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2016 HOSPITAL OPPS FINAL RULES:

PET Tests Moved into Separate APC

On November 13, 2015, the Centers for Medicare & Medicaid Services (CMS) posted the 2016 final rules for the hospital outpatient prospective payment system (OPPS) and ambulatory surgical centers (ASCs), which contain, as always, policy changes, quality provisions, and payment rates. In addition to the regular updates, there also are several radiology-specific changes to the OPPS that take effect on January 1, which are summarized below.

APCs for Imaging

As a part of its 2016 comprehensive review of the structure of the APCs and procedure code assignments, CMS examined those that contain imaging services. As always, its goal was to restructure the APCs to more appropriately reflect the costs and clinical characteristics of the procedures within each grouping in the context of the OPPS.

CMS explains that, currently, APCs for imaging services are divided at the highest level between diagnostic radiology (for example, x-ray, computed tomography [CT], magnetic resonance imaging [MRI], and ultrasound) and nuclear medicine imaging. However, for 2016, it restructured and consolidated the APCs that include radiology and nuclear medicine services to "more appropriately reflect a PPS based on payment for clinically consistent APC groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity," stated CMS.

One key change made was to move positron emission tomography (PET) tests into a separate APC because they involve higher resource costs and are of a clinically distinct imaging modality from non-PET or SPECT imaging services. Specifically, it added new APC 5594—level 4 nuclear medicine and related services, which contains all of the PET scan procedures, in addition to, when appropriate, non-PET scan nuclear medicine tests.

In general, CMS finalized its proposal to reconfigure the imaging-related procedures into 26 APCs, which can be found in table 32 of the final rule. Just five of those 26 are devoted to nuclear medicine procedures for 2016, which are listed below.

APCs	APC Descriptions	2016 Payment Rates
5591	Level 1 nuclear medicine and related services	$332.65
5592	Level 2 nuclear medicine and related services	$441.36
5593	Level 3 nuclear medicine and related services	$1,108.46
5534	Level 4 nuclear medicine and related services	$1,285.17
5661	Therapeutic nuclear medicine	$249.98

Radiopharmaceutical Payments

In 2016, the following will continue to be packaged:

- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure
- Contrast agents
- Stress agents
- Drugs and biologicals that function as supplies when integral to, dependent on, supportive of, or

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adjunctive to a surgical procedure

- Anesthesia drugs.

Therapeutic radiopharmaceuticals that do not have pass-through status will continue to be paid separately under the average sales price (ASP) methodology. If ASP information is unavailable, CMS bases payment on mean unit cost data derived from hospital claims.

Pass-Through Status

Two new level II codes are now available to report use of Beta-amyloid imaging agents. These codes, and payment details, are provided in the table on page 3.

In future years, the time allowed for pass-through payment may be extended—due to several public comments received in response to the proposed rule. The commenters recommended that CMS continue pass-through status for new drugs, specifically diagnostic radiopharmaceuticals and contrast agents, for a full three years (instead of the current two). They asserted that doing so would help provide a more current and accurate data set on which to base payment amounts of the procedure when the diagnostic radiopharmaceutical or contrast agent is subsequently packaged.

Although CMS did not accept this recommendation for 2016, it stated it would take it "under consideration" as it reviews its OPPS pass-through payment policy for 2017.

There also are new technology services that are not eligible for transitional pass-through payments, and there isn't enough clinical information and cost data to appropriately assign them to a clinical APC group. For these, CMS has established special new technology APCs based on costs. Like pass-through payments, an assignment to a new technology APC is temporary. A service remains in this category until the agency acquires sufficient data, and in Table 20 of the final rule CMS lists four additional categories.

Low-Dose CT

CMS issued a national coverage determination (NCD) in early February 2015 announcing that it would allow an annual lung cancer screening with low-dose computed tomography (LDCT) under Medicare. Beginning January 4, 2016, the following codes may be billed for services provided on and after February 5, 2015 (the NCD's effective date):

G0296 Counseling visit to discuss need for lung cancer screening LDCT (service is for eligibility determination and shared decision-making)

G0297 LDCT for lung cancer screening

As indicated in the code descriptions above, the beneficiary first must receive a counseling visit, and, if appropriate, receive the written order for the first LDCT screening. Subsequent annual LDCT screens may be furnished during any appropriate visit with a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist).

Medicare will deny G0296 and G0297 for claims that do not contain one of the following diagnosis codes:

- For services provided until September 30, 2015, assign ICD-9 code V15.82.
- For services provided October 1, 2015, and after, assign ICD-10 code Z87.891—personal history of tobacco use/personal history of nicotine dependence.

Information Sources

- For the 2016 OPPS final rule, go to https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-27943.pdf. The final payment rates for HCPCS codes are included in Addendum B of the final rule, and Addendum A lists the payments for all APCs.
- For transmittal containing billing instructions for the LDCT lung-cancer screening, go to https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3374CP.pdf.

2016 NUCLEAR MEDICINE CODES:
New and Revised for CPT and Level II

For 2016, the American Medical Association (AMA) revised one CPT code and added two more related to motility of the entire gastrointestinal tract (i.e., stomach, small bowel and colon), as provided in Table 1 below along with the hospital outpatient prospective payment system (OPPS) payment rates.

Table 1: New 2016 Nuclear Medicine Codes

Code	Description	MPFS Modifier	MPFS Rate	OPPS APC	OPPS Payment Rate
▲78264	Gastric emptying imaging study (e.g., solid, liquid, or both);	Global TC 26	$348.61 $311.34 $37.26	5591	$332.65
•78265	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel transit	Global TC 26	$415.60 $366.52 $49.52	5591	$332.65
•78266	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days	Global TC 26	$492.99 $438.53 $54.46	5592	$441.36

In addition, the Centers for Medicare & Medicaid Services (CMS) added the two new C codes listed in Table 2 to the pass-through status list for Beta-amyloid imaging agents. These would only be used in hospital OPPS and ambulatory surgical center (ASC) settings. Providers in the Medicare physician fee schedule (MPFS) setting should continue to use level II code A9599 (radiopharmaceutical, diagnostic, for Beta-amyloid positron emission tomography [PET] imaging, per study dose).

Table 2: New Radiopharmaceuticals with Pass-Through Status

Level II Codes	Descriptors	Identifying Information	2016 OPPS Pass-Through Payment Rate
• C9458	Florbetaben F-18, diagnostic per study dose, up to 8.1 millicuries	*Trade Name:* Neuraceq™ Piramal *Generic Name:* Tc 99m florbetaben *National Drug Code (NDC):* 54828-001-30	$989.33
• C9459	Flutemetamol F-18, diagnostic, per study dose, up to 5 millicuries	*Trade Name:* Vizamyl™ G.E. *Generic Name:* Tc 99m flutemetamol *NDC:* 17156-067-10 or # 17156-067-30.	$3,300

Information Source

The January 2016 HCPCS level II codes can be found at this website: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html.

2016 MEDICARE PHYSICIAN FEE SCHEDULE:

Slight Rate Reduction for Nuclear Medicine

On November 16, 2015, the Centers for Medicare & Medicaid Services (CMS) issued the 2016 final rules for the Medicare Physician Fee Schedule (MPFS), which take effect on January 1. As always, CMS updated payment policies and rates, using an estimated 2016 conversion factor (CF) of $35.8279 (slightly down from the 2015 CF), and finalized several new policies.

Table 62 in the MPFS final rule lists the estimated impact on total allowed charges by specialty. For example, CMS estimates a 1 percent decrease for nuclear medicine professionals in addition to the following:

- 0 percent change for diagnostic radiology
- 1 percent increase for interventional radiology
- 2 percent decrease for radiation oncology
- 1 percent decrease for radiation therapy centers.

Policy Revisions

In addition to including changes to the quality reporting initiatives that are associated with payments, the agency provided an update on its progress developing the new Merit-Based Incentive Payment System (MIPS) for physicians and other practitioners (required by the Medicare Access and CHIP Reauthorization Act [MACRA] of 2015). Specifically, CMS is currently in the information-gathering phase of development, which MACRA mandates to be in place with payments for items and services furnished on or after January 1, 2019.

In relation to MIPS, CMS reports that the 2018 Physician Quality Reporting System (PQRS) payment adjustment is the last adjustment that will be issued under that program. Starting in 2019, adjustments to payment for quality reporting and other factors will be made under the MIPS. The value modifier also is set to expire at the end of 2018. Some of the 2016 final policies are intended to "help provide a smooth transition" from the value modifier to MIPS.

Appropriate Use Criteria

The Protecting Access to Medicare Act (PAMA) requires that Medicare establish appropriate use criteria (AUC) for advanced diagnostic imaging services. CMS defines AUC as a set of individual criteria that presents information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). It also states that "evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context."

In the final rule, CMS addressed the initial component of the new program and its plan for implementing the three remaining components, one of which is "AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017." The American College of Radiology (ACR) has been urging CMS to meet this deadline, and, according to a comment on its website, is "disappointed" that CMS does not intend to require ordering professionals to do so.

However, CMS stated that there are different views about how best to roll out AUC into clinical practice, so it will continue the discussion and adopt claims-based reporting requirements in the 2017 and 2018 rulemaking cycles. Details of the AUC plan can be found in Section III.G. of the MPFS final rule.

Radiation Therapy

Although CMS did not take action on its 2012 announcement that radiation therapy codes were potentially misvalued, it did finalize its proposed change for the equipment utilization rate assumption, which is used to determine the per-minute cost of the capital equipment used for radiation therapy.

As explained, the usage of the linear accelerator has increased.

| *2016 Medicare Physician Fee Schedule... continued on page 4* |

| *2016 Medicare Physician Fee Schedule... continued from page 3* |

Specifically, CMS has discovered that the equipment is generally used for 35 hours per week (a 70 percent utilization rate) instead of 25 hours per week (a 50 percent utilization rate). Therefore, instead of applying the default 50 percent assumption, CMS will increase the rate to a 70 percent assumption with a two-year phase-in.

Information Source

The final rule can be found at https://www.federalregister.gov/public-inspection.

NATIONAL CORRECT CODING INITIATIVE:
CMS Posts 2016 Update to Guidelines

In an effort to control improper coding, CMS expanded the National Correct Coding Initiative (NCCI) to include several types of edits. The original CCI edits, now called procedure-to-procedure (PTP) edits, as well as medically unlikely edits (MUE) and add-on-code edits are all now under the NCCI umbrella.

Medicare's most comprehensive bundling policy for professional and technical services is the PTP edit system, which lists code pairs that should not be billed together for the same patient on the same day in most circumstances. PTP edits, which are used for Medicare claims processing for both physician and outpatient hospital services, may change quarterly, and all physician practices and hospital outpatient departments should have access to the most recent version.

Along with the edits, CMS also publishes the *National Correct Coding Initiative Policy Manual for Medicare Services* to explain the rationale for many of the edits. The manual includes 13 chapters—one for each section of the CPT system—and general policies.

Chapter 9 of the *NCCI Policy Manual for Medicare Services* includes the narrative instructions related to radiology services (CPT codes 70000–79999).

In the January 2016 edition of the manual, CMS added and revised guidelines to several areas of radiology, which are summarized below.

General Policy

Physicians should not report radiologic supervision and interpretation (S&I) codes, radiologic guidance codes, or other radiology codes where the radiologic procedure is integral to another procedure being performed at the same patient encounter.

PTP edits that bundle these radiologic codes into the relevant procedure codes have modifier indicators of "1" allowing use of NCCI-associated modifiers to bypass them if and only if the radiologic procedure is performed for a purpose unrelated to the procedure to which it is integral.

For example, fluoroscopy is integral to a cardiac catheterization procedure and should not be reported separately from a cardiac catheterization. However, if on the same date of service (DOS) the physician performs another procedure in addition to the cardiac catheterization and the additional procedure requires fluoroscopy that is not integral to the additional procedure, the fluoroscopy procedure may be reported separately with an NCCI-associated modifier.

Non-interventional Imaging

- CPT code 77063 is an add-on code describing screening digital tomosynthesis for mammography. Since this procedure requires performance of a screening mammography producing direct digital images (HCPCS code G0202), CPT code 77063 may be reported with HCPCS code G0202. However, 77063 (a column 2 code) should not be reported with 77057 (a column 1 code), which describes screening mammography using radiography.
- Screening and diagnostic mammography are normally not performed on the same DOS. However, when the two procedures are performed on the same DOS, Medicare requires that the diagnostic mammography HCPCS/CPT code be reported with modifier GG (performance and payment of a screening and diagnostic mammogram on the same patient, same day), and the screening mammography HCPCS/CPT code can be reported with modifier 59.

Interventional Imaging

3D rendering of an imaging modality (e.g., CPT codes 76376, 76377) should not be reported for mapping the sites of multiple biopsies or other needle placements under radiologic guidance. For example, a provider performing multiple prostate biopsies under ultrasound guidance (e.g., 76942) should not report 76376 or 76377 for developing a map of the locations of the biopsies.

Radiation Oncology

- CPT code 77338 (multi-leaf collimator [MLC] device[s] for intensity modulated radiation therapy [IMRT], design and construction per IMRT plan) should not be reported with 77385 (intensity modulated radiation treatment delivery [IMRT], includes guidance and tracking, when performed; simple) if the IMRT is compensator-based. However, if the IMRT is not compensator-based, 77338 may be reported separately.
- Calculations described by CPT code 77300, if performed, are integral to some clinical brachytherapy procedures (e.g., 77767–77772, 77778). CPT code 77300 should not be reported with these clinical brachytherapy procedure codes.

Information Source

Except for the coding tips, the above is taken from Chapter 9 of the NCCI Manual. This can be found at https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html.

POSITRON EMISSION TOMOGRAPHY (NaF-18):

Coverage with Evidence Development to Continue

Use of a NaF-18 positron emission tomography (PET) scan to identify bone metastasis of cancer will continue under the current Medicare coverage with evidence development (CED) policy. The Centers for Medicare & Medicaid Services (CMS) announced this in a September 15, 2015, proposed decision memo.

Back in March, the National Oncologic PET Registry (NOPR) asked CMS to reconsider the CED data-collection requirements in the context of NaF-18 PET and authorize national coverage of NaF-18 PET for bone metastasis of all oncologic indications. However, in a proposed decision memo (CAG-00065R2), CMS stated that it limited its consideration to NaF-18 PET to identify bone metastasis of cancer.

As described in its proposed decision memo, CMS decided not to authorize national coverage because “evidence is sufficient to determine that use of a NaF-18 positron emission tomography (PET) scan to identify bone metastasis of cancer is not reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member and, therefore, is not covered under §1862(a)(1)(A) of the Social Security Act.”

CMS requested public comments and stated that it would reconsider the NCD when it sees that evidence has been published in a peer-reviewed journal that definitely answers the following questions: Does the addition of NaF-18 PET imaging lead to a change in patient management to more appropriate palliative care or more appropriate curative care? Does it lead to improved quality of life or survival?

Information Sources

The current coverage policy can be found in section 220.6.19 of the *National Coverage Determinations Manual:* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf.

To view the proposed decision memo: https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=279.

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