CMS Considers Broadening Coverage of ^{18}F-FDG PET

On May 8, the Centers for Medicare & Medicaid Services (CMS) opened reconsideration of the national coverage determination (NCD) on ^{18}F-FDG PET. The requestors have asked CMS to reconsider the NCD and broaden national coverage of ^{18}F-FDG PET (without coverage with evidence development restrictions) for the staging of cervical cancer (i.e., in those women who have been diagnosed with cervical cancer but who do not otherwise meet the coverage criteria). The requestors also ask that the use of ^{18}F-FDG PET for diagnosis of cervical cancer not be covered, as it is not helpful for initial diagnosis.

The requestors cite existing literature and a University of Alberta technology assessment that offer strong evidence for the utility of PET for initial staging of cervical cancer. According to the requestors, "given the difference in sensitivity of PET versus CT or MRI alone, in almost all circumstances a patient with CT/MRI of the pelvis showing no extrapelvic metastatic disease will still require a subsequent PET to enable the treating physician to obtain the information necessary for comprehensive initial treatment planning, and this is acknowledged in the current coverage policy. Even if a CT or MRI study is considered 'positive' for extrapelvic metastatic disease because it shows enlarged para-aortic lymph nodes, this is not the complete staging information needed to manage the patient. Additional nodal metastases, not seen by conventional imaging, are frequently detected by PET and are now often treated to higher doses using intensity-modulated radiation therapy (IMRT) rather than with standard para-aortic treatment plans."

Medicare currently covers ^{18}F-FDG PET nationally when it is used by the beneficiary's physician to guide the subsequent management of cervical cancer in women who have undergone anticancer treatment. For example, ^{18}F-FDG PET is covered to determine whether cancer has responded to treatment or to determine if the patient's symptoms are being caused by a recurrence or spreading of cancer.

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In addition, ^{18}F-FDG PET is nationally covered for some uses in women diagnosed with cervical cancer who have not yet received anticancer treatment. Specifically, it is covered as an adjunct test for the detection of pretreatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extrapelvic metastasis.

Medicare coverage of all other uses of ^{18}F-FDG PET related to cervical cancer is restricted to beneficiaries who are enrolled in a prospective clinical study under a Coverage with Evidence Development program, such as the National Oncologic PET Registry.

The public comment period closed on June 7. As SNM has done with the previous PET NCD reconsiderations, we submitted a joint society letter together with the American College of Radiology, Academy of Molecular Imaging, American College of Nuclear Physicians, and American Society for Radiation Oncology. CMS expects to release the proposed decision memo on November 8 and finalize their decision by February 6, 2010.

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