WHITE PAPER

MARWOOD GROUP

Diagnostic Radiopharmacy: Overview And Market Access Considerations

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Nuclear medicine utilizes radioactive tracers (radiopharmaceuticals) to assess systemic functions as well as to diagnose and treat disease. Focusing on the former, SPECT scans are primarily used to diagnose and track the progression of heart disease, such as blocked coronary arteries. PET/CT scans have become the primary imaging tool for the staging of many cancers. Under the Outpatient Prospective Payment System (OPPS), CMS classifies all diagnostic radiopharmaceuticals as "supplies" instead of "drugs". CMS instituted pass-through payments for new diagnostic radiopharmaceuticals to ensure providers receive adequate reimbursement while CMS collects the necessary data to potentially incorporate the cost into the OPPS rates. Parallel commercial payor behavior during and post-expiry of pass-through has ramifications on utilization, pricing and uptake; as does provider organization dynamics in response to reimbursement differentials. Herein, we introduce the fundamentals of nuclear medicine and present a decision-analysis structure in consideration of novel radiopharmaceutical tracers.

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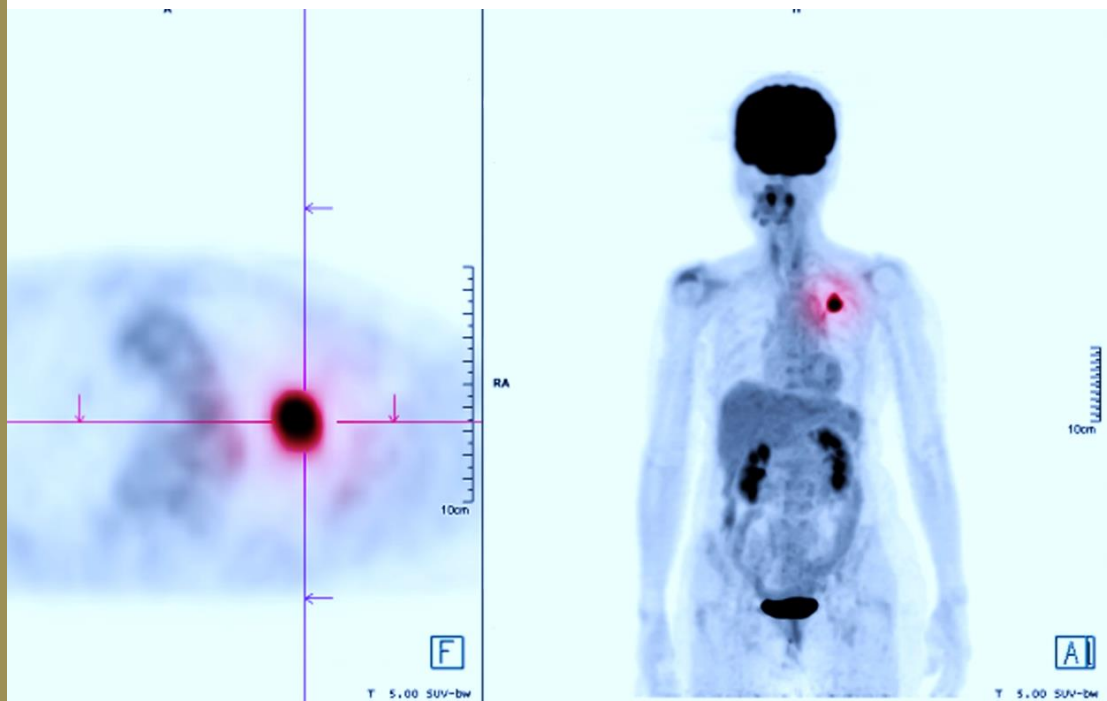

I. Nuclear Medicine Relies On A Radio-isotope Bound To Biological Carrier

Nuclear medicine utilizes radioactive tracers (radiopharmaceuticals) to assess systemic functions as well as to diagnose and treat disease. Radioactive tracers consist of carrier molecules bonded tightly to a radioactive atom. These carrier molecules vary greatly depending on the purpose of the scan. For example, some tracers employ molecules that interact with a specific protein or sugar in the body and can even employ the patient's own cells (ex., labeled red blood cells). The majority of radiotracers are intravenously injected, although these tracers may also be administered by inhalation, oral injection or by direction injection into an organ.

II. The Distinct Physics Of Radioactive Tracer Detection Limits Overlap Between Modalities

SPECT (single photon emission computed tomography) imaging provides three-dimensional (tomographic) images of the distribution of radioactive tracer molecules that have been introduced into the patient's body. SPECT imagers have gamma cameras that can detect the gamma ray emissions from the tracers that have been injected into the patient. PET (positron emission tomography) scans also use radiopharmaceuticals to create three-dimensional images. However, while SPECT scans measure gamma rays, the decay of the radiotracers used with PET scans produce small particles called positrons. These react with electrons to produce a small amount of energy in the form of photons. The detectors in PET scanners measure these photons and use this information to create images of internal organs. Given their distinct physics, not all SPECT tracers can be matched with a PET tracer due to their differing isotope requirements and associated chemistry.

III. SPECT Is The "Workhorse" Of Cardiology

SPECT scans are primarily used to diagnose and track the progression of heart disease, such as blocked coronary arteries. SPECT has been the "workhorse" modality for cardiology practices, with the current cost of PET machines challenging ROI incentives for practices to move away from SPECT imaging. Technetium-99 along with Iodine-123 and Iodine-131 produced in a generator/cyclotron are the primary imaging tracers. While SPECT will remain the technology of choice for cardiac imaging in the hospital, PET will hold a place in larger hospitals and health systems where it serves multiple roles, including as a speaking point in offering the most cutting edge of imaging modalities. Notably, there are also radiotracers to detect disorders in bone, gall bladder disease and intestinal bleeding as well as aiding in the diagnosis of Parkinson's disease.

IV. PET/CT Has Become The Primary Imaging Tool In Oncology

PET/CT has become the primary imaging tool for the staging of most cancers worldwide. PET scans are used to detect cancer and monitor its progression, response to treatment and detect metastasis. In the last 15 years, slightly modified radiolabeled glucose molecules (F-18 labeled deoxyglucose or FDG) have been shown to be the best available tracer for detecting cancer and its metastatic spread in the body. Other key radioisotopes include Sodium Fluoride-18 and Gallium-68. Growth in the PET, and to a lesser extent SPECT markets in oncology are supported by treatment guidelines and a growing radiopharmacy library. Outside of hospitals, oncology practices and radiation therapy providers are looking to incorporate PET and molecular imaging into their practice.

V. CMS Classification Of Diagnostic Radiopharmaceuticals In The Hospital Outpatient Setting Results In Pricing Pressure

Under OPPS, CMS classifies all diagnostic radiopharmaceuticals as "supplies" instead of "drugs," and therefore "packages" them with the cost of the nuclear medicine procedures in a hospital outpatient setting. Note that therapeutic radiopharmaceuticals can be reimbursed separately. As a result, payment for these drugs in the hospital outpatient setting is packaged into an APC. Diagnostic radiopharmaceuticals are packaged with their associated procedure, while therapeutic radiopharmaceuticals receive a separate reimbursement if they exceed the drug packaging threshold.

VI. New Diagnostic Radiopharmaceuticals Can Attain "Pass-Through Status", An Opportunity And A Challenge

New diagnostic radiopharmaceuticals can attain "pass-through status" if they apply for it, thereby getting separate reimbursement at Average Sales Price (ASP)+6 percent for 2-3 years. The agency requires several months to process the application, officially determine eligibility, and implement the pass-through status. CMS instituted pass-through payments for new diagnostic radiopharmaceuticals to ensure providers receive adequate reimbursement while CMS collects the necessary data to incorporate the cost of the drug/device into the OPPS rates.

Payment for diagnostic radio-pharmaceuticals with expired pass-through status are packaged

	SPECT	PET
Applications	• **Heart** – Areas of blood flow; can be used for monitoring for clogged coronary arteries and reduced pumping efficiencies • **Brain** – Determine parts of the brain affected by dementia, clogged blood vessels, seizures, epilepsy, and head injuries • **Bone** – Areas of bone healing, cancer progression in bone, or very small bone fractures that might otherwise be missed through traditional X-rays • **Other examples** –Gall bladder disease, intestinal bleeding, Parkinson's disease	• **Cancer** – The primary purpose of PET scans today is to detect and monitor the progression of cancer, its response to a treatment, and to detect metastases • **Alzheimer's disease** – for diagnosis • **Cardiology**- for diagnosis and detection • Can help physicians to identify areas of the heart that are damaged but salvageable, and can identify if catheterization or coronary artery bypass is indicated
Common Radioisotopes/ Manufacturing	• Technetium-99, manufactured from Molybdenum-99 generator • The generator is a transportable unit • Iodine-123, Iodine-131 produced in a cyclotron	• Fluorodeoxyglucose, or FDG (^{18}F), manufactured with a cyclotron • Sodium Fluoride, Na^{18}F, manufactured with a cyclotron • Gallium-68, manufactured in a generator

Figure 1. Applications and common radioisotopes and their manufacturing requirements

with the associated procedure. All diagnostic radiopharmaceuticals without pass-through status are packaged, with CPT code for the associated diagnostic imaging procedure, into the Ambulatory Payment Classification (APC). At that point providers must decide whether to use the newly packaged agent and potentially take a significant financial loss, revert back to using a less expensive predecessor drug, use an even newer drug that has pass-through status, or provide an alternative service altogether

The methodology below provides a means to think through pass-through dynamics. Hospital P&T Committees manage utilization of diagnostic radiopharmaceuticals. While pass-through status is active, the product is actively utilized given the add-on payment in Medicare and potential for similar commercial modifier. Upon expiry of pass-through status, the Medicare add-on payment ends and commercial payors must re-examine their own utilization management and reimbursement policies. The potential for a significant reimbursement differential, particularly if commercial payors decide to continue granting supplemental reimbursement leads to significant trade off analysis among the Hospital P&T Committee based on commercial versus Medicare insured patient volume, size of addressed population, provider preference and imaging agent alternatives. While using an older agent may be preferable from a financial perspective, a provider may still choose to use a newer diagnostic radiopharmaceutical (with expired pass-through status) for clinical reasons – e.g., if the provider believes the images are so much clearer with the newer agent that it is worth taking a loss to use it. On this last point, absent of provider-perceived differentiation, commoditization may lead to manufacturer pressure to increase discounts or lose ground to established players. Thus, post-market evidence of superiority is a crucial component as the manufacturer seeks to build volume and positively impact reimbursement, to the benefit of the manufacturer.

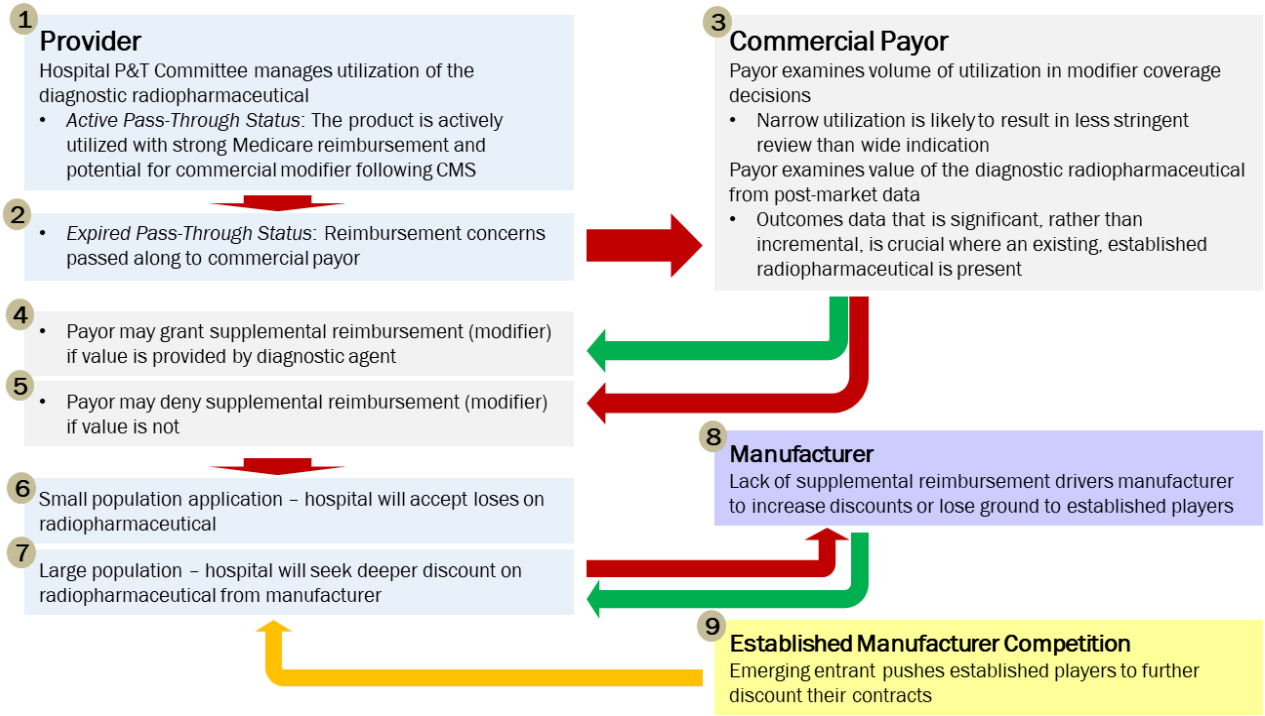

Figure 2. Payor/provider pass-through status dynamics with manufacturers, during and post-expiry

VII. Future Considerations

Target analysis in this environment requires an ability to parse together provider and payor considerations, the latter at the federal and commercial payor interface, to understand adoption and utilization pressures. With extensive experience in granular federal regulatory & legislative considerations, our capability to explore commercial rate variations across these dimensions and tie them to strategic considerations provide a 360° view of target market access considerations.

ABOUT THE AUTHORS

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