December 4, 2020

William Shrank, MD, MSHS
Chief Medical Officer
Humana, Inc.
500 W Main Street
Louisville, KY 40202

Dear Dr. Shrank:

On behalf of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), I am writing to strongly object to Humana's recent policy decision [Policy Number: HCS-0506-010] to refuse coverage for hybrid PET/CT (CPT® codes 78814-78816) and SPECT/CT (CPT® codes 78830, 78832) on the basis they are "experimental/ investigational" and "not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature." The revised policy, to take effect February 4, 2021 reads:

> Humana members may NOT be eligible under the Plan for PET with
> concurrently acquired CT for any indications other than those listed above,
> including, but not limited to:
> > • Cardiac indications;[1]
> > • Gastric or esophageal oncologic indications; OR
> > • Neurologic indications; OR
> > • Total body PET/CT (uEXPLORER) for screening (e.g. cancer)
> . . .
> Humana members may NOT be eligible under the Plan for the following for any
> indications:
> > • SPECT/CT

SNMMI is a nonprofit scientific and professional organization that promotes the science, technology and practical application of nuclear medicine and molecular imaging. SNMMI's 16,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research and practice.

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[1] SNMMI responded to Humana's decision to not cover PET-CT for cardiac indications in a letter dated November 13, 2020. This letter addresses the other exclusions in Humana's new policy decision.

PET/CT with FDG has a well-established role in initial evaluation and response assessment of esophageal cancers and cancers of the gastroesophageal junction,[2] and this has been affirmed by national CMS coverage policies. In addition, several neurologic indications are appropriate for PET/CT imaging including the on-label indication for the specific radiopharmaceutical.[3] While screening low-risk patients for cancer by PET is not routine practice, the appropriateness of evaluating high-risk patients for cancer is defined by the clinical context and the clinical question. Non-coverage for hybrid PET/CT denies patient access to standard-of-care testing required to make life-saving clinical decisions. Furthermore, our recommendations regarding the role of PET/CT have been accepted by the Centers of Medicare and Medicaid Services (CMS), the American Medical Association (AMA) RVS Update Committee (RUC) and multiple payers.

A multi-disciplinary appropriate use criteria (AUC) document[4] published by SNMMI states, "PET/CT provides combined anatomic and physiologic (glucose metabolism) information that may be used for initial diagnosis, staging, restaging, treatment response assessment, and prognosis in patients with cancer. Moreover, PET information can contribute significantly when other imaging modalities are equivocal."

The publication of various peer-reviewed documents has validated the role of hybrid PET/CT for several oncologic indications and led to reimbursement by CMS, and most other payers, for those procedures with Category I codes. Precise pretherapy staging, important in choosing the best available therapy for patients with esophageal and gastroesophageal cancers, makes it essential to use FDG PET/CT and is recommended by National Comprehensive Cancer Network (NCCN) guidelines to exclude metastatic disease.[5,6] For similar reasons, FDG PET/CT evaluation is also recommended in gastric cancers (excluding T1 disease).[7] Several studies assessing response to therapy for esophageal cancer have shown that the FDG uptake after neoadjuvant chemotherapy correlates with histopathologic response and long-term

[2] Lococo F., Cesario A., Margaritora S., & Treglia G. (2020) Evidence-based data on PET in Esophageal Tumors. *Evidence-based Positron Emission Tomography: Summary of Recent Meta-analyses on PET.* Springer Nature Switzerland AG. pp. 47-48. https://doi.org/10.1007/978-3-030-47701-1

[3] Miceli A., Capitanio S., Donegani M.I., Raffa S., Borra A., Bauckneht M., & Morbelli S. (2020) Evidence-Based PET for Neurological Diseases. *Evidence-based Positron Emission Tomography: Summary of Recent Meta-analyses on PET.* Springer Nature Switzerland AG. pp. 125-33. https://doi.org/10.1007/978-3-030-47701-1

[4] Hossein J., Colletti P.M., Delgado-Bolton R., Esposito G., Krause B.J., Iagaru1 A.H., Nadel H., Quinn D.I., Rohren E., Subramaniam R.M., Zukotynski K., Kauffman J., Ahuja S., & Griffeth L. Appropriate Use Criteria for FDG PET/CT in Restaging and Treatment Response Assessment of Malignant Disease. (2017). *J Nucl Med.* 58(12), pp. 2026-2037. doi: 10.2967/jnumed.117.197988

[5] Fletcher J.W., Djulbegovic B., Soares H.P., et al. (2008). Recommendations on the use of 18F-FDG PET in oncology. *J Nucl Med.* 49, pp. 480–508.

[6] National Comprehensive Cancer Network. (2020). *Esophageal and Esophagogastric Junction Cancers (version 4.2020).* Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf.

[7] National Comprehensive Cancer Network. (2020). *Gastric Cancer (version 3.2020).* Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf.

prognosis.[8,9,10] Therefore, assessment with FDG PET/CT scan is recommended 5-8 weeks after the completion of preoperative therapy and prior to surgery.[11]

FDG PET/CT is also well-established method for assessment of brain metabolism and function in people with dementia. Several peer-reviewed studies have demonstrated the high sensitivity and specificity of FDG PET/CT scans to differentiate Alzheimer's dementia (AD) from mild cognitive impairment (MCI) or non-AD dementia, and these scans are reimbursed by CMS.[12] A new FDA-approved PET radiopharmaceutical, F-18 Flortaucipir, indicated for imaging tau protein, a primary marker of AD, is already starting to enter clinical practice for definitive assessment of AD. Moreover, results from the recent Imaging Dementia – Evidence for Amyloid Scanning (IDEAS) study among Medicare beneficiaries with MCI or dementia of unknown etiology showed that use of amyloid PET imaging is associated with substantial changes in clinical management of 60.2% patients with MCI and 63.5% patients with dementia.[13] Overall, there is considerable evidence that PET radiopharmaceuticals are useful in assessment of selected patients with cognitive impairment. Also, negative amyloid PET scan results can be useful for ruling out Alzheimer's pathology in people with cognitive impairment when the cause is uncertain and show that an individual is unlikely to develop AD during the next few years.[14] These are important clinical implications that have been substantiated by evidence and warrant the use of brain PET/CT in appropriate clinical settings.

Nearly all current commercially available PET scanners are now hybrid PET/CT systems, and these newer systems have numerous other improvements compared to older models. Hybrid PET/CT offers various benefits: Integrated PET/CT results in reduced scan time and reduced patient motion leading to higher quality images and CT attenuation can be customized for body habitus, again contributing to a higher quality image. For oncologic PET, there is also extensive medical literature documenting the additional diagnostic value contributed by review of the CT

[8] Ott K, Weber W.A., Lordick F., et al. (2006). Metabolic imaging predicts response, survival, and recurrence in adenocarcinomas of the esophagogastric junction. *J Clin Oncol.* 24, pp. 4692–4698.

[9] van Westreenen H.L., Westerterp M., Bossuyt P.M.M., et al. (2004). Systematic review of the staging performance of 18F-fluorodeoxyglucose positron emission tomography in esophageal cancer. *J Clin Oncol.* 22, pp. 3805- 3812.

[10] Munden R.F., Macapinlac H.A., Erasmus J.J. (2006) Esophageal cancer: the role of integrated CT-PET in initial staging and response assessment after preoperative therapy. *J Thorac Imaging.* 21, pp. 137-145.

[11] National Comprehensive Cancer Network. (2020). *Esophageal and Esophagogastric Junction Cancers (version 4.2020).* Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf.

[12] Bloudek L.M., Spackman D.E., Blankenburg M., Sullivan S.D. (2011) Review and meta-analysis of biomarkers and diagnostic imaging in Alzheimer's disease. J Alzheimers Dis. *26*(4), pp. 627-45.

[13] Livingston G., Huntley J., Sommerlad A., Ames D., Ballard C., Banerjee S., Brayne C., Burns A., Cohen-Mansfield J., Cooper C., Costafreda S.G., Dias A., Fox N., Gitlin L.N., Howard R., Kales H.C., Kivimäki M., Larson E.B., Ogunniyi A., Orgeta V., Ritchie K., Rockwood K., Sampson E.L., Samus Q., Schneider L.S., Selbæk G., Teri L., & Mukadam N. (2020) Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *Lancet. 396*(10248), pp. 413-446.

[14] Rabinovici G.D., Gatsonis C., & Apgar C. (2019). Association of amyloid positron emission tomography with subsequent change in clinical management among Medicare beneficiaries with mild cognitive impairment or dementia. *JAMA.* 321, pp.1286–1294.
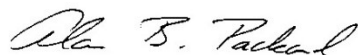
attenuation map image.[15,16,17] With this policy, Humana is thus requiring its members to have oncologic PET studies using less advanced instrumentation.

Single photon emission computed tomography (SPECT) scanners have seen similar improvements to those found in new PET scanners; but despite these improvements, SPECT/CT will succumb to the same fate as hybrid PET/CT as of February, 2021, if this decision is not reversed.[18] SPECT/CT imaging has been found to be more sensitive than SPECT alone, as it combines the functional data pf SPECT with anatomical details of CT thus providing higher spatial resolution images and a superior three-dimensional localization of lesions. SPECT/CT helps by improving the diagnostic capacity of imaging with better lesion conspicuity, reducing false positive interpretation of scans, and better characterization of indeterminate lesions as compared to SPECT alone.

In summary, SNMMI strongly disagrees with Humana's proposed coverage determination to exclude hybrid PET imaging for gastric or esophageal oncologic indications, neurologic indications, and whole-body screening as 'experimental' and 'investigational'. There is ample evidence in the published literature as well as published clinical guidelines and appropriate use criteria supporting the use of hybrid PET/CT that is widely accepted by many payers, including CMS, and by the AMA.

Implementing this revised policy will deny patients access to state-of-the-art imaging procedures that are the standard-of-care for making potentially life-saving clinical decisions. We respectfully insist this new policy be reversed. If you need further information, please contact Sukhjeet Ahuja, Senior Director of Health Policy and Quality, at sahuja@snmmi.org or (703) 326-1195.

Sincerely,

Alan B. Packard, PhD
President, SNMMI

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[15] Beyer T., Townsend D.W., Brun T., Kinahan P.E., Charron M., Roddy R., Jerin J., Young J., Byars L., & Nutt R. (2000) A combined PET/CT scanner for clinical oncology. *J Nucl Med. 41*(8), 1369-79.
[16] Bar-Shalom R., Yefremov N., Guralnik L., Gaitini D., Frenkel A., Kuten A., Altman H., Keidar Z., & Israel O. (2003) Clinical performance of PET/CT in evaluation of cancer: additional value for diagnostic imaging and patient management. *J Nucl Med. 44*(8), pp. 1200-9.
[17] Cohade C. & Wahl R.L. (2003) Applications of positron emission tomography/computed tomography image fusion in clinical positron emission tomography-clinical use, interpretation methods, diagnostic improvements. *Semin Nucl Med. 33*(3), pp. 228-37.

[18] *See* Israel O., Pellet O., Biassoni L., De Palma D., Estrada-Lobato E., Gnanasegaran G., Kuwert T., la Fougère C., Mariani G., Massalha S., Paez D., & Giammarile F. (2019) Two decades of SPECT/CT - the coming of age of a technology: An updated review of literature evidence. *Eur J Nucl Med Mol Imaging. 46*(10), pp. 1990-2012. doi:10.1007/s00259-019-04404-6. Epub 2019 Jul 4. PMID: 31273437; PMCID: PMC6667427.