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Comment: Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services 7500 Security Blvd., Mail Stop C1-09-06
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RE: Comments on Proposed Decision for Positron Emission Tomography (FDG) for Infection and Inflammation (CAG-00382N)

Dear Dr. Phurrough:

GE Healthcare (GEHC) is providing comments to the Centers for Medicare and Medicaid Services (CMS) pertaining to the proposed decision to continue its national non-coverage decision of FDG-PET for infection and inflammation (CAG- 00382N).

GE Healthcare is a \$17 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery and biopharmaceuticals manufacturing technologies. GE Healthcare's broad range of products and services enable healthcare providers to better diagnose and treat cancer, heart disease, neurological diseases and other conditions earlier. Worldwide, GE Healthcare employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

On behalf of GEHC, I am writing to express disappointment in the conclusion of CMS that there is inadequate evidence to warrant a positive National Coverage Determination (NCD) for the use of PET for infection and inflammation. We believe FDG-PET provides physicians with an exceptionally valuable tool for diagnosing infection and inflammation for the indications evaluated by this proposed decision. While we acknowledge the concerns expressed by CMS in its proposed decision memorandum, GEHC believes that there is sufficient evidence in both the peer-reviewed scientific literature and the extensive clinical experience of investigators to support the issuance of an NCD that expands coverage at this time, particularly for the indications of chronic osteomyelitis, infection associated with hip arthroplasty, and fever of unknown origin.

In reconsidering an expansion of FDG-PET coverage, we caution CMS to refrain from implementing restrictive language that would require that FDG- PET totally replace conventional imaging including bone, leukocyte and/or gallium scintigraphy. Patients presenting with symptoms indicative of the conditions discussed in the NCA often represent complicated cases. Therefore, we suggest that CMS consider the role of PET as a replacement for OR as a follow-up to cases where conventional imaging is inconclusive.

In the absence of a decision to provide for expanded national coverage, we are encouraged by CMS's request for comments concerning the potential for providing limited coverage for these indications by means of Coverage with Evidence Development (CED). If CMS cannot provide national coverage on the basis of existing evidence, we strongly encourage a CED

registry similar to the National Oncologic PET Registry, or other means, which would enable CMS to acquire the data necessary to support the issuance of a favorable NCD on PET for infection and inflammation in the future.

In summary, GEHC believes that FDG-PET is clinically effective in diagnosing suspected chronic osteomyelitis, infection associated with hip arthroplasty, and fever of unknown origin, among many other infectious and inflammatory conditions. We strongly urge CMS to provide national coverage of PET for infection and inflammation, or establish a CED opportunity to provide CMS with the additional data it feels are necessary to support expansion of national coverage to include these indications in the future.

Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,

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