Diagnostic Imaging Specialists See More Complex Patients

Andrew Rosenkrantz, MD, from the New York University Langone Medical Center (NY), and colleagues from the Harvey L. Neiman Health Policy Institute (Reston, VA), the University of California Los Angeles, and Emory University School of Medicine (Atlanta, GA) reported in the February issue of *Academic Radiology* (2018;25:219–225) on a study assessing Medicare patient complexity by physician specialty and identifying imaging practice characteristics associated with higher complexity. The authors used 2014 Medicare claims data to research average beneficiary Hierarchical Condition Category (HCC) risk scores (Medicare's preferred measure of clinical complexity) for physicians and compared these scores among physician specialties and within a broad range of radiologic practices. The study included 549,194 physicians across 54 specialties, with a mean HCC risk score of 1.62 ± 0.75. Among these specialties, interventional radiology was 4th highest in patient complexity (2.60 ± 1.29), nuclear medicine ranked 16th (1.87 ± 0.45), and diagnostic radiology ranked 21st (1.75 ± 0.61). Risk scores were highest for those in teaching rather than nonteaching settings, with practice size ≥100 members, in urban settings, and in subspecialized rather than generalized practice. After interventional radiology, patient complexity in imaging was highest for cardiothoracic and lowest for breast imaging. The authors concluded that "radiologists on average serve more clinically complex Medicare patients than most physicians nationally." They added that because this varies widely among practices and because patient complexity is increasingly recognized as a central predictor of clinical outcomes and resource utilization "ongoing insights into complexity measures may assist radiologists navigating emerging risk-based payment models."

Academic Radiology

CMS to Cover Next-Generation Sequencing in Advanced Cancers

The Centers for Medicare & Medicaid Services (CMS) announced on March 16 that it had finalized coverage of next-generation sequencing (NGS) tests for patients with advanced cancers, including recurrent, metastatic, relapsed, refractory, or stage III or IV disease. CMS finalized a National Coverage Determination (NCD) released in 2017. The agency stated in a press release that it "believes when these tests are used as a companion diagnostic to identify patients with certain genetic mutations that may benefit from U.S. Food and Drug Administration (FDA)–approved treatments, these tests can assist patients and their oncologists in making more informed treatment decisions." In addition, when a known cancer mutation cannot be matched to a treatment, "results from the diagnostic lab test using NGS can help determine a patient's candidacy for cancer clinical trials."

This decision was made following parallel review with the FDA, which granted approval of the FoundationOne CDx (F1CDx; Foundation Medicine Inc.; Cambridge, MA) test on November 30, 2017. At the same time, CMS issued a proposed NCD for NGS cancer diagnostics. F1CDx is the first breakthrough-designated, NGS-based in vitro diagnostic test that is a companion diagnostic for 15 targeted therapies as well as featuring the ability to detect genetic mutations in 324 genes and 2 genomic signatures in any solid tumor. "We want cancer patients to have enhanced access and expanded coverage when it comes to innovative diagnostics that can help them in new and better ways," said Seema Verma, MPH, CMS Administrator. "That is why we are establishing clear pathways to coverage, while at the same time supporting laboratories that currently furnish tests to the people we serve."

In addition to covering the FDA-approved F1CDx, CMS is covering FDA-approved or cleared companion in vitro diagnostics when the test has an FDA-approved or cleared indication for use in that patient's cancer and results are provided to the treating physician for management of the patient using a report template to specify treatment options. "These tests can help doctors consult with patients about more targeted care or enrollment in a clinical trial," said Kate Goodrich, MD, CMS Chief Medical Officer and director of the Center for Clinical Standards and Quality. "The expanded coverage in this final NCD now includes additional tests for relapsed, refractory, and earlier stage III cancers to aid in treatment of these cancer patients."

This NCD cited the importance of analytic and clinical validation of diagnostic laboratory tests that are part of FDA approval or clearance and that support national coverage after demonstrating that use of the diagnostic laboratory test guides management and improves health outcomes. Tests that gain FDA approval or clearance as in vitro companion diagnostics will automatically receive full coverage under this final NCD, provided other coverage criteria are also met. Coverage determinations for other diagnostic laboratory tests using NGS for Medicare patients with advanced cancer will be made by local Medicare Administrative Contractors. The final decision also extends coverage to repeat testing when a patient has a new primary cancer diagnosis.

Coverage with evidence development was removed from the final NCD, because many public commenters reported that they are already developing or have developed evidence to demonstrate that these diagnostic laboratory tests using NGS improve health outcomes for Medicare beneficiaries with cancer. Others reported that they are equipped to conduct their own studies to generate evidence that

use of the test guides management and treatment and improves health outcomes for the Medicare population. CMS noted in its press release that "We strongly encourage continuing and publishing the results of these important studies, especially on the endpoints of overall survival, progression-free survival, objective response, and patient-reported outcomes relevant to the quality of life for Medicare beneficiaries. This is not only important to ensuring that patients, caregivers, and their providers can make informed decisions, but also to continue to develop and publish results to develop new technologies in the health care system."

Centers for Medicare & Medicaid Services

Restored ^{18}F-NaF PET Coverage Sought

On March 21, SNMMI, the World Molecular Imaging Society (WMIS), and the American College of Radiology (ACR) reaffirmed their joint recommendation that the Centers for Medicare & Medicaid Services (CMS) reconsider the current restrictive coverage policy for ^{18}F-NaF PET imaging to identify bone metastases. The limited coverage policy became more restrictive on December 14, 2017, when the current National Coverage Decision (NCD) and Medicare coverage for ^{18}F-NaF PET (under coverage with evidence development) expired and the National Oncologic PET Registry (NOPR) stopped allowing new case registrations. In issuing its decision to allow the NCD to expire 24 mo after a 2015 CMS Decision Memorandum announcing the intended expiration, CMS left room for reconsideration with the anticipated publication of additional peer-reviewed data. The SNMMI, WMIS, and ACR have indicated that the NOPR has now provided sufficient evidence of the scan's effectiveness and importance in day-to-day oncology practice.

In a February 12 letter to Tamara Syrek Jensen, Director of the CMS Coverage and Analysis Group, the 3 professional societies requested that CMS reconsider its NCD for ^{18}F-NaF PET in identification of bone metastases of cancer. The letter stated "We believe that the results of the confirmatory analyses performed by the NOPR fulfill the requirements in the CMS Decision Memorandum of December 15, 2015, and demonstrate that the use of NaF PET to assess bone metastasis of cancer informs the selection of more appropriate curative or palliative care for patients." The groups pointed to studies published in *The Journal of Nuclear Medicine* in November and December 2017 as validating that ^{18}F-NaF PET is "reasonable and necessary for Medicare beneficiaries." In the first study, NOPR members analyzed concordance between intended patient management as reported on post–^{18}F-NaF PET treatment plans provided to the NOPR and actual patient management based on Medicare claims data. The study showed substantial concordance between intended and claims-inferred post–^{18}F-NaF treatment plans—concordance levels similar to those that CMS found adequate to support coverage for ^{18}F-FDG PET. In the second study, NOPR data showed high correlations between ^{18}F-NaF PET results, hospice admissions, and survival, with the effect increasing further along in disease progression. The letter urged CMS to begin the reconsideration process for ^{18}F-NaF PET to restore coverage, concluding: "We strongly support covering ^{18}F-NaF PET imaging to identify bone metastases for all oncologic uses when the beneficiary's treating physician determines that the ^{18}F-NaF PET study is needed to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment."

SNMMI

CDC Releases Early Data on Health Insurance Status

The Centers for Disease Control and Prevention (CDC) on March 15 released selected estimates based on data from the January–September 2017 National Health Interview Survey. This report, coauthored by Michael E. Martinez, MPH, MHSA, Emily P. Zammitti, MPH, and Robin A. Cohen, PhD, from the National Center for Health Statistics (NCHS), updated health insurance estimates for selected states, using 2017 National Health Interview Survey data. Highlighted findings included that in the first 9 mo of 2017: (1) 28.9 million (9.0%) individuals of all ages were uninsured at the time of interview, a figure not significantly different from 2016 but 19.7 million fewer than in 2010; (2) among adults aged 18–64 y, 12.7% were uninsured at the time of interview, 19.5% had public coverage, and 69.3% had private health insurance coverage; (3) among children aged 0–17 y, 4.9% were uninsured, 41.9% had public coverage, and 54.6% had private health insurance coverage; (4) among adults aged 18–64 y, 69.3% were covered by private health insurance plans at the time of interview, including 4.4% (8.6 million) covered by private health insurance plans obtained through the Health Insurance Marketplace or state-based exchanges; and (5) the percentage of persons under age 65 y with private health insurance enrolled in a high-deductible health plan increased from 39.4% in 2016 to 43.2%. The complete report is available at https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201802.pdf.

Centers for Disease Control and Prevention