

CMS Response to Public Comments Received for CMS-10152

The Centers for Medicare and Medicaid Services (CMS) received comments from individuals related to CMS-10152. This is the reconciliation of the comments.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received comments questioning the meaning of “reasonable and necessary”. This commenter also questioned the need for data collection.

Response:

CMS appreciates the comment regarding reasonable and necessary and the definition of “FDG” as it applies to National Coverage Analysis CAG00181R1: FDG Positron Emission Tomography for brain, cervical, ovarian, small cell. CMS is indeed stating that PET and PET/CT scans are only reasonable and necessary when the provider and beneficiary are enrolled in a clinical study that is designed to collect additional information at the time of the scan to assist in patient management. When making national coverage determinations under §1862(a)(1)(A) of the Social Security Act, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

As for the second comment, FDG is the abbreviation for F-18 Fluorodeoxyglucose. This radioactive tracer substance (radionuclide) is injected into the patient as part of the PET or PET/CT diagnostic test.