



Council on Radiolabels and Radiopharmaceuticals, Inc.



Ensure Patient Access to Innovative Imaging Drugs

Cosponsor the H.R. 3772 the *Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019*

What is nuclear medicine and molecular imaging?

Molecular imaging provides detailed pictures of what is happening inside the body at the molecular and cellular level. Molecular imaging allows physicians to see how the body is functioning and to measure its chemical and biological processes. Molecular imaging includes the field of *nuclear medicine*, which uses very small amounts of radioactive drugs (*radiopharmaceuticals*) to *diagnose* and *treat* disease. Diagnostic radiopharmaceuticals are necessary for all nuclear medicine and molecular imaging studies.

What are the benefits of nuclear medicine and molecular imaging?

Nuclear medicine and molecular imaging procedures are safe, painless, and cost-effective; they provide a way for physicians to gather medical information that would otherwise be unavailable - or that would be available only through surgery or more expensive diagnostic tests. Physicians can determine—almost in real-time—the effectiveness of a treatment, allowing them to offer patients highly-targeted therapies and to ensure that higher doses of medicine are directed more precisely at problem areas.

What diseases can nuclear medicine diagnose or treat?

Nuclear medicine imaging procedures are used in the diagnosis and evaluation of treatment of cancer, cardiovascular disease, gastrointestinal disorders, lung disorders, lymphoma, melanoma, Alzheimer's disease, Parkinson's disease, epilepsy, renal disorders and thyroid disorders.

Regulatory History

In the Medicare Modernization Act (MMA) of 2003, Congress specifically designated radiopharmaceuticals as drugs. Under the Hospital Outpatient Prospective Payment System (OPPS), radiopharmaceuticals were paid separately.

In 2009, CMS interpreted the MMA provisions as expired and they began to “package” *diagnostic* radiopharmaceuticals into Ambulatory Payment Classifications (APCs). Diagnostic radiopharmaceutical costs may vary widely within a nuclear medicine procedure APC. The cost of some diagnostic radiopharmaceuticals significantly exceeds the APC payment rate (which is intended to cover both the diagnostic radiopharmaceutical cost and the procedure cost).

Summary of H.R. 3772:

Diagnostic radiopharmaceuticals should be reimbursed appropriately under OPPS to ensure that patients receive medically appropriate tests that provide the most accurate diagnosis and treatment plans. The bill:

- Directs the Secretary of HHS to pay separately for all *diagnostic* radiopharmaceuticals with a cost per day of \$500 or more – which will safeguard access to new innovations;
- Ensures Medicare patients receive medically necessary studies their physicians prescribe at readily-accessible healthcare facilities;
- Supports innovations that enhance Medicare patient care, improve clinical outcomes, and deliver more cost efficient care; and
- Ensures that HHS implements these changes in a budget neutral manner.