The Current Environment of Nuclear Medicine Reimbursement

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Activity Type: Knowledge-based
Disclosures

- I am employed by MITA, which represents medical imaging drug and device companies.

- I have Curium stock from a time, long ago, when I worked for Mallinckrodt.
Learning Objectives

1. Gain a better understanding of the current legislative and regulatory environment, with a specific emphasis on reimbursement challenges for nuclear medicine.

2. Understand nuclear medicine coverage, coding and payment challenges under Medicare.

3. Learn the latest on the Centers for Medicare & Medicaid Services’ (CMS) appropriate use criteria implementation.

4. Understand reimbursement challenges from private payers.
1. Assessment Question

1. All PET drugs are considered covered drugs under Medicare.

A. True

B. False
2. Assessment Question

2. Radiopharmaceuticals are paid separately from the procedure in the Medicare hospital outpatient setting.

A. True
B. False
Bunning - Background

- State Government (Ohio)
- Congress
- Corporate Federal Government Affairs
- Corporate Global Government Affairs
- Medical Society
- Device and Drug Trade Association
Medical Imaging and Technology Alliance

MITA is the collective voice of...

- medical imaging equipment,
- radiopharmaceuticals, and
- contrast agents

...manufacturers, innovators and product developers. We represent companies whose sales comprise more than 90 percent of the global market for advanced medical imaging technology.
MITA Positron Emission Tomography (PET) Group

The PET industry (radiopharmaceutical & imaging equipment innovators, developers & distributors) address the unique challenges faced by the PET and single-photon emission computed tomography (SPECT) community.

- PET Work Group
  - Advocacy and Education Committee
  - Value and Evidence Committee
  - Coverage, Coding and Payment Committee
  - Regulatory Committee
- Molecular Imaging Section – Standards
- IDEAS Steering Committee
- QIBA Steering Committee
MITA PET Group Action Plan

- Highlight the value of PET/nuclear medicine to government stakeholders (including Capitol Hill, CMS, FDA), private payers, nuclear medicine practitioners, and referring physicians.

- Achieve appropriate coverage, coding and payment from CMS.

- Gain clarity and drive thinking on evidentiary requirements for coverage from private payers.

- Generate data, evidence and materials that would be searchable to entities developing PET appropriate use criteria.
Political Climate

- Did that really just happen?
- Did the position just flip again?
- Can there be any bipartisan support?
- Was that on purpose?
- Is that Fake News?
- Are things getting done on Capitol Hill or in the federal agencies?
- If so, what does that look like?
Political Climate

- What is going to happen to the remaining provisions of the Affordable Care Act (ACA)?
  - Individual mandate was repealed on the tax reform package.
- What is going to happen to value-based payment and alternative payment models?
  - Former HHS Secretary Price was not a fan of the big bundles.
  - HHS Secretary Azar may focus on drug pricing issues at the outset.
- What is going to happen to drug prices?
  - Mixed signals from the Administration – appears committed to 340B drug pricing.
- What can Congress accomplish in 2018 with the mid-term elections looming?
  - Infrastructure Reform? Defense Spending? Medicare Reform?
Who is Alex Azar?

- Law clerk to Supreme Court Justice Antonin Scalia.

- Previous General Counsel and Deputy Secretary of HHS under President George W. Bush.

- Former Senior Vice President of Corporate Affairs and Communication for Eli Lilly and Company.

- Azar has suggested the ACA is beyond repair but others suggest he will try to fix what he perceives as broken.
Key Decision Makers for Healthcare

Seema Verma (CMS)
CMS Administrator

Scott Gottlieb, MD (FDA)
FDA Commissioner
Key Decision Makers for Healthcare – Senate

- Senate Majority Leader – Mitch McConnell (KY)
- Senate Minority Leader – Chuck Schumer (NY)
- Senate Finance Committee Chairman – Orrin Hatch (UT) *Retiring*
- Senate Finance Committee Ranking – Ron Wyden (OR)
- Senate Finance Health Subcommittee Chair – Pat Toomey (PA)
- Senate Finance Health Sub Ranking – Debbie Stabenow (MI)
The Senate

- 33/100 seats will be contested.

- Current expectations is that the majority will stay in tact, largely due to the fact that Republicans have a chance to take back seats in 10 states Donald Trump won last year.

- **Democrats** need 2 votes to flip GOP-held Senate.

- **Democrats** hoping to flip Nevada and Arizona.

*Source: NBC News*
Key Decision Makers for Healthcare - House

House Speaker – Paul Ryan (WI)

House Minority Leader – Nancy Pelosi (CA)

Ways and Means Committee Chair – Kevin Brady (TX)

Ways and Means Ranking – Richard Neal (MA)

Ways and Means Health Subcommittee Chair – Pat Tiberi (OH) *Retiring*

Ways and Means Health Subcommittee Chair – Sander Levin (MI)

Energy and Commerce Chair – Greg Walden (OR)

Energy and Commerce Ranking – Frank Pallone (NJ)

Energy and Commerce Health Subcommittee Chair – Michael Burgess, MD (TX)

Energy and Commerce Health Subcommittee Ranking – Gene Green (TX)
The House of Representatives

- All 435 seats are up for election.
- **Democrats** would need 24 seats to reach 50/50 split.
- **Democrats** need to win national vote by 53%-58% to take back the chamber.
- **Republicans** are targeting 91 GOP-held seats, and democrats are targeting 36 **Democrat**-held seats.

*Source: NBC News*
Nuclear Medicine Reimbursement Coverage, Coding and Payment – OH MY!
Barriers at CMS

- National non-coverage decision for all non-oncological PET.
  - Resulted in onerous Coverage with Evidence Development for most PET.
  - Beta Amyloid vs new oncologic PET radiopharmaceuticals.
- OPPS – Under the current CMS hospital Outpatient Prospective Payment System (OPPS), radiopharmaceuticals are treated as supplies.
Components of Medicare Coverage

- Local Coverage (MACs)
- Medicare Coverage
  - National Coverage Determination
    - Coverage w/Evidence Development
MAC A/B Jurisdiction Map
National Coverage Determination NCD

- PET imaging; 20 subsections.
- CMS Coverage Analysis Group (CAG) determines coverage through National Coverage Analysis (NCA).
- **ALL** local contractors must follow NCD, but may publish LCDs or policy articles with additional details such as acceptable diagnosis codes or utilization guidelines.
- **Until 2013,** all PET coverage was through NCD, no Local decisions were allowed.
Outcomes of National Coverage Analysis

- **Covered** - evidence shows the procedure is reasonable & necessary.

- **Not Covered** - evidence shows that the procedure is NOT reasonable & necessary.

- **Coverage with Evidence Development (CED)** - evidence suggests the procedure MIGHT be reasonable & necessary, but not compelling enough to cover; requires data collection.

- Local Medicare Administrative Contractors (MACs) must follow the NCD.
1995 - Present

- 1995 to 2005
  - Requests to CMS for specific coverage resulting in coverage for cardiac perfusion and certain oncologic indications using F-18 FDG.

- 2005 to 2013
  - Requests to CMS for specific coverage resulting in Coverage with Evidence Development.
    - F-18 FDG NOPR
    - F-18 NaF NOPR
    - IDEAS (Beta Amyloid)

- 2013 to Present
  - Local coverage allowed for on label oncologic indications.
  - All other PET still subject to NCD.
NCD vs Local Coverage

**National**
- FDA Approval
- Request NCA
  - 9-12 months
- Coverage
  - Instructions to MACs
- Coverage w/Evidence Development
  - Design & propose study
  - CMS input & approval
  - Instructions to MACs
  - Implement study
    - 12 to 20 months for NOPR & IDEAS

**Local**
- FDA Approval
- Submit coverage requests to local MACs
- MACs determine whether to cover
  - If covered, LCD, Article or Silent
  - Could be less than 8 weeks
Example: FDG NOPR

- 2005
  - CED Decision for remaining FDG PET indications.
  - NOPR Created.
  - Patients enrolled 2006.

- 2009
  - NOPR Reconsideration (coverage for cervical, ovarian, multiple myeloma; coverage for 1 initial treatment strategy; cont NOPR for subsequent treatment strategy).
  - Created Initial & Subsequent Treatment Strategy scans; new billing instructions.
  - 270 days between coverage change and ability to bill for newly covered scans.

- 2012
  - Request to end data collection requirement & cover FDG PET for all oncologic indications through NCA process.
  - Data collection ended 2013.
Example: NaF NOPR

2010
- CED Decision for NaF PET bone scans.
- NaF NOPR Created.
- Patients enrolled 2011.

2015
- NaF NOPR Reconsideration.
- CMS Decision allowed additional time to provide information that was in original approved study design (modified secondary endpoint).

2017
- Ongoing NaF NOPR & analysis on secondary endpoint; delays in access to claims.
- NCA closed NaF NOPR.
Outreach to Government Stakeholders

- **May 15, 2017 Stakeholder Meeting with CMS, FDA, NCI**
  - What is considered an “outcome” in imaging?
  - What evidence can be harmonized between FDA and CMS?

- **October 19, 2017 Meeting with CMS Office of the Administrator**
  - CMS Senior Advisor for Medicare: Carla DiBlasio
  - National PET Non-coverage Policy
  - Bundled payment in HOPPS
CMS HCPCS Coding Decision

- In 2017, the HCPCS Workgroup departed from previous PET drug descriptors of “per study dose.”

- Logistical challenges (e.g. delivery delays or patient scheduling changes) can lead to decay resulting in a different administered dose than the prescribed dose.

- Both NETSPOT® and Axumin® were both given “per millicurie” descriptors which has created confusion.

- All other PET drugs have the “per study dose” descriptors.
Separate Payment for Imaging Drugs in HOPPS
How Congress and FDA Treat Nuclear Medicine – A Drug

- FDC Act defines “drug” as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or an article intended to affect the structure or function of the body of man or other animals;

- New drugs are subject to the following requirements (among others):
  - FDA must approve marketing application demonstrating safety and effectiveness;
  - Label must bear adequate directions for use;
  - FDA may inspect any facility in which drugs are manufactured, processed, packed, or held, including inspection of records;
  - May not be adulterated or misbranded.
How CMS Treats Nuclear Medicine – A Supply

- No separate payment like other drugs, such as therapeutic radiopharmaceuticals.
- “Packaged” payment under hospital Outpatient Prospective Payment System (OPPS) **EXCEPT during pass-through.**
  - Payment rate determined by the weighted average of hospital charges.
    - Underpayment for higher cost / lower volume radiopharmaceuticals.
    - CMS reduced the number of Ambulatory Payment Classifications (APCs) for nuclear medicine to four.
- Diagnostic radiopharmaceuticals are paid as drugs in the Physician Office setting.
Why is it Inappropriate to Package Radiopharmaceuticals in APCs?

- Radiopharmaceuticals, particularly the newer, low volume, higher cost drugs, that allow for a more accurate personalized diagnosis, are bundled with significantly lower cost drugs.

- In the Medicare hospital outpatient setting, all diagnostic imaging drugs are “packaged” into the Ambulatory Payment Classification (APC) – even if the cost of the drug exceeds the reimbursement for the entire APC.

- Due to charge compression, it is particularly difficult for hospitals to recoup its costs on the lower volume-higher cost drugs, resulting in some facilities ceasing to perform the affected imaging procedures.

- This can lead to patient access issues, as hospitals cannot afford to take a significant loss every time the procedure is performed.
“Separate” Medicare Payment in OPPS

- Industry representatives and medical societies are working together to advance federal legislation reversing diagnostic imaging drug “packaging”.

- The current legislative draft calls for a change to the hospital OPPS where CMS would make a separate payment for any diagnostic radiopharmaceuticals if it exceeds $500.

- In subsequent years, the $500 could increase by the percentage of the fee schedule increase factor for the applicable year (e.g. market basket update).

- Over the next three years, newer agents are coming off pass-through (separate payment) and will be packaged.
“Separate” Medicare Payment Legislation

- The Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2017 would require CMS to make a separate payment for diagnostic RPs that exceeds $500, instead of packaging the cost into the procedure payment. This would ensure that all Medicare patients have access to the most appropriate diagnostic imaging available requiring RP drug.

H.R. ---/S. -- DRAFT (8-28-17) 115th CONGRESS 1st Session

To amend title XVIII of the Social Security Act to ensure equitable payment for, and preserve Medicare beneficiary access to, diagnostic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system.

SECTION 1. SHORT TITLE.
This Act may be cited as the “Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2017.”

SEC. 2. SEPARATE PAYMENT FOR CERTAIN DIAGNOSTIC 1 RADIOPHARMACEUTICALS.
Private Payer Outreach and Challenges
Private Payer Outreach and Challenges

- MITA conducted a blinded panel of private payers to get insight into what they wanted in order to achieve positive coverage decisions. There is an elevated demand for evidence prior to coverage decisions.

- Findings of the panel include:
  - There is a divergence of evidence criteria between FDA and payers.
  - Strategies for successful commercialization must include early and frequent engagement to identify how to align clinical trial measures with payer expectations.
  - Evidence for new tests must address unmet clinical and economic needs.
  - Ongoing collaboration can uncover surrogate measures (e.g. change in patient management).
  - Collaboration can also enhance a manufacturer’s understanding of the appropriate cost measurements and off-sets that payers most value.
Private Payer Outreach and Challenges

- In May, 2017, MITA partnered with ASNC and held a face-to-face meeting with representatives from eviCor and AIM (combined represents over one million beneficiaries) to gain additional perspective on private payer decision making.
  - #1 radiology benefit manager priority – additional test avoidance.
  - #1 participant priority – reduce pre-authorization.

- In 2017, Palmetto released guidance in conflict with CMS, disallowing the use of the JW HCPCS modifier for discarded Part B drugs. After a year, Palmetto rescinded the policy.

- In 2017, AmeriHealth bundled PET reimbursement in the “office setting.”
Appropriate Use Criteria

“Americans can always be trusted to do the right thing, once all other possibilities have been exhausted.” Winston Churchill (maybe!)
The Protecting Access to Medicare Act of 2014 (PAMA)

- Establishes a program requiring clinician adherence to Appropriate Use Criteria (AUC) for advanced imaging services.

- Every health care professional who orders an advanced diagnostic imaging test must consult AUC using a clinical decision support mechanism (CDSM) that has been qualified by CMS ordered on or after Jan. 1, 2020 (this date was not in the original bill).

- Every health care professional who furnishes an advanced diagnostic imaging test must report on the consulting of AUC by the ordering professional.

- CMS is proposing a combination of G-codes and HCPCS modifiers that furnishing professionals will need to report for every single advanced diagnostic imaging test included on a Medicare claim form. Furnishing professionals who do not report a G-code for AUC consultation will not be paid for the advanced diagnostic imaging test provided.
Appropriate Use Criteria

- AUCs have a direct impact on reimbursement:
  - Need to develop searchable evidence for AUCs.
  - Participate on writing committees developing AUCs.
  - For nuclear medicine, there is a need for additional AUCs to counter the negative AUCs already published.
SNMMI Appropriate Use Criteria

- Somatostatin Receptor PET Imaging in Neuroendocrine Tumors – 9/9/17
- FDG PET/CT Restaging and Response Assessment of Malignant Disease – 6/9/17
- Hepatobiliary Scintigraphy in Abdominal Pain – 6/5/17
- Ventilation/Perfusion (V/Q) Imaging in Pulmonary Embolism – 1/20/17
- Bone Scintigraphy in Prostate and Breast Cancer – 1/20/17
- Amyloid Imaging – 1/28/13
SNMMI AUC Expected in 2018

- PET MPI
- Infection Imaging
- Gastrointestinal Transit
- Prostate Cancer Imaging and Treatment
- Treatment and Evaluation of Differentiated Thyroid Cancer
Other Activities Impacting Nuclear Medicine
Outreach Initiatives

Increase patient access to PET imaging by informing physicians, patients and policy makers about the appropriate use and benefits of PET imaging

**Physician Education**
Leverage medical society meetings/key industry events to enable KOLs to present PET imaging cases to educate peers

**Media Relations**
Pursue coverage in traditional media — top-tier and industry trade publications, both print and online — to reach physicians

**Digital/Social Media**
Use digital platforms and social media to make educational information easily accessible to physicians and patients

**Third-Party Relationships**
Identify coalition-building opportunities with patient advocacy groups and professional societies to influence health policy makers
NCCN Guidelines

- Work with identified physician champions to update National Comprehensive Cancer Network (NCCN) guidelines for the inclusion of published clinical evidence that support the appropriate use of PET and PET/CT imaging.
  - NCCN panel reevaluated prostate submissions in 2017.
    - C-11 Choline included.
    - Did not include our recommendations for fluciclovine F18.
  - MITA sent request for the inclusion of PET-CT for breast cancer.
    - Did not include our recommendations for PET and PET/CT staging I & IIB patients.
Drive Awareness and Value of PET

- **PETImagingResources.com**
  - A new website to better organize and present available educational materials (e.g., DETAIL kit materials, PET imaging case studies and industry news) to provide a single online home for all of MITA’s PET imaging resources.
Outreach Learning Modules

- Modules currently being developed – Head and Neck Cancer, Lymphoma and Neuroendocrine Tumors.

- Amyloid PET Imaging Basics: Background Information for Outreach Activities with Neurologists and Dementia Specialists (PDF)
- Prostate Cancer Basics: Background Information for Outreach Activities with Oncologists, Urologists and Surgeons (PDF)
- Using PET/CT in Prostate Cancer (PDF)
- Advantages of PET Myocardial Imaging (PDF)
- PET vs. SPECT: An MPI Case Review (PDF)
- PET for the Evaluation of Myocardial Viability (PDF)
- Which Patient Types May Benefit from a PET MPI Study? (PDF)
- Strategies for Reducing Radiation Exposure with PET (PDF)
MITA Regulatory Committee

- Recent FDA Approvals – Partner with FDA and CMS on evidence harmonization to ensure adequate coverage and payment.
- **Definition of Radiopharmaceutical Compounding Coming Soon** – New FDA Guidance and New USP Chapter 823.
- Ensure productive Part 212 Inspections.
- MDUFA – New paradigm for approval, User Fees.
Summary – Coverage, Coding and Payment Challenges

- CMS National Non-coverage Decision for Non-Oncologic PET.
- Coverage with Evidence Development (e.g. IDEAS, Sodium Fluoride).
- “Separate Payment” in the Medicare Hospital Outpatient Setting.
- Appropriate Use Criteria, Radiology Benefit Managers, Pre-Authorization.
- JW Modifier Exclusion at Palmetto; Coverage in the Physician Office Setting at AmeriHealth.
- Coding “Per Study Dose” Versus “Per Millicurie.”
1. Assessment Question

1. All PET drugs are considered covered drugs under Medicare.

A. True

B. False

Answer: B-False
2. Radiopharmaceuticals are paid separately from the procedure in the Medicare hospital outpatient setting.

A. True

B. False

Answer: B- False
Thank You! Any Questions?

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