CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11801	**Date: January 20, 2023**
	Change Request 13031

Transmittal 11737 issued December 08, 2022, is being rescinded and replaced by Transmittal 11801, dated, January 20, 2023, to update tables 5, 6 and add table 20 in order to update the pass-through status of 5 devices that will be extended pass-through status for a 1-year period beginning on January 1, 2023. All other information remains the same.

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to describe changes to and billing instructions for various payment policies implemented in the January 2023 Outpatient Prospective Payment System (OPPS) update. The January 2023 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this 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 January 2023 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2023 I/OCE CR.

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/10.2.3/Comprehensive APCs

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: 11801	Date: January 20, 2023	Change Request: 13031

Transmittal 11737 issued December 08, 2022, is being rescinded and replaced by Transmittal 11801, dated, January 20, 2023, to update tables 5, 6 and add table 20 in order to update the pass-through status of 5 devices that will be extended pass-through status for a 1-year period beginning on January 1, 2023. All other information remains the same.

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

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to describe changes to and billing instructions for various payment policies implemented in the January 2023 Outpatient Prospective Payment System (OPPS) update. The January 2023 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.8 (Annual Updates to the OPPS Pricer for Calendar Year (CY) 2007 and Later).

The January 2023 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2023 I/OCE CR.

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

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

On August 19, 2022, the FDA amended the EUA of the "Novavax COVID-19 Vaccine, Adjuvanted" to authorize its use for the prevention of COVID-19 for individuals 12 through 17 years of age. This is a change from the July 13, 2022 revision that authorized its use for the prevention of COVID-19 for individuals 18 years of age and older. Therefore, CPT code 91304 describing the "Novavax COVID-19 Vaccine, Adjuvanted" and CPT codes 0041A and 0042A, which describe the service to administer the vaccine's first and second dose, respectively, can be billed for ages 12 years and older.

On August 31, 2022, the AMA released eight new codes for the bivalent COVID-19 vaccine booster doses from Moderna and Pfizer-BioNTech. The updated boosters are adapted for the BA.4 and BA.5 Omicron subvariants and the original coronavirus strain in a single dose.

On August 31, 2022, FDA authorized the "Moderna COVID-19 Vaccine, Bivalent" (91313) for use as a single booster dose in individuals 18 years of age and older and the "Pfizer-BioNTech COVID-19 Vaccine, Bivalent" (91312) for use as a single booster dose in individuals 12 years of age and older. CMS identifies an effective date of 08/31/2022 for both of the Pfizer-BioNTech and Moderna COVID-19 vaccine, bivalent administration CPT codes, 0124A and 0134A, respectively, which describe the service to administer the bivalent formulations of the vaccines for use as a booster dose.

Effective August 31, 2022, CPT codes 0124A and 0134A are assigned to status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the January 2023 I/OCE update.

Effective August 31, 2022, CPT codes 91312 and 91313 are assigned to status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the January 2023 I/OCE update.

Beneficiary cost-sharing shall not apply to CPT codes 0124A and 0134A.

On October 12, 2022, FDA authorized the "Moderna COVID-19 Vaccine, Bivalent" (91314) for use as a single booster dose in individuals 6 years through 11 years and the "Pfizer-BioNTech COVID-19 Vaccine, Bivalent" (91315) for use as a single booster dose in individuals 5 years through 11 years. CMS identifies an effective date of 10/12/2022 for both the Pfizer-BioNTech and Moderna COVID-19 vaccine, bivalent administration CPT codes, 0154A and 0144A, respectively, which describe the service to administer the bivalent formulations of the vaccines for use as a booster dose.

Effective October 12, 2022, CPT codes 91314 and 91315 are assigned to status indicator "L" in the January 2023 IOCE update.

Effective October 12, 2022, CPT codes 0144A and 0154A are assigned to status indicator "S", APC 9398 in the January 2023 IOCE update.

Beneficiary cost-sharing shall not apply to CPT codes 0144A and 0154A

On October 12, 2022, the FDA amended the EUA of the "Moderna COVID-19 Vaccine, Bivalent" (91313) to authorize its use as a single booster for ages 12 years and older. This is a change from the August 31, 2022 revision that authorized its use as a single booster dose for ages 18 years and older. Therefore, the CPT code 91313 describing the "Moderna COVID-19 Vaccine, Bivalent" for use as a booster dose and the CPT code 0134A describing the service to administer the "Moderna COVID-19 Vaccine, Bivalent" can be billed for ages 12 years and older.

The AMA released new vaccine administration code (0044A) for the administration of a booster dose of the "Novavax COVID-19 Vaccine, Adjuvanted" (91304). On October 19, 2022, the FDA amended the EUA of the "Novavax COVID-19 Vaccine, Adjuvanted" to authorize its use as a first booster dose for individuals 18 years and older. CMS identifies an effective date of 10/19/2022 for CPT code 0044A, which describes the service to administer the "Novavax COVID-19 Vaccine, Adjuvanted" as a booster dose for patients ages 18 years and older.

Effective October 19, 2022, CPT code 0044A is assigned to status indicator "S", APC 9398 in the January 2023 IOCE update.

Beneficiary cost-sharing shall not apply to CPT code 0044A.

On November 16, 2022, The AMA has released a new vaccine product code (91316) and a new vaccine administration code (0164A) for the administration of a booster dose of the Moderna bivalent vaccine product to address severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) for patients aged 6 months through 5 years. These codes will become effective upon receiving emergency use authorization (EUA) from the Food and Drug Administration (FDA).

Therefore, CPT codes 0164A and 91316 were assigned to status indicator "E1" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) in the January 2023 IOCE update.

CMS will provide future direction to the contractors as EUAs and/or approvals become available.

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

2. Updated Payment rates for Covid-19 Vaccine Administration APCs 9397 and 9398 and New Covid-19 Vaccine Home Administration APC 9399.

Effective January 1, 2023, we are updating payment rates for Covid-19 vaccine administration APCs 9397 and 9398. We are also creating new Covid-19 vaccine home administration APC 9399 and we are re-assigning HCPCS code, M0201 (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) from APC 1494 to new APC 9399. Table 2, attachment A lists the APC titles for the three Covid-19 vaccine administration APCs.

The Covid-19 vaccine administration APCs along with their status indicators and payment rates are listed in the January 2023 OPPS Addendum A that is posted on the CMS website.

The Covid-19 vaccine administration CPT codes assigned to these three APCs, along with their short descriptors, status indicators, APCs, and payment rates are listed in the January 2023 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2023 OPPS/ASC final rule for the latest definitions.

3. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective January 1, 2023

The AMA CPT Editorial Panel established 9 new PLA codes, specifically, CPT codes 0355U through 0363U, effective January 1, 2023.

Table 3, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the January 2023 I/OCE with an effective date of January 1, 2023. In addition, the codes, along with their short descriptors and status indicators, are listed in the January 2023 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 2023 OPPS/ASC final rule for the latest definitions.

4. Status Indicator Change for CPT PLA Code 0343U

We are changing the status indicator for CPT PLA code, 0343U from status indicator “E1” (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to indicator “A” (Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS) effective October 1, 2022 in the January 2023 I/OCE Update. Table 4, in the attachment A lists the official long descriptor and status indicator for CPT code 0343U. Short descriptor and status indicator for CPT code 0343U can be found in Addendum B of the January 2023 OPPS Update that is posted on the CMS website.

5. a. New Device Pass-Through Category Effective January 1, 2023

Section 1833(t)(6)(B) of the Social Security Act requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. In addition, section 1833(t)(6)(B)(ii)(IV) of the Act requires that we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

As discussed in section IV.A.2. (New Device Pass-Through Applications for CY 2023), of the CY 2023 OPPS/ASC final rule with comment period, for the January 2023 update, we approved three (3) new devices for pass-through status under the OPPS, specifically, HCPCS codes C1747, C1826, and C1827. For the full

discussion on the criteria used to evaluate device pass-through applications, refer to the CY 2023 OPPS/ASC final rule with comment period, which was published in the ***Federal Register*** in November of CY 2022. Refer to Table 5, attachment A, for the long descriptor, status indicator, APC, and offset amount for these three (3) HCPCS codes.

Furthermore, we are adding these three (3) new device category codes and their pass-through expiration dates to Table 6, attachment A. We note we are updating the device category long descriptor for device HCPCS code C1831, which was effective October 1, 2021, from "Personalized, anterior and lateral interbody cage (implantable)" to "Interbody cage, anterior, lateral or posterior, personalized (implantable)" effective January 1, 2023. Refer to Table 6 for the complete list of device category HCPCS codes and definitions used for present and previous transitional pass-through payment.

b. Device Offset from Payment for the Following HCPCS Codes

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.

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 (Device-Intensive Procedures for CY 2023) of the CY 2023 OPPS/ASC final rule with comment period for the most current OPPS HCPCS Offset file. Addendum P is available via the Internet on the CMS website, specifically, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

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

For devices that have received FDA marketing authorization and a Breakthrough Device designation from the FDA, CMS provides an alternative pathway to qualify for device pass-through payment status, under which devices would not be evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining device pass-through payment status. The devices would still need to meet the other criteria for pass-through status. This applies to devices that receive pass-through payment status effective on or after January 1, 2020. For information on the device criteria to qualify for pass-through status under the OPPS, refer to this CMS website, specifically at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.

e. Expiring Pass-through Status for Six Device Category HCPCS Codes Effective January 1, 2023

As specified in section 1833(t)(6)(B) of the Social Security Act, under the OPPS, categories of devices are eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. As discussed in section IV.A.1. b. (Expiration of Transitional Pass-Through Payments for Certain Devices) of the CY 2023 OPPS/ASC final rule with comment period, the pass-through period for several device category HCPCS code will expire on December 31, 2022. These codes are listed below in Table 5B, attachment A. We note that these device category HCPCS codes will remain active, however, their payment will be included in the primary service. As a reminder, for OPPS billing, because charges related to packaged services are used for outlier and future rate setting, hospitals are advised to report the device category HCPCS codes on the claim whenever they are provided in the HOPD setting. It is extremely

important that hospitals report all HCPCS codes consistent with their descriptors, CPT and/or CMS instructions and correct coding principles, as well as all charges for all services they furnish, whether payment for the services is made separately or is packaged. For the entire list of current and historical device category codes created since August 1, 2000, which is the implementation date of the hospital OPPS, refer to Table 6. We note this list can also be found in section 60.4.2 (Complete List of Device Pass-through Category Codes) of the Medicare Claims Processing Manual.

6. Dental Coding Updates

a) New HCPCS Code Describing Facility Services for Dental Rehabilitation Procedure(s)

For the CY 2023 OPPS update, CMS established HCPCS code G0330 to describe facility services for dental rehabilitation procedures performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care)) and use of an operating room. CMS established the code to enable Hospital Outpatient Departments (HOPDs) to bill the technical, facility-fee component of dental rehabilitation services only. We believe this code will mainly be used to describe the facility fees for services performed on vulnerable populations, including patients with disabilities, who require these procedures to be performed under anesthesia due to special health needs. Table 7, attachment A, lists the long descriptor, status indicator, and APC assignment for HCPCS code G0330. For information on the payment amount associated with HCPCS code G0330, refer to the January 2023 OPPS Addendum B, specifically, at this CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.

b) Clarification of CPT Code 41899 (APC 5161)

In the CY 2023 OPPS/ASC final rule, we clarified that CPT code 41899 (Unlisted procedure, dentoalveolar structures) may be used more broadly to describe other dental or dental-related procedures on the teeth and gums, not otherwise described by other HCPCS codes currently assigned to APCs, such as those performed in the clinical dental scenarios as described in the CY 2023 Medicare Physician Fee Schedule (PFS) final rule, as well as covered non-surgical dental services and surgical dental services provided to patients who do not require monitored anesthesia and the use of an operating room. As a reminder, in accordance with existing billing practices, providers should continue to use existing, specific Codes on Dental Procedures and Nomenclature (CDT) codes already assigned to APCs when available, instead of reporting CPT code 41899. For more information, refer to the CY 2023 OPPS/ASC final rule with comment period.

7. Changes to the Inpatient-Only list (IPO) for CY 2023

The Medicare Inpatient Only (IPO) list includes procedures that are typically only provided in the inpatient setting and therefore are not paid under the OPPS. For CY 2023, CMS is removing eleven procedures from the IPO list. CMS is also adding eight procedures to the IPO list. The changes to the IPO list for CY 2023 are included in Table 8, attachment A.

8. MiVu Mucosal Integrity Testing System (APC 5303): Clarification on the Reporting of HCPCS Code C9777

In the CY 2022 OPPS/ASC final rule (86 FR 63517 and 63558), we stated that when both a MiVu test and an esophagoscopy or esophagogastroduodenoscopy (EGD) test are performed together, HOPDs should report only HCPCS code C9777 and should not report a separate HCPCS code for the esophagoscopy or esophagogastroduodenoscopy. We are clarifying to indicate that a diagnostic esophagoscopy or EGD is included in HCPCS code C9777, and therefore, should not be reported separately.

Finally, the code, along with the short descriptor and status indicator assignment is listed in the January 2023 OPPS Addendum B that is posted on the CMS website. For information on the status indicator definitions for all codes reported under the OPPS, refer to OPPS Addendum D1 of the CY 2023 OPPS/ASC

final rule.

9. Payment for Behavioral Health Services Furnished Remotely to Beneficiaries in Their Homes

Beginning on January 1, 2023 CMS will consider behavioral health services furnished remotely by clinical staff of hospital outpatient departments, including staff of critical access hospitals (CAHs), through the use of telecommunications technology to beneficiaries in their homes, covered outpatient services for which payment is made under the OPPS. CMS will require that payment for behavioral health services furnished remotely to beneficiaries in their homes may only be made if the beneficiary receives an in-person service within 6 months prior to the first time hospital clinical staff provides the behavioral health services remotely. However, in instances where there is an ongoing clinical relationship between practitioner and beneficiary at the time the Public Health Emergency (PHE) ends, the in-person requirement for ongoing, not newly initiated, treatment will apply. CMS will require in-person service without the use of communications technology within 12 months of each behavioral health service furnished remotely by hospital clinical staff. Exceptions to the in-person visit requirement will be permitted when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it, among other requirements.

CMS will also allow audio-only interactive telecommunications systems may be used to furnish these services in instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. The codes are listed in Table 9, attachment A.

10. Software as a Service (SaaS)

As discussed in the CY 2023 OPPS/ASC final rule, we are adopting a policy that Software as a Service (SaaS) add-on codes are not among the "certain services described by add-on codes" for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18). Effective January 1, 2023, we are paying separately for select SaaS CPT add-on codes. Please see Table 10, attachment A for a list of recognized SaaS CPT codes, their add-on codes, status indicator and APC assignments. For further information on this policy, refer to Section X.G (OPPS Payment for Software as a Service) of the CY 2023 OPPS/ASC final rule that was published in the ***Federal Register*** in November of CY 2022.

11. Drugs, Biologicals, and Radiopharmaceuticals

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

Three (3) 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 January 1, 2023. These drugs and biologicals will receive drug pass-through status starting January 1, 2023. These HCPCS codes are listed in Table 11, attachment A.

b. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Starting Pass-Through Status as of January 1, 2023

There are two (2) existing HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status start on January 1, 2023. These codes are listed in Table 12, attachment A. Therefore, effective January 1, 2023, the status indicator for these codes is changing to Status Indicator = "G" (Pass-Through Drugs and Biologicals. Paid under OPPS; separate APC payment).

c. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on December 31, 2022

There are thirty-two (32) HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on December 31, 2022. These codes are listed in Table 13, attachment A. Therefore, effective January 1, 2023, the status indicator for these codes is changing from "G" to either "K" (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals. Paid under OPPS; separate APC payment) or "N" (Items and Services Packaged into APC Rates. Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment). For more information on OPPS status indicators, refer to OPPS Addendum D1 of the Calendar Year 2023 OPPS/ASC final rule for the latest definition. These codes, along with their short descriptors and status indicators are also listed in the January 2023 Update of the OPPS Addendum B.

d. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of January 1, 2023

Forty-five (45) new drug, biological, and radiopharmaceutical HCPCS codes have been established on January 1, 2023. These HCPCS codes are listed in Table 14, attachment A.

e. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted on December 31, 2022

Four (4) drug, biological, and radiopharmaceutical HCPCS codes have been deleted on December 31, 2022. These HCPCS codes are listed in Table 15, attachment A.

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

For CY 2023, payment for the majority of nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals is made at a single rate of ASP + 6 percent (or ASP + 6 percent of the reference product for biosimilars. In CY 2023, 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 January 1, 2023, payment rates for many drugs and biologicals have changed from the values published in the CY 2023 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from second quarter of CY 2022. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2023 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the January 2023 update of the OPPS. However, the updated payment rates effective January 1, 2023, can be found in the January 2023 update of the OPPS Addendum A and Addendum B on the CMS website at https:/www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS

g. 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.

h. Drugs and Biologicals Reported using HCPCS Code C9399 (Unclassified drugs or biologicals)

Beginning January 1, 2023, HCPCS code C9399 (Unclassified drugs or biologicals) have been added to the comprehensive APC (C-APC) exclusions list. Please see the updated CMS internet only manual language in the Medicare Claims Processing Manual, Pub.100-04, Chapter 4, section 10.2.3 – Comprehensive APCs for a list of all CAPC exclusions, including the new exclusion of any drug or biological described by HCPCS code C9399.

i. New Modifier "JZ" Available for Use as of January 1, 2023

Beginning January 1, 2023, modifier JZ will be available for voluntary provider use when no amount of drug is discarded from a single dose or single use packaging. Providers must report the JZ modifier for all applicable drugs with no discarded drug amounts beginning no later than July 1, 2023.

j. Billing Instructions for 340B-Acquired Drugs

As finalized in the CY 2023 OPPS/ASC final rule with comment period, separately payable Part B drugs (assigned SI "K"), other than vaccines (assigned SI "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) or "M" (Items and Services Not Billable to the MAC Not paid under OPPS.)) and drugs on passthrough payment status (assigned SI "G") that are acquired through the 340B Program or through the 340B prime vendor program, will be generally paid at the Average Sales Price (ASP) plus six percent, when billed by a hospital paid under the OPPS.

For CY 2023, we are maintaining the requirement for 340B providers to report the "JG" and "TB" modifiers for informational purposes. Under the OPPS, select entities including rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals should continue to bill the modifier "TB" on claim lines for drugs acquired through the 340B Program. All other 340B providers should continue to report the modifier "JG."

12. Skin Substitutes

The payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. For payment packaging purposes, the skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products. New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless CMS has pricing data that demonstrates that the cost of the product is above either the mean unit cost of $47 or the per day cost of $837 for CY 2023.

a. New Skin Substitute Products as of January 1, 2023

There are four (4) new skin substitute HCPCS codes that will be active as of January 1, 2023. These codes are listed in Table 16, attachment A.

b. Deletion of HCPCS Code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) Effective December 31, 2022

HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) has been deleted as of December 31, 2022. HCPCS code C1849 is listed in Table 17, attachment A.

c. Skin substitute assignments to high cost and low costs groups for CY 2023

Table 18, attachment A, lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable.

13. Status Indicator Changes

For CY 2023, we are revising the definition of status indicator "A" to include unclassified drugs and biologicals that are reportable under HCPCS code C9399. When HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's average wholesale price (AWP) using the Red Book or an equivalent recognized compendium, and processes the claim for payment. The payment at 95 percent of AWP is made under the OPPS.

We are also revising the definition of status indicator "F" by removing hepatitis B vaccines. Hepatitis B vaccines should not be subject to deductible and coinsurance similar to other preventive vaccines, but services that are currently listed under the definition of status indicator "F" are subject to deductible and coinsurance. We are also revising the definition of status indicator "L" by adding hepatitis B vaccines to the list of other preventive vaccines that are not subject to deductible and coinsurance.

14. New C-APC Procedures effective January 1, 2023

The following 19 (nineteen) new procedures are Comprehensive APC (C-APC) codes. The HCPCS codes, descriptors and OPPS status indicators are listed in table 19 (see Attachment A). The C-APC payment rates for the codes can be found in the January 2023 Addendum J.

15. Payment Adjustment Amount under the Inpatient Prospective Payment System (IPPS) and OPPS for Domestic NIOSH-approved Surgical N95 Respirators

CMS established new payment adjustments under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. This payment adjustment is codified in the regulations at § 412.113(f) for the IPPS and § 419.43(j) for the OPPS. This payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. In order to calculate the payment adjustment for each eligible cost reporting period, we are creating a new supplemental cost reporting form that will collect from hospitals additional information to be used along with other information already collected on the hospital cost report to calculate the IPPS and OPPS payment adjustment amounts. (For additional information refer to the CY 2023 IPPS/ASC final rule.

Under the finalized policy, we also indicated that these payments would be provided biweekly as interim lump-sum payments to the hospital and reconciled at cost report settlement for cost reporting periods beginning on or after January 1, 2023. Any IPPS and or OPPS provider can make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts shall be determined by the MAC, consistent with existing policies and procedures for biweekly payments (for example, consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance, which are paid on interim biweekly basis as described in CMS Pub 15-1 2405.2). Initially MACs can determine an interim lump-sum biweekly payment amount based on information the hospital provides that reflects the information that will be included on the N95 supplemental cost reporting form. In the future, MACs will determine the interim biweekly lump-sum payments utilizing information from the prior year's surgical N95 supplemental cost reporting form, which may be adjusted as appropriate based on the most current information available.

16. Payment Adjustment for Certain Cancer Hospitals Beginning CY 2023

For certain cancer hospitals that receive interim monthly payments associated with the cancer hospital adjustment at 42 Code of Federal Regulation (CFR) 419.43(i), Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent CYs, the target Payment-to-Cost Ratio (PCR) that should be

used in the calculation of the interim monthly payments and at final cost report settlement is reduced by 0.01. For CY 2023, the target PCR, after including the reduction required by Section 16002(b), is 0.89.

17. Method to Control for Unnecessary Increases in Utilization of Outpatient Services/G0463 with Modifier PO

In CY 2019, CMS finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus Provider-Based Department (PBD) (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). We completed the phase-in of the policy in CY 2020.

The PFS-equivalent amount paid to nonexcepted off-campus PBDs is approximately 40 percent of OPPS payment (60 percent less than the OPPS rate) for CY 2023. Specifically, the total 60-percent payment reduction will apply in CY 2023, which means these departments will be paid 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that applies in CY 2023) for the clinic visit service in CY 2023.

We note that in the CY 2023 OPPS/ASC final rule, we finalized an exemption of rural sole community hospitals from the payment reduction associated with this policy. Therefore, the payment reduction described in this section will not apply to rural sole community hospitals in the CY 2023 OPPS.

18. Changes to OPPS Pricer Logic

a. Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2023. The rural SCH and EACH payment adjustment excludes drugs, biologicals, items and services paid at charges reduced to cost, and items paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

b. New OPPS payment rates and copayment amounts will be effective January 1, 2023. All copayment amounts will be limited to a maximum of 40 percent of the APC payment rate. Copayment amounts for each service cannot exceed the CY 2023 inpatient deductible of $1,600. For most OPPS services, copayments are set at 20 percent of the APC payment rate.

c. For hospital outlier payments under OPPS, there will be no change in the multiple threshold of 1.75 for 2023. This threshold of 1.75 is multiplied by the total line-item APC payment to determine eligibility for outlier payments. This factor also is used to determine the outlier payment, which is 50 percent of estimated cost less 1.75 times the APC payment amount. The payment formula is (cost-(APC payment x 1.75))/2.

d. The fixed-dollar threshold for OPPS outlier payments increases in CY 2023 relative to CY 2022. The estimated cost of a service must be greater than the APC payment amount plus $8,625 in order to qualify for outlier payments.

e. For outliers for Community Mental Health Centers (bill type 76x), there will be no change in the multiple threshold of 3.4 for 2023. This threshold of 3.4 is multiplied by the total line-item APC payment for APC 5853 to determine eligibility for outlier payments. This multiple amount is also used to determine the outlier payment, which is 50 percent of estimated costs less 3.4 times the APC payment amount. The payment formula is (cost-(APC 5853 payment x 3.4))/2.

f. Continuing our established policy for CY 2023, the OPPS Pricer will apply a reduced update ratio of 0.9807 to the payment and copayment for hospitals that fail to meet their hospital outpatient quality data reporting requirements or that fail to meet CMS validation edits. The reduced payment amount will be used

to calculate outlier payments.

g. Effective January 1, 2023, CMS is adopting the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) post-reclassification wage index values with application of the CY 2023 out-commuting adjustment authorized by Section 505 of the MMA to non- IPPS (non-Inpatient Prospective Payment System) hospitals as implemented through the Pricer logic.

h. Effective January 1, 2023, for claims with APCs, which require implantable devices and have significant device offsets (greater than 30%), a device offset cap will be applied based on the credit amount listed in the "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) value code. The credit amount in value code "FD" which reduces the APC payment for the applicable procedure, will be capped by the device offset amount for that APC. The offset amounts for the above referenced APCs are available on the CMS website.

i. Effective January 2023, rural sole community hospitals will no longer receive payment reductions for HCPCS code G0463 when billed with modifier "PO" based our final CY 2023 policy to exempt rural sole community hospitals from the method to control for unnecessary increases in volume policy.

19. Update the Outpatient Provider Specific File (OPSF)

Effective January 1, 2023, contractors shall maintain the accuracy of the provider records in the Outpatient Provider Specific File (OPSF) as changes occur in data element values.

a) Updating the OPSF for the Supplemental Wage Index and Supplemental Wage Index Flag Fields

In CY 2023, the Supplemental Wage Index and Supplemental Wage Index Flag fields will be used to implement the cap on wage index decrease policy. The Pricer requires the hospital's applicable CY 2022 OPPS wage index in the Supplemental Wage Index field in order to properly apply all wage index policies and determine the hospital's CY 2023 OPPS wage index. Therefore, for CY 2023, in order to accurately pay claims for providers paid through the OPPS for whom we expect the capped wage index policy to apply, the Supplemental Wage Index Flag must be "1" and have a wage index in the Supplemental Wage Index field .

MACs shall ensure that no OPPS providers have a "1" or "2" in the Special Payment Indicator field and no wage index value in the Special Wage Index field with an effective date of January 1, 2023. Unless otherwise instructed by CMS, MACs must seek approval from the CMS Central Office to use a "1" or "2" in the Special Payment Indicator field and a wage index value in the Special Wage Index field.

We note that there generally are several types of assignments for the supplemental wage index that would apply under the OPPS. We note that in all of the case below the Supplemental Wage Index field would be "1" and the effective dates of such changes include for the steps outlined below would be January 1, 2023

1) If the MAC receives approval from the CMS Central Office to assign an OPPS provider a special wage index in CY 2022 and the use of either "1" or "2" in the Special Payment Indicator field, MACs shall do the following

- Enter the value from the Special Wage Index for CY 2022 into the Supplemental Wage index Field.
- Enter a "1" in the Supplemental Wage Index Flag field.
- Ensure that the Special Wage Index and Special Payment Indicator fields are blank.
- Establish the record with an effective date of January 1, 2023.

2) If the MAC did not email CMS during CY 2022 for a provider's CY 2022 wage index:

i. For IPPS hospitals that are also paid under the OPPS

For these hospitals, as described in detail in the instructions in MAC Implementation File 5 at https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page the 2022 wage index should be obtained from the Table 2 associated with the FY 2023 IPPS final rule (or Correction Notice, if applicable). In other instances in which there is an IPPS value derived through the steps outlined in the "MAC Implementation File 5" instructions document, that same FY 2022 wage index value entered into the Supplemental Wage index for the IPSF shall also be entered into the Supplemental Wage Index Field and would apply into the OPPS on a calendar year basis.

In this case MACs shall do the following:

- Enter the value from the Special Wage Index for CY 2022 (from Table 2 or through the steps outlined in MAC Implementation File 5) into the Supplemental Wage Index Field.
- Enter a "1" in the Supplemental Wage Index Flag field.
- Ensure that the Special Wage Index and Special Payment Indicator fields are blank.
- Establish the record with an effective date of January 1, 2023.

ii. For Non-IPPS hospitals, CMHCs, and other OPPS providers

We have made the Supplemental Wage Index assignments (based on the CY 2022 OPPS wage index) for non-IPPS hospitals, CMHCs, and other OPPS providers available on the CMS website at www.cms.gov/HospitalOutpatientPPS/ under "*Annual Policy Files*."

In this case, MACs, shall do the following:

- The CY 2022 Wage index from the Excel file available online shall be entered into the Supplemental Wage Index field.
- Enter a "1" in the Supplemental Wage Index Flag field.
- Ensure that the Special Wage Index and Special Payment Indicator fields are blank.
- Establish the record with an effective date of January 1, 2023.

b) Updating the OPSF for Expiration of Transitional Outpatient Payments (TOPs)

Cancer and children's hospitals are held harmless under section 1833(t)(7)(D)(ii) of the Social Security Act and continue to receive hold harmless TOPs permanently. For CY 2023, cancer hospitals will continue to receive an additional payment adjustment.

c) Updating the OPSF for the Hospital Outpatient Quality Reporting (HOQR) Program Requirements

Effective for OPPS services furnished on or after January 1, 2009, subsection (d) hospitals that have failed to submit timely hospital outpatient quality data as required in Section 1833(t)(17)(A) of the Act will receive payment under the OPPS that reflects a 2 percentage point reduction from the annual OPPS update for failure to meet the HOQR program requirements. This reduction will not apply to hospitals not required to submit quality data or hospitals that are not paid under the OPPS.

For January 1, 2023, contractors shall maintain the accuracy of the provider records in the OPSF by updating the Hospital Quality Indicator field. CMS will release a Technical Direction Letter that lists Subsection (d) hospitals that are subject to and fail to meet the HOQR program requirements. Once this list is released, A/B Medicare Administrative Contractors (MACs) will update the OPSF by removing the '1', (that is, ensure that the Hospital Quality Indicator field is blank) for all hospitals identified on the list and will ensure that the OPSF Hospital Quality Indicator field contains '1' for all hospitals that are not on the list. CMS notes that if these hospitals are later determined to have met the HOQR program requirements, A/B MACs shall update the OPSF. For greater detail regarding updating the OPSF for the HOQR program

requirements, see Transmittal 368, CR 6072, issued on August 15, 2008.

d) Updating the OPSF for Cost to Charge Ratios (CCR)

As stated in publication 100-04, Medicare Claims Processing Manual, chapter 4, section 50.1, contractors must maintain the accuracy of the data and update the OPSF as changes occur in data element values, including changes to provider cost–to-charge ratios and, when applicable, device department cost-to-charge ratios. The file of OPPS hospital upper limit CCRs and the file of Statewide CCRs are located on the CMS website at www.cms.gov/HospitalOutpatientPPS/ under "*Annual Policy Files*."

e) Updating the "County Code" Field

Prior to CY 2018, in order to include the outmigration in a hospital's wage index, we provided a separate table that assigned wage indexes for hospitals that received the outmigration adjustment. For the CY 2023 OPPS, the OPPS Pricer will continue to assign the out migration adjustment using the "County Code" field in the OPSF. Therefore, MACs shall ensure that every hospital has listed in the "County Code" field the Federal Information Processing Standards (FIPS) county code where the hospital is located to maintain the accuracy of the OPSF data fields.

f) Updating the "Wage Index Location Core-Based Statistical Areas (CBSA)" Field

We note that under historical and current OPPS wage index policy, hospitals that have wage index reclassifications for wage adjustment purposes under the IPPS would also have those wage index reclassifications applied under the OPPS on a calendar year basis. Therefore, MACs shall ensure that wage index reclassifications applied under the FY 2023 IPPS are also reflected in the OPSF on a CY 2023 OPPS basis.

g) Updating the "Payment Core-Based Statistical Areas (CBSA)" Field

In the prior layout of the OPSF, there were only two CBSA related fields: the "Actual Geographic Location CBSA" and the "Wage Index Location CBSA." These fields are used to wage adjust OPPS payment through the Pricer if there is not an assigned Special Wage Index (as has been used historically to assign the wage index for hospitals receiving the outmigration adjustment).

In Transmittal 3750, dated April 19, 2017, for Change Request 9926, we created an additional field for the "Payment CBSA," similar to the IPPS, to allow for consistency between the data in the two systems and identify when hospitals receive dual reclassifications. In the case of dual reclassifications, similar to the IPPS, the "Payment CBSA" field will be used to note the Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Act (§ 412.103). This "Payment CBSA" field is not used for wage adjustment purposes, but to identify when the 412.103 reclassification applies, because rural status is considered for rural sole community hospital adjustment eligibility. We further note that whereas the IPPS Pricer allows the Payment CBSA, even when applied as the sole CBSA field (without a Wage Index CBSA), to be used for wage adjusting payment, that field is not used for wage adjustment the OPPS.

20. Wage Index Policies in the CY 2023 OPPS Final Rule

In the FY 2023 IPPS and CY 2023 OPPS final rules, we finalized the following changes to the wage index: increased the wage index values for hospitals with a wage index value below the 25th percentile wage index value of 0.8427 across all hospitals, and applied a 5 percent cap for CY 2023 on any wage index values that decreased relative to CY 2022.

21. 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	
13031.1	Medicare Contractors shall update the PRMODERN PARM's OPPS Pricer Cloud CY Dates to pay OPPS claims for dates of service on or after January 1, 2023 when notified via CMS email to make this update.	X		X						
13031.2	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of the January 2023 OPPS I/OCE.	X		X						
13031.3	As specified in chapter 4, section 50.1, of the Claims Processing Manual, Medicare contractors shall maintain the accuracy of the data and update the OPSF file as changes occur in data element values. For CY 2023, this includes all changes to the OPSF identified in Section 19 of this Change Request.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13031.4	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN	X		X		

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

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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