

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10997	Date: September 16, 2021
	Change Request 12436

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

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

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

EFFECTIVE DATE: October 1, 2021

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

IMPLEMENTATION DATE: October 4, 2021

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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: 10997	Date: September 16, 2021	Change Request: 12436
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SUBJECT: October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: October 1, 2021

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I. GENERAL INFORMATION

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

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

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

On July 30, 2021, the AMA released new Current Procedural Terminology (CPT) code 0003A, which describes the service to administer the third dose Pfizer-BioNTech vaccine. Effective August 12, 2021, the Food and Drug Administration (FDA) updated the Emergency Use Authorization (EUA) for this product to allow a third dose in certain populations. CPT code 0003A has been included in the October 2021 I/OCE with status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose).

Please note that the APC title for APC 9398 was revised from (Covid-19 Vaccine Administration Dose 2 of 2 or Single Dose Product) to (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the October I/OCE.

On August 16, 2021, the American Medical Association (AMA) released new CPT code, 0013A, associated with administration of the third dose Moderna vaccine. Effective August 12, 2021, the FDA updated the EUA for this product to allow a third dose in certain populations. CPT code 0013A has been included in the October 2021 I/OCE with status indicator "S", APC 9398.

Table 1, attachment A, lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the October 2021 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/Ambulatory Surgical Center (ASC) final rule for the latest definitions.

2. New COVID-19 HCPCS Vaccine Administration Code for Administering in the Beneficiary's Home

Effective June 8, 2021, the Centers for Medicare & Medicaid Services (CMS) is creating new HCPCS Level II code M0201. This code describes the additional payment that can be billed when a COVID-19 vaccine is administered in the beneficiary's home. M0201 may be billed in addition to the existing COVID-19 vaccine administration CPT codes: 0001A, 0002A, 0003A, 0011A, 0012A, 0013A and 0031A. Because it is covered

and paid for under the COVID-19 vaccine benefit, no beneficiary cost-sharing applies.

HCPCS code M0201 is assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 1494 (New Technology - Level 1D (\$31-\$40)) effective June 8, 2021, in the October I/OCE.

Table 2, attachment A, lists the long descriptor for the code. The code, along with its short descriptor, status indicator, and payment rate is also listed in the October 2021 OPSS Addendum B that is posted on the CMS website. For information on the OPSS status indicators, refer to OPSS Addendum D1 of the CY 2021 OPSS/ASC final rule for the latest definitions.

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

<https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/COVID-19-vaccines-and-mono-clonal-antibodies>

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

a. New COVID-19 Monoclonal Antibody Therapy and Administration codes for Sotrovimab

On May 26, 2021, the Food and Drug Administration (FDA) released an Emergency Use Authorization (EUA) for Sotrovimab, a COVID-19 monoclonal antibody product.

In response to the COVID-19 Public Health Emergency, CMS is creating new Category II Healthcare Common Procedure Coding System (HCPCS) codes for Sotrovimab and the services to administer (infuse) it in a health care setting and the home. These HCPCS codes are: M0247, M0248, and Q0247. The codes, along with their long descriptors, are identified in Table 3, attachment A.

New HCPCS code M0247 is assigned to status indicator “S” and APC 1506 (New Technology - Level 6 (\$401 - \$500)) effective May 26, 2021, in the October I/OCE.

New HCPCS code M0248 is assigned to status indicator “S” and APC 1509 (New Technology - Level 9 (\$701 - \$800)) effective May 26, 2021, in the October I/OCE.

New HCPCS code Q0247 is assigned to status indicator “L” (Not paid under OPSS. Paid at reasonable cost; not subject to deductible or coinsurance) effective May 26, 2021, in the October I/OCE.

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

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

<https://www.cms.gov/medicare/COVID-19/monoclonal-antibody-COVID-19-infusion>

<https://www.cms.gov/medicare/COVID-19/monoclonal-antibody-COVID-19-infusion#Payment>

b. Changes for COVID-19 Monoclonal Antibody Combination Product Casirivimab and Imdevimab

1.) New HCPCS Code Q0244 that Reflects an Updated Dosing Regime for Monoclonal Antibody Combination Product Casirivimab and Imdevimab

On June 3, 2021, the Food and Drug Administration (FDA) released a revised Emergency Use Authorization (EUA) for Regeneron's COVID-19 monoclonal antibody combination product casirivimab and imdevimab. The updated EUA includes a new dosing regime (1200 mg vs. 2400 mg) and allows a new route of administration.

In response to the COVID-19 public health emergency, CMS is creating a new Category II HCPCS code Q0244 that reflects an updated dosing regime for casirivimab and imdevimab that was authorized by the FDA in the June 3, 2021 EUA. Therefore, effective June 3, 2021, HCPCS code Q0244 is assigned to status indicator "L" in the October I/OCE. Table 3, attachment A describes the long descriptor for the code.

2.) New HCPCS codes M0240, M0241 Describing Repeat Administration for Casirivimab and Imdevimab and New HCPCS code Q0240 for New Product Code that Describes the New Dosing for Casirivimab and Imdevimab

In response to the COVID-19 Public Health Emergency (PHE), and the updated July 30, 2021 EUA for casirivimab and imdevimab, the Centers for Medicare & Medicaid Services (CMS) is creating new Healthcare Common Procedure Coding System (HCPCS) Level II code Q0240 to account for the new dosage (300 mg of casirivimab and 300 mg of imdevimab, for a total dose of 600 mg) and new HCPCS codes M0240 and M0241 to account for repeat administrations of casirivimab and imdevimab.

Therefore, new HCPCS code Q0240 is assigned to status indicator "L" in the October I/OCE effective July 30, 2021.

New HCPCS code M0240 is assigned to status indicator "S" and APC 1506 (New Technology - Level 6 (\$401 - \$500)) effective July 30, 2021, in the October I/OCE.

New HCPCS code M0241 is assigned to status indicator "S" and APC 1509 (New Technology - Level 9 (\$701 - \$800)) effective July 30, 2021, in the October I/OCE.

Table 3, attachment A describes the long descriptors for the codes.

3.) Updates to the Descriptors for the HCPCS Codes M0243 and M0244 that Describe the Services to Administer Casirivimab and Imdevimab to Reflect the Addition of a New Potential Route of Administration

CMS is updating the code descriptors for the HCPCS codes M0243 and M0244 that describe the services to administer casirivimab and imdevimab to reflect the addition of a new potential route of administration. The effective date of the descriptor change for the HCPCS code M0243 is 11/21/2020 and the effective date of the descriptor change for the HCPCS code M0244 is 05/06/2021. APC assignments and payment rates for these codes are not changing in the October Update.

All the coding changes described above, specifically, the codes along with their long descriptors, are identified in Table 3, attachment A. The COVID-19 monoclonal antibody therapy products and administration HCPCS codes, along with their short descriptors, status indicators, APCs, and payment rates (where applicable) are listed in the October 2021 OPSS Addendum B that is posted on the CMS website. For information on the OPSS status indicators, refer to OPSS Addendum D1 of the CY 2021 OPSS/ASC final rule for the latest definitions.

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

<https://www.cms.gov/medicare/COVID-19/monoclonal-antibody-COVID-19-infusion>

<https://www.cms.gov/medicare/COVID-19/monoclonal-antibody-COVID-19-infusion#Payment>

c. New COVID-19 Monoclonal Antibody Therapy and Administration codes for Tocilizumab

On June 24, 2021, the Food and Drug Administration (FDA) released an Emergency Use Authorization (EUA) for Tocilizumab, for its new COVID-19 indication monoclonal antibody product.

In response to the COVID-19 Public Health Emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) is creating new Category II Healthcare Common Procedure Coding System (HCPCS) codes for Tocilizumab and the services to administer (infuse) it. These codes are: M0249, M0250, and Q0249. The codes along with their long descriptors are identified in Table 3, attachment A.

New HCPCS codes M0249 and M0250 are assigned to status indicator “S” and APC 1506 (New Technology - Level 6 (\$401 - \$500)) effective June 24, 2021, in the October I/OCE.

New HCPCS code Q0249 is assigned to status indicator “L” effective June 24, 2021, in the October I/OCE.

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

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

<https://www.cms.gov/medicare/COVID-19/monoclonal-antibody-COVID-19-infusion>

<https://www.cms.gov/medicare/COVID-19/monoclonal-antibody-COVID-19-infusion#Payment>

4. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective October 1, 2021

The AMA CPT Editorial Panel deleted two PLA codes, specifically, 0139U and 0168U, revised one PLA code, specifically, 0051U, and established thirty new PLA codes, specifically, CPT codes 0255U through 0284U, effective October 1, 2021. Table 4, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the October 2021 I/OCE with an effective date of October 1, 2021. In addition, the codes, along with their short descriptor and status indicators, are listed in the October 2021 OPSS Addendum B that is posted on the CMS website. For more information on OPSS status indicators, refer to OPSS Addendum D1 of the Calendar Year 2021 OPSS/ASC final rule for the latest definitions.

5. Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Change Effective October 1, 2021

The AMA CPT Editorial Panel established one new MAAA code, specifically, 0018M, effective October 1, 2021. Table 5, attachment A, lists the long descriptor and SI for CPT code 0018M. The code has been added to the October 2021 I/OCE with an effective date of October 1, 2021. In addition, the code, along with its short descriptor and status indicator, is listed in the October 2021 OPSS Addendum B that is posted on the CMS website. For more information on OPSS status indicators, refer to OPSS Addendum D1 of the Calendar Year 2021 OPSS/ASC final rule for the latest definitions.

6. New HCPCS Code Describing the Endoscopic Submucosal Dissection (ESD) Procedure

CMS is establishing a new HCPCS code, C9779, to describe the endoscopic submucosal dissection (ESD) perform during an endoscopy or colonoscopy. Table 6, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9779. For information on OPSS status indicators, please refer to OPSS Addendum D1 of the CY 2021 OPSS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the October 2021 Update

of the OPSS Addendum B.

7. New HCPCS Code Describing a Procedure Utilizing the Surfacar Inside-Out Access Catheter System

CMS is establishing a new HCPCS code, C9780, to describe a procedure utilizing the Surfacar Inside-Out Access Catheter System. Table 7, attachment A, lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9780. For information on OPSS status indicators, please refer to OPSS Addendum D1 of the CY 2021 OPSS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the October 2021 Update of the OPSS Addendum B.

8. a. New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act requires that, under the OPSS, categories of devices be eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices. We are establishing one new device pass-through category as of October 1, 2021. We are also updating the device offset from payment information for the device category described by HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) Table 9, attachment A, provides a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

b. Device Offset from Payment

Section 1833(t)(6)(D)(ii) of the Act requires that we deduct from pass-through payments for devices an amount that reflects the device portion of the APC payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-through payments for the applicable passthrough device.

i. We have determined that the offset amounts for APCs 5115 and 5116 are associated with costs of the device category described by HCPCS code C1831 (Personalized, anterior and lateral interbody cage (implantable)). The device(s) in the category described by HCPCS code C1831 should always be billed with one of the primary Current Procedural Terminology (CPT) codes 22558, 22586, 22612, 22630, or 22633 and add-on code 22853 or 22854. Refer to Table 8, attachment A, for code long descriptors and APC assignments (if applicable). The codes, along with their short descriptors, status indicators, APC assignments, and payment rates are also listed in the October 2021 Update of the OPSS Addendum B.

ii. In the July 2021 Update of the Hospital Outpatient Prospective Payment System (OPSS) (Transmittal 10825, dated June 11, 2021), we stated that the device in the category described by HCPCS C1761 should always be billed with either CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch) or HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch). We are updating this list to include the following CPT codes: CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), CPT code 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel), HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), and HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel). This change is retroactive to July 1, 2021. The device in the category described by HCPCS code C1761 should always be billed with one of the

following Current Procedural Terminology (CPT) codes listed below.

- CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5194 for Calendar Year (CY) 2021
- CPT code 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel), which is assigned to APC 5193 for Calendar Year (CY) 2021
- HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5194 for Calendar Year (CY) 2021
- HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel), which is assigned to APC 5194 for Calendar Year (CY) 2021
- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5193 for Calendar Year (CY) 2021;
- HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5193 for Calendar Year (CY) 2021

We have determined that the device offset amounts for APC 5193 - Level 3 Endovascular Procedures and APC 5194 - Level 4 Endovascular Procedures are associated with the costs of the device category described by HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) when this device is billed with CPT codes 92933, 92943, C9602, or C9607. Therefore, we are applying a device offset to C1761 when billed with these codes.

c. Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned to APCs and identified by the I/OCE as eligible for payment based on the reasonable cost of the new device reduced by the amount included in the APC for the procedure that reflects the packaged payment for device(s) used in the procedure. The I/OCE will determine the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. All related payment calculations will be returned on the same APC line and identified as a designated new device. We refer readers to Addendum P of the CY 2021 final rule with comment period for the most current OPDS HCPCS Offset file. Addendum P is available via the Internet on the CMS website.

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

For devices that have received FDA marketing authorization and a Breakthrough Device designation from the FDA, CMS provided an alternative pathway to qualify for device pass-through payment status, under which devices would not be evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining device pass-through payment status. The devices would still need to meet the other criteria for pass-through status. This applies to devices that receive pass-through payment status effective on or after January 1, 2020.

9. Drugs, Biologicals, and Radiopharmaceuticals

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

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 October 1, 2021. These drugs and biologicals will receive drug pass-through status starting October 1, 2021. These HCPCS codes are listed in Table 10, attachment A.

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

Three (3) existing HCPCS codes used to report drugs, biologicals, and radiopharmaceuticals in the hospital outpatient setting will receive drug pass-through status starting October 1, 2021. These HCPCS codes are listed in Table 11, attachment A.

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

There are three (3) HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on September 30, 2021. These codes are listed in Table 12, attachment A. Therefore, effective October 1, 2021, the status indicator for these codes is changing from “G” to either “K” or “N”. For more information on OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year 2021 OPPS/ASC final rule for the latest definition. These codes, along with their short descriptors and status indicators are also listed in the October 2021 Update of the OPPS Addendum B.

d. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2021

Twenty (20) new drug, biological, and radiopharmaceutical HCPCS codes will be established on October 1, 2021. These HCPCS codes are listed in Table 13, attachment A.

e. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals with Revised Long Descriptors as of October 1, 2021

The long descriptors for HCPCS code J1443 and HCPCS code J2407 will be revised on October 1, 2021. These long descriptor changes are reported in Table 14, attachment A.

f. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted as of October 1, 2021

Twelve (12) drug, biological, and radiopharmaceutical HCPCS codes will be deleted on October 1, 2021. These HCPCS codes are listed in Table 15, attachment A.

g. Radiopharmaceuticals that Will Retroactively Changed from Packaged Status to Pass-Through Status Effective July 1, 2021, in the October I/OCE Update

The status indicators for HCPCS code A9593 (Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie) and for HCPCS code A9594 (Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie) effective July 1, 2021, will be changed retroactively from status indicator = “N” to status indicator = “G” in the October I/OCE Update. These drugs/biologicals are reported in Table 16, attachment A.

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

For CY 2021, payment for the majority of nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP + 6 percent of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP – 22.5 percent (or ASP - 22.5 percent of the biosimilar’s ASP if a biosimilar is acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead

costs associated with the drug, biological, or therapeutic radiopharmaceutical. In CY 2021, a single payment of ASP + 6 percent for pass-through drugs, biologicals, and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP + 6 percent of the reference product for biosimilars). Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective October 1, 2021, payment rates for many drugs and biologicals have changed from the values published in the CY 2021 OPPTS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from third quarter of CY 2020. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the October 2021 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the October 2021 update of the OPPTS. However, the updated payment rates effective October 1, 2021, can be found in the October 2021 update of the OPPTS Addendum A and Addendum B on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS>

i. 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/OPPTS-Restated-Payment-Rates.html>

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

10. 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 2021.

a. New Skin Substitute Products as of October 1, 2021

There are three (3) new skin substitute HCPCS codes that will be active as of October 1, 2021. These codes are listed in Table 17, attachment A.

b. Skin Substitute Products Deleted as of October 1, 2021

There are two (2) skin substitute HCPCS codes that will be deleted as of October 1, 2021. These codes are listed in Table 18, attachment A.

11. Vaccine CPT code Status Indicator Change Effective October 1, 2021

The status indicator for CPT code 90677 (Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use) will change from status indicator = "E1" to status indicator = "L" effective October 1, 2021. This change is listed in Table 19, attachment A.

12. New Blood Product HCPCS Codes Effective October 1, 2021

Two (2) new blood product HCPCS codes will be established on October 1, 2021. These HCPCS codes are listed in Table 20, attachment A.

Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared-System Maintainers				Other
		A	B		H H H	F M V C	I C M W	S S S F	
	device off-set amount to the claim. These adjustments shall be processed within 120 days from the implementation of this CR.								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E	C E D I	M A C
		A	B	H H H			
12436.5	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
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
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
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Table 2.— New COVID-19 HCPCS Vaccine Administration Code for Administering in the Beneficiary’s Home

CPT Code	Type	Long Descriptor
M0201	Administration/ Infusion Code	Covid-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only covid-19 vaccine administration is performed at the patient's home

Table 3. — COVID-19 Monoclonal Antibody Therapy Products and Administration Codes

CPT Code	Type	Long Descriptor
M0240	Administration/ Infusion Code	Intravenous infusion or subcutaneous injection, 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 4. – PLA Coding Changes Effective October 1, 2021

CPT Code	Long Descriptor	OPPS SI
0051U	Prescription drug monitoring, evaluation of drugs present by liquid chromatography tandem mass spectrometry (LC-MS/MS), urine or blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service	Q4
0139U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α -ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	D
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	D
0255U	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score	Q4
0256U	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report	Q4
0257U	Very long chain acyl- coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood	Q4
0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin- surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics	A
0259U	Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative	Q4

0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	A
0261U	Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score	Q4
0262U	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score	A
0263U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, α -ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	Q4
0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	A
0265U	Rare constitutional and other heritable disorders, whole- genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants	A
0266U	Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and next-generation sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes	A

0267U	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole-genome sequencing	A
0268U	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	A
0269U	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	A
0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid	A
0271U	Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	A
0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood, buccal swab, or amniotic fluid, comprehensive	A
0273U	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU) blood, buccal swab, or amniotic fluid	A
0274U	Hematology (genetic platelet disorders), genomic sequence analysis of 43 genes, blood, buccal swab, or amniotic fluid	A
0275U	Hematology (heparin-induced thrombocytopenia) platelet antibody reactivity by flow cytometry, serum	Q4
0276U	Hematology (inherited thrombocytopenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	A
0277U	Hematology (genetic platelet function disorder), genomic sequence analysis of 31 genes, blood, buccal swab, or amniotic fluid	A
0278U	Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid	A
0279U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen III binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen III binding	Q4

0280U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen IV binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen IV binding	Q4
0281U	Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level	Q4
0282U	Red blood cell antigen typing, DNA, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes	A
0283U	von Willebrand factor (VWF), type 2B, platelet-binding evaluation, radioimmunoassay, plasma	Q4
0284U	von Willebrand factor (VWD), type 2N, factor VIII and VWF binding evaluation, enzyme-linked immunosorbent assays (ELISA), plasma	Q4

Table 5. – MAAA CPT Coding Change Effective October 1, 2021

CPT Code	Long Descriptor	OPPS SI
0018M	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	Q4

Table 6. – New HCPCS Code Describing the Endoscopic submucosal dissection (ESD) procedure Effective October 1, 2021

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9779	Esd endoscopy or colonoscopy	Endoscopic submucosal dissection (esd), including endoscopy or colonoscopy, mucosal closure, when performed	J1	5313

Table 7. – New HCPCS Code Describing a Procedure Utilizing the Surfacr Inside-Out Access Catheter System Effective October 1, 2021

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
C9780	Insert cv cath inf & sup app	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

Table 8. – CPT codes billed with C1831

CPT Code	Long Descriptor	CY 2021 OPSS SI	CY 2021 OPSS APC
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (list separately in addition to code for primary procedure)	N	
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure)	N	
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	J1	5116
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	J1	5115
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar	J1	5115

Table 9. — New Device Code Effective October 1, 2021

HCPCS code	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Device Offset Amount(s)
C1831	10/1/2021	H	2034	Personalized interbody cage	Personalized, anterior and lateral interbody cage (implantable)	CPT code 22558 - \$7,662.72 CPT code 22630 - \$7,837.27 CPT code 22586 - \$4,919.12 CPT code 22633 - \$6,851.93 CPT code 22612 – \$5,301.50
C1761	7/1/2021	H	2033	Cath, trans intra litho/coro	Catheter, transluminal intravascular lithotripsy, coronary	CPT code 92933 – \$8,778.98 CPT code 92943 - \$4,278.29 CPT code C9602 - \$9,129.17 CPT code C9607 - \$8,677.77

Table 10. — New CY 2021 HCPCS Codes Effective October 1, 2021 for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 SI	CY 2021 APC
J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427
C9081	Idecabtagene vicleucel, up to 460 million autologous anti-BCMA car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422
C9082	Injection, dostarlimab-gxly, 100 mg	G	9423
C9083	Injection, amivantamab-vmjw, 10 mg	G	9424
C9084	Injection, loncastuximab tesirine-lpyl, 0.1 mg	G	9425

Table 11. – Existing CY 2021 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Effective October 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 SI	CY 2021 APC
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410
J1823	Injection, inebilizumab-cdon, 1 mg	G	9394

Table 12. – HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending Effective September 30, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	July 2021 SI	October 2021 SI	October 2021 APC
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	K	9099
Q5105	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units	G	N	N/A
Q5106	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for non-esrd use), 1000 units	G	K	9097

Table 13. – Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2021

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
C9081	N/A	Idecabtagene vicleucel, up to 460 million autologous anti-BCMA car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422
C9082	N/A	Injection, dostarlimab-gxly, 100 mg	G	9423
C9083	N/A	Injection, amivantamab-vmjw, 10 mg	G	9424
C9084	N/A	Injection, loncastuximab tesirine-lpyl, 0.1 mg	G	9425
J0699	N/A	Injection, cefiderocol, 10 mg	G	9426
J0741	C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414
J1305	C9079	Injection, evinacumab-dgnb, 5mg	G	9416
J1426	C9075	Injection, casimersen, 10 mg	G	9412
J1445	N/A	Injection, ferric pyrophosphate citrate solution (triferic avnu), 0.1 mg of iron	E2	N/A
J1448	C9078	Injection, trilaciclib, 1mg	G	9415
J2406	N/A	Injection, oritavancin (kimyrza), 10 mg	G	9427
J7294	N/A	Segesterone acetate and ethinyl estradiol 0.15mg, 0.013mg per 24 hours; yearly vaginal system, each	E1	N/A
J7295	J7303	Ethinyl estradiol and etonogestrel 0.015mg, 0.12mg per 24 hours; monthly vaginal ring, each	E1	N/A
J9247	C9080	Injection, melphalan flufenamide, 1mg	G	9417
J9318	C9065	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428
J9319	J9315	Injection, romidepsin, lyophilized, 0.1 mg	K	9429
Q2054	C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413
Q4251	N/A	Vim, per square centimeter	N	N/A
Q4252	N/A	Vendaje, per square centimeter	N	N/A
Q4253	N/A	Zenith amniotic membrane, per square centimeter	N	N/A

Table 14. — HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals with Revised Long Descriptor as of October 1, 2021

July 2021 HCPCS Code	July 2021 Long Descriptor	October 2021 HCPCS Code	October 2021 Long Descriptor
J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron	J1443	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron
J2407	Injection, oritavancin, 10 mg	J2407	Injection, oritavancin (orbactiv), 10 mg

Table 15. – HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted as of October 1, 2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 SI	APC
C9065	Injection, romidepsin, non-lyophilized (e.g. liquid), 1mg	G	9379
C9075	Injection, casimersen, 10 mg	G	9412
C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413
C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414
C9078	Injection, trilaciclib, 1mg	G	9415
C9079	Injection, evinacumab-dgnb, 5mg	G	9416
C9080	Injection, melphalan flufenamide hydrochloride, 1 mg	G	9417
J0693	Injection, cefiderocol, 5 mg	G	9380
J7303	Contraceptive supply, hormone containing vaginal ring, each	E1	N/A
J9315	Injection, romidepsin, 1 mg	K	9265
Q4228	Bionextpatch, per square centimeter	N	N/A
Q4236	Carepatch, per square centimeter	N	N/A

Table 16. – Radiopharmaceuticals that Will Retroactively Change from Packaged Status to Pass-Through Status effective July 1, 2021 in the October I/OCE Update

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	N	G	9409	07/01/2021
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	N	G	9410	07/01/2021

Table 17. – New Skin Substitute Products Low Cost Group/High Cost Group Assignment Effective October 1, 2021

CY 2021 HCPCS Code	Short Descriptor	CY 2021 SI	Low/High Cost Skin Substitute
Q4251	Vim, per square centimeter	N	Low
Q4252	Vendaje, per square centimet	N	Low
Q4253	Zenith amniotic membrane psc	N	Low

Table 18. – Skin Substitute Products Deleted as of October 1, 2021

CY 2021 HCPCS Code	Short Descriptor	CY 2021 SI
Q4228	Bionextpatch, per sq cm	N
Q4236	Carepatch per sq cm	N

Table 19. – Vaccine that Will Change its Status Indicator from “E1” to “L” effective October 1, 2021

HCPCS Code	Long Descriptor	Old SI	New SI	Effective Date
90677	Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use	E1	L	10/01/2021

Table 20.— New Blood Product HCPCS Codes that are Effective October 1, 2021

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
P9025	N/A	Plasma, cryoprecipitate reduced, pathogen reduced, each unit	R	9538
P9026	N/A	Cryoprecipitated fibrinogen complex, pathogen reduced, each unit	R	9539