DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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January 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers who submit claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice (HH&H) MACs for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

Provider Action Needed

This article is based on Change Request (CR) 9930 which describes changes to the OPPS to be implemented in the January 2017 update. Make sure your billing staffs are aware of these changes.

Background

Change Request (CR) 9930 describes changes and billing instructions for various payment policies being implemented in the January 2017 OPPS update. The January 2017 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer 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 9930.

Key Changes in CR9930

Key changes to and billing instructions for various payment policies implemented in the January 2017 OPPS updates are as follows:

New Device Pass-Through Policies

a. New Device Pass-Through Categories

The Social Security Act (Section 1833(t)(6)(B)) 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 Social Security Act requires that the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices that are not described by existing or previously existing categories of devices.

b. Policy

In the Calendar Year (CY) 2017 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) final rule with comment period that was published in the Federal Register on November 14, 2016, CMS adopted a policy to revise the pass-through payment time period by having the pass-through start date begin with the date of first payment and by allowing pass-through status to expire on a quarterly basis, such that the duration of device pass-through payment will be as close to 3 years as possible.

In addition, in calculating the pass-through payment, the "Implantable Devices Charged to Patients Cost-to-Charge Ratio (CCR)" will replace the hospital-specific CCR, when available and device offsets will be calculated from the HCPCS payment rate, instead of the APC payment rate (81 FR 79655 through 79657). Refer to the CY 2017 OPPS/ASC final rule with comment period for complete details of these policy changes for device pass-through that will become effective on January 1, 2017. Effective January 1, 2017, there are three device categories eligible for pass-through payment: (1) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); (2) HCPCS code C2613 (Lung biopsy plug with delivery system); and (3) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system). Also, refer to **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html** for the most current device pass-through information.

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. Refer to **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html** for the most current OPPS HCPCS Offset File.

Device Intensive Procedures

Effective January 1, 2017, CMS will assign device-intensive status at the HCPCS code level for all procedures requiring the implantation of a medical device, in which the individual HCPCS level device offset is greater than 40 percent. All new procedures requiring the insertion of an implantable medical device will be assigned a default device offset percentage of at least 41 percent, and be assigned device intensive status, until claims data is available. In certain rare instances, CMS may temporarily assign a higher offset percentage, if warranted, with additional information. Effective January 1, 2017, CMS will no longer assign device-intensive status based upon the APC level device offset percentage.

In light of this policy change, CMS is modifying Sections 20.6.4 and 61.2 of Chapter 4 of the "Medical Claims Processing Manual."

Argus Retinal Prosthesis Add-on Code (C1842)

Effective January 1, 2017, CMS is creating HCPCS code C1842 (Retinal prosthesis, includes all internal and external components; add-on to C1841) and assigning it a status indicator (SI) of N. HCPCS code C1842 was created to resolve a claims processing issue for ASCs and should not be reported on institutional claims by hospital outpatient department providers.

Additionally, although HCPCS code C1842 was not included in the CY 2017 Annual HCPCS file, the code has been included in the January 2017 I/OCE. Therefore, MACs will add this code to their HCPCS system.

Services Eligible for New Technology APC Assignment and Payments

Under OPPS, services eligible for payment through New Technology APCs are those codes that are assigned to the series of New Technology APCs published in Addendum A of the latest OPPS update. OPPS considers any HCPCS code assigned to the APCs below to be a "new technology procedure or service." As of January 1, 2017, the range of New Technology APCs include:

- APCs 1491 through 1500
- APCs 1502 through 1537
- APCs 1539 through 1585
- APCs 1589 through 1599
- APCs 1901 through 1906

The application for consideration as a New Technology procedure or service is available at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html**. Under the "Downloads" section, refer to the document titled "For a New Technology Ambulatory Payment Classification (APC) Designation Under the Hospital Outpatient Prospective Payment System (OPPS)" for information on the requirements for submitting an application.

The list of HCPCS codes and payment rates assigned to New Technology APCs are in Addendum B of the latest OPPS update regulation each year at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html**.

Expiration of modifier "L1" for unrelated lab tests in the OPPS

As a result of the CY 2014 OPPS policy to package laboratory services in the hospital outpatient setting, the "L1" modifier was used on type of bill (TOB) 13x to identify unrelated laboratory tests that were ordered for a different diagnosis and by a different practitioner than the other OPPS services on the claim.

In the CY 2016 OPPS final rule, CMS established status indicator "Q4," which conditionally packaged clinical diagnostic laboratory services. Status indicator "Q4" designates packaged APC payment when billed on the same claim as a HCPCS code assigned status indicator "J1," "J2," "S," "T," "V," "Q1," "Q2," or "Q3". The "Q4" status indicator was created to identify 13X bill type claims where there are only laboratory HCPCS codes that appear on the clinical laboratory fee schedule (CLFS); to automatically change their status indicator to "A"; and to pay them separately at the CLFS payment rates. In the CY 2017 OPPS/ASC final rule with comment period, CMS

finalized a policy to eliminate the L1 modifier. Beginning January 1, 2017, CMS is discontinuing the use of the "L1" modifier to identify unrelated laboratory tests on claims.

Conditional packaging change to apply at claim level

When conditional packaging was initially adopted under the OPPS, it was based on the date of service associated with other items and services furnished on the claim. When CMS established the comprehensive APCs in the CY 2015 OPPS, packaging was applied on a claim basis. To promote consistency and ensure appropriate packaging under OPPS policy, CMS finalized a change in the CY 2017 OPPS to apply conditional packaging for status indicators "Q1" and "Q2" on a claim basis.

Exception for laboratory packaging in the OPPS for Advanced Diagnostic Laboratory Tests (ADLTs)

Beginning in the CY 2014 OPPS, CMS established that laboratory tests for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 are not packaged in the OPPS.

In the CY 2017 OPPS, CMS is expanding the laboratory packaging exclusion that currently applies to Molecular Pathology tests (described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479) to all laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) that meet the criteria of the Social Security Act (Section 1834A(d)(5)(A)).

FX Modifier (X-ray Taken Using Film)

In accordance with provisions allowed under Section 1833(t)(16)(F)(iv) of the Social Security Act, CMS has established a new modifier "FX" to identify imaging services that are X-rays taken using film. Effective January 1, 2017, hospitals are required to use this modifier on claims for imaging services that are X-rays.

The use of this modifier will result in a payment reduction of 20 percent in CY 2017 for the X-ray services taken using film when the service is paid separately. The use of the FX modifier and subsequent reduction in payment under the OPPS is applicable to all imaging services that are X-rays taken using film. All imaging services that are X-rays are listed in Addendum B of the CY 2017 OPPS/ASC Final Rule. CMS is updating the "Medicare Claims Processing Manual", Chapter 4, Section 20.6.13, to include this new modifier.

Computed Tomography (CT) Modifier ("Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR–29–2013 standard")

In accordance with the Social Security Act (Section 1834(p)), CMS established modifier "CT", effective January 1, 2016, to identify CT scans that are furnished on equipment that does not meet the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management." Hospitals are required to use this modifier on claims for CT scans described by applicable HCPCS codes that are furnished on non-NEMA Standard XR-29-2013-compliant equipment. The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes).

Effective January 1, 2017, the use of this modifier will result in a payment reduction of 15 percent for the applicable CT services when the service is paid separately. The 15 percent payment reduction will also be applied to the APC payment for the HCPCS codes listed above that are subject to the multiple imaging composite policy. This includes procedures assigned to the two APCs (8005 and 8006) in the CT and CT angiography (CTA) imaging family.

Billing for Items and Services Furnished at Off-Campus Hospital Outpatient Departments

In accordance with the Social Security Act (Section 1833(t)(21)), as added by Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), CMS has established a new modifier "PN" (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay nonexcepted items and services billed on an institutional claim. Effective January 1, 2017, non-excepted off-campus provider-based departments of a hospital are required to report this modifier on each claim line for non-excepted items and services. The use of modifier "PN" will trigger a payment rate under the Medicare Physician Fee Schedule. CMS expects the PN modifier to be reported with each nonexcepted item and service including those for which payment will not be adjusted, such as separately payable drugs, clinical laboratory tests, and therapy services.

Excepted off-campus provider-based departments of a hospital must continue to report existing modifier "PO" (Services, procedures and/or surgeries provided at off-campus provider-based outpatient departments) for all excepted items and services furnished. Use of the off-campus provider-based department (PBD) modifier became mandatory beginning January 1, 2016.

CMS would not expect off-campus PBDs to report both the PO and PN modifiers on the same claim line. However, if services reported on a claim reflect items and services furnished from both an excepted and a nonexcepted off-campus PBD of the hospital, the PO modifier should be used on the excepted claim lines and the PN modifier should be used on the nonexcepted claim lines.

Neither the PO nor the PN modifier is to be reported by the following hospital departments:

- A dedicated emergency department as defined in existing regulations at 42 CFR 489.24(b)
- A PBD that is "on the campus," or within 250 yards, of the hospital or a remote location of the hospital as defined under 42 CFR 413.65

Partial Hospitalization Program (PHP)

a. Update to PHP Per Diem Costs

The CY 2017 OPPS/ASC final rule with comment period replaces the existing two-tiered APC structure for PHPs with a single APC by provider type for providing three or more services per day. Specifically, CMS is replacing existing Community Mental Health Center (CMHC) APCs 5851 (Level 1 Partial Hospitalization (3 services)) and 5852 (Level 2 Partial Hospitalization (4 or more services)) with a new CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)), and replacing existing hospital-based PHP APCs 5861 (Level 1 Partial Hospitalization (3 services)) and 5862 (Level 2 Partial Hospitalization (4 or more services)) with a new hospital‑based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)).

b. CMHC Provider-Level Outlier Cap

The CY 2017 OPPS/ASC final rule with comment period implements a CMHC outlier payment cap to be applied at the provider level. In any given year, an individual CMHC will receive no more than 8 percent of its CMHC total per diem payments in outlier payments. The provider-level cap on

CMHC outlier payments would be managed by the claims processing system. The existing outlier reconciliation process remains in place to adjust outlier payments at final cost report settlement, based on changes in the provider's CCR.

c. PHP Payments under Section 603 (Off-Campus Policy)

The Social Security Act (Section 1861(ff)(3)(A)) specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a CMHC. The Social Security Act (Section 1833(t)(1)(B)(i)) provides the Secretary with the authority to designate the outpatient department services to be covered under the OPPS. As a part of the OPPS, hospital-based (HB), PHPs are affected by this new legislation. CMHCs are not affected because they are not a hospital or a department/unit of a hospital. The CY 2017 OPPS/ASC final rule with comment adopts payment for non-excepted hospital-based PHPs under the MPFS, paying the CMHC per diem rate for APC 5853, for providing 3 or more PHP services per day.

Changes to Policies related to Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

a. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) (C-APC 5244)

Effective January 1, 2017, CMS is assigning procedures described by CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) to newly established comprehensive APC (C-APC) 5244 (Level 4 Blood Product Exchange and Related Services). CPT code 38240 will be assigned status indicator "J1". The assignment of CPT code 38240 to C-APC 5244 and status indicator "J1" will allow for all other OPPS payable services and items reported on the claim (including donor acquisition costs) to be deemed adjunctive services representing components of a comprehensive service and result in a single prospective payment through C-APC 5244 for the comprehensive service based on the costs of all reported services on the claim.

b. New Revenue Code 0815 for Allogeneic Stem Cell Acquisition Services

Effective January 1, 2017, hospitals are required to report revenue code 0815 when billing donor acquisition costs associated with allogeneic hematopoietic stem cell transplantation (HSCT). CMS is also implementing a code edit (edit 100) effective January 1, 2017, that will require donor acquisition charges for allogeneic HSCT reported with revenue code 0815 to be included on a claim with CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor). Donor acquisition charges for allogeneic HSCT are described in the "Medicare Claims Processing Manual", Chapter 4, Section 231.11. Revenue code 0819 is no longer required for the reporting of donor acquisition charges for allogeneic HSCT. CMS is updating the "Medicare Claims Processing Manual", Chapter 4, Section 231.11 and Chapter 3, Section 90.3.1 to reflect the new billing guidelines for allogeneic HSCT.

Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2017 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2017, 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 1 below.

Table 1 − New CY 2017 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2017 HCPCS Code	CY 2017 Long Descriptor	CY 2017 SI	CY 2017 APC
90682	Influenza virus vaccine, quadrivalent (RIV4), derived from recombinant DNA, hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use	L	
90750	Zoster (shingles) vaccine (HZV), recombinant, sub-unit, adjuvanted, for intramuscular injection	E1	
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056
A9588	Fluciciovine f-18, diagnostic, 1 millicurie	G	9052
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified	N	
A9598	Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified	N	
C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.	G	9043
J0570	Buprenorphine implant, 74.2 mg	G	9058
J1130	Injection, diclofenac sodium, 0.5 mg	E2	
J7175	Injection, factor x, (human), 1 i.u.	K	1857
J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059
J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861
Q4166	Cytal, per square centimeter	N	
Q4167	Truskin, per square centimeter	N	
Q4168	Amnioband, 1 mg	N	
Q4169	Artacent wound, per square centimenter	N	
Q4170	Cygnus, per square centimenter	N	
Q4171	Interfyl, 1 mg	N	
Q4173	Palingen or palingen xplus, per square centimenter	N	
Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc	N	
Q4175	Miroderm, per square centimeter	N	

b. Other Changes to CY 2017 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 2017. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2016, and replaced with permanent HCPCS codes in CY 2017. 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 2017 HCPCS and CPT codes.

Table 2 (below) notes the drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2016 HCPCS/CPT code and long descriptor are noted in the two left hand columns. The CY 2017 HCPCS/CPT code and long descriptor are noted in the adjacent right hand columns.

Table 2 − Other CY 2017 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2016 HCPCS/ CPT Code	CY 2016 Long Descriptor	CY 2017 HCPCS/ CPT Code	CY 2017 Long Descriptor
C9461	Choline C 11, diagnostic, per study dose	A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9599	Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging, per study dose	A9599	Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging, per study dose, not otherwise specified
C9121	Injection, argatroban, per 5 mg	J0883	Injection, argatroban, 1 mg (for non-esrd use)
C9121	Injection, argatroban, per 5 mg	J0884	Injection, argatroban, 1 mg (for esrd on dialysis)
C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	J7207	Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u.
C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	J7209	Injection, factor viii, (antihemophilic factor, recombinant), (nuwiq), 1 i.u.
C9139	Injection, factor ix, albumin fusion protein (recombinant), idelvion, 1 i.u.	J7202	Injection, factor ix, albumin fusion protein, (recombinant), idelvion, 1 i.u.
C9349	Puraply, and puraply antimicrobial, any type, per square centimeter	Q4172	Puraply or puraply am, per square centimeter
C9470	Injection, aripiprazole lauroxil, 1 mg	J1942	Injection, aripiprazole lauroxil, 1 mg
C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	J7322	Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg
C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units
C9473	Injection, mepolizumab, 1 mg	J2182	Injection, mepolizumab, 1 mg
C9474	Injection, irinotecan liposome, 1 mg	J9205	Injection, irinotecan liposome, 1 mg
C9475	Injection, necitumumab, 1 mg	J9295	Injection, necitumumab, 1 mg
C9476	Injection, daratumumab, 10 mg	J9145	Injection, daratumumab, 10 mg
C9477	Injection, elotuzumab, 1 mg	J9176	Injection, elotuzumab, 1 mg
C9478	Injection, sebelipase alfa, 1 mg	J2840	Injection, sebelipase alfa, 1 mg

CY 2016 HCPCS/ CPT Code	CY 2016 Long Descriptor	CY 2017 HCPCS/ CPT Code	CY 2017 Long Descriptor
C9479	Instillation, ciprofloxacin otic suspension, 6 mg	J7342	Installation, ciprofloxacin otic suspension, 6 mg
C9480	Injection, trabectedin, 0.1 mg	J9352	Injection, trabectedin, 0.1 mg
C9481	Injection, reslizumab, 1 mg	J2786	Injection, reslizumab, 1 mg
J0571	Buprenorphine, oral, 1 mg	J0571	Buprenorphine oral 1 mg
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 3.1 to 6 mg	J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J3357	Injection, ustekinumab, 1 mg	J3357	Ustekinumab, for subcutaneous injection, 1 mg
J1745	Injection, infliximab, 10 mg	J1745	Injection, infliximab, excludes biosimilar, 10 mg
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu	J7201	Injection, factor ix, fc fusion protein (recombinant), Alprolix, per iu
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension	J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension, 100 ml
Q9981	Rolapitant, oral, 1 mg	J8670	Rolapitant, oral, 1 mg
Q4105	Integra dermal regeneration template (drt), per square centimeter	Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter
Q4131	Epifix, per square centimeter	Q4131	Epifix or epicord, per square centimeter
Q2039	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (not otherwise specified)	Q2039	Influenza virus vaccine, not otherwise specified

c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective January 1, 2017

For CY 2017, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals continues to be made at a single rate of ASP plus 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In addition, in CY 2017, a single payment of ASP plus 6 percent continues to be made for pass-through drugs, biologicals and radiopharmaceuticals 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, 2017, payment rates for many drugs and biologicals have changed from the values published in the CY 2017 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 2016. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2017 Fiscal Intermediary Standard System (FISS)

release. CMS is not publishing the updated payment rates in this CR implementing the January 2017 update of the OPPS. However, the updated payment rates effective January 1, 2017, are available in the January 2017 update of the OPPS Addendum A and Addendum B at **http://www.cms.gov/HospitalOutpatientPPS/**.

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-ServicePayment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html**. Providers may resubmit claims that were impacted by adjustments to previous quarter's payment files.

e. Biosimilar Biological Product Payment Policy

Effective January 1, 2017, the payment rate for a biosimilar biological product under the OPPS will continue to be the same as the payment rate in the physician office setting, (that is, calculated as the ASP of the biosimilar(s) described by the HCPCS code plus 6 percent of the ASP of the reference product). Biosimilar biological products are also be eligible for transitional pass-through payment; however, pass-through payment will be made to the first eligible biosimilar biological product to a reference product. Subsequent biosimilar biological products to a reference product will not meet the newness criterion, and therefore, will be ineligible for pass-through payment.

As a reminder, OPPS claims for separately paid biosimilar biological products are required to include a modifier (see Table 3, below) that identifies the manufacturer of the specific product. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code but are made by different manufacturers.

Table 3 – Biosimilar Biological Product Payment and Required Modifiers

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC	HCPCS Code Effective Date	HCPCS Modifier	HCPCS Modifier Effective Date
Q5101	Inj filgrastim g-csf biosim	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	1822	03/06/2015	ZA-Novartis/ Sandoz	01/01/2016
Q5102	Inj., infliximab biosimilar	Injection, Infliximab, Biosimilar, 10 mg	K	1847	04/05/2016	ZB-Pfizer/ Hospira	04/01/2016

f. Billing and Payment for New Drugs, Biologicals, or Radiopharmaceuticals Approved by the Food and Drug Administration (FDA) but Before Assignment of a Product-Specific HCPCS Code

Hospital outpatient departments are allowed to bill for new drugs, biologicals, and therapeutic radiopharmaceuticals that are approved by the FDA on or after January 1, 2004, for which pass-through status has not been approved and a C-code and APC payment have not been assigned using

the "unclassified" drug/biological HCPCS code C9399 (Unclassified drugs or biological). Drugs, biologicals, and therapeutic radiopharmaceuticals that are assigned to HCPCS code C9399 are contractor priced at 95 percent of AWP.

Diagnostic radiopharmaceuticals and contrast agents are policy packaged under the OPPS unless they have been granted pass-through status. Therefore, new diagnostic radiopharmaceuticals and contrast agents are an exception to the above policy and should not be billed with C9399 prior to the approval of pass-through status but, instead, should be billed with the appropriate "A" NOC code as described below.

1. Diagnostic Radiopharmaceuticals – All new diagnostic radiopharmaceuticals are assigned to either HCPCS code A9597 (Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified), HCPCS code A9598 (Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified), HCPCS code A9599 (Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (PET) imaging, per study dose), or HCPCS code J3490 (Unclassified drugs) (applicable to all new diagnostic radiopharmaceuticals used in non-beta-amyloid PET imaging). HCPCS code A9597, A9598, A9599, or J3490, whichever is applicable, should be used to bill a new diagnostic radiopharmaceutical until the new diagnostic radiopharmaceutical has been granted pass-through status and a C-code has been assigned. HCPCS codes A9597, A9598, A9599, and J3490 are assigned status indicator "N" and, therefore, the payment for a diagnostic radiopharmaceutical assigned to any of these HCPCS codes is packaged into the payment for the associated service.

2. Contrast Agents – All new contrast agents are assigned HCPCS code A9698 (Non-radioactive contrast imaging material, not otherwise classified, per study) or A9700 (Supply of injectable contrast material for use in echocardiography, per study). HCPCS code A9698 or A9700 should be used to bill a new contrast agent until the new contrast agent has been granted pass-through status and a C-code has been assigned. HCPCS code A9698 is assigned status indicator "N" and, therefore, the payment for a drug assigned to HCPCS code A9698 is packaged into the payment for the associated service. The status indicator for A9700 will change from SI=B (Not paid under OPPS) to SI=N (Payment is packaged into payment for other services) and, therefore, the payment for a drug assigned to HCPCS code A9700 is packaged into the payment for the associated service.

g. 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 4 lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable. CMS will implement an OPPS edit that requires hospitals to report all high-cost skin substitute products in combination with one of the skin application procedures described by CPT codes 15271-15278 and to report all low-cost skin substitute products in combination with one of the skin application procedures described by HCPCS codes C5271-C5278. All pass-through skin substitute products are to be reported in combination with one of the skin application procedures described by CPT codes 15271-15278.

Table 4 – Skin Substitute Product Assignment to High Cost/Low Cost Status for CY 2016

CY 2017 HCPCS Code	CY 2017 Short Descriptor	CY 2017 SI	Low/High Cost Skin Substitute
C9363	Integra Meshed Bil Wound Mat	N	High
Q4100	Skin Substitute, NOS	N	Low
Q4101	Apligraf	N	High
Q4102	Oasis Wound Matrix	N	Low
Q4103	Oasis Burn Matrix	N	High
Q4104	Integra BMWD	N	High
Q4105	Integra DRT	N	High
Q4106	Dermagraft	N	High
Q4107	GraftJacket	N	High
Q4108	Integra Matrix	N	High
Q4110	Primatrix	N	High
Q4111	Gammagraft	N	Low
Q4115	Alloskin	N	Low
Q4116	Alloderm	N	High
Q4117	Hyalomatrix	N	Low
Q4121	Theraskin	N	High
Q4122	Dermacell	N	High
Q4123	Alloskin	N	High
Q4124	Oasis Tri-layer Wound Matrix	N	Low
Q4126	Memoderm/derma/tranz/integup	N	High
Q4127	Talymed	N	High
Q4128	Flexhd/Allopatchhd/Matrixhd	N	High
Q4131	Epifix	N	High
Q4132	Grafix Core	N	High
Q4133	Grafix Prime	N	High
Q4134	hMatrix	N	Low
Q4135	Mediskin	N	Low
Q4136	Ezderm	N	Low
Q4137	Amnioexcel or Biodexcel, 1cm	N	High
Q4138	Biodfence DryFlex, 1cm	N	High
Q4140	Biodfence 1cm	N	High
Q4141	Alloskin ac, 1cm	N	High
Q4143*	Repriza, 1cm	N	High

CY 2017 HCPCS Code	CY 2017 Short Descriptor	CY 2017 SI	Low/High Cost Skin Substitute
Q4146*	Tensix, 1CM	N	High
Q4147	Architect ecm, 1cm	N	High
Q4148	Neox 1k, 1cm	N	High
Q4150	Allowrap DS or Dry 1 sq cm	N	High
Q4151	AmnioBand, Guardian 1 sq cm	N	High
Q4152	Dermapure 1 square cm	N	High
Q4153	Dermavest 1 square cm	N	High
Q4154	Biovance 1 square cm	N	High
Q4156	Neox 100 1 square cm	N	High
Q4157*	Revitalon 1 square cm	N	High
Q4158*	MariGen 1 square cm	N	High
Q4159	Affinity 1 square cm	N	High
Q4160	NuShield 1 square cm	N	High
Q4161	Bio-Connekt per square cm	N	Low
Q4162	Amnio bio and woundex flow	N	Low
Q4163*	Amnion bio and woundex sq cm	N	High
Q4164	Helicoll, per square cm	N	High
Q4165	Keramatrix, per square cm	N	Low
Q4166*	Cytal, per square cm	N	Low
Q4167*	Truskin, per square cm	N	Low
Q4168*	Amnioband, 1 mg	N	Low
Q4169*	Artacent wound, per square cm	N	Low
Q4170*	Cygnus, per square cm	N	Low
Q4171*	Interfyl, 1 mg	N	Low
Q4172	PuraPly, PuraPly antimic	G	High
Q4173*	Palingen or palingen xplus, per sq cm	N	Low
Q4175*	Miroderm, per square cm	N	Low

*HCPCS codes Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, and Q4175 were assigned to the low cost group in the CY 2017 OPPS/ASC final rule with comment period. Upon submission of updated pricing information, Q4143, Q4146, Q4157, Q4158, and Q4163 are assigned to the high cost group for CY 2017.

h. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group – Retroactive Change

One existing skin substitute product has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The start date on this change is retroactive to October 1, 2016. The product is listed in Table 5 below.

Table 5 – Updated Skin Substitute Product Assignment to High Cost Status Retroactive to October 1, 2016

HCPCS Code	Short Descriptor	Status Indicator	Low/High Cost Status
Q4158	MariGen 1 square cm	N	High

Changes to OPPS Pricer Logic

a. Rural sole community hospitals and essential access community hospitals (EACHs) will continue to receive an additional 7.1 percent payment for most services in CY 2017. 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 the Social Security Act (Section 1833(t)(13)(B)), 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, 2017. 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 2017 inpatient deductible of $1,316. 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 2017. 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 2017 relative to CY 2016. The estimated cost of a service must be greater than the APC payment amount plus $3,825 in order to qualify for outlier payments.

e. For outliers for CMHCs (bill type 76x), there will be no change in the multiple threshold of 3.4 for 2017. 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 2017, 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, 2017, CMS is adopting the FY 2017 IPPS post-reclassification wage index values with application of out-commuting adjustment authorized by Section 505 of the MMA to non-IPPS hospitals discussed below.

h. Effective January 1, 2014, for claims with APCs, which require implantable devices and have significant device offsets (greater than 40 percent), 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.

i. Effective January 1, 2017 conditional packaging for status indicators "Q1" and "Q2" will apply at the claim level rather than the date-of-service level.

j. The Payment Rate field in the Pricer file will be expanded from 7 digits to 8 digits to accommodate APC payment rates greater than or equal to $100,000.

Update the Outpatient Provider Specific File (OPSF) for New Core-Based Statistical Area (CBSA) and Wage Indices for Non-IPPS Hospitals Eligible for the Out-Commuting Adjustment Authorized by Section 505 of the MMA

CR9930 provides instructions to the MACs for updating the OPSF, effective 2017. This includes updating the CBSA in the provider records, as well as updating the "special wage index" value for those providers who qualify for the Section 505 adjustment as annotated in Table 6 in Attachment A of CR 9930.

NOTE: Although the Section 505 adjustment is static for each qualifying county for 3 years, the special wage index will need to be updated (using the final wage index in Table 6, Attachment A in CR9930) because the post-reclassification CBSA wage index has changed. Also, note that payment for Distinct Part Units (DPUs) located in an acute care hospital is based on the wage index for the labor market area where the hospital is located, even if the hospital has a reclassified wage index. If the DPU falls in a CBSA eligible to receive the section 505 out-commuting adjustment, the DPU's final wage index should consist of the geographic wage index plus the appropriate out-commuting adjustment.

a) Updating the OPSF for Expiration of Transitional Outpatient Payments (TOPs)

Cancer and children's hospitals are held harmless under the Social Security Act (Section 1833(t)(7)(D)(ii)) and continue to receive hold harmless TOPs permanently. For CY 2017, 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 the Social Security Act (Section 1833(t)(17)(A))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 the Outpatient CCR

As stated in Pub. 100-04, "Medicare Claims Processing Manual", 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 CCRs. The file of OPPS hospital upper limit CCRs and the file of Statewide CCRs are available at **www.cms.gov/HospitalOutpatientPPS/** under "Annual Policy Files."

d) Application of the Out Migration Adjustment for IPPS hospitals that also receive OPPS Payment

CR9930 provides instructions to the MACs regarding the application of the out migration adjustment for hospitals located in a county eligible for the out migration adjustment, if the hospital is NOT located in a rural county deemed as a Lugar county (only applicable to 1886(d) hospitals), or the hospital has NOT been approved to reclassify as rural under Section 1886(d)(8)(E) of the Social Security Act (42 CFR 412.103), or the hospital does NOT have an MGCRB reclassification.

Note: Hospitals that are LUGAR (and did not waive their LUGAR status) or qualify for MGCRB or 412.103 reclassification are not eligible for the out migration adjustment.

e) Updating the OPSF for Hospitals Reclassified as Rural Hospitals Under Section 412.103 and Hospitals Reclassified under the Medicare Geographic Classification Review Board (MGCRB)

An urban hospital that reclassifies as a rural hospital under Section 412.103 is considered rural for all OPPS purposes. Prior to April 21, 2016, the regulations at Section 412.230(a)(5)(ii) and Section 412.230(a)(5)(iii) prohibited hospitals from simultaneously receiving an urban to rural reclassification under Section 412.103 and a reclassification under the MGCRB. Also, the regulations did not allow a LUGAR hospital to keep its LUGAR status if it was approved for an urban to rural reclassification under Section 412.103. The court decisions in Geisinger Community Medical Center v. Secretary, United States Department of Health and Human Services, 794 F.3d 383 (3d Cir. 2015) and Lawrence + Memorial Hospital v. Burwell, No. 15-164, 2016 WL 423702 (2d Cir. Feb. 4, 2015) ruled as unlawful the regulation precluding a hospital from maintaining simultaneous MGCRB and Section 412.103 reclassifications.

Therefore, on April 18, 2016, CMS issued an interim final rule with comment period (CMS-1664-IFC) amending the regulations to conform to the court decisions. The IFC is effective April 21, 2016, and was finalized on August 2, 2016. The IFC allows hospitals nationwide that have an MGCRB reclassification or LUGAR status during FY 2016 and subsequent years the opportunity to simultaneously seek urban to rural reclassification under Section 412.103 for IPPS payment and other purposes, and keep their existing MGCRB reclassification or LUGAR status.

At any point during a calendar year, MACs may be notified by the CMS Regional Offices of hospitals located in an urban CBSA that are approved to reclassify as rural under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103). The regulations at Section 412.103(a)(c) provide the CMS Regional Offices with up to 60 days to review and approve an urban to rural reclassification request. If the request is approved by CMS Regional Office, the approval is effective as of the filing date of the request (typically specified in the CMS Regional Office's approval letter).

Instructions for Updating the OPSF if a Hospital is Approved for an Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Social Security Act (§ 412.103) with an Effective Date of April 21, 2016 and After for CY 2016

CR9930 provides instruction to MACs for updating the OPSF when a hospital is approved for an urban to rural reclassification under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103) with an effective date of April 21, 2016, and after for CY 2016.

Instructions for Updating the OPSF for Treatment of Certain Urban Hospitals Reclassified as Rural Hospitals Under Section 412.103 in CY 2017 but with no other Reclassifications

An urban hospital that reclassifies as a rural hospital under Section 412.103 is considered rural. In order to ensure correct payment under the OPPS, the rural CBSA (2-digit State code) in the Wage Index Location CBSA and the special payment indicator field must be updated. CR9930 provides instructions to MACs to make that update.

Instructions for Updating the OPSF if a Hospital is Approved for an Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103) with an Effective Date of January 1, 2017, and After for CY 2017

CR9930 provides instructions to the MACS for updating the OPSF using Table 7 in the attachment to CR9930.

Instructions for Updating the OPSF if a Hospital Cancels an Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103)

For a hospital that notifies the CMS Regional Office that it wishes to cancel its urban to rural reclassification under Section 1886(d)(8)(E) of the Social Security Act (42 CFR 412.103), CR9930 provides instructions to the MACS for updating their OPSF.

CR9930 also provides instructions to the MACs for updating the OPSF for hospitals that have both a MGCRB reclassification/LUGAR status and a Section 412.103 urban to rural reclassification and cancel their Urban to Rural reclassification under Section 1886 (d)(8)(E) of the Social Security Act (412.103) in the middle of the Fiscal Year.

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. Medicare Administrative Contractors (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 instructions, CR 9930, issued to your MAC regarding this change are available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3685CP.pdf** and **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R232BP.pdf.**

You may refer to **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html** for the most current OPPS HCPCS Offset File.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/**.