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Hospital Outpatient Prospective Payment System: July 2024 Update

Related CR Release Date: May 31, 2024

Effective Date: July 1, 2024

Implementation Date: July 1, 2024

MLN Matters Number: MM13632

Related Change Request (CR) Number: CR 13632

Related CR Transmittal Number: R12665CP

Related CR Title: July 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Affected Providers

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

Action Needed

Make sure your billing staffs know about these payment system updates for July:

- New CPT and HCPCS codes
- Covered devices for OPPS pass-through payments
- Drugs, biologicals, and radiopharmaceuticals
- Skin substitutes

Background

CR 13632 gives instructions on coding changes and policy updates effective July 1, 2024, for the OPPS. The OPPS changes are:

1. Update for COVID-19 Monoclonal Antibody Therapy Product and Administration Code

On March 22, 2024, the FDA released an Emergency Use Authorization (EUA) for the emergency use of PEMGARDA (pemivibart) for the pre-exposure prophylaxis of COVID-19 in certain adults and adolescents. The HCPCS code for PEMGARDA is Q0224. The HCPCS code for the service to administer PEMGARDA in health care settings is M0224. These codes along with their descriptors are in Table 1 of CR 13632.

Effective March 22, 2024, CMS assigned Q0224 to status indicator “L” (Not paid under OPPS.

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Paid at reasonable cost; not subject to deductible or coinsurance). Effective March 22, 2024, we assigned M0224 to status indicator "S" (Paid under OPPS; separate APC payment), Ambulatory Payment Classification (APC) 1506 (New Technology - Level 6 ($401 - $500)).

Note: We didn't create a HCPCS code describing the service to administer PEMGARDA in the home or residence setting since the EUA states, "PEMGARDA should only be administered in settings in which healthcare providers have immediate access to medications to treat a severe hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary."

Patient cost-sharing doesn't apply to the PEMGARDA product code or the administration of the dose of PEMGARDA in a health care setting.

2. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective July 1, 2024

The American Medical Association (AMA) CPT Editorial Panel established 26 new PLA codes, specifically, CPT codes 0450U-0475U, effective July 1, 2024. Table 2 of CR 13632 lists the long descriptors and status indicators for the codes. For more information on OPPS status indicators, see OPPS Addendum D1 of the CY 2024 OPPS/Ambulatory Surgical Center (ASC) final rule for the latest definitions.

3. OPPS Device Pass-Through

a. New Device Pass-Through Categories Effective July 1, 2024
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. The Act requires us to create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

We preliminarily approved 2 new devices for pass-through status under the OPPS with an effective date of July 1, 2024. We preliminarily approved HCPCS codes C1605 and C1606 as part of the device pass-through quarterly review process.

We'll discuss the device applications associated with HCPCS codes C1605 and C1606 in the CY 2025 OPPS/ASC proposed and final rules. Table 3A of CR 13632 has the long descriptor, status indicator, APC, and offset amount for these 2 HCPCS codes.

We're also adding these 2 new device category codes and their pass-through expiration dates to Table 4 of CR 13632. Table 4 has the complete list of device category HCPCS codes and definitions used for present and previous transitional pass-through payment.

b. Clarification for an Existing Device Pass-Through Category C1601
As we discussed in Section IV.A.2. New Device Pass-Through Applications for CY 2024 of the CY 2024 OPPS/ASC final rule with comment period, we approved HCPCS code C1601 (Endoscope, single-use (i.e. disposable), pulmonary, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2024.

As referenced in the code descriptor for HCPCS code C1601, this category is specific to devices that are single-use (in other words, disposable) devices and doesn't include reprocessed devices, including devices that may be referred to as "reprocessed single-use devices" or any other devices used more than once regardless of how the device is described.

c. Clarification for an Existing Device Pass-through Category C1602
As we discussed in Section IV.A.2. New Device Pass-Through Applications for CY 2024 of the CY 2024 OPPS/ASC final rule with comment period, we approved HCPCS code C1602 (Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2024.

d. Updates for Device Offset Amounts to an Existing Device Code C1604
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 portions of the APC amount that are 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.

Effective January 1, 2024, we pair CPT code 0505T to be billed with HCPCS code C1604, as listed in the January 2024 Update of the Hospital OPPS, CR 13488, Transmittal 12421, dated December 21, 2023.

Note: We're updating the device offset amount for the CPT code paired with HCPCS code C1604 $0.00, effective January 1, 2024.

e. Expiring Pass-through Status for Device Category HCPCS Code C1761 Effective July 1, 2024
As specified in Section 1833(t)(6)(B) of the Act, under the OPPS, categories of devices are eligible for transitional pass-through payments for at least 2, but not more than 3 years. For the July 2024 update, the pass-through status period for 1 device category, HCPCS code C1761, will expire on June 30, 2024. This device category HCPCS code will remain active; however, its payment will be included in the primary service. Table 3B and Table 4 of CR 13632 have the long descriptor associated with HCPCS code C1761.

For OPPS billing, we use charges related to packaged services for outlier and future rate setting. So, we advise hospitals to report the device category HCPCS codes on the claim whenever they're provided in the outpatient setting. As we state in Section 10.4 of the Medicare Claims Processing Manual, Chapter 4, 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 payment for the services is made separately or is packaged.

Table 4 of CR 13632 has the entire list of current and historical device category codes created since August 1, 2000.

4. New CPT Category III Codes Effective July 1, 2024

The AMA releases CPT Category III codes twice per year: in January, for implementation starting the following July, and in July, for implementation starting the following January.

For the July 2024 update, we're implementing 34 new CPT Category III codes that the AMA released in January 2024 for implementation on July 1, 2024. The status indicators and APC assignments for these codes are in Table 5 of CR 13632.

5. Medicare Category B Investigational Device Exemption (IDE) Coverage of Elios System to Reduce Intraocular Pressure in Patients with Primary Open-Angle Glaucoma

On November 30, 2023, we granted Medicare coverage, as a Category B IDE study, for the clinical trial associated with Elios Vision's Elios System to reduce intraocular pressure in patients with primary open angle glaucoma as a standalone surgical procedure. Currently, the code to describe this standalone surgical procedure is CPT code 0621T (Trabeculostomy ab interno by laser). Based on the Medicare coverage approval, we're revising the code payment assignment from status indicator "E1" (not covered/not payable by Medicare) to APC 5492 (Level 2 Intraocular Procedures) and OPPS status indicator "J1" (Hospital Part B Services Paid Through a Comprehensive APC; paid under OPPS.) effective January 1, 2024.

Table 6 of CR 13632 shows the information associated with the clinical study, which is also posted on the CMS approved IDE studies website.

Table 7 of CR 13632 lists the long descriptor, status indicator, and APC assignment for CPT code 0621T.

6. New HCPCS Code Describing Endoscopic Defect Closure Within the Entire Gastrointestinal Tract Including Upper Endoscopy or Colonoscopy When Performed

We created HCPCS code C9901 to describe endoscopic defect closure within the entire gastrointestinal tract including upper endoscopy or colonoscopy when performed. Table 8 of CR 13632 lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9901.

7. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2024 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Effective July 1, 2024
We're creating 6 new HCPCS codes for reporting drugs and biologicals in the hospital outpatient setting, where there haven't been specific codes available starting on July 1, 2024. These drugs and biologicals will get drug pass-through status starting July 1, 2024. These HCPCS codes are listed in Table 9 of CR 13632.

b. Existing CY 2024 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Retroactive to

January 1, 2024
HCPCS code J7353 will get drug pass-through status retroactive to January 1, 2024. See Table 10 of CR 13632.

c. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on June 30, 2024
There are 11 HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on June 30, 2024. These HCPCS codes are in Table 11 of CR 13632. Effective July 1, 2024, the status indicator for these codes is changing from "G" to "K" or "N."

d. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of July 1, 2024
Table 12 of CR 13632 lists 49 new drug, biological, and radiopharmaceutical HCPCS codes we're establishing on July 1, 2024.

e. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Deleted as of June 30, 2024
Table 13 of CR 13632 lists 4 drug, biological, and radiopharmaceutical HCPCS codes we're deleting on June 30, 2024.

f. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals Changing Payment Status on July 1, 2024
Table 14 of CR 13632 lists 9 drug, biological, and radiopharmaceutical HCPCS codes with a revised payment status on July 1, 2024. It was too late to change the status indicator for the HCPCS code J9324 from status indicator "E2" to status indicator "K," APC 0782, in the July 2024 Integrated Outpatient Code Editor (I/OCE) Update, due to the operational timelines. We'll include this change in the October 2024 I/OCE Update retroactive to July 1, 2024.

g. HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals with Descriptor Changes as of July 1, 2024
Table 15 of CR 13632 lists 3 drug, biological, and radiopharmaceutical HCPCS codes with a substantive descriptor change as of July 1, 2024.

h. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals with a Descriptor Change Retroactive to April 1, 2024
We changed the descriptor for HCPCS code C9167 retroactive to April 1, 2024, as we show in Table 16 of CR 13632.

i. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)
For CY 2024, payment for the majority of non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals is at a single rate of ASP + 6% (or ASP plus 6 or 8% of the reference product for biosimilars). In CY 2024, a single payment of ASP plus 6% for pass-through drugs,

biologicals, and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP plus 6 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 are available. Effective July 1, 2024, payment rates for many drugs and biologicals have changed from the values published in the CY 2024 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from third quarter of CY 2023. In cases where adjustments to payment rates are necessary, changes to the payment rates will be made to the July 2024 Fiscal Intermediary Standard System (FISS) release. We're not publishing the updated payment rates in CR 13632.

However, the updated payment rates effective July 1, 2024, are in the July 2024 update of the OPPS Addendum A and Addendum B updates.

j. 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 we correct retroactively. These retroactive corrections typically occur on a quarterly basis. See the list of drugs and biologicals with corrected payments rates on the first date of the quarter for these corrected rates. You may resubmit claims affected by adjustments to a previous quarter's payment files.

8. 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:

1. High cost skin substitute products
2. Low cost skin substitute products

New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless we have pricing data that shows the cost of the product is above either the mean unit cost of $47 or the per day cost of $807 for CY 2024.

a. New Skin Substitute Products as of July 1, 2024
Table 17 of CR 13632 lists 23 new skin substitute HCPCS codes that will be active as of July 1, 2024.

b. Skin Substitute Product Codes Deleted Effective June 30, 2024
Table 18 of CR 13632 lists 2 skin substitute product codes we're deleting as of June 30, 2024.

9. Coverage Determinations

As a reminder, the fact that we assign a HCPCS code and a payment rate under the OPPS to a drug, device, procedure, or service 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 13632 to your MAC as the official instruction for this change.

For more information, find your MAC's website.

Document History

Date of Change	Description
June 3, 2024	Initial article released.