

# Healthcare Operations Utilization Management Protocol

Positron Emission Tomography (PET)/Fluorodeoxyglucose Positron Emission Tomography (FDG-PET)

HEALTH PLAN OF NEVADA, INC.™ SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.®

Number  
RAD023

## Approved for Commercial, Medicare, & Medicaid

For Sierra HealthCare Options products, please review plan documents prior to issuing a determination.

For Sierra Health & Life Private Fee-for-Service Medicare plans, Advance Coverage Determinations are based on Medicare guidelines. Please review Medicare guidelines before making Advance Coverage Determination if requested.

## Requires Medical Director Review Approval

### Description:

Positron emission tomography (PET) is a three-dimensional (3-D) noninvasive nuclear imaging technique for detection of normal and abnormal function of living tissue. In contrast with traditional diagnostic techniques, such as x-rays, computed tomography (CT) scans, magnetic resonance imaging (MRI) and ultrasonography (US), which produce images of the body's anatomy, PET produces images of the body's basic biochemistry or function. The use of PET imaging in cancer patients is based on the premise that metabolic processes and blood flow in tumors typically differ from those of normal adjacent tissue and the radiolabeled sugars or other tracers, such as 18-fluoro-2-deoxyglucose, injected during a PET procedure become concentrated within the cancer cells.

### Covered Indications:

- I. Cardiac Indications** - Positron emission tomography (PET) is considered medically necessary for the following cardiac indications:
  - A. Evaluation of Coronary Artery Disease
  - B. Assessment of Myocardial Viability
  
- II. Neurological Indications** - Positron emission tomography (PET) is considered medically necessary for the following neurological indications:
  - A. FDG PET for Dementia and Neurodegenerative Diseases  
*Note: FDG-PET for Dementia and Neurodegenerative Diseases approved for **MEDICARE ONLY**; not covered for Commercial and Medicaid.*
  - B. FDG PET for Refractory Seizures
  
- III. Oncologic Indications** - Positron emission tomography (PET) is considered medically necessary for the following oncologic indications, when the following general criteria (See Section IV) and disease-specific criteria (See Section IV) for diagnosis, staging, restaging, or monitoring are met:

\* These protocols are to be used as guidelines in the decision-making process and do not represent standards of care of any individual patient. They are proprietary documents and may not be copied or distributed without express permission.

- A. Breast cancer
- B. Cervical cancer
- C. Colorectal cancer
- D. Esophageal cancer
- E. Head and Neck cancers (excluding cancers of the central nervous system)
- F. Lymphoma
- G. Melanoma
- H. Non-small cell lung cancer
- I. Solitary Pulmonary Nodule
- J. Thyroid cancer (excluding metastatic thyroid cancer)

*Note: PET is considered medically necessary for the following oncologic indications for **MEDICARE** individuals who are enrolled in specifically defined prospective clinical studies or trials:*

- A. Brain cancer
- B. Ovarian cancer
- C. Pancreatic cancer
- D. Small cell lung cancer
- E. Soft tissue sarcoma
- F. Testicular cancer

#### IV. General Criteria

- A. **Diagnosis** - PET is considered medically necessary in situations in which the PET results may assist in:
  - 1. Avoiding an invasive diagnostic procedure; or
  - 2. Determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made before the performance of PET scanning. PET scans following a tissue diagnosis are generally performed for the purpose of staging, not diagnosis.

- B. Staging** - PET is considered medically necessary in situations in which clinical management of the member would differ depending on the stage of the cancer identified and *either*:
1. The stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); *or*
  2. The use of PET would potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.
- C. Restaging** - PET is considered medically necessary for restaging in the following situations:
1. After completion of treatment for the purpose of detecting residual disease; and/or
  2. Detecting suspected recurrence; and/or
  3. Determining the extent of recurrence or metastasis; and/or
  4. Determining the extent of a known recurrence; and/or
  5. If it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member. Restaging applies to testing after a course of treatment is completed, and is medically necessary subject to the conditions above.
- D. Monitoring Response to Treatment** - Refers to the use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated). It is not considered medically necessary except for breast cancer.

## V. Disease-specific Indications

### A. Cardiac Indications

1. Evaluation of Coronary Artery – PET is considered medically necessary for the following disease-specific cardiac indications:
  - a. PET scans using rubidium-82 (Rb-82) or N-13 ammonia performed at rest or with pharmacological stress for noninvasive imaging of the perfusion of the heart for the diagnosis and management of members with known or suspected coronary artery disease, provided such scans meet *either* one of the two following criteria:

- i. The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- ii. The PET scan, whether at rest alone, or rest with stress, is used following an inconclusive SPECT scan (i.e., the results of the SPECT are equivocal, technically uninterpretable, or discordant with a member's other clinical data).

*Note: In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the member.*

2. Assessment of Myocardial Viability –PET is considered medically necessary for the following disease-specific cardiac indications:
  - a. The identification of members with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests such as FDG PET distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect the management decisions in members with ischemic cardiomyopathy and left ventricular dysfunction; or
  - b. The determination of myocardial viability following an inconclusive SPECT; or
  - c. FDG PET scan for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT; or
  - d. In the event an individual receives a SPECT test with inconclusive results, a PET scan *may* be covered. However, if an individual receives a FDG PET study with inconclusive results, a follow up SPECT is not considered medically necessary.

## **B. Neurologic Indications**

1. Dementia and Neurodegenerative Diseases – Approved for **MEDICARE ONLY**, not covered for Commercial and Medicaid product lines. FDG PET is considered medically necessary for the following disease-specific neurologic indications:
  - a. The differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer’s disease (AD) under specific requirements; OR, its use in a CMS approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases.

- b. A recent diagnosis of dementia and a documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD and who have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.
- c. The following additional conditions must be met:
  - i. The member's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD.
  - ii. The individual has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the member and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by a cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);
  - iii. The evaluation of the member has been conducted by a physician experienced in the diagnosis and assessment of dementia;
  - iv. The evaluation of the member did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through FDG PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;
  - v. The FDG PET scan is performed in an accredited facility and the scan is read by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;
  - vi. A brain single photon emission computed tomography (SPECT) or FDG PET scan has not been obtained for the same indication. (The indication can be considered to be different in members who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed

above, including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or FDG PET scan must have been inconclusive or in the case of SPECT, difficult to interpret due to immature or inadequate technology;

- vii. The referring provider has documented the appropriate evaluation of the member and has established the medical necessity of an FDG PET scan by ensuring the member's medical record contains the following information:
  - 1) Date of onset of symptoms;
  - 2) Diagnosis of clinical syndrome (normal aging, mild cognitive impairment (MCI); mild, moderate or severe dementia);
  - 3) Mini mental status exam (MMSE) or similar test score;
  - 4) Presumptive cause (possible, probably, uncertain AD);
  - 5) Any neuropsychological testing performed;
  - 6) Relevant laboratory tests (B12, thyroid hormone); and
  - 7) Number and name of prescribed medications
- d. FDG PET scan is considered medically necessary in members with mild cognitive impairment or early dementia as part of a qualifying clinical trial.

*Note: FDG PET is considered experimental or investigational for members with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probably AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease).*

- 2. Refractory Seizures - FDG-PET is considered medically necessary only for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

### C. Oncologic Indications

- 1. **Brain Cancer** - Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials.
- 2. **Breast Cancer** - FDG-PET scans are considered medically necessary (as an adjunct to other imaging modalities) for members with breast cancer for the following indications, where general medical necessity criteria for oncologic indications (listed above) are met:

- a. Staging members with distant metastases or restaging members with loco-regional recurrence or metastases; *or*
- b. Monitoring tumor response to treatment for persons with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

*Note: FDG-PET is considered experimental and investigational for the initial diagnosis of breast cancer and for the staging of axillary lymph nodes.*

3. **Cervical Cancer** - FDG-PET scans are considered medically necessary for the detection of pre-treatment metastases in women who are newly diagnosed with cervical cancer and have negative conventional imaging (CT or MRI).

*Note: PET scans are considered experimental and investigational for the evaluation of any other indications not listed as medically necessary in this protocol.*

#### 4. **Colorectal Cancer**

- a. FDG PET scans are considered medically necessary for diagnosis\*, staging, and/or restaging of colorectal cancer when the general criteria for oncologic indications (listed above) are met. Medical evidence supports the use of FDG PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting the treatment regimen. Use of FDG PET is also supported in evaluating recurrent colorectal cancer where the member presents with clinical signs or symptoms of recurrence.
- b. FDG PET for monitoring response to treatment for colorectal cancer is considered medically necessary only when provider and individual are participating in qualifying clinical trials/studies.

*\*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of colorectal cancer is rarely considered medically necessary.*

5. **Esophageal Cancer** - FDG PET is considered medically necessary for the diagnosis\*, staging and/or re-staging and monitoring of esophageal carcinoma when general medical necessity criteria for oncologic indications (listed above) are met. Medical evidence is present to support the use of FDG PET in pre-surgical staging of esophageal cancer.

*\*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of esophageal cancer is rarely considered medically necessary.*

## 6. Head and Neck Cancers

- a. FDG-PET scans are considered medically necessary for the diagnosis, staging, and restaging of head and neck cancers, excluding cancers of the central nervous system (CNS) when general criteria for oncologic indications (listed above) are met.
- b. The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Persons with head and neck cancers may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Persons with cancer of the head and neck are left with two options, either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET scanning attempts to reveal the site of primary tumor to prevent adverse effects of random biopsies or unneeded radiation.

*Note: PET scans of the CNS are considered experimental and investigational.*

## 7. Lymphoma

- a. FDG PET scans are considered medically necessary for the diagnosis\*, staging and restaging of lymphoma when the general criteria for oncologic indications (listed above) are met.
- b. FDG PET for monitoring response to treatment for lymphoma is considered medically necessary for **Medicare individuals only** when provider and individual are participating in qualifying clinical trials/studies.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of lymphoma is rarely considered medically necessary.*

## 8. Melanoma

- a. FDG-PET scans are considered medically necessary for the diagnosis\*, staging, and restaging of melanoma when the general criteria for oncologic indications (listed above) are met.

*\* Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of melanoma is rarely considered medically necessary*

- b. FDG PET for monitoring response to treatment for lymphoma is considered medically necessary for **Medicare individuals only** when provider and individual are participating in qualifying clinical trials/studies.
  - c. FDG PET is considered medically necessary for members with recurrent melanoma prior to surgery for tumor evaluation.
  - d. FDG PET is considered experimental and investigational and *not* medically necessary for use in evaluating regional nodes in persons with melanoma.
9. **Non-Small Cell Lung Carcinoma (NSCLC)** - FDG-PET scans are considered medically necessary for diagnosis, staging, and restaging of non-small cell lung carcinoma (NSLC) when the general criteria for oncologic indications (listed above) are met.
10. **Ovarian Cancer** - Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials.
11. **Pancreatic Cancer** - Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials.
12. **Small Cell Lung Cancer** - Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials.
13. **Soft Tissue Sarcoma** - Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials.
14. **Solitary Pulmonary Nodules (SPNs)**
- a. FDG-PET is considered medically necessary for the characterization of suspected SPNs when the general criteria for oncologic indications (above) are met *and* the following conditions are met:
    - i. An indeterminate or possibly malignant lesion, not exceeding 4 cm in diameter, has been detected (usually by CT); *and*
    - ii. A concurrent thoracic CT has been performed, which is necessary to ensure that the PET scan is properly coordinated with other diagnostic modalities.
  - b. The primary purpose of the PET scan of SPN should be to determine the likelihood of malignancy in order to plan the management of the member.

*Note: A biopsy is **not** considered medically necessary in the case of a negative PET scan for SPNs, because the member is presumed not to have a malignant lesion, based upon the PET scan results.*

*Note: In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans are **not** considered medically necessary if repeated within 90 days following a previous negative PET scan.*

## 15. Thyroid Cancer

- a. FDG-PET scans are considered medically necessary for the following situations when general criteria for oncologic indications (listed above) are met:
  - i. Restaging of recurrent or residual thyroid cancers of follicular cell origin previously treated by thyroidectomy and radioiodine ablation with an elevated or rising serum Tg greater than 10 ng/ml and negative I-131 whole body scintigraphy (whole body scan performed).
  - ii. Diagnosis, other staging, and restaging, restaging of medullary cell tumors and monitoring response to treatment only when provider and individual are participating in qualifying clinical trials/studies.
- b. FDG-PET is considered **not** medically necessary for determining which members with metastatic thyroid cancer are at highest risk for death, because this information is for informational purposes only and has not been demonstrated to alter member management.
- c. FDG-PET scans are considered experimental and investigational for other thyroid cancer indications, including:
  - i. Use for the initial staging of post-surgical thyroid cancer of cell types that concentrate I-131 poorly; *and/or*
  - ii. Use of FDG PET for re-staging of previously treated thyroid cancer of medullary cell origin in persons with an elevated serum calcitonin and negative standard imaging tests.

## 16. Testicular Cancer

- a. Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials.

## 17. All other Cancers not listed herein

- a. Covered for **Medicare individuals only** who are enrolled in specifically defined prospective clinical studies or trials based on the National Coverage Determination (NCD) for PET Scans, effective January 28, 2005.

### Non Covered Indications:

- I. PET is considered **not** medically necessary in the following situations for:

\* These protocols are to be used as guidelines in the decision-making process and do not represent standards of care of any individual patient. They are proprietary documents and may not be copied or distributed without express permission.

- A. Routine screening of asymptomatic members, regardless of the number and severity of risk factors applicable to the member. Therefore, the use of PET in the diagnosis of lymphoma, esophageal carcinoma, colorectal cancers, and melanoma is rarely considered medically necessary.
- B. Evaluation of soft tissue sarcoma, dementia or other neurodegenerative diseases and other indications not listed as medically necessary in this policy.

### Review History:

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Corporate Medical Affairs Committee Approval Dates: 2/20/03, 6/26/03, 2/19/04, 4/21/05, 9/21/06, 12/20/07, 9/18/08, 12/3/08

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