Subject: Lutathera® (lutetium Lu 177 dotatate) Policy

Effective Date: 08/2018

DESCRIPTION

Lutathera (lutetium Lu 177 dotatate) is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEPNETs), including foregut, midgut and hindgut neuroendocrine tumors in adults.

Lutathera is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure. Radiopharmaceuticals, including LUTATHERA, should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.

The recommended Lutathera dose is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. It is available in 370 MBq/mL (10 mCi/mL) single-dose vials. Long-acting somatostatin analogs (e.g., long-acting octreotide) should be discontinued at least 4 weeks prior to initiating Lutathera. Short-acting octreotide can be administered as needed, but should be discontinued at least 24 hours prior to initiating Lutathera. During Lutathera treatment, long-acting octreotide 30 mg should be administered intramuscularly between 4 to 24 hours after each Lutathera dose. Do not administer long-acting octreotide within 4 weeks of each subsequent dose. Long-acting octreotide 30 mg intramuscularly should be administered every 4 weeks after completed the fourth Lutathera dose either until disease progression or for up to 18 months following treatment initiation.

DEFINITIONS

Gastroenteropancreatic neuroendocrine tumor (GEP-NET): Carcinoids and islet cell tumors derived from neuroendocrine cells that can occur anywhere along the gastrointestinal tract and comprise a heterogeneous family of neoplasms with a wide and complex spectrum of clinical behavior. They traditionally have been divided into foregut (esophagus, stomach, proximal duodenum, liver and pancreas), midgut (distal duodenum ileum, jejunum, ascending colon and proximal two thirds of transverse colon) and hindgut tumors (distal third of transverse colon, descending colon, sigmoid colon and rectum).

COVERAGE

The OSU Health Plan considers Lutathera (lutetium Lu 177 dotatate) medically necessary when the following criteria are met:

- 18 years of age and older, and
- Metastasized or locally advanced, inoperable gastroenteropancreatic neuroendocrine tumors, and
- Ki-67 index < 20% documented by pathology, and
- Patient has progressive disease despite treatment with octreotide LAR 20mg or 30mg every 3-4 weeks for at least 12 weeks, and

- Somatostatin receptor-positive documented by appropriate imaging on all target lesions (imaging results required), and
- Karnofsky performance score > 60, and
- Presence of at least 1 measurable site of disease, and
- Member has not received a prior course of therapy with Lutathera (i.e., maximum of 4 doses at intervals of at least 8 weeks).

EXCLUSIONS

Lutathera is not covered when the above criteria are not met.

Pregnant women should be advised that Lutathera can cause fetal harm. There is no data existing which evaluate Lutathera use in pregnant women. No animal studies using lutetium Lu 177 dotatate have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including Lutathera, have the potential to cause fetal harm.

Lutathera 7.4 GBq (200 mCi) is administered every 8 weeks for a total of 4 doses. Increased dosing, more frequent administration or more than 4 doses are considered experimental and not covered.

PRIOR AUTHORIZATION

Prior authorization is required for Lutathera® (lutetium Lu 177 dotatate).

CODES

There is currently no specific HCPCS code for Lutathera® (lutetium Lu 177 dotatate).

REFERENCES

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