

BEXLUTRY FACT SHEET



Please see below for key product information for BEXLUTRY.

Brand Name	BEXLUTRY (lutetium Lu 177 dotatate injection)
FDA Approval Date	09/14/2026
Product Descriptor	Lutetium Lu 177 dotatate, therapeutic, 1 mCi
Indication¹	Indicated for the treatment of adults with somatostatin receptor–positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.
Product NDC	10-digit code: 69945-177-01 (FDA-assigned format) ¹ 11-digit code: 69945-0177-01 (Billing format) ²
Product HCPCS Codes	• A9699 Radiopharmaceutical, therapeutic, not otherwise classified (for Medicare and Commercial beneficiaries in physician offices & freestanding clinics)³ • C9399 Unclassified drugs or biologicals (for Medicare Hospital Outpatient Prospective Payment System [HOPPS] claims)⁴ Providers may initially use the miscellaneous HCPCS codes for BEXLUTRY claims submission until a product-specific code becomes available.⁵ Codes are billed as 1 unit. Curium has applied for a permanent product-specific A-code in accordance with CMS coding processes.
Procedure CPT Code⁶	79101 Radiopharmaceutical therapy, by intravenous administration <i>Please refer to the Billing and Coding Guide for a complete list of codes.</i>
Product Nomenclature¹	An intravenous radioligand therapy (RLT); also known as peptide receptor radionuclide therapy (PRRT)
How Supplied¹	Supplied as a single-dose vial in a lead-shielded, sealed plastic container, or as a syringe when supplied through the nuclear pharmacy
Dosing and Administration¹	The recommended BEXLUTRY dosage for adult patients is a 7.4 GBq (200 mCi) infusion every 8 weeks ($\pm$ 1 week) for a total of 4 doses Administer antiemetics prior to treatment infusion, as appropriate. Initiate the recommended intravenous amino acid solution 30 minutes before BEXLUTRY administration; continue during infusion and for at least 3 hours following completion of the infusion.
Storage and Handling¹	• BEXLUTRY is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure • Store upright at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F); excursions permitted to 15 °C to 30 °C (59 °F to 86° F) • Store in shielded container to protect from ionizing radiation • Calibration is 21 hours from end of product formulation. Reference administration time is 48 hours after calibration • Expiration is 3 hours after reference administration time. Discard appropriately at 72 hours

Abbreviations: CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on pages 3 and 4 and full Prescribing Information.

IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **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.

- **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.



Bexlutry™

(lutetium Lu 177 dotatate injection)
for intravenous use

IMPORTANT SAFETY INFORMATION (cont'd)

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.

References: 1. BEXLUTRY. Prescribing information. Curium US LLC; 2026. 2. National Drug Codes (NDCs) are required for outpatient claims. Anthem. Published June 6, 2025. Accessed May 22, 2026. <https://providernews.anthem.com/ohio/articles/national-drug-codes-ndcs-are-required-for-outpatient-claims-25586> 3. Billing and coding: additional claim documentation requirements for not otherwise classified (NOC) drugs and biological products with specific FDA label indications. Centers for Medicare & Medicaid Services. Updated on June 5, 2025. Accessed May 20, 2026. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=54880&ver=10&=6> 4. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). Centers for Medicare & Medicaid Services. Updated December 17, 2024. Accessed June 9, 2026. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55913> 5. Overview of coding and classification system. Centers for Medicare & Medicaid Services. Accessed May 22, 2026. <https://www.cms.gov/cmsguide-medical-technology-companies-and-other-interested-parties/coding/overview-coding-classification-systems> 6. Jagmin CL, Levy BS, Ashley SL, et al, eds. CPT 2026 Professional Edition. American Medical Association; 2025.

Please see additional Important Safety Information on pages 2-3 and full Prescribing Information.