



LETTER OF MEDICAL NECESSITY TEMPLATE

INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Risk From Radiation Exposure:** Bexlutry contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. These risks of radiation associated with the use of Bexlutry are greater in pediatric patients than in adults.

Radiation can be detected in the urine for up to 30 days following Bexlutry administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with Bexlutry 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.

- **Myelosuppression:** In NETTER-1, myelosuppression occurred more frequently in patients receiving lutetium Lu 177 dotatate injection with long-acting octreotide compared to patients receiving high-dose long-acting octreotide (all Grades/Grade 3 or 4): anemia (81%/0) versus (54%/1%); thrombocytopenia (53%/1%) versus (17%/0); and neutropenia (26%/3%) versus (11%/0). 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 nineteen 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 Bexlutry based on the severity of myelosuppression.
- **Secondary Myelodysplastic Syndrome (MDS) 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 lutetium Lu 177 dotatate injection with long-acting octreotide compared to no patients receiving high-dose long-acting octreotide. In ERASMUS, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (9 to 45 months) for MDS and 55 months (32 to 125 months) for acute leukemia.
- **Renal Toxicity:** In ERASMUS, 8 patients (< 1%) developed renal failure 3 to 36 months following lutetium Lu 177 dotatate injection. Two of these patients had underlying renal impairment or risk factors for renal failure (e.g., diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during and after Bexlutry 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 the day after administration of Bexlutry. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue Bexlutry based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure.
- **Hepatotoxicity:** In ERASMUS, 2 patients (< 1%) 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, serum albumin, and international normalized ratio (INR) during treatment. Withhold dose, reduce dose, or permanently discontinue Bexlutry based on the severity of hepatotoxicity.

Please see additional Important Safety Information on page 4 and [full Prescribing Information](#).

CURIUM

SAMPLE LETTER OF MEDICAL NECESSITY



This template is designed to assist providers in developing a letter of medical necessity specific to your organization. The letter should be submitted to the patient's insurance plan to request coverage determination or approval, when necessary. **Fill in all copper bracketed placeholder text with provider- and patient-specific information.** Make sure to familiarize yourself with your patient's health plan coverage criteria and verify the plan's preferred submission method (email, online portal, or fax) before sending.

[Date]

[Health plan name]

[Patient's Name]

ATTN: [Department]

[Patient's plan-specific member ID]

[Medical/Pharmacy Director Name (if available)]

[Date of birth]

[Health plan address]

[Case number]

[City, State, ZIP Code]

[Dates of service]

Re: Letter of Medical Necessity for BEXLUTRY™ (lutetium Lu 177 dotatate injection)

Dear [Medical/Pharmacy Director Name]:

My name is [Physician Name], and I am a [medical specialty]. I am writing this letter of medical necessity on behalf of [Patient Name] to request coverage for BEXLUTRY for the treatment of [indication] associated with ICD-10-CM code(s) [insert ICD-10 code(s)]. This letter provides the clinical rationale and relevant information about the patient's medical and treatment history.

I have been treating [Patient Name] since [Date]. My rationale for prescribing BEXLUTRY is summarized below.

[Include relevant medical information and/or documentation and explain why BEXLUTRY is the most appropriate treatment option. Examples may include:

1. Summary of patient's medical history

- Documentation of patient's history
- Documentation of patient's diagnosis
 - Somatostatin receptor-positive (SSTR+) gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors
- Documentation that the patient has demonstrated progressive disease on somatostatin analog (SSA) therapy (such as octreotide LAR or lanreotide) OR presents with clinically significant tumor burden or symptomatic disease
 - Include the date of and/or time since assessment
- Previous treatment documentation that shows patient has not received prior SSTR radioligand therapy, if applicable

2. Summary of clinical documentation and provider assessment

- SSTR-based imaging (such as Cu 64 dotatate PET/CT or SSTR scintigraphy) results that confirm target lesions are SSTR+
 - Include the date of and/or time since assessment
- Documentation of existing medical conditions that would preclude the use of alternate treatments
- Explanation of why the health plan's preferred therapies are not clinically appropriate for this specific patient
- Clinical assessment of patient's expected prognosis or disease progression without treatment with BEXLUTRY

Abbreviations: CT, computed tomography; LAR, long-acting release; PET, positron emission tomography.

Please see Important Safety Information on pages 1 and 4 and full Prescribing Information.

SAMPLE LETTER OF MEDICAL NECESSITY

3. Supporting trial and guidance recommendations

- Clinical support for your recommendation, eg, clinical trial data from the BEXLUTRY (lutetium Lu177 dotatate injection) prescribing information
- Outline that the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend lutetium Lu 177 dotatate (the reference radioligand therapy) for SSTR+ GEP-NETs*
 - o Eligibility criteria include patients with well-differentiated NETs, SSTR+ status confirmed by SSTR-PET, and adequate bone marrow, renal, and hepatic function
 - o Preferred first-line therapy
 - ☐ Grade 1/2 GEP-NETs: Ki-67 $\geq 10\%$ with clinically significant tumor burden
 - ☐ Grade 3 GEP-NETs (locally advanced/metastatic, unresectable): with clinically significant tumor burden or disease progression OR with favorable biology (Ki-67 $< 55\%$, slow-growing)
 - o Preferred therapy after progression on SSAs
 - ☐ Grade 1/2 GEP-NETs following progression on octreotide LAR/lanreotide

In my medical judgment, this patient is an appropriate candidate for treatment with BEXLUTRY. I have included the full prescribing information for BEXLUTRY, as well as supporting documentation.

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

[Physician name]

[Physician NPI]

[Name of practice]

[Phone number]

Enclosures:

[List and attach additional documents, which may include prescribing information, clinical notes/medical records, testing or imaging results, clinical studies and efficacy data, prior authorization number, and/or clinical practice guidelines.]

Abbreviation: NCCN, National Comprehensive Cancer Network® (NCCN®).

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Neuroendocrine and Adrenal Tumors V.1.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed June 11, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

This letter is provided as an example and is meant for educational purposes only. Insurance coverage or reimbursement is not guaranteed. Since coverage and reimbursement policies differ across payers, plans, patients, and care settings, healthcare providers must ensure that all information and statements submitted to obtain reimbursement are accurate and complete.

Please see Important Safety Information on pages 1 and 4 and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, occurred in patients treated with lutetium Lu 177 dotatate injection. Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis, during and following Bexlutry administration for a minimum of 2 hours in a setting where 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 or 2 hypersensitivity reactions to Bexlutry before subsequent doses. Permanently discontinue Bexlutry in patients who experience Grade 3 or 4 hypersensitivity reactions.
- **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 lutetium Lu 177 dotatate injection 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 analogs, fluids, corticosteroids, and electrolytes as indicated.
- **Embryo-Fetal Toxicity:** Based on its mechanism of action, Bexlutry can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating Bexlutry. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Bexlutry and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with Bexlutry and for 4 months after the last dose.
- **Risk of Infertility:** Bexlutry may cause infertility in males and females. The recommended cumulative dose of 29.6 GBq of Bexlutry results in a radiation absorbed dose to the testes and ovaries within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

ADVERSE REACTIONS

The most common Grade 3-4 adverse reactions ($\geq 4\%$ with a higher incidence in lutetium Lu 177 dotatate injection arm) reported in NETTER-1 were lymphopenia, increased GGT, vomiting, nausea, increased AST, increased ALT, hyperglycemia and hypokalemia.

With a median follow-up time of more than 4 years, 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%).

DRUG INTERACTIONS

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

Glucocorticoids: Glucocorticoids can induce down-regulation of subtype 2 somatostatin receptors (SSTR2). Avoid repeated administration of high doses of glucocorticoids during treatment with Bexlutry.

USE IN SPECIFIC POPULATIONS

Lactation

Advise women not to breastfeed during treatment with Bexlutry and for 2.5 months after the last dose.

Pediatric Use

Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors: The risks of radiation exposure associated with Bexlutry are greater in pediatric patients than in adult patients due to longer life expectancy. The safety and effectiveness of Bexlutry have not been established in pediatric patients younger than 12 years old with somatostatin receptor-positive GEP-NETs.

Pediatric use information is approved for Advanced Accelerator Applications USA INC's LUTATHERA (lutetium Lu 177 dotatate) injection for intravenous use. However, due to Advanced Accelerator Applications USA Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

LUTATHERA® is a registered trademark of Advanced Accelerator Applications International SA.

**Please see additional Important Safety Information
on page 1 and full Prescribing Information.**