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2014 HOSPITAL OPPS FINAL RULE:
More Packaged Items and Services

In the 2014 final rule for the hospital outpatient prospective payment system (OPPS), the Centers for Medicare & Medicaid Services (CMS) state that they will continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care.

This plan is not a new one since CMS has been packaging numerous services for 15 years or so. For the last six years, payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs has been packaged into payment for the associated procedure. In 2014, these items will continue to be packaged.

Starting with dates of service on and after January 1, 2014, CMS will "unconditionally or conditionally" package:

- Drugs, biologicals, and radiopharmaceuticals that function as supplies ***when used in a diagnostic test or procedure*** except when pass-through status applies
- Drugs and biologicals that function as supplies (including devices) ***when used in a surgical procedure***
- Certain clinical diagnostic laboratory tests
- Certain procedures described by add-on codes
- Device-removal procedures when they are performed with a repair or replacement.

Of particular interest to nuclear medicine professionals are the key points related to the first two bullets above, starting with CMS's summary related to stress agents that are used in diagnostic tests to evaluate certain aspects of cardiac function.

Focus on Stress Agents. The primary diagnostic test in which these agents are used is myocardial perfusion imaging (MPI)—the highest-cost nuclear medicine procedure in the OPPS. According to CMS, the following CPT code is included in 96 percent of Medicare claims that report these agents. Looking at the big picture, total Medicare payments for this procedure exceeded $800 million in 2012.

78452 MPI, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

For 2014, all stress agents that function as supplies will be packaged when used in a diagnostic test or procedure.

New Code. CMS also made one change to the codes that could be used to report stress agents. In 2013, the following codes were used, and three of these will continue to be used:

J0152 Injection, adenosine for diagnostic use, 30 mg (separately paid in the OPPS 2013)

J1245 Injection, dipyridamole, per 10 mg (packaged in the OPPS 2013)

J1250 Injection, dobutamine hydrochloride, per 250 mg (packaged in the OPPS 2013)

J2785 Injection, regadenoson, 0.1 mg (separately paid in the OPPS 2013)

For 2014, CMS deleted code J0152, and providers must assign the following code instead:

J0151 Injection, adenosine for diagnostic use, 1 mg (not to be used to report any adenosine phosphate compounds, instead use A9270)

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Code J2785 will continue to be used, but it will have a status indicator (SI) of N (unconditional packaging) as will J0151.

Exception to Add-on Code Rule. CMS announced two exceptions to its current rule of unconditionally packaging all OPPS procedures described by add-on codes. Specifically, the add-on codes for drug-administration services and the codes assigned to device-dependent APCs will continue to receive separate payment.

New Classification for Cysview. In its discussion of the packaging of drugs, contrast agents, and radiopharmaceuticals, CMS provided an in-depth analysis of the indications and usage for Cysview® (hexaminolevulinate hydrochloride). The pass-through status for Cysview expired on December 31, 2012, and beginning in 2013, it was unconditionally packaged in the OPPS as a contrast agent.

Based on its analysis, CMS determined that Cysview is not a contrast agent but can more appropriately be described as a drug used in a procedure to diagnose bladder cancer. Therefore, HCPCS code C9275 (Cysview) has been assigned a SI of N (unconditionally) for 2014.

Pass-through Status Changes

December 31, 2013, is the last day for the following to receive pass-through status.

A9584 Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries)

However, CMS granted pass-through status to another radiopharmaceutical beginning October 1, 2013: C1204—technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries. Note that the agency changed the code to report it as follows: A9520—technetium Tc 99m tilmanocept, diagnostic,up to 0.5 millicuries. Addendum B lists the payment for A9520 as $223.15 with minimum unadjusted copayment of $44.63.

Non-pass-through therapeutic radiopharmaceuticals are paid the average sales price (ASP) + 6 percent, while those without available ASP information receive the wholesale acquisition cost (WAC) + 6 percent. If the WAC is not available, payment is based on 95 percent of the product's most recently published average wholesale price (AWP).

Other Important Changes

Edits for Nuclear Medicine Procedure-to-Radiolabeled Products. In 2014, edits will be turned off and claims will no longer be returned to providers when HCPCS codes do not appear with the nuclear medicine procedures. Of course, hospitals will still be expected to adhere to the guidelines of correct coding and append the correct radiolabeled product code to the claim when applicable.

Modifier FB. Providers have been using this modifier since January 1, 2011, for hospital OPPS claims when they receive a radiopharmaceutical or a device "free of charge." Hospitals will no longer be required to append this modifier to specified nuclear medicine procedures or to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is received at no cost or full credit. Under this finalized policy, the OPPS payment amount for nuclear medicine procedures is not reduced when a diagnostic radiopharmaceutical is received at no cost or full credit.

Information Source: For the final hospital OPPS rule, go to *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

THE NEW ICD-10 CODING SYSTEM: The Countdown Has Begun

In less than a year—October 1, 2014, to be exact, the new ICD-10-CM and ICD-10-PCS coding systems will be implemented. Rumor has it that some providers, mainly physicians, still aren't taking this deadline seriously, but most healthcare industry leaders are taking it very seriously, and, in fact, some are already performing end-to-end testing with payers to ensure that their claims can be sent and payment can be received using ICD-10 codes.

All entities covered by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, not just those that submit Medicare and Medicaid claims, must switch to ICD-10. This includes healthcare providers and suppliers, payers, clearinghouses, and billing services.

Organizations that are not covered by HIPAA (such as Workers' Compensation programs, property and casualty insurance plans, and prison health systems) are not required to switch to ICD-10-CM. Providers who submit claims to non-HIPAA entities may have to continue to use ICD-9-CM for non–HIPAA-covered payers and ICD-10-CM for those covered under HIPAA.

The changes to these two code sets do not affect CPT coding for outpatient procedures and physicians' services nor do they affect HCPCS level II codes.

Front-End Testing with Medicare Payers

The Centers for Medicare & Medicaid Services (CMS) recently announced that front-end ICD-10 testing will be conducted between Medicare administrative contractors (MACs) and their trading partners between March 3 and March 7, 2014. During this five-day period, suppliers and providers can submit test claims through the CEM (Common Edits and Enhancements Module) or the DME CEDI (Durable Medical Equipment Common Electronic Data Interchange). This virtual event that will be posted on several websites, including MACs and CMS.

During this testing period, all trading partners will have access to real-time help desk support, at a minimum, from 9 a.m. to 4 p.m. local contractor time. CMS advises providers to make their billing staff aware that MACs will:

- Announce and actively promote the testing week via listserv messages and posts on their websites.
- Host a registration site for the testing week, or provide an email address to provide registration information. These options will be available and publicized at least four weeks before the testing week.
- Send electronic confirmations to participating providers and suppliers during testing week to let them know that submitted test claims were accepted or rejected.

Looking Ahead to Billing

ICD-10 diagnosis and procedure codes must be used for services provided on or after October 1, 2014. Claims that contain ICD-9 diagnosis and inpatient procedure codes after that date cannot be

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processed. Claims for services provided before October 1, 2014, must use ICD-9 diagnosis and inpatient procedure codes.

CMS provides the following billing guidelines: If the date of service was before the October 1, 2014, implementation deadline, use the ICD-9 diagnosis code; if it is after October 1, use the ICD-10 diagnosis code. However, depending upon your payer, you may not be able to use ICD-9 and ICD-10 codes on the same claim. You may have to submit two claims: one with the ICD-9 diagnosis codes and another with the ICD-10 diagnosis codes.

In addition, some trading partners may request that ICD-9 and ICD-10 codes be submitted on the same claim when dates of service span the compliance date. Trading partner agreements will determine the need for split claims.

Resources are Plentiful

During the last few months, CMS has been encouraging all HIPAA-covered entities to visit its website *(http://www.cms.gov/Medicare/Coding/ICD10/index.html)* and download tools needed for the transition. At this site, there are specific resources for providers, payers, and vendors in addition to:

- ICD-10 implementation timelines
- 2014 ICD-10-CM and ICD-10-PCS general equivalence mappings (GEMs)
- Links to a variety of national provider educational teleconferences to help with the transition.

Many other organizations also are actively involved in the training of personnel (coders and physicians) and planning for the implementation of new ICD-10 coding system, including the:

- American Hospital Association at *http://www.aha-centraloffice.com/ahacentraloffice/shtml/ICD10overview.shtml*
- Workgroup for Electronic Data Interchange (WEDI) at http://www.wedi.org/workgroups/icd-10)
- National Center for Health Statistics' at *http://www. cdc.gov/nchs/icd/icd10cm.htm*
- American Health Information Management Association (AHIMA) at *http://www.ahima.org/education/onlineed/Programs/ICD10.*

ENSURING THE QUALITY OF RADIOPHARMACEUTICALS:
FDA Approval Required for Medicare Payment

In order for Medicare to cover drugs, biologicals, and radiopharmaceuticals (collectively known just as drugs), they must be approved by the U.S. Food and Drug Administration (FDA) as safe and effective. Industry leaders recommend that hospitals and physicians manage their risk, and that of their patients, by choosing only FDA-approved drugs.

The FDA has been called the "the safest and most advanced pharmaceutical system in the world," and its job is to enforce the federal Food, Drug, and Cosmetic Act. The job of the FDA's Center for Drug Evaluation and Research (CDER) is to ensure that the health benefits of brand-name and generic products outweigh their known risks before they can be sold.

Example of Medicare Policy

In March 2013, the Centers for Medicare & Medicaid Services (CMS) determined that if a specific national coverage determination (NCD) does not exist, local Medicare administrative contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals—***as long as*** the FDA has approved the labeled indications for oncologic imaging. If a product does not meet this standard, it is not covered. (Per PET decision memo CAG-00065R2.)

Note, however, that this decision does not change coverage for any use of PET with the following radiopharmaceuticals: FDG (2-deoxy-2-[F-18] fluoro-D-Glucose [fluorodeoxyglucose]), NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82). This decision also does not prevent CMS from determining national coverage for radiopharmaceutical usage in the future, and if such determinations are made, CMS's position would supersede local contractor determination.

Checklist for Quality

When shopping for a drug vendor, consider whether the company:

- Supplies FDA-approved radiopharmaceutical products exclusively
- Operates an internal safety-audit program with strict quality-control (QC) parameters
- Possesses the required licenses and permits, such as from the Board of Pharmacy, the Nuclear Regulatory Commission (NRC), and those required by the state
- Follows FDA and industry compounding guidelines (such as those published by the American Society for Health System Pharmacists [ASHP] and others).

Recent drug-contamination scandals reinforce the need for hospitals and physicians to pay close attention to products they purchase. A good place to start is to ensure they are FDA-approved—a guideline that CMS uses in its Medicare payment decisions.

Q & A: Focus on Nuclear Medicine

When does Medicare cover Beta-Amyloid PET?

At the end of September, 2013, the Centers for Medicare & Medicaid Services (CMS) issued a decision memo related to the use of beta-amyloid positron emission tomography (PET) in dementia and neurodegenerative disease. The final decision memo can be found at *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=265*

In that memo, CMS stated that the use of PET Aß imaging is promising in two scenarios:

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- To exclude Alzheimer's disease (AD) in narrowly defined and clinically difficult differential diagnoses, such as AD versus frontotemporal dementia (FTD)
- To enrich clinical trials seeking better treatments or prevention strategies for AD, by allowing for selection of patients on the basis of biological as well as clinical and epidemiological factors.

Therefore, Medicare will cover one PET Aß scan per patient through coverage with evidence development (CED) when the clinical studies meet the criteria and receive its approval. The study objectives must be to develop better treatments or prevention strategies for AD or as a strategy to identify subpopulations at risk for developing AD, ***or*** resolve clinically difficult differential diagnoses (e.g., FTD versus AD) where the use of PET Aß imaging appears to improve health outcomes. These may include short-term outcomes related to changes in management as well as longer term dementia outcomes.

How many units should be billed if a nuclear pharmacy supplies three syringes of a radiopharmaceutical?

Most, but not all, radiopharmaceuticals are billed "per study dose," so if all three syringes are given as part of one study, the billing unit would be one (1). However, always check the radiopharmaceutical HCPCS code description.

For example, Tc-99M sestamibi is "per study dose," but Thallium is "per millicurie." In the case of sestamibi, if separate doses are given for the stress and rest scans, you would code A9500 x 2.

A9500 Technetium Tc-99M sestamibi, diagnostic, per study dose

A9505 Thallium TI-201 thallous chloride, diagnostic, per millicurie

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