

# Hospital Outpatient Prospective Payment System: October 2025 Update

Related CR Release Date: September 22, 2025	MLN Matters Number: MM14223
Effective Date: October 1, 2025	Related Change Request (CR) Number: <u>CR 14223</u>
Implementation Date: October 6, 2025	Related CR Transmittal Number: R13425CP

### **Affected Providers**

- Hospitals
- Physicians
- Other providers billing Medicare Administrative Contractors (MACs) for outpatient hospital services

### **Action Needed**

Make sure your billing staff knows about these Hospital Outpatient Prospective Payment System (OPPS) updates effective October 1, 2025, including coding and billing changes for:

- New COVID-19 monoclonal antibody and pleural-peritoneal shunt HCPCS codes
- CPT proprietary laboratory analyses (PLA) and Hospital OPPS device categories
- Status indicator updates
- Drugs, biologicals, and radiopharmaceuticals
- Skin substitutes

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# **Background**

CR 14233 provides instructions on coding changes and policy updates that are effective October 1, 2025, for the Hospital OPPS.

**Note:** For more information on status indicators and the latest definitions, refer to <u>Addendum D1</u> of the CY 2025 Hospital OPPS and Ambulatory Surgical Center (ASC) final rule.

# **Key Updates**

### **Status Indicator Changes for a COVID-19 Vaccine Code**

On April 1, 2025, the American Medical Association (AMA) released CPT code 91323 associated with a COVID-19 vaccine. On August 27, 2025, FDA approved the vaccine and code.

Effective August 27, 2025, CMS is retroactively changing the code's status indicator from E1 to L in the October 2025 Integrated Outpatient Code Editor (I/OCE). See <u>Table 1</u> and the <u>October 2025 Hospital OPPS Addendum B</u> for the descriptors and status indicator.

### **New COVID-19 Monoclonal Antibody Products & Administration Codes**

We established HCPCS Level II code Q0237 to describe AVTOZMA® for post-exposure prophylaxis or treatment of COVID-19 and its associated administrative codes. HCPCS Level II codes Q0237, M0237, and M0238 have the same effective date as FDA approval to align with the appropriate Medicare payment policies.

- Q0237 Injection, tocilizumab-anoh, for hospitalized adult patients 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
- M0237 Intravenous infusion, tocilizumab-anoh, for hospitalized adult patients 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
- M0238 Intravenous infusion, tocilizumab-anoh, for hospitalized adult patients 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

Effective January 24, 2025, in the October 2025 I/OCE update, we're assigning:

- HCPCS code Q0237 to status indicator L
- HCPCS codes M0237 and M0238 to status indicator S and ambulatory payment classification (APC) 1506

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We're also establishing a not otherwise classified COVID-19 monoclonal antibody product HCPCS Level II code and associated administrative codes for any newly FDA-approved products that we haven't assigned to a unique HCPCS Level II code while the <a href="Emergency Use Authorization"><u>Emergency Use Authorization</u></a> declaration under section 564 of the <a href="Federal Food">Federal Food</a>, <a href="Drug">Drug</a>, and <a href="Cosmetic Act remains in effect">Cosmetic Act remains in effect</a>.

- Q0235 Injection, monoclonal antibody products with an indication for post-exposure prophylaxis
  or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving
  systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical
  ventilation, or extracorporeal membrane oxygenation (ECMO) only, not otherwise classified, 1 mg
- M0235 Intravenous infusion, monoclonal antibody products with an indication for post-exposure
  prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients 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, not otherwise classified, first dose
- M0236 Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients 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, not otherwise classified, second dose

Effective October 1, 2025, in the October 2025 I/OCE update, we're assigning:

- HCPCS code Q0235 to status indicator L
- HCPCS codes M0235 and M0236 to status indicator S and APC 1506

### **CPT PLA Coding Changes**

#### **New CPT PLA Codes**

The AMA CPT Editorial Panel established 25 new PLA codes, CPT codes 0575U–0599U, effective October 1, 2025. See <u>Table 2</u> for the list of codes and their status indicators. Refer to Addendum B for the short descriptors and status indicators.

### **Status Indicator Change for CPT PLA Code**

We're changing the status indicator for CPT PLA code 0211U from E1 to A effective November 5, 2024. See <u>Table 3</u> for the code and its status indicator. Refer to Addendum B for the short descriptor and status indicator.

# **Hospital OPPS Device Pass-Through**

Section 1833(t)(6)(B) of the <u>Social Security Act</u> requires that, under the Hospital OPPS, categories of devices be eligible for transitional pass-through payments for at least 2 but not more than 3 years. Also, section 1833(t)(6)(B)(ii)(IV) of the Social Security 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.

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### **New Device Pass-Through Category**

Through our quarterly review process, we preliminarily approved 3 new device HCPCS codes C1740–C1742 for pass-through status under the Hospital OPPS with an effective date of October 1, 2025. We'll include and discuss the device applications associated with these codes in the CY 2027 Hospital OPPS and ASC proposed and final rules.

See <u>Table 4A</u> for the list of codes. See <u>Table 5</u> for the complete list of device category HCPCS codes and definitions we used for past and present transitional pass-through payment.

### **Device Offset from Payment**

Section 1833(t)(6)(D)(ii) of the <u>Social Security Act</u> requires that we deduct an amount that reflects the device portion of the APC amount from pass-through payments for devices. This deduction is the device offset or the portion of the APC amount that's 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.

### Descriptor Updates to Existing Device Pass-Through Category HCPCS Code C1739

In CR 13933, we noted that we preliminarily approved HCPCS code C1739 as part of the device pass-through quarterly review process with an effective date of January 1, 2025. We'll include and discuss the device application associated with this code in the CY 2026 Hospital OPPS and ASC proposed and final rules.

Effective January 1, 2025, we're updating the descriptors for HCPCS code C1739:

- Long descriptor: Tissue marker, uniquely detectable and identifiable with probe/sensor, any method (implantable), with delivery system
- Short descriptor: Marker uniq detect w/prbe

See <u>Table 4B</u> for the long descriptor and the <u>Medicare Claims Processing Manual, Chapter 4</u>, section 60.4.2 for the entire list of current and historical device category codes.

# New HCPCS Code Describing the Insertion of a Pleural-Peritoneal Shunt with Intercostal Pump Chamber

We're establishing a new HCPCS code C8006 to describe the procedure to insert a pleural-peritoneal shunt with an intercostal pump chamber. See <u>Table 6</u> for the long descriptor, status indicator, and APC assignment. Refer to Addendum B for the short descriptor, status indicator, and payment rate.

# **Descriptor Revision for HCPCS Code C1982**

We're revising the long descriptor for HCPCS code C1982 (Catheter, pressure-generating, (e.g., one-way valve, intermittently occlusive)) to align the device descriptor with the procedure descriptors. C1982 describes a pressure-generating catheter that's used with vascular embolization or occlusion procedures and simulation procedures.

See <u>Table 7</u> for the code and its status indicator. Refer to Addendum B for the short descriptor, status indicator, and payment rate.



### **Drugs, Biologicals & Radiopharmaceuticals**

# New CY 2025 HCPCS Codes & Dosage Descriptors for Certain Drugs, Biologicals & Radiopharmaceuticals Receiving Pass-Through Status

We created 7 new HCPCS codes for reporting drugs and biologicals in the hospital outpatient setting where specific codes weren't previously available starting on October 1, 2025. See <u>Table 8</u> for the list of these codes that will receive drug pass-through status starting October 1, 2025.

# Existing HCPCS Codes for Certain Drugs, Biologicals & Radiopharmaceuticals Starting Pass-Through Status

Three existing HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting will have their pass-through status start on October 1, 2025, with a status indicator of G. See Table 9 for the list of codes.

# Existing HCPCS Codes for Certain Drugs, Biologicals & Radiopharmaceuticals with Pass-Through Status

Seven HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting will have their pass-through status end on September 30, 2025, with a new status indicator of G, K, or N. See <u>Table 10</u> for the list of codes. Refer to Addendum B for the short descriptors and status indicators.

### Newly Established HCPCS Codes for Drugs, Biologicals & Radiopharmaceuticals

We're establishing 35 new drug, biological, and radiopharmaceutical HCPCS codes on October 1, 2025. See Table 11 for the list of codes.

### Deleted HCPCS Codes for Drugs, Biologicals & Radiopharmaceuticals as of October 1, 2025

We're deleting 2 drug, biological, and radiopharmaceutical HCPCS codes on September 30, 2025. See <u>Table 12</u> for the list of codes.

### Reinstated HCPCS Codes for Drugs, Biologicals & Radiopharmaceuticals

We're reinstating 1 drug, biological, and radiopharmaceutical HCPCS code on October 1, 2025. See <u>Table 13</u> for the code and its status indicator.

# Payment Status Indicator Changes to HCPCS Codes for Drugs, Biologicals & Radiopharmaceuticals

We're changing payment status indicators for 44 drug, biological, and radiopharmaceutical HCPCS codes on October 1, 2025. We listed the status indicators for these HCPCS codes as E2 and G in the July 2025 Addendum B.

See <u>Table 14</u> for the list of codes and their status indicators. We're making these changes in the October 2025 I/OCE update effective October 1, 2025.



# Retroactive Payment Status Indicator Changes to HCPCS Codes for Drugs, Biologicals & Radiopharmaceuticals

We're changing payment status indicators for 6 drug, biological, and radiopharmaceutical HCPCS codes to K, M, or N retroactive to July 1, 2025. We listed the status indicators for these HCPCS codes as E2 in the July 2025 Addendum B.

See <u>Table 15</u> for the list of codes and their revised status indicators. We're making these changes in the October 2025 I/OCE update effective October 1, 2025.

### Descriptor Changes to HCPCS Codes for Drugs, Biologicals & Radiopharmaceuticals

We're making substantial descriptor changes to 2 drug, biological, and radiopharmaceutical HCPCS codes as of October 1, 2025. See Table 16 for the list of codes.

### **Drugs & Biologicals with Payments Based on Average Sales Price**

For CY 2025, we pay for most non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals at a single rate of average sales price (ASP) +6% (or ASP +6 or 8% of the reference product for biosimilars). In CY 2025, we make a single payment of ASP +6% for pass-through drugs, biologicals, and radiopharmaceuticals for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP +6 or 8% of the reference product for biosimilars). We update payments for drugs and biologicals based on ASPs quarterly as later-quarter ASP submissions become available.

Starting January 1, 2025, we've changed the payment rates for many drugs and biologicals from the values we published in the CY 2025 Hospital OPPS and ASC final rule because of new ASP calculations from sales price submissions in the second quarter of CY 2025. When we need to adjust payment rates, we'll incorporate them into the October 2025 Fiscal Intermediary Standard System release. We aren't publishing the updated payment rates in this CR; however, you can find the updated payment rates effective October 2025 in the October 2025 Hospital OPPS Addendums A and B.

### Drugs & Biologicals Based on ASP Methodology with Restated Payment Rates

We'll retroactively correct payment rates for some drugs and biologicals based on ASP methodology. These corrections occur quarterly. Find the latest list of drugs and biologicals with <u>corrected payment rates</u> on the first date of each quarter.

You may resubmit claims affected by adjustments to a prior quarter's payment files.

#### Skin Substitutes

We package payment for skin substitute products that don't qualify for pass-through status into the payment for the associated skin substitute application procedure. We divide skin substitute products into 2 groups for payment purposes:

- High-cost skin substitute products
- Low-cost skin substitute products



We assign new skin substitute HCPCS codes into the low-cost skin substitute group unless we have pricing data demonstrating the product cost is above either the mean unit cost of \$50 or the per-day cost of \$833 for CY 2025.

#### **New Skin Substitute Products**

Nineteen new skin substitute HCPCS codes will be active as of October 1, 2025. See <u>Table 17</u> for the list of codes.

### Skin Substitute Products Reassigned to the High-Cost Skin Substitute Group

We're reassigning 1 skin substitute HCPCS code from the low-cost to the high-cost skin substitute group as of October 1, 2025. See <u>Table 18</u> for the code.

### **Coverage Determinations**

Remember, when we assign a HCPCS code and payment rate to a drug, device, procedure, or service under the Hospital OPPS, it doesn't imply Medicare coverage. It only indicates how we pay for the product, procedure, or service if covered. MACs decide whether a drug, device, procedure, or other service meets program requirements for coverage. For example, MACS decide that it's reasonable and necessary to treat the patient's condition and whether it's excluded from payment.

**Note:** Your MAC will adjust claims you bring to their attention with any retroactive changes received prior to implementing the October 2025 Hospital OPPS Pricer.

### **More Information**

We issued CR 14223 to your MAC as the official instruction for this change. For more information, find your MAC's website.

# **Document History**

Date of Change	Description
September 25, 2025	Initial article released.

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