Advanced Accelerator Applications
A Novartis Company

AAA PatientCONNECT™

Program Enrollment Form

PHONE: 1-844-NETS-AAA • FAX: 1-844-NETS-FAX

NOTE: The application cannot be processed without both prescriber and patient signatures.

Expected LUTATHERA® Treatment Date: _____

**Indicates Required Field*

PATIENT INFORMATION

*Patient Name:		*Date of Birth:
*Address:		
*City:	*State:	*Zip:
*Phone: ☐ Home:	☐ Cell:	
Social Security #:		*Sex: ☐ M ☐ F

INSURANCE INFORMATION *(Required for Benefit Verification and Copay Assistance)*

Carrier #1 ☐ Patient has no insurance		
*Carrier:	*Health Plan:	
*Carrier Phone Number:	*Policy ID #:	
*Group #:	*Policy Holder Name:	
*Policy Holder Gender: ☐ M ☐ F	*Policy holder DOB:	*Policy Holder Relationship:

Carrier #2		
Carrier:	Health Plan:	
Carrier Phone Number:	Policy ID #:	
Group #:	Policy Holder Name:	
Policy Holder Gender: ☐ M ☐ F	Policy Holder DOB:	Policy Holder Relationship:

PRESCRIBER INFORMATION

*Ordering Physician Name:		*Specialty:
*Physician Practice Name:		*Practice NPI #:
*Office Manager's Name:	*Office Manager's Phone:	Ext:
*Physician Address:		
*City:	*State:	*Zip:
*Physician Phone:	*Physician Fax:	
Physician Email:		
*Physician NPI:	*State License #:	*Tax ID #:
☐ Check this box to request AAA PatientCONNECT™ portal access | Email:		

SITE OF TREATMENT INFORMATION

*Administering Facility:	☐ Hospital Outpatient ☐ Free Standing / Physician Office	
*Facility Address:		
*City:	*State:	*Zip:
*Facility Phone:	*Facility Fax:	
*Facility NPI:	*Tax ID #:	*PTAN:
*Facility Contact Person:	*Facility Contact Phone:	Ext:
☐ Check this box to request AAA PatientCONNECT™ portal access | Email:		

*Patient Name:	*Date of Birth:

CLINICAL INFORMATION

*Include at least one ICD-10 code below. Please refer to page 4 for a list of potential ICD-10 code options.

Diagnosis (ICD-10 Code): _____ Description: _____

Diagnosis (ICD-10 Code): _____ Description: _____

AAA PatientCONNECT™ will conduct the benefit verification for LUTATHERA® and its administration procedure.

PHYSICIAN CERTIFICATION

I hereby represent, covenant, and certify as follows: (a) I have obtained from my patient all required authorization to release to AAA PatientCONNECT™ and its representatives/agents all patient information needed for this application, including, without limitation, my patient's financial and medical information; (b) I understand that this information is for the sole use of AAA PatientCONNECT™ and its representatives/agents to assess the patient's eligibility for participation in AAA PatientCONNECT™ (c) I have not received, nor will I seek or accept reimbursement from any federal, state, or private payers for any drug provided for my patient by PatientCONNECT™ Patient Assistance Program; (d) I have not received, nor will I seek or accept payment from my patient for any coinsurance amount paid for by the AAA Commercial Copay Assistance Program for LUTATHERA®; (e) I understand that if my patient's insurance or financial status changes, the patient may no longer be eligible under this program. I will notify AAA PatientCONNECT™ if I become aware of any such changes; (f) I understand that I am under no obligation to prescribe any AAA drug and I have not received and will not receive any benefit from AAA for prescribing a AAA drug; (g) the information contained in this form is complete and accurate to the best of my knowledge; and (h) I will notify AAA PatientCONNECT™ of any errors regarding the foregoing, and will make every effort to correct those errors.

*Physician Printed Name:	*Physician Signature:	*Date:

PATIENT FINANCIAL INFORMATION *(Required only for Patient Assistance)*

Number of People in the Household: _____ Household Income: _____ ☐ Annual ☐ Monthly

Income documentation will be required to assess eligibility for uninsured patients applying for Patient Assistance. Acceptable forms of documentation include the most recent copy of US federal tax return, Social Security income statements, recent pay stubs.

PATIENT CONSENT

By submitting this form, I am applying to be enrolled in AAA PatientCONNECT™ Program ("the program") for LUTATHERA® which provides copay and patient assistance services. I have read or have had read to me the informed consent information about LUTATHERA®. I have also had the opportunity to ask questions regarding LUTATHERA® prior to my informed consent and the answers were satisfactory. I understand that my personal information will be used by the program to help me get assistance with the cost of my LUTATHERA®, or as otherwise allowed under the law.

By signing this authorization, I hereby authorize my health plans, physicians, and pharmacy providers (collectively, my "Providers") to disclose my personal health information ("PHI"), including but not limited to, information relating to my medical condition, medical history, treatment, care management, and health insurance (including information concerning substance abuse, mental health (excluding psychotherapy notes) and HIV information, as well as information provided on this form and any prescription (collectively, "Personal Health Information") to eMAX Health, which administers the program, and its representatives, agents, and contractors, for purposes of: (1) establishing my eligibility for benefits for coverage of LUTATHERA®; (2) obtaining any authorization or precertification for the coverage of LUTATHERA®, (3) communicating with my health care providers, including pharmacy providers, and me about my medical care; (4) identifying LUTATHERA-specific out-of-pocket costs; (5) preparing and providing reports, excluding PHI, to the manufacturer of LUTATHERA® regarding my health insurance coverage and reimbursement for LUTATHERA® prescriptions in general; provided that, the de-identification process used complies with the requirements set forth in 45 CRF 164.514(b). My authorization applies to any PHI governed and protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and under the rules and regulations thereunder.

I understand that disclosure of certain PHI will be made to the site of care provider and/or the ordering physician. I further understand that my PHI used or disclosed under this authorization may be re-disclosed by the person(s) or class of person(s) receiving it and may no longer be protected by federal privacy laws. I understand that my health care providers and insurance company will not condition my medical treatment, payment of treatment, insurance enrollment, or eligibility for insurance benefits on my signing this authorization. I understand, however, that if I do not sign this authorization, I will not be eligible to receive assistance through the program.

I understand that I am entitled to a copy of this authorization. I understand that I shall be contacted by the program as part of the assistance process. The program will contact my provider as necessary to administer these services. I also understand that the program will share program-related information with my provider. I understand that I may cancel this authorization at any time by mailing a letter requesting such cancellation to AAA PatientCONNECT™, 23611 Chagrin Blvd., Ste. 380, Beachwood, OH, 44122; but that this cancellation will not apply to any information already used or disclosed. The Personal Health Information that is used or disclosed pursuant to this authorization may be re-disclosed by eMAX Health as described above. This authorization expires one (1) year from the date signed below. I understand that I may call the program's toll-free number 844-NETS-AAA at any time.

I understand that I may pay the full copay amount to my healthcare provider when I receive each infusion. I understand that my provider or I will need to submit my Explanation of Benefit (EOB) or Remittance Advice (RA) to the program following each infusion. The program will use the information my provider or I submit to determine the amount of the cost for LUTATHERA® that the program will reimburse. A check with that amount will be mailed to me (the patient), and I may then be responsible to pay the healthcare provider for remaining balance. I further understand that if my provider or I do not submit an EOB or RA, the program cannot process copay assistance request. If this authorization is being signed by the patient's legal representative, I must provide legal documentation authorizing you to act on my behalf (legal guardianship, power of attorney, personal representative).

COPAY ASSISTANCE PROGRAM (CAP) TERMS AND CONDITIONS

To receive benefits under CAP, the patient must enroll in the program and be accepted as eligible. The program is subject to the following terms and conditions:

- CAP is valid only for patients with commercial insurance and who have a valid prescription. This program is not valid under Medicare, Medicaid, or any other federal or state program, for cash-paying patients, where the product is not covered by the patient's commercial insurance, or where the patient's insurer reimburses the patient for the entire cost of LUTATHERA®. This offer is not valid where prohibited by law and is only valid in the United States and Puerto Rico.
- The patient must be 18-years-old or older and a resident of the United States or the Commonwealth of Puerto Rico. LUTATHERA® must be administered to patient in the United States or the Commonwealth of Puerto Rico.
- The patient must be prescribed LUTATHERA® for an FDA-approved indication.
- CAP is not insurance. The offer may not be combined with any other rebate, coupon, or other offer(s).
- Patient must have an out-of-pocket cost for LUTATHERA® and be administered LUTATHERA® prior to the expiration date of CAP. The benefit available under CAP is valid for the patient's out-of-pocket cost for LUTATHERA® only. It is not valid for any other out-of-pocket costs (for example, office visit charges or medication administration charges) even if such costs are associated with the administration of LUTATHERA®.

*Patient Name:	*Date of Birth:

CAP Terms and Conditions Continued

- Eligible patients may receive up to a maximum of $15,000 over the course of the treatment (i.e. 4 LUTATHERA® infusions). The patient's eligibility expires on the one year anniversary of patient enrollment in the program.
- Patients with commercial insurance will be responsible for the first $25 and CAP may pay the remaining copay or coinsurance until the patient reaches the maximum of $15,000 during the eligibility year. After the program maximum, the patient will be responsible for the difference.
- An EOB from the patient's private health insurance or Remittance Advice (RA) from the provider must be submitted within 365 days of the administration date for the patient to receive copay assistance benefit. The EOB or RA must reflect the patient's out-of-pocket cost for the LUTATHERA® and submission of the claim by the patient's physician for the cost of the LUTATHERA®.
- The patient and the physician agree not to seek reimbursement for all or any part of the benefit received by the patient through CAP. Patient and physician are responsible for reporting receipt of copay assistance benefits to any insurer, health plan, or other third party who pays for or reimburses any part of the medication cost paid for by CAP, as may be required.
- CAP may apply to patient out-of-pocket costs incurred for LUTATHERA® within 90 days prior to the date patient is enrolled in CAP, subject to annual program maximum and the applicable Terms and Conditions based on LUTATHERA® administration date.
- All information applicable to CAP requested on this form must be provided, and all certifications must be signed. Forms that are modified or do not contain all the necessary information will not be eligible for benefits under CAP.
- CAP is void where prohibited by law, taxed, or restricted. CAP is not transferable. No substitutions are permitted.
- If at any time patients begin receiving coverage under any federal-, state-, or government-funded healthcare program, patients will no longer be eligible to participate in AAA PatientCONNECT™ Program and must call 1-844-NETS-AAA Monday through Friday, 8:00 am-8:00 pm ET to stop participation.
- AAA reserves the right to rescind, revoke, or amend CAP at any time without notice.
- Data related to patient's receipt of Copay Assistance Program benefits may be collected, analyzed, and shared with AAA, for market research and other purposes related to assessing Copay Assistance Programs. Data shared with AAA will be aggregated and de-identified, meaning it will be combined with data related to other Copay Assistance Program redemptions and will not identify patient.

Expiration Date: 12/31/2019

PATIENT ASSISTANCE PROGRAM (PAP) TERMS AND CONDITIONS

To receive benefits under PAP, the patient must enroll in the program and be accepted as eligible. The program is subject to the following terms and conditions:

- The patient must be at least 18-year-old and resident of the United States or the Commonwealth of Puerto Rico. LUTATHERA® must be administered to patient in the United States or the Commonwealth of Puerto Rico.
- Treatment is being provided in a physician office or hospital outpatient setting.
- The patient must be prescribed LUTATHERA® for an FDA-approved indication.
- The patient must not be a participant in any federal-, state-, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE.
- Patient does not have any insurance.
- The patient must meet income cap criteria.
- The benefit available under the program is valid for the patient's out-of-pocket cost for the LUTATHERA® only. It is not valid for any other out-of-pocket costs (for example, office visit charges or medication administration charges) even if such costs are associated with the administration of the LUTATHERA®.
- Patient's eligibility expires on the anniversary of patient enrollment in the program.
- Program coverage is not retroactive and does not cover deductible incurred prior to the registration in the program.
- Patient and physician agree not to seek reimbursement for all or any part of the benefit received by the patient through the program.
- All information applicable to the program requested on this form must be provided, and all certifications must be signed. Forms that are modified or do not contain all the necessary information will not be eligible for benefits under PAP.
- This program is not health insurance. The offer may not be combined with any other rebate, coupon, or other offer(s).
- PAP form may not be sold, purchased, traded, or counterfeited. Void if reproduced.
- PAP is void where prohibited by law, taxed, or restricted. PAP is not transferable. No substitutions are permitted.
- If at any time patients begin receiving coverage under any federal-, state-, or government-funded healthcare program, patients will no longer be eligible to participate in LUTATHERA® PAP and must call 1-844-NETS-AAA Monday through Friday, 8:00 am-8:00 pm ET to stop participation.
- AAA reserves the right to rescind, revoke, or amend LUTATHERA® PAP at any time without notice.
- Data related to patient's receipt of PAP benefits may be collected, analyzed, and shared with AAA, for market research and other purposes related to assessing LUTATHERA® PAPs. Data shared with AAA will be aggregated and de-identified, meaning it will be combined with data related to other LUTATHERA® PAP redemptions and will not identify patient.

Expiration Date: 12/31/2019

PATIENT CERTIFICATION

APPLICANT DECLARATIONS AND AUTHORIZATION: I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program assistance will terminate if the program becomes aware of any fraud or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for this program. I certify that I cannot afford this medication. I certify that I will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have this prescription or any cost associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that AAA PatientCONNECT™ reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice.

My signature below signifies that I have read and agree to the Patient Consent and Certification (Signature Required):

*Print Patient Name (or Responsible Party and Relationship, if applicable):	*Date:
*Patient or Responsible Party Signature:	

ICD-10 Codes

The tables below list the ICD-10 potential diagnosis codes which you may consider for patient treatment with LUTATHERA®.

ICD-10 CODE	DESCRIPTION
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.092	Malignant carcinoid tumor of the stomach
C7A.094	Malignant carcinoid tumor of the foregut NOS
C7A.095	Malignant carcinoid tumor of the midgut NOS
C7A.096	Malignant carcinoid tumor of the hindgut NOS
C7A.098	Malignant carcinoid tumors of other site
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.04	Secondary carcinoid tumors of peritoneum
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

Please visit www.LUTATHERA.com for full Prescribing Information

*This information is taken from publicly available sources. It is not intended to guarantee, increase or maximize reimbursement by any payer. It is the provider's responsibility to report the codes that accurately describe the products and services furnished to individual patients. Reimbursement is dynamic. We recommend that providers consult their payer organizations regarding local policies and rates. Laws and regulations regarding reimbursement change frequently and providers are solely responsible for all decisions related to coding and billing including determining, if and under what circumstances, it is appropriate to seek reimbursement for products and services and obtaining pre-authorization, if necessary. AAA makes no representation or warranty regarding this information or its completeness or accuracy and will bear no responsibility for the results or consequences of the use of this information. You should reference the current CPT®, ICD-10-CM and HCPCS manuals and follow the "Documentation Guidelines for Evaluation and Management Services" for the most detailed and up-to-date information. Current Procedural Terminology (CPT©) is copyright and trademark of the 2012 American Medical Association (AMA). All Rights Reserved.

INDICATION

LUTATHERA is a radiolabeled somatostatin analog 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 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 LUTATHERA clinical trials, hematological adverse reactions occurred 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. Dose modification or cessation of treatment may be necessary.
- **Secondary Myelodysplastic Syndrome and Leukemia:** 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 compared to no patients receiving high-dose long-acting octreotide. In 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) for MDS 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 a Phase I/II clinical trial <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 during 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.
- **Hepatotoxicity:** In LUTATHERA clinical trials, <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 crises:** Manifesting with flushing, diarrhea, bronchospasm and hypotension, neuroendocrine hormonal crisis occurred in 1% of patients 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 and males of reproductive potential to use effective contraception during treatment and after. Verify pregnancy status of females of reproductive potential prior to initiating LUTATHERA.
- **Risk of Infertility:** 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 observed in LUTATHERA clinical trials were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), elevated AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%).

The following serious adverse reactions are rare but 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.

Please see full Prescribing Information.

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

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