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Payment for Precision Diagnostic Imaging Radiopharmaceuticals in OPPS

I am Ann Marie Dawidczyk, from GE Healthcare Pharmaceutical Diagnostics. I am here today as the Chair of MITA's Coverage, Coding and Payment Committee for MITA's PET Group. MITA, the Medical Imaging and Technology Alliance, is a trade association that represents manufacturers of imaging equipment, radiopharmaceuticals and contrast agents. We appreciate the panel considering our comments:

- **CMS should address inappropriate packaging for certain diagnostic radiopharmaceuticals**

While packaging can be a useful tool for certain items and services that are truly supplies, like gauze, the blanket packaging of entire classes of products such as diagnostic radiopharmaceuticals, reduces patient access to important tools used in precision medicine. Packaging of products that are regulated by the FDA is counterproductive to continued patient access, proper diagnosis and innovation in these areas. We urge CMS to utilize the existing CMS framework for separately payable drugs with no adjustments for diagnostic radiopharmaceuticals. This would apply to diagnostic radiopharmaceuticals that were approved by the FDA on or after January 1, 2008 and have a cost that meets or exceeds $500 per day.

When discussing advanced or precision diagnostic radiopharmaceuticals, I am referring to the following:
CPT Codes - Range included by not limited to 78811-78816, 78800-78835.
HCPCS – A9584, A9582, A9586, A9515, A9587, A9588, Q9982, Q9983
APCs: 5592, 5593, 5594

Advanced imaging radiopharmaceuticals and other imaging services are inappropriately packaged in the Medicare hospital outpatient setting. Under the current inequitable payment methodology, many hospitals are unable to cover the cost of newer, targeted diagnostic radiopharmaceuticals. They should be treated like other FDA approved drugs and paid separately.

Advanced diagnostic nuclear imaging procedures using newer diagnostic radiopharmaceuticals offer precise accuracy, sensitivity, and specificity in the assessment, and often support earlier diagnosis or improved treatment decision making in an increasing number of disease states. These tests using precision diagnostic radiopharmaceuticals provide necessary information to clinicians and support changes in management which may lead to more appropriate treatment and reduce the utilization of unnecessary treatments that may be both expensive and debilitating.

Current CMS payment methodology for diagnostic radiopharmaceuticals creates a significant barrier to patient access to the newer, more precise generation of diagnostic imaging tests.

- Specifically, after a three-year period of separate or "pass-through" reimbursement, CMS deems diagnostic radiopharmaceuticals as supplies and reimburses only as part of a packaged reimbursement rate (APC) far below (often 10-20 percent of) actual costs.
- It inadvertently harms patients by disincentivizing the use of the best diagnostic; most of the products affected are not interchangeable, so there is not a cheaper alternative that is as clinically appropriate for the patient.
- It does not allow hospitals to adequately recoup the cost of the procedure, because in most cases, the value of this new class of precision diagnostics is more than the reimbursement for the entire procedure.
- There is little incentive for companies to go through the rigors of the FDA approval process only to dive off the pass-through cliff after three years. It also hinders development of generics, which could encourage a more competitive marketplace.

Hospitals have stopped or never started offering these clinically advanced, but money-losing imaging procedures. In turn, less precise imaging information can lead to suboptimal clinical decisions. Some patients may receive therapeutic treatments or undergo surgical procedures that have little or no probability of success that could have been ruled out by image-based diagnoses and/or clinical staging.

- **Solution – Fix the problem that needs fixing**

It was suggested by CMS some time ago to "fix the problem that needs fixing." We urge CMS to utilize the existing CMS framework for separately payable drugs with no adjustments for diagnostic radiopharmaceuticals. This would apply to diagnostic radiopharmaceuticals that were approved by the FDA on or after January 1, 2008. We also recommend increasing the drug packaging threshold for diagnostic radiopharmaceuticals to a cost of $500 per day. These thresholds are important because they specifically address the solution only on those radiopharmaceuticals that are severely underpaid due to the payment methodology after transitional pass-through.

This would effectively target the newer-generation, non-generic diagnostics that comprise less than 1-2% of total imaging procedures, while maintaining the current methodology for "legacy" agents. These are the drugs negatively impacted by the way in which CMS averages and bundles the nuclear medicine APCs.

In the June 2020 MedPAC Report discussing separately payable drugs, they stated, "Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit…" It is our belief that these precision diagnostic drugs are the reason for the visit.

Thank you.

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, contrast and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its

continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.