SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

*** Transmitted by USPS and Email to: S034590@Aetna.com***

April 18, 2018

Harold L. Paz, M.D., M.S.
Executive Vice President and Chief Medical Officer
Aetna Inc.
151 Farmington Avenue
Hartford, CT 06156

Re: Aetna's Positron Emission Tomography (PET) Coverage Policy Number 0071 – Reviewed March 30, 2018 on gallium Ga 68 Dotatate.

Dear Dr. Paz,

The Society of Nuclear Medicine and Molecular Imaging's (SNMMIs) more than 15,000 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.

We recommend that Aetna reconsider and change its PET Coverage Policy in relationship to Gallium Ga 68 dotatate PET. The policy may be found at: http://www.aetna.com/cpb/medical/data/1_99/0071.html and it states:

> "39. Gallium Ga 68 dotatate PET:
> Aetna considers gallium Ga 68 dotatate PET (NETSPOT) experimental and investigational for neuroendocrine tumors and for all other indications."

We suggest that Aetna reconsider these coverage policies because they do not reflect recent evidence. In June 2016, the US Food and Drug Administration (FDA) approved the use of this PET imaging for the localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients. Additionally, Aetna's policy is inconsistent with the recommendations contained in the updated guidelines of the National Comprehensive Cancer Network (NCCN) Guideline®, and multi-stakeholder appropriate use criteria (AUC).

The NCCN's updated guidelines for neuroendocrine tumor management include Gallium Ga 68 dotatate PET. The updated guideline states that "Gallium Ga 68 dotatate PET has been made the preferred somatostatin receptor-based imaging modality." This radiopharmaceutical is mentioned many other times throughout the document. The document is available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf after a free registration on that website.

Additionally, SNMMI recently published the "Appropriate Use Criteria for Somatostatin Receptor PET Imaging in Neuroendocrine Tumors". It was published online on October 12, 2017 and in print in January 2018. Twelve large

organizations were represented in the development of that document.[1] Copies of the AUC are available at: http://snmmi.files.cms-plus.com/Quality/jnm202275_pv2.pdf. The AUC refers to Ga 68-dotatate and another radiopharmaceutical Ga 68-DOTATOC as somatostatin receptor (SSTR) PET. The document reports that SSTR PET is appropriate or may be appropriate in many scenarios for patients with neuroendocrine tumors. This document also states that these agents have several benefits over 111In-pentetreotide, including improved detection sensitivity, improved patient convenience due to the 2-h length of the study, decreased radiation dose, decreased biliary excretion due to earlier imaging after radiotracer administration, and the ability to quantify uptake.

Aetna's policy on Tumor Scintigraphy dated 4/11/2018 finds however that "an OctreoScan, using octreotide (Sandostatin) tagged with radiolabeled 111-Indium-pentetreotide, medically necessary for the diagnosis and staging of persons with primary and metastatic neuroendocrine tumors bearing somatostatin receptors." Aetna's policies are in direct conflict with the AUC and the NCCN guidelines.

We know that Aetna prides itself on allowing its patients access to state of the art care and we trust that you will consider revising this policy. If you or your staff would like to discuss this coverage policy further, please contact Wayne Powell, Director of Health Policy and Regulatory Affairs at 703.326.1182 or wpowell@snmmi.org.

Thank you for the consideration of these comments.

Sincerely,

Munir Ghesani

Munir Ghesani, MD, FACNM
Chair Advocacy Domain
SNMMI

[1] Society of Nuclear Medicine and Molecular Imaging, Reston, Virginia; American College of Radiology, Reston, Virginia; American Society of Clinical Oncology, Alexandria, Virginia; North American Neuroendocrine Tumor Society, European Association of Nuclear Medicine, Endocrine Society, Society of Surgical Oncology, National Comprehensive Cancer Network, NorCal CarciNET, American College of Physicians, American Gastroenterological Association and Society of Interventional Oncology.