FOR IMMEDIATE RELEASE January 26, 2021

RadioMedix & Curium Announce Permanent HCPCS Code for Detectnet™ (copper Cu 64 dotatate injection)

(St. Louis, MO – January 26, 2021) - RadioMedix Inc. and its commercial partner Curium announced today that the Centers for Medicare & Medicaid Services (CMS) has granted Detectnet a permanent Healthcare Common Procedure Coding System (HCPCS) code – A9592 – effective April 1, 2021. The descriptor for this product specific A code will be: Copper Cu-64, dotatate, diagnostic, 1 millicurie. Beginning on April 1, 2021, this code will be available to bill claims for Medicare patients in non-hospital imaging centers and for private insurance patients in all imaging facilities. This information follows the recent news that Detectnet was granted Transitional Pass-Through Status by CMS (C9068) effective January 1, 2021. C9068 is used to bill Detectnet for Medicare patients seen in the hospital outpatient department.

“Once in effect, having both a permanent HCPCS code and Transitional Pass-Through Status will simplify the reimbursement process for all imaging centers that desire to use Detectnet,” said Curium CEO, North America, Dan Brague. “We remain focused on helping physicians and patients in the neuroendocrine community and anticipate the simplified reimbursement process may increase access to the product. We would like to thank CMS for their timely release of both codes, especially in light of the current COVID-19 pandemic.”

“The response to Detectnet from the neuroendocrine community is outstanding,” said Ebrahim Delpassand, MD, CEO of RadioMedix. “The Phase III results demonstrate the clinical sensitivity, specificity, and accuracy of Detectnet. Further, the 12.7 hour half-life of Detectnet enables it to be produced centrally and shipped to sites throughout the U.S. The HCPCS code and Transitional Pass-Through Status should now provide access to patients nationwide.”

About Detectnet

INDICATIONS

Detectnet is indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult patients.

IMPORTANT RISK INFORMATION

WARNINGS AND PRECAUTIONS

Radiation Risk

Diagnostic radiopharmaceuticals, including Detectnet, contribute to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

Risk for Image Misinterpretation
The uptake of copper Cu 64 dotatate reflects the level of somatostatin receptor density in NETs, however, uptake can also be seen in a variety of other tumors that also express somatostatin receptors. Increased uptake might also be seen in other non-cancerous pathologic conditions that express somatostatin receptors including thyroid disease or in subacute inflammation, or might occur as a normal physiologic variant (e.g. uncinate process of the pancreas).

A negative scan after the administration of Detectnet in patients who do not have a history of NET disease does not rule out disease.

ADVERSE REACTIONS

In clinical trials, adverse reactions occurred at a rate of < 2% and included nausea, vomiting and flushing. In published trials nausea immediately after injection was observed.

DRUG INTERACTIONS

Somatostatin Analogs
Non-radioactive somatostatin analogs and copper Cu 64 dotatate competitively bind to somatostatin receptors (SSTR2). Image patients just prior to dosing with somatostatin analogs. For patients on long-acting somatostatin analogs, a wash-out period of 28 days is recommended prior to imaging. For patients on short-acting somatostatin analogs, a washout period of 2 days is recommended prior to imaging.

USE IN SPECIFIC POPULATIONS

Pregnancy
All radiopharmaceuticals, including Detectnet, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. Advise a pregnant woman of the potential risks of fetal exposure to radiation from administration of Detectnet.

Lactation
Advise a lactating woman to interrupt breastfeeding for 12 hours after Detectnet administration in order to minimize radiation exposure to a breastfed infant.

Pediatric use
The safety and effectiveness of Detectnet have not been established in pediatric patients.

Geriatric use
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

OVERDOSAGE

In the event of a radiation overdose, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by reinforced hydration and frequent bladder voiding. A diuretic might also be considered.

Please see Full prescribing information by clicking here.

About RadioMedix

RadioMedix, Inc. is a clinical stage biotechnology company, based in Houston, Texas, focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring, and therapy of cancer. The company is commercializing radiopharmaceuticals for PET imaging and therapeutic (alpha and beta-labeled) radiopharmaceuticals. RadioMedix has also established contract service facilities for academic and industrial partners: Full cGMP manufacturing and analytical suites for human clinical trials, and commercial phase manufacturing of the radiopharmaceuticals, and probe development and small animal Molecular Imaging Facility for pre-clinical evaluation of radiopharmaceuticals in animal models. To learn more, visit www.radiomedix.com. For more information about this press release, please contact: media@radiomedix.com

About Curium

Curium is the world's largest nuclear medicine company. We develop, manufacture and distribute world-class radiopharmaceutical products to help patients around the globe. Our proven heritage combined with a pioneering approach are the hallmarks to deliver innovation, excellence and unparalleled service.

With manufacturing facilities across Europe and the United States, Curium delivers SPECT, PET and therapeutic radiopharmaceutical solutions for life-threatening diseases to over 14 million patients annually. The name 'Curium' honors the legacy of pioneering radioactive researchers Marie and Pierre Curie, after whom the radioactive element curium was named and emphasizes our focus on nuclear medicine. To learn more, visit curiumpharma.com. For more information about this press release, please contact Janet Ryan, media contact for Curium: janet@ryan-pr.com.

About Neuroendocrine Tumors

Neuroendocrine tumors (NETs) are a heterogeneous group of rare neoplasms that originate from neuroendocrine cells. These neoplasms occur mostly in the gastrointestinal tract, pancreas and liver, but can also occur in other tissues including lung, thymus and other uncommon sites such as cervix, heart and prostate. Most NETs strongly express somatostatin receptors (SSTRs).

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