CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3425	**Date: December 18, 2015**
	Change Request 9486

SUBJECT: January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to and billing instructions for various payment 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 this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.8.

The January 2016 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2016 I/OCE CR.

EFFECTIVE DATE: January 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/Table of Contents
R	4/10.2.1./Composite APCs
R	4/10.2.3/Comprehensive APCs
R	4/10.4/Packaging
R	4/20.6.4/Use of Modifiers for Discontinued Services
N	4/20.6.12/ Use of HCPCS Modifier – CT
R	4/50.4/Transitional Pass-Through Payments for Designated Devices
R	4/60/Billing for Devices Eligible for Transitional Pass-Through Payments and Items Classified in “New Technology” APCs
R	4/60.1/60.1/Categories for Use in Coding Devices Eligible for Transitional Pass-Through Payments Under the Hospital OPPS
R	4/60.3/Devices Eligible for Transitional Pass-Through Payments
R	4/60.4/General Coding and Billing Instructions and Explanations
R	4/60.5/Services Eligible for New Technology APC Assignment and Payments
R	4/61.2/ Edits for Claims on Which Specified Procedures are to be Reported With Device Codes and For Which Specific Devices are to be Reported With Procedure Codes
R	4/180.7/Inpatient-only Services
R	4/200.1/Billing for Corneal Tissue
R	4/200.3.1/Billing Instructions for IMRT Planning
R	4/200.3.2/Billing for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS) Planning and Delivery
D	4/200.3.3/Billing for Stereotactic Radiosurgery (SRS) Planning and Delivery
R	4/290.5.1/Billing and Payment for Observation Services Furnished Between January 1, 2008 and December 31, 2015
R	4/290.5.2/Billing and Payment for Direct Referral for Observation Care Furnished Beginning January 1, 2008
N	4/290.5.3/Billing and Payment for Observation Services Furnished Beginning January 1, 2016
R	16/30.3/Method of Payment for Clinical Laboratory Tests - Place of Service Variation
R	16/40.6.2.1/ Separately Billable ESRD Laboratory Tests Furnished by Hospital-Based Facilities

III. FUNDING:
For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3425	Date: December 18, 2015	Change Request: 9486

SUBJECT: January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: January 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2016

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment 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 this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.8.

The January 2016 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2016 I/OCE CR.

B. Policy:

1. New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security 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 we 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 (Outpatient Prospective Payment System/Ambulatory Surgical Center) final rule that was 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.

a. Device Offset from Payment for New Device Category: 1833(t)(6)(D)(ii) of the Act requires that we deduct from pass-through payments for devices an amount that reflects the portion of the APC payment amount.

We have 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 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, in Attachment A, provides a listing of new coding and payment information concerning the new device category for transitional pass-through payment.

b. Revised Short and Long Descriptors for HCPCS Code C1820

With the establishment of HCPCS code C1822, we are 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, attachment A.

We 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, we 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 Pub. 100-04, Medicare Claims Processing Manual, chapter 4, sections 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 Section 20.6.4 of the Chapter 4 of the Medicare Claims Processing Manual, 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 (Outpatient Prospective Payment System/Ambulatory Surgical Center) final rule, that was published in the Federal Register on November 13, 2015, 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 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 may be found on the CMS Web site, currently at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html

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 http://www.cms.hhs.gov/HospitalOutpatientPPS/HOPPSTrans/list.asp#TopOfPage. Please note that this link may change depending on CMS Web design requirements.

6. New Brachytherapy Source Payment

Section 1833(t)(2)(H) of the Social Security Act mandates the creation of additional groups of covered 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, attachment A.

7. Modifier "CA"

We are revising our billing instructions to state that 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 will make a single comprehensive payment for all services reported on the claim.

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 Pub. 100-04, 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 we have 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, hospitals and suppliers are required to use this modifier on claims for computed tomography (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 computed tomography (CT) services when the service is paid separately. The 5 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 computed tomography (CT) and computed tomographic angiography (CTA) imaging family.

CMS is updating Pub. 100-04, 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 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 Pub. 100-04, Medicare Claims Processing Manual, chapter 4, sections 10.2.1, 10.2.3, 10.4, 290.5.1 and 290.5.2 and adding new Pub. 100-04, Medicare Claims Processing Manual, chapter 4, 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, attachment A.

For CY 2016, HCPCS codes G0296 and G0297 have been 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 Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, Section 220, as well as in Transmittal 3374, CR 9246 that 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 (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.

1**2. Billing for Stereotactic Radiosurgery (SRS) Planning and Delivery**

Effective for cranial single session stereotactic radiosurgery 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, attachment A, will be paid according to their assigned status indicator when furnished 30 days prior or 30 days post SRS treatment delivery.

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 below) 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

As finalized 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 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, we are 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 that 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 CCR methodology. Therefore, we are establishing interim payment rates for these three HCPCS P-codes based on a crosswalk to existing blood product HCPCS codes that we believe provide the best proxy for the costs of the three new blood products described by the above listed new HCPCS P-codes. These new codes are listed in Table 6, attachment A.

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, attachment A.

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, attachment A, 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.

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 Change Request 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 on the CMS Web site at http://www.cms.gov/HospitalOutpatientPPS/.

d. Correction to effective dates for certain vaccines

The effective date for vaccine CPT code 90620 and 90621 have been revised. The revised effective dates are listed in table 9, attachment A.

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 CMS Web site on the first date of the quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html.

Providers may resubmit claims that were impacted by adjustments to previous quarter's payment files.

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 average sales price (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, attachment A, 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.

17.Changes to OPPS Pricer Logic

a. Rural sole community hospitals (SCH) 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 2015. 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-(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, we are 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 Web site.

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 discussed below.

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

18. Update the Outpatient Provider Specific File (OPSF)

For January 1, 2016, contractors shall maintain the accuracy of the provider records in the Outpatient Provider Specific File (OPSF) as changes occur in data element values.

Update the 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

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 11, attachment A. As always, the OPPS applies the IPPS fiscal year 2016 post-reclassification wage index values to all hospitals and community mental health centers participating in the OPPS for the 2016 calendar year.

Contractors shall do the following to update the OPSF (effective January 1, 2016):

1. Update the CBSA value for each provider in Table 11, attachment A;

2. For non-IPPS providers who qualify for the 505 adjustment in CY 2016 (Table 11, attachment A);

a. Create a new provider record, effective January 1, 2016 and

b. Enter a value of "1" in the Special Payment Indicator field on the OPSF; and

c. Enter the final wage index value (given for the provider in Table 11, attachment A) in the Special Wage Index field in the OPSF.

3. For non-IPPS providers who received a special wage index in CY 2015, but no longer receive it in CY 2016;

a. Create a new provider record, effective January 1, 2016 and

b. Enter a blank in the Special Payment Indicator field; and

c. Enter zeroes in the special wage index field.

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 11, attachment A) because the post-reclassification CBSA wage index has changed.

NOTE: 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 permanently held harmless under section 1833(t)(7)(D)(ii) of the Social Security Act and continue to receive hold harmless TOPs permanently. For CY 2016, cancer hospitals will continue to receive an additional payment adjustment.

b) Updating the OPSF for the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) Requirements

Effective for OPPS services furnished on or after January 1, 2009, Subsection (d) hospitals that have failed to submit timely hospital outpatient quality data as required in Section 1833(t)(17)(A) of the Act will receive payment under the OPPS that reflects a 2 percentage point deduction from the annual OPPS update for failure to meet the HOP QDRP requirements. This reduction will not apply to hospitals not required to submit quality data or hospitals that are not paid under the OPPS.

For January 1, 2016, contractors shall maintain the accuracy of the provider records in the OPSF by updating the Hospital Quality Indicator field. CMS will release a Technical Direction Letter that lists Subsection (d) hospitals that are subject to and fail to meet the HOP QDRP requirements. Once this list is

released, Medicare Administrative Contractors (MAC) will update the OPSF by removing the '1', (that is, ensure that the Hospital Quality Indicator field is blank) for all hospitals identified on the list and will ensure that the OPSF Hospital Quality Indicator field contains '1' for all hospitals that are not on the list. CMS notes that if these hospitals are later determined to have met the HOP QDRP requirements, MACs shall update the OPSF. For greater detail regarding updating the OPSF for the HOP QDRP requirements, see Transmittal 368, CR 6072, issued on August 15, 2008.

c) Updating the OPSF for the Outpatient Cost to Charge Ratio (CCR)

As stated in Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, Section 50.1, contractors must maintain the accuracy of the data and update the OPSF as changes occur in data element values, including changes to provider cost–to-charge ratios. The file of OPPS hospital upper limit CCRs and the file of Statewide CCRs are located on the CMS Web site at www.cms.gov/HospitalOutpatientPPS/ under "*Annual Policy Files*."

d) Updating the OPSF for Treatment of Certain Urban Hospitals Reclassified as Rural Hospitals Under §412.103

An urban hospital that reclassifies as a rural hospital under §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.

MACs shall do the following to update the OPSF (effective January 1, 2016):

a. Create a new provider record, effective January 1, 2016, and

b. Enter a value of "Y" in the Special Payment Indicator field on the OPSF; and

c. Enter the rural CBSA (2-digit State code) in the Wage Index Location CBSA field for each provider marked "Y" in the column "Hospital Reclassified as Rural Under Section 1886(d)(8)(E) of the Act (412.103)" found in Table 2 of the FY 2016 IPPS Final rule.

19. 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.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9486 - 04.1	Medicare contractors shall install the January 2016 OPPS Pricer.	X				X				BCRC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9486 - 04.2	As specified in chapter 4, section 50.1, Medicare contractors shall maintain the accuracy of the data and update the OPSF file as changes occur in data element values. For CY 2016, this includes all changes to the OPSF identified in Section 18 of this Change Request.	X		X						BCRC
9486 - 04.3	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of January 2016 OPPS Pricer.	X		X						BCRC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9486 - 04.4	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova, marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)
(Rev.3425, Issued: 12-18-15)

20.6.12 - Use of HCPCS Modifier – CT
50.4 - Transitional Pass-Through *Payments* for Designated Devices
200.3.1 – Billing *Instructions* for IMRT Planning

200.3.2 - Billing *for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS)* Planning *and Delivery*

290.5.1 - Billing and Payment for Observation Services *Furnished Between* January 1, 2008 *and December 31, 2015*

290.5.3 - Billing and Payment for Observation Services Furnished Beginning January 1, 2016

10.2.1 - Composite APCs
(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Composite APCs provide a single payment for a comprehensive diagnostic and/or treatment service that is defined, for purposes of the APC, as a service typically reported with multiple HCPCS codes. When HCPCS codes that meet the criteria for payment of the composite APC are billed on the same date of

service, CMS makes a single payment for all of the codes as a whole, rather than paying individually for each code.

The table below identifies the composite APCs that are currently effective for services furnished on or after January 1, 2008. See Addendum A at www.cms.hhs.gov/HospitalOutpatientPPS/ for the national unadjusted payment rates for these composite APCs.

Composite APC	**Composite APC Title**	**Criteria for Composite Payment**
8000	Cardiac Electrophysiologic Evaluation and Ablation Composite	At least one unit of CPT code 93619 or 93620 and at least one unit of CPT code 93650 on the same date of service; or, at least one unit of CPT codes 93653, 93654, or 93656 (no additional concurrent service codes required).
8001	Low Dose Rate Prostate Brachytherapy Composite	One or more units of CPT codes 55875 and 77778 on the same date of service.
0034	Mental Health Services Composite	Payment for any combination of mental health services with the same date of service exceeds the payment for APC 0173 in years prior to 2011 or APC 0176 after January 1, 2011. For the list of mental health services to which this composite applies, see the I/OCE supporting files for the pertinent period.
8004	Ultrasound Composite	Payment for any combination of designated imaging procedures within the Ultrasound imaging family on the same date of service. For the list of imaging services included in the Ultrasound imaging family, see the I/OCE specifications document for the pertinent period.
8005	Computed Tomography (CT) and Computed Tomographic Angiography (CTA) without Contrast Composite	Payment for any combination of designated imaging procedures within the CT and CTA imaging family on the same date of service. If a "without contrast" CT or CTA procedure is performed on the same date of service as a "with contrast" CT or CTA procedure, the IOCE will assign APC 8006 rather than APC 8005. For the list of imaging services included in the CT and CTA imaging family, see the I/OCE specifications document for the pertinent period.
8006	CT and CTA with Contrast Composite	
8007	Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA) without Contrast Composite	Payment for any combination of designated imaging procedures within the MRI and MRA imaging family on the same date of service. If a "without contrast" MRI or MRA procedure is performed on the same date of service as a "with contrast" MRI or MRA procedure, the I/OCE will assign APC 8008 rather than APC 8007. For the list of imaging services included in the MRI and MRA imaging family, see the I/OCE specifications document for the pertinent period.
8008	MRI and MRA with Contrast Composite	

Future updates will be issued in a Recurring Update Notification.

10.2.3 - Comprehensive APCs

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

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

HCPCS codes assigned to comprehensive APCs are designated with status indicator J1, See Addendum B at www.cms.hhs.gov/HospitalOutpatientPPS/ for the list of HCPCS codes designated with status indicator J1.

Claims reporting at least one J1 procedure code will package the following items and services that are not typically packaged under the OPPS:

- major OPPS procedure codes (status indicators P, S, T, V)
- lower ranked comprehensive procedure codes (status indicator J1)
- non-pass-through drugs and biologicals (status indicator K)
- blood products (status indicator R)
- DME (status indicator Y)
- therapy services (HCPCS codes with status indicator A reported on therapy revenue centers)

The following services are excluded from comprehensive APC packaging:

- brachytherapy sources (status indicator U)
- pass-through drugs, biologicals and devices (status indicators G or H)
- corneal tissue, CRNA services, and Hepatitis B vaccinations (status indicator F)
- influenza and pneumococcal pneumonia vaccine services (status indicator L)
- ambulance services
- mammography
- certain preventive services

The single payment for a comprehensive claim is based on the rate associated with *either* the J1 service *or the specific combination of J2 services*. When multiple J1 services are reported on the same claim, the single payment is based on the rate associated with the highest ranking J1 service. When certain pairs of J1 services (or in certain cases a J1 service and an add-on code) are reported on the same claim, the claim is eligible for a complexity adjustment, which provides a single payment for the claim based on the rate of the next higher comprehensive APC within the same clinical family. *When a J1 service and a J2 service are reported on the same claim, the single payment is based on the rate associated with the J1 service, and the combination of the J1 and J2 services on the claim does not make the claim eligible for a complexity adjustment.* Note that complexity adjustments will not be applied to discontinued services (reported with mod -73 or -74).

10.4 - Packaging

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Under the OPPS, packaged services are items and services that are considered to be an integral part of another service that is paid under the OPPS. No separate payment is made for packaged services, because the cost of these items and services is included in the APC payment for the service of which they are an integral part. For example, routine supplies, anesthesia, recovery room use, and most drugs are considered to be an integral part of a surgical procedure so payment for these items is packaged into the APC payment for the surgical procedure.

A. Packaging for Claims Resulting in APC Payments

If a claim contains services that result in an APC payment but also contains packaged services, separate payment for the packaged services is not made since payment is included in the APC. However, charges related to the packaged services are used for outlier and Transitional Corridor Payments (TOPs) as well as for future rate setting.

Therefore, it is extremely important that hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged.

B. Packaging for Claims Resulting in No APC Payments

If the claim contains only services payable under cost reimbursement, such as corneal tissue, and services that would be packaged services if an APC were payable, then the packaged services are not separately payable. In addition, these charges for the packaged services are not used to calculate TOPs.

If the claim contains only services payable under a fee schedule, such as clinical diagnostic laboratory tests, and also contains services that would be packaged services if an APC were payable, the packaged services are not separately payable. In addition, the charges are not used to calculate TOPs.

If a claim contains services payable under cost reimbursement, services payable under a fee schedule, and services that would be packaged services if an APC were payable, the packaged services are not separately payable. In addition, the charges are not used to calculate TOPs payments.

C. Packaging Types Under the OPPS

1. Unconditionally packaged services are services for which separate payment is never made because the payment for the service is always packaged into the payment for other services. Unconditionally packaged services are identified in the OPPS Addendum B with status indictor of N. See the OPPS Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/ for the most recent Addendum B (HCPCS codes with status indicators). In general, the charges for unconditionally packaged services are used to calculate outlier and TOPS payments when they appear on a claim with a service that is separately paid under the OPPS because the packaged service is considered to be part of the package of services for which payment is being made through the APC payment for the separately paid service.

2. STV-packaged services are services for which separate payment is made only if there is no service with status indicator S, T, V or reported with the same date of service on the same claim. If a claim includes a service that is assigned status indicator S, T, V reported on the same date of service as the STV- packaged service, the payment for the STV-packaged service is packaged into the payment for the service(s) with status indicator S, T, V and no separate payment is made for the STV-packaged service. STV-packaged services are assigned status indicator Q1. See the OPPS Webpage at http://www.cms.hhs.gov/HospitalOutpatientPPS/ for identification of STV-packaged codes.

3. T-packaged services are services for which separate payment is made only if there is no service with status indicator T reported with the same date of service on the same claim. When there is a claim

that includes a service that is assigned status indicator T reported on the same date of service as the T-packaged service, the payment for the T-packaged service is packaged into the payment for the service(s) with status indicator T and no separate payment is made for the T-packaged service. T-packaged services are assigned status indicator Q2. See the OPPS Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/ for identification of T-packaged codes.

4. A service that is assigned to a composite APC is a major component of a single episode of care. The hospital receives one payment through a composite APC for multiple major separately identifiable services. Services mapped to composite APCs are assigned status indicator Q3. See the discussion of composite APCs in section 10.2.1.

5. J1 services are assigned to comprehensive APCs. Payment for all adjunctive services reported on the same claim as a J1 service is packaged into payment for the primary J1 service. See the discussion of comprehensive APCs in section 10.2.*3*.

6. *J2 services are assigned to comprehensive APCs when a specific combination of services are reported on the claim. Payment for all adjunctive services reported on the same claim as a J2 service is packaged into payment for the J2 service when certain conditions are met. See the discussion of comprehensive APCs in section 10.2.3*.

20.6.4 - Use of Modifiers for Discontinued Services

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

A. General

Modifiers provide a way for hospitals to report and be paid for expenses incurred in preparing a patient for a procedure and scheduling a room for performing the procedure where the service is subsequently discontinued. This instruction is applicable to both outpatient hospital departments and to ambulatory surgical centers.

Modifier -73 is used by the facility to indicate that a procedure requiring anesthesia was terminated due to extenuating circumstances or to circumstances that threatened the well being of the patient after the patient had been prepared for the procedure (including procedural pre-medication when provided), and been taken to the room where the procedure was to be performed, but prior to administration of anesthesia. For purposes of billing for services furnished in the hospital outpatient department, anesthesia is defined to include local, regional block(s), moderate sedation/analgesia (“conscious sedation”), deep sedation/analgesia, or general anesthesia. This modifier code was created so that the costs incurred by the hospital to prepare the patient for the procedure and the resources expended in the procedure room and recovery room (if needed) could be recognized for payment even though the procedure was discontinued.

Modifier -74 is used by the facility to indicate that a procedure requiring anesthesia was terminated after the induction of anesthesia or after the procedure was started (e.g., incision made, intubation started, scope inserted) due to extenuating circumstances or circumstances that threatened the well being of the patient. This modifier may also be used to indicate that a planned surgical or diagnostic procedure was discontinued, partially reduced or cancelled at the physician's discretion after the administration of anesthesia. For purposes of billing for services furnished in the hospital outpatient department, anesthesia is defined to include local, regional block(s), moderate sedation/analgesia (“conscious sedation”), deep sedation/analgesia, and general anesthesia. This modifier code was created so that the costs incurred by the hospital to initiate the procedure (preparation of the patient, procedure room, recovery room) could be recognized for payment even though the procedure was discontinued prior to completion.

Coinciding with the addition of the modifiers -73 and -74, modifiers -52 and -53 were revised. Modifier -52 is used to indicate partial reduction, cancellation, or discontinuation of services for which anesthesia is not planned. The modifier provides a means for reporting reduced services without disturbing the identification

of the basic service. Modifier -53 is used to indicate discontinuation of physician services and is not approved for use for outpatient hospital services.

The elective cancellation of a procedure should not be reported.

Modifiers -73 and -74 are only used to indicate discontinued procedures for which anesthesia is planned or provided.

B. Effect on Payment

Procedures that are discontinued after the patient has been prepared for the procedure and taken to the procedure room but before anesthesia is provided will be paid at 50 percent of the full OPPS payment amount. Modifier -73 is used for these procedures. *As of January 1, 2016, for procedures that append modifier -73 and that involve implantable devices that are assigned to a device-intensive APC (defined as those APCs with a device offset greater than 40 percent), we will reduce the APC payment amount for the discontinued device-intensive procedure, by 100 percent of the device offset amount prior to applying the additional payment adjustments that apply when the procedure is discontinued as modified by means of a final rule with comment period and published in the November 13, 2015 "Federal Register" (80 FR 70424).*

Procedures that are discontinued, partially reduced or cancelled after the procedure has been initiated and/or the patient has received anesthesia will be paid at the full OPPS payment amount. Modifier -74 is used for these procedures.

Procedures for which anesthesia is not planned that are discontinued, partially reduced or cancelled after the patient is prepared and taken to the room where the procedure is to be performed will be paid at 50 percent of the full OPPS payment amount. Modifier -52 is used for these procedures.

20.6.12 - Use of HCPCS Modifier – CT

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Effective January 1, 2016, the definition of modifier – CT is ***"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."*** *This modifier is required to be reported on claims for computed tomography (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).*

This modifier should not be reported with codes that describe CT scans not listed above.

50.4 - Transitional Pass-Through *Payments* for Designated Devices

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

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 for the most current OPPS APC Offset File.

60 - Billing for Devices Eligible for Transitional Pass-Through Payments and Items Classified in "New Technology" APCs

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

The list of devices eligible for transitional pass-through payments changes as new device categories are approved for pass-through payment status on an ongoing basis, and as device categories expire from transitional pass-through payment and their costs are included in APC rates for associated surgical procedures. To view or download the latest complete list of currently payable and previously payable pass-through device categories, refer to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html* Please note that this link may change depending on CMS Web design requirements.

Hospitals are required to report device category codes that have expired from pass-through payment on claims when such devices are used in conjunction with procedures billed and paid for under the OPPS. In a Federal Register notice dated November 15, 2004 we summarized several provisions (69 FR 65762) related to the required reporting of HCPCS codes for devices.

The most recent information concerning applications requesting CMS to establish coding and payment and eligibility requirements for additional (new) device categories for pass-through payment is located on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*. This Web link may change from time to time, depending on CMS Web design requirements.

60.1 - Categories for Use in Coding Devices Eligible for Transitional Pass-Through Payments Under the Hospital OPPS

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 requires establishing categories for purposes of determining transitional pass-through payment for devices, effective April 1, 2001. Each category is defined as a separate code in the C series or occasionally a code in another series (e.g., certain codes in the L series) of HCPCS. C-codes are assigned by CMS for this purpose when other HCPCS codes for the eligible item do not exist. Only devices specifically described by the long descriptions associated with the currently payable pass-through category codes are qualified for transitional pass-through payments. The complete list of currently and previously payable pass-through category codes can be viewed and/or downloaded from the CMS Web site, currently at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*

Each item that qualifies for transitional pass-through payments fits in one of the device categories currently active for pass-through payments. Devices may be billed using the currently active category codes for pass-through payments, as long as they:

- Meet the definition of a device that qualifies for transitional pass-through payments and other requirements and definitions put forth below in §60.3.

- Are described by the long descriptor associated with a currently active pass-through device category HCPCS code assigned by CMS and

- Are described according to the definitions of terms and other general explanations issued by CMS to accompany coding assignments in program instructions. The current definitions and explanations are located with the latest complete list of currently payable and previously payable pass-through device categories, found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/HospitalOutpatientPPS/passthrough_payment.html. Please note that this link may change depending on CMS Web design requirements.

If a device does not meet the description and other coding instructions for currently payable categories, even though it appears to meet the other requirements in this section, it may not be billed using one of the HCPCS codes for currently payable categories for transitional pass-through payments unless an applicable category is established by CMS, as discussed in section 60.3 below.

Transitional pass-through payment for a device is based on the charge on the individual provider's bill, reduced to cost, and subject (in some instances) to a deduction that represents the cost of similar devices already included in the APC payment rate of the APC billed with the device category and, possibly, a pro-rata reduction. The *OCE* software determines the reduction to cost and the deduction for similar devices.

The eligibility of a device category for transitional pass-through payments is temporary, lasting for at least 2 but no more than 3 years. (The initial categories expired on January 1, 2003 or on January 1, 2004. The underlying provision is permanent, and categories established later have expired or will expire in successive years.) At the time of expiration, APC payment rates are adjusted to reflect the costs of devices (and drugs and biologicals) that received transitional pass-through payments. These adjustments are based on claims data that reflect the use of transitional pass-through devices, drugs and biologicals in conjunction with the associated procedures.

60.3 - Devices Eligible for Transitional Pass-Through Payments

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

The definition of and criteria for devices eligible for establishment of new categories for transitional pass-through payments was discussed and defined in a final rule with comment period published in the "Federal Register" on November 1, 2002, (67 FR 66781). Two of the criteria were also modified by means of a final rule with comment period published in the "Federal Register" on November 10, 2005 (70 FR 68628). *As of January 1, 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or natural orifice) are being evaluated for device pass-through payment as modified by means of a final rule with comment period and published in the November 20, 2009 "Federal Register" (74 FR 60471). As of January 1, 2015, skin substitutes are being evaluated for device pass-through payment as modified by means of a final rule with comment period and published in the November 10, 2015 "Federal Register" (79 FR 66885). As of January 1, 2016, the application process for device pass-through payments will add a rulemaking component to the existing quarterly process and a requirement will ensure that medical devices seeking pass-through payments are "new," as modified by means of a final rule with comment period and published in the November 13, 2015 "Federal Register (80 FR 70417).* The regulations regarding transitional pass-through payment for devices are compiled at 42 CFR 419.66. Additionally, the eligibility criteria for CMS to establish a new category for pass-through payment are discussed on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

60.4 - General Coding and Billing Instructions and Explanations

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Explanations of Terms

Device Kits

Manufacturers frequently package a number of individual items used with a device in a particular procedure in a kit. Generally, to avoid complicating the device pass-through category list unnecessarily and to avoid the possibility of double coding, CMS has not established HCPCS codes for such kits. However, hospitals may purchase and use such kits. If the kits contain individual items that separately qualify for transitional pass-through payments, these items should be separately billed using applicable HCPCS codes. Hospitals may not bill for transitional pass-through payments for supplies that may be contained in kits.

Reporting Multiple Units of Pass-Through Device Categories

Hospitals must bill for multiple units of items that qualify for transitional pass-through payments when such items are used with a single procedure by entering the number of units used on the bill.

Reporting of Multiple Device Categories

For items with multiple component devices that fall in more than one category (e.g., kits or systems other than those explicitly identified in the long descriptors), hospitals should code the appropriate category separately for each component. For example, the "Rotablator Rotational Angioplasty System (with catheter and advancer)" consists of both a catheter and an advancer/sheath. Hospitals should report category C1724 for the catheter and C1894 for the advancer/sheath.

Also, for items packaged as kits that contain a catheter and an introducer, hospitals should report both appropriate categories. For example, the "Clinicath 16G Peripherally Inserted Central Catheter (PICC) Dual-Lumen PolyFlow Polyurethane" contains a catheter and an introducer. To appropriately bill for this item, hospitals should report category C1751 for the catheter and C1894 for the introducer. (Please note that the device categories C1724, C1894 and C1751 are no longer eligible for pass-through payments, but are used here for illustrative purposes for reporting multiple categories. However, hospitals should continue to report devices on claims in this manner even after the category is no longer eligible for pass-through payment.)

Reprocessed Devices

Hospitals may bill for transitional pass-through payments only for those devices that are "single use." Reprocessed devices may be considered "single use" if they are reprocessed in compliance with enforcement guidance of the Food and Drug Administration (FDA) relating to the reprocessing of devices applicable at the time the service is delivered. The FDA phased in new enforcement guidance relating to reprocessing during 2001 and 2002. For further information, see FDA's guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," published August 14, 2000, or any later FDA guidance or enforcement documents currently in effect. For a complete list of currently and previously payable device categories related to pass-through payments and specific definitions of such device categories, refer to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html and locate the most current List of Pass Through Payment Device Category Codes.*

60.5 - Services Eligible for New Technology APC Assignment and Payments

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

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 may be found on the CMS Web site, currently at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

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 http://www.cms.hhs.gov/HospitalOutpatientPPS/HOPPSTrans/list.asp#TopOfPage. Please note that this link may change depending on CMS Web design requirements.

61.2 - Edits for Claims on Which Specified Procedures are to be Reported With Device Codes and For Which Specific Devices are to be Reported With Procedure Codes

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

The OCE will return to the provider any claim that reports a HCPCS code for a procedure *assigned to a device-intensive APC, for which the procedure requires the implantation of a device* that does not also report

at least one device HCPCS code required for that procedure. If the claim is returned to the provider for failure to pass the edit, the hospital will need to modify the claim by either correcting the procedure code or ensuring that one of the required device codes is on the claim before resubmission. While all devices that have device HCPCS codes and that were used in a given procedure should be reported on the claim, only one of the possible device codes is required to be on the claim for payment to be made, unless otherwise specified.

The device edit *does* not apply to the specified procedure code if the provider reports one of the following modifiers with the procedure code:

52 - Reduced Services;
73 -- Discontinued outpatient procedure prior to anesthesia administration; and
74 -- Discontinued outpatient procedure after anesthesia administration.

Where a procedure that normally requires a device is interrupted, either before or after the administration of anesthesia if anesthesia is required or at any point if anesthesia is not required, and the device is not used, hospitals should report modifier 52, 73 or 74 as applicable. The device edit *is* not applied in these cases.

The OCE will also return to the provider claims for which specified devices are billed without the procedure code that is necessary for the device to have therapeutic benefit to the patient. If the claim is returned to the provider for failure to pass the edit, the hospital will need to modify the claim by either correcting the device code or ensuring that one of the required procedure codes is on the claim before resubmission.

180.7 - Inpatient-only Services

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Section 1833(t)(1)(B)(i) of the Act allows CMS to define the services for which payment under the OPPS is appropriate and the Secretary has determined that the services designated to be "inpatient only" services are not appropriate to be furnished in a hospital outpatient department. "Inpatient only" services are generally, but not always, surgical services that require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. An example of an "inpatient only" service is CPT code 33513, "Coronary artery bypass, vein only; four coronary venous grafts." The designation of services to be "inpatient-only" is open to public comment each year as part of the annual rulemaking process. Procedures removed from the "inpatient only" list may be appropriately furnished in either the inpatient or outpatient settings and such procedures continue to be payable when furnished in the inpatient setting.

There is no payment under the OPPS for services that CMS designates to be "inpatient-only" services. These services have an OPPS status indicator of "C" in the OPPS Addendum B and are listed together in Addendum E of each year's OPPS/ASC final rule. For the most current Addendum B and for Addendum E published with the OPPS notices and regulations, see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Excluding the handful of exceptions discussed below, CMS does not pay for an "inpatient-only" service furnished to a person who is registered in the hospital as an outpatient and reports the service on the outpatient hospital bill type (TOB 13X). CMS also does not pay for all other services on the same day as the "inpatient only" procedure.

There are two exceptions to the policy of not paying for outpatient services furnished on the same day with an "inpatient-only" service that would be paid under the OPPS if the inpatient service had not been furnished:

Exception 1: If the "inpatient-only" service is defined in CPT to be a "separate procedure" and the other services billed with the "inpatient-only" service contain a procedure that can be paid under the OPPS and that has an OPPS SI=T on the same date as the "inpatient-only" procedure, then the "inpatient-only" service is denied but CMS makes payment for the separate procedure and any remaining payable OPPS services. The list of "separate procedures" is available with the Integrated Outpatient Code Editor (I/OCE) documentation. See http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/.

Exception 2: 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.

200.1 - Billing for Corneal Tissue

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Corneal tissue will be paid on a cost basis, not under OPPS, *only when it is used in a corneal transplant procedure described by one of the following CPT codes: 65710, 65730, 65750, 65755, 65756, 65765, 65767, and any successor code or new code describing a new type of corneal transplant procedure that uses eye banked corneal tissue. In all other procedures cornea tissue is packaged.* To receive cost based reimbursement hospitals must bill charges for corneal tissue using HCPCS code V2785.

200.3.1 - Billing *Instructions* for IMRT Planning

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

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 (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.

200.3.2- Billing *for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS)* Planning *and Delivery*

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Effective for services furnished on or after January 1, 2014, hospitals must report SRS planning and delivery services using only the CPT codes that accurately describe the service furnished. For the delivery services, hospitals must report CPT code 77371, 77372, or 77373.

CPT Code	*Long Descriptor*
77371	*Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source cobalt 60 based*
77372	*Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based*
77373	*Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions*

As instructed in the CY 2014 OPPS/ASC final rule, CPT code 77371 is to be used only for single session cranial SRS cases performed with a Cobalt-60 device, and CPT code 77372 is to be used only for single

session cranial SRS cases performed with a linac-based device. The term "cranial" means that the pathological lesion(s) that are the target of the radiation is located in the patient's cranium or head. The term "single session" means that the entire intracranial lesion(s) that comprise the patient's diagnosis are treated in their entirety during a single treatment session on a single day. CPT code 77372 is never to be used for the first fraction or any other fraction of a fractionated SRS treatment. CPT code 77372 is to be used only for single session cranial linac-based SRS treatment. Fractionated SRS treatment is any SRS delivery service requiring more than a single session of SRS treatment for a cranial lesion, up to a total of no more than five fractions, and one to five sessions (but no more than five) for non-cranial lesions. CPT code 77373 is to be used for any fraction (including the first fraction) in any series of fractionated treatments, regardless of the anatomical location of the lesion or lesions being radiated. Fractionated cranial SRS is any cranial SRS that exceeds one treatment session and fractionated non-cranial SRS is any non-cranial SRS, regardless of the number of fractions but never more than five. Therefore, CPT code 77373 is the exclusive code (and the use of no other SRS treatment delivery code is permitted) for any and all fractionated SRS treatment services delivered anywhere in the body, including, but not limited to, the cranium or head. 77372 is not to be used for the first fraction of a fractionated cranial SRS treatment series and must only be used in cranial SRS when there is a single treatment session to treat the patient's entire condition.

In addition, for the planning services, hospitals must report the specific CPT code that accurately describes the service provided. The planning services may include but are not limited to CPT code 77290, 77295, 77300, 77334, or 77370.

CPT Code	***Long Descriptor***
77290	*Therapeutic radiology simulation-aided field setting; complex*
77295	*Therapeutic radiology simulation-aided field setting; 3-dimensional*
77300	*Basic radiation dosimetry calculation, central axis depth dose calculation, tdf, nsd, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician*
77334	*Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)*
77370	*Special medical radiation physics consultation*

Effective for cranial single session stereotactic radiosurgery 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 the table below will be paid according to their assigned status indicator when furnished 30 days prior or 30 days post SRS treatment delivery.

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 below) 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).

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*
77295	*3-d radiotherapy plan*	*S*
77336	*Radiation physics consult*	*S*

290.5.1 - Billing and Payment for Observation Services *Furnished Between* January 1, 2008 *and December 31, 2015*

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). Beginning January 1, 2008, HCPCS code G0378 for hourly observation services is assigned status indicator N, signifying that its payment is always packaged. No separate payment is made for observation services reported with HCPCS code G0378, and APC 0339 is deleted as of January 1, 2008. In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. *From January 1, 2014 through December 31, 2015,* in certain circumstances when observation care *was* billed in conjunction with a clinic visit, high level Type A emergency department visit (Level 4 or 5), high level Type B emergency department visit (Level 5), critical care services, or a direct referral as an integral part of a patient's extended encounter of care, payment may be made for the entire extended care encounter through APC 8009 (Extended Assessment and Management Composite) when certain criteria are met. Prior to January 1, 2014, in certain circumstances when observation care was billed in conjunction with a high level clinic visit (Level 5), high level Type A emergency department visit (Level 4 or 5), high level Type B emergency department visit (Level 5), critical care services, or a direct referral as an integral part of a patient's extended encounter of care, payment could be made for the entire extended care encounter through one of two composite APCs (APCs 8002 and 8003) when certain criteria were met. APCs 8002 and 8003 are deleted as of January 1, 2014 *and APC 8009 is deleted as of January 1, 2016*. For information about payment for extended assessment and management composite APC, see §10.2.1 (Composite APCs) of this chapter.

There is no limitation on diagnosis for payment of APC 8009; however, composite APC payment will not be made when observation services are reported in association with a surgical procedure (T status procedure) or the hours of observation care reported are less than 8. The I/OCE evaluates every claim received to determine if payment through a composite APC is appropriate. If payment through a composite APC is inappropriate, the I/OCE, in conjunction with the Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim.

All of the following requirements must be met in order for a hospital to receive an APC payment for an extended assessment and management composite APC:

1. Observation Time

   a. Observation time must be documented in the medical record.

   b. Hospital billing for observation services begins at the clock time documented in the patient's medical record, which coincides with the time that observation services are initiated in accordance with a physician's order for observation services.

c. A beneficiary's time receiving observation services (and hospital billing) ends when all clinical or medical interventions have been completed, including follow-up care furnished by hospital staff and physicians that may take place after a physician has ordered the patient be released or admitted as an inpatient.

d. The number of units reported with HCPCS code G0378 must equal or exceed 8 hours.

2. Additional Hospital Services

a. The claim for observation services must include one of the following services in addition to the reported observation services. The additional services listed below must have a line item date of service on the same day or the day before the date reported for observation:

- A Type A or B emergency department visit (CPT codes 99284 or 99285 or HCPCS code G0384); or
- A clinic visit (HCPCS code G0463 beginning January 1, 2014; CPT code 99205 or 99215 prior to January 1, 2014); or
- Critical care (CPT code 99291); or
- Direct referral for observation care reported with HCPCS code G0379 (APC 0633) must be reported on the same date of service as the date reported for observation services.

b. No procedure with a T status indicator can be reported on the same day or day before observation care is provided.

3. Physician Evaluation

a. The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by outpatient registration, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.

b. The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.

Criteria 1 and 3 related to observation care beginning and ending time and physician evaluation apply regardless of whether the hospital believes that the criteria will be met for payment of the extended encounter through extended assessment and management composite payment.

Only visits, critical care and observation services that are billed on a 13X bill type may be considered for a composite APC payment.

Non-repetitive services provided on the same day as either direct referral for observation care or observation services must be reported on the same claim because the OCE claim-by-claim logic cannot function properly unless all services related to the episode of observation care, including hospital clinic visits, emergency department visits, critical care services, and T status procedures, are reported on the same claim. Additional guidance can be found in chapter 1, section 50.2.2 of this manual.

If a claim for services provided during an extended assessment and management encounter including observation care does not meet all of the requirements listed above, then the usual APC logic will apply to separately payable items and services on the claim; the special logic for direct admission will apply, and payment for the observation care will be packaged into payments for other separately payable services provided to the beneficiary in the same encounter.

290.5.2 - Billing and Payment for Direct Referral for Observation Care Furnished Beginning January 1, 2008

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Direct referral for observation is reported using HCPCS code G0379 (Direct referral for hospital observation care). Prior to January 1, 2010, the code descriptor for HCPCS code G0379 was (Direct admission of patient for hospital observation care). Hospitals should report G0379 when observation services are the result of a direct referral for observation care without an associated emergency room visit, hospital outpatient clinic visit, or critical care service on the day of initiation of observation services. Hospitals should only report HCPCS code G0379 when a patient is referred directly to observation care after being seen by a physician in the community.

Payment for direct referral for observation care will be made either separately as a hospital visit under APC *5013* (Level 3 Examinations & Related Services) or packaged into payment for *comprehensive APC 8011 (Comprehensive Observation Services)* or packaged into the payment for other separately payable services provided in the same encounter. For information about *comprehensive* APC*s*, see §10.2.*3* (*Comprehensive* APCs) of this chapter.

The criteria for payment of HCPCS code G0379 under either APC *5013* or APC *8011* include:

1. Both HCPCS codes G0378 (Hospital observation services, per hr.) and G0379 (Direct referral for hospital observation care) are reported with the same date of service.

2. No service with a status indicator of T or V or Critical Care (APC *5041*) is provided on the same day of service as HCPCS code G0379.

If either of the above criteria is not met, HCPCS code G0379 will be assigned status indicator N and will be packaged into payment for other separately payable services provided in the same encounter.

Only a direct referral for observation services billed on a 13X bill type may be considered for a *comprehensive* APC payment *through the Comprehensive Observation Services APC (APC 8011)*.

290.5.3 - Billing and Payment for Observation Services Furnished Beginning January 1, 2016

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). Beginning January 1, 2008, HCPCS code G0378 for hourly observation services is assigned status indicator N, signifying that its payment is always packaged. No separate payment is made for observation services reported with HCPCS code G0378, and APC 0339 is deleted as of January 1, 2008. In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. Beginning January 1, 2016, in certain circumstances when observation services are billed in conjunction with a clinic visit, Type A emergency department visit (Level 1 through 5), Type B emergency department visit (Level 1 through 5), critical care services, or a direct referral as an integral part of a patient's extended encounter of care, comprehensive payment may be made for all services on the claim including, the entire extended care encounter through comprehensive APC 8011 (Comprehensive Observation Services) when certain criteria are met. For information about comprehensive APCs, see §10.2.3 (Comprehensive APCs) of this chapter.

There is no limitation on diagnosis for payment of APC 8011; however, comprehensive APC payment will not be made when observation services are reported in association with a surgical procedure (T status procedure) or the hours of observation care reported are less than 8. The I/OCE evaluates every claim received to determine if payment through a comprehensive APC is appropriate. If payment through a comprehensive APC is inappropriate, the I/OCE, in conjunction with the Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim.

All of the following requirements must be met in order for a hospital to receive a comprehensive APC payment through the Comprehensive Observation Services APC (APC 8011):

1. *Observation Time*

   a. *Observation time must be documented in the medical record.*

   b. *Hospital billing for observation services begins at the clock time documented in the patient's medical record, which coincides with the time that observation services are initiated in accordance with a physician's order for observation services.*

   c. *A beneficiary's time receiving observation services (and hospital billing) ends when all clinical or medical interventions have been completed, including follow-up care furnished by hospital staff and physicians that may take place after a physician has ordered the patient be released or admitted as an inpatient.*

   d. *The number of units reported with HCPCS code G0378 must equal or exceed 8 hours.*

2. *Additional Hospital Services*

   a. *The claim for observation services must include one of the following services in addition to the reported observation services. The additional services listed below must have a line item date of service on the same day or the day before the date reported for observation:*

   - *A Type A or B emergency department visit (CPT codes 99281 through 99285 or HCPCS codes G0380 through G0384); or*
   - *A clinic visit (HCPCS code G0463); or*
   - *Critical care (CPT code 99291); or*
   - *Direct referral for observation care reported with HCPCS code G0379 (APC 5013) must be reported on the same date of service as the date reported for observation services.*

   b. *No procedure with a T status indicator or a J1 status indicator can be reported on the claim.*

3. *Physician Evaluation*

   a. *The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by outpatient registration, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.*

   b. *The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.*

Criteria 1 and 3 related to observation care beginning and ending time and physician evaluation apply regardless of whether the hospital believes that the criteria will be met for payment of the extended encounter through the Comprehensive Observation Services APC (APC 8011).

Only visits, critical care and observation services that are billed on a 13X bill type may be considered for a comprehensive APC payment through the Comprehensive Observation Services APC (APC 8011).

Non-repetitive services provided on the same day as either direct referral for observation care or observation services must be reported on the same claim because the OCE claim-by-claim logic cannot function properly unless all services related to the episode of observation care, including hospital clinic visits, emergency department visits, critical care services, and T status procedures, are reported on the same claim. Additional guidance can be found in chapter 1, section 50.2.2 of this manual.

If a claim for services provided during an extended assessment and management encounter including observation care does not meet all of the requirements listed above, then the usual APC logic will apply to separately payable items and services on the claim; the special logic for direct admission will apply, and payment for the observation care will be packaged into payments for other separately payable services provided to the beneficiary in the same encounter.

Chapter 16 - Laboratory Services

30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

The following apply in determining the amount of Part B payment for clinical laboratory tests:

Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule (CLFS) will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS.

Independent laboratory or a physician or medical group - Payment to an independent laboratory or a physician or medical group is the lesser of the actual charge, the fee schedule amount or the national limitation amount. Part B deductible and coinsurance do not apply.

Reference laboratory - For tests performed by a reference laboratory, the payment is the lesser of the actual charge by the billing laboratory, the fee schedule amount, or the national limitation amount (NLA). (See §50.5 for carrier jurisdiction details.) Part B deductible and coinsurance do not apply.

Outpatient of **OPPS** hospital - For hospitals paid under the OPPS, beginning January 1, 2014 outpatient laboratory tests are generally packaged as ancillary services and do not receive separate payment. Only in the following circumstances are *lab tests* eligible for separate payment under the CLFS.

(1) Outpatient lab tests only - If the hospital only provides outpatient laboratory tests to the patient (directly or under arrangement) and the patient does not also receive other hospital outpatient services on that day. *Do not report with modifier L1.*

(2) Unrelated outpatient lab tests- If the hospital provides an outpatient laboratory test (directly or under arrangement) on the same date of service as other hospital outpatient services that is clinically unrelated to the other hospital outpatient services, meaning the laboratory test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services *and* for a different diagnosis *than the other hospital outpatient services.* Beginning July 1, 2014, report on TOB 13X with modifier L1.

Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, furnished to an outpatient of the hospital, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS.

Exception: Reasonable cost reimbursement has been provided for outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning on July 1, 2004 through 2008 (per the following legislation: Section 416 of the Medicare Modernization Act (MMA) of 2003, Section 105 of the Tax Relief and Health Care Act (TRHCA) of 2006, and Section 107 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Extension Act of 2007). Section 3122 of the Patient Protection and Affordable Care Act re-institutes the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011. Section 109 of the Medicare and Medicaid Extenders Act extends the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2011, through June 30, 2012.

Non-Patient (Referred) Laboratory Specimen- A non-patient is defined as a beneficiary that is neither an inpatient nor an outpatient of a hospital, but that has a specimen that is submitted for analysis to a hospital and the beneficiary is not physically present at the hospital. All hospitals (including Maryland waiver hospitals and CAHs) bill non-patient lab tests on TOB 14X. They are paid under the clinical laboratory fee

schedule at the lesser of the actual charge, the fee schedule amount, or the NLA (including CAH and MD Waiver hospitals). Part B deductible and coinsurance do not apply.

Inpatient without Part A – Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS. For hospitals subject to the OPPS, beginning January 1, 2014 Part B inpatient laboratory tests are packaged as ancillary services and do not receive separate payment unless the service with which the labs would otherwise be packaged is not a payable Part B inpatient service (see Chapter 6, Section 10 of the Medicare Benefit Policy Manual, Pub. 100-02). Payment to a SNF inpatient without Part A coverage is made under the laboratory fee schedule.

Inpatient or SNF patient with Part A - Payment to a hospital for laboratory tests furnished to an inpatient, whose stay is covered under Part A, is included in the PPS rate for PPS facilities or is made on a reasonable cost basis for non-PPS hospitals and is made at 101 percent of reasonable cost for CAHs. Payments for lab services for beneficiaries in a Part A stay in a SNF, other than a swing bed in a CAH are included in the SNF PPS rate. For such services provided in a swing bed of a CAH, payment is made at 101 percent of reasonable cost.

Sole community hospital – Sole community hospitals are subject to the OPPS, therefore OPPS packaging rules apply. When the OPPS exceptions for separate payment of outpatient laboratory tests under the CLFS apply, a sole community hospital with a qualified hospital laboratory identified on the hospital's certification in the Provider Specific File is paid the least of the actual charge, the 62 percent fee schedule amount, or the 62 percent NLA. The Part B deductible and coinsurance do not apply.

Waived Hospitals - Payment for outpatient (bill type13X), to a hospital which has been granted a waiver of Medicare payment principles for outpatient services is subject to Part B deductible and coinsurance unless otherwise waived as part of an approved waiver. Specifically, laboratory fee schedules do not apply to laboratory tests furnished by hospitals in States or areas that have been granted waivers of Medicare reimbursement principles for outpatient services. The State of Maryland has been granted such a waiver. Payment for non-patient laboratory specimens (bill type14X) is based on the fee schedule**.** Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be paid based on current methodology.

Critical Access Hospital - When the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the laboratory fee schedule. If the beneficiary is an outpatient of the CAH, the CAH bills using an 85x bill type and is paid based on 101 percent of reasonable cost.

Beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to CAH clinical laboratory services.

<u>Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA)</u>

Effective for services furnished on or after July 1, 2009, the beneficiary is no longer required to be physically present in a CAH at the time the specimen is collected in order for the CAH to be paid based on 101 percent of reasonable cost. However, the beneficiary must be an outpatient of the CAH, as defined at 42 CFR §410.2 and be receiving services directly from the CAH. In order for the beneficiary to be receiving services directly from the CAH if he/she is not present in the CAH when the specimen is collected, the beneficiary must either be receiving outpatient services in the CAH on the same day the specimen is collected, or the specimen must be collected by an employee of the CAH or of a facility provider-based to the CAH.

Dialysis facility - Effective for items and services furnished on or after January 1, 2011 Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) requires that all ESRD-related laboratory tests be reported by the ESRD facility whether provided directly or under arrangements with an independent

laboratory. When laboratory services are billed by a laboratory other than the ESRD facility and the laboratory service furnished is designated as a laboratory test that is included in the ESRD PPS (i.e., ESRD-related), the claim will be rejected or denied. The list of items and services subject to consolidated billing located at http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD. In the event that an ESRD-related laboratory service was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the supplier may submit a claim for separate payment using modifier "AY". See Pub.100-04, Chapter 8 for more information regarding Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims.

Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC) - Payment to a RHC/FQHC for laboratory tests performed for a patient of that clinic/center is not included in the all-inclusive rate and may be billed separately by either the base provider for a provider-based RHC/FQHC, or by the physician for an independent or free-standing RHC/FQHC. Payment for the laboratory service is not subject to Part B deductible and coinsurance. If the RHC/FQHC is provider-based, payment for lab tests is to the base provider (i.e., hospital). If the RHC/FQHC is independent or freestanding, payment for lab tests is made to the practitioner (physician) via the clinical lab fee schedule. (See Sections 30.1.1 and 40.5 for details on RHC/FQHC billing.)

Enrolled in Managed Care - Payment to a participating health maintenance organization (HMO) or health care prepayment plan (HCPP) for laboratory tests provided to a Medicare beneficiary who is an enrolled member is included in the monthly capitation amount.

Non-enrolled Managed Care - Payment to a participating HMO or HCPP for laboratory tests performed for a patient who is not a member is the lesser of the actual charge, or the fee schedule, or the NLA. The Part B deductible and coinsurance do not apply.

Hospice - Payment to a hospice for laboratory tests performed by the hospice is included in the hospice rate.

40.6.2.1 - Separately Billable ESRD Laboratory Tests Furnished by Hospital-Based Facilities

(Rev.3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Independent laboratories and independent dialysis facilities with the appropriate clinical laboratory certification in accordance with CLIA may be paid for ESRD clinical laboratory tests that are separately billable. The laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare laboratory fee schedule for independent laboratories. (See §40.3 for details on Part B hospital billing rules for laboratory services.)

Hospital-based laboratories providing separately billable laboratory services to dialysis patients of the hospital's dialysis facility or any other dialysis facility bill and are paid in accordance with the hospital outpatient laboratory provisions in Chapter 16, section 40.3.

Attachment A − Tables for the Policy Section

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

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

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

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

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
77295	3-d radiotherapy plan	S
77336	Radiation physics consult	S

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	Crosswalked HCPCS P-Code	Crosswalked HCPCS P-Code Long Descriptor	Payment
P9070	1/1/2016	Plasma, pooled multiple donor, pathogen reduced,	P9059	Fresh frozen plasma between 8-24 hours of collection, each unit	$73.08

		frozen, each unit			
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

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	

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
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

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

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
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

CY 2016 HCPCS Code	CY 2016 Short Descriptor	CY 2016 SI	Low/High Cost Skin Substitute
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.

Table 11 – Wage Index by CBSA for Non-IPPS Hospitals that are Eligible for the Section 505 Out-Commuting Adjustment

Provider	CBSA	Section 505 Out Commuting Adjustment	Final Wage Index for Calendar Year 2016
012011	11500	YES	0.7165
013027	19300	YES	0.7514
014009	19460	YES	0.7402
014016	01	YES	0.7082

Provider	CBSA	Section 505 Out Commuting Adjustment	Final Wage Index for Calendar Year 2016
042007	38220	YES	0.7924
042011	04	YES	0.7457
052034	36084	YES	1.6916
053301	36084	YES	1.6916
054074	46700	YES	1.6425
054110	36084	YES	1.6916
054122	34900	YES	1.5574
054151	42220	YES	1.6410
062017	22660	YES	1.0014
063033	24540	YES	0.9727
064007	14500	YES	0.9748
074003	25540	YES	1.1598
082000	48864	YES	1.0707
083300	48864	YES	1.0707
084002	48864	YES	1.0707
102028	45540	YES	0.8717
114018	11	YES	0.7596
132001	17660	YES	0.9424
134010	13	YES	0.7652
144037	20994	YES	1.0295
153040	15	YES	0.8367
154014	15	YES	0.8359
154035	15	YES	0.8293
183028	21060	YES	0.7898
184012	21060	YES	0.7898
192022	19	YES	0.7077
192026	43340	YES	0.8347
192034	19	YES	0.7141
192036	25220	YES	0.8238
192050	29180	YES	0.7938
193047	29180	YES	0.7900
193055	19	YES	0.7161
193067	19	YES	0.7093
193069	19	YES	0.7091
193091	29180	YES	0.7845
194074	19	YES	0.7077
194075	19	YES	0.7093
194081	19	YES	0.7063

Provider	CBSA	Section 505 Out Commuting Adjustment	Final Wage Index for Calendar Year 2016
194082	19	YES	0.7093
194083	19	YES	0.7091
194085	29180	YES	0.7938
194087	19	YES	0.7077
194092	19	YES	0.7061
194095	19	YES	0.7141
194097	29180	YES	0.7938
212002	25180	YES	0.9068
214001	12580	YES	0.9618
222000	15764	YES	1.3032
222043	39300	YES	1.2997
223026	15764	YES	1.3032
224007	15764	YES	1.3032
224021	39300	YES	1.2997
232019	19804	YES	0.9295
232025	35660	YES	0.8435
232027	19804	YES	0.9295
232028	12980	YES	1.0300
232031	19804	YES	0.9295
232032	19804	YES	0.9295
232036	27100	YES	0.9250
233027	19804	YES	0.9295
233300	19804	YES	0.9295
234038	19804	YES	0.9295
252011	25	YES	0.7718
264005	26	YES	0.8064
303026	40484	YES	1.1470
304001	40484	YES	1.1470
312018	35614	YES	1.3235
312020	35084	YES	1.1521
312024	35084	YES	1.1495
313025	35084	YES	1.1495
313027	45940	YES	1.1377
313300	35614	YES	1.3235
314011	35614	YES	1.3235
314018	15804	YES	1.1176
334004	35614	YES	1.3069
334017	35614	YES	1.3467

Provider	CBSA	Section 505 Out Commuting Adjustment	Final Wage Index for Calendar Year 2016
334049	10580	YES	0.8426
344001	39580	YES	0.9708
344014	39580	YES	0.9708
344029	34	YES	0.8267
362016	15940	YES	0.8319
364040	44220	YES	0.8544
364042	36	YES	0.8260
364043	36	YES	0.8289
372017	37	YES	0.7610
372019	37	YES	0.7887
384008	41420	YES	1.0664
392031	27780	YES	0.8432
392034	10900	YES	1.1391
392040	29540	YES	0.9482
392048	33874	YES	1.0311
393025	33874	YES	1.0311
393026	39740	YES	0.9163
393032	33874	YES	1.0577
393037	49620	YES	0.9875
394020	30140	YES	0.9938
394034	33874	YES	1.0577
394052	39740	YES	0.9163
422004	43900	YES	0.8306
423029	24860	YES	0.8892
423031	43900	YES	0.8306
424011	24860	YES	0.8892
424013	42	YES	0.8207
424014	16740	YES	0.9074
442016	28700	YES	0.7318
444008	44	YES	0.7626
444019	17300	YES	0.7994
452018	23104	YES	0.9374
452019	23104	YES	0.9374
452028	23104	YES	0.9374
452088	23104	YES	0.9374
452110	23104	YES	0.9374
453040	23104	YES	0.9374
453041	23104	YES	0.9374

Provider	CBSA	Section 505 Out Commuting Adjustment	Final Wage Index for Calendar Year 2016
453042	23104	YES	0.9374
453089	45	YES	0.7825
453094	23104	YES	0.9374
453300	23104	YES	0.9374
454009	45	YES	0.7889
454012	23104	YES	0.9374
454101	45	YES	0.7892
462005	39340	YES	0.9410
464014	39340	YES	0.9410
522005	39540	YES	1.0786
523302	36780	YES	0.9352
524025	22540	YES	0.9019
673035	23104	YES	0.9374
673044	23104	YES	0.9374
673048	23104	YES	0.9374