

Cost-Impacting Factors of Mo-99 Series: A Closer Look at Full-Cost Recovery

As a leader in the production of technetium-99m (Tc-99m) generators and molybdenum-99 (Mo-99), its parent isotope, Mallinckrodt has faced significant challenges as the organization strives to provide customers with an uninterrupted supply of product. Mallinckrodt has taken action to strengthen its global supply stability, which has come at considerable cost. In this issue, Roy Brown, Senior Director of Strategic Alliances at Mallinckrodt, provides an overview of full-cost recovery and how it is impacting the nuclear medicine industry and Mallinckrodt.

The nuclear medicine industry has faced challenges with ensuring a long-term, reliable supply of Mo-99 for the global market. With only eight reactor facilities and five processing facilities serving the worldwide industry, all of us have felt the effects of outages at facilities from routine maintenance and unplanned shutdowns. Due to these planned and unplanned shutdowns, it's been challenging to meet customer demand. Over the last few years, stakeholders from across the industry have been working to determine and implement an economically sustainable solution to alleviate disruptions in the supply chain.

A global nuclear cooperative of industry stakeholders has developed a plan that will sustain the industry going forward - but comes at increased costs to everyone along the supply chain. To continue meeting production capacity and demand for Mo-99 and Tc-99m generators, the Nuclear Energy Agency (NEA) within the Organisation for Economic Co-operation and Development (OECD) developed an approach asking all producers and consumers of these products in the global market to follow. Previous approaches were felt to

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2015 CPT/HCPCS Code Changes for Nuclear Medicine

By Barbara Ossias

For 2015, the American Medical Association (AMA) made no revisions to the nuclear medicine Current Procedural Terminology* (CPT) codes in the radiology section, but did add new codes in the related area of Radiation Oncology/Radiation Therapy.

For dose Calculation and Planning, five new CPT codes were issued:

- 77306 - Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)
- 77307 - Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)
- 77316 - Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)

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Mallinckrodt Department Spotlight: Imaging Marketing Team

Reliably receiving radioactive pharmaceuticals is critical for hospitals and nuclear pharmacies. Mallinckrodt Pharmaceuticals' Imaging Marketing Team works to support the management of our nuclear products to ensure a steady, uninterrupted supply for our customers and the patients they serve as our top priority. Sandy Borgschulte, Senior Director of Marketing, Imaging Marketing Team, North America, discusses her team's efforts behind the scenes to fulfill that commitment to customers.

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

A: The Imaging Marketing Team focuses on four key areas:

- **Product planning and brand management** - As our marketplace changes and evolves, we track both the near-term and long-range market dynamics, which helps us identify opportunities to position our products and best support our customers' needs. With over 40 years of experience in the radiopharmaceutical industry, we have a proven track record of providing a broad selection of nuclear medicine products and a long history of superior service.
- **Customer listening** - Our team connects with customers and works with the sales department to gather customer feedback. We listen to understand what is working and what is not - to create programs that will be of most interest to our customers. We also develop tools that enhance our sales teams' interaction with customers.
- **Value through education** - We remain steadfast in our commitment to the imaging community with education as a top priority. We invest a significant portion of our time and resources in defining and developing educational programs to help our customers meet their educational needs through Leader-led CE programs and online educational resources. Our department is also responsible for all of our national meetings, symposiums and conventions.
- **New product business development** - From the ground up, we work with our R&D partners to assess new product opportunities and help determine if they would bring value to the Mallinckrodt product offering. Whether we are looking at a potential new product or a product that we have been manufacturing for a long time, we are the corporate champions for the nuclear medicine portfolio.

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

A: Our department stands by Mallinckrodt's core values of quality, integrity and service, and our work is guided by our Cultural Hallmarks. We collaborate on a daily basis to deliver the best outcome for our customers, with the ultimate goal of

enhancing clinicians' ability to serve their patients and facilitate their path to treatment. We are also committed to managing and maintaining a robust educational program for our pharmacy and hospital customers.

Q: How has your team evolved to showcase the greater value you bring to nuclear medicine customers?

A: We listen. As we receive feedback from our customers, the Imaging Marketing Team evaluates ways that we can improve our products and programs. We utilize our depth of knowledge to continually enhance our customers' experience.

Q: What is the goal of your department?

A: Our ultimate goal is to ensure that our customers have reliable and quality products. We support the management of our products in collaboration with our production facility to ensure customers receive the products they need, when they need them.

We also strive to enhance awareness of the importance of nuclear medicine to ensure that hospitals - and most importantly the patients we all serve - have access to nuclear medicine products that lead to a timely diagnosis and patient treatment plan.



Customer Profile: Rio Grande Valley Isotopes

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



Lucio Garza, R.Ph., is co-owner and principal manager of Rio Grande Valley Isotopes, a radiopharmacy located in Harlingen, Texas, that provides products and services to the Rio Grande Valley market. He has worked in nuclear pharmacy for 21 years after having received his bachelor's degree in pharmacy from the University of Houston. When Lucio is not working, he enjoys spending time with his family, fishing and working out.

What attracted you to a career in nuclear medicine?

Ever since junior high, I had an interest in pharmacy, chemistry and patient care. Nuclear medicine allowed me to combine all of these interests and pursue a career that I enjoy practicing daily.

What keeps you interested in the industry?

The best part of my job is getting to work with future pharmacists. We've built a relationship with a local college of pharmacy and serve as a rotation site for their final-year students. It has been very rewarding and motivating to share my knowledge of nuclear medicine with pharmacist students who are coming into the market.

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

The main challenge facing the nuclear medicine industry is the economy. We are seeing cuts in reimbursement and

higher costs in the manufacturing of nuclear medicine products. Our entire supply chain is affected, but we strive to do our best to budget for this.

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

I would provide more education around nuclear medicine. It is such a small niche and often overlooked based on its cost. Also, not a lot of people are aware of the ways nuclear medicine can improve the industry. We need to share our knowledge and educate others on how nuclear medicine can lead to improved patient outcomes.

If you could go back in time and talk to yourself at the beginning of your career, what advice would you give?

Ask "why." Early in my career, I was learning nuclear medicine through hands-on experience. You begin to understand what you are doing and how it is done. But, it's critical to take things

Industry Scan

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

Joint Declaration on Security of Supply for Molybdenum *World Nuclear News*

Eleven countries have committed to the Joint Declaration on the Security of Supply of Medical Radioisotopes, a coordinated, global effort to ensure an uninterrupted supply of molybdenum-99 (Mo-99) and technetium-99m (Tc-99m). The declaration promotes full-cost recovery for isotope production and outage reserve capacity.

Read the full article.

The Business of Molecular Imaging: A Panoply of Challenges *Molecular Imaging*

The business of molecular imaging has experienced many challenges, including reimbursement, regulatory and supply of product issues. All of the moving parts in molecular imaging need to be coordinated to overcome these business-related obstacles and ensure stabilized production.

Read the full article.

one step further and to fully understand "why" you are doing what you are doing for patients. It's the "why" that provides motivation for me to do my job well.

What is your pharmacy's motto?

We are committed to providing ultimate patient care for our community. I often remind our employees that everything we do should be done as if we are treating a family member

- every single time. The Rio Grande Valley is where I grew up, and I'm proud to serve and make a difference for patients in this community every day. We're here to improve patient outcomes and foster our community.

Mallinckrodt History

For nearly 150 years, Mallinckrodt has provided outstanding quality and value for our patients, customers and communities. Guided by our core values of quality, integrity and service, we've grown to become an important player in global healthcare. In this series, we take a look back at Mallinckrodt's rich heritage and the milestones that have helped us evolve as a leader in global nuclear imaging and pharmaceuticals.

Founded by Mallinckrodt brothers Edward, Otto and Gustav, G. Mallinckrodt & Company was established in St. Louis, Missouri, in 1867, and was the only chemical manufacturing company west of the Mississippi River. In our early years, Mallinckrodt produced aqua ammonia, spirits of nitrous ether and carbolic acid. As business grew, we entered new markets by manufacturing products that included morphine and codeine, hydrogen peroxide, and gallic and pyrogallic acids. In the 1920s, Mallinckrodt showcased our position as an innovative leader in the industry, introducing new products, such as high-purity analytical reagents, phenobarbital, and Iodeikon (the first medium for X-ray visualization of the gall bladder).

Mallinckrodt became an industry leader and recognized for our commitment to quality, integrity and service:

- **Mallinckrodt's quality and attention to detail set us apart.** At a time when patients worried about contaminated medicines, our finely ground powders displayed a meticulous attention to quality. Our customers learned to rely on the Mallinckrodt name for safety and quality.
- **Mallinckrodt stands for integrity, and the company has always done what's right for our businesses, our communities, our employees and our customers.** While the business faced challenges during the Great Depression, Mallinckrodt was committed to ensuring that each of its employees remained employed.
- **Mallinckrodt has an excellent reputation for our service.** The U.S. government also turned to Mallinckrodt to fulfill its need for large quantities of anesthetics to treat injured soldiers during World War II. The company accepted the challenge. Rather than profit from the substantial order, we produced medications for soldiers at a discounted rate. Our teams often worked three shifts to meet the Army's demands and ensured our other clients were served as well.

Throughout Mallinckrodt's formative years, we established credibility for developing innovative products, manufacturing quality medicines and providing superior service to our customers. In the next issue, we will explore Mallinckrodt's emergence into nuclear medicine as a manufacturer of radiopharmaceuticals.

Cyclotron Corner



Dr. Bill Uhland, Principal Chemist and Development Engineer, shares fun facts and statistics that highlight the science and history behind nuclear imaging. In the fifth edition, we explore iodine-123.

Iodine-123 is cyclotron produced. Due to its short half-life of 13.2 hours and gamma energy of 159 keV, iodine-123 is easy to image and gives a minimal radiation dose to the patient. Iodine in the iodide state (an iodine ion with a minus one charge, to wit, I⁻) is taken by the body directly to the thyroid without any additional guiding molecule to take it there. Hence, the iodine is sold in the form of the inorganic salt, sodium iodide. Since the body can transport iodine easily to the thyroid, a painful intravenous injection is not needed and the sodium iodide can be swallowed in the form of a capsule. Producing a capsule as a final product is much easier than an intravenous solution, as a capsule does not have to be sterile. Iodine-123 also can be chemically bonded to barbiturates, which can cross the blood-brain barrier and be used for brain imaging, or other agents, which can take it to the heart for cardiac imaging. However, due to the short half-life of iodine-123, these chemical bonding procedures must be quick.

Once iodine-123 capsules are made, they are rushed to their final destination while they still have enough activity for meaningful images. Serious side effects of Sodium Iodide I-123 include chest pain, tachycardia, rash and hives. [Click here](#) for important risk information regarding Sodium Iodide I-123 capsules.

Unlike the other radiopharmaceuticals we've discussed previously that use solid targets (e.g., thallium-203, cadmium-112 and zinc-68), iodine-123 production requires an enriched xenon-124 target. If any tear or hole occurs in the cell during cyclotron bombardment, \$10,000 worth of enriched xenon-124 can be lost to the atmosphere. High-energy protons from the cyclotron transmute the xenon-124 atoms into cesium-123, not iodine. The newly created cesium has a half-life of 5.94 minutes and decays to xenon-123, which has a 2.0 hour half-life. It is the xenon-123 that decays into the desired iodine-123. Due to this last step, the cyclotron target of xenon gas is not processed immediately after the cyclotron is shut off. It is held for several hours to allow more iodine-123 to form from the decay of the xenon-123.

The purification of the iodine-123 from its xenon-124 target is relatively easy. Iodine is a very reactive halogen, and xenon is a noble gas; therefore, a chemical separation is not required.

For more information, reference the full [U.S. Prescribing Information](#).

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not be sustainable, and producers and consumers cannot continue to absorb the price increases from the reactors irradiating the Mo-99 targets.

The approach provides guidance and a methodology for full-cost recovery, which means charging customers for the full cost of production of Mo-99 at each step of the process. With foreign governments no longer providing subsidies for the reactors where the targets are irradiated, full-cost recovery implementation will help to guarantee sustainable operations for those reactors. With these reactors implementing full-cost recovery, it is felt they will be better able to reinvest in their facilities, which will lead to a more sustainable operation and a more stable supply of Mo-99.

Mallinckrodt recognizes the need for a transformation to full-cost recovery in the global market. We also understand the increased prices not only affect Mallinckrodt, but everyone throughout the Mo-99 supply chain. To provide customers with a stable, uninterrupted supply of nuclear medicine products to meet patient needs, we've begun implementing a series of price increases for our customers over the next several years.

Mallinckrodt has taken several steps to offset the increase in Mo-99 costs to minimize the cost impact on our customers, including:

- Identifying and increasing efficiencies in purchasing raw materials and production.
- Collaborating with the Council on Radionuclides & Radiopharmaceuticals (CORAR) and the Society of Nuclear Medicine & Molecular Imaging (SNMMI) to try to achieve fair and equitable reimbursement for nuclear medicine procedures.
- Providing insights on the current state of the supply chain to the

OECD and the nuclear medicine community on behalf of Mallinckrodt and our customers.

We remain committed to providing our customers with a sustainable, uninterrupted supply of nuclear medicine products to meet patient needs. We will discuss two additional cost-driving factors for Mo-99 in the next two issues of @nuclear. For questions, please contact your local Mallinckrodt sales representative.

More about the NEA Full-Cost Recovery Methodology

The OECD's full-cost recovery methodology outlines how producers should calculate the full cost to irradiate targets in the reactors, whether it's a new or old production facility. The methodology helps to level the playing field for reactors in the market by factoring in key cost elements:

- Capital costs
- General overhead costs
- General operational costs
- Decommissioning: costs for older reactors as new reactors are being built

- Specific Mo-99 target irradiation costs

While these cost elements offer standards for establishing full-cost recovery, reactors may interpret these varying costs differently, leading to inconsistencies in the cost determination.

With full-cost recovery, the price increases in the global market will flow through the supply chain and eventually should be reimbursed by healthcare systems. However, in the U.S., the Centers for Medicare & Medicaid Services (CMS) and private health insurance companies have not been able to keep up with the impact of full-cost recovery on radiopharmaceutical reimbursement. Reimbursement for Tc-99m-based patient doses does not adequately reflect the true costs of production. CMS bases its reimbursement rates on collection of real data, which can take several years to collect and recognize a price increase. Private health insurance companies follow CMS' lead and also lag on increases for reimbursement rates.



2015 CPT*/HCPCS Code Changes for Nuclear Medicine

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- 77317 - Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
- 77318 - Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)

These new bundled codes were created to reflect the current process of care for teletherapy and brachytherapy isodose planning. 2014 CPT codes 77305-77315 and 77327-77328 were deleted in 2015.

For Intensity Modulated Radiation Treatment (IMRT), three new CPT codes were created:

- 77385 - Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
- 77386 - Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
- 77387 - Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed

Radiation treatment delivery codes (77403, 77404, 77406, 77408, 77409, 77411, 77413, 77414, 77416, 77418 and 77421) along with Category III codes (0073T and 0197T) were deleted as of January 1, 2015.

The Centers for Medicare & Medicaid Services (CMS) issued the new HCPCS level II codes below for 2015:

- A9606 - Radium Ra-223 dichloride, therapeutic, per microcurie
- J0153 - Injection, adenosine, 1 mg

Billing Claims with the New -59 Modifier Subsets XE, XS, XP, XU

As of January 5, 2015, CMS requires new Healthcare Common Procedure Coding System (HCPCS) modifiers to be used in place of modifier -59 for all Medicare claims. These new subset modifiers are known as -X {ESPU} and are defined as follows:

1. XE - separate encounter, a service that is distinct because it occurred during a separate encounter (a distinct and separate encounter)
2. XS - separate structure, a service that is distinct because it was performed on a separate organ/structure (a distinct and separate service performed on a separate organ/structure)
3. XP - separate practitioner, a service that is distinct because it was performed by a different practitioner (a service that was performed by a different practitioner)
4. XU - unusual non-overlapping service, the use of a service that is distinct because it does not overlap usual components of the main service (a distinct service that

does not overlap usual components of the main service)

Sustainable Growth Rate (SGR) Update

Legislation on March 31, 2014, placed a 13-month hold on mandated SGR (the formula that mandates physician reimbursement from Medicare in the Part B setting be pegged to the U.S. Gross Domestic Product) cuts that were to have taken effect April 1 last year. The Protecting Access to Medicare Act of 2014 hold on any SGR reductions will expire on April 1, and unless there is legislative action to either permanently fix the SGR or apply another "Band-Aid," reductions of 21 percent will take effect at that time. At this point, there is no legislation in process related to SGR.

CMS Independent Diagnostic Testing Facility (IDTF) Fact Sheet Published

The IDTF Fact Sheet (ICN 909060) has been released and is now available from CMS online. It is designed to provide education on requirements for providers in the IDTF setting on topics such as:

- Enrollment
- Effective date of billing privileges
- Billing issues
- Ordering of tests
- Place of service issues
- Requirements for multi-state IDTFs, physicians and technicians

Radiology Benefit Management (RBM) Consolidation

There were very few significant players in RBM, and now, there are even fewer. With the recent merger of CareCore National and MedSolutions, we have gone from five RBMs managing access to care for 85 percent of all lives subject to RBM review to three - the others being American Specialty Health, Health Help and National Imaging Associates. While CareCore National-MedSolutions claimed it would not begin instituting new clinical criteria without notice, providers have reported having all PET/CT and other advanced nuclear studies submitted to MedSolutions for peer-to-peer review. A peer-to-peer review adds another layer of difficulty to securing prior authorization and also delays getting a patient diagnosed and into treatment. In the past, CareCore imposed specialty restrictions on which providers could perform studies and required a minimum of five imaging modalities be performed in order to approve studies in a facility, but MedSolutions has not. Providers have reported denials for approval when the office performing the scan is not an approved specialty.

**Current Procedural Terminology (CPT) copyright: 2015 AMA*

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