

Humana Reverses Nononcologic PET/CT Noncoverage Policy

Humana, Inc. (Louisville, KY) convened a medical review board in late May to address its previous decision to deny coverage for PET/CT for cardiac indications and PET/CT and SPECT/CT for neurologic indications. This followed a decision earlier in the year to reverse previous denial of coverage for PET/CT imaging in gastric and esophageal oncologic indications. The result of the May meeting was a broad cardiac PET/CT coverage policy that is current with scientific evidence and the Centers for Medicare and Medicaid Services National Coverage Decision on ¹⁸F-FDG PET for infection and inflammation. The policy, which in July was still in draft form, included the following coverage areas: (1) myocardial viability assessment as indicated by 1 or more of the following: chronic secondary mitral regurgitation, and individual is candidate for revascularization if viable myocardium identified; known or suspected ischemic cardiomyopathy with left ventricular ejection fraction 35% or less; SPECT myocardial perfusion scan or stress echocardiogram findings inconclusive or no viable myocardium evident; OR (2) suspected prosthetic valve endocarditis as indicated by ALL of the following: clinical suspicion of endocarditis; AND nondiagnostic echocardiogram results; AND prosthetic valve implanted more than 3 months prior; OR (3) sarcoidosis with suspected cardiac involvement. The draft policy also made changes to SPECT/CT and PET/CT for neurologic indications, including that Humana members may be eligible for SPECT with concurrently acquired CT for preoperative localization of parathyroid adenomas and for PET with concurrently acquired CT for presurgical evaluation to localize the focus of refractory seizure activity.

Since November 2020, SNMMI has worked closely with several other

medical societies in communicating with Humana about expanding its coverage.

Humana, Inc.

CMS and Nononcologic ¹⁸F-FDG PET

In December 2020, the Centers for Medicare and Medicaid Services (CMS) retired the National Coverage Determination (NCD) for ¹⁸F-FDG PET for infection and inflammation, effective January 1, 2021. In the absence of an NCD, coverage determinations for PET for infection and inflammation were then to be made at the discretion of local Medicare Administrative Contractors (MACs). The CMS decision to retire the NCD for ¹⁸F-FDG PET in infection and inflammation opened a path to reimbursement and improved care in a range of disease settings.

On June 8, 2021, CMS published an updated transmittal with lists of nationally covered and noncovered ICD-10-CM indications for the various NCDs. To the surprise of the nuclear medicine community, the ICD-10-CM codes for some osteomyelitis and fever of unknown origin codes were listed as noncovered under the infection and inflammation NCD that was retired. Because the transmittal was binding on MACs, those indications would not be covered by local MACs.

On July 13, however, CMS published its CY 2022 Medicare Physician Fee Schedule Proposed Rule, which included a proposal to remove the “exclusionary language” from the NCD transmittal. This will leave nononcologic PET indications (unless noted by NCD 220.6.1-220.6.20) to the discretion of local MACs. CMS stated, “We believe that extending local contractor discretion for nononcologic indications of PET provides an immediate avenue to potential coverage in appropriate candidates and provides a framework that better serves the needs of the Medicare program and

its beneficiaries.” New U.S. Food and Drug Administration–approved nononcologic radiopharmaceuticals will be covered under MAC discretion.

In online commentary on the latest proposed rule, SNMMI noted: “Unfortunately, in this proposal, the national noncoverage determination for beta amyloid PET (NCD 220.6.20) remains. SNMMI and our partners are working to resolve this coverage discrepancy. Also, to our dismay, the proposed rule proposes to cut the conversion factor to \$33.58 in CY 2022, as compared to \$34.89 in CY 2021; this follows the expiration of the 3.75% payment increase, a 0.00% conversion factor update, and a budget neutrality adjustment. SNMMI will work with the medical community to prevent cuts to physician reimbursement.”

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Centers for Medicare and Medicaid Services

SNMMI “Ones to Watch” in 2021

SNMMI announced on July 16 its annual list of 30 early-career professionals selected as “Ones to Watch” in 2021. Launched in 2018, the society’s Ones to Watch campaign aims to recognize those with the potential to shape the future of precision medicine across all areas of the field. Members can nominate themselves or others whose actions, work, or studies have set them apart as future thought leaders in nuclear medicine and molecular imaging. Recipients are selected with the help of the SNMMI Committee on Councils and Centers. The honorees included Olayinka Abiodun-Ojo, MD, MPH (Emory University School of Medicine); Eduardo Aluicio-Sarduy, PhD (University of Wisconsin–Madison); Benjamin Auer, PhD (University of Massachusetts Medical School); Eric Berg, PhD (University of California, Davis); Jessica J. Comstock, PharmD, BCNP (PharmaLogic Holdings); Matthew F. Covington, MD (University of Utah/Huntsman

Cancer Institute); Carolina de Aguiar Ferreira, PhD (University of Wisconsin–Madison); Shreya Goel, PhD (University of Texas MD Anderson Cancer Center); Junior Gonzales (Memorial Sloan Kettering Cancer Center); Javier Hernández-Gil, PhD (Memorial Sloan Kettering Cancer Center); Hyung-Jun Im, MD, PhD (Seoul National University); Amir Iravani, MD (Washington University in St. Louis); Simone Susanne Krebs, MD, MS (Memorial Sloan Kettering Cancer Center); Courtney Lawhn-Heath, MD (University of California, San Francisco); Zhibo Liu, PhD (Beijing University); Dominique S. Newallo, MD, RT(R)(CT) (Emory University); Thomas Ng, MD, PhD (Harvard Medical School/Massachusetts General Hospital); Negar Omidvari, PhD (EXPLORER Molecular Imaging Center, University of California, Davis); Alejandro D. Arroyo Pacheco, PhD (Memorial Sloan Kettering Cancer Center); Austin Patel, MD, MSTR (University of Pennsylvania); Sonya Youngju Park, MD (St. Mary’s Hospital, Seoul); Giacomo Pirovano, PhD (Memorial Sloan Kettering Cancer Center); Chaitanya Rojulpote, MD (The Wright Center for Graduate Medical Education); Brian Horacio Santich, PhD (Y-mABs Therapeutics, Inc.); Lino M. Sawicki, MD, PhD (Heinrich Heine University Dusseldorf); Jennifer Anne Schroeder, MD (Wake Forest University/Baptist Medical Center); Mark A. Sellmyer, MD, PhD (Perelman School of Medicine at the University of Pennsylvania); Senthil Selvaraj, MD (University of Pennsylvania); Hong Song, MD, PhD (Stanford Health Care/Stanford University); and Ning Zhao, PhD (University of California, San Francisco).

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National Coverage Determination Analysis on AD Treatment Opens

The Centers for Medicare and Medicaid Services (CMS) announced on July 12 the opening of a National Coverage Determination (NCD) Analysis to provide data to determine whether Medicare will establish a national

coverage policy for monoclonal antibodies targeting amyloid in the treatment of Alzheimer disease (AD). This NCD analysis will be applicable to national coverage considerations for aducanumab, which was recently approved by the U.S. Food and Drug Administration, as well as any future monoclonal antibodies that target amyloid for treatment of AD. As part of the NCD process, a 30-day public comment period was opened from July 12 to August 11. CMS hosted 2 public listening sessions to provide an opportunity for public input.

“Alzheimer’s is a devastating illness that has touched the lives of millions of American families, and as CMS opens our NCD analysis, we invite interested stakeholders to participate,” said CMS Administrator Chiquita Brooks-LaSure. “We want to consider Medicare coverage of new treatments very carefully in light of the evidence available. That’s why our process will include opportunities to hear from many stakeholders, including patient advocacy groups, medical experts, states, issuers, industry professionals, and family members and caregivers of those living with this disease.”

The nuclear medicine and molecular imaging community is a key stakeholder, with projected uses of PET in AD diagnosis and monitoring of treatment. One of the 5 focal areas to be addressed in the analysis is “What health care providers should be included as part of the patient’s treatment team? Should medical specialists be included in the care team of patients receiving treatment? If so, which specialists should be included in the care?”

To determine whether a national policy is appropriate, CMS will follow a standard process that includes multiple opportunities for the public to participate and present comments through both listening sessions and the CMS Coverage website. The analysis will determine whether the evidence meets the Medicare law’s requirements that items or services be “reasonable and necessary for the diagnosis or treatment of illness or injury . . .” To make this determination, CMS uses a formal

process that includes an assessment of clinical evidence, such as published clinical studies, professional society guidelines, and public comments. Following this analysis, CMS will post a *proposed* NCD, which will be open to a second 30-day public comment period. After review, CMS will announce its *final* decision for a national policy, which could range from Medicare coverage of this product type, coverage with evidence development, noncoverage, or deference to local Medicare Administrative Contractors. A proposed decision is expected to be posted within 6 months and a final within 9 months.

NCDs are posted with additional developing information on the CMS Medicare Coverage Center website: <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center#skipNavTarget>.

To submit or view public comments, see: <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=305>.

Centers for Medicare and Medicaid Services

Annual Report on U.S. Cancer Status

Overall cancer death rates continue to decline for all racial and ethnic groups in the United States, according to the latest *Annual Report to the Nation on the Status of Cancer*. From 2001 to 2018, these declines accelerated for lung cancer death rates and, more recently, melanoma death rates, the latter reflecting advances in treatment for metastatic melanoma. Declines in prostate, colorectal, and female breast cancers, however, have slowed and in some disease settings disappeared. Overall incidence of cancer increased slightly for females, children, and adolescents and young adults but remained stable for males in this period.

The report was published on July 8 ahead of print in *JNCI: The Journal of the National Cancer Institute* and featured in a press release from the American Cancer Society (ACS) on the same day. All trends in the report covered the period before the COVID-

19 pandemic. The annual publication is a collaborative effort from the ACS, the Centers for Disease Control and Prevention, the National Cancer Institute (NCI), and the North American Association of Central Cancer Registries (NAACCR).

Death rates decreased for 11 of the 19 most common cancers among men and 14 of the 20 most common cancers among women. Death rates increased for a few cancers, including brain, other nervous system, and pancreas in both sexes; oral cavity and pharynx in males; and liver and uterus in females.

The report also found that overall cancer death rates decreased in every racial and ethnic group during the period from 2014 to 2018, despite significant disparities remaining. “When evaluating health disparities, it is critical to acknowledge the social factors that influence the health of the communities and access to health care,” said Betsy A. Kohler, MPH, NAACCR Executive Director. “Social and economic indicators, particularly based on small area assessments, are increasingly important to understanding the burden of cancer.”

Preventable disease was also addressed in detail in the report. “The continued decline in cancer death rates should be gratifying to the cancer research community, as evidence that scientific advances over several decades are making a real difference in outcomes at the population level,” said Norman E. “Ned” Sharpless, MD, director of

NCI. “I believe we could achieve even further improvements if we address obesity, which has the potential to overtake tobacco use to become the leading modifiable factor associated with cancer.”

American Cancer Society

JNCI: The Journal of the National Cancer Institute

Sharp Declines in Breast and Cervical Cancer Screening

The total number of cancer screening tests received by women through the Centers for Disease Control and Prevention (CDC) National Breast and Cervical Cancer Early Detection Program declined by 87% for breast cancer and 84% for cervical cancer in April 2020 compared with the previous 5-year averages for that month. These findings were published online on June 30 ahead of print in *Preventive Medicine* and accompanied on the same day by a press release from CDC. The authors concluded that prolonged delays in screening related to the COVID-19 pandemic may lead to delayed diagnoses, poor health consequences, and an increase in cancer disparities among women already experiencing health inequities.

“This study highlights a decline in cancer screening among women of racial and ethnic minority groups with low incomes when their access to medical services decreased at the beginning of the pandemic,” said Amy DeGross, PhD, MPH, CDC health scientist and

lead author of the study. “They reinforce the need to safely maintain routine health care services during the pandemic, especially when the health care environment meets COVID-19 safety guidelines.”

Effects on health equity were highlighted with specific data, noting, for example, that declines in breast cancer screening varied from 84% percent among Hispanic women to 98% among American Indian/Alaskan Native women and that declines in cervical cancer screening varied from 82% among Black women to 92% among Asian Pacific Islander women. Screening volumes had begun to recover in all groups by June 2020, the end of the observation period.

“CDC encourages health care professionals to help minimize delays in testing by continuing routine cancer screening for women having symptoms or at high risk for breast or cervical cancer,” said DeGross. “The Early Detection Program can help women overcome barriers to health equity by educating them about the importance of routine screening, addressing their concerns about COVID-19 transmission, and helping them to safely access screening through interventions like patient navigation.” For more information about CDC’s work on breast and cervical cancer, see <https://www.youtube.com/watch?v=mDIYzBjgNHQ> and <https://www.cdc.gov/cancer/nbcedp/>.