Lutetium Lu 177 dotatate (Lutathera) to become a Benefit of Texas Medicaid Effective June 1, 2019

Information posted September 6, 2019

Note: *Texas Medicaid managed care organizations (MCOs) must provide all medically necessary, Medicaid-covered services to eligible clients. Administrative procedures such as prior authorization, pre-certification, referrals, and claims/encounter data filing may differ from traditional Medicaid (fee-for-service) and from MCO to MCO. Providers should contact the client's specific MCO for details.*

Effective for dates of service on or after June 1, 2019, procedure code A9513 is a benefit of Texas Medicaid. Procedure code A9513 is diagnosis restricted for dates of service June 1, 2019, through September 30, 2019.

Effective for dates of service on or after October 1, 2019, procedure code A9513 will no longer be diagnosis restricted, but it will require prior authorization.

Lutetium lu 177 dotatate (Lutathera) procedure code A9513 intravenous injection is indicated for the treatment for clients 18 years old or older with a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) including foregut, midgut, and hindgut neuroendocrine tumors.

For all other indications, Lutetium lu 177 dotatate (Lutathera) procedure code A9513 injection for intravenous use is not proven to be medically effective and is considered experimental.

Providers administering Lutetium lu 177 dotatate (Lutathera) procedure code A9513 should read the manufacturer’s insert for all specific instructions and be aware of the detailed instructions on dosing and withholding the treatment for contraindicated circumstances. Providers should be familiar with the restrictions and usage of long-and short-acting octreotide agents before, during, and after Lutetium lu 177 dotatate (Lutathera), including the recommended use of antiemetics and a specialized amino acid solution.

Limitations and Reimbursement

Lutetium lu 177 (Lutathera) procedure code A9513 is a benefit for clients who are 18 years old and older and may be reimbursed to physician, clinic/group, and radiation therapy center providers that are licensed and authorized to administer radiopharmaceuticals in the outpatient hospital setting. Lutetium lu 177 dotatate (Lutathera) procedure code A9513 must be administered under the control of an oncologist or a nuclear medicine specialist licensed and authorized to administer radiopharmaceuticals.

Lutetium lu 177 (Lutathera) procedure code A9513 is limited to one service every 60 days for a total of four services per lifetime, any provider.

The following diagnosis codes may be reimbursed for dates of service June 1, 2019, through September 30, 2019, for procedure code A9513:

Diagnosis Codes					
C7A00	C7A010	C7A011	C7A012	C7A019	C7A020
C7A021	C7A022	C7A023	C7A024	C7A025	C7A026
C7A029	C7A092	C7A094	C7A095	C7A096	

Prior Authorization Effective October 1, 2019

Effective for dates of service on or after October 1, 2019, procedure code A9513 will no longer be diagnosis restricted, but it will require prior authorization.

Prior authorization requests for procedure code A9513 must be submitted to the Special Medical Prior Authorization (SMPA) department at TMHP using the Special Medical Prior Authorization (SMPA) Request Form.

A SMPA Request Form must be completed, signed, and dated by the prescribing provider. The SMPA form will not be accepted after 90 days from the date of the prescribing provider's signature.

The completed SMPA Request Form must be maintained by the prescribing provider in the client's medical record and is subject to retrospective review.

Documentation of the client's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units/millicuries per injection, and the dosage calculation must be submitted in Section C of the SMPA Request Form under the Statement of Medical Necessity.

To facilitate determination of medical necessity and avoid unnecessary denials, the prescribing provider must submit correct and complete information, including documentation for medical necessity for the equipment or supplies requested, procedure codes, and numerical quantities for the services requested. The provider must maintain documentation of medical necessity in the client's medical record.

Documentation

Lutetium lu 177 dotatate (Lutathera) procedure code A9513 will be considered with documentation that meets all of the following criteria:

- The client has a diagnosis of GEP-NETs (diagnosis restricted June 1, 2019 through September 1, 2019)
- The prior authorization request is submitted (for dates of service on or after October 1, 2019)
- The client is 18 years old or older
- The client is not pregnant or breastfeeding

- The official pathology report documents a GEP-NET with Ki67 index less than 20%
- The disease is metastatic, or locally advanced and unresectable:
    - Positive somatostatin receptor scintigraphy with correlative magnetic resonance imaging (MRI) or computed tomography (CT) imaging of metastatic measurable disease or 68-Ga-Dotate positron emission tomography (PET) scan positive for metastatic disease
- The client experienced disease progression while on a long-acting somatostatin analog (e.g. octreotide, lanreotide)
- The client has not had prior treatment with Peptide Receptor Radionuclide Therapy (PRRT), and has not had prior external radiation therapy to more than 25% of the bone marrow
- The documentation includes an oncologist or nuclear medicine specialist's complete written order and prescription for Lutetium lu 177 dotatate intravenous infusion
- A treatment plan that includes all of the following documentation:
    - Lutetium lu 177 dotatate 7.4 GBq (200 mCi) every 60 days for a total of 4 doses will be administered in a facility under the control of physician(s) licensed and authorized to administer radiopharmaceuticals
    - The treatment includes the recommended use of premedication and concomitant medications of somatostatin analogs, antiemetics and specialized amino acid solution
    - The restrictions and usage of long- and short-acting octreotide agents before, during, and after lutetium lu 177 dotatate intravenous infusions
    - Details of withholding the treatments for contraindicated circumstances including, but not limited to:
        - Thrombocytopenia
        - Anemia neutropenia
        - Renal toxicity
        - Hepatotoxicity
        - Other non-hematologic toxicities

For more information, call the TMHP Contact Center at 1-800-925-9126.