DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9486 **Related Change Request (CR) #: CR 9486**

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Related CR Transmittal #: R3425CP **Implementation Date: January 4, 2016**

January 2016 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 and Hospice MACs, for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System.

Provider Action Needed

This article is based on Change Request (CR) 9486, which implements changes to and billing instructions for various policies implemented in the January 2016 OPPS update. The January 2016 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 CR9486. CR9486 also implements several changes related to outpatient observation services, finalized in the Calendar Year (CY) 2016 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Final Rule. In addition, CR9486 also implements several changes in the manual requirements of the "Medicare Benefit Policy," Pub. 100-02, Chapter 6, related to outpatient observation services that were finalized in the **CY 2016 OPPS /ASC Final Rule**. Make sure that your billing personnel are aware of these changes.

Background

The key changes to and billing instructions for various payment policies implemented in the January 2016 OPPS update are as follows:

1. 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 for new medical devices not described by existing or previously existing categories of devices.

For the January 2016 update, HCPCS code C1822 is being added to the OPPS pass-through list as a pass-through device. This HCPCS code will be assigned to OPPS status indicator "H" (Pass-Through Device Categories), effective January 1, 2016.

In the CY 2016 OPPS/ASC final rule, published in the Federal Register on November 13, 2015, CMS finalized a payment policy whereby the application process for device pass-through payments will add a rulemaking component to the existing quarterly process and a newness criterion. Refer to the **CY 2016 OPPS/ASC final rule with comment period** for complete details of these policy and process changes for device pass-through. Also, refer to **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html** for updated device pass-through application instructions.

Device Offset from Payment for New Device Category

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 HCPCS code C1822 is reflected in APC 5464. The HCPCS code C1822 device should always be billed with Current Procedural Terminology (CPT) Code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) which is assigned to APC 5464 for CY 2016. The device offset from payment represents a deduction from pass-through payments for the device in category C1822.

Table 1 below 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

HCPCS Code	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Device Offset from Payment
C1822	01-01-2015	H	1661	Gen, neuro, HF, rechg bat	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	$22,478.58

Revised Short and Long Descriptors for HCPCS Code C1820

With the establishment of HCPCS code C1822, CMS is modifying the short and long descriptors for existing HCPCS code C1820 to appropriately differentiate between HCPCS code C1822 and C1820. Effective January 1, 2016, the short and long descriptors for HCPCS code C1820 are listed in Table 2 below.

Table 2 - Revised Short and Long Descriptors for HCPCS Code C1820

HCPCS Code	Short Descriptor	Long Descriptor	CY 2016 OPPS SI
C1820	Gen, neuro, non-HF rechg bat	Generator, neurostimulator (implantable), non-high-frequency with rechargeable battery and charging system	N

Note that HCPCS code C1820 describes an implantable **non high-frequency** neurostimulator generator device with rechargeable battery and charging system, while HCPCS code C1822 describes an implantable **high-frequency** neurostimulator generator device with rechargeable battery and charging system.

2. Device Edit for Procedures Assigned to Device- Intensive APCs

For CY 2016, CMS will no longer restrict the device code reporting requirement to only those device-intensive APCs (APCs with a device offset of greater than 40 percent) which were formerly device-dependent APCs. Therefore, effective January 1, 2016, procedures requiring the implantation of a device which are assigned to device intensive APCs will require a device code to be present on the claim. CMS is updating the “Medicare Claims Processing Manual,” Chapter 4, Section 61.2 to reflect these changes to the reporting guidelines for procedures assigned to device-intensive APCs.

3. Removal of Device Portion from Procedures that are Assigned to a Device-Intensive APC and that are Discontinued Prior to the Administration of Anesthesia

In accordance with the regulations at **42 CFR 419.44(b)** and the "Medicare Claims Processing Manual," Chapter 4, Section 20.6.4, when a surgical procedure, for which anesthesia is planned, is terminated **after** the patient is prepared and taken to the room where the procedure is to be performed, but prior to the administration of anesthesia, hospitals are instructed to append modifier "73" to the procedure line item on the claim. Medicare processes these line items by removing one-half of the full program allowance.

In the CY 2016 OPPS/ASC final rule, CMS revised its payment policy for surgical procedures for which anesthesia is planned and that are discontinued prior to the administration of anesthesia, appended with modifier 73.

Specifically, effective January 1, 2016, for such procedures that are assigned to a device-intensive APC (defined as those APCs with a device offset greater than 40 percent), CMS will remove the full device portion of the device-intensive APC procedure payment prior to applying the additional payment adjustments that apply when the procedure is discontinued.

4. 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 devices used in the procedures assigned to the APC. 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** on the CMS website for the most current OPPS APC Offset File.

5. 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 these APCs to be a "new technology procedure or service."

Procedures for applying for assignment of new services to New Technology APCs are available at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html** on the CMS website.

The list of HCPCS codes indicating the APCs to which each is assigned can be found 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** on the CMS website.

6. New Brachytherapy Source Payment

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered Outpatient Department (OPD) services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. CivaSheet is a new brachytherapy source. The HCPCS code assigned to this source and the payment rate under OPPS are listed in Table 3 below.

Table 3 – New Brachytherapy Source Code, Effective January 1, 2016

HCPCS	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Payment	Minimum Unadjusted Copayment
C2645	1/1/2016	U	2648	Brachytx planar, p-103	Brachytherapy planar source, palladium - 103,per square millimeter	$4.69	$0.94

7. Modifier "CA"

Effective January 1, 2016, if an "inpatient-only" service is furnished but the patient expires before inpatient admission or transfer to another hospital and the hospital reports the "inpatient only" service with modifier "CA," then CMS makes a single payment for all services reported on the claim, including the "inpatient only" procedure, through one unit of APC 5881, (Ancillary outpatient services when the patient dies). Hospitals should report modifier "CA" on only one procedure. CMS is updating the "Medicare Claims Processing Manual," Chapter 4, Section 180.7 to reflect the revised payment policy.

8. Modifier "CT"

In accordance with Section 1834(p) of the Act, CMS has established a new modifier "CT" to identify Computed Tomography (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."

Effective January 1, 2016, Medicare requires that hospitals and suppliers 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).

The use of this modifier will result in a payment reduction of 5 percent in CY 2016 for the applicable CT services when the service is paid separately. The 5percent 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 Computed Tomographic Angiography (CTA) imaging family. CR0486 updates the "Medicare Claims Processing Manual," Chapter 4, Section 20.6.12, to include this new modifier.

9. Comprehensive Observation Services C-APC (APC 8011)

Effective January 1, 2016, CMS will provide payment for all qualifying extended assessment and management encounters through newly created C-APC 8011 (Comprehensive Observation Services). Any clinic visit, Type A Emergency Department (ED) visit, Type B ED visit, critical care visit, or direct referral for observation services furnished in a non-surgical encounter by a hospital in conjunction with observation services of eight or more hours, will qualify for comprehensive payment through C-APC 8011. Effective January 1, 2016, CMS will no longer provide payment for extended assessment and management encounters through APC 8009 (Extended Assessment and Management Composite) and APC 8009 is deleted, effective January 1, 2016.

Also effective January 1, 2016, CMS has created new Status Indicator (SI) J2 to designate specific combinations of services that, when performed in combination with each other and reported on a hospital Medicare Part B outpatient claim, would allow for all other OPPS payable services and items reported on the claim (excluding all preventive services and certain Medicare Part B inpatient services) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment through C-APC 8011 for the comprehensive service based on the costs of all reported services on the claim. CMS is updating the "Medicare Claims Processing Manual," Chapter 4, Sections 10.2.1, 10.2.3, 10.4, 290.5.1 and 290.5.2 and adding a new Section 290.5.3 to reflect the new billing guidelines for this new comprehensive APC.

10. Billing for Lung Cancer Screening Counseling and Shared Decision Making Visit, and Annual Screening for Lung Cancer with LDCT

Effective February 5, 2015, a CMS National Coverage Determination (NCD) added lung cancer screening counseling and shared decision making visit, and for certain beneficiaries, annual screening for lung cancer with Low Dose Computed Tomography (LDCT), as an additional screening service benefit under the Medicare program if all eligibility criteria described in the NCD are met.

For purposes of Medicare coverage of lung cancer screening with LDCT, beneficiaries must meet all of the following eligibility criteria:

- Age 55 – 77 years;
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current smoker or one who has quit smoking within the last 15 years; and
- Receives a written order for lung cancer screening with LDCT that meets the requirements described in the NCD. Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary's medical records.

To implement this recent coverage determination, CMS created two new G-codes to report lung cancer screening counseling and shared decision making visit, and annual screening for lung cancer with LDCT. The long descriptors for both G-codes appear in Table 4 below.

Table 4 – Lung Cancer Screening Counseling and Shared Decision Making Visit, and Annual Screening for Lung Cancer with LDCT

HCPCS Code	Long Descriptor	Status Indicator	CY 2015 APC	CY 2016 APC
G0296	Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)	S	0432	5822
G0297	Low dose CT scan (LDCT) for lung cancer screening	S	0332	5570

For CY 2016, HCPCS codes G0296 and G0297 are assigned to APC 5822 (Level 2 Health and Behavior Services) and APC 5570 (Computed Tomography without Contrast), respectively, and both given a status indicator assignment of "S." Further reporting guidelines on lung cancer screening counseling and shared decision making visit and annual screening for lung cancer with LDCT can be found in the "Medicare Claims Processing Manual," Chapter 18, Section 220, as well as in MLN Matters® Article **MM9246** which was published on October 15, 2015.

11. Billing Instructions for IMRT Planning

Payment for the services identified by CPT codes 77014, 77280 through 77295, 77305 through 77321, 77331, and 77370 is included in the APC payment for CPT code 77301 (Intensity Modulated Radiation Therapy (IMRT) planning). These codes should not be reported in addition to CPT code 77301 (on either the same or a different date of service) unless these services are being performed in support of a separate and distinct non-IMRT radiation therapy for a different tumor.

12. Billing for Stereotactic Radiosurgery (SRS) Planning and Delivery

Effective for cranial single session Stereotactic Radiosurgery (SRS) procedures (CPT code 77371 or 77372) furnished on or after January 1, 2016 until December 31, 2017, costs for certain planning and preparation CPT codes are not factored into the APC payment rate for APC 5627 (Level 7 Radiation Therapy). Rather, the ten planning and preparation codes listed in Table 5 below will be paid according to their assigned status indicator when furnished 30 days prior or 30 days post SRS treatment delivery.

Table 5 – Excluded Planning and Preparation CPT Codes

CPT Code	CY 2016 Short Descriptor	CY 2016 Status Indicator
70551	Mri brain stem w/o dye	Q3
70552	Mri brain stem w/dye	Q3
70553	Mri brain stem w/o & w/dye	Q3
77011	Ct scan for localization	N
77014	Ct scan for therapy guide	N
77280	Set radiation therapy field	S
77285	Set radiation therapy field	S
77290	Set radiation therapy field	S

CPT Code	CY 2016 Short Descriptor	CY 2016 Status Indicator
77295	3-d radiotherapy plan	S
77336	Radiation physics consult	S

In addition, hospitals must report modifier "CP" (Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification [C-APC] procedure) on TOB 13X claims for any other services (aside from the ten codes in Table 5) that are adjunctive or related to SRS treatment but billed on a different date of service and within 30 days prior or 30 days after the date of service for either CPT codes 77371 (Radiation treatment delivery, stereotactic radiosurgery, complete course of treatment cranial lesion(s) consisting of 1 session; multi-source Cobalt 60-based) or 77372 (Linear accelerator based). The "CP" modifier should be reported under all circumstances in which a service adjunctive or related to SRS treatment is provided within one month of SRS treatment. This means that if multiple physicians within the same health system furnish an adjunctive SRS service, then all claims from these physicians would need to report the "CP" modifier with the HCPCS code for the related SRS adjunctive service(s).

13. Billing Instructions for Corneal Tissue

In the CY 2016 OPPS/ASC Final Rule with Comment Period (80 FR 70472), procurement /acquisition of corneal tissue will be paid separately only when it is used in corneal transplant procedures. Specifically, corneal tissue will be separately paid when used in procedures performed in the Hospital Outpatient Department (HOPD) only when the corneal tissue is used in a corneal transplant procedure described by one of the following CPT codes:

- 65710 (Keratoplasty (corneal transplant); anterior lamellar);
- 65730 (Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia));
- 65750 (Keratoplasty (corneal transplant); penetrating (in aphakia));
- 65755 (Keratoplasty (corneal transplant); penetrating (in pseudophakia));
- 65756 (Keratoplasty (corneal transplant); endothelial);
- 65765 (Keratophakia);
- 65767 (Epikeratoplasty); and
- Any successor code or new code describing a new type of corneal transplant procedure that uses eye banked corneal tissue.

HCPCS code V2785 (Processing, preserving and transporting corneal tissue) should only be reported when corneal tissue is used in a corneal transplant procedure; V2785 should not be reported in any other circumstances.

14. Revisions to Laboratory Test Packaging

For CY 2016, CMS is implementing a conditional packaging status indicator "Q4" for packaged laboratory services. Status indicator "Q4" designates packaged APC payment if 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), automatically change their status indicator to "A," and pay them

separately at the CLFS payment rates. With the assignment of the "Q4" status indicator, the "L1" modifier would only be used to identify unrelated laboratory tests that are ordered for a different diagnosis and by a different practitioner than the other OPPS services on the claim.

15. New CY 2016 HCPCS Codes for Pathogen-Reduced Blood Products

For CY 2016, three new HCPCS P-codes have been created for new pathogen-reduced blood products. The term "pathogen reduction" describes various techniques (including treatment with Amotosalen and UVA light) used on blood products to eliminate certain pathogens and reduce the risk of transfusion-associated infections. Because these three HCPCS P-codes are new for CY 2016, there are currently no claims data on the charges and costs for these blood products upon which to apply our blood-specific Cost to Charge Ratio (CCR) methodology. Therefore, CMS is establishing interim payment rates for these three HCPCS P-codes based on a crosswalk to existing blood product HCPCS codes that CMS believes provides the best proxy for the costs of the three new blood products described by the new HCPCS P-codes. These new codes are listed in Table 6 below.

Table 6 -- New Pathogen-Reduced Blood Products HCPCS P-Codes and Interim Payment Rates and Crosswalk for CY 2016

HCPCS P-Code	Effective Date	Long Descriptor	Cross walked HCPCS P-Code	Cross walked HCPCS P-Code Long Descriptor	Payment
P9070	1/1/2016	Plasma, pooled multiple donor, pathogen reduced, frozen, each unit	P9059	Fresh frozen plasma between 8-24 hours of collection, each unit	$73.08
P9071	1/1/2016	Plasma (single donor), pathogen reduced, frozen, each unit	P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit	$72.56
P9072	1/1/2016	Platelets, pheresis, pathogen reduced, each unit	P9037	Platelets, pheresis, leukocytes reduced, irradiated, each unit	$641.85

16. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2016, 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 7 below.

Table 7 – New CY 2016 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2016 HCPCS Code	CY 2016 Long Descriptor	CY 2016 SI	CY 2016 APC
C9458	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458
C9459	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
C9460	Injection, cangrelor, 1 mg	G	9460
Q9980	'Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg	E	
J0714	'Injection, ceftazidime and avibactam, 0.5g/0.125g	K	1825
J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immuneglobulin	K	1826
J7188	Injection, factor viii (antihemophilic factor, recombinant), (obizur), per i.u.	K	1827
J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg	E	
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension	K	1828
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	E	
Q4161	Bio-connekt wound matrix, per square centimeter	N	
Q4162	Amniopro flow, bioskin flow, biorenew flow, woundex flow, amniogen-a, amniogen-c, 0.5 cc	N	
Q4163	Amniopro, bioskin, biorenew, woundex, amniogen-45, amniogen-200, per square centimeter	N	
Q4164	Helicoll, per square centimeter	N	
Q4165	Keramatrix, per square centimeter	N	

b. Other Changes to CY 2016 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 2016. In addition, several temporary HCPCS C-codes have been deleted, effective December 31, 2015, and replaced with permanent HCPCS codes in CY 2016. 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 2015 HCPCS and CPT codes.

Table 8 below notes those drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2015 HCPCS/CPT code and long descriptor are noted in the two left hand columns and the CY 2016 HCPCS/CPT code and long descriptor are noted in the adjacent right hand columns.

Table 8 – Other CY 2016 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2015 HCPCS/ CPT code	CY 2015 Long Descriptor	CY 2016 HCPCS/ CPT Code	CY 2016 Long Descriptor
C9025	Injection, ramucirumab, 5 mg	J9308	Injection, ramucirumab, 5 mg
C9026	Injection, vedolizumab, 1 mg	J3380	Injection, vedolizumab, 1 mg
C9027	Injection, pembrolizumab, 1 mg	J9271	Injection, pembrolizumab, 1 mg
Q9975	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu	J7205	Injection, factor viii fc fusion protein (recombinant), per iu
C9442	Injection, belinostat, 10 mg	J9032	Injection, belinostat, 10 mg
C9443	Injection, dalbavancin, 10 mg	J0875	Injection, dalbavancin, 5 mg
C9444	Injection, oritavancin, 10 mg	J2407	Injection, oritavancin, 10 mg
C9445	Injection, c-1 esterase inhibitor (recombinant), Ruconest, 10 units	J0596	Injection, c1 esterase inhibitor (recombinant), ruconest, 10 units
C9446	Injection, tedizolid phosphate, 1 mg	J3090	Injection, tedizolid phosphate, 1 mg
Q9978	Netupitant 300 mg and Palonosetron 0.5 mg, oral	J8655	Netupitant 300 mg and palonosetron 0.5 mg
C9449	Injection, blinatumomab, 1 mcg	J9039	Injection, blinatumomab, 1 microgram
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	J7313	Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg
C9451	Injection, peramivir, 1 mg	J2547	Injection, peramivir, 1 mg
C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg
C9453	Injection, nivolumab, 1 mg	J9299	Injection, nivolumab, 1 mg
C9454	Injection, pasireotide long acting, 1 mg	J2502	Injection, pasireotide long acting, 1 mg
C9455	Injection, siltuximab, 10 mg	J2860	Injection, siltuximab, 10 mg
C9456	Injection, isavuconazonium sulfate, 1 mg	J1833	Injection, isavuconazonium, 1 mg
C9457	Injection, sulfur hexafluoride lipid microsphere, per ml	Q9950	Injection, sulfur hexafluoride lipid microspheres, per ml
J0571	Buprenorphine, oral, 1 mg	J0571	Buprenorphine, oral, 1 mg
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg	J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine

CY 2015 HCPCS/ CPT code	CY 2015 Long Descriptor	CY 2016 HCPCS/ CPT Code	CY 2016 Long Descriptor
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg	J0573	Buprenorphine/naloxone, greater than 3 mg, but less than or equal to 3.1 to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg	J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg
J0575	Buprenorphine/naloxone, oral, greater than 10 mg	J0575	Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine
J1446	Injection, tbo-filgrastim, 5 micrograms	J1447	Injection, tbo-filgrastim, 1 microgram
J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg	J7297	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg, 3 year duration
J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg	J7298	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg, 5 year duration
J7506	Prednisone, oral, per 5mg	J7512	Prednisone, immediate release or delayed release, oral, 1 mg
J7508	Tacrolimus, extended release, oral, 0.1 mg	J7508	Tacrolimus, extended release, (astagraf xl), oral, 0.1 mg
Q9979	Injection, alemtuzumab, 1 mg	J0202	Injection, alemtuzumab, 1 mg
Q4153	Dermavest, per square centimeter	Q4153	Dermavest and plurivest, per square centimeter
Q9976	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron	J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron
Q9977	Compounded Drug, Not Otherwise Classified	J7999	Compounded Drug, Not Otherwise Classified
S5011	5% dextrose in lactated ringer's, 1000 ml	J7121	5% dextrose in lactated ringers infusion, up to 1000 cc

c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective January 1, 2016

For CY 2016, payment for non-pass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2016, 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, 2016, payment rates for many drugs and biologicals have changed from the values published in the CY 2016 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 2015. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2016 release of the OPPS Pricer. CMS is not publishing the updated payment rates in this CR implementing the January 2016 update of the OPPS. However, the updated payment rates, effective January 1, 2016, can be found in the January 2016 update of the OPPS Addendum A and Addendum B, available at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html** on the CMS website.

d. Correction to Effective Dates for Certain Vaccines

CR9486 revises the effective dates for vaccine CPT codes 90620 and 90621 as shown in Table 9 below.

Table 9 – Corrected Effective Dates for Certain Vaccine Codes

CPT	SI	APC	Short Descriptor	Long Descriptor	Corrected Effective Date
90620	K	1807	Menb rp w/omv vaccine im	Meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B, 2 dose schedule, for intramuscular use	1/23/2015
90621	K	1808	Menb rlp vaccine im	Meningococcal recombinant lipoprotein vaccine, serogroup B, 3 dose schedule, for intramuscular use	10/29/2014

e. 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** on the CMS website. Providers may resubmit claims that were impacted by adjustments to previous quarter's payment files.

f. Payment Correction for Diagnostic Radiopharmaceutical C9458

The payment rate listed in Addendum B of the CY 2016 OPPS/ASC final rule with comment period for HCPCS code C9458 (Florbetaben F18) is incorrect. The corrected payment rate of $2,968 per study dose for HCPCS code C9458 is listed in Addendum B of this January update and has been installed in the January 2016 OPPS Pricer, effective for services furnished on or after January 1, 2016.

g. Biosimilar Payment Policy

Effective January 1, 2016, the payment rate for biosimilars in the OPPS will be the same as the payment rate in the physician office setting, calculated as the ASP of the biosimilar(s) described by the HCPCS code + 6% of the ASP of the reference product. Biosimilars will 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.

h. Updated Guidance: 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 follows:

1. Diagnostic Radiopharmaceuticals – All new diagnostic radiopharmaceuticals are assigned to either HCPCS code A4641 (Radiopharmaceutical, diagnostic, 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 A4641, 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 A4641, 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.

i. 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 10 below 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 code C5271-C5278. All pass-through skin substitute products are to be reported in combination with one of the skin application procedures described by CPT code 15271-15278.

Table 10 – Skin Substitute Product Assignment to High Cost/Low Cost Status for CY 2016

CY 2016 HCPCS Code	CY 2016 Short Descriptor	CY 2016 SI	Low/High Cost Skin Substitute
C9349	PuraPly, PuraPly antimic	G	High
C9363	Integra Meshed Bil Wound Mat	N	High
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
Q4119	Matristem Wound Matrix	N	Low
Q4120	Matristem Burn Matrix	N	High
Q4121	Theraskin	G	High
Q4122	Dermacell	N	High
Q4123	Alloskin	N	High
Q4124	Oasis Tri-layer Wound Matrix	N	Low

CY 2016 HCPCS Code	CY 2016 Short Descriptor	CY 2016 SI	Low/High Cost Skin Substitute
Q4126	Memoderm/derma/tranz/integup	N	High
Q4127	Talymed	N	High
Q4128	Flexhd/Allopatchhd/Matrixhd	N	High
Q4129	Unite Biomatrix	N	Low
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	Low
Q4146	Tensix, 1CM	N	Low
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	Low
Q4158	MariGen 1 square cm	N	Low
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	Low
Q4164	Helicoll, per square cm	N	Low
Q4165	Keramatrix, per square cm	N	Low

*HCPCS codes Q4151, Q4152, Q4154, and Q4156 were assigned to the low cost group in the CY 2016 OPPS/ASC final rule with comment period. Upon submission of updated pricing information, Q4151, Q4152, Q4154, and Q4156 are assigned to the high cost group for CY 2016.

17. Changes to OPPS Pricer Logic

a. Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2016. 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, 2016. 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 2016 inpatient deductible.

c. For hospital outlier payments under OPPS, there will be no change in the multiple threshold of 1.75 for 2016. 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 increases in CY 2016 relative to CY 2015. The estimated cost of a service must be greater than the APC payment amount plus $3,250 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 2016. This threshold of 3.4 is multiplied by the total line-item APC payment for APC 0173 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 for nuclear medicine procedures –[APC 0173 payment x 3.4])/2.

f. Effective October 1, 2013, and expiring December 31, 2015, one device (C1841 - Retinal prosthesis, includes all internal and external components) was eligible for pass-through payment in the OPPS Pricer logic. After pass-through status expires for a medical device, the payment for the device is packaged into the payment for the associated procedure.

Effective January 1, 2016, CMS is packaging C1841 and assigning CPT code 0100T (which includes the retinal prosthesis device) to New Technology APC 1599, which has a final payment of $95,000 for CY 2016.

g. Effective January 1, 2015, and continuing for CY 2016, 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.

h. Effective January 1, 2016, there will be three diagnostic radiopharmaceuticals and one contrast agent receiving pass-through payment in the OPPS Pricer logic. For APCs containing nuclear medicine procedures, Pricer will reduce the amount of the pass-through diagnostic radiopharmaceutical or contrast agent payment by the wage-adjusted offset for

the APC with the highest offset amount when the radiopharmaceutical or contrast agent with pass-through appears on a claim with a nuclear procedure. The offset will cease to apply when the diagnostic radiopharmaceutical or contrast agent expires from pass-through status. The offset amounts for diagnostic radiopharmaceuticals are the "policy-packaged" portions of the CY 2016 APC payments for nuclear medicine procedures and may be found on the CMS website.

i. Effective January 1, 2016, there will be two skin substitute products receiving pass-through payment in the OPPS Pricer logic. For skin substitute application procedure codes that are assigned to APC 5054 (Level 4 Skin Procedures) or APC 5055 (Level 5 Skin Procedures), Pricer will reduce the payment amount for the pass-through skin substitute product by the wage-adjusted offset for the APC when the pass-through skin substitute product appears on a claim with a skin substitute application procedure that maps to APC 5054 or APC 5055. The offset amounts for skin substitute products are the "policy-packaged" portions of the CY 2016 payments for APC 5054 and APC 5055.

j. Pricer will update the payment rates for drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals with pass-through status when those payment rates are based on ASP on a quarterly basis.

k. Effective January 1, 2016, CMS is adopting the FY 2016 IPPS post-reclassification wage index values with application of out-commuting adjustment authorized by Section 505 of the MMA to non-IPPS hospitals.

l. 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 at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html** on the CMS website.

Coverage Determinations

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, CR9486, issued to your MAC regarding this change, is available at **http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3425CP.pdf** on the Centers for Medicare & Medicaid Services (CMS) website. The portions of Medicare manuals updated by CR9486 are attached to the CR.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** on the CMS website under - How Does It Work.