

Detectnet™ (copper Cu 64 dotatate injection)

Letter of Medical Necessity Template

INDICATIONS AND USAGE

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

IMPORTANT SAFETY 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.

Hypersensitivity Reactions

Hypersensitivity reactions following administration of somatostatin receptor imaging agents predominantly consisted of cutaneous reactions such as rash and pruritus. Reactions reversed either spontaneously or with routine symptomatic management. Less frequently hypersensitivity reactions included angioedema or cases with features of anaphylaxis.

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 washout 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 click [here](#) for full Prescribing Information.

[PHYSICIAN / PRACTICE LETTERHEAD]

[Practice name | Address | Telephone | Fax]

Place on the provider's own letterhead. Replace bracketed text and delete drafting instructions before submission.

[Date]

[Health plan name]

ATTN: [Utilization Management / Medical Director]

[Medical Director name, if known]

[Health plan address]

[City, State ZIP]

Fax: [Fax number]

Patient: [Patient full name]

DOB: [MM/DD/YYYY]

Member ID: [Member ID]

Group #: [Group number]

Case / Ref #: [If applicable]

Requested DOS: [Date]

Re: Letter of Medical Necessity for Detectnet™ (copper Cu 64 dotatate injection) with PET imaging

Diagnosis: [Diagnosis and ICD-10-CM code(s)] **Requested service:** HCPCS A9592 and PET/PET-CT CPT [code]

Dear Medical Director:

I am [physician name and credentials], a [medical specialty], treating [patient name]. I am requesting prior authorization and coverage for PET imaging with Detectnet, including the radiopharmaceutical and associated imaging service. Detectnet is FDA approved for use with PET to localize somatostatin receptor-positive neuroendocrine tumors in adult patients.

[Patient name] is a [age]-year-old adult with [diagnosis; primary site; pathology, grade, and stage; date of diagnosis; symptoms; and relevant biomarkers]. Prior evaluation includes [CT, MRI, prior nuclear imaging, pathology, and laboratory findings with dates]. These findings demonstrate [brief clinical summary and the unresolved diagnostic question].

The requested study is medically necessary to [localize the primary tumor; define disease extent; evaluate suspected recurrence or progression; clarify inconclusive or discordant findings; or answer another patient-specific question]. Existing information is insufficient because [explain the limitation of prior or conventional imaging]. The result will directly inform the proposed management plan by [describing the decision that will follow the scan, such as biopsy, surgery, selection or change of systemic or somatostatin receptor-targeted treatment, another intervention, or avoidance of an inappropriate procedure].

The anticipated adult dose is 148 MBq (4 mCi) intravenously, in accordance with the prescribing information and the qualified imaging facility's protocol. Detectnet is reported with HCPCS A9592 (copper Cu-64, dotatate, diagnostic, 1 millicurie); the ordered PET/PET-CT procedure is [CPT code and description] at [facility and setting] on [date]. The actual dose and billing units will be documented in the medical and billing records.

In my medical judgment, [Detectnet PET imaging is appropriate and medically necessary for this patient. Without it, the care team may be unable to localize disease accurately or make the next treatment decision using complete diagnostic information.] I respectfully request authorization and coverage for Detectnet and the associated PET/PET-CT service.

Please contact me at [telephone number] or [email address] if additional information or a peer-to-peer discussion is required. Thank you for your consideration.

Sincerely,

[Physician signature and date]

[Physician name, credentials] | NPI: [NPI] | Tax ID: [if required]

[Practice / facility] | [Telephone] | [Fax]

Enclosures: [Office note; pathology; laboratory results; prior imaging reports; imaging order; applicable payer materials; Detectnet Prescribing Information; other patient-specific support]