CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11305	**Date: March 24, 2022**
	Change Request 12666

SUBJECT: April 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2022 OPPS update. The April 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 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).

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

EFFECTIVE DATE: April 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 4, 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
R	4/61.1/Requirement that Hospitals Report Device Codes on Claims on Which They Report Specified Procedures

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: 11305	Date: March 24, 2022	Change Request: 12666

SUBJECT: April 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: April 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 4, 2022

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2022 OPPS update. The April 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 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).

The April 2022 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2022 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 and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) for each coronavirus vaccine as well as administration codes unique to each vaccine and dose. These codes are effective upon receiving Emergency Use Authorization (EUA) or approval from the Food and Drug Administration (FDA).

On September 3, 2021, the AMA released new CPT Category I codes for reporting SARS-CoV-2 vaccines and their administration: a new code describing a new tris-sucrose formulation of the Pfizer BioNTech COVID-19 vaccine (91305) and an affiliated set of codes that describe the services to administer the first dose, second dose, third dose and booster dose (0051A, 0052A, 0053A, 0054A, respectively).

The FDA authorized the tris-sucrose formulation of the Pfizer BioNTech COVID-19 vaccine on October 29, 2021. The effective date has been revised to January 3, 2022. CMS identifies an effective date of January 3, 2022, for this formulation and its administration. This effective date corresponds with when the product was first made available to Medicare providers and suppliers. Therefore, vaccine product HCPCS code 91305 and administration HCPCS codes 0051A, 0052A, 0053A and 0054A are effective on January 3, 2022.

Effective January 3, 2022, CPT code 91305 is assigned to status indicator “L” (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the April 2022 I/OCE.

Effective January 3, 2022, CPT code 0051A is assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 9397 (Covid-19 Vaccine Admin Dose 1 of 2) in the April 2022 I/OCE.

Effective January 3, 2022, CPT codes 0052A, 0053A and 0054A are assigned to status indicator “S”, APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the April 2022 I/OCE.

On January 12, 2022, the AMA released new CPT Category I code which describes the service to administer the third pediatric dose of Pfizer BioNTech's COVID-19 vaccine.

CMS identifies an effective date of January 3, 2022, for CPT code 0073A. This effective date corresponds with updates to FDA EUAs and/or approvals.

Therefore, effective January 3, 2022, CPT code 0073A is assigned to status indicator "S" and APC 9398 in the April 2022 I/OCE.

On February 1, 2022, the AMA released new CPT Category I codes to report immunization administration for Pfizer First and Second Dose SARS-CoV-2 vaccine for pediatric patients ages 6 months through up to 5 years of age (0081A and 0082A) and the new Pfizer pediatric vaccine product (91308). These codes will be available for use once the vaccine receives EUA or approval from the FDA.

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 April 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.

2. Changes for COVID-19 Monoclonal Antibody Therapy Product and Administration Codes

a. New COVID-19 Monoclonal Antibody Product Code and Administration Codes for EVUSHELD™ (Tixagevimab Co-packaged with Cilgavimab)

On December 8, 2021 (and updated on December 10, 2021), the Food and Drug Administration (FDA) released an Emergency Use Authorization (EUA) "… for the emergency use of EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in certain adults and pediatric individuals."

In response to the COVID-19 Public Health Emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) is creating new Healthcare Common Procedure Coding System (HCPCS) Level II codes for EVUSHELD™ and its affiliated injections. That is, EVUSHELD™ is to be administered as two separate consecutive intramuscular injections (one injection per monoclonal antibody, given in immediate succession).

These HCPCS codes are: Q0220, M0220 and M0221. The codes, along with their long descriptors, are identified in Table 2, attachment A.

The HCPCS code describing EVUSHELD™ (tixagevimab co-packaged with cilgavimab), is Q0220. It is assigned to status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) effective December 8, 2021, in the April 2022 I/OCE.

The HCPCS code describing the service to administer EVUSHELD™ in healthcare settings is M0220. It is assigned to status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 1503 (New Technology - Level 3 ($101 - $200)) effective December 8, 2021, in the April 2022 I/OCE.

The HCPCS code describing the service to administer EVUSHELD™ in the home is M0221. It is assigned to status indicator "S", APC 1504 (New Technology - Level 4 ($201 - $300)) effective December 8, 2021, in the April 2022 I/OCE.

The COVID-19 monoclonal antibody product and administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the April 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.

For more information on payment and coverage of COVID-19 Monoclonal Antibodies under Medicare during the Public Health Emergency, refer to the following CMS websites:

https://www.cms.gov/monoclonal

https://www.cms.gov/monoclonal#Payment

b. Revisions to EVUSHELD™ Dosing

On February 24, 2022 the Food and Drug Administration (FDA) released a revised Emergency Use Authorization (EUA) for AstraZeneca's EVUSHELD™ (tixagevimab co-packaged with cilgavimab). With this EUA revision, FDA has increased the initial authorized dose to 300 mg of tixagevimab and 300 mg of cilgavimab. Additionally, FDA stated that patients who have already received the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise their monoclonal antibody levels to those expected for patients receiving the higher dose.

In response to the COVID-19 Public Health Emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) is creating a new Healthcare Common Procedure Coding System (HCPCS) Level II code (Q0221) that reflects an updated dosing regime for EVUSHELDTM that was authorized by the FDA in the February 24, 2022 EUA.

The HCPCS code describing the dose of 300 mg of tixagevimab and 300 mg of cilgavimab for EVUSHELD™ is Q0221 and it is assigned to status indicator "L" effective February 24, 2022, in the April 2022 I/OCE.

The code along with its long descriptor, is identified in Table 2, attachment A.

The COVID-19 monoclonal antibody product and administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the April 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.

For more information on payment and coverage of COVID-19 Monoclonal Antibodies under Medicare during the Public Health Emergency, refer to the following CMS websites:

https://www.cms.gov/monoclonal

https://www.cms.gov/monoclonal#Payment

c. New COVID-19 Monoclonal Antibody Therapy Product Code and Administration Codes for Bebtelovimab

On February 11, 2022 the Food and Drug Administration (FDA) released an Emergency Use Authorization (EUA) "… for the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients.

In response to the COVID-19 Public Health Emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) is creating new Healthcare Common Procedure Coding System (HCPCS) Level II codes for bebtelovimab and its affiliated administration. That is, bebtelovimab is to be administered as a single intravenous injection over at least 30 seconds.

These HCPCS codes are: Q0222, M0222 and M0223. The codes, along with their long descriptors, are identified in Table 2, attachment A.

The HCPCS code describing bebtelovimab, is Q0222. It is assigned to status indicator "L" effective February 11, 2022 in the April 2022 I/OCE.

The HCPCS code describing the service to administer bebtelovimab in healthcare settings is M0222 and it is assigned to status indicator "S", APC 1505, (New Technology - Level 5 ($301 - $400)), effective February 11, 2022 in the April 2022 I/OCE.

The HCPCS code describing the service to administer bebtelovimab in the home is M0223 and it is assigned to status indicator "S", APC 1507 (New Technology - Level 7 ($501 - $600)) effective February 11, 2022 in the April 2022 I/OCE.

The COVID-19 monoclonal antibody product and administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the April 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.

For more information on payment and coverage of COVID-19 Monoclonal Antibodies under Medicare during the Public Health Emergency, refer to the following CMS websites:

https://www.cms.gov/monoclonal

https://www.cms.gov/monoclonal#Payment

3. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective April 1, 2022

The AMA CPT Editorial Panel established 17 new PLA codes, specifically, CPT codes 0306U through 0322U, effective April 1, 2022.

Table 3, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the April 2022 I/OCE with an effective date of April 1, 2022. In addition, the codes, along with their short descriptor and status indicators, are listed in the April 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.

4. Device Offset from Payment for HCPCS Codes C1748

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.

In the January 2021 OPPS quarterly update CR (Transmittal 10541, Change Request 12120, dated December 31, 2020), we listed the procedure codes reportable with device category HCPCS code C1748 (Endoscope, single-use (i.e. disposable), Upper GI, imaging/illumination device (insertable)). The long descriptors for the codes were listed in the same transmittal. We note that we specified the device offset amounts for the procedure codes associated with HCPCS code C1748. That is, we stated that CPT codes 43260 through 43265 and CPT codes 43274, 43276 through 43278 have an offset amount of $0.00.

Effective April 1, 2022, we are updating the list of procedure codes associated with HCPCS code C1748. Specifically, the device described by device category HCPCS code C1748 may also be billed with one of the following CPT codes: 0652T, 0653T, 0654T, 43197, and 43198. The long descriptors for the CPT codes are

listed below. The offset amounts for the CPT codes can be found in Table 3. We note that the codes are assigned to APC 5301 (Level 1 Upper GI Procedures) and APC 5302 (Level 2 Upper GI Procedures).

- CPT code 0652T - Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
- CPT code 0653T - Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple
- CPT code 0654T - Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter
- CPT code 43197 - Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
- CPT code 43198 - Esophagoscopy, flexible, transnasal; with biopsy, single or multiple

5. New HCPCS Code Describing the InSpace Subacromial Tissue Spacer System Procedure

CMS is establishing a new HCPCS code, C9781, to describe the implantation of a saline-filled balloon for the shoulder to treat irreparably torn rotator cuff tendons. Table 5, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9781. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2021 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 April 2022 Update of the OPPS Addendum B.

6. Medical Procedures Effective April 1, 2022, New HCPCS codes C9782 and C9783

Table 6, attachment A, describes new separately payable procedure codes for medical procedures that are effective April 1, 2022.

7. Status Indicator and APC Corrections for CPT codes 66989 and 66991 Effective January 1, 2022

In the CY 2022 OPPS/ASC final rule that was published in the Federal Register on November 16, 2021, we inadvertently assigned CPT codes 66989 and 66991 to APC 1526 (New Technology - Level 26 ($4001-$4500)) with status indicator "S" (86 FR 63544). We corrected these errors in the 2022 Correction Notice (87 FR 2058) that was published in the Federal Register on January 13, 2022, but it was too late to include these corrections in the January 2022 I/OCE Update, and therefore, we are including them in the April 2022 I/OCE Update, by re-assigning CPT codes 66989 and 66991 to APC 1563 (New Technology - Level 26 ($4001-$4500)) with status indicator "T" (Procedure or Service, Multiple Procedure Reduction Applies. Paid under OPPS; separate APC payment) retroactive to January 1, 2022. Table 7, attachment A lists long descriptors, status indicator, APC, and APC title for these codes. The payment rates for these codes can be found in Addendum B of the April 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 April 1, 2022

Five (5) 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 April 1, 2022. These drugs and biologicals will receive drug pass-through status starting April 1, 2022. These HCPCS codes are listed in Table 8, attachment A.

b. Existing CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting April 1, 2022

Three (3) drugs and biologicals with existing HCPCS codes will receive drug pass-through status starting April 1, 2022. These HCPCS codes are listed in Table 9, attachment A.

c. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of April 1, 2022

Twelve (12) new drug, biological, and radiopharmaceutical HCPCS codes will be established on April 1, 2022. These HCPCS codes are listed in Table 10, attachment A.

d. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals Deleted retroactive to January 1, 2022

In the CY 2022 OPPS/ASC final rule Addendum B that was published on the CMS website on November 1, 2021, we inadvertently assigned new HCPCS code A2003 (Bio-connekt wound matrix, per square centimeter) to status indicator ''A''. Since this code was created in error, we deleted this code through the 2022 Correction Notice (87 FR 2060) that was published in the Federal Register on January 13, 2022, but it was too late to include this correction in the January 2022 I/OCE Update, and therefore, we are including it in the April 2022 I/OCE Update. HCPCS code A2003 is deleted retroactive to January 1, 2022 in April 2022 I/OCE Update. HCPCS code A2003 is listed in Table 11, attachment A.

e. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals Deleted Retroactive to February 28, 2022

HCPCS code M1145 (Most favored nation (mfn) model drug add-on amount, per dose, (do not bill with line items that have the jw modifier)) will be deleted retroactive to February 28, 2022 in April 2022 I/OCE Update. HCPCS code M1145 is listed in Table 12, attachment A.

f. Rabies Vaccine that Will Retroactively Change from Non-Payable Status to Payable Status Effective January 1, 2021

The status indicator for CPT code 90377 (Rabies immune globulin, heat- and solvent/detergent-treated (right s/d), human, for intramuscular and/or subcutaneous use) effective January 1, 2021, will be changed retroactively from status indicator = "E2" to status indicator = "K" in the April 2022 I/OCE Update. This vaccine is reported in Table 13, attachment A.

g. Hepatitis-B Vaccine that Is Retroactively Is Payable at Reasonable Cost Effective January 11, 2022

CPT code 90759 (Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule, for intramuscular use) is retroactively payable at reasonable cost (SI = F) effective January 11, 2022 in the April 2022 I/OCE Update. This vaccine is reported in Table 14, attachment A.

h. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Is Separately Payable Retroactively Effective December 23, 2021 until March 31, 2022 in the April I/OCE

HCPCS code J0248 (Injection, remdesivir, 1 mg) will be separately payable with SI=K, retroactive to December 23, 2021 until March 31, 2022 in the April 2022 I/OCE Update. HCPCS code J0248 is reported in Table 15, attachment A.

i. Update on the Payment Rate for HCPCS code J3399

HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes) is a separately paid drug under the OPPS with a payment rate of the drug's Average Sales Price (ASP) plus 6 percent. Due to technical reasons, HCPCS code J3399 is assigned to status indicator = "A" which allows MACs to manually pay claims appropriately reporting the drug at the ASP plus 6 percent rate.

j. 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 plus 6 percent (or ASP plus 6 percent of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP minus 22.5 percent (or ASP minus 22.5 percent of the biosimilar's ASP if a biosimilar is acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical. In CY 2022, a single payment of ASP plus 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 plus 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 April 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 third quarter of CY 2021. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the April 2022 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the April 2022 update of the OPPS. However, the updated payment rates effective April 1, 2022, can be found in the April 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

k. 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.

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. New Skin Substitute Products as of April 1, 2022

There are nine (9) new skin substitute HCPCS codes that will be active as of April 1, 2022. These codes are listed in Table 16, attachment A.

b. Skin Substitute Products Reassigned to the High Cost Skin Substitute Group as of April 1, 2022

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 April 1, 2022. The code is listed in Table 17, attachment A.

c. Skin Substitute Products with Individual HCPCS Codes Reassigned to Be Payable and Packaged as of April 1, 2022

There are nine (9) skin substitute products assign HCPCS codes in the range of A2001 through A2010 that have a status indicator = "A" (Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS.) that will be reassigned to status indicator = "N" (Paid under OPPS; payment is packaged into payment for other services.) as of April 1, 2022. Since these codes are now payable in the OPPS, they have been assigned to either the high cost or low cost skin substitute group as of April 1, 2022. The codes are listed in Table 18, attachment A.

10. Blood Products

a. New Blood Product Effective April 1, 2022 in the April I/OCE

There is one (1) new blood product HCPCS code effective April 1, 2022 in the April I/OCE. It will be assigned to SI=R (Blood and Blood products. Separate APC payment under OPPS). The code is listed in Table 19, attachment A.

b. Retroactive Payment of a Blood Product HCPCS Code Effective December 28, 2021 until March 31, 2022 in the April I/OCE

HCPCS code C9507 (Plasma, high titer COVID-19 convalescent, each unit) will be separately payable with SI=S retroactive to December 28, 2021 until March 31, 2022 in the April 2022 I/OCE Update. HCPCS code C9507 is reported in Table 20, attachment A.

11. Billing for Devices Under OPPS

We are revising Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, section 61.1, to provide clarification to hospitals for reporting devices that are not described by a specific HCPCS code.

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 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	
12666.1	Medicare contractors shall install the April 2022 OPPS Pricer.	X		X		X				
12666.2	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of	X		X						

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	the April 2022 OPPS Pricer.									
12666.3	Medicare contractors shall reprocess claims with the HCPCS codes 66989 and 66991, with the dates of service January 1, 2022 through March 31, 2022.	X		X						
12666.4	Medicare contractors shall manually apply Reason Code W7013 to Type of Bill (TOB) 012x, and 013x claim lines with HCPCS J0879, until the status indicator is updated in the July 2022 IOCE quarter release. The current version of the IOCE could not be corrected to match addendum B prior to the April 2022 installation.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12666.5	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 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

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

Table 2. ─ COVID-19 Monoclonal Antibody Therapy Products and Administration Codes

CPT Code	Type	Long Descriptor
M0220	Administration/Injection Code	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post

		administration monitoring
M0221	Administration/Injection Code	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency
Q0220	Product Code	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg
Q0221	Product Code	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 600 mg
M0222	Administration/Injection Code	Intravenous injection, bebtelovimab, includes injection and post administration monitoring
M0223	Administration/ Injection Code	Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency
Q0222	Product Code	Long descriptor: Injection, bebtelovimab, 175 mg
M0240	Administration/	Intravenous infusion or subcutaneous injection,

	Infusion Code	casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses
M0241	Administration/ Infusion Code	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency, subsequent repeat doses
M0243	Administration/ Infusion Code	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring
M0244	Administration/ Infusion Code	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency
Q0240	Product Code	Injection, casirivimab and imdevimab, 600 mg
Q0243	Product Code	Injection, casirivimab and imdevimab, 2400 mg
Q0244	Product Code	Injection, casirivimab and imdevimab, 1200 mg
M0245	Administration/ Infusion Code	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring
M0246	Administration/ Infusion Code	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid 19 public health emergency
Q0245	Product Code	Injection, bamlanivimab and etesevimab, 2100 mg
M0247	Administration/ Infusion Code	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
M0248	Administration/ Infusion Code	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency.
Q0247	Product Code	Injection, sotrovimab, 500 mg
M0249	Administration/ Infusion Code	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic

		corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose
M0250	Administration/ Infusion Code	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose
Q0249	Product Code	Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg

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

CPT Code	Long Descriptor	OPPS SI
0306U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for MRD	A
0307U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD	A
0308U	Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for obstructive CAD	Q4
0309U	Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event	Q4

0310U	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD	Q4
0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)–based antimicrobial susceptibility for each organisms identified	Q4
0312U	Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment	Q4
0313U	Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)	A
0314U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)	A
0315U	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B)	A
0316U	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine	Q4
0317U	Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer	A

0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood	A
0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection	A
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection	A
0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique	Q4
0322U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma, results reported as negative or positive for risk of metabolic subtypes associated with ASD	Q4

Table 4. — Device Offset Amounts for the CPT Procedure Codes Associated with HCPCS Code C1748 Effective April 1, 2022

HCPCS Code	Long Descriptor	SI	APC	Device Offset Codes
C1748	Endoscope, single-use (i.e. disposable), Upper GI, imaging/illumination device (insertable)	H	2029	• CPT code 0652T - $0.00 • CPT code 0653T - $0.00 • CPT code 0654T - $0.00 • CPT code 43197 - $0.00 • CPT code 43198 - $0.00 • CPT code 43260 - $0.00 • CPT code 43261 - $0.00 • CPT code 43263 - $0.00 • CPT code 43264 - $0.00 • CPT code 43265 - $0.00 • CPT code 43274 - $0.00 • CPT code 43276 - $0.00 • CPT code 43277 - $0.00 • CPT code 43278 - $0.00

Table 5. ─ New HCPCS Code Describing the Endoscopic Submucosal Dissection (ESD) Procedure Effective April 1, 2022

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9781	Arthro/shoul surg; w/spacer	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed	J1	5114

Table 6. – New Separately Payable Procedure Codes for Medical Procedures Effective April 1, 2022

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9782	Blind myocar trpl bon marrow	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), performed in an approved Investigational Device Exemption (IDE) study	T	1574
C9783	Blind cor sinus reducer impl	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and	J1	5193

		interpretation when performed in an approved Investigational Device Exemption (IDE) study		

Table 7. – Status Indicator and APC Corrections for CPT codes 66989 and 66991 Effective January 1, 2022

CPT Code	Long Descriptor	SI	APC	APC Title
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more))	T	1563	New Technology - Level 26 ($4001-$4500)
66991	(Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more))	T	1563	New Technology - Level 26 ($4001-$4500)

Table 8. – New CY 2022 HCPCS Codes Effective April 1, 2022 for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

CY 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 SI	CY 2022 APC
C9090	Injection, plasminogen, human-tvmh, 1 mg	G	9206

CY 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 SI	CY 2022 APC
C9091	Injection, sirolimus protein-bound particles, 1 mg	G	9241
C9092	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358
C9093	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439
J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204

Table 9. ─ Existing CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting April 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor	Jan 2022 SI	April 2022 SI	April 2022 APC
C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	N	G	9440
J0248	Injection, remdesivir, 1 mg	K	G	9200
J9304	Injection, pemetrexed (pemfexy), 10 mg	E2	G	9442

Table 10. ─ Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of April 1, 2022

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
C9090	N/A	Injection, plasminogen, human-tvmh, 1 mg	G	9206
C9091	N/A	Injection, sirolimus protein-bound particles, 1 mg	G	9241
C9092	N/A	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358
C9093	N/A	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439
J0219	C9085	Injection, avalglucosidase alfa-ngpt, 4 mg	G	9433
J0248	N/A	Injection, remdesivir, 1 mg	G	9200
J0491	C9086	Injection, anifrolumab-fnia, 1 mg	G	9434
J0879	N/A	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	E2	N/A
J9071	C9087	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203
J9273	N/A	Injection, tisotumab vedotin-tftv, 1 mg	G	9204

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
J9359	C9084	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205
Q5124	N/A	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	E2	N/A

Table 11. – HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted Retroactive to January 1, 2022

CY 2022 HCPCS Code	Long Descriptor	CY 2021 SI	APC
A2003	Bio-connekt wound matrix, per square centimeter	A	N/A

Table 12. – HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted Retroactive to February 28, 2022

CY 2022 HCPCS Code	Long Descriptor	CY 2021 SI	APC
M1145	Most favored nation (mfn) model drug add-on amount, per dose, (do not bill with line items that have the jw modifier)	E1	N/A

Table 13. – Rabies Vaccine that Will Retroactively Change from Non-Payable Status to Payable Status Effective January 1, 2021.

HCPCS Code	Long Descriptor	Old SI	New SI	New APC	Effective Date
90377	Rabies immune globulin, heat- and solvent/detergent-treated (rig-ht s/d), human, for intramuscular and/or subcutaneous use	E2	K	9201	01/01/2021

Table 14. – Hepatitis-B Vaccine that Is Retroactively Payable at Reasonable Cost Effective January 11, 2022.

HCPCS Code	Long Descriptor	New SI	New APC	Effective Date

90759	Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule, for intramuscular use	F	N/A	01/11/2022

Table 15. – HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Is Separately Payable Retroactively Effective December 23, 2021 until March 31, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor	New SI	New APC	Effective Date
J0248	Injection, remdesivir, 1 mg	K	9200	12/23/2021-03/31/22

Table 16. – New Skin Substitute Products Low Cost Group/High Cost Group Assignment Effective April 1, 2022

CY 2022 HCPCS Code	Short Descriptor	CY 2022 SI	Low/High Cost Skin Substitute
A2011	Supra sdrm, per sq cm	N	Low
A2012	Suprathel, per sq cm	N	Low
A2013	Innovamatrix fs, per sq cm	N	Low
A4100	Skin sub fda clrd as dev nos	N	Low
Q4224	Hhf10-p per sq cm	N	Low
Q4225	Amniobind, per sq cm	N	Low
Q4256	Mlg complet, per sq cm	N	Low
Q4257	Relese, per sq cm	N	Low
Q4258	Enverse, per sq cm	N	Low

Table 17. – Skin Substitute Products Reassigned to the High Cost Skin Substitute Group as of April 1, 2022

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2022 SI	Old Low/High Cost Skin Substitute Group	April 2022 Low/High Cost Skin Substitute Group
Q4199	Cygnus matrix, per sq cm	N	Low	High

Table 18. – Skin Substitute Products with Individual HCPCS Codes Reassigned to Be Payable and Packaged as of April 1, 2022

CY 2022 HCPCS Code	CY 2022 Short Descriptor	Jan CY 2022 SI	April CY 2022 SI	Low/High Cost Skin Substitute Group
A2001	Innovamatrix ac, per sq cm	A	N	Low
A2002	Mirragen adv wnd mat per sq	A	N	Low
A2004	Xcellistem, per sq cm	A	N	Low
A2005	Microlyte matrix, per sq cm	A	N	Low
A2006	Novosorb synpath per sq cm	A	N	Low
A2007	Restrata, per sq cm	A	N	High
A2008	Theragenesis, per sq cm	A	N	Low
A2009	Symphony, per sq cm	A	N	Low
A2010	Apis, per square centimeter	A	N	Low

Table 19. ─ New Blood Products Effective April 1, 2022 in the April I/OCE

CY 2022 HCPCS Code	Long Descriptor	SI	APC	Payment Rate
C9507	Plasma, high titer COVID-19 convalescent, each unit	R	9540	$750.50

Table 20. ─ Retroactive Payment of a Blood Product HCPCS Code Effective December 28, 2021 until March 31, 2022 in the April I/OCE

CY 2022 HCPCS Code	Long Descriptor	SI	APC	Payment Rate	Effective Date
C9507	Plasma, high titer COVID-19 convalescent, each unit	S	1509	$750.50	12/28/2021-03/31/22

61.1 - Requirement that Hospitals Report Device Codes on Claims on Which They Report Specified Procedures

(Rev. 11305; Issued: 03-24-22; Effective: 04-01-22; Implementation: 04-04-22)

Effective January 1, 2005, hospitals paid under the OPPS (bill types 12X and 13X) that report procedure codes that require the use of devices must also report the applicable HCPCS codes and charges for all devices that are used to perform the procedures where such codes exist and are designated with a status indicator of "N" (for packaged payment) or "H" (for pass-through device payment) in the OPPS Addendum B that applies to the date of service. If there are device HCPCS codes with status indicators other than "N" or "H" that describe devices that are used to perform the procedure or that are furnished because they are necessary for the function of an implanted device, hospitals should report the charges for those other devices on an uncoded revenue code line, but should not report the HCPCS codes for those items. Typically, payment for the costs of all internal and external components required for the function of a nonpass-through device is packaged into the APC payment for the associated procedure in which the device is used. Accurate reporting of HCPCS codes and charges for these internal and external device components is necessary so that the OPPS payment for the associated procedures will be correct in future years in which the claims are used to set the APC payment rates.

For procedure codes that require the use of devices that are not described by a specific HCPCS code, hospitals should report HCPCS code C1889 (Implantable/insertable device, not otherwise classified) and charges for all devices that are used to perform the procedures. Such devices must:

- *Have received FDA marketing authorization, have received an FDA investigational device exemption (IDE) and have been classified as a Category B device by FDA in accordance with 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;*
- *Be an integral part of the service furnished;*
- *Be used for one patient only;*
- *Come in contact with human tissue;*
- *Be surgically implanted or inserted (either permanently or temporarily); and*
- *Not be either of the following:*

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

(b) A material or supply furnished to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Manufacturers frequently package a number of individual items used with a device in a particular procedure. In cases of devices that are described by device category HCPCS codes whose pass-through status has expired, or HCPCS codes that describe devices without pass-through status, and that are packaged in kits with other items used in a particular procedure, hospitals may consider all kit costs in their line-item charge for the associated device/device category HCPCS code that is assigned status indicator "N" for packaged payment. That is, hospitals may report the total charge for the whole kit with the associated device/device category HCPCS code. Payment for device/device category HCPCS codes without pass-through status is packaged into payment for the procedures in which they are used, and these codes are assigned status indicator "N." In the case of a device kit, should a hospital choose to report the device charge alone under a device/device category HCPCS code with SI="N," the hospital should report charges for other items that may be included in the kit on a separate line on the claim. Hospitals may use the same revenue code to report all components of the kit.