

Fred Gattas, Pharm.D., BCNP, FAPhA
Curium
2703 Wagner Place
Maryland Heights, MO 63043
314-595-4659
Fred.gattas@curiumpharma.com

Date of Request: 07Oct2019
NCCN Guidelines Panel: Neuroendocrine Tumors Panel

On behalf of Curium, I respectfully request the National Comprehensive Cancer Network (NCCN) Neuroendocrine Tumors Panel to review the enclosed data for inclusion of copper Cu 64 dotatate injection as an example of PET somatostatin receptor-based imaging by removing the “ie” for 68Ga Dotatate and including “eg” to denote an example for the NCCN Clinical Practice Guidelines in Oncology Neuroendocrine and Adrenal Tumors version 1.2019-March 5, 2019 and also include 64Cu-dotatate as an example. I would considerately ask that this is also updated in similar spirit for the corresponding NCCN Evidence Blocks guideline as well as the NCCN Guidelines for Patients for Neuroendocrine Tumors 2018.

Specific Changes: For all locations, replacing the definition of somatostatin receptor-based imaging of:

1. *Somatostatin receptor-based imaging (ie, 68Ga-dotatate imaging preferred [PET/CT or PET/MRI] or somatostatin receptor scintigraphy) with*

Somatostatin receptor-based imaging (eg, 68Ga-dotatate or 64Cu-dotatate imaging preferred [PET/CT or PET/MRI] or somatostatin receptor scintigraphy)

And for all locations, replacement of the imaging footnote:

2. *Gallium-68 dotatate (68Ga-dotatate) PET/CT or PET/MRI is more sensitive than somatostatin receptor scintigraphy with SPECT/CT for determining somatostatin receptor status... with*

Gallium-68 dotatate (68Ga-dotatate), Copper-64 dotatate (64Cu-dotatate) PET/CT, or PET/MRI is more sensitive than somatostatin receptor scintigraphy with SPECT/CT for determining somatostatin receptor status...

FDA Clearance: copper Cu 64 dotatate injection for intravenous use is not yet FDA approved but has been submitted for approval. It is understood that the panel will not act on the submission before FDA approval.

Rationale: While PET somatostatin imaging is the preferred imaging modality over SPECT imaging when available, Gallium-68 dotatate (68Ga-dotatate) is no longer the only moiety that fulfills that

definition. It is expected that copper Cu 64 dotatate injection will be widely available to also fulfil that definition and has the same ligand as the current listed drug.

The following articles are submitted in support of this proposed change in addition to the Clinical Summary that was submitted to the FDA for approval.

1. Pfeifer A, Knigge U, Mortensen J, et al. Clinical PET of neuroendocrine tumors using 64Cu-DOTATATE: first-in-humans study. *J Nucl Med.* 2012;53:1207–1215.
2. Pfeifer A, Knigge U, Binderup T, et al. 64Cu-DOTATATE PET for neuroendocrine tumors: a prospective head-to-head comparison with 111In-DTPA-octreotide in 112 patients. *J Nucl Med.* 2015;56:847–854.
3. Johnbeck C, Knigge U, Loft A, et al. Head-to-Head Comparison of 64Cu-DOTATATE and 68Ga-DOTATOC PET/CT: A Prospective Study of 59 Patients with Neuroendocrine Tumors. *J Nucl Med.* 2017;58:451-457
4. 2.5 Clinical Overview NDA Submission of 64Cu-DOTATATE
5. Kjaer A, Binderup T, Johnbeck C, et al. (2019, October) *64Cu DOTATATE somatostatin receptor imaging in neuroendocrine tumor patients: experience from more than 1,200 patients.* Poster session presented at the Annual Symposium of the North American Neuroendocrine Tumor Society, Boston, MA.

Thank you for your time and consideration. Sincerely,

Fred Gattas, Pharm.D., BCNP, FAPhA
Director of Medical and Safety Affairs-North America