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Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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PET (FDG) Scan for Solid Tumors

Policy Number: HS-112

Original Effective Date: 6/18/2009

Revised Date(s): 8/2/2011; 4/5/2012;
5/3/2012 RETIRED

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Centers for Medicare and Medicaid Services Decision Memo: April 3, 2009

CMS was asked to reconsider Section 220.6 of the National Coverage Determination (NCD) Manual to end the prospective data collection requirements across all oncologic indications of FDG PET except for monitoring response to treatment. Section 220.6 of the NCD Manual established the requirement for prospective data collection for FDG PET used in the diagnosis, staging, restaging and monitoring response to treatment for brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers, as well as for cancer indications not previously specified in Section 220.6 in its entirety.

We received public input indicating that the coverage framework which required cancer-by-cancer consideration of diagnosis, staging, restaging and monitoring response to treatment should be replaced by a more omnibus framework. Thus, we broadened the scope of this review through an announcement on our website and solicited additional public comment on the use of FDG PET imaging for solid tumors so that we could transparently consider this possibility. Therefore, after receiving public comments as required by § 1862(l) of the Social Security Act (the ACT), we are revising Section 220.6 of the Medicare NCD Manual to reflect a new framework for most solid tumor oncologic indications and for myeloma. This decision replaces sections 220.6.2 (FDG PET for lung cancer); 220.6.3 (FDG PET for esophageal cancer); 220.6.4 (FDG PET for colorectal cancer); 220.6.5 (FDG PET for lymphoma); 220.6.6 (FDG PET for melanoma); 220.6.7 (FDG PET for head and neck cancers non-CNS/thyroid); 220.6.10 (FDG PET for breast cancer); 220.6.11 (FDG PET for thyroid cancer); 220.6.12 (FDG PET for soft tissue sarcoma); 220.6.14 (FDG PET for brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers), and 220.6.15 (FDG PET for all other cancer indications) of the NCD Manual with a single section that outlines coverage of PET scans for oncologic conditions. Section 220.6, a general section on PET scanning, will be modified as required by this decision. Coverage determinations in Sections 220.6.1 (PET for perfusion of the heart); 220.6.8 (FDG PET for myocardial viability); 220.6.9 (FDG PET for refractory seizures); 220.6.13 (FDG PET for dementia and neurodegenerative diseases), and 220.6.16 (FDG PET for infection and inflammation) describe coverage of PET imaging for non-oncologic conditions and will not be modified.

CMS is adopting a coverage framework that replaces the four-part diagnosis, staging, restaging and monitoring response to treatment categories with a two-part framework that differentiates FDG PET imaging used to inform the initial antitumor treatment strategy from other uses related to guiding subsequent antitumor treatment strategies after the completion of initial treatment. We are making this change for all NCDs that address coverage of FDG PET for the specific oncologic conditions addressed in this decision.

Initial Treatment Strategy

CMS has determined that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial treatment strategy for beneficiaries with suspected solid tumors and myeloma and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act.

Therefore, CMS will cover only one FDG PET study for beneficiaries who have solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or

- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

As exceptions to the initial treatment strategy section above:

- a. CMS has reviewed evidence on the use of FDG PET imaging to determine initial antitumor treatment in patients with adenocarcinoma of the prostate. CMS has determined that the available evidence does not demonstrate that FDG PET imaging improves physician decision making in the determination of initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate, does not improve health outcomes and is thus not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act. Therefore, FDG PET is nationally non-covered for this indication of this tumor type.
- b. CMS received no new evidence demonstrating a change was warranted with respect to the use of FDG PET imaging to determine initial antitumor treatment in breast cancer; thus CMS is not making any change to the current coverage policy for FDG PET in breast cancer. We continue to cover FDG PET imaging for the initial treatment strategy for male and female breast cancer only when used in staging distant metastasis. FDG PET imaging for diagnosis and initial staging of axillary nodes will remain non-covered.
- c. CMS received no new evidence demonstrating a change was warranted with respect to use of FDG PET imaging of regional lymph nodes in melanoma; thus we are not changing the current NCD for FDG PET in melanoma. CMS will continue non-coverage of FDG PET for the evaluation of regional lymph nodes in melanoma. Other uses to determine initial treatment strategy remain covered.
- d. CMS received no new evidence demonstrating a change was warranted with respect to use of FDG PET imaging in the initial treatment strategy for cervical cancer. We continue to cover FDG PET imaging as an adjunct test for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis. All other uses of FDG PET for the initial treatment strategy for beneficiaries diagnosed with cervical cancer will continue to only be covered as research under §1862(a)(1)(E) of the Act through Coverage with Evidence Development (CED) as outlined immediately below and in Section 3.

Therefore, we will cover one initial FDG PET study for newly diagnosed cervical cancer when not used as an adjunct test for the detection of pre-treatment metastases following conventional imaging that is negative for extra-pelvic metastasis only when the beneficiary's treating physician determines that the FDG PET study is needed to inform the initial antitumor treatment strategy and the beneficiary is enrolled in, and the FDG PET provider is participating in, the following type of prospective clinical study:

- An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and all patient confidentiality, privacy, and other Federal laws must be followed.

The clinical studies for which we will provide coverage must answer one or more of the following questions: Prospectively, in Medicare beneficiaries with newly diagnosed cervical cancer who have not been found following conventional imaging to be negative for extra-pelvic metastases and whose treating physician determines that the FDG PET study is needed to inform the initial antitumor treatment strategy, does the addition of FDG PET imaging lead to:

- A change in the likelihood of appropriate referrals for palliative care;
- Improved quality of life; or
- Improved survival?

The study must adhere to the standards of scientific integrity and relevance to the Medicare population as described in part 3, items a through m, below.

Subsequent Treatment Strategy

CMS reviewed evidence on the use of FDG PET in the subsequent treatment strategy for patients with tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung and thyroid.

For tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid, CMS has determined that the available evidence is not adequate to determine that FDG PET imaging improves physician decision making in the determination of subsequent anti-tumor treatment strategy or improves health outcomes in Medicare beneficiaries and thus is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act.

However, CMS has determined that the available evidence is sufficient to determine that FDG PET imaging for subsequent anti-tumor treatment strategy for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid may be covered as research under §1862(a)(1)(E) of the Act through Coverage with Evidence Development (CED).

Therefore, we will cover a subsequent FDG PET study for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung and thyroid when the beneficiary's treating physician determines that the FDG PET study is needed to inform the subsequent antitumor treatment strategy and the beneficiary is enrolled in, and the FDG PET provider is participating in, the following type of prospective clinical study:

- An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the FDG PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and all patient confidentiality, privacy and other Federal laws must be followed.

As exceptions to the subsequent treatment strategy section above:

- a. CMS has reviewed evidence on the use of FDG PET imaging to determine subsequent treatment strategy in patients with ovarian cancer. CMS has determined that the available evidence is adequate to determine that FDG PET imaging improves physician decision making in the determination of subsequent treatment strategy in Medicare beneficiaries who have ovarian cancer, improves health outcomes and is thus reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, CMS has determined that FDG PET imaging is nationally covered for this indication for this tumor type.
- b. CMS has reviewed evidence on the use of FDG PET imaging to determine subsequent treatment strategy in patients with cervical cancer. CMS has determined that the available evidence is adequate to determine that FDG PET imaging improves physician decision making in the determination of subsequent treatment strategy in Medicare beneficiaries who have cervical cancer, improves health outcomes and is thus reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, CMS has determined that FDG PET imaging is nationally covered for this indication for this tumor type.

CMS reviewed evidence on the use of FDG PET in the initial and subsequent treatment strategy for myeloma. CMS has determined that the available evidence is sufficient to determine that FDG PET imaging improves physician decision making for these uses in Medicare beneficiaries who have myeloma, improves health outcomes and is thus reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, CMS has determined that FDG PET imaging is nationally covered for this indication for this tumor type.

Clinical Study Requirements: Coverage with Evidence Development Structure

The clinical studies for which it will provide coverage must answer one or more of the following questions: Prospectively, in Medicare beneficiaries whose treating physician determines that the FDG PET study is needed to inform the subsequent anti-tumor treatment strategy, does the addition of FDG PET imaging lead to:

- A change in the likelihood of appropriate referrals for palliative care;
- Improved quality of life; or
- Improved survival

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The research study does not unjustifiably duplicate existing studies.
- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56.
- g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
- h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the Centers for Medicare and Medicaid Services (CMS) determines meet the above-listed standards and address the above-listed research questions.

CMS Update 2010

New Coverage for Initial Treatment Strategy

- **Myeloma:** CMS will nationally cover the use of FDG PET imaging to determine initial treatment strategy in patients with myeloma.
- **Prostate:** CMS will nationally non-cover the use of FDG PET imaging to determine initial treatment strategy in patients with adenocarcinoma of the prostate.
- **All other cancers not listed herein:** CMS will nationally cover the use of FDG PET imaging to determine initial treatment strategy in patients with all other cancers not listed herein provided under CED.
- **3. Subsequent Treatment Strategy**
- The CMS will non-cover FDG PET imaging for subsequent anti-tumor treatment strategy for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid, unless the FDG PET is provided under CED.

New Coverage for Subsequent Treatment Strategy

- **Ovarian:** CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with ovarian cancer.
- **Cervical:** CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with cervical cancer.
- **Myeloma:** CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with myeloma.
- **All other cancers not listed herein:** CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with all other cancers not listed herein provided under CED.

POSITION STATEMENT

1) Initial Treatment Strategy

PET (FDG) scans **are considered medically necessary and a covered benefit** for determination of initial treatment strategy for the following solid tumor types:

- Brain; **OR,**
- Colorectal; **OR,**
- Esophagus; **OR,**
- Head and neck (not thyroid or CNS); **OR,**
- Lymphoma; **OR,**
- Non-small cell lung; **OR,**
- Ovary; **OR,**
- Pancreas; **OR,**
- Small cell lung; **OR,**

- Soft tissue sarcoma; **OR**,
- Thyroid; **OR**,
- Testes; **OR**,
- Myeloma

Breast (female and male): PET (FDG) scans are considered medically necessary and a covered benefit for initial staging of metastatic disease. PET (FDG) scans are considered NOT medically necessary and not a covered benefit for initial staging of axillary lymph nodes.

Cervix: PET (FDG) scans are considered medically necessary and a covered benefit for detection of pre-treatment metastases (i.e. staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are under the coverage with evidence development structure (CED, see background for more information on CED).

Melanoma: PET (FDG) scans are considered medically necessary and a covered benefit for the initial staging of melanoma, with the exception of initial staging of regional lymph nodes.

Prostate: PET (FDG) scans are considered NOT medically necessary for the initial staging of prostate cancer.

All other cancers: PET (FDG) scans for initial staging of all other cancers are covered under the CED structure.

2) Subsequent Treatment Strategy

PET (FDG) scans **are considered medically necessary and a covered benefit** for determination of subsequent treatment strategy for the following solid tumor types:

- Breast (male and female); **OR**,
- Cervix; **OR**,
- Colorectal **OR**,
- Esophagus; **OR**,
- Head and neck (not thyroid or CNS); **OR**,
- Lymphoma; **OR**,
- Melanoma; **OR**,
- Non-small cell lung; **OR**,
- Ovary; **OR**,
- Myeloma

PET (FDG) scans are covered under the “coverage with evidence development” (CED) structure for determination of subsequent treatment strategy for the following solid tumor types:

- Brain; **OR**,
- Pancreas; **OR**,
- Prostate; **OR**,
- Small cell lung; **OR**,
- Soft tissue sarcoma; **OR**,
- Testes; **OR**,
- All other cancers

Thyroid: PET (FDG) scans are considered medically necessary and a covered benefit for the determination of subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by

thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10 ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are covered through the CED structure.

CODING

Covered CPT® Codes

- 78608** Brain imaging, positron emission tomography (PET); metabolic evaluation
- 78609** Brain imaging, positron emission tomography (PET); perfusion evaluation
- 78811** Positron emission tomography (PET) imaging; limited area
- 78812** Positron emission tomography (PET) imaging; skull base to mid-thigh.
- 78813** Positron emission tomography (PET) imaging; whole body.
- 78814** Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area.
- 78815** Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; Skull base to mid-thigh.
- 78816** Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; Whole body.

ICD-9-CM Procedure Codes

- 92.01** Radioisotope Scan of Thyroid
- 92.04** Radioisotope Scan Bowel, Gastrointestinal, Pancreatic
- 92.11** Radioisotope Scan Cerebral
- 92.12** Radioisotope Scan Head
- 92.14** Radioisotope Scan Bone
- 92.15** Radioisotope Scan Lung, Pulmonary
- 92.18** Radioisotope Scan Total Body
- 92.19** Radioisotope Scan of Other Sites

HCPCS Codes

- G0235** PET imaging, any site, not otherwise specified
- G0252** PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
- A9552** Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries

Covered ICD-9-CM Diagnosis Codes

- 140.0 – 140.9** Malignant Neoplasm of Lip
- 141.0 – 141.9** Malignant Neoplasm of Tongue
- 142.0 – 142.9** Malignant Neoplasm of Major Salivary Glands
- 143.0 – 143.9** Malignant Neoplasm of Gum
- 144.0 – 144.9** Malignant Neoplasm of Floor of Mouth
- 145.0 – 145.9** Malignant Neoplasm of Other and Unspecified Parts of Mouth
- 146.0 – 146.9** Malignant Neoplasm of Oropharynx
- 147.0 – 147.9** Malignant Neoplasm of Nasopharynx
- 148.0 – 148.9** Malignant Neoplasm of Hypopharynx
- 149.0 – 149.9** Malignant Neoplasm of other and ill-defined sites within the lip, oral cavity and pharynx
- 150.0 – 150.9** Malignant Neoplasm of Esophagus

153.0 – 153.9	Malignant Neoplasm of Colon
154.0 – 154.9	Malignant Neoplasm of Rectum, Rectosigmoid junction, Anal Canal and Anus Unspecified
157.0 – 157.9	Malignant Neoplasm of Pancreas
160.0 – 160.9	Malignant Neoplasm of Nasal Cavities, Middle Ear and Accessory Sinuses
161.0 – 161.9	Malignant Neoplasm of Larynx
162.0 – 162.9	Malignant Neoplasm of Trachea, Bronchus and Lung
172.0 – 172.9	Malignant Melanoma of Skin
174.0 – 174.9	Malignant Neoplasm of Female Breast
175.0 – 175.9	Malignant Neoplasm of Male Breast
180.0 – 180.9	Malignant Neoplasm of Cervix Uteri
183.0 – 183.9	Malignant Neoplasm of Ovary
186.0 – 186.9	Malignant Neoplasm of Testes
191.0 – 191.9	Malignant Neoplasm of Brain
193.0	Malignant Neoplasm of Thyroid
195.0	Malignant Neoplasm of Head, Face and Neck
200.00 - 200.88	Lymphosarcoma and Reticulosarcoma
201.00 - 201.98	Hodgkin's Disease
202.00 - 202.98	Other Malignant Neoplasms of Lymphoid and Histiocytic tissue
203.00	Multiple Myeloma Failed Remission
203.02	Multiple Myeloma In Relapse
209.00 - 209.69	Neuroendocrine tumors
V70.7+	Examination of Participant in Clinical Trial <u>+Only assigned for participants registered in CMS Approved Clinical Trial</u>

Non-Covered ICD-9-CM Diagnosis Codes

185 Malignant Neoplasm of Prostate

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed - N/A

Government Agencies, Professional and Medical Organizations

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HISTORY AND REVISIONS

Date	Action
5/3/2012	<ul style="list-style-type: none">• Retired by MPC; covered by CareCore criteria.
4/5/2012	<ul style="list-style-type: none">• Approved by MPC. Added information from CMS re: coverage for initial and subsequent treatment strategies; coverage remains unchanged.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/2/2011	<ul style="list-style-type: none">• Approved by MPC. No changes.