



FOR IMMEDIATE RELEASE

March 23, 2021

## **RadioMedix & Curium Announce Simplified Coding for Detectnet™ (copper Cu 64 dotatate injection)**

(St. Louis, MO – March 23, 2021) - RadioMedix Inc. and its commercial partner Curium announced today that the Centers for Medicare & Medicaid Services (CMS) has simplified the coding process for Detectnet. Effective April 1, 2021, all sites of care will use code A9592 to submit for reimbursement for all patients. While Transitional Pass-Through Status remains in effect for Detectnet, the current C9068 HCPCS code will be retired April 1, 2021. For services performed prior to April 1<sup>st</sup>, C9068 should continue to be used for Medicare patients at Hospital Outpatient Department Imaging Facilities. The descriptor for Detectnet remains: Copper Cu-64, dotatate, diagnostic, 1 millicurie.

“Once in effect, having one code for all patients regardless of the site of care will simplify the billing process for our customers,” said Curium Vice President of Sales, North America, Andy Farrow. “We remain focused on helping physicians and patients in the neuroendocrine community and anticipate this change to positively impact coding and billing procedures for all sites.”

“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 single HCPCS code is another step to simplifying the insurance billing process for imaging centers 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. uncinatate 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](http://www.radiomedix.com). For more information about this press release, please contact: [media@radiomedix.com](mailto: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](http://curiumpharma.com). For more information about this press release, please contact Janet Ryan, media contact for Curium: [janet@ryan-pr.com](mailto: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).