CMS Issues Decision and Draft Memos on PET Coverage

Two documents released in March by the Centers for Medicare & Medicaid Services (CMS) relative to the use of PET in oncologic applications will have direct effects on clinical practice in the nuclear medicine and oncologic communities in the near future.

MACs and Radiopharmaceutical Coverage

On March 7, CMS issued its final Decision Memorandum (CAG-00065R2), stating that "unless there is a specific national coverage determination, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for PET using radiopharmaceuticals for their Food and Drug Administration (FDA)–approved labeled indications for oncologic imaging." The effect of this decision is to remove the national noncoverage for FDA-approved labeled oncologic uses of radiopharmaceuticals that are not more specifically determined nationally. The decision does not change coverage for any use of PET with ^{18}F-FDG, ^{18}F-NaF, ^{13}N-ammonia, or ^{82}Rb and does not prevent CMS from determining national coverage for any uses of any radiopharmaceuticals in the future.

Although the decision was welcomed by many in the imaging community, the omission of cardiac and neurologic tracers from the final decision was widely noted. Gail Rodriguez, executive director of the Medical Imaging & Technology Alliance (MITA), said, "MITA is concerned that CMS stopped short of our complete request, which called for local coverage of all PET tracers that are newly approved by the FDA, not just oncologic tracers. We are disappointed that these applications were not included in the decision memorandum and believe that the consideration of coverage for PET tracers should be no different than for other items and services." She added, "We are hopeful CMS will continue to evaluate the preponderance of evidence that guides physician utilization of PET tracers in specialties outside of oncology in order to avoid lengthy, bureaucratic reviews of items and services that are rapidly becoming the standard of care." The complete Decision Memorandum is available at www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=261.

Draft Decision on PET in Solid Tumors

In the second document, issued on March 13, CMS detailed its "Proposed Decision Memorandum for Positron Emission Tomography (FDG) for Solid Tumors" (CAG-00181R4). The draft proposed ending the coverage with evidence development (CED) requirement for ^{18}F-FDG for most oncologic indications, which would remove the current requirement for prospective data collection by the National Oncologic PET Registry (NOPR). The agency also proposed that a single ^{18}F-FDG PET scan would be covered for reimbursement "when used to guide subsequent physician management of antitumor treatment strategy after completion of initial anticancer therapy." Coverage of any additional PET imaging to guide subsequent treatment after completion of initial therapy would be at the discretion of policy set by local MACs.

The exception to these policies is in prostate cancer, where the agency stated that PET for subsequent treatment strategy "is not reasonable and necessary under § 1862(a)(1)(A) [of the Social Security Act] and therefore is nationally noncovered by Medicare." The draft decision memorandum pointed to "inconsistencies" in the national coverage data on ^{18}F-FDG PET in prostate cancer and to a perceived shift of focus to other radiopharmaceuticals (ie, ^{11}C-choline). Despite NOPR data indicating that physicians value the use of ^{18}F-FDG PET data in guiding subsequent treatment strategies, CMS stated that at this point "we believe that the body of evidence as a whole argues against the persuasiveness of the NOPR results on this issue." The agency expressed an interest in feedback from the community on this specific exclusion, stating: "We are particularly interested in public comment that might describe a supportable scientific rationale for the NOPR-reported changes in physician management in this case."

In its summary statement, CMS concluded that "We have not found direct evidence that FDG PET improves health outcomes, despite a diligent search," adding that "we have, from NOPR and other sources, a body of evidence that FDG PET changes physician management in this context."

Barry Siegel, MD, NOPR cochair and a professor of radiology and chief of the Division of Nuclear Medicine at Washington University School of Medicine (St. Louis), pointed out several challenging aspects of the draft decision. "The first is the noncoverage decision on PET for monitoring and management of prostate cancer after initial therapy," Siegel told Newsline. "Such a decision ignores the fact that late-stage prostate cancer is a very different disease, in terms of management, from early-stage disease. We find that physicians want the kind of personalized information that PET can bring to crucial decision making and management in this group of patients that is increasing in numbers along with the aging population." Siegel encouraged members of the nuclear medicine and oncology communities to submit comments to CMS. He added, however, that the community also has a responsibility to champion the rational and appropriate use of PET in all applications. "We need to come out strongly against inappropriate use of surveillance imaging, for example, in patients with no clinical evidence of active disease," he said. "Campaigns such as the 'Image Wisely' initiative are addressing these issues, but as a group we need to impress on CMS the fact that we are advocating PET for monitoring cancer treatment and

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suggests—as did many of the informal interactions at the workshop—that physicians and scientists involved in targeted radionuclide therapy share common hopes and interests in its development and future applications."

Janis O'Malley, MD, from the University of Alabama at Birmingham, summarized the results of the breakout group focusing on targeted radionuclide therapy in lymphoma. The group identified, among other long- and short-term targets, the need for more evidence-based clinical trials to generate new data on therapy effectiveness; creation of centers of excellence to coordinate and translate advances from basic science to clinical use; and increased interaction among the various disciplines and professional organizations with investments in targeted therapy.

Quinn presented the results of the group focusing on bone therapy, which detailed elements affecting current and future standards of care, as well as key questions for future clinical trials. The group also noted that radionuclide research today exists outside current cooperative group mechanisms and that consideration of integration into these groups or initiation of a new cooperative group might be a positive step in advancing radionuclide therapy.

Wolfgang Weber, MD, from Memorial Sloan–Kettering Cancer Center, described discussions in the breakout group on solid tumors. After a review of the current status of radionuclides and solid tumors, the group looked in detail at the immediate challenges, the most promising technologic and radiopharmaceutic advances, and most likely near-term disease targets.

Ananth Srinivasan, PhD, from Stanford University (CA), reported on the breakout group on neuroendocrine and other targeted therapies. The group looked at both the strengths and weaknesses of current radionuclide therapy in neuroendocrine tumors, including the discrepancy between the wide availability of such treatment in Europe and its lack of coverage in the United States. As in the other breakout sessions, participants called for more basic scientific work to enhance understanding of the biology of radionuclide therapy.

Hossein Jadvar, MD, PhD, MPH, MBA, from the University of Southern California (Los Angeles) provided a summary overview and highlights of the workshop, emphasizing group consensus in areas including the regulatory and economic environment, basic biology, and radiochemistry. He summarized the workshop findings with a list of major current and future issues for consideration. He noted that new partnerships are needed among federal agencies, academia, pharmaceutical companies, patients and their advocates, providers, payers, professional societies, and philanthropic and venture capital supporters.

In concluding remarks Fahey pointed to the significance of the workshop as the first of its kind to bring together diverse stakeholders in targeted radionuclide therapy and expressed the hope that similar and expanded gatherings can be scheduled in the future. "We want to identify specific next steps that can build on the important goals participants have discussed at this meeting," he said. "This is clearly a community with diverse but complementary interests in advancing this unique therapeutic approach and realizing its promise in a broad range of disease." A white paper on the workshop consensus findings, including a full bibliography of sources and evidence cited, will be published later this year.

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posttreatment management only in those groups of patients for whom some type of benefit is most likely to occur."

Siegel also cited the problematic nature of leaving the decision to local carriers on coverage of most oncologic scans after the single covered posttreatment scan. "The risk for nonuniformity is very real," he said. "Local carriers have always had the discretion to set frequency limits, but a 1-scan limit is not consistent with current oncology practice. Different hospitals in different areas may now have widely varying coverage in posttreatment oncologic PET, and this will doubtless be confusing for oncologists and their patients."

At Newsline press time, NOPR was compiling its formal comments on the proposed decision memorandum, including urging CMS to consider extension of ^{18}F-FDG PET coverage in the posttreatment period. Siegel said, "The NOPR working group is pleased that data collection over almost 7 years has helped to shape Medicare policy in respect to PET coverage. We look forward to providing additional information to CMS over the coming months to help the agency craft a final decision memo that reflects the optimal use of PET in the right patients."

The complete proposed Decision Memorandum is available at www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=263. The comment period was slated to close on April 13. A final decision memo will be issued later this year.