or determine bone quality.
- Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the Food and Drug Administration (FDA) under 21 CFR part 807, or approved for marketing under 21 CFR part 814.
- Includes a physician’s interpretation of the results.

The change to the status indicator will be included in the October 2022 IOCE retroactive to July 1, 2019, which is the effective date of the CPT codes. The codes, along with their short descriptors and status indicators are also listed in the October 2022 OPPS Addendum B that is posted on the CMS website. For the definitions to all the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2022 OPPS/Ambulatory Surgical Center (ASC) final rule. For the latest HCPCS codes for all Medicare preventive services, including bone mass measurements, refer to this MLN Educational Tool website:
https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html

6. a. New Device Pass-Through Category Effective October 1, 2022

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. In addition, 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.

For the October 2022 update, we approved a new device for pass-through status under the OPPS. Consequently, we are establishing a new device category, specifically, HCPCS code C1834 (Pressure sensor system, includes all components (e.g., introducer, sensor), intramuscular (implantable), excludes mobile (wireless) software application), effective October 1, 2022. Refer to Table 4, attachment A, for the long descriptor, status indicator, APC, and offset amount for HCPCS code C1834.

Furthermore, we are including the pass-through expiration dates for several device category codes. Refer to Table 5, attachment A, for the complete list of device category HCPCS Codes and Definitions used for present and previous transitional pass-through payment.

b. Device Offset from Payment for HCPCS Code C1834

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.

(1) Device Offset for HCPCS Code C1834

i. New device category HCPCS code C1834 should always be billed with CPT code 20950 (Monitoring of interstitial fluid pressure (includes insertion of device, eg, wick catheter technique, needle manometer technique) in detection of muscle compartment syndrome), which is assigned to APC 5071 (Level 1 Excision/ Biopsy/ Incision and Drainage) for Calendar Year (CY) 2022. Refer to Table 4, attachment A, for the offset amount.

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 2022 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 provides 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.

7. New Procedure to Assess Coronary Disease Severity Using Computed Tomographic Angiography

In the CY 2021 OPPS/ASC final rule that was published in the Federal Register on December 29, 2020, we assigned CPT code 0625T (*Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography*), which was effective January 1, 2021, to OPPS status indicator "E1" to indicate that the code is not payable by Medicare because the device associated with the code had not received FDA clearance. We note that CPT code 0625T describes the procedure to assess coronary disease severity using computed tomographic angiography.

The device associated with the procedure to assess coronary disease severity using computed tomographic angiography received FDA clearance in October 2020. We are reassigning CPT code 0625T from status indicator “E1” to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and assigning it to APC 1511 (New Technology - Level 11 ($900 - $1000)) effective October 1, 2022. Table 6, attachment A, lists the official long descriptor, status indicator, and APC assignment for CPT code 0625T. The payment rate for CPT code 0625T can be found in Addendum B of the October 2022 OPPS Update that is posted on the CMS website.

8. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting October 1, 2022

Six (6) new certain drugs, biologicals, and radiopharmaceuticals receiving pass-through status HCPCS codes will be established on October 1, 2022. These HCPCS codes are listed in Table 7, attachment A.

There is one (1) new drug, biological, and radiopharmaceutical receiving pass-through status HCPCS code with a status indicator change for October 1, 2022. This code is listed in Table 8, attachment A.

b. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2022

Eleven (11) new drug, biological, and radiopharmaceutical HCPCS codes will be established on October 1, 2022. These HCPCS codes are listed in Table 9, attachment A.

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

For CY 2022, 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). In CY 2022, 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 October 1, 2022, payment rates for many drugs and biologicals have changed from the values published in the CY 2022 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the fourth quarter of CY 2021. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the October 2022 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the October 2022 update of the OPPS. However, the updated payment rates effective October 1, 2022, can be found in the October 2022 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

d. 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.

e. CPT Codes Approved for Smallpox & Monkeypox Immunizations

The CPT Editorial Panel has approved of code 90622 to identify vaccinia (smallpox) virus vaccine product; and addition of code 90611 to identify monkeypox and smallpox virus vaccine product. The new vaccine product codes are described in Table 10, attachment A, along with their OPPS status indictors. The codes, along with their short descriptors and status indicators are also listed in the October 2022 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the CY 2022 OPPS/Ambulatory Surgical Center (ASC) final rule.

9. 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 the per day cost of $949 for CY 2022.

a. Skin Substitute Products with Descriptor Changes as of October 1, 2022

There is one (1) skin substitute HCPCS code with a descriptor change for October 1, 2022. This code is listed in Table 11, attachment A.

b. New Skin Substitute Products as of October 1, 2022

There are five (5) new skin substitute HCPCS codes that will be active as of October 1, 2022. These codes are listed in Table 12, attachment A.

10. Payment Change for Q0222 Injection, Bebtelovimab, 175 mg effective August 15, 2022

CMS is changing how it processes OPPS claims for Eli Lilly's monoclonal antibody treatment, bebtelovimab (Healthcare Common Procedure Coding System (HCPCS) Q0222), to align with the commercial distribution. Effective for OPPS claims with dates of service on or after August 15, 2022, when obtained commercially, CMS began paying, bebtelovimab (HCPCS Q0222) at 95% average wholesale price (AWP).

Effective August 15, 2022, the revised status indicator (SI) assigned to HCPCS Q0222 is "K" [Paid under OPPS; separate APC payment.] The revised APC is 9401.

We note that HCPCS code Q0222 has no associated co-insurance or deductible. Providers who obtained bebtelovimab (HCPCS Q0222) at no cost shall continue to bill with a token charge.

Providers who believe that they were paid improperly for Q0222 may request an adjustment from their MAC.

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	
12885.1	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of the October 2022 OPPS I/OCE.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12885.2	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 content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	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 Laboratory Tests and Service and Other Laboratory Tests Codes

HCPCS Code	Long Descriptor	Add Date	OPPS SI
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	02/04/2020	A
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	02/04/2020	A
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020	A
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020	A
U0005	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (List separately in addition to either HCPCS code U0003 or U0004) as described by CMS-2020-01-R2.	01/01/2021	A
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source	03/01/2020	Q1
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source	03/01/2020	B
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source	03/01/2020	B
86328	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent	04/10/2020	A

HCPCS Code	Long Descriptor	Add Date	OPPS SI
	strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])		
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen	08/10/2020	A
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer	08/10/2020	A
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative	09/08/2020	A
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020	A
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])	06/25/2020	A
87428	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B	11/10/2020	A
87593	Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each	07/26/2022	A
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	03/13/2020	A
87636	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique	10/06/2020	A
87637	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]),	10/06/2020	A

HCPCS Code	Long Descriptor	Add Date	OPPS SI
	influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique		
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	10/06/2020	A
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)	02/21/2022	A
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	05/20/2020	A
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	06/25/2020	A
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed	06/25/2020	A
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	08/10/2020	A
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum	08/10/2020	A
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected	10/06/2020	A

HCPCS Code	Long Descriptor	Add Date	OPPS SI
0241U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected	10/06/2020	A
0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [ha], procollagen iii amino terminal peptide [piiinp], tissue inhibitor of metalloproteinase 1 [timp-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years	04/01/2020	Q4

Table 2. ─ Covid-19 Vaccine Product and Administration CPT Codes

CPT Code	Type	Labeler	Long Descriptor
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
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
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 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
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
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
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
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

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 (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
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 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
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
0053A	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; 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, mRNALNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; booster dose

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
0064A	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, 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
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
0072A	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; 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
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 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
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
0082A	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; 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
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
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
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
0093A	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/0.5mL 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
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/ Immunization Code	Sanofi Pasteur	Immunization administration by intramuscular 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
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
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
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

Table 3. ─ PLA Coding Changes Effective October 1, 2022

CPT Code	Long Descriptor	OPPS SI
0332U	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy	A

0333U	Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in high-risk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gamma-carboxy-prothrombin (DCP), algorithm reported as normal or abnormal result	Q4
0334U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	A
0335U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants	A
0336U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent)	A
0337U	Oncology (plasma cell disorders and myeloma), circulating plasma cell immunologic selection, identification, morphological characterization, and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood	Q4
0338U	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and	Q4

	quantification of HER2 protein biomarker–expressing cells, peripheral blood	
0339U	Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer	A
0340U	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate	A
0341U	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid	A
0342U	Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline	E1
0343U	Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high- risk prostate of cancer	E1
0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH	Q4

0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	A
0346U	Beta amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma	Q4
0347U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes	A
0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes	A
0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis including reported phenotypes and impacted gene-drug interactions	A
0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes	A
0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection	Q4
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis–associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas	Q4

	vaginalis, vaginal-fluid specimen, each result reported as detected or not detected	
0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected	Q4
0354U	Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)	Q4

Table 4. — New Device Pass-Through Code Effective October 1, 2022

HCPCS Code	Long Descriptor	SI	APC	Device Offset Amount(s)
C1834	Pressure sensor system, includes all components (e.g., introducer, sensor), intramuscular (implantable), excludes mobile (wireless) software application	H	2037	• CPT code 20950 $0.00

Table 5. — List of Device Category HCPCS Codes and Definitions Used for Present and Previous Pass-Through Payment ***

	HCPCS Codes	Category Long Descriptor	Date First Populated	Pass-Through Expiration Date***
1.	C1883*	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	8/1/00	12/31/02
2.	C1765*	Adhesion barrier	10/01/00 – 3/31/01; 7/1/01	12/31/03
3.	C1713*	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)	8/1/00	12/31/02
4.	L8690	Auditory osseointegrated device, includes all internal and external components	1/1/07	12/31/08
5.	**C1832**	**Autograft suspension, including cell processing and application, and all system components**	**1/1/22**	**12/31/2024**

6.	C1715	Brachytherapy needle	8/1/00	12/31/02
7.	C1716#	Brachytherapy source, non-stranded, Gold-198, per source	10/1/00	12/31/02
8.	C1717#	Brachytherapy source, non-stranded, high dose rate Iridium-192, per source	1/1/01	12/31/02
9.	C1718#	Brachytherapy source, Iodine 125, per source	8/1/00	12/31/02
10.	C1719#	Brachytherapy source, non-stranded, non-high dose rate Iridium-192, per source	10/1/00	12/31/02
11.	C1720#	Brachytherapy source, Palladium 103, per source	8/1/00	12/31/02
12.	C2616#	Brachytherapy source, non-stranded, Yttrium-90, per source	1/1/01	12/31/02
13.	C2632	Brachytherapy solution, iodine – 125, per mCi	1/1/03	12/31/04
14.	C1721	Cardioverter-defibrillator, dual chamber (implantable)	8/1/00	12/31/02
15.	C1882*	Cardioverter-defibrillator, other than single or dual chamber (implantable)	8/1/00	12/31/02
16.	C1722	Cardioverter-defibrillator, single chamber (implantable)	8/1/00	12/31/02
17.	C1888*	Catheter, ablation, non-cardiac, endovascular (implantable)	7/1/02	12/31/04
18.	C1726*	Catheter, balloon dilatation, non-vascular	8/1/00	12/31/02
19.	C1727*	Catheter, balloon tissue dissector, non-vascular (insertable)	8/1/00	12/31/02
20.	C1728	Catheter, brachytherapy seed administration	1/1/01	12/31/02
21.	C1729*	Catheter, drainage	10/1/00	12/31/02
22.	C1730*	Catheter, electrophysiology, diagnostic, other than 3D mapping (19 or fewer electrodes)	8/1/00	12/31/02
23.	C1731*	Catheter, electrophysiology, diagnostic, other than 3D mapping (20 or more electrodes)	8/1/00	12/31/02
24.	C1732*	Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping	8/1/00	12/31/02
25.	C1733*	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip	8/1/00	12/31/02
26.	C2630*	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip	10/1/00	12/31/02
27.	C1886	Catheter, extravascular tissue ablation, any modality (insertable)	01/01/12	12/31/13
28.	C1887*	Catheter, guiding (may include infusion/perfusion capability)	8/1/00	12/31/02
29.	C1750	Catheter, hemodialysis/peritoneal, long-term	8/1/00	12/31/02
30.	C1752	Catheter, hemodialysis/peritoneal, short-term	8/1/00	12/31/02
31.	C1751	Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)	8/1/00	12/31/02
32.	C1759	Catheter, intracardiac echocardiography	8/1/00	12/31/02

33.	C1754	Catheter, intradiscal	10/1/00	12/31/02
34.	C1755	Catheter, intraspinal	8/1/00	12/31/02
35.	C1753	Catheter, intravascular ultrasound	8/1/00	12/31/02
36.	C2628	Catheter, occlusion	10/1/00	12/31/02
37.	C1756	Catheter, pacing, transesophageal	10/1/00	12/31/02
38.	**C1982**	**Catheter, pressure-generating, one-way valve, intermittently occlusive**	**1/1/20**	**12/31/2022**
39.	C2627	Catheter, suprapubic/cystoscopic	10/1/00	12/31/02
40.	C1757	Catheter, thrombectomy/embolectomy	8/1/00	12/31/02
41.	C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	4/1/15	12/31/17
42.	C1885*	Catheter, transluminal angioplasty, laser	10/1/00	12/31/02
43.	C1725*	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)	8/1/00	12/31/02
44.	C1714	Catheter, transluminal atherectomy, directional	8/1/00	12/31/02
45.	C1724	Catheter, transluminal atherectomy, rotational	8/1/00	12/31/02
46.	**C1761**	**Catheter, transluminal intravascular lithotripsy, coronary**	**7/1/21**	**6/30/2024**
47.	C1760*	Closure device, vascular (implantable/insertable)	8/1/00	12/31/02
48.	L8614	Cochlear implant system	8/1/00	12/31/02
49.	C1762*	Connective tissue, human (includes fascia lata)	8/1/00	12/31/02
50.	C1763*	Connective tissue, non-human (includes synthetic)	10/1/00	12/31/02
51.	C1881	Dialysis access system (implantable)	8/1/00	12/31/02
52.	C1884*	Embolization protective system	1/01/03	12/31/04
53.	C1749	Endoscope, retrograde imaging/illumination colonoscope device (implantable)	10/01/10	12/31/12

54.	**C1748**	**Endoscope, single-use (i.e. disposable), Upper GI, imaging/illumination device (insertable)**	**7/1/20**	**6/30/2023**
55.	C1764	Event recorder, cardiac (implantable)	8/1/00	12/31/02
56.	**C1824**	**Generator, cardiac contractility modulation (implantable)**	**1/1/20**	**12/31/2022**
57.	C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	1/1/16	12/31/17
58.	C1767**	Generator, neurostimulator (implantable), non-rechargeable	8/1/00	12/31/02
59.	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	1/1/06	12/31/07
60.	**C1825**	**Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)**	**1/1/21**	**12/31/2023**
61.	**C1823**	**Generator, neurostimulator (implantable), nonrechargeable , with transvenous sensing and stimulation leads**	**1/1/19**	**12/31/2022^**
62.	C1768	Graft, vascular	1/1/01	12/31/02
63.	C1769	Guide wire	8/1/00	12/31/02
64.	**C1052**	**Hemostatic agent, gastrointestinal, topical**	**1/1/21**	**12/31/2023**
65.	C1770	Imaging coil, magnetic resonance (insertable)	1/1/01	12/31/02
66.	C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components	1/1/15	12/31/16
67.	C1891	Infusion pump, non-programmable, permanent (implantable)	8/1/00	12/31/02
68.	C2626*	Infusion pump, non-programmable, temporary (implantable)	1/1/01	12/31/02
69.	C1772	Infusion pump, programmable (implantable)	10/1/00	12/31/02
70.	C1818*	Integrated keratoprosthesis	7/1/03	12/31/05
71.	C1821	Interspinous process distraction device (implantable)	1/1/07	12/31/08
72.	**C1062**	**Intravertebral body fracture augmentation with implant (e.g., metal, polymer)**	**1/1/21**	**12/31/2023**
73.	C1893	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, other than peel-away	10/1/00	12/31/02
74.	C1892*	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, peel-away	1/1/01	12/31/02
75.	C1766	Introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away	1/1/01	12/31/02
76.	C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	8/1/00	12/31/02
77.	C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	1/1/01	12/31/02
78.	**C1839**	**Iris prosthesis**	**1/1/20**	**12/31/2022**
79.	C1776*	Joint device (implantable)	10/1/00	12/31/02

80.	C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)	8/1/00	12/31/02
81.	C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)	8/1/00	12/31/02
82.	C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)	8/1/00	12/31/02
83.	C1900*	Lead, left ventricular coronary venous system	7/1/02	12/31/04
84.	C1778	Lead, neurostimulator (implantable)	8/1/00	12/31/02
85.	C1897	Lead, neurostimulator test kit (implantable)	8/1/00	12/31/02
86.	C1898	Lead, pacemaker, other than transvenous VDD single pass	8/1/00	12/31/02
87.	C1779*	Lead, pacemaker, transvenous VDD single pass	8/1/00	12/31/02
88.	C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)	1/1/01	12/31/02
89.	C1780*	Lens, intraocular (new technology)	8/1/00	12/31/02
90.	C1840	Lens, intraocular (telescopic)	10/01/11	12/31/13
91.	C2613	Lung biopsy plug with delivery system	7/1/15	12/31/17
92.	C1878*	Material for vocal cord medialization, synthetic (implantable)	10/1/00	12/31/02
93.	C1781*	Mesh (implantable)	8/1/00	12/31/02
94.	**C1833**	**Monitor, cardiac, including intracardiac lead and all system components (implantable)**	**1/1/22**	**12/31/2024**
95.	C1782*	Morcellator	8/1/00	12/31/02
96.	C1784*	Ocular device, intraoperative, detached retina	1/1/01	12/31/02
97.	C1783	Ocular implant, aqueous drainage assist device	7/1/02	12/31/04
98.	**C1734**	**Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)**	**1/1/20**	**12/31/2022**
99.	C2619	Pacemaker, dual chamber, non rate-responsive (implantable)	8/1/00	12/31/02
100.	C1785	Pacemaker, dual chamber, rate-responsive (implantable)	8/1/00	12/31/02
101.	C2621*	Pacemaker, other than single or dual chamber (implantable)	1/1/01	12/31/02
102.	C2620	Pacemaker, single chamber, non rate-responsive (implantable)	8/1/00	12/31/02
103.	C1786	Pacemaker, single chamber, rate-responsive (implantable)	8/1/00	12/31/02
104.	C1787*	Patient programmer, neurostimulator	8/1/00	12/31/02
105.	**C1831**	**Personalized, anterior and lateral interbody cage (implantable)**	**10/1/21**	
106.	C1788	Port, indwelling (implantable)	8/1/00	12/31/02
107.	C1830	Powered bone marrow biopsy needle	10/01/11	12/31/13
108.	C2618	Probe, cryoablation	4/1/01	12/31/03
109.	**C2596**	**Probe, image-guided, robotic, waterjet ablation**	**1/1/20**	**12/31/2022**
110.	C2614	Probe, percutaneous lumbar discectomy	1/1/03	12/31/04

111.	C1789	Prosthesis, breast (implantable)	10/1/00	12/31/02
112.	C1813	Prosthesis, penile, inflatable	8/1/00	12/31/02
113.	C2622	Prosthesis, penile, non-inflatable	10/1/01	12/31/02
114.	C1815	Prosthesis, urinary sphincter (implantable)	10/1/00	12/31/02
115.	C1816	Receiver and/or transmitter, neurostimulator (implantable)	8/1/00	12/31/02
116.	C1771*	Repair device, urinary, incontinence, with sling graft	10/1/00	12/31/02
117.	C2631*	Repair device, urinary, incontinence, without sling graft	8/1/00	12/31/02
118.	C1841	Retinal prosthesis, includes all internal and external components	10/1/13	12/31/15
119.	C1814*	Retinal tamponade device, silicone oil	4/1/03	12/31/05
120.	C1773*	Retrieval device, insertable	1/1/01	12/31/02
121.	C2615*	Sealant, pulmonary, liquid (implantable)	1/1/01	12/31/02
122.	C1817*	Septal defect implant system, intracardiac	8/1/00	12/31/02
123.	C1874*	Stent, coated/covered, with delivery system	8/1/00	12/31/02
124.	C1875*	Stent, coated/covered, without delivery system	8/1/00	12/31/02
125.	C1876*	Stent, non-coated/non-covered, with delivery system	8/1/00	12/31/02
126.	C1877	Stent, non-coated/non-covered, without delivery system	8/1/00	12/31/02
127.	C2625*	Stent, non-coronary, temporary, with delivery system	10/1/00	12/31/02
128.	C2617*	Stent, non-coronary, temporary, without delivery system	10/1/00	12/31/02
129.	C1819	Tissue localization excision device	1/1/04	12/31/05
130.	C1879*	Tissue marker (implantable)	8/1/00	12/31/02
131.	C1880	Vena cava filter	1/1/01	12/31/02

BOLD codes are still actively receiving pass-through payment.

Italicized codes have received preliminary approval for pass-through payment.

*** Refer to the definition below for further information on this device category code.**

**** Effective 1/1/06 C1767 descriptor was changed for succeeding claims. See CR 4250, Jan. 3, 2006 for details.**

***** Although the pass-through payment status for device category codes has expired, these codes are still active and hospitals are still required to report the device category C-codes (except the brachytherapy source codes, which are separately paid under the OPPS) on claims when such devices are used in conjunction with procedures billed and paid under the OPPS.**

 # The brachytherapy descriptors were changed to the ones shown above, effective 7/1/07. These 6 brachytherapy source codes were paid as pass-through devices from 2000 through 2002, as noted. Beginning in 2004, all brachytherapy sources have been paid separately as non-pass-through items from the procedure with which they are billed, and additional brachytherapy source HCPCS codes have been added for payment. To see the most current comprehensive list of brachytherapy source codes, see the latest OPPS/ASC final rule.

^We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 for C1823 whose pass-through payment status expired on December 31, 2021. Adjusted separate payment for HCPCS code C1823 will end on December 31, 2022.

Table 6. — SI/APC Reassignment for CPT Code 0625T Effective October 1, 2022

CPT Code	Long Descriptor	SI	APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

Table 7. ─ Newly Established HCPCS Codes for Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting October 1, 2022

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
C9142	N/A	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048
C9101	N/A	Injection, oliceridine, 0.1 mg	G	9049
A9602	N/A	Fluorodopa f-18, diagnostic, per millicurie	G	9053
A9607	N/A	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054
A9800	N/A	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055
J9298	N/A	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057

Table 8. ─ Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status with Status Indicator Change Starting October 1, 2022

Current HCPCS Code	Long Descriptor	Old SI	New SI	APC
J1952	Leuprolide injectable, camcevi, 1 mg	E2	G	9050

Table 9. ─ Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2022

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
J1302	C9094	Injection, sutimlimab-jome, 10 mg	G	9444
J2777	C9097	Injection, faricimab-svoa, 0.1 mg	G	9496
J9274	C9095	Injection, tebentafusp-tebn, 1 microgram	G	9446
Q2056	C9098	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498
Q5125	C9096	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447
C9142	N/A	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048
C9101	N/A	Injection, oliceridine, 0.1 mg	G	9049
J1932	N/A	Injection, lanreotide, (cipla), 1 mg	K	9051
A9602	N/A	Fluorodopa f-18, diagnostic, per millicurie	G	9053
A9607	N/A	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054
A9800	N/A	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055
J9298	N/A	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057

Table 10. ─ CPT Codes Approved for Smallpox & Monkeypox Immunizations

CPT Code	Long Descriptor	Add Date	OPPS SI	OPPS APC
90611	Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use	07/26/2022	K	9068
90622	Vaccinia (smallpox) virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use	07/26/2022	K	9101

Table 11. ─ Skin Substitute Products with Descriptor Changes as of October 1, 2022

CY 2022 HCPCS Code	July 2022 Long Descriptor	October 2022 Long Descriptor
Q4128	Flex hd, allopatch hd, or matrix hd, per square centimeter	Flex hd, or allopatch hd, per square centimeter

Table 12. ─ New Skin Substitute Products as of October 1, 2022

CY 2022	Short Descriptor	CY 2022 SI	Low/High Cost Skin Substitute

HCPCS Code			
A2014	Omeza collag per 100 mg	N	N/A
A2015	Phoenix wnd mtrx, per sq cm	N	Low
A2016	Permeaderm b, per sq cm	N	Low
A2017	Permeaderm glove, each	N	Low
A2018	Permeaderm c, per sq cm	N	Low