



April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)

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Note: We revised this article on October 29, 2019, to add a reference to a related article, [SE19009](#) which replaces Section 6 - Chimeric Antigen Receptor (CAR) T- Cell Therapy - instructions on pages 5-7 of this article. All other information is unchanged.

PROVIDER TYPES AFFECTED

This MLN Matters Article is for hospital outpatient facilities, physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for hospital outpatient services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11216 describes changes to, and billing instructions for, various payment policies implemented in the April 2019 OPPS update. The April 2019 Integrated Outpatient Code Editor (I/OCE) will reflect the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in CR11216. Make sure your billing staffs are aware of these changes.

BACKGROUND

The April 2019 revisions to I/OCE data files, instructions, and specifications are provided in CR 11192. You will find an article related to that CR at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11192.pdf>. The following summarizes the OPPS changes for April 2019.

Proprietary Laboratory Analyses (PLA) Current Procedural Terminology (CPT) Coding Changes Effective January 1, 2019

The American Medical Association (AMA) CPT Editorial Panel established four new PLA CPT codes, specifically, CPT codes 0080U through 0083U effective January 1, 2019. Because the codes were released on November 30, 2018, they were too late to include in the January 2019 OPPS update and are instead included in the April 2019 update with an effective date of January 1, 2019.

Table 1 lists the long descriptors and status indicators for CPT codes 0080U through 0083U. For more information on OPPS status indicators "A" and "Q4", refer to OPPS Addendum D1 of the Calendar Year (CY) 2019 OPPS/ASC (Ambulatory Surgery Center) final rule for the latest definitions. CPT codes 0080U through 0083U have been added to the April 2019 I/OCE with an effective date of January 1, 2019. These codes, along with their short descriptors and status indicators, will also be in the April 2019 OPPS Addendum B at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>.

Table 1 – Proprietary Laboratory Analyses (PLA) CPT Coding Changes Effective January 1, 2019

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0080U	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy	Q4	N/A
0081U	Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	A	N/A
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service	Q4	N/A
0083U	Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations	Q4	N/A

2. New Advanced Diagnostic Laboratory Test (ADLT) Under the Clinical Lab Fee Schedule (CLFS)

On December 21, 2018, effective January 1, 2019, the laboratory test described by CPT code 81538 (Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival), was approved as an ADLT. Based on the ADLT designation, the Centers for Medicare & Medicaid Services (CMS) revised the OPPS status indicator for CPT code 81538 from "Q4" to "A" effective January 1, 2019. However, because the code's ADLT designation was made in

December 2018, it was too late to include this change the January 2019 OPPS update, therefore, CMS is including this change in the April 2019 update with an effective date of January 1, 2019. The latest list of ADLT codes is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/List-of-Approved-ADLTs.pdf>.

For more information on the OPPS status indicators “A” and “Q4”, refer to OPPS Addendum D1 of the CY 2019 OPPS/ASC final rule for the latest definitions. CMS has added CPT code 81538 to the April 2019 I/OCE with an effective date of January 1, 2019. CPT code 81538, along with its short descriptor and status indicator, is also listed in the April 2019 OPPS Addendum B.

3. The Comprehensive APC (C-APC) Exclusion List

CR 11216 updates the Comprehensive APC (C-APC) exclusion list in section 10.2.3, chapter 4 of the Medicare Claims Processing Manual to match the list provided in Addendum J of the CY 2019 OPPS/ASC Final Rule. The additions to the list included brachytherapy sources, self-administered drugs, services assigned to status indicators F and L, certain part B inpatient services, and therapy services.

4. Drugs, Biologicals, and Radiopharmaceuticals

a. New HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2019, seven 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. These new codes are listed below in Table 2.

Table 2 – New HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective April 1, 2019

HCPCS Code	Long Descriptor	SI	APC
C9040	Injection, fremanezumab-vfrm, 1mg	G	9197
C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198
C9141	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299
C9043	Injection, levoleucovorin, 1 mg	G	9303
C9044	Injection, cemiplimab-rwlc, 1 mg	G	9304
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307

b. Separately Payable Drugs and Biologicals that Will Receive Pass-Through Status (Status Indicator “G”) Effective April 1, 2019

Some separately payable drugs and biologicals will change from status indicator “K” to status indicator “G” effective April 1, 2019 as these drugs and biologicals have been given pass-through status. These drugs and biologicals are reported below in Table 3.

Table 3 – Other CY 2019 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective April 1, 2019

HCPCS Code	Long Descriptor	Old SI	New SI	APC
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	K	G	9173
J3245	Injection, tildrakizumab, 1 mg	E2	G	9306
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	K	G	9193
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenycya), 0.5 mg	K	G	9195

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

For CY 2019, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP - 22.5 percent if acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2019, 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. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available.

Effective April 1, 2019, payment rates for some drugs and biologicals have changed from the values published in the January 2019 update of the OPSS Addendum A and Addendum B available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>. CMS is not publishing the updated payment rates in this CR implementing the April 2019 update of the OPSS. However, the updated payment rates effective April 1, 2019 are in the April 2019 update of the OPSS Addendum A and Addendum B available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>.

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

Some drugs and biologicals 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 impacted by adjustments to previous quarter's payment files.

5. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group

Four skin substitute products, HCPCS codes Q4183, Q4184, Q4194, and Q4203 have been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The products are listed in Table 4.

Table 4 – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective April 1, 2019

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2019 SI	Low/High Cost Skin Substitute
Q4183	Surgigraft, 1 sq cm	N	High
Q4184	Cellesta, 1 sq cm	N	High
Q4194	Novachor 1 sq cm	N	High
Q4203	Derma-gide, 1 sq cm	N	High

6. Chimeric Antigen Receptor (CAR) T- Cell Therapy

Note: These instructions for CAR T-Cell Therapy are replaced by those in MLN Matters Special Edition article [SE19009](#).

(CAR) T-cell therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention.

As stated in the CY 2019 OPSS/ASC final rule, CMS is continuing OPSS pass-through payment status for CAR T HCPCS codes Q2041 (Yescarta) and Q2042 (Kymriah) (see long descriptors in Table 5). The OPSS pass-through payment rate is determined following the standard ASP methodology, updated on a quarterly basis if applicable information indicates that adjustments to the payment rates are necessary.

As shown in Table 5, the HCPCS Q-code for each currently approved CAR T-cell therapy includes leukapheresis and dose preparation procedures. The procedures described by CPT codes 0537T, 0538T, and 0539T describe various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. Therefore, in the CY 2019 OPSS/ASC final rule, CPT codes 0537T, 0538T, and 0539T were assigned to status indicator "B" (Codes that are not recognized by OPSS when submitted on an outpatient hospital Part B bill type (12x and 13x). However, as noted in the OPSS final rule, it will be possible for Medicare to track utilization and cost data from hospitals reporting these services, even for HCPCS codes reported for services in which no separate payment is made under the OPSS. The CAR T-cell related revenue codes and value code established by the National Uniform Billing Committee (NUBC) will be reportable on Hospital Outpatient Department (HOPD) claims, and will be available for tracking utilization and cost data, effective for claims received on or after April 1, 2019.

Table 5 – CAR T-cell Therapy Codes

HCPCS Code	Long Descriptors	SI	APC
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194
0537T	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	B	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)	B	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	5694

Effective April 1, 2019, hospitals may report CPT codes 0537T, 0538T, and 0539T, as non-covered items/services to allow for Medicare to track these services when furnished in the outpatient setting. Also, hospitals may report the CAR T-cell related revenue codes 087X

(Cell/Gene Therapy) and 089X (Pharmacy) as well as new value code 86 (Invoice Cost) established by the NUBC on HOPD claims.

CMS reminds hospitals that the administration of CAR T-cells in the hospital outpatient setting is paid separately under CPT code 0540T, which is assigned status indicator “S”.

Below is further clarification on billing of CAR-T related items and services in various clinical scenarios.

- **Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Setting:** In those instances when the CAR-T drug is administered in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As stated in the CY 2019 OPPTS/ASC final rule, the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect the cells and prepare the genetically modified T-cells are not separately payable. However, these services may be reported as non-covered charges on the outpatient claim.
- **Scenario 2: CAR-T Dosing and Preparation Services Administered in Hospital Outpatient Setting, but Viable T-cells not Administered:** In those instances when the CAR-T drug is not ultimately administered to the patient, but the CAR-T preparation services are initiated or performed in the HOPD facility, hospital outpatient departments may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim as non-covered charges.
- **Scenario 3: CAR-T Dosing and Preparation Services Administered in Hospital Outpatient Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:** When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting following inpatient admission to the hospital more than 3days after the related outpatient services are furnished, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). However, the charges associated with the CAR T-cell dosing and preparation services as described by CPT codes 0537T, 0538T, and 0539T may be reported on the inpatient claim (bill type 11x) using revenue code 0891 – Special Processed Drugs – FDA (Food and Drug Administration) Approved Cell Therapy - Charges for Modified cell therapy.

Providers who have additional questions not covered by CR 11216 should consult their MAC for additional guidance on billing for these services.

7. Modifier “ER”

Effective January 1, 2019, hospitals were required to report new HCPCS modifier “ER” (Items and services furnished by a provider-based off-campus emergency department) on every claim line that contains a CPT/HCPCS code for an outpatient hospital service furnished in an off-campus provider-based emergency department. Modifier ER would be reported on the UB-04

form (CMS Form 1450) for hospital outpatient services. Critical Access Hospitals (CAHs) would not be required to report this modifier.

Modifier ER is required to be reported in provider-based off-campus emergency departments that meet the definition of a “dedicated emergency department” as defined in 42 Code of Federal Regulations (CFR) 489.24 under the Emergency Medical Treatment and Labor Act (EMTALA) regulations. Per 42 CFR 489.24, a “dedicated emergency department” means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
- (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- (3) During the calendar year immediately preceding the calendar year in which a determination under 42 CFR 489.24 is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

This policy change is in the revised section 20.6.18 of Chapter 4 of the Medicare Claims Processing Manual, which is attached to CR 11216.

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 OPSS 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. 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.

ADDITIONAL INFORMATION

The official instruction, CR11216, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4255CP.pdf>.

See MLN Matters article SE19009 at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19009.pdf> for more current information on the instructions for CAR T-Cell therapy.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
October 29, 2019	We revised this article to add a reference to a related article, SE19009 which replaces CAR-T instructions in CR 11216 (page 7 in this article).
March 19, 2019	Initial article released.

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