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

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Note: This article was revised on January 18, 2019, to reflect an updated Change Request (CR) that corrected the link to the list of drugs and biologicals with corrected payments rates in Section I.B.11.d of that CR. The transmittal number, CR release date and link to the transmittal also changed. All other information is unchanged

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended 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 11099 describes changes to and billing instructions for various payment policies implemented in the January 2019 OPPS update. The January 2019 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 CR 11099. Be sure your billing staffs are aware of these changes.

BACKGROUND

The January 2019 revisions to I/OCE data files, instructions, and specifications listed below are provided in CR 11068. (See the related article, MM11068, at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11068.pdf.

1. a. New Device Pass-Through Categories

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 that the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

CMS is establishing one new device pass-through category as of January 1, 2019. Table 1 provides a listing of new coding and payment information concerning the new device

category for transitional pass-through payment.

Table 1 – New Device Pass-Through Code Effective January 1, 2019

HCPCS Code	Effective Date	Status Indicator (SI)	APC	Short Descriptor	Long Descriptor	Device Offset from Payment
C1823	01/01/2019	H	2993	Gen, neuro, trans sen/stim	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	$20,626.59

1. b. Device Offset from Payment

Section 1833(t)(6)(D)(ii) of the Act requires that CMS deduct from pass-through payments for devices an amount that reflects the portion of the APC payment amount. CMS has determined that a portion of the APC payment amount associated with the cost of C1823 is reflected in APC 5464 (Level 4 Neurostimulator and Related Procedures). The C1823 device should always be billed with Current Procedural Terminology (CPT) Code 0424T (Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)), which is assigned to APC 5464 for Calendar Year (CY) 2019. The device offset from payment represents a deduction from pass-through payments for the device in category C1823. Refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html for the most current device pass-through information.

1. c. Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned to APCs and identified by the 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. 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. CMS refers readers to Addendum P of the CY 2019 final rule with comment period for the most current OPPS HCPCS Offset file, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-CN2.html.

2. New Separately Payable Procedure Code

Effective January 1, 2019, new HCPCS codes C9751, C9752, C9753, C9754, and C9755 have been created as described in Table 2.

Table 2 – New Separately Payable Procedure Codes Effective January 1, 2019

HCPCS Code	Short Descriptor	Long Descriptor	APC	SI
C9751	Microwave bronch, 3D, EBUS	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	1571	T
C9752	Intraosseous des lumb/sacrum	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum	5115	J1
C9753	Intraosseous destruct add'l	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (List separately in addition to code for primary procedure)	N/A	N
C9754	Perc AV fistula, any site	Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)	5193	J1

HCPCS Code	Short Descriptor	Long Descriptor	APC	SI
C9755	RF magnetic-guided AV fistula	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed	5193	J1

3. Device Intensive Procedures

Effective January 1, 2019, CMS is modifying the device-intensive criteria to lower the device offset percentage threshold from greater than 40 percent to greater than 30 percent and to allow procedures that involve single-use devices, regardless of whether or not they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. Accordingly, effective January 1, 2019, all new procedures requiring the insertion of an implantable medical device will be assigned a default device offset percentage of at least 31 percent (previously at least 41 percent), and thereby assigned device intensive status, until claims data are available. In certain rare instances, CMS may temporarily assign a higher offset percentage if warranted by additional information. In light of this policy change, CMS is modifying the Medical Claims Processing Manual, chapter 4, section 20.6.4.

4. New HCPCS Code C1890 For When No Device Is Used in ASCs for Device-Intensive Procedures Effective January 1, 2019

In the CY2019 OPPS/ASC Final Rule, CMS finalized its policy to apply the ASC device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system, when the device intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices). Because devices are packaged into the procedure payment for device-intensive procedures, and ASCs do not report packaged codes, it is necessary to implement a mechanism to report when an ASC performs a device-intensive procedure without an implantable or inserted medical device. To implement this policy, CMS is establishing a new C-code that ASCs must report, specifically, HCPCS C1890, along with the device-intensive procedure code, to signify that the device was not furnished with the device-intensive procedure. This code is payable in the ASC setting only, and should not be reported on institutional claims by hospital outpatient department providers. Therefore, HCPCS code C1890 is assigned to SI=E1 (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) under the OPPS.

Since this HCPCS code is not included on the current 2019 Alphanumeric HCPCS release, MACs will add this code to their system. The C1890 short descriptor is: No device w/dev-

intensive px. The long descriptor is: No implantable/insertable device used with device-intensive procedures.

5. Three New Comprehensive APCs (C-APCs) Effective January 1, 2019

Comprehensive APCs provide a single payment for a primary service, and payment for all adjunctive services reported on the same claim is packaged into payment for the primary service. With few exceptions, all other services reported on a hospital outpatient claim in combination with the primary service are considered to be related to the delivery of the primary service and packaged into the single payment for the primary service.

Each year, in accordance with section 1833(t)(9)(A) of the Act, CMS reviews and revises the services within each APC group and the APC assignments under the OPPS. As stated in the CY 2019 OPPS/ASC final rule with comment period, as a result of this annual review of the services and the APC assignments under the OPPS, CMS finalized the addition of three new C-APCs under the existing C-APC payment policy, effective January 1, 2019.

The new C-APCs include: C-APC 5163 (Level 3 Ear, Nose, and Throat (ENT) Procedures), C-APC 5183 (Level 3 Vascular Procedures), and C-APC 5184 (Level 4 Vascular Procedures). A list of these new C-APCs is in the following table.

Table 3 — New Comprehensive C-APCs for CY 2019

CY 2019 C-APC	CY 2019 C-APC Descriptor
5163	Level 3 ENT Procedures
5183	Level 3 Vascular Procedures
5184	Level 4 Vascular Procedures

The addition of these new C-APCs increases the total number of C-APCs to 65 for CY 2019. CMS notes that Addendum J to the CY 2019 OPPS/ASC final rule with comment period contains all of the data related to the C-APC payment policy methodology, including the list of complexity adjustments and other information for CY 2019. In addition, CMS notes that HCPCS codes assigned to comprehensive APCs are designated with status indicator J1 in the latest OPPS Addendum B, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html

6. Changes to the Inpatient-Only List (IPO) for CY 2019

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 2019, CMS is removing four procedures from the IPO list. CMS is also adding one procedure to the IPO list. The changes to the IPO list for CY 2019 are included in Table 4.

Table 4 — Changes to the IPO list for CY 2019

CY 2019 CPT Code	CY 2019 Long Descriptor	Action	CY 2019 OPPS APC Assignment	CY 2019 OPPS SI
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	Removed	5153	J1
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	Removed	N/A	N
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed).	Removed	5463	J1
00670	Anesthesia for extensive spine and spinal cord procedures (e.g., spinal instrumentation or vascular procedures)	Removed	N/A	N
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	Added	N/A	C

7. Modifier "ER"

Effective January 1, 2019, hospitals are required to report new HCPCS modifier "ER" (Items and services furnished by a provider-based off-campus emergency department) with every claim line for outpatient hospital services 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:

a. It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
b. 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
c. 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.

In light of this policy change, CMS is creating a new section in the Medical Claims Processing Manual, chapter 4, section 20.6.18. This new manual section is attached to CR 11099.

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

For CY 2019, CMS is finalizing a policy to use its 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).

The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (that is, 60 percent less than the OPPS rate) for CY 2019. CMS is phasing this policy in over a two-year period. Specifically, half of the total 60-percent payment reduction, a 30-percent reduction, will apply in CY 2019. In other words, these departments will be paid 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that applies in CY 2019) for the clinic visit service in CY 2019.

9. Partial Hospitalization Program (PHP)

a. Technical Change to the OPPS Revenue-Code-to-Cost-Center Crosswalk

For CY 2019 and subsequent years, hospital‑based PHPs will follow a new PHP-only Revenue-Code-to-Cost‑Center crosswalk, which maps all PHP revenue codes to cost center 93.99 "Partial Hospitalization Program" as the primary source for the Cost-to-Charge Ratios (CCR) used in hospital-based PHP rate setting. Cost center 93.99 ("Partial Hospitalization Program") is for recording costs providing partial hospitalization programs, and became effective for hospital cost reporting periods ending on or after September 30, 2017.

The new PHP-only Revenue-Code-to-Cost Center crosswalk is available online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html in the **CY** 2019 OPPS/ASC final rule with comment period.

b. Updates to PHP Allowable HCPCS Codes

In the CY 2019 OPPS/ASC final rule with comment period, CMS proposed to delete six existing PHP allowable HCPCS codes (96101, 96102, 96103, 96118, 96119, 96120) and to replace them with 9 new PHP allowable codes (96130, 96131, 96132, 96133, 96136, 96137, 96138, 96139, 96146) for APCs 5853 and 5863, as of January 1, 2019, as detailed in Table 5.

Table 5 — Proposed CY 2019 Changes to the Allowable HCPCS Codes for PHP APCs 5853 and 5863

Existing Code	Proposed CY 2019 Action	Proposed CY 2019 Replacement(s) Codes	Proposed CY 2019 APC Action
96101	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96102	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96103	Delete	96130, 96131, and may also include 96136 96137, 96138, 96139, 96146	Add
96118	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96119	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96120	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add

10. Payment Adjustment for Certain Cancer Hospitals Beginning CY 2019

For certain cancer hospitals that receive interim monthly payments associated with the cancer hospital adjustment at 42 CFR 419.43(i), Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent calendar years, 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 2019, the target PCR, after including the reduction required by Section 16002(b), is 0.88.

11. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2019 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2019, several 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 in Table 6.

Table 6 – New CY 2019 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 SI	CY 2019 APC
C9035	Injection, aripiprazole lauroxil (aristada initio), 1 mg	G	9179
C9036	Injection, patisiran, 0.1 mg	G	9180
C9037	Injection, risperidone (perseris), 0.5 mg	G	9181
C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182
C9039	Injection, plazomicin, 5 mg	G	9183
C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	G	9184
C9408	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9185
J0584	Injection, burosumab-twza 1 mg	K	9187
J0841	Injection, crotalidae immune f(ab')2 (equine), 120 mg	K	9188
J1746	Injection, ibalizumab-uiyk, 10 mg	K	9189
J2186	Injection, meropenem and vaborbactam, 10mg/10mg (20mg)	K	9178
J2787	Riboflavin 5'-phosphate, opthalmic solution, up to 3 mL	N	N/A
J3397	Injection, vestronidase alfa-vjbk, 1 mg	K	9190
J3591	Unclassified drug or biological used for esrd on dialysis	B	N/A
J7177	Injection, human fibrinogen concentrate (fibryga), 1 mg	K	9191
J7329	Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg	K	9196
J9044	Injection, bortezomib, not otherwise specified, 0.1 mg	K	9192
Q4183	Surgigraft, per square centimeter	N	N/A
Q4184	Cellesta, per square centimeter	N	N/A
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc	N	N/A
Q4186	Epifix, per square centimeter	N	N/A
Q4187	Epicord, per square centimeter	N	N/A
Q4188	Amnioarmor, per square centimeter	N	N/A
Q4189	Artacent ac, 1 mg	N	N/A
Q4190	Artacent ac, per square centimeter	N	N/A
Q4191	Restorigin, per square centimeter	N	N/A
Q4192	Restorigin, 1 cc	N	N/A
Q4193	Coll-e-derm, per square centimeter	N	N/A
Q4194	Novachor, per square centimeter	N	N/A
Q4195	Puraply, per square centimeter	G	9175

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 SI	CY 2019 APC
Q4196	Puraply am, per square centimeter	G	9176
Q4197	Puraply xt, per square centimeter	N	N/A
Q4198	Genesis amniotic membrane, per square centimeter	N	N/A
Q4200	Skin te, per square centimeter	N	N/A
Q4201	Matrion, per square centimeter	N	N/A
Q4202	Keroxx (2.5g/cc), 1cc	N	N/A
Q4203	Derma-gide, per square centimeter	N	N/A
Q4204	Xwrap, per square centimeter	N	N/A
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	E2	N/A
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	K	9173
Q5109	Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg	E2	N/A
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	K	9193
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	K	9195

b. Other Changes to CY 2019 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have undergone changes in their HCPCS and CPT code descriptors that will be effective in CY 2019. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2018 and replaced with permanent HCPCS codes effective in CY 2019. Hospitals should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the active CY 2019 HCPCS and CPT codes. Table 7 notes those drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2018 HCPCS/CPT code and long descriptor are noted in the two left-hand columns and the CY 2019 HCPCS/CPT code and long descriptor are noted in the adjacent right-hand columns.

Table 7. – Other CY 2019 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2019 HCPCS Code	CY 2019 Long Descriptor
C9031	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	A9513	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	A9589	Instillation, hexaminolevulinate hydrochloride, 100 mg

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2019 HCPCS Code	CY 2019 Long Descriptor
C9463	Injection, aprepitant, 1 mg	J0185	Injection, aprepitant, 1 mg
C9466	Injection, benralizumab, 1 mg	J0517	Injection, benralizumab, 1 mg
C9014	Injection, cerliponase alfa, 1 mg	J0567	Injection, cerliponase alfa, 1 mg
C9015	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units
C9034	Injection, dexamethasone 9%, intraocular, 1 mcg	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram
C9493	Injection, edaravone, 1 mg	J1301	Injection, edaravone, 1 mg
C9033	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
C9029	Injection, guselkumab, 1 mg	J1628	Injection, guselkumab, 1 mg
C9497	Loxapine, inhalation powder, 10 mg	J2062	Loxapine for inhalation, 1 mg
C9464	Injection, rolapitant, 0.5 mg	J2797	Injection, rolapitant, 0.5 mg
Q9993	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
C9016	Injection, triptorelin, extended-release, 3.75 mg	J3316	Injection, triptorelin, extended-release, 3.75 mg
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Q9995	Injection, emicizumab-kxwh, 0.5 mg	J7170	Injection, emicizumab-kxwh, 0.5 mg
C9468	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu
C9465	Hyaluronan or derivative, durolane, for intra-articular injection, per dose	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg
C9030	Injection, copanlisib, 1 mg	J9057	Injection, copanlisib, 1 mg
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine
C9492	Injection, durvalumab, 10 mg	J9173	Injection, durvalumab, 10 mg
C9028	Injection, inotuzumab ozogamicin, 0.1 mg	J9229	Injection, inotuzumab ozogamicin, 0.1 mg

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2019 HCPCS Code	CY 2019 Long Descriptor
C9467	Injection, rituximab and hyaluronidase, 10 mg	J9311	Injection, rituximab 10 mg and hyaluronidase
J9310	Injection, rituximab, 100 mg	J9312	Injection, rituximab, 10 mg
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

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

For CY 2019, payment for non-pass-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 January 1, 2019, payment rates for many drugs and biologicals have changed from the values published in the CY 2019 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2018. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2019 Fiscal Intermediary Shared System (FISS) release. CMS is not publishing the updated payment rates in CR 11099 implementing the January 2019 update of the OPPS. However, the updated payment rates effective January 1, 2019, are available in the January 2019 update of the OPPS Addendum A and Addendum B 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 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.

e. Biosimilar Payment Policy

For CY 2019, the payment rate for biosimilars in the OPPS will generally continue to be calculated as the ASP of the biosimilar described by the HCPCS code + 6 percent of the ASP of the reference product. Biosimilars will also continue to be eligible for transitional pass-through payment for which payment will be made at ASP of the biosimilar described by the HCPCS code + 6 percent of the ASP of the reference product.

Effective January 1, 2019, a biosimilar acquired under the 340B Program that does not have pass-through status, but instead has status indicator of "K," will be paid the ASP of the biosimilar minus 22.5 percent of the biosimilar's ASP. A list of the biosimilar biological product HCPCS codes and modifiers is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html.

f. Payment of Drugs, Biologicals, and Radiopharmaceuticals if ASP Data Are Not Available

Starting in January 2019, CMS will pay separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B Program at Wholesale Acquisition Cost (WAC) + 3 percent instead of WAC + 6 percent, in cases where WAC-based payment applies.

12. Skin Substitute Procedure Edits

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. The skin substitute products are divided into two groups: 1) high cost skin substitute products, and 2) low cost skin substitute products for packaging purposes. Table 8 lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable.

Table 8—Skin Substitute Assignments to High Cost and Low Cost Groups for CY 2019

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High*
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High
Q4110	Primatrix	High	High*

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High*
Q4127	Talymed	High	High
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High*
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per sq centimeter	Low	Low

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4169	Artacent wound, per sq cm	High	High*
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm	High	High
Q4176	Neopatch, per sq centimeter	Low	Low
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	Low	Low
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High*
Q4182	Transcyte, per sq centimeter	Low	Low
Q4183	Surgigraft, 1 sq cm	Low	Low
Q4184	Cellesta, 1 sq cm	Low	Low
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	Low
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	Low
Q4194	Novachor 1 sq cm	Low	Low
Q4195+	Puraply 1 sq cm	High	High
Q4196+	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1sqcm	Low	Low
Q4200	Skin te 1 sq cm	Low	Low
Q4201	Matrion 1 sq cm	Low	Low
Q4203	Derma-gide, 1 sq cm	Low	Low
Q4204	Xwrap 1 sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2019, but are assigned to the high cost group because they were assigned to the high cost group in CY 2018.

+ Pass-through payment status in CY 2019.

13. Allow HCPCS Code Q4122 (Dermacell, per square centimeter) to Be Billed with Either Revenue Code 0278 (Other implants) or Revenue Code 0636 (Drugs requiring detailed coding)

HCPCS code Q4122 (Dermacell, per square centimeter) may be billed with either revenue code 0278 (Other implants) or revenue code 0636 (Drugs requiring detailed coding). HCPCS code Q4122 is used both as an applied skin substitute and as an implanted biologic used in breast reconstruction, and these procedures are reported with two different revenue codes. This

request is described in Table 9.

Table 9 – Allow HCPCS Code Q4122 (Dermacell, per square centimeter) to Be Billed with Either Revenue Code 0278 (Other implants) or Revenue Code 0636 (Drugs requiring detailed coding)

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 SI	Allowed Revenue Codes for Billing
Q4122	Dermacell, per square centimeter	N	0278, 0636

14. Billing Instructions for 340B-Acquired Drugs Furnished in Nonexcepted Off-Campus Provider-Based Departments (PBDs) of a Hospital

As finalized in the CY 2019 OPPS/ASC final rule with comment period, separately payable Part B drugs (assigned status indicator "K"), other than vaccines (assigned status indicator "L" or "M") and drugs on pass-through payment status (assigned status indicator "G"), that are acquired through the 340B Program or through the 340B prime vendor program, will continue to be paid at the ASP minus 22.5 percent when billed by hospitals paid under the OPPS (other than a type of hospital excluded from the OPPS or excepted from the 340B drug payment policy for CY 2019) and will now also be paid at the ASP minus 22.5 percent when billed by nonexcepted off-campus PBDs of a hospital paid under the PFS. Hospital types that are excepted from the 340B payment policy in CY 2019 include rural Sole Community Hospitals (SCHs), children's hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals. These hospitals will continue to receive ASP + 6 percent payment for separately payable drugs.

Medicare will continue to pay separately payable drugs that were not acquired under the 340B Program at ASP + 6 percent.

To effectuate the payment adjustment for 340B-acquired drugs and biologicals, CMS implemented modifier "JG", effective January 1, 2018. Accordingly, beginning January 1, 2019, nonexcepted off-campus PBDs of a hospital paid under the PFS (departments that bill the "PN" modifier on claim lines) are required to report modifier "JG" on the same claim line as the drug or biological HCPCS code acquired under the 340B Program to identify a 340B-acquired drug or biological and will now be paid ASP minus 22.5 percent for that drug or biological. Since rural SCHs, children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment in CY 2019, these hospitals will report informational modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP + 6 percent. The 340B modifiers and their descriptors are listed in Table 10.

Table 10 – Modifiers for 340B-Acquired Drugs

2-Digit HCPCS Modifier	Short Descriptor	Long Descriptor	Effective Date
JG	340b acquired drug	Drug or biological acquired with 340b drug pricing program discount	Hospitals paid under the OPPS - 01/01/2018 Nonexcepted off-campus PBDs paid under the PFS - 01/01/2019
TB	Tracking 340b acquired drug	Drug or biological acquired with 340b drug pricing program discount, reported for informational purposes	Hospitals paid under the OPPS - 01/01/2018 Nonexcepted off-campus PBDs paid under the PFS - 01/01/2019

MACs are being advised that guidance on use of the aforementioned modifiers related to drugs acquired under the 340B program is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf

15. Changes to OPPS Pricer Logic

a. Rural sole community hospitals and Essential Access Community Hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2019. 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, 2019. 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 2019 inpatient deductible of $1,364. 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 2019. 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 2019 relative to CY 2018. The estimated cost of a service must be greater than the APC payment amount plus $4,825 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 2019. 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 CMS established policy for CY 2019, the OPPS Pricer will apply a reduced update ratio of 0.980 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, 2019, CMS is adopting the FY 2019 IPPS post-reclassification wage index values with application of the CY 2019 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, 2019, 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.

16. Update the Outpatient Provider Specific File (OPSF)

For January 1, 2019, MACs will maintain the accuracy of the provider records in the OPSF as changes occur in data element values.

a) 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 2019, cancer hospitals will continue to receive an additional payment adjustment.

b) 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 deduction 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.

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

As stated in the Medicare Claims Processing Manual, Pub. 100-04, chapter 4, section 50.1, MACs 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 at http://www.cms.gov/HospitalOutpatientPPS/ under "*Annual Policy Files*."

d) Updating the "County Code" field

Prior to CY 2018, in order to include the out-migration in a hospital's wage index, CMS provided a separate table that assigned wage indexes for hospitals that received the outmigration adjustment. For the CY 2019 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.

e) 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 out-migration adjustment).

In Transmittal 3750, Change Request 9926, dated April 19, 2017, CMS 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 (CFR section 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. CMS further notes 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.

17. 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. 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, CR 11099, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4204CP.pdf. 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
January 18, 2019	This article was revised to reflect an updated CR that corrected the link to the list of drugs and biologicals with corrected payments rates in Section I.B.11.d of that CR. The transmittal number, CR release date and link to the transmittal also changed.
January 4, 2019	Initial article released.