

PRE-ACTIVATION CHECKLIST FOR BEXLUTRY™ (lutetium Lu 177 dotatate injection)



Confirm administrative and regulatory requirements

- ☐ AU approval under NRC/state regulations with RAM license including Lu 177 for therapeutic use
- ☐ P&T review or formulary pathway (if required by institution)
- ☐ Product purchase agreement
- ☐ Distribution pathway (direct vs commercial nuclear pharmacy)
- ☐ Curium Connects™ site enrollment and onboarding
- ☐ Internal SOPs



Review radiation safety and shielding requirements

- ☐ RSC approval (if required)
- ☐ ALARA compliance (time, distance, and shielding) to minimize radiation exposure to staff and the public
- ☐ Patient discharge criteria are in alignment with federal (NRC)/state regulatory guidelines, including 10 CFR 35.75 release criteria, as applicable



Confirm billing and reimbursement processes

- ☐ Benefits verification established
- ☐ Prior authorization process defined
- ☐ Chargemaster build (drug, administration, amino acids, and/or imaging, if applicable)
- ☐ Coding information for miscellaneous HCPCS code (A-code or C-code) and JW/JZ modifier process (if applicable to dosing and waste)
- ☐ Reimbursement pathway information ("Buy-and-Bill" vs specialty pharmacy)
- ☐ Patient enrollment in Curium Connects



Consider establishing multidisciplinary plan and team alignment

- ☐ Tumor board and/or multidisciplinary review process to determine RLT candidacy
- ☐ Medical oncologist and nuclear medicine physician to coordinate referral
- ☐ Medical oncology meeting with radiation oncology (if not part of tumor board discussion)
- ☐ RSC to provide protocol approval (if required)

Abbreviations: ALARA, as low as reasonably achievable; AU, authorized user; CFR, Code of Federal Regulations; HCPCS, Healthcare Common Procedure Coding System; P&T, Pharmacy and Therapeutics; NRC, Nuclear Regulatory Commission; RAM, radioactive materials; RLT, radioligand therapy; RSC, radiation safety committee; SOP, standard operating procedure.



Conduct training

- ☐ Physicians (eg, patient selection, dosing, safety monitoring)
- ☐ Nuclear medicine technologists (eg, handling, administration, contamination control)
- ☐ Nurses (eg, handling, administration, concomitant medications, patient education and counseling)
- ☐ Pharmacists (eg, reviewing for interactions, preparing and dispensing pre- and concomitant medications and BEXLUTRY [if onsite], and coordinating with nuclear pharmacy)



Define patient workflow and experience

- ☐ Referral
- ☐ Evaluation
- ☐ Scheduling (eg, dose ordering timelines, coordination with manufacturing, delivery windows, cycle timing, and bed/chair availability)
- ☐ Pretreatment (eg, number of cycles, timing between cycles, in-home lab tests from Curium, and monitoring requirements)
- ☐ Treatment (eg, side effect monitoring)
- ☐ Follow-up (eg, radiation precautions at home, side effect management)



Set up ordering workflow and systems

- ☐ Coordination with nuclear pharmacy (if applicable)
- ☐ Coordination with Curium manufacturing/delivery windows
- ☐ Standardized BEXLUTRY order set (including premeds, amino acids, antiemetics)
- ☐ EMR order set
- ☐ BEXLUTRY administration record (eg, dose, time, residual, disposal)
- ☐ Ordering workflow (eg, cutoff times, scheduling lead times)
- ☐ Radiation spill and contamination response procedures



Gather equipment and infrastructure requirements

- ☐ Dose calibrator validation for Lu 177 in Curium vial or syringe, as applicable
- ☐ Amino acid procurement, pharmacy coordination, and infusion timing protocol set up
- ☐ Shielding (vial/storage), contamination control materials, and compliant radioactive waste handling and decay-in-storage workflow
- ☐ Infusion and administration supplies
- ☐ Designated radiation treatment space/chair and own bathroom (if possible) with spill protection

Abbreviation: EMR, electronic medical record.

CURIUM