AAA **Patient**CONNECT™

Assistance for Your LUTATHERA® (lutetium Lu 177 dotatate) Patients

AAA PatientCONNECT™
www.aaapatientconnect.com

Phone: 1-844-NETS-AAA
(1-844-638-7222)

FAX: 1-844-NETS-FAX
(1-844-638-7329)

Advanced Accelerator Applications

LUTATHERA® (lutetium Lu 177 dotatate) injection, for intravenous use

AAA **Patient**CONNECT™ — Facilitating Patient Access to LUTATHERA® (lutetium Lu 177 dotatate)

AAA **Patient**CONNECT™ provides services to facilitate your patient's access to LUTATHERA® treatment.[1] This may include:

Patient Financial Assistance

- Uninsured patient assistance
- Commercial patient copay assistance

Other Assistance

- Insurance benefits verification
- Prior authorization eligibility check
- Financial assistance for eligible patients

AAA PatientCONNECT™
Patient Navigators may be reached by calling
1-844-NETS-AAA (1-844-638-7222)
Monday-Friday from 8:00AM-8:00PM EST

[1]Eligibility restrictions may apply. For full terms and conditions, please call AAA **Patient**CONNECT™ at 1-844-NETS-AAA (1-844-638-7222).

Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the copayment support provided under this program, e.g., copay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law or restricted.

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Financial Assistance for Uninsured Patients

AAA **Patient**CONNECT™ may provide LUTATHERA® (lutetium Lu 177 dotatate) at no cost to patients who are uninsured and meet certain eligibility criteria.*

Eligibility criteria include:

- Proof of financial need based on adjusted gross household income. Documentation of income is required when applying; please speak with a Patient Navigator to learn about acceptable forms of documentation
- Treatment is being provided in an outpatient setting
- Permanent residency in the United States, including any of its territories, or the District of Columbia

For more information on enrolling your patient in
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Financial Assistance for Patients with Commercial Insurance

AAA **Patient**CONNECT™ may provide copay assistance for LUTATHERA® treatment to patients who have commercial insurance and meet certain eligibility criteria.[1]

Eligibility criteria include:

- Patient has commercial insurance and certifies that they do not have any government insurance
- Treatment is being provided in an outpatient setting
- Permanent residency in the United States, including any of its territories, or the District of Columbia

Copay assistance is not available through the AAA **Patient**CONNECT™ program for patients who have public or government insurance, such as insurance available through Medicare, Department of Veterans Affairs, or the Department of Defense. AAA **Patient**CONNECT™ is not an insurance program and is not a substitute for medical insurance.

Enrolling and Accessing Financial Assistance for Your Patient

Enrolling your patient in AAA **Patient**CONNECT™ and accessing financial assistance is a simple 3-step process:

Step 1: Access the Enrollment Forms

Enrollment forms for AAA **Patient**CONNECT™ may be accessed online at www.aaapatientconnect.com, by calling 1-844-NETS-AAA (1-844-638-7222), or by speaking with your local AAA representative.

Step 2: Complete and Sign the Enrollment Forms

Complete all required sections of the enrollment forms and make sure that **both you and your patient sign the form.** Fax this form to 1-844-NETS-FAX (1-844-638-7329).

Step 3: Speak with a Patient Navigator

A Patient Navigator will follow up with you to confirm enrollment and inform your patient of the next steps. They may also contact your patient if there are any questions that your patient would have to answer or information needed.

Online Portal

An online portal is also available for enrollment. Visit www.aaapatientconnect.com to learn more.

Receiving Copay Financial Assistance

Upon approval, AAA **Patient**CONNECT™ will send the patient an approval letter and outline of the copay assistance funds that are available for their treatment.

Proof of LUTATHERA® (lutetium Lu 177 dotatate) treatment and claims processed must be submitted to AAA **Patient**CONNECT™ for distribution of copay assistance funds.

Upon receipt of required documents, copay assistance funds will be processed.

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INDICATION

LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

IMPORTANT SAFETY INFORMATION[1]

WARNINGS AND PRECAUTIONS

- **Radiation Exposure:** Treatment with LUTATHERA contributes to a patient's overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with LUTATHERA consistent with institutional good radiation safety practices and patient management procedures.

- **Myelosuppression:** In NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide at the following rates (all grades/grade 3 or 4): anemia (81%/0), thrombocytopenia (53%/1%), and neutropenia (26%/3%). Blood cell counts must be monitored prior to, during, and after treatment. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.

- **Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 24 months, myelodysplastic syndrome (MDS) was reported in 2.7% of patients receiving LUTATHERA with long-acting octreotide. In ERASMUS, a Phase I/II clinical study, 15 patients (1.8%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to the development of MDS was 28 months (9 to 41 months) and 55 months (32 to 155 months) for acute leukemia.

- **Renal Toxicity:** Treatment with LUTATHERA will expose kidneys to radiation, which may impair renal function. In ERASMUS <1% of patients developed renal failure 3 to 36 months following LUTATHERA. Monitor serum creatinine and creatinine clearance to assess changes in renal function. Advise patients to urinate frequently during and after administration of LUTATHERA. A concomitant intravenous infusion of amino acids before, during, and after LUTATHERA administration is mandatory for renal protection. Patients with baseline renal impairment may be at greater risk of toxicity. Perform more frequent assessments of renal function in patients with mild or moderate impairment. Withhold, reduce dose, or permanently discontinue based on severity of reaction. Do not decrease the dose of amino acid solution if the dose of LUTATHERA is reduced. LUTATHERA has not been studied in patients with severe renal impairment (CrCL < 30 mL/min).

- **Hepatotoxicity:** In ERASMUS, <1% of patients were reported to have hepatic tumor hemorrhage, edema, or necrosis, with one patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, and serum albumin during treatment. Withhold, reduce dose, or permanently discontinue based on severity of reaction.

- **Neuroendocrine Hormonal Crisis:** Manifesting with flushing, diarrhea, bronchospasm, and hypotension, neuroendocrine hormonal crisis occurred in 1% of patients in ERASMUS and typically occurred during or within 24 hours following the initial LUTATHERA dose. Monitor patients for flushing, diarrhea, hypotension, bronchoconstriction, or other signs and symptoms of tumor-related hormonal release. Administer intravenous somatostatin analogs, fluids, corticosteroids, and electrolytes as indicated.

- **Embryo-Fetal Toxicity:** LUTATHERA can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 7 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the final dose. Verify pregnancy status of females of reproductive potential prior to initiating LUTATHERA.

- **Risk of Infertility:** LUTATHERA may cause infertility in males and females. Radiation absorbed by testis and ovaries from the recommended cumulative LUTATHERA dose falls within the range in which temporary or permanent infertility can be expected following external beam radiotherapy.

ADVERSE REACTIONS

The most common Grade 3-4 adverse reactions (≥ 4% with a higher incidence in LUTATHERA arm) observed in NETTER-1 were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), elevated AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%). In ERASMUS, the following serious adverse reactions have been observed with a median follow-up time of more than 4 years after treatment with LUTATHERA: myelodysplastic syndrome (2%), acute leukemia (1%), renal failure (2%), hypotension (1%), cardiac failure (2%), myocardial infarction (1%), and neuroendocrine hormonal crisis (1%). Patients should be counseled and monitored in accordance with the LUTATHERA Prescribing Information.

DRUG INTERACTIONS

Somatostatin and its analogs competitively bind to somatostatin receptors and may interfere with the efficacy of LUTATHERA. Discontinue long-acting somatostatin analogs at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose. Administer short- and long-acting octreotide during LUTATHERA treatment as recommended.

SPECIFIC POPULATIONS

- **Lactation:** Because of the potential risk for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment with LUTATHERA and for 2.5 months after the final dose.

To report SUSPECTED ADVERSE REACTIONS, contact Advanced Accelerator Applications USA, Inc. at 1-844-863-1930, or us-pharmacovigilance@adacap.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information.

Distributed by: Advanced Accelerator Applications USA, Inc., NJ 07041

Reference: 1. LUTATHERA® [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; July 2018.

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Advanced Accelerator Applications

LUTATHERA®
(lutetium Lu 177 dotatate)
injection, for intravenous use

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AAA-AAAPC-US-0021 | 09/2019