Reclassifying Diagnostic Radiopharmaceuticals

Patient advocates for a wide range of health conditions—including neuroendocrine tumors, lymphoma, and cancers of the lung, breast, and prostate—went to Washington, DC, for March 14 meetings on Capitol Hill to urge support for a bill that would require the Centers for Medicare & Medicaid Services (CMS) to reclassify diagnostic radiopharmaceuticals as drugs. After a breakfast meeting, the patient advocates visited with key Congressional staff to outline their support for such a bill. The day's activities were part of a joint effort by SNMMI, the Medical Imaging and Technology Alliance (MITA), and the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) and were organized by the Alpine Group (Washington, DC). The patient advocates, members of the SNMMI Patient Advocacy Advisory Board, were joined by representatives of CORAR, MITA, the Alpine Group, Curium, Advanced Accelerator Applications, GE Healthcare, Avid/Eli Lilly, and Massie Partners.

CMS currently classifies most FDA-approved diagnostic radiopharmaceuticals as supplies incorporated into bundled payments under Ambulatory Payment Classifications (APCs) in the Medicare Hospital Outpatient Prospective Payment System (OPPS), despite the fact that Congress, in the Medicare Modernization Act of 2003, specifically designated all radiopharmaceuticals (both therapeutic and diagnostic) as drugs. Reimbursement based on APCs is calculated from the average of all costs within each APC, an approach that is equitable only when most costs within an APC are similar. However, CMS packages a number of diagnostic radiopharmaceutical drugs into APCs, even when their costs vary widely. As a result, the cost of some of these drugs significantly exceeds the total APC procedural payment, which is intended to adequately cover the combined radiopharmaceutical drug and nuclear medicine procedure costs. This provides a strong disincentive for hospitals to utilize newer, more targeted diagnostic radiopharmaceutical drugs and serves to discourage investment in research and development.

CMS has packaged diagnostic radiopharmaceutical drugs into APCs for more than a decade. During that time, the nuclear medicine industry has evolved, including development of tailored diagnostic radiopharmaceutical drugs for difficult-to-diagnose diseases and conditions. CMS payment methodology has remained unchanged under the OPPS, and the net effect of this policy has been discouragement of innovation. The advocates participating in the March 14 meetings also pointed toward potential barriers to Medicare beneficiary access to the latest and most effective nuclear medicine procedures.

SNMMI, MITA, and CORAR have long advocated for reclassification of diagnostic radiopharmaceuticals as drugs and are currently lobbying for the legislation to resolve this problem. In a wrap-up statement to the day of advocacy, the group reported on the SNMMI website that "We anticipate that a bill will soon be introduced in Congress. As soon as

Left to right: Wayne Powell, SNMMI director of Health Policy and Regulatory Affairs; Giuseppe Esposito, MD, cochair of the SNMMI Outreach Committee; Theresa Wickerman, ThyCa: Thyroid Cancer Survivor's Association; Josh Mailman, MBA, NorCal CarciNET Community; Stephen Schwartz, Lymphoma Research Foundation; Rosemary Ciotti, Facing Our Risk of Cancer Empowered; Jeri Francoeur, Susan G. Komen Race for the Cure; and Linda Budzinski, SNMMI director of Outreach. Not pictured: Ramon Llamas, Men's Health Network. *Photo by Josh Mailman.*

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Fifty Years Ago in *JNM*

In the March 1968 issue of *The Journal of Nuclear Medicine* (*JNM;* 1968;9[3]:NP), SNM president Merrill A. Bender, MD, addressed the steps the society had taken to establish an organization that could certify competence in the practice of nuclear medicine. SNM had come to a fork in the road, at which members and leadership needed to choose from a range of options, including having multiple boards incorporate distinct components of nuclear medicine in their own certification processes. In early 1968, the SNM Board of Trustees voted to establish a primary board in nuclear medicine. In his *JNM* editorial Bender stated "We would all prefer this course of action, but it may take us many years to achieve this goal. I hope that in the interim we will not see a proliferation in the number of limited examinations given by various boards. I believe this would inevitably result in a duplication in effort and expenditure within our hospitals. I believe that centralized departments of nuclear medicine, staffed by physicians competent in all aspects of our work, have the best chance of providing the highest quality service to our patients."

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that happens, we will be asking all SNMMI members to contact their representatives requesting cosponsoring of the bill."

Signs of Related Relief in 2018 Congressional Budget Bill

Section 1301 of appropriations included in the 2018 Budget Bill, passed and signed into law on March 23, will reverse the decision of the CMS to take some drugs off of pass-through status effective January 1, 2018. They will return to pass-through status on October 1, 2018, through December 31, 2019. The payment rate for the APC groups will be adjusted downward to make this a revenue-neutral change. This will not affect radiopharmaceuticals that went off pass-through status earlier or those scheduled to go off pass-through status in the future. According to a press release issued by SNMMI on March 23, however, "there is hope that this action will encourage CMS to treat high-value radiopharmaceuticals better in the future."

The law also mandates that the Government Accountability Office (GAO) study CMS's "policy for packaging high-cost drugs and biologicals after their pass-through status...has expired." The study will analyze the impact of CMS's policy on utilization of these drugs, the availability of treatment options, the resulting impacts on health outcomes, and the effect on price competition and cost sharing. The report is due to Congress no later than March 1, 2021, and should include whatever legislative and regulatory changes the GAO deems appropriate.

Munir Ghesani, MD, chair of the SNMMI Committee on Government Relations, noted that "while it is good to see Congress taking some action on this problem, much more needs to be done. CMS should stop taking radiopharmaceuticals off of pass-through status and should return to pass-through status many that were taken off earlier. The GAO study is welcome, but we hope it can be completed before 2021 as more action is needed before then."

SNMMI

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with biological response for cellular, animal, and clinical trials data; (5) Address other critical and timely dosimetry issues that may impact the current practice of nuclear medicine; (6) Develop, test, and publish software and Internet tools that implement MIRD calculation models and techniques, including dose–response data and biological effective or equivalent dose quantities; and (7) Actively work with other national and international committees through joint meetings and symposia to establish uniformity in dosimetry models, techniques, named special quantities, and units of dose and biological response. In addition to publishing pamphlets and reports on various internal dosimetry topics, the MIRD Committee also sponsors regular sessions at the SNMMI Annual Meeting, including continuing education offerings. Nominations for the 2019 Loevinger–Berman Award may be submitted by e-mail to gsgouros@jhmi.edu. The nominee's CV and a cover letter, outlining why the nominee would be an appropriate candidate for the Loevinger–Berman Award should be included. The deadline for nominations is November 30, 2018.