Oncology Reimbursement Update 2016

BY CINDY PARMAN, CPC, CPC-H, RCC

There is a popular song by Demi Lovato called *Here We Go Again* that includes the lyrics "You think that by now I'd know, 'cause here we go go go again." True words in many settings, but especially with the 2016 final regulations, code updates, and other reimbursement changes. Again this year oncology practices and cancer programs scramble to update their respective chargemasters, fee schedules, and other reimbursement documents to ensure compliance with coding and billing guidelines. To help ACCC members with this arduous task, here is a concise coding update, followed immediately by regulatory updates for both the hospital and practice setting. Be sure to pass this critical information on to all of your billers and coders. And—if they are not receiving *Oncology Issues* as part of their membership benefit—email membership@accc-cancer.org today to ensure that all of your billers and coders receive critical coding, billing, and compliance information year round.

New and Revised Procedure Codes

Each year there are new Current Procedural Terminology (CPT) codes, revised CPT codes, and updates to coding guidelines. For calendar year (CY) 2016, two new codes have been created for prolonged clinical staff services performed under the direct supervision of a physician or qualified non-physician healthcare professional in a non-facility setting:

- **+99415**: Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient E/M service).
- **+99416**: Each additional 30 minutes (List separately in addition to code for primary procedure).

These codes cannot be reported by facilities (e.g., hospitals, skilled nursing facilities), and the time spent performing separately reportable services is not counted toward the prolonged services time. Prolonged staff time of less than 45 minutes total duration on a given date is not separately reported and these codes cannot be reported for more than two simultaneous patients.

There are also two new codes for soft tissue marker placement:

- **10035**: Placement of soft tissue localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.
- **+10036**: Each additional lesion (List separately in addition to code for primary procedure).

If a more specific site descriptor than soft tissue is applicable (e.g., breast), use the site-specific codes for marker placement at that site. Procedure codes **10035** and **+10036** are reported only once per target, regardless of the number of markers used to define the target.

Once again there are a number of code changes for radiation oncology, many of which consolidate basic dosimetry calculations into other procedure codes. There is an update to the notes in the *CPT® Manual*, that states calculations (code **77300**) is not reported separately with codes **77306**, **77307**, **77316**, **77317**, **77318**, **77321**, **77767**, **77768**, **77770**, **77771**, **77772**, **0394T**, or **0395T**.

High-dose rate brachytherapy procedure codes **77785**, **77786**, and **77787** have been deleted effective Jan. 1, 2016, and replaced with the following codes:

- **77770**: Remote afterloading high-dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.
- **77771**: 2-12 channels.
- **77772**: Over 12 channels.

As part of the revised definitions, all of these brachytherapy administration codes include basic dosimetry calculations. This means that code **77300** (basic radiation dosimetry calculation) will not be reported on the same day as the HDR brachytherapy codes. The following codes are new for CY 2016 and also include basic calculations:

- **77767**: Remote afterloading high-dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel.
- **77768**: Lesion diameter over 2.0 cm and 2 or more channels or multiple lesions.

In addition to the new and revised codes for radionuclide HDR, procedure code **0182T** has been deleted and replaced by the following codes for electronic brachytherapy:

- **0394T**: High-dose rate electronic brachytherapy, skin surface application,

per fraction, includes basic dosimetry, when performed.
- **0395T**: High-dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed.

In the same manner as the other brachytherapy procedure codes, these electronic brachytherapy treatments include the charge for basic calculations. There have also been coding changes relating to the interstitial brachytherapy services. Procedure codes **77776** (simple interstitial brachytherapy) and **77777** (intermediate interstitial brachytherapy) have been deleted. For CY 2016, unlisted procedure code **77799** (unlisted procedure, clinical brachytherapy) will be reported when the service constitutes simple or intermediate interstitial brachytherapy.

The procedure code for complex interstitial brachytherapy has been revised to include supervision, handling, and loading of the radiation source:
- **77778**: Interstitial radiation source application, complex, includes supervision, handling, and loading of radiation source, when performed.

This means that procedure code **77790** (supervision, handling, loading of radiation source) will not be reported when a complex interstitial brachytherapy procedure is performed. Last, procedure code **77417** has received an updated definition: Therapeutic radiology port image(s). This code, which stated "port films" in the past, has been clarified as reporting either film or electronic imaging.

HCPCS Level II Code Updates

There are several new HCPCS modifiers, some of which are discussed in more detail in other sections of this article:
- **Modifier CP**: Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim.
- **Modifier CT**: Computed tomography (CT) services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard.
- **Modifier EX**: Expatriate beneficiary.
- **Modifier ZA**: Novartis/Sandoz.

A biosimilar product has no clinically meaningful differences from a previously-approved reference product, only minor differences in clinically inactive components. The first biosimilar approved by the Food and Drug Administration (FDA) is Zarxio, which is a biosimilar version of filgrastim. HCPCS modifier ZA will be appended to the following HCPCS Level II drug code to identify Zarxio. For CY 2016, the definition of the code for filgrastim is:
- **J1442**: Injection, filgrastim (G-CSF), 1 microgram.

A new code for TBO-filgrastim (Granix) has been created: **J1447**: Injection, TBO-filgrastim, 1 microgram; prior code **J1446**: Injection, TBO-filgrastim, 5 micrograms has been deleted. Also, a new Q-code was added in July 2015 for biosimilar versions of filgrastim. It appears that code **Q5101**: Injection, filgrastim (G-CSF), biosimilar, 1 microgram, will be reported for any filgrastim biosimilar, and a modifier such as ZA will be added to show which particular biosimilar was administered. Additional instructions will be forthcoming from CMS to clarify these billing requirements.

Compounded drugs are made to order for a specific patient; for example, to provide a combination of drugs that is not available commercially or a liquid version of a drug that is only available in pill form. Compounded drugs were reported with **modifier JF** between April 2015 and July 2015; this modifier was subsequently deleted. The following code update is effective Jan. 1, 2016, for compound drugs: **J7999**: Compounded drug, not otherwise classified; code **Q9977**: Compounded drug, not otherwise classified, has also been deleted.

In 2016 there are again new and revised codes for clotting factors. CPT code **J7205**: Injection, factor VIII FC fusion (recombinant), per IU, has replaced these two deleted codes: **C9136**: Injection, factor VIII, FC fusion protein (recombinant), per IU, and **Q9975**: Injection, factor VIII FC fusion (recombinant), per IU.

There is also a new 2016 code for the netupitant/palonosetron combination. CPT code **J8655**: Netupitant 300 mg and palonosetron, replaces deleted codes **C9448**: Netupitant 300 mg and palonosetron 0.5 mg, oral, and **Q9978**: Netupitant 300 mg and palonosetron 0.5 mg.

Table 1, page 3 identifies CY 2016 replacement codes for chemotherapy drugs. Other drugs with replacement codes for CY 2016 include those shown in Table 2, page 3.

Tacrolimus is an immunosuppressive drug; a new code has been created and the existing code has been revised to distinguish between the two brands:
- **J7508**: Tacrolimus, extended release, (Astragraf XL), oral, 0.1 mg.
- **J7503**: Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg.

Alemtuzumab (Lemtrada) is used to treat multiple sclerosis; there is a single replacement code **J0202**: Injection, alemtuzumab, 1 mg, for the two deleted HCPCS codes: **J9010**: Injection, alemtuzumab, 10 mg and **Q9979**: Injection, alemtuzumab, 1 mg.

New drug HCPCS codes effective Jan. 1, 2016, include:
- **J7121**: 5% dextrose in lactated Ringer's infusion, up to 1,000 cc.
- **J1575**: Injection, immune globulin/hyaluronidase (Hyqvia), 100 mg immune globulin.

HCPCS codes that will be deleted on Jan. 1, 2016, include:
- **J0886**: Injection, epoetin alfa, 1,000 units (for ESRD on dialysis).
- **S3721**: Prostate cancer antigen 3 (PCA3) testing.
- **S3854**: Gene expression profiling panel for use in the management of breast cancer treatment.
- **S3890**: DNA analysis, fecal, for colorectal cancer screening.

- **S5011**: 5% dextrose in lactated ringer's, 1,000 ml.

Effective Oct. 1, 2015, CMS authorized the use of the following HCPCS Level II code:

- **C9743**: Injection/implantation of bulking or spacer material (any type) with or without imaging guidance (not to be used if more specific code applies).

This code may apply when a gel or other substance is inserted into a space created by pushing the prostate away from the rectum (performed prior to radiation treatment in some facilities).

There is also a new HCPCS code, effective Jan. 1, 2016, for Pd-103 brachytherapy sources:

- **C2645**: Brachytherapy planar source, palladium-103, per square millimeter.

Effective Jan. 1, 2016 CMS will bundle basic dosimetry calculations (code **77300**) into 3D computer planning (code **77295**). These new bundling instructions are included in Chapter 9 of the National Correct Coding Policy Manual located at: cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/nationalcorrectcodinited. This means that both professional and technical charges for a 3D plan will include basic dosimetry calculations; as a result, this instruction applies to hospitals, freestanding treatment centers, and physician charges. Therefore, when code **77295** is billed after Jan. 1, 2016, the facility or physician practice will continue to report treatment devices, but will not also report basic calculations.

In addition to the codes listed in this article, there are a number of changes to HCPCS quality measure codes, diagnostic imaging agents, and other medical supplies. Remember that the existence of a procedure or supply code *does not* guarantee reimbursement; payment for a service depends on the patient's insurance policy, medical necessity, and other determining factors. OI

Table 1. CY 2016 Replacement CPT Codes for Chemotherapy Drugs

2016 CODES		DELETED 2015 CODES	
J9271	Injection, pembrolizumab, 1 mg	C9027	Injection, pembrolizumab, 1 mg
J9308	Injection, ramucirumab, 5 mg	C9025	Injection, ramucirumab, 5 mg
J9032	Injection, belinostat, 10 mg	C9442	Injection, belinostat, 10 mg
J9039	Injection, blinatumomab, 1 mcg	C9449	Injection, blinatumomab, 1 mcg
J9299	Injection, nivolumab, 1 mg	C9453	Injection, nivolumab, 1 mg
J2860	Injection, situximab, 10 mg	C9455	Injection, situximab, 10 mg

Table 2. Select Drugs with Replacement Codes for CY 2016

2016 CODES		DELETED 2015 CODES	
J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron	Q9976	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron
J0596	Injection, C1 esterase inhibitor (recombinant), Ruconest, 10 units	C9445	Injection, C-1 esterase inhibitor (recombinant), Ruconest, 10 units
J7512	Prednisone, immediate release or delayed release, oral, 1 mg	J7506	Prednisone, oral, per 5 mg
J3380	Injection, vedolizumab, 1 mg	C9026	Injection, vedolizumab, 1 mg
J2502	Injection, pasireotide long acting, 1 mg	C9454	Injection, pasireotide long acting, 1 mg

Hospital Regulatory Update

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The Hospital Outpatient Prospective Payment System (HOPPS or OPPS) is not intended to be a fee schedule, in which separate payment is made for each coded line item. Instead, the OPPS is currently a prospective payment system that packages some items and services, but not others. The overarching goal of the Centers for Medicare & Medicaid Services (CMS) is to make payments for all services covered under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. For CY 2016, CMS will continue to base payments on geometric mean costs.

In the 2016 OPPS Final Rule, CMS estimates that total payments, including the beneficiary cost share, to the approximately 4,000 facilities paid under OPPS will decrease by approximately $133 million compared to CY 2015 payments. Outpatient hospital payment rates will decrease by -0.3 percent and CMS will continue the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements. The CY 2015 conversion factor of $74.173 decreases to $73.725 in 2016, but for hospitals that fail to meet the OQR (Outpatient Quality Reporting) requirements, the conversion factor will drop to $72.251.

CMS will also continue the policy of providing additional payments to the 11 designated cancer hospitals so that the hospitals' payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals.

And last, CMS will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC (ambulatory payment classification) payment amount when both the 1.75 multiple threshold and the final fixed dollar threshold of $3,250 are met.

New Code Process Changes

In the 2015 OPPS Proposed Rule, CMS outlined plans for changing the way it handles new procedure codes and this plan was adopted as proposed. Beginning with the 2016 rulemaking process, CMS published APC assignments for new codes as part of the Proposed Rule, because the codes and code descriptors were available in a timely fashion.

Packaged Services

For CY 2016, CMS will continue to unconditionally or conditionally package drugs and biologicals that function as supplies when used in a surgical procedure or a diagnostic test. In addition, CMS will continue to package image guidance, including guidance performed during radiation therapy treatment delivery.

Under current policy, certain clinical laboratory tests listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged into the payment of the primary service performed the same outpatient stay. This means that laboratory tests are only separately paid under the OPPS when the lab test is the only service provided to the patient during that outpatient encounter, or the test is performed on the same date as the primary procedure but for a different diagnosis than the other outpatient hospital services. CMS has clarified that some hospital outpatient stays span more than a single date of service (such as observation); laboratory services provided during this outpatient stay are considered to be integral, supporting, dependent, or adjunctive to the primary service (unless they meet one of the documented exceptions).

The 2016 OPPS Final Rule states that the hospital should continue to append **modifier L1** (separately payable laboratory test) on the clinical laboratory procedure code to indicate when the specified billing exceptions are met. Of importance to oncology programs, all molecular pathology tests will be excluded from this packaging policy for CY 2016.

CMS has continued to review categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which payment would be appropriately packaged into the payment of the primary service they support. For CY 2015, CMS conditionally packaged payment for ancillary services with a geometric mean cost of less than or equal to $100 (primarily minor diagnostic tests and procedures). In the 2016 OPPS Final Rule, CMS states that the $100 cost target was a basis for selecting the initial set of APCs for conditional packaging. For CY 2016, CMS will not limit conditional or unconditional packaging to APCs with a geometric mean cost of $100 or less.

After consideration of all comments received on the 2016 OPPS Proposed Rule, CMS will conditionally package ancillary

services assigned to APCs **5734** (Level 4 minor procedures), **5673** (Level 3 pathology), and **5674** (Level 4 pathology) beginning Jan. 1, 2016. Of importance to oncology departments, **APC 5674** includes procedure codes for the collection of blood from a vascular access device (CPT codes **36591**, **36592**).

Radiosurgery Comprehensive APC

With the advent of C-APCs (Comprehensive-APCs), the Outpatient Prospective Payment System now includes of a wide array of payment methodologies. A comprehensive-APC, by definition, will provide a single payment that includes the primary service and all adjunct services performed to support the delivery of the primary service. For services that trigger a comprehensive-APC payment, the comprehensive-APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment for the comprehensive service. This means that hospitals will continue to report procedure codes for all services performed, but will receive a single payment for the total service and collect a single beneficiary co-payment for the procedure.

Effective Jan. 1, 2015, CMS implemented a C-APC for single fraction stereotactic radiosurgery (SRS). The intent of this reimbursement change was to ensure that all services performed in connection with SRS were billed on the same hospital claim form, even if the related services (such as patient visit and computer planning) occurred on different service dates. In the 2016 OPPS Final Rule, CMS states that it is aware that certain "planning and preparation" services that are integrally associated with the direct provision of SRS have been incorrectly billed on separate claim forms. This generally occurred because of the different billing patterns when services are performed on Cobalt-60 treatment equipment as opposed to linear accelerator SRS. Cobalt-60 Gamma Knife® treatments typically included all services on a single claim form, while facilities performing SRS on linear accelerators tended to charge simulation, patient visits, and planning services on separate claim forms. CMS stated that payment for these pre-procedure services performed prior to treatment administration was included in the C-APC allowance, and should not have been separately billed and separately paid. As a result of the SRS claims data findings, CMS will remove the following services from the C-APC payment calculation:

- CT and/or MRI localization
- Simulation
- 3D computer planning
- Continuing physics.

These services, represented by CPT codes **77014**, **77011**, **70551**, **70552**, **70553**, **77280**, **77285**, **77290**, and **77295** are the *only* codes CMS plans to remove from the C-APC bundle. Other services, such as the immobilization device, calculations, and beam-shaping devices are still included in the C-APC reimbursement (when performed within one month of treatment delivery). For CY 2016 and CY 2017, these codes will not be included in the C-APC payment for SRS even if they are furnished on the same date of service. The 2016 OPPS Final Rule states, in part:

"However, we remind hospitals that procedure codes related to the primary SRS service should either be reported on the same claim, or, if furnished on a different date than the primary service, must include modifier 'CP' that we are adopting in this Final Rule with comment period."

This means that any service that is integral, ancillary, supportive, dependent, and adjunctive to the primary service identified by HCPCS codes **77371** or **77372** and that is reported on a different claim than the primary service must be billed with this HCPCS modifier:

- **Modifier CP**: Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim.

CMS expects providers to identify all adjunctive services provided during the 30-day period prior to SRS. This means the hospital has two choices when billing services for outpatient cranial radiosurgery:

1. All services related to the SRS procedure are billed on one claim submission, regardless of the date of service. This includes all preparatory and planning services that occur in the 30-day period leading up to treatment—from the initial patient visit through the delivery of radiosurgery.
2. The hospital can report preparatory and planning services on separate claims, as they occur, appending modifier CP to each procedure code that constitutes a service related to the SRS procedure. Every service that occurs up to 30 days prior to treatment related to the single-fraction SRS procedure billed on a separate claim must have this modifier.

CMS will then allow separate payment for the 10 procedure codes considered to be "unbundled" from the C-APC and include all other services in the C-APC reimbursement. CMS intends to issue further subregulatory guidance on use of the modifier CP with respect to SRS services prior to Jan. 1, 2016.

Radiation Oncology Services

Section 1833(t)(2)(A) of the Social Security Act requires CMS to develop a classification system for covered outpatient department (OPD) services. In accordance with these provisions, CMS developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs). The APCs are organized so that each group is homogenous—both clinically and in terms of resource use. As part of its continuing review of the structure of APC families, CMS reviewed and is restructuring nine APC clinical families for CY 2016. This includes renumbering some APCs so that the levels in each family have consecutive APC numbers. In some cases, CMS also consolidated procedures into a smaller number of APCs.

The APCs for radiation oncology services have been significantly impacted in CY 2016 by this restructuring. There will be a four-level configuration for Therapeutic Radiation Treatment Preparation APCs:

- **APC 5611**: Level 1 Therapeutic Radiation Treatment Preparation.
- **APC 5612**: Level 2 Therapeutic Radiation Treatment Preparation.
- **APC 5613**: Level 3 Therapeutic Radiation Treatment Preparation.
- **APC 5614**: Level 4 Therapeutic Radiation Treatment Preparation.

As a result of comments received regarding planning resources expended, CMS has agreed to assign procedure code **77307** (teletherapy isodose plan; complex) to new **APC 5613** and code **77306** (teletherapy isodose plan; simple) to new **APC 5612**.

CMS also took an opportunity to address simulation services performed prior to IMRT planning in the 2016 OPPS Final Rule. The IMRT computer planning code (**77301**) will be assigned to the highest level APC in the group, **APC 5614**. CMS reminded hospitals that the Medicare Claims Processing Manual, Chapter 4, Section 200.3.2, includes the following directive (effective Jan. 1, 2008):

"Payment for the services identified by CPT® codes ***77014***, ***77280***-***77295***, ***77305***-***77321***, ***77331***, ***77336***, *and* ***77370*** *is included in the APC payment for IMRT planning when these services are performed as part of developing an IMRT plan that is reported using CPT code* ***77301****. Under those circumstances, these codes should not be billed in addition to CPT code* ***77301*** *for IMRT planning."*

In addition to the CMS Manual guidance, there is National Correct Coding Initiative (NCCI) guidance in the NCCI Policy Manual for Medicare Services, Chapter 9, Page IX-17, which states:

"Intensity modulated radiotherapy (IMRT) plan (CPT® code ***77301****) includes therapeutic radiology simulation-aided field settings. Simulation field settings for IMRT should not be reported separately with CPT® codes* ***77280*** *through* ***77295****. Although procedure-to-procedure edits based on this principal exist in NCCI for procedures performed on the same date of service, these edits should not be circumvented by performing the two procedures described by a code pair edit on different dates of service."*

While the hospital guidance was implemented Jan. 1, 2008, the NCCI guidance added the same criteria for physicians and freestanding centers effective Jan. 1, 2014. CMS also indicated its intent to clarify this coding guidance going forward as follows:

"Payment for 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."*

This clarification means that the provider of service will *not* charge for an initial simulation or a verification simulation associated with an IMRT plan. It appears that this coding guidance will be included in the 2016 edition of the National Correct Coding Policy Manual; as a result, it will apply universally to hospitals, freestanding radiation treatment centers, and physicians.

There were a number of comments and CMS responses concerning the resources expended for specific radiation therapy procedures. For CY 2016, there will be seven levels for Radiation Therapy APCs and final APC code assignments to these complexity levels (Table 3, below).

For CY 2016, CMS will maintain intraoperative radiation therapy (IORT) codes **77424** and **77425** in newly renamed and renumbered **C-APC 5093** (Level 3 Breast/Lymphatic

Table 3. CY 2016 Radiation Therapy APCs & Final APC Code Assignments

2016 APC	TITLE	CODES ASSIGNED TO APC
5621	Level 1 Radiation Therapy	77401, 77402, 77407, 77789, 77799
5622	Level 2 Radiation Therapy	0394T, 77412, 77422, 77600, 77750, 77767, 77768
5623	Level 3 Radiation Therapy	77385, 77386, 77423, 77470, 77520, 77610, 77615, 77620, 77761, 77762
5624	Level 4 Radiation Therapy	0395T, 77605, 77763, 77770, 77771, 77772, 77778
5625	Level 5 Radiation Therapy	77522, 77523, 77525
5626	Level 6 Radiation Therapy	77373
5627	Level 7 Radiation Therapy	77371, 77372

Surgery & Related Procedures). CMS will also continue paying for low-dose rate prostate brachytherapy using composite **APC 8001**. In order for the hospital to receive the higher composite APC reimbursement, both code **77778** (Interstitial radiation source application; complex) and **55875** (Transperineal placement of needles or catheters into prostate for interstitial radioelement application with or without cystoscopy) must be billed on the same claim.

Medical Oncology & Hematology Services

For CY 2016, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status will continue to be set at the statutory default of average sales price (ASP)+6 percent. In addition, CMS will pay for biosimilar biological products based on the payment allowance for the product as determined under section 1847A of the Social Security Act. CMS will also extend pass-through payment eligibility to biosimilar biological products and set payment at the difference between the payment amount of the product as determined under section 1847A of the Act, and otherwise applicable Hospital Outpatient Department fee schedule amount.

Again for CY 2016, CMS finalized the proposed policy to continue to establish payment rates for blood and blood products using a blood-specific cost-to-charge methodology. In addition, CMS will pay for blood clotting factors at ASP+6 percent, consistent with the payment for other non-pass-through, separately payable drugs and biologicals and to continue the policy of paying a furnishing fee using an updated amount (to be announced at a later date).

Effective Jan. 1, 2016, the HCPCS Workgroup established three new HCPCS codes for pathogen-reduced blood products:

- **P9070**: Plasma, pooled multiple donor, pathogen reduced, frozen, each unit.
- **P9071**: Plasma (single donor), pathogen reduced, frozen, each unit.
- **P9072**: Platelets, pheresis, pathogen reduced, each unit.

CMS clarified the definition of "pathogen reduction" as describing 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.

Section 1833 of the Social Security Act permits CMS to make pass-through payments for a period of at least two, but not more than three years after the product's first payment as a hospital outpatient service under Medicare Part B. The long-standing practice has been to provide pass-through payment for a period of two to three years, with expiration of pass-through status proposed and finalized through the annual rulemaking process. CMS included a list of the drugs for which pass-through status will expire on Dec. 31, 2015, in Table 43 of the Final Rule. These drugs are identified in Table 4, right.

Other medications and substances remain approved for pass-through during CY 2016. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the rate of ASP+6 percent. In the 2016 Final Rule CMS states:

"Therefore, for CY 2016, we proposed to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2016. We proposed that a $0.00 pass-thorough payment amount would be paid for most pass-through drugs and biologicals under the CY 2016 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: contrast agents; diagnostic radiopharmaceuticals; anesthesia drugs; drugs, biological, and radiopharmaceuticals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2016, because if not for their pass through status, payment for these products would be packaged into the associated procedure."

CMS finalized its proposal to continue to set the associated co-payment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs to zero for CY 2016 and future years. Table 5, page 9, identifies the drugs and biologicals that will continue or have been granted pass-through status as of Jan. 1, 2016.

Drugs and therapeutic radiopharmaceuticals without pass-through status are paid separately only if the average per diem cost is greater than that year's packaging threshold. For CY 2016, the threshold is $100, up from $95 in CY 2015. CMS adds that packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule.

The 2016 OPPS Final Rule also included a technical correction related to verbiage associated with self-administered drugs, according to CMS:

"Specifically, we proposed to delete the phrase 'any drug or biological that can be self-administered' and replace it with the phrase 'any drug or biological which is usually self-administered by the patient.' We did not receive any public comments on this proposal. Therefore, we are finalizing our proposed technical correction to § 410.29 to amend the description of self-administered drugs and biologicals to more appropriately reflect the statutory language."

OPPS Payment for Biosimilar Biological Products

The Affordable Care Act (ACA) authorized an abbreviated pathway for the licensing of biosimilar biological products. Under this abbreviated pathway, a proposed biological product that is demonstrated to be

Table 4. Drugs & Biologicals for Which Pass-Through Status Will Expire Dec. 31, 2015

CY 2016 HCPCS CODE	CY 2016 LONG DESCRIPTOR	FINAL CY 2016 SI	FINAL CY 2016 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	N	N/A
C9132	Prothrombin complex concentrate (human), Kcentra, per IU of Factor IX activity	K	9132
J1556	Injection, immune globulin (Bivigam), 500 mg	K	9130
J3060	Injection, taliglucerase alfa, 10 units	K	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	N	N/A
J7316	Injection, Ocriplasmin, 0.125 mg	K	9298
J9047	Injection, carfilzomib, 1 mg	K	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	K	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	K	9131
J9400	Injection, Ziv-Aflibercept, 1 mg	K	9296
Q4122	Dermacell, per square centimeter	N	N/A
Q4127	Talymed, per square centimeter	N	N/A

biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure. Section 3139 of the ACA amended section 1847 of the Social Security Act to add the definition of a biosimilar biological product and set forth a payment methodology for biosimilar biological products.

The HCPCS codes and modifiers for biosimilar biological products will be established based on policy documented in the Medicare Physician Fee Schedule (MPFS) Final Rule with comment period. CMS refers readers to the CY 2016 MPFS Final Rule (also reviewed on pages 11-15) for additional detail. Under the OPPS, CMS will assign pass-through status to the first eligible biosimilar biological for each reference product. Subsequent biosimilars for that same reference product will not receive pass-through status.

OPPS Payment for Hospital Outpatient Visits

Since April 7, 2000, CMS has instructed hospitals to report facility resources for clinic and emergency department (ED) hospital outpatient visits. As part of the 2014 OPPS Final Rule, CMS finalized a policy that created HCPCS code **G0463** (hospital outpatient clinic visit for assessment and management of a patient) to report all hospital clinic visits under the OPPS. For CY 2016, HCPCS code **G0463** will be reassigned to **APC 5012** (Level 2 Examinations and Related Services) and CY 2014 claims data will be used to develop the 2016 OPPS payment rate for this service. CMS will also continue the policy of recognizing existing CPT procedure codes for critical care services and payment for these services will be established based on historical claims data.

One commenter recommended that CMS return to a tiered payment structure for clinic visits, citing that providers such as cancer hospitals were unfairly penalized since they provide care for more severely ill Medicare beneficiaries. CMS stated that it continues to believe that the spectrum of hospital resources provided during an outpatient hospital clinic visit is appropriately captured and reflected in the single level of payment.

Advanced care planning services (codes **99497**, **99498**) will be payable under the OPPS with a status change to **Q1** (conditionally packaged) effective Jan. 1, 2016. This means that advance care planning will be paid to the hospital when it is the only service provided that day. Add-on code **99498** will be unconditionally packaged and not separately reimbursed. CMS adds:

"Therefore, based on the code descriptors, we expect that physicians or qualified non-physician practitioners (as defined by 42

(*continued on page 10*)

Table 5. Drugs & Biologicals with Pass-Through Status in CY 2016

CY 2015 HCPCS CODE	CY 2016 HCPCS CODE	CY 2016 LONG DESCRIPTOR	CY 2016 SI	CY 2016 APC
A9586	A9586	Florbetapir fl8, diagnostic, per study dose, up to 10 mci	G	1664
C9025	J9035	Injection, ramucirumab, 5 mg	G	1488
C9026	J3380	Injection, vedolizumab, 1 mg	G	1489
C9027	C9027	Injection, pembrolizumab, 1 mg	G	1490
C9349	C9349	PuraPly, and PuraPly Antimicrobial, any type, per sq cm	G	1657
C9442	J9032	Injection, belinostat, 10 mg	G	1658
C9443	J0875	Injection, dalbavancin, 5 mg	G	1659
C9444	J2407	Injection, oritavancin, 10 mg	G	1660
C9445	J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9446	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9449	J9039	Injection, blinatumomab, 1 mcg	G	9449
C9450	J7313	Injection fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	J2547	Injection peramivir, 1 mg	G	9451
C9452	J0695	Injection, ceftolozane, 50 mg and tazobactam, 25 mg	G	9452
C9453	J9299	Injection, nivolumab, 1 mg	G	9453
C9454	J2502	Injection, pasireotide long acting, 1 mg	G	9454
C9455	J2860	Injection, siltuximab, 10 mg	G	9455
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
C9022	J1322	Injection, elosulfase alfa, 1 mg	G	1480
Q9970	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
J1446	J1446	Injection, TBO-Filgrastim, 5 mcg	G	1477
C9023	J3145	Injection, testosterone undecanoate, 1 mg	G	1487
C9134	J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per IU	G	1746
C9133	J7200	Factor IX (antihemophilic factor, recombinant), Rixubus, per IU	G	1467
C9135	J7201	Factor IX (antihemophilic factor, recombinant), Alprolix, per IU	G	1486
J7508	J7508	Tacrolimus, extended release, oral, 0.1 mg	G	1465
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476
J9371	J9371	Injection, vincristine sulfate liposome, 1 mg	G	1466
Q4121	Q4121	Theraskin, per square centimeter	G	1479
Q9975	J7205	Injection factor VIII, fc fusion protein, (recombinant), per IU	G	1656
Q9978	J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448
C9456	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
C9457	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457
N/A	C9458	Florbetan F18, diagnostic, per study dose, up to 8.1 mci	G	9458
N/A	C9459	Flutemetamol F18, diagnostic, per study dose, up to 5 mci	G	9459
N/A	C9460	Injection, cangrelor, 1 mg	G	9460
Q5101	Q5101	Injection, Filgrastim (G-CSF), biosimilar, 1 mcg	G	1822

(*continued from page 8*)
CFR 410.27(g)) will be involved (beyond just providing direct supervision of hospital staff) in providing these services to patients in the outpatient setting."

Lung Cancer Screening with Low-Dose Computed Tomography

On Feb. 5, 2015, CMS issued a National Coverage Determination (NCD) for Medicare coverage of a lung cancer screening counseling and shared decision-making visit, and for appropriate beneficiaries, annual screening with low-dose computed tomography (LDCT) as an additional preventive benefit. There are new HCPCS Level II codes for these covered services listed in the 2016 HOPPS Final Rule:

- **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).
- **G0297**: Low-dose CT scan (LDCT) for lung cancer screening.

Because the counseling visit and LDCT are covered as preventive benefits, there is no patient co-payment or deductible for these services. These new codes and APC assignments are effective Feb. 5, 2015, (the date the NCD was finalized) and may be billed under the OPPS beginning Jan. 1, 2016. Of importance, CMS states that it is in the process of developing claims processing, coding, and billing instructions for those services performed in CY 2015 that must be billed retroactively. CMS recently issued an *MLN Matters* to update coverage and charging requirements for lung cancer screening with LDCT. Learn more at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9246.pdf.

Off-Campus Provider-Based Departments

While this issue was not in the 2016 OPPS Final Rule, it is included because the PO HCPCS modifier remains active for CY 2016. According to CMS, research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resulting increase in the delivery of physician services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office.

For physician/practitioner professional claims, CMS has implemented new and revised place of service (POS) codes rather than a modifier. For hospital claims, CMS established the following modifier; reporting of the modifier is voluntary until Jan. 1, 2016, at which point it will become mandatory.

- **Modifier PO**: Services, procedures, and/or surgeries provided at off-campus provider-based outpatient departments.

Hospitals will append the modifier to *every* code for all outpatient hospital services furnished in an off-campus provider-based department of a hospital. CMS defines the campus as *"the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."*

The modifier should *not* be used on services performed at remote locations of the hospital, satellite facilities of the hospital, or emergency departments. A remote location is defined as *"a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider."* CMS states that questions about whether a particular location requires the modifier should be referred to the CMS regional offices.

While not part of the 2016 OPPS Final Rule, the Bipartisan Budget Act of 2015 was signed into law on Nov. 2, 2015 and includes the following:

SEC. 603. Treatment of New Off-Campus Outpatient Departments of a Provider. Section 603 would codify the CMS definition of provider-based (PBD) off-campus hospital outpatient departments (HOPDs) as those locations that are not on the main campus of a hospital and are located more 250 yards from the main campus. The section defines a "new" PBD HOPD as an entity that executed a CMS provider agreement [after the date of enactment]. Any PBD HOPD executing a provider agreement after the date of enactment would not be eligible for reimbursements from CMS' Outpatient Prospective Payment System. New PBD HOPDs, as defined by this section, would be eligible for reimbursements from either the Ambulatory Surgical Center (ASC PPS) or the Medicare Physician Fee Schedule. OI

Physician & Freestanding Center Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other suppliers under the Medicare Physician Fee Schedule (MPFS). For reimbursement purposes, relative values are assigned to more than 7,000 services to reflect the amount of work, the direct and indirect (overhead) practice expenses, and the malpractice expenses typically involved in furnishing that specific service. After applying a geographic practice cost indicator, the resulting relative value units (RVUs) are summed for each service and multiplied by a fixed-dollar conversion factor to establish the payment amount for each visit or procedure.

The CY 2016 conversion factor is estimated to be $35.8279, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under MACRA (Medicare Access and CHIP Reauthorization Act of 2015), and the 0.77 percent target recapture adjustment required by statute. CMS notes that "several specialties, including gastroenterology and radiation oncology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and inputs used to develop RVUs for the codes that describe particular services." Table 6, right, shows the estimated impact of projected payment increases or decreases by specialty (without considering the potential conversion factor change).

Terminology Update

This year, CMS states that throughout the 2016 MPFS Final Rule with comment period and unless otherwise noted, the term "practitioner" is used to describe both physicians and those non-physician practitioners (NPPs) who are permitted to separately bill Medicare under the Physician Fee Schedule.

Radiation Treatment & Image Guidance Codes

While the new CPT procedure codes for brachytherapy services will be used in all practice settings (hospitals, freestanding cancer treatment centers, and physician offices), there remain different treatment delivery and image guidance codes for the hospital and freestanding radiation centers for CY 2016. The 2016 MPFS Final Rule includes a lengthy discussion of issues and challenges involved in setting RVUs for the new CPT procedure codes. As a result, CMS has decided not to implement these new procedure codes for MPFS reimbursement; the G-codes will continue to be reported during CY 2016. CMS states that "significant changes" are required to the codes themselves before CMS can develop accurate payment rates. These changes would include:

- Developing a code set that recognizes the differences in costs between kinds of imaging modalities.
- Making sure that this code set facilitates valuation that incorporates the cost of imaging based on how frequently it is actually provided.
- Developing treatment delivery codes that are structured to differentiate payment based on equipment resources used.

Equipment Utilization Rate for Linear Accelerators

The 2016 MPFS Final Rule states that: *"The cost of the capital equipment is the primary determining factor in the payment rates for these services."* For each procedure code, the equipment costs are estimated based on multiplying the assumed number of minutes the linear accelerator is used for each treatment by the per-minute cost of the specific piece of equipment. CMS currently uses two default equipment usage assumptions when allocating capital equipment costs to practice expense (PE) RVUs:

1. The equipment is available to be used during what are assumed to be regular business hours for a physician's office: 10 hours per day, 5 days per week (50 hours per week), and 50 weeks per year.
2. The equipment is in use only 50 percent of the time it is available for use. This translates to 25 hours per week out of a 50-hour work week.

Based on RUC (Relative Value Update Committee) recommendations for the new and revised radiation treatment delivery and image guidance codes, CMS believes that a usage assumption of 50 percent is inaccurate for the linear accelerator used in radiation treatment services. Further review indicates a 45 percent increase in the amount of time a treatment machine is used (a total of 95 percent of equipment

usage time). As a result, CMS proposed to use a 70 percent assumption rate for the amount of time a linear accelerator is used on a daily basis, phased in over two years. This means that the equipment utilization rate for CY 2016 will be 60 percent and for CY 2017 it will be 70 percent. The more frequently a piece of equipment is used, the lower the reimbursement for each individual treatment. As a result, treatment delivery payments could see a reduction in both CY 2016 and CY 2017.

Superficial Radiation Treatment Delivery

In the CY MPFS 2015 Final Rule with comment period, CMS requested additional information on the physician work involved in superficial radiation therapy (code **77401**), and which services should be considered inclusive in this service. Conflicting comments were received, and CMS is considering the development of a new code that would include all work associated with the delivery of superficial radiation.

Lung Cancer Screening

On Feb. 5, 2015, CMS issued an NCD for Medicare coverage of a lung cancer screening counseling and shared decision-making visit, and for appropriate beneficiaries, annual screening with low dose computed tomography (LDCT) as an additional preventive benefit. The new HCPCS Level II codes for these services include:

- **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).
- **G0297**: Low dose CT scan (LDCT) for lung cancer screening.

CMS added that as long as the NCD requirements for the counseling and shared decision-making visit are met, the counseling visit may be billed on the same day as a medically necessary E/M service or with an annual wellness visit. **Modifier 25** (significant, separately identifiable service) would be required on code **G0296**, as well as separate documentation for the counseling visit. Because the counseling visit and LDCT are covered as preventive benefits, there is no patient co-payment or deductible for these services. These new codes and APC assignments are effective Feb. 5, 2015, (the date the NCD was finalized) and may be billed under the MPFS beginning Jan. 1, 2016. Of importance, CMS states that it is in the process of developing claims processing, coding, and billing instructions for those services performed in CY 2015.

Incident-To Update

The 2016 MPFS Final Rule includes yet another clarification that the physician or non-physician practitioner who bills for incident-to services (i.e., the individual listed on the claim form as the performing provider) must be the individual who provided direct supervision of the auxiliary personnel who performed the services. This means that although the physician of record for an individual patient may have ordered a particular service, the practitioner who provides the direct supervision in the office is the provider name that is billed on the claim form.

In addition, CMS explicitly prohibits the provision of incident-to services by auxiliary personnel who have been excluded from federal health programs or who have had their enrollment revoked. There were no changes to the definition of an incident-to service or to the list of non-physician

Table 6. Estimated Impact of Projected Payment Increases or Decreases by Specialty*

SPECIALTY	Allowed Charges (millions)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
Hematology/Oncology	$1,788	0%	0%	0%	0%
Radiation Oncology	$1,766	0%	-2%	0%	-2%
Radiation Therapy Centers	$52	0%	-2%	0%	-1%

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.

Allowed Charges: The aggregate estimated MPFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates.

Impact of Work RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.

Impact of Practice Expense RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.

Impact of Malpractice RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five year review and update of MP RVUs.

Combined Impact: The estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns.

*Without consideration of the potential conversion factor change.

practitioners who can perform services that are billed incident-to by a physician. CMS provided the following definitions in the MPFS Final Rule:

"Consistent with this terminology, when referring in this discussion to the physician or other practitioner furnishing the service, we are referring to the physician or other practitioner who is billing for the incident-to service. When we refer to the "auxiliary personnel" or the person who "provides" the service, we are referring to an individual who is personally performing the service or some aspect of it as distinguished from the physician or other practitioner who bills for the incident-to service.

As described in this Final Rule with comment period, incident-to a physician's or other practitioner's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's or other practitioner's personal professional services in the course of diagnosis or treatment of an injury or illness."

Off-Campus Provider-Based Departments

Although not included in the 2016 MPFS Final Rule with comment period, CMS announced in *MLN Matters* MM9231 (Aug. 6, 2015) that there would be two place of service codes billed by physicians on CMS1500 claim form when services are performed in the outpatient hospital setting:

1. **POS Code 19**: A portion of an *off-campus hospital provider-based department,* which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
2. **POS Code 22**: A portion of a *hospital's main campus,* which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

These place of service codes are effective Jan. 1, 2016, and are required on all Medicare professional claims for outpatient hospital services. Other insurers may or may not require this level of outpatient facility differentiation.

Potentially Misvalued Codes

In the CY 2015 MPFS Final Rule with comment period, CMS finalized the proposal to transition and revalue all 10- and 90-day global surgery services with 0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. However, MACRA was enacted into law on April 16, 2015, and included a paragraph that prohibits CMS from implementing this global surgery policy change. This same Act requires CMS to develop, through rulemaking, a process to gather information needed to value surgical services and requires that this data collection shall begin no later than Jan. 1, 2017.

Consistent with amendments made by the ACA, CMS has been engaged in a vigorous effort over the past several years to identify and review potentially misvalued codes and make adjustments where appropriate. CMS and the RUC have taken several steps to improve the review process, examining potentially misvalued services in several categories. In the 2016 MPFS Final Rule, CMS stated that it intended to proceed with a review of the high expenditure screen for 2016, while excluding codes with a 10-day or 90-day global period. The top 20 codes by specialty were identified, with patient visits excluded from review, as well as any codes that have already been reviewed since calendar year 2010. Table 7, right, shows the final list of potentially misvalued codes identified through the high expenditure specialty screen, specific to services that may be performed by medical or radiation oncologists.

Part B Drugs

Section 3139 of the ACA amended the Act to define a biosimilar biological product and a reference biological product and to provide for Medicare payment of biosimilar biological products using ASP methodology. A biosimilar biological product is defined as a biological product approved under an abbreviated application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). A reference biological product for a biosimilar biological product is defined as the biological product licensed under section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

CMS stated that because of the degree of similarity that biosimilars share with their reference products, it is appropriate to price biosimilar products in groups in a manner similar to how multiple source or generic drugs are currently priced. After considering all comments, CMS stated that the payment amount for a biosimilar biological product is based on the ASP of all NDCs (National Drug Codes) assigned to the biosimilar biological products included within the same billing and payment code.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program to promote utilization of appropriate use criteria (AUC) for advanced diagnostic imaging services. Advanced diagnostic imaging services include diagnostic imaging exams performed using CT, MR, and nuclear medicine (including PET). AUC are criteria that help professionals who order and furnish imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual patient. CMS can only approve AUC that are developed or endorsed by provider-led entities (PLEs), such as national professional medical specialty societies. In most cases the AUC will be evidence-based, and CMS can approve more than one set of AUC for a given imaging service.

An ordering physician/practitioner (including hematologists, medical oncologists, and radiation oncologists) will access AUC through a clinical decision support (CDS) tool, such as a CDS module in an electronic health record (EHR) or a web-based system. The ordering professional will enter patient information into the CDS tool, and it will provide immediate feedback about the appropriateness of the proposed imaging exam. Under PAMA, ordering physicians/practitioners will be required to consult AUC and to communicate the results of this consultation to the entity that furnishes the imaging study. When the imaging provider bills Medicare, it will then be required to include information on the claim about the ordering physician's consultation with AUC. This requirement applies to imaging studies billed under the Physician Fee Schedule, the Outpatient Prospective Payment System, and the Ambulatory Surgical Center Payment System. It does not apply to inpatient studies billed under Part A, to certain emergency studies, or to ordering physicians/practitioners who qualify for a hardship exception.

CMS will initially pay for the imaging study regardless of whether it was recommended by the AUC. Eventually, however, CMS will identify those ordering professionals who are consistently failing to follow AUC recommendations, and these "outliers" will be required to obtain prior authorization for advanced imaging studies they wish to order. PAMA called for CMS to meet the following deadlines:

- Establish AUC by Nov. 15, 2015.
- Establish CDS by April 1, 2016.
- Implement AUC consultation by ordering physicians/practitioners by Jan. 1, 2017.
- Identify "outlier" ordering professionals for services furnished after Jan. 1, 2017.

Due to the timing of the PAMA legislation, CMS was unable to meet the November 2015 deadline for establishing AUC, and this will in turn delay the other steps. In the 2016 MPFS Final Rule, CMS stated that it expects to establish rules and requirements for CDS mechanisms (including the process for communicating the AUC consultation information between providers and on the claim) during 2016 for the 2017 rulemaking cycle. Approved CDS mechanisms should be in place in summer of 2017.

Advance Care Planning

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning services:

- **99497**: Advance care planning, including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or

Table 7. Potentially Misvalued Codes Performed by Medical and/or Radiation Oncologists

CODE	DESCRIPTION
31575	Laryngoscopy, flexible fiberoptic; diagnostic
38221	Bone marrow; biopsy, needle or trocar
51720	Bladder instillation of anticarcinogenic agent (including retention time)
77263	Therapeutic radiology treatment planning; complex
77334	Treatment devices, design and construction; complex
77470	Special treatment procedure
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96372	Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular
96374	Therapeutic, prophylactic or diagnostic injection; IV push, single or initial drug
96375	Therapeutic, prophylactic or diagnostic injection; each additional sequential IV push of a new substance/drug
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic
96409	Chemotherapy administration; IV push, single or initial substance/drug
96411	Chemotherapy administration; IV push, each additional substance/drug

other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.

- **+99498:** Each additional 30 minutes. (List separately in addition to code for primary procedure).

In the CY 2016 MPFS Final Rule, these services were assigned a status indicator of "I" (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services). For CY 2016, CMS will provide reimbursement for these services, and the agency recommends that when a beneficiary elects to receive advance care planning, the practitioner should notify the patient that Part B cost sharing (e.g., co-payment and/or deductible) will apply for this optional, voluntary service in the same manner as for other physician services. CMS also states that it will monitor utilization over time to ensure that these codes are used appropriately. This means, in part, that only one physician member of the patient's multispecialty care team will be permitted to bill for advance care planning within a reasonable time period.

Last, CMS clarified that a number of comments were received on existing or recommended practice patterns for the provision of advance care planning services, including recommendations for individuals who could perform this service as part of a global care team. CMS states in the MPFS Final Rule:

"We note that the CPT code descriptors describe the services as furnished by physicians and other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore, only these practitioners may report CPT codes ***99497*** *or* ***99498****.*

We agree with commenters that advance care planning as described by the proposed CPT codes is primarily the provenance of patients and physicians. Accordingly, we expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision."

CMS added that these codes will be separately payable to the billing physician or practitioner in both facility and non-facility settings and are not limited to particular physician specialties. In response to specific comments, CMS agreed that advance care planning can be separately reimbursed when performed at the same time as an annual wellness visit. **Modifier 33** (preventive services) would be reported on the advance care planning charge in this scenario, and the patient would not have a co-payment or deductible.

Other Issues

In addition to the specific topics listed above, CMS also provided details on the Physician Compare Website, the Electronic Health Record Incentive Program, the Medicare Shared Savings Program, the Value-Based Modifier, Physician Self-Referral Updates, and Physician Quality Reporting Systems. CMS also received a number of comments in response to the request for recommendations on how to improve Medicare compensation mechanisms for primary care services and collaborative care. Many commenters complained specifically about the administrative burden associated with billing for transitional care and chronic care. These comments will be considered during future rulemaking.

Bipartisan Budget Act of 2015

While not part of the MPFS Final Rule, the Bipartisan Budget Act of 2015 was signed into law on Nov. 2, 2015, and includes the following:

Sec. 101. Amendments to the Balanced Budget and Emergency Deficit Control Act of 1985. Subsection 101(b) provides for the implementation of the sequester of direct spending as if the amendments in subsection 101(a) had not been made. The President is required by law to implement the sequester of direct spending ordered on February 2, 2015 and the one in the Sequestration Preview Report for Fiscal Year 2017 as if the amendments in subsection 101(a) had not been made. 2 Subsection 101(c) reduces spending by $14 billion in fiscal year 2025 by requiring the President to sequester the same percentage of direct spending in 2025 as will be sequestered in 2021. It also replaces the arbitrary dips and increases in the Medicare sequester percentages in 2023 and 2024 with a flat two-percent rate as applies under current law in fiscal years 2016 through 2022.

This means that Congress extended the annual 2 percent sequestration reduction of Medicare provider reimbursement one more year, into 2025. This pay cut, created by the sequestration provisions of the Budget Control Act of 2011, was supposed to expire in 2021, but Congress has now added additional years to this reimbursement reduction. OI