

May 9, 2008

BY ELECTRONIC DELIVERY

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, Maryland 21244

Re: Positron Emission Tomography (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (CAG-00181R)

Dear Mr. Caplan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Tracking Sheet for Positron Emission Tomography (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (CAG-00181R).¹ BIO agrees with the formal request for reconsideration letter and believes that CMS should remove the prospective data collection requirements associated with using Positron Emission Tomography (PET) that uses the radioisotope 2-[F-18] Fluro-D-Glucose (FDG) for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers.² BIO believes that a recently published scientific study satisfies the coverage with evidence development (CED) criteria established by CMS. Consequently, consistent with its own CED policy, BIO urges CMS to end its data collection requirements associated with using FDG-PET and to provide coverage

¹ The Tracking Sheet is available at: <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=218>.

² The NCD is available at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=220.6.14&ncd_version=1&basket=ncd%3A220%2E6%2E14%3A1%3APET+%28FDG%29+for+Brain%7C%7C+Cervical%7C%7C+Ovarian%7C%7C+Pancreatic%7C%7C+Small+Cell+Lung%7C%7C+and+Testicular+Cancers.



across all oncologic indications for diagnosis, staging, and restaging/suspected recurrence.

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

As the representative of an industry dedicated to discovering new therapies and ensuring patient access to them, BIO understands that the practice of medicine constantly evolves through the incorporation of new clinical evidence into the standard of care. BIO strongly supports increasing the body of evidence available in order to diagnose and treat all diseases. Our members invest millions of dollars each year on clinical studies, both before and after Food and Drug Administration (FDA) approval of their products, to produce high-quality evidence to further clinical decision-making. We also support the dissemination of this evidence to further clinical knowledge and enhance and improve the clinical decision-making process. In this regard, we support the use of CED for clearly defined purposes that share our goal of expanding available clinical information and ensuring Medicare beneficiaries have access to state-of-the-art care.

On April 18, 2005, CMS implemented a National Coverage Determination (NCD) requiring the collection of patient management data on a prospective basis when using FDG-PET to detect the metastases of brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers.³ CMS required providers and patients to participate in a prospective clinical study designed to collect additional information prior to and immediately after the FDG-PET.

CMS states that the purposes of CED are to generate data on the utilization and impact of the item or service so Medicare can ascertain the appropriateness of use of that item or service in Medicare beneficiaries, consider future changes in coverage for the item or service, and generate clinical information that will improve the evidence base on which providers base their recommendations to

³ The NCD is available at:

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=220.6.14&ncd_version=1&basket=ncd%3A220%2E6%2E14%3A1%3APET+%28FDG%29+for+Brain%7C%7C+Cervical%7C%7C+Ovarian%7C%7C+Pancreatic%7C%7C+Small+Cell+Lung%7C%7C+and+Testicular+Cancers.

Medicare beneficiaries regarding the item or service.⁴ CMS further states that the length of data collection requirement will depend on the results of the registry, specifically if it provides satisfactory answers to the questions posed in the NCD that were used to establish the registry.⁵ Sufficient data should be collected to satisfy the hypotheses that established the registry and should be published in peer reviewed journals. BIO believes that as a result of the efforts of the National Oncologic PET Registry (NOPR) Working Group, the conditions that CMS established for ending data collection via a registry have been satisfied.

The NOPR was developed to meet the CED coverage requirements and to assess how FDG-PET affects care decisions, specifically physician intended management.⁶ In a March 2008 study published in the *Journal of Clinical Oncology*, the authors state that the data collected demonstrate that PET utilization is associated with a 36.5% change in the treatment or no-treatment decision, including the full scope of potential uses of PET in the diagnosis and treatment of a particular cancer.⁷ These data led the authors to conclude that physicians often changed their intended management of the respective cancer based on the FDG-PET scan results.⁸ This peer reviewed study shows that the goal of the registry – to ascertain how FDG-PET affects physician's intended management decisions – was met.

BIO believes that these clinical data clearly show that FDG-PET is a valuable tool in the detection, diagnosis, and treatment of a variety of cancers. Additionally, BIO believes that these results accomplish CMS' larger goal of using CED to generate additional evidence to inform the clinical decision-making process. As such, BIO urges CMS to end the data collection requirements for diagnosis, staging, and restaging/suspected reoccurrence for PET scans across all cancer types. BIO, however, also recommends that CMS and NOPR continue collecting data for the coverage of PET for treatment monitoring until such time that these data also are published in a peer reviewed journal.

⁴ National Coverage Determination with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006, at 2. The NCD is available at:

http://www.cms.hhs.gov/CoverageGenInfo/03_CED.asp#TopOfPage

⁵ Id.

⁶ Hillner BE, Siegel BA, Liu D, et al. Impact of Positron Emission Tomography/Computed Tomography and Positron Emission Tomography Alone on Expected Management of Patients with Cancer: Initial Results from the National Oncologic PET Registry. *J.Clin Oncol* 2008.

⁷ Id.

⁸ Id.



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BIO appreciates this opportunity to submit these comments. For the reasons stated above, we urge CMS to remove the current prospective data collection requirements associated with using FDG-PET and to provide coverage across all oncologic indications for diagnosis, staging, and restaging/suspected recurrence. If you have any questions or would like to discuss these matters further, please contact me at (202) 962-6677.

Respectfully Submitted,

/s/

John M. Taylor
Executive Vice President, Health
Biotechnology Industry Organization

cc: Katherine Tillman, RN MA, Analyst
Steve Phurrough, M.D., M.P.A., Director Coverage and Analysis Group

