



GE Healthcare

3000 N. Grandview Blvd.  
Waukesha, WI 53188

June 2, 2009

Charlene Frizzera, Administrator  
Attn: Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 21244-1850

**Re: NCA for Positron Emission Tomography (FDG) for Cervical Cancer (CAG-00181R2)**

Dear Ms. Frizzera:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) National Coverage Analysis (NCA) tracking sheet for reconsideration of the current coverage determinations for FDG-PET imaging related to cervical cancer.

GEHC, a \$17 billion unit of General Electric Company with headquarters in the United Kingdom, has expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery, and biopharmaceuticals manufacturing technologies. GEHC's broad range of products and services enables healthcare providers to offer patients earlier and better diagnosis and treatment of cancer, heart disease, neurological diseases, and other conditions to improve the quality and length of life. Worldwide, GEHC employs more than 46,000 people committed to serving healthcare professionals and their patients.

Overall, we applaud the responsiveness of CMS within the National Coverage Determination (NCD) process to open a reconsideration of the existing coverage decision on FDG PET as it pertains specifically to cervical cancer. At the same time, **GEHC recognizes the inherent value of the comprehensive NCD approach on PET for the many oncologic indications.**

GEHC fully supports the response submitted jointly on behalf of the Academy of Molecular Imaging (AMI), the American College of Radiology (ACR), the American Society for Therapeutic Radiology and Oncology (ASTRO), the Society of Nuclear Medicine (SNM), the American Society of Clinical Oncology (ASCO) and the American College of Nuclear Physicians (ACNP). Collectively, these professional societies represent physicians and PET healthcare providers focused on the delivery of quality medical care for oncology patients. There are two key points consistent with their collaborative response that are important to reinforce.

**GEHC supports CMS broadening the PET national coverage for the initial staging of cervical cancer by eliminating the current legacy coverage restrictions.**

Currently, PET for initial staging of cervical cancer is covered only after a negative CT or MRI exam for extrapelvic metastatic disease. If no metastases are found, Medicare then covers PET. However, if extrapelvic metastatic disease is found, PET is covered only under a Coverage with Evidence Development approach through the NOPR data registry. The additional step of requiring a CT or MRI prior to routine coverage for PET is unique to cervical cancer and should be eliminated. No similar prerequisites exist for obtaining Medicare coverage of PET for initial staging of other covered cancers. Removing this additional CT and/or MRI exam barrier to cervical cancer staging will:

- 1) simplify the CMS coverage policy for use of PET for initial staging across all covered cancers consistent with the CMS NCD objective
- 2) accelerate the initial staging, and subsequent treatment planning process for patients
- 3) streamline the reimbursement of providers primarily focused on clinical care of oncology and gynecology patients
- 4) reduce healthcare costs by avoiding an unnecessary diagnostic imaging exam.


Thus, the current NCD should be revised to treat initial staging of cervical cancer in an identical manner to all other covered cancers.

**CMS should uniquely, issue a national non-coverage for the use of PET for diagnosis of cervical cancer.**

Analysis by healthcare providers indicates that PET is not necessary for diagnosis of cervical cancer, and as a result of this clinical practice, non-coverage for the use of PET for diagnosis of cervical cancer is prudent.

GEHC applauds CMS efforts to expand oncologic PET coverage for Medicare beneficiaries. GEHC also reiterates its support of “CMS to reconsider the NCD and nationally cover FDG PET more broadly (without the CED restriction) 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”.

Sincerely,



Hugh Zettel  
GE Healthcare, Strategic Reimbursement Executive