

A Guide to **NURSING CARE** FOR REFERRING MEDICAL ONCOLOGY PRACTICES

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



Identifying patients for LUTATHERA and helping them understand the referral and treatment process

Not an actual patient.

INDICATION

LUTATHERA[®] (lutetium Lu 177 dotatate) is indicated for the treatment of adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

IMPORTANT SAFETY INFORMATION 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, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.

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 **NOVARTIS**



Patients and Results

About LUTATHERA

Safety

Patient Conversations

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Coordinating care: Multidisciplinary roles and responsibilities



As a nurse in the referring oncologist's practice, you play a key role in helping your patients understand the treatment journey and can change lives by identifying patients who may be eligible for treatment.

It is important to keep in mind that guidelines may vary by institution.

1: IDENTIFY

Referring Medical Oncology Practice

Identify and test appropriate patients for LUTATHERA

- Your medical oncology practice identifies a patient with an SSTR+ GEP-NET in the foregut, midgut, or hindgut¹
- LUTATHERA has evidence in both newly diagnosed patients and those who have progressed on an SSA, and can be used across grade 1, 2, and 3 well-differentiated SSTR+ GEP-NETs¹⁻³

The referring oncologist examines the patient holistically, including testing for SSTR presence and tumor localization via imaging—part of each patient's staging and eligibility process for LUTATHERA.^{1,4}

Referring nurses may help identify appropriate patients for LUTATHERA early by¹⁻³:

- Monitoring patients with newly diagnosed SSTR+ metastatic or advanced GEP-NETs
- Closely monitoring patients for disease progression on an SSA—regardless of the presence of symptoms

2: REFER

Referring Medical Oncology Practice

Refer patient to treatment site

Nurse coordinates patient care with treatment site care team, and makes sure to follow the recommendations from the treating physician such as:

- Discontinue long-acting SSA ≥ 4 weeks prior to the administration of LUTATHERA¹
- Administer short-acting octreotide as needed; discontinue at least 24 hours prior to initiating LUTATHERA¹
- Confirm schedule of periodic laboratory testing¹
- Pregnancy status must be verified for patients of childbearing potential¹

3: ADMINISTER

Administering Nuclear Medicine or Radiation Oncology Practice

Initiate LUTATHERA at treatment site

- Patient may undergo additional testing at the treatment site to confirm eligibility or readiness to initiate treatment^{1,4}
- Recommended dosing is 4 cycles of treatment at 8-week intervals¹

GEP-NET, gastroenteropancreatic neuroendocrine tumor; SSA, somatostatin analogue; SSTR, somatostatin receptor; SSTR+, somatostatin receptor-positive.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Myelosuppression:** In the NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide compared with patients receiving high-dose long-acting octreotide (all grades/grade 3/4): anemia (81%/0 vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0), and neutropenia (26%/3% vs 11%/0).

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Coordinating care for LUTATHERA administration and follow-up



While this page covers treatment day administration and follow-up support, it may also be a useful resource for answering patient questions about process details.

Treatment Site: Administering Nuclear Medicine or Radiation Oncology Practice

Before^{1,4}

- Patient is checked in for treatment and provided assessment, expectations for the day, and orientation of the room
- Antiemetics are administered 30 minutes before the recommended amino acid solution to prevent nausea and vomiting
- An IV sterile amino acid solution containing L-lysine and L-arginine is initiated 30 minutes before administering LUTATHERA
- Patients who have had prior grade 1/2 hypersensitivity reactions to LUTATHERA are premedicated

During¹

- Infusion is continued during and for at least 3 hours after the completion of the infusion of LUTATHERA
- The dose of the amino acid solution is not decreased if a reduced dose of LUTATHERA is administered
- Patients who experience grade 3/4 hypersensitivity reactions to LUTATHERA are not rechallenged

Treatment Site: Administering Nuclear Medicine or Radiation Oncology Practice

AFTER each dose of LUTATHERA¹

- Long-acting octreotide 30 mg IM is administered between 4 and 24 hours after each dose of LUTATHERA
- Patient is monitored for adverse reactions and laboratory abnormalities
- Patient is reminded when and where they will receive their next SSA treatment

IM, intramuscular; IV, intravenous.

Referring Medical Oncology Practice

AFTER all doses of LUTATHERA are completed^{1,3}

- Long-acting octreotide 30 mg IM should continue every 4 weeks until disease progression or for 18 months following treatment initiation at the discretion of the physician
- Patients are closely monitored for disease progression on an SSA—regardless of the presence of symptoms

Have you confirmed where your patient will receive their long-acting SSA infusion, as well as other details, with their treatment center?

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Myelosuppression (continued):** In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose. Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to grade 1, 9 to grade 2, and 1 to grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of myelosuppression.

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LUTATHERA was studied in newly diagnosed patients with well-differentiated, grade 2/3 advanced GEP-NETs^{2,5}

NETTER-2 is a phase 3, randomized, open-label, active comparator, multicenter study of the efficacy of LUTATHERA with 30 mg octreotide LAR (n=151) vs 60 mg octreotide LAR (n=75) in patients with newly diagnosed, well-differentiated, grade 2/3 advanced SSTR+ GEP-NETs. SSA-naïve patients were eligible, as well as patients previously treated with SSAs in the absence of progression. The primary end point of the study was centrally assessed PFS.^{2,5,*}

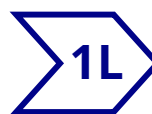
*Defined as the time from randomization to first documented progression (centrally assessed according to RECIST v1.1) or death due to any cause.²

Consider these characteristics



Diagnosis^{1,5}

Well-differentiated, SSTR+, metastatic or locally advanced, inoperable GEP-NETs

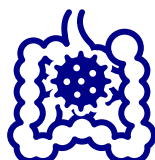


Treatment stage^{1,5}

Newly diagnosed (within the last 6 months)



Ki-67
≥10% and ≤55%
Grade 2/3⁵



Any GEP-NET
primary site¹



Karnofsky
Performance Score
≥60⁵

1L, first line; LAR, long-acting release; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (MDS) was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose long-acting octreotide. In ERASMUS, a phase 2 clinical study, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia.

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Results: LUTATHERA as 1L therapy* for newly diagnosed patients^{2,5}

LUTATHERA demonstrated a statistically significant improvement in PFS for newly diagnosed patients with well-differentiated, grade 2/3 advanced GEP-NETS^{2,5}

72% REDUCTION in the risk of disease progression or death with LUTATHERA + 30 mg octreotide LAR vs 60 mg octreotide LAR^{2,5}

The median PFS in the LUTATHERA arm was 22.8 months (95% CI, 19.4-NE) vs 8.5 months (95% CI, 7.7-13.8) in the control arm (HR, 0.28 [95% CI, 0.18-0.42]; $P < .0001$).^{2,5}

Summary of key characteristics seen in NETTER-2^{2,5,6}

- ✓ Newly diagnosed (within last 6 months), well-differentiated SSTR+ GEP-NET
- ✓ Karnofsky PS: 90 to 100
- ✓ Ki-67 index: $\geq 10\%$ to $\leq 55\%$ (tumor grade 2/3)
- ✓ Disease burden: moderate to extensive

Representation of typical patients in NETTER-2; not intended to be exhaustive of all inclusion/exclusion criteria.

*In NETTER-2, 44 patients (19.5%) received prior treatment in the absence of progression, including CAPTEM (1 patient), everolimus (1 patient), and SSAs (42 patients, with the majority receiving 1 or 2 doses).^{5,6}

By keeping these characteristics in mind, referring nurses may help identify appropriate patients for LUTATHERA early

CAPTEM, capecitabine and temozolomide; HR, hazard ratio; NE, not evaluable; PS, performance score.

Overall response rate (ORR)⁶

- LUTATHERA + 30 mg octreotide LAR delivered a statistically significant increase ($>4x$) in ORR compared with 60 mg octreotide LAR (ORR was a secondary end point)
- 43% of patients (65/151) saw partial or complete tumor shrinkage with LUTATHERA + 30 mg octreotide LAR compared with 9.3% of patients (7/75) with 60 mg octreotide LAR alone

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Renal Toxicity:** In ERASMUS, 8 patients ($<1\%$) developed renal failure 3 to 36 months following LUTATHERA. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during, and after LUTATHERA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys. Advise patients to hydrate and to urinate frequently before, on the day of, and on the day after administration of LUTATHERA.

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LUTATHERA was studied in patients with well-differentiated, grade 1/2 advanced GEP-NETs after SSA progression^{1,3}

NETTER-1 was a pivotal, phase 3, randomized, multicenter, open-label study of LUTATHERA with 30 mg octreotide LAR (n=116) vs 60 mg octreotide LAR (n=113) in patients with locally advanced, inoperable, or metastatic SSTR+ GEP-NETs. The primary end point of the study was centrally assessed PFS.^{1,3,7,*}

*Defined as the time from randomization to first documented progression (centrally assessed according to RECIST v1.1) or death due to any cause.²

Consider these characteristics



Diagnosis^{1,3}

Well-differentiated, SSTR+, metastatic or locally advanced, inoperable GEP-NETs



Treatment stage^{1,3}

Any prior disease progression while on an SSA



Ki-67 \leq 20%
Grade 1 or 2³



Any GEP-NET primary site¹



Karnofsky Performance Score \geq 60³

2L, second line; 3L, third line.

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

- **Renal Toxicity (continued):** Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure; perform more frequent assessments of renal function in patients with baseline mild or moderate impairment. LUTATHERA has not been studied in patients with baseline severe renal impairment (creatinine clearance <30 mL/min) or those with end-stage renal disease.

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Results: LUTATHERA as therapy for patients after SSA progression^{1,3}

LUTATHERA demonstrated a statistically significant improvement in PFS for patients with well-differentiated, grade 1/2 advanced GEP-NETs after SSA progression^{1,3}

79% REDUCTION in the risk of disease progression or death with LUTATHERA + 30 mg octreotide LAR vs 60 mg octreotide LAR^{1,3,8}

The median PFS in the LUTATHERA arm was not reached (95% CI, 18.4-NE) vs 8.5 months (95% CI, 6.0-9.1) in the control arm (HR, 0.21 [95% CI, 0.13-0.32]; $P < .0001$).^{1,3,8}

Summary of key characteristics seen in NETTER-1^{1,3,8}

- ✓ Well-differentiated SSTR+ GEP-NET and progression on SSA
- ✓ Karnofsky PS: 75 to 95
- ✓ Ki-67 index: <10% (tumor grade 1/2)

Representation of typical patients in NETTER-1; not intended to be exhaustive of all inclusion/exclusion criteria.

LUTATHERA can be used to treat SSTR+ GEP-NETs in the foregut, midgut, and hindgut.¹
Which of your patients could be eligible for LUTATHERA?

Final OS analysis (secondary end point)

- OS was analyzed at the final analysis, which occurred 66 months after the primary PFS analysis. There was no statistically significant difference in OS between the 2 treatment arms. Because the assumptions for the Cox model for OS were not fulfilled, the HR is uninterpretable^{1,9}
- Prespecified OS analysis was completed 5 years after the last patient was randomized (data cutoff: January 18, 2021)⁹
- Median duration of follow-up was 76.3 months in the LUTATHERA + 30 mg octreotide LAR arm and 76.5 months in the 60 mg octreotide LAR arm⁹

OS, overall survival.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Hepatotoxicity:** In ERASMUS, 2 patients (<1%) were reported to have hepatic tumor hemorrhage, edema, or necrosis, with 1 patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, serum albumin, and the international normalized ratio during treatment. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of hepatotoxicity.

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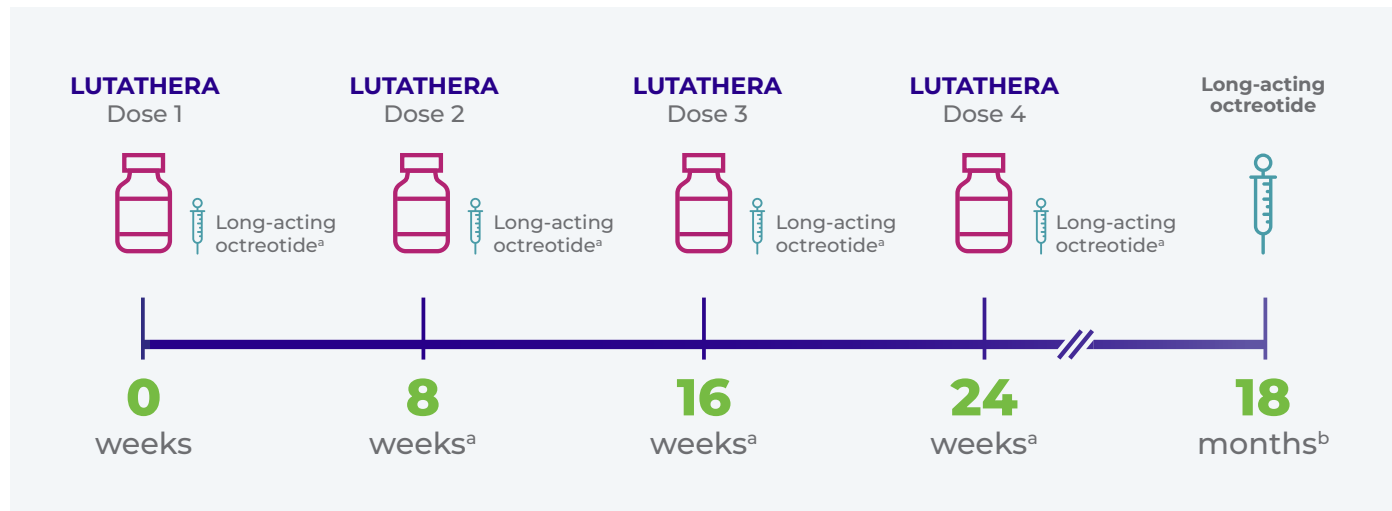
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Regardless of patient type, the dosing regimen for LUTATHERA remains the same¹

The defined 4-dose LUTATHERA regimen is available at treatment centers nationwide¹



^aThe interval between infusions may be extended up to 16 weeks in the case of a dose modification due to an adverse reaction. Permanently discontinue LUTATHERA in patients who experience grade 3/4 hypersensitivity reactions. Please see the Prescribing Information for additional information on dose modifications.¹

^bContinue long-acting octreotide 30 mg IM every 4 weeks after completing LUTATHERA until disease progression or for 18 months following treatment initiation at the discretion of the physician.¹

During treatment, long-acting octreotide 30 mg IM will be administered between 4 and 24 hours after each dose of LUTATHERA¹

- LUTATHERA dosage should be modified based on hematologic, renal, hepatic, hypersensitivity, or other adverse reactions (see full Prescribing Information)¹
- For reduced dose administration instructions, refer to section 2.5 (Preparation and Administration) of the full Prescribing Information

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, occurred in patients treated with LUTATHERA. Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis, during and following LUTATHERA administration for a minimum of 2 hours in a setting in which cardiopulmonary resuscitation medication and equipment are available. Discontinue the infusion upon the first observation of any signs or symptoms consistent with a severe hypersensitivity reaction and initiate appropriate therapy. Premedicate patients with a history of grade 1/2 hypersensitivity reactions to LUTATHERA before subsequent doses. Permanently discontinue LUTATHERA in patients who experience grade 3/4 hypersensitivity reactions.

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Dosing regimen (continued)

Before each dose of LUTATHERA¹

LONG-ACTING SSAs	Must be withheld at least 4 weeks
SHORT-ACTING SSAs	Must be withheld at least 24 hours
AMINO ACID INFUSION	START 30 minutes before and CONTINUE during LUTATHERA infusion and for at least 3 hours after
TIMING	Time for the actual LUTATHERA infusion ranges from 30 to 40 minutes depending on the method of administration See the LUTATHERA Prescribing Information for additional infusion protocol

Your patients can find the nearest treatment centers at www.LUTATHERA-treatmentsites.com



IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

- **Neuroendocrine Hormonal Crisis:** Neuroendocrine hormonal crises, manifesting with flushing, diarrhea, bronchospasm, and hypotension, occurred in <1% of patients in ERASMUS and typically occurred during or within 24 hours following the initial LUTATHERA dose. Two (<1%) patients were reported to have hypercalcemia. Monitor patients for flushing, diarrhea, hypotension, bronchoconstriction, or other signs and symptoms of tumor-related hormonal release. Administer intravenous somatostatin analogues, fluids, corticosteroids, and electrolytes as indicated.

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Patient management

Patient tips for treatment day and follow-up

When discussing treatment day and onward, these reminders can help prepare your patients for LUTATHERA. Patients will receive additional specific details from the treatment facility.



Infusion day medications

- Any required **antinausea therapy will be given on the same day**, before both the amino acid solution and LUTATHERA^{1,4}
- **Amino acid infusion will be started on the same day 30 minutes before—and last for at least 3 hours after—the LUTATHERA infusion¹**



Staying hydrated

- **Patients should drink liquids and urinate frequently before, on the day of, and on the day after administration of LUTATHERA¹**



Breastfeeding

- **Patients should not breastfeed during treatment with LUTATHERA and for 2.5 months after the last infusion of LUTATHERA¹**



Using birth control

- **Patients should use effective birth control during treatment with LUTATHERA and for¹:**
 - 7 months after the last dose if the patient is able to get pregnant
 - 4 months after the last dose if the patient has a partner who is able to get pregnant

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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

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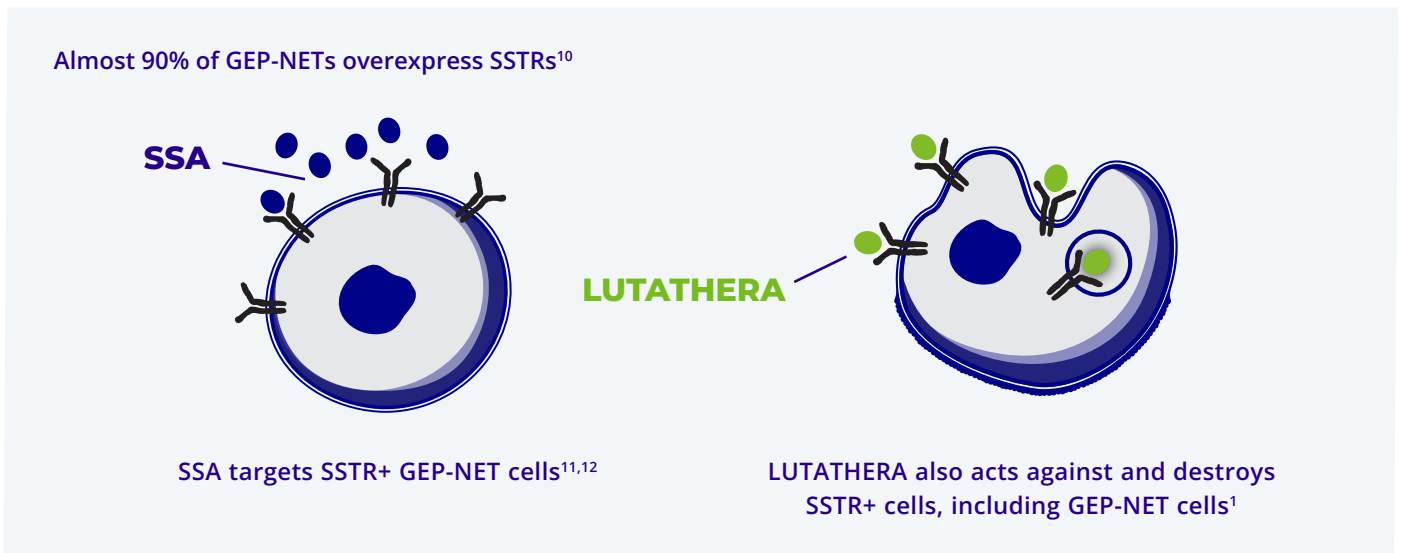
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How LUTATHERA works

LUTATHERA is a targeted treatment that uses radiation to damage SSTR+ cancer cells and neighboring cells¹

- ✓ LUTATHERA contains a targeting component that helps find cells with SSTRs, including GEP-NET cancer cells.
- ✓ Once it finds these target cells, LUTATHERA binds to the SSTRs located on the outside of the cells and enters into the cell.
- ✓ LUTATHERA then delivers radiation that causes damage to the SSTR+ cells and nearby cells.



Based on preclinical models. LUTATHERA delivers radiation that causes damage to the SSTR+ cells as well as neighboring, healthy cells.

LUTATHERA delivers tumor-destroying radiation to SSTR+ GEP-NET cells and neighboring cells¹

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

- **Risk of Infertility:** LUTATHERA may cause infertility in males and females. Radiation absorbed by testes 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.

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Radiation guidelines for patients

Posttreatment patient safety guidelines (NANETS/SNMMI consensus and Mayo Clinic recommendations)

Your patients will receive more details from the treatment center, but here are some frequently discussed topics regarding posttreatment LUTATHERA radiation precautions.



Using the toilet

For at least 3 days, patients should use the toilet in a seated position (even for men) and flush the toilet twice after use.⁴



Showering and personal hygiene

For at least 7 days, patients should shower daily. Patients should use separate towels and washcloths.^{4,13}



Sleeping

For at least 3 days, patients should sleep in a separate bed and avoid intimate contact.⁴



Interacting with others

For at least 3 days, patients should use a general distance guideline of no closer than 3 feet for no more than 1 hour per day. They should try to maintain a distance of 6 feet from others and minimize public transportation and use of public facilities.⁴

For more specific guidance, consult your patient's treatment center

NANETS, North American Neuroendocrine Tumor Society; SNMMI, Society of Nuclear Medicine and Molecular Imaging.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most common grade 3/4 adverse reactions ($\geq 4\%$ with a higher incidence in the LUTATHERA arm) observed in NETTER-1 were lymphopenia (44%), increased gamma-glutamyl transferase (20%), vomiting (7%), nausea (5%), increased aspartate aminotransferase (5%), increased alanine aminotransferase (4%), hyperglycemia (4%), and hypokalemia (4%).

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Radiation guidelines for HCPs and caregivers

HCP and caregiver radiation exposure was tested in a 4-patient, 4-bed outpatient center¹⁴

Radiation exposure in HCPs and caregivers following outpatient treatment with Lutetium 177 on the LUTATHERA dosing regimen was tested in an outpatient study with 4 sequentially treated patients in a 4-bed room.

Exposures to HCPs and caregivers were within ICRP limits (ICRP radiation exposure limit is 20 mSv per year)^{14,15}

Exposure to nurses was similar to that of a flight crew on regular round-trip flights from Los Angeles to Honolulu^{14,16}

Mean whole-body radiation exposures per therapy treatment day with 4 patients when administering Lutetium 177 ranged from 6.8 μ Sv (nuclear medicine technologist) to 33.2 μ Sv (nurse).¹⁴

Exposure to caregivers

For caregivers, mean total exposure during the day of therapy and at home for a period of up to 5 days was 90 μ Sv, with a median exposure of 40 μ Sv and range of 10 μ Sv to 470 μ Sv.¹⁴



Exposure is 14.5 μ Sv on a 5.2-hour flight from Los Angeles to Honolulu¹⁶

Patients are discharged from the treatment center only when radiation exposure to third parties does not exceed regulatory thresholds¹⁴

Seventy-six patients with progressive, metastatic NETs received 4 cycles of 7.8 GBq of Lutetium 177 at 8-week intervals in an outpatient setting at 1 treatment center. Four patients were treated sequentially on each therapy day in a 4-bed room in the hospital's day procedure unit, with each patient remaining until radiation exposure was below the release limit. Radiation exposures to HCPs and caregivers were monitored by personal dosimeter. Twenty-five carers were provided with electronic dosimeters. In the nearby staff office with a 50% staff occupancy factor, the mean (range) exposure rate measured on 10 different therapy administration days was 1.6 μ Sv/h (1.3–2.0 μ Sv/h), and at the nursing station with 100% staff occupancy it was 3.5 μ Sv/h (2.9–4.0 μ Sv/h).¹⁴

GBq, gigabecquerel; HCPs, health care professionals; ICRP, International Commission on Radiological Protection; μ Sv, microsievert; mSv, millisievert; NETs, neuroendocrine tumors.

IMPORTANT SAFETY INFORMATION (continued) ADVERSE REACTIONS (continued)

In ERASMUS, the following serious adverse reactions have been observed with a median follow-up time of >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 crisis (1%). Patients should be counseled and monitored in accordance with the LUTATHERA Prescribing Information.

Adverse reactions observed in pediatric patients were similar to those observed in adults treated with LUTATHERA.

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Most of the adverse reactions seen in the LUTATHERA arm in NETTER-1 were grade 1/2¹

Adverse Reactions Occurring at a Higher Incidence in the LUTATHERA Arm (Between-Arm Difference of $\geq 5\%$ [All Grades] or $\geq 2\%$ [Grade 3/4])¹

Adverse reaction ^a	LUTATHERA + 30 mg octreotide LAR (n=111)		60 mg octreotide LAR (n=112)	
	All grades, %	Grade 3/4, %	All grades, %	Grade 3/4, %
Gastrointestinal disorders				
Nausea	65	5	12	2
Vomiting	53	7	10	0
Abdominal pain	26	3	19	3
Diarrhea	26	3	18	1
Constipation	10	0	5	0
General disorders				
Fatigue	38	1	26	2
Peripheral edema	16	0	9	1
Pyrexia	8	0	3	0
Metabolism and nutrition disorders				
Decreased appetite	21	0	11	3
Nervous system disorders				
Headache	17	0	5	0
Dizziness	17	0	8	0
Dysgeusia	8	0	2	0
Vascular disorders				
Flushing	14	1	9	0
Hypertension	12	2	7	2
Musculoskeletal and connective tissue disorders				
Back pain	13	2	10	0
Pain in extremity	11	0	5	0
Myalgia	5	0	0	0
Neck pain	5	0	0	0
Renal and urinary disorders				
Renal failure ^b	13	3	4	1
Radiation-related urinary tract adverse reactions ^c	8	0	3	0
Psychiatric disorders				
Anxiety	12	1	5	0
Skin and subcutaneous tissue disorders				
Alopecia	12	0	2	0
Respiratory, thoracic, and mediastinal disorders				
Cough	11	1	6	0
Cardiac disorders				
Atrial fibrillation	5	1	0	0

^aNational Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03. Only displays adverse reactions occurring at a higher incidence in LUTATHERA-treated patients (between-arm difference of $\geq 5\%$ [all grades] or $\geq 2\%$ [grade 3/4]).¹

^bIncludes the terms glomerular filtration rate decreased, acute kidney injury, acute prerenal failure, azotemia, renal disorder, renal failure, and renal impairment.¹

^cIncludes the terms dysuria, micturition urgency, nocturia, pollakiuria, renal colic, renal pain, urinary tract pain, and urinary incontinence.¹

The most common grade 3/4 adverse reactions with a higher incidence in the LUTATHERA arm were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), increased AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%).¹

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase.

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NETTER-2 and long-term safety

Safety data from NETTER-2 are consistent with the established profile of LUTATHERA

- The most common adverse events ($\geq 20\%$ in either arm) were nausea (27% vs 18%), diarrhea (26% vs 34%), and abdominal pain (18% vs 27%) for LUTATHERA + 30 mg octreotide LAR vs 60 mg octreotide LAR, respectively⁵
- The most common grade 3/4 adverse events ($>3\%$ in either arm) were lymphocyte count decreased (5% vs 0%), GGT increased (5% vs 3%), small intestinal obstruction (3% vs 0%), and abdominal pain (3% vs 4%) for LUTATHERA + 30 mg octreotide LAR vs 60 mg octreotide LAR, respectively⁵

No new safety signals were reported in the 5-year, long-term follow-up for NETTER-1^{1,9,*}

Adverse Events	During the long-term follow-up, only serious adverse events (SAEs) deemed related to treatment with LUTATHERA and AEs of special interest (hematotoxicity, cardiovascular events, and nephrotoxicity, regardless of causality) in the LUTATHERA arm were reported ⁹
Grade ≥ 3 Treatment-Related SAEs During the Entire Study	7 (6%) of 111 patients treated in the LUTATHERA arm ⁹
Incidence of Treatment-Related SAEs During the Long-Term Follow-Up Period	3 (3%) of 111 patients treated with LUTATHERA⁹ — 2 (1.8%) patients experienced at least 1 grade ≥ 3 SAE (1 grade 5 MDS event) ⁹ — 1 (0.9%) patient experienced an SAE leading to study discontinuation ⁹
MDS or Acute Leukemia	No new cases were reported during long-term follow-up⁹ — MDS incidence from the Prescribing Information for LUTATHERA: In NETTER-1, with a median follow-up time of 76 months in the main study, MDS was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose, long-acting octreotide ^{1,9} — In ERASMUS, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia ^{1,a}
Diffuse Large B-Cell Lymphoma	One patient developed diffuse large B-cell lymphoma during long-term follow-up that was deemed unrelated to treatment with LUTATHERA ⁹
Nephrotoxicity of Grade ≥ 3, Regardless of Causality	Reported in 6 (5%) of 111 patients in the LUTATHERA arm and 4 (4%) of 112 patients in the control arm during the study ⁹

*Cutoff date for final analysis was January 18, 2021.⁹

^aERASMUS study design: Retrospective safety data are available from 1214 patients in ERASMUS, an international, single-institution, single-arm, open-label trial of patients with SSTR+ tumors (neuroendocrine and other primaries). The median duration of follow-up was >4 years.¹

AEs, adverse events; MDS, myelodysplastic syndrome.

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ERASMUS: The retrospective, long-term safety study for LUTATHERA¹

ERASMUS was a retrospective study analyzing safety in a long-term (median, >4 years) follow-up after LUTATHERA treatment

<p>Study Design</p>	<p>Retrospective safety data are available from 1214 patients in ERASMUS, an international, single-institution, single-arm, open-label trial of patients with SSTR+ tumors (neuroendocrine and other primaries). The median duration of follow-up was >4 years</p>
<p>Administration</p>	<p>LUTATHERA 7.4 GBq (200 mCi) was administered every 6 to 13 weeks for up to 4 doses with or without octreotide. Retrospective medical record review was conducted on a subset of 811 patients to document serious adverse reactions</p> <p>— 81% of patients in the subset received a cumulative dose ≥ 22.2 GBq (≥ 600 mCi)</p>
<p>Safety Data</p>	<p>The following rates of serious adverse reactions were reported in ERASMUS: myelodysplastic syndrome (2%), acute leukemia (1%), renal failure (2%), hypotension (1%), cardiac failure (2%), myocardial infarction (1%), and neuroendocrine hormonal crisis (1%)</p>

Please see Warnings and Precautions in the full Prescribing Information for myelosuppression, MDS, and leukemia. Monitor blood cell counts¹

mCi, millicurie.



IMPORTANT SAFETY INFORMATION (continued) DRUG INTERACTIONS

Discontinue long-acting somatostatin analogues at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose.

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Dosing modifications

LUTATHERA dosing may require modification for patients who experience adverse reactions

See more details regarding adverse reactions in the LUTATHERA full Prescribing Information.

Adverse Reaction ¹	Severity of Adverse Reaction ^{1,a}	Dose Modification ¹
Thrombocytopenia	Grade 2, 3, or 4	Withhold dose until complete or partial resolution (grade 0 to 1). Resume LUTATHERA at 3.7 GBq (100 mCi) in patients with complete or partial resolution. If reduced dose does not result in grade 2, 3, or 4 thrombocytopenia, administer LUTATHERA at 7.4 GBq (200 mCi) for next dose. Permanently discontinue LUTATHERA for grade 2 or higher thrombocytopenia requiring a treatment delay of 16 weeks or longer.
	Recurrent grade 2, 3, or 4	Permanently discontinue LUTATHERA.
Anemia and Neutropenia	First occurrence of grade 3 or 4	Withhold dose until complete or partial resolution (grade 0, 1, or 2). Resume LUTATHERA at 3.7 GBq (100 mCi) in patients with complete or partial resolution. If reduced dose does not result in grade 3 or 4 anemia or neutropenia, administer LUTATHERA at 7.4 GBq (200 mCi) as next dose. Permanently discontinue LUTATHERA for grade 3 or higher anemia or neutropenia requiring a dosing interval beyond 16 weeks.
	Recurrent grade 3 or 4	Permanently discontinue LUTATHERA.
Renal Toxicity	First occurrence of: <ul style="list-style-type: none"> • Creatinine clearance less than 40 mL/min; calculated using Cockcroft-Gault formula with actual body weight, or • 40% increase from baseline serum creatinine, or • 40% decrease from baseline creatinine clearance; calculated using Cockcroft-Gault formula with actual body weight 	Withhold dose until resolution or return to baseline. Resume LUTATHERA at 3.7 GBq (100 mCi) in patients with resolution or return to baseline. If reduced dose does not result in renal toxicity, administer LUTATHERA at 7.4 GBq (200 mCi) as next dose. Permanently discontinue LUTATHERA for renal toxicity requiring a dosing interval beyond 16 weeks.
	Recurrent renal toxicity	Permanently discontinue LUTATHERA.

^aGrading of severity is defined in the most current National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).

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Dosing modifications (continued)

Adverse Reaction ¹	Severity of Adverse Reaction ^{1,a}	Dose Modification ¹
Hepatotoxicity	First occurrence of: <ul style="list-style-type: none"> • Bilirubinemia greater than 3 times the upper limit of normal (grade 3 or 4), or • Serum albumin less than 30 g/L with international normalized ratio (INR) >1.5 	Withhold dose until resolution or return to baseline. Resume LUTATHERA at 3.7 GBq (100 mCi) in patients with resolution or return to baseline. If reduced LUTATHERA dose does not result in hepatotoxicity, administer LUTATHERA at 7.4 GBq (200 mCi) as next dose. Permanently discontinue LUTATHERA for hepatotoxicity requiring a dosing interval beyond 16 weeks.
	Recurrent hepatotoxicity	Permanently discontinue LUTATHERA.
Hypersensitivity Reactions ^b	First occurrence of grade 3 or 4	Permanently discontinue LUTATHERA.
Any Other Adverse Reactions ^c	First occurrence of grade 3 or 4	Withhold dose until complete or partial resolution (grade 0 to 2). Resume LUTATHERA at 3.7 GBq (100 mCi) in patients with complete or partial resolution. If reduced dose does not result in grade 3 or 4 toxicity, administer LUTATHERA at 7.4 GBq (200 mCi) as next dose. Permanently discontinue LUTATHERA for grade 3 or higher adverse reactions requiring a dosing interval beyond 16 weeks.
	Recurrent grade 3 or 4	Permanently discontinue LUTATHERA.

^aGrading of severity is defined in the most current National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).

^bIncluding allergic reaction and anaphylaxis.

^cNo dose modification required for hematological toxicities of grade 3 or grade 4 solely due to lymphopenia.

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Patient considerations

Below are a few treatment journey considerations you can discuss with your patients to put them at ease and educate them on next steps.

Eligibility for LUTATHERA

You might be eligible for LUTATHERA if you have an SSTR+ foregut, midgut, or hindgut GEP-NET and your oncologist has considered your specific case appropriate for LUTATHERA treatment.¹ Your health care professionals may ask for tests to confirm your eligibility and that you are ready to start treatments.

LUTATHERA and radiation

LUTATHERA uses targeted radiation to destroy SSTR+ cells and nearby cells, including the cells on your GEP-NET.¹ Your treatment center will provide instructions on radiation precautions and release you to go home when the radiation levels are safe for you and the people regularly around you.

LUTATHERA and side effects

LUTATHERA may cause side effects. Some can be serious, and your treatment may need to be adjusted or stopped, so please talk to a health care professional if you experience any. In clinical trials, the most common grade 3/4 (severe) adverse reactions occurring with a greater frequency among patients receiving LUTATHERA included^{1,5}:

- Decreased blood cell counts
- Nausea
- Decreased blood potassium levels
- Increased liver enzymes
- Increased blood glucose
- Small intestinal obstruction
- Vomiting

There are other possible side effects and safety considerations when it comes to LUTATHERA. For more information, talk to a health care professional.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Dosing and treatment centers

Once your oncologist has confirmed you are ready to begin LUTATHERA, you will go to a treatment center to receive it. You can find the nearest treatment centers online.

At the treatment center, you will be given 2 medicines before each LUTATHERA infusion. These include medication intended to help with vomiting or an upset stomach that you may experience because of the treatment and an IV sterile amino acid solution to help protect your kidneys.¹

You may receive LUTATHERA up to 3 more times after your first infusion. These doses will be between 8 and 16 weeks apart, depending on how you may tolerate the medication. Your oncologist will decide how many doses, and how long between each dose, is right for you.¹

Throughout your treatment journey, you will have tests to evaluate your body's responses to LUTATHERA, and you will receive long-acting octreotide on treatment days and afterward depending on your oncologist's instructions.¹

FDA, US Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (continued) SPECIFIC POPULATIONS

Lactation: Advise patients not to breastfeed during LUTATHERA treatment.

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Novartis Patient Support™

Support to help your patients start and stay on therapy

Designed to provide support in the following areas:



Access & Reimbursement



Affordability



Acquisition



Patient Education

Novartis Patient Support Co-pay Savings

We help make treatment more affordable for your patients through co-pay savings.

**\$25
CO-PAY***

Eligible patients may pay as little as \$25 per dose*

Enrollment in Novartis Patient Support is required to determine eligibility and participation.

*Limitations apply. Valid only for those with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Enrollment Forms for details.



Here's How to Enroll

Simply download the Start Form at www.novartis-patientsupport.com/RLT, fill it out, and fax it to 1-844-638-7329 OR you can also access support by registering for our portal. Registration is required.

Have questions about the enrollment process? Call us at 1-844-638-7222.



Additional Educational Support Is Available for Your Patients

After the decision to start LUTATHERA is made, our dedicated team of Patient Navigators can help answer some of the most common treatment questions. To put your patients in contact with one of our Patient Navigators, call 1-844-638-7222.

Patients must be enrolled in Novartis Patient Support to be considered for financial support.

Visit our website at www.novartis-patientsupport.com/RLT for more information

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GEP-NET advocacy organizations

Are your patients ready to explore more about GEP-NETs on their own?

The following support networks may help patients with general information and social support.



The Carcinoid Cancer
Foundation (CCF)

www.carcinoid.org



The Healing NET Foundation

415 Spence Lane
Nashville, TN 37210
1-615-369-6463

info@thehealingnet.org

www.thehealingnet.org



Learn • Advocate • Connect
A Neuroendocrine Tumor
Society (LACNETS)

PO Box 370466
Denver, CO 80237

info@lacnets.org

www.lacnets.org



The Neuroendocrine
Cancer Awareness Network
(NCAN)

3074 Brookchase Boulevard
Fort Mill, SC 29707
1-866-850-9555

info@netcancerawareness.org

www.netcancerawareness.org



Neuroendocrine Tumor
Research Foundation
(NETRF)

31 St. James Avenue, Suite 365
Boston, MA 02116
1-617-946-1780

info@netrf.org

www.netrf.org



Northern California
CarciNET Community
(NorCal CarciNET)

info@norcalcarcinet.org

www.norcalcarcinet.org

These are provided for informational purposes only. This is not intended to be a recommendation or endorsement of any organization.

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For patients in your care with SSTR+ GEP-NETs,¹⁻³
find out which of them are ready to

START STRONG WITH LUTATHERA

Having a greater understanding of LUTATHERA can help
strengthen ongoing care for your patients with GEP-NETs



By coordinating with your patients' treatment center teams, you can direct your patients appropriately and help ensure continuity of care



Treatment with LUTATHERA consists of a 4-dose treatment regimen, given every 8 weeks at their LUTATHERA treatment center¹



Prepare patients for what to expect before treatment, on their infusion days, and beyond with conversations that can set them up for a successful transition to their treatment center

Help identify which patients in your care could be appropriate candidates
for treatment with LUTATHERA

IMPORTANT SAFETY INFORMATION 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, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.

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