October 4, 2012

Louis B. Jacques, MD
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Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

By Online Submission

RE: World Molecular Imaging Society (WMIS), Society of Nuclear Medicine and Molecular Imaging (SNMMI), and American College of Radiology (ACR) Joint Comment on Reconsideration of Section 220.6 of the NCD on Positron Emission Tomography (FDG) (CAG-00181R4)

Dear Dr. Jacques:

The World Molecular Imaging Society (WMIS), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the American College of Radiology (ACR) are pleased to provide this joint comment in support of the proposal of the National Oncologic PET Registry (NOPR) Working Group that the Centers for Medicare & Medicaid Services (CMS) end the remaining prospective data collection requirements under Coverage with Evidence Development (CED) for all oncology indications for FDG-PET imaging, and that CMS revise accordingly the National Coverage Determination (NCD) and related manual provisions (CAG-00181R4).[1]

Background

All three of the signatories to this comment —WMIS, SNMMI, and ACR (hereinafter "the Joint Societies") — have been deeply involved in supporting the NOPR CED process, as well as in ensuring the success of the NOPR's mission to collect evidence and publish its findings over the past seven years.

WMIS is an international scientific educational organization dedicated to the understanding of biology and medicine through multimodal in vivo imaging of cellular and molecular events involved in normal and pathologic processes, and the utilization of quantitative molecular imaging in patient care. WMIS was formed in 2011, as a result of the merger of two of

[1] National Coverage Analysis (NCA) for Positron Emission Tomography (CAG-00181N), *available at* https://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=92&ver=19&NcaName=Positron+Emission+Tomography+&x28FDG&x29+for+Brain%2c+Cervical%2c+Ovarian%2c+Pancreatic%2c+Small+Cell+Lung%2c+and+Testicular+Cancers&bc=BEAAAAAAAAAA&.

the premier molecular imaging societies — the Academy of Molecular Imaging (AMI) and the Society for Molecular-Genetic Imaging. Between 2006 and 2011, AMI was the sponsor of the original NOPR, and post-merger, WMIS has continued to sponsor the current iteration of the registry, NOPR 2009.

SNMMI (formerly the Society of Nuclear Medicine) is an international scientific and professional organization that promotes the science, technology and practical application of nuclear medicine. SNMMI's more than 19,000 members set the standard for nuclear medicine and molecular imaging by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues.

ACR is a professional society with 36,000 members, drawn from radiologists, radiation oncologists, medical physicists, interventional radiologists, nuclear medicine physicians and allied health professionals. For over three quarters of a century, the ACR has devoted its resources to making imaging safe, effective and accessible to those who need it.

Comments

The Joint Societies Support Ending the CED Prospective Data Collection Requirements for FDG-PET

As CMS is aware, the NOPR was one of the first CED projects, and the Joint Societies worked closely with CMS staff on the design and implementation of all aspects of the NOPR. Although CMS had covered PET for certain oncologic indications (excluding treatment monitoring and surveillance) as early as 2001, the Joint Societies and others in the imaging community had become increasingly concerned that a quarter of Medicare beneficiaries with cancer had developed forms of cancer that were not covered for PET under the then-existing protocols. The Joint Societies realized that the absence of coverage, in conjunction with the lack of evidence about the efficacy of PET for these cancers, meant that such beneficiaries might face a perpetual Catch-22: The non-coverage of PET for such cancers due to a dearth of evidence, and a dearth of evidence because PET was not being performed for such cancers due to non-coverage.

In an effort to break this cycle, we and others worked closely with CMS to launch the NOPR in 2006 as a clinical study, in response to a CMS proposal to expand coverage for FDG-PET to cancers and indications not previously eligible for Medicare reimbursement. As the NOPR Working Group noted in its reconsideration request, CED allowed Medicare beneficiaries with less common cancer types to have equal access to PET for the first time, thus informing clinical management decisions while simultaneously allowing prospective clinical data collection.[2] Between both its 2006 and 2009 iterations, the NOPR has collected in excess of 230,000 scans over the past seven years, creating a rich and robust data source from which to analyze the value of FDG-PET for oncologic indications.

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[2] Tunis S, Whicher D. The National Oncologic PET Registry: lessons learned for coverage with evidence development. J Am Coll Radiol. 2009;6:360–365.

Relying on the CED clinical data collected by the NOPR, the NOPR Working Group has published seven peer-reviewed clinical studies, including reports on the impact of FDG-PET on intended patient management, analyses of data collected during the first year of operation, two-year data restricted to patients with confirmed cancer and analyzed with respect to specific cancer type, data related to the use of FDG-PET as an adjunct for treatment monitoring, and data for dedicated oncologic brain PET.[3,4, 5, 6, 7] The Joint Societies have each reviewed all these studies carefully and are persuaded by their central conclusion: that PET was associated with a reported change in intended management in about one third of cases, with minimal differences across analyses by cancer type or indication that were not clinically important.

We thus fully concur that the peer-reviewed research, based on the CED evidence, demonstrates that PET is both reasonable and necessary for subsequent treatment strategy of oncologic indications. In particular, we believe that the NOPR Working Group's recent *Journal of Nuclear Medicine* article offers strong and compelling evidence that, after comparing the NOPR 2006 and NOPR 2009 cohorts, there remains no clinical need to continue CED data collection for FDG-PET oncologic indications, and that it is unlikely that new useful information will be obtained by extending the coverage of certain cancer types and indications only under CED.[8]

Conclusion

The Joint Societies — WMIS, SNMMI, and ACR — believe that the NOPR has successfully achieved the purposes for which CED was intended: to provide a rich and robust clinical data source from which to analyze the value of FDG-PET for oncologic indications, while simultaneously providing Medicare beneficiaries diagnosed with cancer with access to advanced imaging technology. We believe that the published peer-reviewed clinical research demonstrates that FDG-PET is reasonable and necessary as to physician decision making for oncologic indications, and that CED data collection can be terminated without detriment to CMS, providers, or Medicare beneficiaries.

We look forward to continuing to work collaboratively with CMS to make innovative imaging technology available to the providers and patients who will benefit most from its use,

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[3] Hillner BE, Liu D, Coleman RE, et al. The National Oncologic PET Registry (NOPR): design and analysis plan. J Nucl Med. 2007;48:1901–1908.
[4] Hillner BE, Siegel BA, Shields AF, et al. The impact of positron emission tomography (PET) on expected management during cancer treatment: findings of the National Oncologic PET Registry. Cancer. 2009;115:410–418.
[5] Hillner BE, Siegel BA, Shields AF, et al. Relationship between cancer type and impact of PET and PET/CT on intended management: findings of the National Oncologic PET Registry. J Nucl Med 2008;49:1928–1935.
[6] Hillner BE, Siegel BA, Liu D, et al. Impact of positron emission tomography/computed tomography and positron emission tomography (PET) alone on expected management of patients with cancer: initial results from the National Oncologic PET Registry. J Clin Oncol. 2008;26:2155–2161.
[7] Hillner BE, Siegel BA, Shields AF, et al. Impact of dedicated brain PET on intended patient management in participants of the National Oncologic PET Registry. Mol Imaging Biol. 2011;13:161–165.
[8] Hillner BE, Siegel BA, Hanna L, et al. Impact of 18F-FDG PET Used After Initial Treatment of Cancer: Comparison of the National Oncologic PET Registry 2006 and 2009 Cohorts. J Nucl Med 2012; 53:1-7.

and are of course pleased to provide CMS with any additional information that it may find useful in reaching its decision on this reconsideration request.

Sincerely,

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President, WMIS

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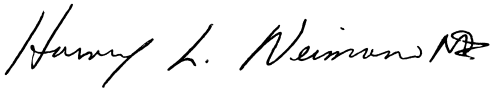
President, SNMMI



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