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By Online Submission

RE: American College of Radiology (ACR), American College of Nuclear Medicine (ACNM), American Society of Neuroradiology (ASNR), Society of Nuclear Medicine and Molecular Imaging (SNMMI), and World Molecular Imaging Society (WMIS) Joint Comment on Proposed Decision Memorandum for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4)

Dear Dr. Jacques:

The American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society of Neuroradiology (ASNR), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the World Molecular Imaging Society (WMIS) are pleased to provide this joint comment on the proposal of the Centers for Medicare & Medicaid Services (CMS) to revise the current coverage status of FDG positron emission tomography (FDG PET) for oncologic indications. Echoing our October 2012 comment letter, the joint societies strongly support the CMS proposal to end Coverage with Evidence Development (CED) data collection for the use of FDG PET for oncologic indications.

However, we strongly oppose the proposal that FDG PET coverage for subsequent patient management be limited to a single nationally-covered scan. We recognize and endorse the concerns of CMS regarding the potential for overuse of FDG PET for surveillance purposes. However, the one-scan limitation will have significant adverse effects for beneficiaries and treating physicians alike. We strongly urge CMS to revisit this proposal, and to adopt language in the Final Decision that instead provides for national coverage of FDG PET for subsequent patient management, subject to frequency limitations at the discretion of the local Medicare Administrative Contractors (MACs).

Background on ACR, ACNM, ASNR, SNMMI, and WMIS

The signatories to this comment — WMIS, SNMMI, ACR, ACNM, and ASNR (the Joint Societies) — have been deeply involved in supporting the CED process through the National
Oncologic PET Registry (NOPR), as well as in ensuring the success of the NOPR’s mission to collect evidence and publish its findings over the past seven years. 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. Between both its 2006 and 2009 iterations, the NOPR has collected information related to nearly 280,000 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.

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.

ACNM is comprised of physicians and other nuclear medicine professionals dedicated to enhancing the practice of nuclear medicine through the study, education and improvement of clinical practice. The goal of ACNM is to assure a legislative, legal, regulatory and economic framework that encourages and makes practicable the safe, appropriate use of nuclear medicine procedures to improve the quality of health care service available to patients.

ASNR is the premier professional association for neuroradiology, a subspecialty concerned with the diagnostic radiology of diseases of the central nervous system, brain, head and neck, through the use of advanced imaging technologies. ASNR is comprised of over 5,000 physicians specializing in neuroradiology, all of whom must devote approximately one-half or more of their professional practice to neuroradiology.

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.

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 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.

**Comments**

1. **CMS Should Finalize the Removal of CED Requirements.**

The Joint Societies 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 access to advanced imaging technology. We agree with CMS 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 and should be terminated without detriment to CMS, providers, or Medicare beneficiaries.

2. **CMS Should Not Finalize the Proposed One-Scan Limit.**

   The Joint Societies oppose the proposed one-scan coverage limit for subsequent physician management of anti-tumor treatment strategy. We believe that such a blanket restriction is both contrary to clinical good practice (as well as the clinical standard of care for certain oncologic indications) and will create significant administrative complications. We urge that CMS revisit this proposal, and instead adopt national coverage of FDG PET for subsequent treatment management, with the option of having MACs establish frequency limits if deemed necessary.

   As a preliminary matter, the Joint Societies believe that the Proposed Decision is unclear as to the scope of the indications to which the reconsideration applies. The Proposed Decision expressly states that its scope is “limited to these uses currently covered only under CED,” which should include only those solid tumors that were not previously nationally covered via CAG-00183R3 (2009). We believe that the Final Decision should make changes only in coverage for those indications that were finally addressed in CAG-00181R3, and which CMS itself acknowledges were not the subject of this reconsideration.

   Turning to the merits, the Joint Societies oppose the proposed one-scan limit for both clinical and administrative reasons. As to the former, we first fully recognize the concern that there exists a potential for the misuse of FDG PET for surveillance purposes. However, we believe that this concern can be safeguarded without a blanket one-scan restriction that penalizes the vast majority of beneficiaries and treating physicians. We propose several potential solutions below. Second, we are greatly concerned that the Proposed Decision would roll back established coverage for many patients where the standard of care requires more than one subsequent patient management scan. Many major cancers fall under this category, particularly those for which multiple lines of therapy can be effective if the initial treatment fails. These include breast cancer, lymphoma, lung cancer, melanoma, colorectal cancer, gynecological malignancies, and many more.

   The Joint Societies are equally opposed to the proposed one-scan limit because of the administrative complications that will ensue in practice. First, under the Proposed Decision, local contractors would have the discretion to allow additional scans beyond the one nationally covered scan. However, as noted above, there are numerous situations in which more than one scan is not only “reasonable,” but also clinically “necessary.” A national policy that establishes the default coverage of only one subsequent treatment strategy scan encourages MACs to be skeptical of the necessity of subsequent scans, in deference to the NCD. Finalizing a national one-scan limitation will inevitably lead to a flood of physician appeals for coverage of what are medically necessary routine additional scans. Not only will these appeals require that MACs
devote significant time and resources to reviewing these requests, but these appeals will inevitably lead to delayed treatment and reimbursement for beneficiaries and physicians alike.

Typically, with fee-for-service Medicare claims, the first-level appeals go through the customer service areas for the MACs, which almost always result in the same denial as the electronic submitted claim, forcing the facilities to enter into the second level of appeal. The second level at times will reach the medical policy staff to reverse the denial. However, those second level appeals also often can be unsuccessful, forcing the provider to give up in frustration, adopting a fallback position of using Advance Beneficiary Notifications (see below) or continuing the appeal process through the Administrative Law Judge. Under this administrative framework, a one-scan limit will inevitably lead to delays in coverage and reimbursement to the detriment of patients, physicians, and the MACs. Second, although the proposed decision nominally provides MACs with the discretion to approve additional scans, MACs in practice typically will take their lead from the NCD, which establishes that a single scan should be the default. This default position sends a strong message from CMS to the MACs that additional scans should be approved sparingly, which will lead to further expense and delays in the form of appeals.

The Medicare Advantage plans add a different layer of complexity through the prior authorization process that will lead to similar barriers to these medically necessary services. In the prior authorization process, a first-level review is almost always denied by non-clinical staff based on very restrictive rules. Next providers are forced to request a further medical prior authorization in the form of a peer-to-peer review. These reviews are labor intensive for the MACs and for referring physicians, taking away valuable time for both. It will thus be near impossible to schedule patients in a timely and efficient manner (which, in turn, will delay the appropriate treatment) leading to the possibility of severe adverse impacts on patient outcomes.

Based on our past experience working with local contractor policies for FDG PET, we believe that PET facilities will feel compelled to require their patients to complete Advance Beneficiary Notification (ABN) forms for medically necessary scans beyond the proposed one-scan national coverage limit. As a practical matter, it will be nearly impossible for providers to assure beneficiaries at the time of delivery that these additional scans will be covered, since under the Proposed Decision, coverage of all such additional scans will automatically be at the discretion of the MAC. As a result, we expect that thousands of beneficiaries will be forced to make the choice of either foregoing treatment or agreeing to pay out of pocket for the scan pending the determination of the MAC. Many beneficiaries may decline to sign the ABN, and therefore would not receive a scan. CMS should avoid placing its cancer patients in the entirely unnecessary position of having to potentially choose between continuing their recommended treatment and incurring thousands of dollars of out of pocket costs. This result is particularly troubling for those patients who are in the midst of treatment, as well as for those whose cancers require multiple subsequent scans due to the initiation of alternative treatments pursuant to the prevailing standard of care.
3. **CMS Should Finalize National Coverage, Subject to Local Frequency Limits.**

The Joint Societies encourage CMS to set aside the proposed one-scan limitation in favor of a policy that would nationally cover FDG PET for oncologic indications without restriction, but allow local contractor discretion to establish frequency limitations as medically reasonable, as is currently within their authority. Furthermore, as explained above, we support supplementing such a proposal with a strong statement that CMS will not cover FDG PET for surveillance purposes in low-risk patients.

The Joint Societies recognize that the difference between national coverage (with the option for local frequency limits) and a national one-scan limitation (with the option for additional scans at local discretion) may at first seem semantic. However, the practical implications are substantial and wide-reaching. First, by instituting national coverage rather than a one-scan limit, CMS would acknowledge that FDG-PET is reasonable and necessary for all uses other than surveillance. Second, national coverage ensures that FDG PET will be available for indications that require multiple scans as standard of care, thus significantly reducing the stress and uncertainty that comes with the need to obtain ABN forms from beneficiaries. Third, MACs rightly look to CMS for cues as to when and how they should exercise their local discretion. The establishment of a one-scan limit encourages MACs to “enforce” that limit and to exercise their discretion sparingly, whereas a decision establishing a default of national coverage encourages MACs to establish frequency limits (if any) based on the type of cancer and its established treatment protocols.

The Joint Societies again acknowledge that CMS is rightly concerned about the use of FDG PET for surveillance purposes. We believe that there are alternative approaches available to CMS that could obtain the same desired result without establishing a one-scan across-the-board restriction. For instance, we believe that it would be possible to establish protocols requiring physician documentation of a patient’s clinical symptoms, in conjunction with a claim submitted with a V-code for the patient’s history of cancer. Moreover, it appears to be reasonable to indicate that a second, third, or fourth line of therapy is being considered, which in turn requires a new-“baseline” scan for subsequent response assessments. Together, this documentation plus coding could be utilized to demonstrate that a clinician’s request for additional imaging scans is grounded in both clinical judgment and the patient’s own clinical history, thus reducing the possibility that an additional scan will be ordered for a patient who is not presenting with either evidence of (or suspicion of) cancer. The Joint Societies would be pleased to collaborate with CMS to develop protocols that can be implemented to accomplish this end.

4. **CMS Should Reverse its Proposal to Non-Cover Prostate Cancer.**

The Joint Societies believe that CMS should revisit the proposal to non-cover prostate cancer. While the Proposed Decision states that “the body of evidence as a whole argues against the persuasiveness of the NOPR results on [prostate cancer],” we believe that this conclusion does not reflect the available clinical literature.
We want to bring to the attention of CMS several clinical studies in the literature that provide evidence that FDG PET is quite useful in the imaging evaluation of men with castrate resistant prostate cancer.\(^1\) These include assessment of the extent of metabolically active disease sites, treatment response evaluation, and prognostication. Based on the evidence provided in these peer-reviewed published articles, we strongly believe that CMS should include the use of FDG PET in the specific case of patients with castrate resistant metastatic prostate cancer.

5. **CMS Should Make Technical Corrections Regarding PET/MRI.**

It appears that in the Proposed Decision, CMS inadvertently failed to reference PET MRI in the definition on scanner technology. The recent Final Decision in CAG-00065R2 includes PET/MRI in the definition of PET:

> “We include integrated positron emission tomography/computerized tomography (PET/CT) and integrated positron emission tomography/magnetic resonance imaging (PET/MRI) in the term PET.”\(^2\)

We encourage CMS to clarify in the final decision memorandum that PET/MRI is included in the definition of what constitutes PET for purposes of FDG.

6. **The Effective Date of the NCD Should Ensure Continuity of Coverage for Beneficiaries.**

It is imperative that as FDG PET moves from CED to national coverage, beneficiaries who are currently receiving coverage pursuant to CED are transitioned seamlessly to national coverage. To ensure a smooth transition, we would request that CMS establish the termination date for NOPR data collection to be the same as the effective date of the final NCD (for PET scans performed on or after the effective date).

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Conclusion

The Joint Societies—ACR, ACNM, ASNR, SNMMI, and WMIS—appreciate the opportunity to comment on the Proposed Memorandum, and to voice our overall support for the termination of CED and data collection requirements for FDG PET for cancer.

However, we continue to have very significant concerns about the proposal to limit subsequent patient management scans to one scan per patient per cancer. We strongly believe that limiting the use of FDG PET for surveillance can be achieved through less burdensome means, and without the adverse impact on beneficiaries, physicians, and local contractors that would be created through adoption of a blanket one-scan limitation.

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, and are of course pleased to provide CMS with any additional information that it may find useful in reaching its final decision in this regard.

Sincerely,

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