



RADIOACTIVITY DOSE CALIBRATION GUIDE

The information contained in this document is not intended, nor should it be used, to establish a legal standard of care. It is important to adhere to the full Prescribing Information and all applicable regulations when administering BEXLUTRY.

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.

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LUTETIUM Lu 177 RADIOACTIVITY DECAY INFORMATION

Lutetium 177 (Lu 177) is typically produced in a reactor* via the non-carrier-added (indirect) process, which eliminates Lu 177m impurities (a radioactive isomer with a 160-day half-life). Lu 177 undergoes 100% beta-minus decay to stable hafnium 177 (Hf 177) with a half-life of 6.647 days, as shown in the following equation¹⁻⁵:



Lu 177 emits beta-minus radiation with a maximum energy of 0.498 MeV (79%) and gamma photons of 0.208 MeV (11%) and 0.113 MeV (6.2%).⁴

Continuous radioactive decay makes accurate calibration at the time of BEXLUTRY administration essential to confirm that each patient receives the prescribed activity prior to treatment.^{4,6}

*While Lu 177 can also be produced via cyclotron using deuteron bombardment, reactor production yields are significantly higher and are more suitable for meeting clinical demands.⁵

DOSE CALIBRATOR MEASUREMENT CONSIDERATIONS

Lutetium Lu 177 presents unique challenges for accurate activity measurements due to its mixed emission spectrum.¹ Gamma emissions are the primary contributors to radioactivity dose calibrator response and form the basis of activity measurement. The combination of beta minus particles, low-energy X-rays, and gamma rays results in measurement variations depending on^{1,6}

- Container composition (glass vs plastic)
- Fill volume and geometry
- Positioning within the dose calibrator chamber
- Attenuation of low-energy photons by container walls

For beta-emitters like Lu 177, calibrator activity measurement is mainly based on secondary detection of Bremsstrahlung radiation produced by the slowing of the beta particles as they interact with the solution volume and container composition.^{1,6} Geometric differences can include different types of containers and different filling volumes within the same container.⁶

BEXLUTRY is supplied in a glass vial but may be administered using a syringe pump method.⁴ Since these containers have different photon absorption characteristics, separate syringe calibration is required to maintain accurate activity.⁶

Lu 177 REFERENCE STANDARD INFORMATION

Treatment sites may utilize the Lu 177 BEXLUTRY vial provided by Curium to establish appropriate radioactivity dose calibrator dial settings. The vial is measured at the Curium manufacturing facility and supplied as lutetium Lu 177 dotatate.⁴

The BEXLUTRY vial is provided⁴

- In a 30-mL, clear, colorless, Type I glass vial (the same container used to provide the patient-ready dose)
- In a volume range between 23 and 25 mL
- With an activity of 7.4 GBq (200 mCi) at 5:00 PM ET day of administration

BEXLUTRY has a consistent calibration time at 5:00 PM ET for 200 mCi and expires 3 hours after reference administration time at 8:00 PM ET.^{1,4}

The labeling with the BEXLUTRY vial contains the following information^{4,7}

- Activity measured at Curium manufacturing facility
- Reference time and date
- Product volume
- Lot number

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 **Bexlutry™**
(lutetium Lu 177 dotatate injection)
for intravenous use

STEPS FOR MEASURING ACTIVITY OF BEXLUTRY

Step 1: Premeasurement requirements for treatment site

IMPORTANT NOTE: All measurements and testing described in these steps must be performed on the same dose calibrator. If geometry testing or calibration is to be performed on a different dose calibrator model, all of these measurement steps must be repeated on that instrument.⁷

Complete the following before proceeding with the measurement of BEXLUTRY activity:

Safety

All personnel must follow the established radiopharmaceutical safety protocols of the treatment site and complete the required training for proper handling of radioactive materials.⁷

Quality control

The treatment site must conduct dose calibrator quality control testing, including constancy measurements, according to device manufacturer, site, and regulatory requirements.⁷

Calibrator dial settings

Select the Lu 177 default setting on your dose calibrator.⁸ If the equipment does not have a preprogrammed Lu 177 option, contact your device manufacturer for the appropriate setting.^{7,8} Curium's established dose calibrator settings for Lu 177 liquid in a 30-mL tubing vial for Capintec dose calibrator models were determined based on the volume of the reference standard.^{1,8}

Curium current dose calibrator dial settings^{1*}

Measurement geometry		Dose calibrator model					
Container type	Volume	Lu 177 radioactivity assay range	Capintec CRC-15R	Capintec CRC-25R	Capintec CRC-55tr	Capintec CRC-55tPET	Capintec Smart Chamber HL
Curium's 30-mL vial	15-20 mL	1 mCi-250 mCi				246 x 10	
	22-25 mL	1 mCi-250 mCi				263 x 10	
	5-25 mL	1 mCi-250 mCi	486 x 10	485 x 10	478 x 10		485 x 10

*Ionization chamber calibration factors for assay of Lu 177 radioactivity.¹

It is important for facilities to accurately determine their own calibrated dial settings, as the manufacturer's radionuclide dial setting may not be applicable to the particular geometries used in practice.^{7,9}

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 **Bexlutry**TM
(lutetium Lu 177 dotatate injection)
for intravenous use

STEPS FOR MEASURING ACTIVITY OF BEXLUTRY (CONTINUED)

Step 2: Measurement of Lu 177 activity

CALIBRATION REPORT FORM						
Dose calibrator potentiometer setting						
Model/Model	Serial number	Performed by	Reference date and time (RT)			
Standard source data (measured at Curium manufacturing site)						
Source geometry	Lot number	Reference date and time (RT)	Reference self activity (Bq/g or mCi)	Volume (mL)		
BEXLUTRY™ Bismuth Lu 177 dotatate injection for intravenous use, 30 mL						
Geometry setting for vial						
Date and time (RT) of dose calibrator set up for vial	Curium reference self activity (Bq/g or mCi)	Decay or correction factor	Measured activity (Bq/g or mCi)	Vial volume (mL)	% Difference*	Dial setting for vial
Geometry setting for syringe						
Date and time (RT) of dose calibrator set up for syringe	Calculated initial activity in vial (Bq/g or mCi)	Measured activity in vial (Bq/g or mCi)	Calculated activity in syringe (initial activity × dilution factor)	Measured activity in syringe (Bq/g or mCi)	Syringe volume (mL)	% Difference* Dial setting for syringe
*% Difference = [(Calculated - measured) / calculated activity] × 100						
Comments:						
Performed By: Name		Signature		Date		
BID Review Name		Signature		Date		

NOTE: Treatment site personnel should record all information on the accompanying **Calibration Report form** on page 9 and retain for future reference and regulatory compliance.⁷

Determine expected activity of Lu 177

To accurately determine the current activity of the dose, the treatment sites must account for radioactive precalibration or decay since calibration.⁹ The decay matrix table on the next page tabulates the percentage of remaining Lu 177 radioactivity as a function of time (1 through 99 hours), allowing for calculation of the actual activity at administration time. Values were calculated using the following decay equation¹:

$$A(t) = A_0 \times e^{[-t/(\ln(2)/T_{1/2})]}$$

Where:

A(t) = Activity at time t

A₀ = Initial activity at calibration

t = Time elapsed (hours)

T_{1/2} = Half-life of Lu 177 (159.53 hours)

Using the Lu 177 decay table on the next page, identify the correct decay factor based on the number of elapsed hours between the manufacturer's reference measurement date and time and the measurement of the dose calibration procedure.^{1,9}

Divide the reference activity supplied by the manufacturer by the decay factor if at a precalibration date/time or multiply the reference activity supplied by the manufacturer by the decay factor to compute the expected activity at the time of calibration.^{1,9}

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 **Bexlutry™**
(lutetium Lu 177 dotatate injection)
for intravenous use

Lu 177 radioactivity decay matrix¹

Hours	Hours									
	0	1	2	3	4	5	6	7	8	9
	0	1.00	99.57	99.14	98.71	98.28	97.85	97.43	97.00	96.58
	10	95.75	95.33	94.92	94.51	94.10	93.69	93.28	92.88	92.48
	20	91.68	91.28	90.88	90.49	90.10	89.71	89.32	88.93	88.55
	30	87.78	87.40	87.02	86.64	86.27	85.89	85.52	85.15	84.78
	40	84.05	83.68	83.32	82.96	82.60	82.24	81.88	81.53	81.18
	50	80.47	80.12	79.78	79.43	79.09	78.74	78.40	78.06	77.72
	60	77.05	76.72	76.39	76.05	75.72	75.40	75.07	74.74	74.42
	70	73.78	73.46	73.14	72.82	72.50	72.19	71.88	71.57	71.26
	80	70.64	70.33	70.03	69.72	69.42	69.12	68.82	68.52	68.23
	90	67.64	67.34	67.05	66.76	66.47	66.18	65.89	65.61	65.32

Measure, validate, and document Lu 177 activity^{7,9,10}

Position the reference standard in the dose calibrator and record the measured activity.

Calculate the accuracy percentage using the following formula:

$$\text{Accuracy percentage} = \frac{\text{Activity measured by nuclear medicine department}}{\text{Corrected activity measured by Curium manufacturing facility}} \times 100$$

If your accuracy percentage falls outside your accepted percentage, adjust the dose calibrator dial setting to best align with the corrected activity. All testing should be performed within 1 hour to keep error due to decay at less than 0.5%.



IMPORTANT NOTE: This vial calibration procedure must be completed before proceeding with syringe calibration. See additional instructions on the next page if measuring activity using a syringe calibrator.⁷

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 **Bexlutry**[™]
(lutetium Lu 177 dotatate injection)
for intravenous use

STEPS FOR MEASURING ACTIVITY OF BEXLUTRY (CONTINUED)

Establish separate calibration factor if using syringe for administration of BEXLUTRY



IMPORTANT NOTE: A separate calibration factor may be established for syringe geometry once the vial calibration is complete. Return the dose calibrator to Lu 177 factory default settings and remove the vial from the dose calibrator.⁷

Dose calibration of syringe: Using a sterile syringe fitted with a syringe shield and a sterile needle that is 9-cm (3.5-in), 18-gauge needle, withdraw either half or all of the volume of the BEXLUTRY contents from the vial into the syringe depending on whether you want a geometry of 100 mCi or 200 mCi.^{4,7,11,12}

- To aid withdrawal, a filtered 2.5-cm (1-in), 20-gauge needle (short venting needle) can be used to reduce resistance from the pressurized vial⁴
- Ensure that the short venting needle does not touch the lutetium Lu 177 dotatate injection solution⁴

Vial control: Using a clean syringe, draw up the same volume of saline solution (0.9% NaCl) as the drawn BEXLUTRY contents and inject this saline solution into the glass vial and equilibrate the pressure by having the venting needle in place or pull back on the syringe the same volume as injected. Place the vial in the dose calibrator using the predetermined BEXLUTRY vial setting for Lu 177. Calculate and record the residual activity in the vial.^{7,11,12}

Calculation of the activity in the syringe: Take the difference between the first and second measurements of the glass vial to calculate the activity of BEXLUTRY in the syringe.^{7,11,12}

Adjust the dose calibrator potentiometer setting to match the calculated syringe activity value. This setting becomes your standard for measuring all BEXLUTRY doses in plastic syringes at your facility for that specific dose calibrator.^{7,9}

Accurate decay correction and geometry testing for each dose ensures proper calibration for each patient and is the foundation of safe and effective treatment with BEXLUTRY.^{4,6,7}

CALIBRATION REPORT FORM

Dose calibrator potentiometer setting

Make/model	Serial number	Performed by	Reference date and time (ET)

Standard source data (measured at Curium manufacturing site)

Source geometry	Lot number	Reference date and time (ET)	Reference vial activity (MBq or mCi)	Volume (mL)
BEXLUTRY™ (lutetium Lu 177 dotatate injection) for intravenous use, 30 mL				

Geometry setting for vial

Date and time (ET) of dose calibrator dial setting for vial	Curium reference vial activity from above (MBq or mCi)	Decay or precalibration factor	Decay-corrected activity (MBq or mCi)	Measured activity (MBq or mCi)	Vial volume (mL)	% Difference*	Dial setting for vial

Geometry setting for syringe

Date and time (ET) of dose calibrator dial setting for syringe	Calculated initial activity in vial	Residual activity in vial (MBq or mCi)	Calculated activity in syringe (initial activity – residual activity)	Measured activity in syringe	Syringe volume (mL)	% Difference*	Dial setting for syringe

*% Difference = [(calculated – measured) / calculated activity] × 100.

Comments:

Performed By: Name

Signature

Date

RSO Review: Name

Signature

Date

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **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.

- **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.

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 **Bexlutry™**
(lutetium Lu 177 dotatate injection)
for intravenous use

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 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.

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(lutetium Lu 177 dotatate injection)
for intravenous use

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