@nuclear
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Medicare Reimbursement Changes for 2014

By Barbara Ossias

The annual updates to the Medicare reimbursement for two major settings have been implemented as of 2014. Below provides an overview of the changes related to nuclear medicine.

2014 Final Rule for Medicare Reimbursement for HOPPS

In late November 2013, the Centers for Medicare and Medicaid Services (CMS) released the 2014 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule, which included some significant changes to how relative payment weights were calculated for select imaging procedures.

CMS is calculating HOPPS relative payment weights using distinct cost-to-charge ratios (CCR) for cardiac catheterization, CT and MRI procedures. While the 2014 Final Rule change to CCR reimbursement *does not affect nuclear imaging procedures*, we need to monitor because CMS may adopt the methodology for other modalities in future years. CMS will allow four years for hospitals to transition to the cost allocation methods identified in the Final Rule.

The HOPPS 2014 Final Rule does impact nuclear medicine rates. A comparison of 2013 Final Rule rates for nuclear medicine Ambulatory Payment Classification (APC) shows increases in all areas except one: Level I Nervous System Imaging.

The add-on payment for use of non-highly enriched uranium source will continue, at the rate of $10 per dose.

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APC	Group Title	Final 2013	Final 2014	Change
308	PET Imaging	$1,056.12	$1,310.64	24.1%
377	Level II Cardiac Imaging	$679.68	$1,153.42	69.7%
378	Level II Pulmonary Imaging	$336.40	$430.93	28.1%
390	Level I Endocrine Imaging	$150.04	$183.35	22.2%
391	Level II Endocrine Imaging	$232.94	$286.98	23.2%
394	Hepatobiliary Imaging	$314.39	$372.55	18.5%
395	GI Tract Imaging	$256.76	$323.77	26.1%
396	Bone Imaging	$261.68	$323.96	23.8%
398	Level I Cardiac Imaging	$308.99	$383.15	24%
400	Hematopoietic Imaging	$279.95	$346.30	23.7%
401	Level I Pulmonary Imaging	$220.96	$306.03	38.5%
402	Level II Nervous System Imaging	$458.34	$533.05	16.3%
403	*Level I Nervous System Imaging*	*$264.09*	*$162.68*	*-38.4%*
404	Renal & GU Studies	$332.91	$417.14	25.3%
406	Level I Tumor/ Infection Imaging	$300.09	$382.91	27.6%
408	Level III Tumor/ Infection Imaging	$955.60	$1,157.23	21.1%
414	Level II Tumor/ Infection Imaging	$502.54	$656.82	30.7%

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Mallinckrodt Pharmaceuticals

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Mallinckrodt Department Spotlight: Distribution & Traffic

Receiving radioactive pharmaceutical products on time is critical for hospitals and pharmacies. Mallinckrodt Pharmaceuticals' Distribution and Traffic Department ensures nuclear medicine customers receive a reliable, uninterrupted supply of product to better serve their patients. Tom McCormack, Transportation Manager, and Nick Piotraschke, Transportation Supervisor, discuss their team's efforts behind the scenes to fulfill that commitment to customers.

Q: What services does your team provide to nuclear medicine customers?

Tom: The Distribution and Traffic Department is responsible for delivering radioactive materials to our customers on time to help maximize the use of radioactivity. Our team coordinates inbound and outbound shipments, prepares documentation for radioactive transport to follow International Air Transport Association (IATA) and Department of Transportation (DOT) regulations, and manages and communicates transportation delays.

Nick: Our Production Team receives raw materials from facilities around the world, and we work around the clock to ship the products once in final form. We coordinate with Mallinckrodt's Production Teams to determine how and when products should be released to meet customer timelines.

We have 12 distribution employees dedicated to packaging and preparing more than 3,000 orders each week for transport to customers across the United States, Canada, South America and Latin America.

Q: How does the team deliver on its commitments to nuclear medicine customers?

Nick: It takes a great deal of knowledge and experience to navigate our specialized business. Our six traffic expeditors have a combined expertise of more than 82 years in the industry shipping radioactive pharmaceutical products. They know how to best rectify challenges with shipping and make certain our customers receive their product.

Tom: We use four modes of transportation to send our product to customers – truck, charter, commercial airlines and small couriers – for shipping flexibility. Knowledge of our routes and network helps us to meet our commitments to our customers.

While there's always potential for manufacturing and delivery delays due to flight delays, customs, weather and government regulations, our team is the front line for making sure our customers receive their shipment. We communicate with our customers throughout the process and provide real-time updates.

And, we're constantly looking to better serve our customers. We review our current routes and modes of transportation to see where improvements can be made to increase efficiencies and reduce costs.

Q: What is the goal of your department?

Tom: We focus on working closely with our customers to meet delivery expectations. Not only do we understand the important nature of our products, but we also know that delays in shipment can affect their commitment to patients. It can be a domino effect. We proactively work to minimize disruptions and provide the most efficient and reliable route.

Nick: We recognize that our customers are receiving these products for a reason – maybe to identify or treat a disease. Mallinckrodt's nuclear medicine products are imperative for our customers to work toward better outcomes for their patients.

Cyclotron Corner

Dr. Bill Uhland, Principal Chemist and Development Engineer, highlights the science and history behind nuclear imaging. In this edition, we cover how thallium went from poison to important diagnostic imaging agent.

Thallium is similar – both chemically and biologically – to potassium. Because of this, the heart takes up thallium similar to how it takes up potassium. However, large amounts of thallium prevent the heart muscle from contracting and cause death. In 1973, Elliot Lebowitz discovered that thallium's radioactive isotope, thallium-201 (Tl-201), in small doses, can actually be used to assist in the diagnosis of areas with poor heart muscle perfusion.

In nature, thallium consists of two stable isotopes – 203 (30 percent) and 205 (70 percent). To make the Tl-201, Mallinckrodt starts with 90 percent enriched thallium 203 (Tl-203). Chemists place as much as three grams of Tl-203 in the cyclotron at a time, where it is bombarded with high-energy protons. The result is isotope lead-201 (Pb-201). Chemical separation removes the lead from the target thallium, and then the lead decays to leave the desired Tl-201.

Like potassium, our cells, tissues and organs, such as the heart, readily absorb Tl-201. As Tl-201 decays (it has a half-life of 73 hours, or 3.05 days), gamma cameras capture the amount of thallium that is absorbed by the heart muscle.

Customer Profile: Dan Guarasci, M.S., PharmD, BCNP, DABSNM

In each issue, @nuclear will profile one of Mallinckrodt Pharmaceuticals' most valued customers.

Dan Guarasci, R.Ph., is the President of CRS Nuclear Services in Cheektowaga, NY. He has worked in nuclear pharmacy for 27 years after receiving his bachelor's, master's and doctorate of Pharmacy degrees from the University at Buffalo. When Dan is not working, he enjoys spending time with his wife and four children.

1. What attracted you to a career in nuclear medicine?

As an undergraduate, I took a course at Buffalo State College called Introduction to Radiation Science. As part of the last laboratory experiment, we injected radiopharmaceutical into a mouse and had to calculate the organ uptake. It was fascinating! I knew at that moment I wanted to pursue a career in the nuclear medicine profession.

2. What keeps you interested in the industry?

The best part of my job is working with my staff and the nuclear medicine technologists in western New York. We serve the low-energy radiopharmaceutical market in the region. It is a tightknit nuclear medicine community.

Because of our affiliation with the Department of Nuclear Medicine at the University at Buffalo, the majority of technologists in the area have spent time at CRS Nuclear Services. They are extremely intelligent and a pleasure to work with on a daily basis.

3. What do you think are the main challenges facing the nuclear medicine industry?

In addition to the molybdenum-99 (Mo-99) supply issue our country continues to face, we have three main challenges:

- Preauthorization of diagnostic studies.
- Decreasing radiation exposure to patients.
- The aging population of nuclear medicine physicians.

These are challenges our industry will face well into the next decade.

4. If you could do one thing to improve the industry, what would you do?

As a nuclear pharmacist, I would certainly change the Mo-99 supply chain. It is very hard to understand and explain why the United States performs the greatest number of nuclear medicine studies in the world, yet we still rely on other countries to supply us with the raw material necessary to perform these studies.

5. In your opinion, what's been the biggest advancement in nuclear medicine since you started your career?

I've been around so long; there have been so many… hardware advances, software advances, single photon emission computed tomography (SPECT) imaging, and technetium-99m cardiac tracers have all significantly advanced our profession.

However, I think the advancement of positron emission tomography (PET) tracers and three-dimensional imaging of physiological processes with detail anatomical differentiation of CT and MRI could certainly advance the profession to another level in the medical community.

Industry Scan

Stay informed with the latest nuclear medicine industry news and insights.

Use Registered Compounders, FDA Says
MedPage Today

In response to the recently passed Drug Quality and Security Act, the U.S. Food and Drug Administration will encourage hospitals and other healthcare providers to use compounding facilities registered with the agency. Registered compounders will be subject to increased federal oversight and regulations.
Read the full article.

Imaging Ranks Near Bottom of Medicare Spending Growth Drivers
HealthImaging

According to a study published in the December issue of the American Journal of Roentgenology, Medicare spending on imaging services has decreased since the early 2000s. Industry professionals are advocating for policy-makers to focus cost-cutting initiatives on the leading categories of spending (non-imaging services).
Read the full article.

Radioisotopes: The Medical Testing Crisis
Nature

The world's medical-isotope supply chain anticipates shortages as nuclear reactors that produce technetium-99m, or molybdenum, are requiring repairs and some will stop producing isotopes altogether. Innovative companies are exploring new methods of producing medical isotopes to diversify the supply chain.
Read the full article.

On Closer Inspection:
Compliance with Department of Transportation HazMat Employee Training

Successful inspections are a critical component to managing nuclear medicine and nuclear pharmacy operations. To better serve customers, Mallinckrodt Pharmaceuticals offers teams to assist with training and answer questions you may have about inspections. In this issue, Mallinckrodt Pharmaceuticals' Director of Transportation Compliance Programs, Scott Surovi, talks about compliance for Department of Transportation HazMat employee training.

The U.S. Department of Transportation (DOT) has general training requirements for any employee involved in the preparation of packages containing hazardous materials, such as radioactive material. These employees must undergo training and receive certification as a HazMat Employee to prepare radioactive material for transportation, per 49 CFR 172.700-704 of the Hazardous Materials Regulations (HMR). The U.S. Nuclear Regulatory Commission (NRC) and state regulatory authorities also reference the DOT training requirements in both licensing guidance and regulations.

Over the years, DOT representatives speaking at industry meetings have noted that many HMR compliance issues are related to HazMat Employee training. The most common HMR violations are a failure to provide the training or to maintain adequate training documentation.

Employers must ensure any employee performing a function subject to the HMR first receives instruction on the applicable DOT requirements (e.g., preparing packages for shipment, marking and labeling a package containing radioactive material, etc.). Employees can receive this training through their employer, or from other public or private sources.

According to 49 CFR 172.704(a), HazMat Employee training must, at a minimum, include:

- **General Awareness/Familiarization Training**: Teaches the HMR requirements and how to identify hazardous materials, including Class 7 – Radioactive Materials.
- **Function-Specific Training**: Addresses specific requirements and procedures a HazMat Employee may encounter when preparing hazardous materials for transportation. This training also includes provisions and requirements specific to the intended mode of transport (typically ground or air for nuclear medicine).
- **Safety Training:** Includes measures, methods and procedures to protect the employee and avoid accidents when preparing hazardous material for transportation (including emergency response information).
- **Security Awareness Training:** Teaches HazMat Employees about security risks associated with hazardous material transportation and ways to enhance transportation security. Don't confuse this with site and facility security measures; this is specific to the offering and transporting of hazardous material, including radioactive material.
- **In-depth Security Training**: Required only for HazMat Employees who directly work under the provisions of a Transportation Security Plan required by 49 CFR 172.800. It's not typically required for nuclear medicine professionals because the types and quantities of radioactive material received, used or shipped are below the threshold for Transportation Security Plan requirements.

An employer must then document and retain a HazMat Employee training record that includes the preceding three years, the full length of time at that employer, and 90 days after employment. Training records must contain:

- The HazMat Employee's name.
- The most recent HazMat Emloyee training completion date.
- Description, copy or location of the training materials used.
- Name and address of the person who provided the training.
- Certification the HazMat Employee has been trained and tested.

Employers must be prepared to present a HazMat Employee's training record if requested by an authorized regulatory authority.

Mallinckrodt Pharmaceuticals supports the professional development of nuclear pharmacists, technologists and other healthcare providers through educational grants to develop online training programs like the Nuclear Education Online (NEO) Training for Shippers and Transporter of Radiopharmaceuticals Program. The program meets federal requirements for the shipment of radiopharmaceuticals by ground and air transportation, and is approved through the Society of Nuclear Medicine, Verification of Involvement in Continuing Education (VOICE).

Mallinckrodt offers its customers free access to NEO to help nuclear medicine professionals receive necessary training, as well as meet the applicable documentation requirements. Customers will need an enrollment key for registration. Please contact your Mallinckrodt account manager for more information and to obtain the current enrollment key.

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Packaging Continues in 2014

CMS continues packaging many of the products used to perform medical imaging tests, including contrast media and diagnostic radiopharmaceuticals. In 2014, this also includes pharmacologic stress agents used in nuclear cardiology procedures. The reimbursement for these agents, like adenosine and Lexiscan®, are now packaged or bundled into the APC payment for the related procedure. Previously, these agents were reimbursed from an ASP methodology.

Separately Payable Drugs and Biologicals

CMS will continue its policy of reimbursing separately payable drugs and biologicals without pass-through status at ASP plus 6 percent with no adjustment for pharmacy overhead costs. The ASP plus methodology applies to all separately payable therapeutic radiopharmaceuticals. The 2014 threshold for separate payment for outpatient drugs is a cost per day that exceeds $90, compared to $80 in 2013.

2014 Final Rule for MPFS

The 2014 Final Rule for the Medicare Physician Fee Schedule (MPFS) also was released in late November 2013, covering all services performed in the Medicare Part B setting — Independent Diagnostic Testing Facilities (IDTFs) and Physicians' offices. The leading news for 2014 was the threat of steep reductions due to the application of the Sustainable Growth Rate (SGR). Not considering the SGR reduction, overall impacts to radiology-related services are:

- Radiology (including MR and CT): -2 percent.
- Interventional Radiology: -2 percent.
- Nuclear Medicine: 0 percent.
- Radiation Oncology: 1 percent.

There are codes that will see a greater impact due to a re-valuing of their Relative Value Unit (RVU).

Sustainable Growth Rate

Each year since 2003, physicians have faced large payment rate reductions for all procedures based on the application of the SGR formula. The SGR formula took the 2014 conversion factor down to $27.20 and, while this is less of a reduction than the 24.4 percent projected earlier this year, it will still result in dramatic reductions throughout the Medicare Part B setting. The reduction came out at a lower rate than in the 2014 Proposed Rule due to 4.72 percent adjustment to the conversion factor that offsets a decrease in physician reimbursement set to take place in 2014 as RVUs are adjusted to come in line with revisions to the Medicare Economic Index (MEI) for 2014.

The SGR-mandated reductions were delayed by legislative intervention when President Obama signed H.J. Res. 59, the Bipartisan Budget Act of 2013, which includes the Pathway for SGR Reform Act of 2013 on December 26, 2013. The Pathway for SGR Reform Act of 2013 delays implementation of the SGR reductions until April 1, 2014. During this time, Congress is to work on a permanent alternative to the SGR. The act also gives providers a .05 percent increase for services provided through March 31, 2014.

Multiple Procedure Payment Reduction

The 2014 Final Rule for the MPFS has no new codes added to the Multiple Procedure Payment Reduction (MPPR), but certain Current Procedural Terminology (CPT) codes (e.g., CPT 93015) were reduced per the MPPR in a fashion that shows CMS does not understand how the reduced codes relate to the procedures with which they are paired.

In 2014, Medicare continues to fully reimburse the highest paid diagnostic service then reduces the technical component payment for subsequent diagnostic procedure by 25 percent when furnished by the same physician or group practice to the same patient on the same day. CMS notes in the Final Rule that although it's not implementing any new MPPR policies for 2014, it continues to look at expanding the MPPR based on efficiencies when multiple procedures are furnished together. As a result, we may see new codes added in 2015.

2014 HCPCS Coding Changes

Medicare issued a new Healthcare Common Procedure Coding System (HCPCS) code in January for reporting the use of adenosine (J0151 Injection, adenosine Diagnostic, 1 mg).

Medicare will reimburse this new code from average sales price (ASP) in the Medicare Physician Fee Schedule (MPFS) setting. The first quarter 2014 rate is set at $3.312 per milligram. The old code, J0152, has been deleted as of December 31, 2013.

Other new HCPCS codes in nuclear medicine include:

- A9520 Tc99m tilmanocept, diagnostic, up to 0.5 mCi.
- A9586 Florbetapir f18, diagnostic, per study dose, up to 10 mCi.
- A9599 Radiopharmaceutical, diagnostic, for Beta-amyloid PET, per study dose.

Barbara Ossias is a healthcare consultant with expertise in all phases of reimbursement support. She is founder and principal of Revenue Reimbursement Solutions, and has more than 20 years of experience working in the industry.

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