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Hospital Outpatient Prospective Payment System: April 2023 Update

Related CR Release Date: March 31, 2023

Effective Date: April 1, 2023

Implementation Date: April 3, 2023

MLN Matters Number: MM13136

Related Change Request (CR) Number: CR 13136

Related CR Transmittal Number: R11937CP

Related CR Title: April 2023 Update of the Hospital Outpatient Prospective Payment System (OPPS)

What's Changed: A revision to CR 13136 changed a reference to ASP calculations based on sales price submissions from the third quarter of CY 2022 to the fourth quarter. We made the same change in Section 5g (page 6) of the Article. The change is in dark red.

Affected Providers

- Physicians
- Hospitals
- Other providers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about payment system updates and new codes for:

- COVID-19
- Drugs, biologicals, and radiopharmaceuticals
- Devices
- Other items and services

Background

CR 13136 describes coding changes and policy updates effective April 1, 2023, for the hospital OPPS. The updates include changes for new services, pass-through drug and devices, COVID-19 treatments, and other items and services. The April 2023 revisions to the related Integrated Outpatient Code Editor (I/OCE) are in CR 13125.

The key points of CR 13136 are:

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1. New COVID-19 CPT Vaccines and Administration Codes

The American Medical Association (AMA) has been issuing unique CPT Category I codes which it develops based on collaboration with CMS and the CDC for each COVID-19 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 FDA.

The CPT Editorial Panel recently approved CPT codes:

- 91316 describing the "Moderna COVID-19 Vaccine, Bivalent" for use as a booster for ages 6 months through 5 years
- 0164A describing the service to administer the "Moderna COVID-19 Vaccine, Bivalent" 91316
- 91317 describing the "Pfizer-BioNTech COVID-19 Vaccine, Bivalent" for use as a third primary series dose for ages 6 months through 4 years
- 0173A describing the service to administer the "Pfizer-BioNTech COVID-19 Vaccine, Bivalent" 91317

CMS uses an effective date of December 8, 2022, for the Moderna and Pfizer-BioNTech "COVID-19 Vaccine, Bivalent" administration CPT codes, 0164A and 0173A, respectively. This effective date corresponds with the FDA EUA effective date for these vaccines.

We assigned status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance) in the April 2023 I/OCE update to CPT codes 91316 and 91317. We assigned status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate ambulatory payment classification (APC) assignment) and APC 9398 (COVID-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the April 2023 I/OCE update for codes 0164A and 0173A.

Patient cost sharing doesn't apply to the new vaccine product codes or the new administration codes.

Table 1 of CR 13136 lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates, where applicable, are also in the April 2023 OPPS Addendum B. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2023 OPPS/Ambulatory Surgical Center (ASC) final rule for the latest definitions.

2. OPPS Payment for COVID-19 Treatments after the Public Health Emergency (PHE)

After the PHE, we'll package payment for COVID-19 treatments into the payment for a comprehensive APC (C-APC) when you bill these services on the same outpatient claim, subject to standard exclusions under the C-APC policy. See the updated language in Attachment 2 of CR 13136.

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

The AMA CPT Editorial Panel established 23 new PLA codes, specifically, CPT codes 0364U through 0386U, effective April 1, 2023. Table 2 of CR 13136 lists the long descriptors and status indicators for the codes. These codes are in the April 2023 I/OCE with an effective date of April 1, 2023. The codes, along with their short descriptors and status indicators, are also in the April 2023 OPPS Addendum B.

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

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

We approved 3 new devices, HCPCS codes C1747, C1826, and C1827, for pass-through status under the CY 2023 OPPS/ASC final rule with comment period. See Table 3A of CR 13136 for the long descriptor, status indicator, APC, and offset amount for these 3 HCPCS codes.

We're adding these 3 new device category codes and their pass-through expiration dates to Table 4 of CR 13136. We're 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. See Table 4 of CR 13136 for a 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 us to deduct from pass-through payments for devices an amount reflecting the device portion of the APC payment amount. This deduction is known as the device offset, or the portions of the APC amount 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

We assign certain designated new devices to APCs 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 devices used in the procedure. The I/OCE decides the proper payment amount for these APCs as well as the coinsurance and any applicable deductible.

We return all related payment calculations on the same APC line and identified as a designated new device. See 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.

Section 4141 of the Consolidated Appropriations Act (CAA) of 2023 amended Section 1833(t)(6) of the Act extending pass-through status for certain devices for a 1-year period beginning on January 1, 2023. The pass-through devices getting this extension are in Table 3B of CR 13136 and noted in Table 4 of CR 13136.

Since the pass-through status for these devices were set to expire on December 31, 2022, the pass-through device costs were packaged into the cost of the associated procedures which determined the procedure's CY 2023 APC assignment. The changes require that we don't remove the packaged cost of the extended pass-through device from the payment amount for a covered outpatient department (OPD) service for which it's packaged. We're maintaining the APC assignment for these procedures associated with these pass-through devices for CY 2023.

We're continuing the CY 2022 device offset amount, the device offset amount prior to packaging the pass-through device costs, for the procedures that are associated with the extended pass-through devices. The CY 2023 device offset amounts are in Table 3B of CR 13136. The device offset amounts for the associated procedures performed with the extended pass-through devices aren't reflected in Addendum P of the CY 2023 OPPS/ASC final rule with comment period.

d. Alternative Pathway for Devices That Have an FDA Breakthrough Designation

For devices that have FDA marketing authorization and a Breakthrough Device designation from the FDA, we provide an alternative pathway to qualify for device pass-through payment status. Under this, the devices wouldn't 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 getting pass-through payment status effective on or after January 1, 2020. See the current information on the device criteria to qualify for pass-through status under the OPPS.

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

Under the OPPS, categories of devices are eligible for transitional pass-through payments for at least 2 but not more than 3 years. Table 3C of CR 13136 lists the code. The device category HCPCS code will remain active, but we include its payment in the primary service.

As a reminder, for OPPS billing, because we use charges related to packaged services for outlier and future rate setting, you should report the device category HCPCS codes on the claim whenever they're provided in the OPD setting. It's extremely important that hospitals report all HCPCS codes consistent with their descriptors, CPT, and CMS instructions and correct coding principles, as well as all charges for all services they provide, whether we pay for the services separately or 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, see Table 4 of CR 13136.

f. Device Pass-Through Category Removal

As discussed in the October 2022 OPPS and ASC Update CRs, we conditionally approved a new device for pass-through status effective October 1, 2022. We established HCPCS code C1834 (Pressure sensor system, includes all components (e.g., introducer, sensor), intramuscular (implantable), excludes mobile (wireless) software application), effective October 1, 2022. After further review, we determined that the conditional approval was in error, and we're deleting the code on March 31, 2023. Note that we have no claims data for C1834, so there should be no reprocessing of claims for HCPCS code C1834.

5. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2023 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting April 1, 2023

HCPCS codes for 12 new drugs, biologicals, and radiopharmaceuticals will get pass-through status on April 1, 2023. These HCPCS codes are in Table 5 of CR 13136.

There are 2 new drugs, biologicals, and radiopharmaceuticals getting pass-through status HCPCS codes with a status indicator change for April 1, 2023. These codes are in Table 6 of CR 13136.

b. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on March 31, 2023

There are 8 HCPCS codes for drugs, biologicals, and radiopharmaceuticals in the outpatient setting with pass-through status ending on March 31, 2023. These codes are in Table 7 of CR 13136. Effective April 1, 2023, the status indicator for these codes is changing from "G" to either "K" or "N."

c. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of April 1, 2023

We established 21 new drug, biological, and radiopharmaceutical HCPCS codes on April 1, 2023. These HCPCS codes are in Table 8 of CR 13136.

d. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted on March 31, 2023

We're deleting 2 drug, biological, and radiopharmaceutical HCPCS codes on March 31, 2023. These HCPCS codes are in Table 9 of CR 13136.

e. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Will Have a Changing Status Indicator and APC for April 1, 2023

One drug, biological, and radiopharmaceutical HCPCS code will have a changing status

indicator and APC for April 1, 2023. See Table 10 of CR 13136.

f. Drugs and Biologicals that Will Have Manual Adjudication Status on April 1, 2023

HCPCS code J1411 (Injection, etranacogene dezaparvovec-drlb, per therapeutic dose) is receiving pass-through status starting April 1, 2023. MACs will manually pay these claims following the average sales price (ASP) methods. Due to the manual payment for HCPCS code J1411, we assign a zero ($0.00) payment rate to APC 9138, which will serve as an additional prompt for the MAC to manually price the code.

HCPCS code J3399 (Injection, Onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes) is having its status indicator changed from "A" to "K" starting April 1, 2023, as listed in Table 10 of CR 13136. MACs will manually pay these claims following the ASP methods. We'll assign a zero ($0.00) payment rate to APC 9141, which will serve as an additional prompt for the MAC to manually price the code.

g. Drugs and Biologicals with Payments Based on ASP

For CY 2023, payment for the majority of non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals is generally made at a single rate of ASP plus 6%—or ASP plus 6 or 8% of the reference product for biosimilars. In CY 2023, a single payment of ASP plus 6% for pass-through drugs, biologicals, and radiopharmaceuticals is generally made to provide payment for the acquisition cost and pharmacy overhead costs of these pass-through items—or ASP plus 6 or 8% of the reference product for biosimilars. We update payments for drugs and biologicals based on ASPs on a quarterly basis as later quarter ASP submissions become available.

Effective April 1, 2023, payment rates for many drugs and biologicals have changed from the values published in the CY 2023 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the fourth quarter of CY 2022. In cases where adjustments to payment rates are necessary, changes to the payment rates are incorporated in the April 2023 Fiscal Intermediary Standard System (FISS) release. The updated payment rates effective April 1, 2023, are in the April 2023 update of the OPPS Addendum A and Addendum B.

h. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Some drugs and biologicals paid based on ASP methods will have retroactive corrected payment rates. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be available on the first date of the quarter. You may resubmit claims affected by adjustments to a prior quarter's payment files.

6. Skin Substitutes

The payment for skin substitute products that don't qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. For payment packaging purposes, we divide the skin substitute products into 2 groups: high cost

skin substitute products and low cost skin substitute products. We assign new skin substitute HCPCS codes into the low-cost skin substitute group unless we have 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 April 1, 2023

There are 7 new skin substitute HCPCS codes that will be active as of April 1, 2023. These codes are in Table 11 of CR 13136.

7. OPPS Payment Files (Addenda A and B) Format Change

Effective January 1, 2023, the Inflation Reduction Act (IRA) of 2022 specifies that drug companies that raise their prices for certain Medicare Part B drugs faster than the rate of inflation must pay Medicare a rebate. We'll adjust patient coinsurance for certain Part B drugs, including biological products, with prices that increased at a rate faster than the rate of inflation so patient coinsurance is based on the lower inflation-adjusted payment amount. This new inflation rebate applies to certain Part B single source drugs and biological products, including biosimilar biological products.

Starting April 1, 2023, when the Part B payment amount for a Part B rebatable drug for a calendar quarter is higher than the inflation-adjusted payment amount:

- Patient coinsurance will be based on 20% of the inflation-adjusted payment amount for the quarter and will be reflected as a percentage that's less than 20% of the Part B payment amount
- The Medicare portion of the payment will be increased to the difference between the Part B payment amount and patient coinsurance, minus any Part B deductible and sequestration
- Patients will be charged the correct amount of coinsurance, which may change quarterly

More information about the IRA and its impact is included in the CY 2023 OPPS/ASC final rule.

Due to this change, effective April 1, 2023, the OPPS Addenda A and B will include the following changes:

- Addition of a new column for **"Adjusted Beneficiary Copayment"** to identify any copayment adjustment due to either the inpatient deductible amount copayment cap, or the inflation-adjusted copayment of a Part B rebatable drug per IRA provisions
- Revision to the **"Note"** column which can now contain multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code will be capped at the inpatient deductible of $1,600.00, or that the 8% of the reference product add-on applied for a biosimilar

8. 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 doesn't imply coverage by the Medicare Program but indicates only how the product, procedure, or service may be paid if covered by the Program. MACs determine whether a drug, device, procedure, or other service meets all Program requirements for coverage. For example, MACs determine that it's reasonable and necessary to treat the patient's condition and whether it's excluded from payment.

More Information

We issued CR 13136 to your MAC as the official instruction for this change.

For more information, find your MACs' website.

Document History

Date of Change	Description
April 3, 2023	A revision to CR 13136 changed a reference to ASP calculations based on sales price submissions from the third quarter of CY 2022 to the fourth quarter. We made the same change in Section 5g (page 6) of the Article. The change is in dark red.
March 17, 2023	Initial article released.