Austin Radiological Association

Nuclear Medicine Procedure

PLUVICTO

(Lu-177 vipivotide tetraxetan)

Overview

- PLUVICTO is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy

Procedure Time

- 30 minutes - prep the room
- 30 minutes – administration of Pluvicto
- Availability for patient restroom throughout the procedure
- 45 minutes - clean up, decontamination, and survey

Patient Preparation

- Patient should have had a PSMA-11 scan prior to treatment (radiologist discretion)
- Coordinator to perform consult and verify labs and treatment plan with radiologist prior to treatment and throughout treatment plan.
- Authorized User obtains written consent and provides written directive

Equipment & Energy Windows

- NA – No imaging post-treatment

Radiopharmaceutical, Dose, & Technique of Administration

- Radiopharmaceutical: Lu-177 vipivotide tetraxetan PLUVICTO recommended Dosage: Administer 7.4 GBq (200 mCi) every 6 weeks for up to 6 doses

- The recommended dosage of PLUVICTO may be administered intravenously as an injection using a disposable syringe fitted with a syringe shield (with or without a syringe pump), as an infusion using the gravity method (with or without an infusion pump), or as an infusion using the vial (with a peristaltic infusion pump). A reduced dose of PLUVICTO should be administered using the syringe method (with or without a syringe pump) or the vial method (with a peristaltic infusion pump). Using the gravity method to administer a reduced dose of PLUVICTO is not recommended since it may result in delivery of the incorrect volume of PLUVICTO, if the dose is not adjusted prior to administration. Prior to administration, flush the intravenous catheter used exclusively for PLUVICTO administration with ≥ 10 mL of 0.9% sterile sodium chloride solution to ensure patency and to minimize the risk of extravasation. Manage cases of extravasation as per institutional guidelines.

- Insert a 2.5 cm, 20-gauge needle (short needle) into the PLUVICTO vial and connect via a catheter to 500 mL 0.9% sterile sodium chloride solution (used to transport the PLUVICTO solution during the infusion). Ensure that the short needle does not touch the PLUVICTO solution in the vial and do not connect the short needle directly to the patient. Do not allow the sodium chloride solution to flow into the PLUVICTO vial prior to the initiation of the PLUVICTO infusion and do not inject the PLUVICTO solution directly into the sodium chloride solution.

- Insert a second needle that is 9 cm, 18 gauge (long needle) into the PLUVICTO vial, ensuring that the long needle touches and is secured to the bottom of the PLUVICTO vial during the entire infusion. Connect the long needle to the patient by an intravenous catheter that is pre-filled with 0.9% sterile sodium chloride solution and that is used exclusively for the PLUVICTO infusion into the patient.

- Use a clamp or an infusion pump to regulate the flow of the sodium chloride solution via the short needle into the PLUVICTO vial (the sodium chloride solution entering the vial through the short needle will carry the PLUVICTO solution from the vial to the patient via the intravenous catheter connected to the long needle within approximately 30 minutes).

- During the infusion, ensure that the level of solution in the PLUVICTO vial remains constant.

- Disconnect the vial from the long needle line and clamp the saline line once the level of radioactivity is stable for at least five minutes.

- Follow the infusion with an intravenous flush of ≥ 10 mL of 0.9% sterile sodium chloride solution through the intravenous catheter to the patient.

- ***Be aware the gravity method is the method we prefer however if the dose is reduced you can no longer use the gravity method and will need to use the syringe method listed below.***

- After disinfecting the vial stopper, withdraw an appropriate volume of PLUVICTO solution to deliver the desired radioactivity by using a disposable syringe fitted with a syringe shield and a disposable sterile needle.

- Administer PLUVICTO to the patient by slow intravenous push within approximately 1 to 10 minutes (either with a syringe pump or manually without a syringe pump) via an intravenous catheter that is pre-filled with 0.9% sterile sodium chloride solution and that is used exclusively for PLUVICTO administration to the patient.

- Once the desired PLUVICTO radioactivity has been administered, perform an intravenous flush of ≥ 10 mL of 0.9% sterile sodium chloride solution through the intravenous catheter to the patient.

Post Treatment Restrictions

- Follow PLUVICTO Patient Discharge Instructions

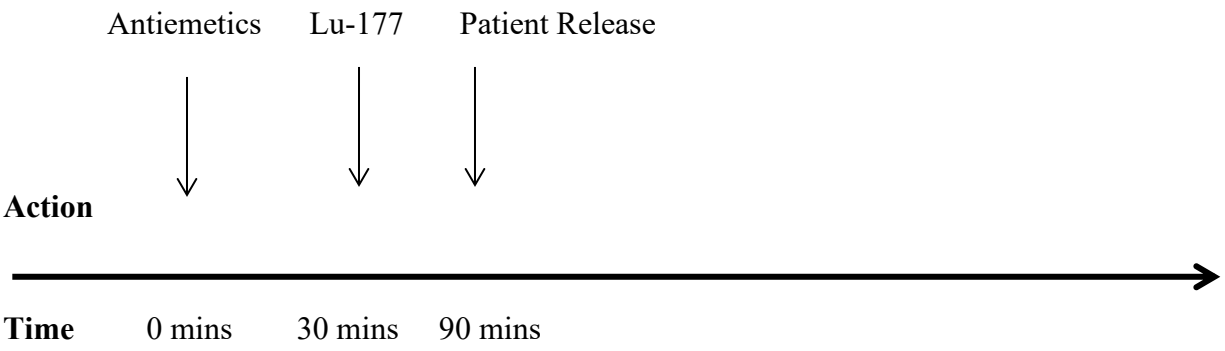
Patient Position & Imaging Field

- NA

Acquisition Protocol

- NA

Protocol Summary Diagram



Data Processing

- NA

Optional Maneuvers

- NA

Method for timely correction of Data Analysis and reporting errors and notification of referring parties

- Data Analysis and reporting errors are reported to the interpreting physician and appropriate clinic manager for timely correction and notification of the referring physician via report addendum or STAT call if error is significant.

Principle Radiation Emission Data Lu-177

- Physical half-life = 6.647 days
- Decays to stable Hf 177.

Radiation	Energy (keV)	Iβ%	Iγ%
β-	176.5	12.2	
β-	248.1	0.05	
β-	384.9	9.1	
β-	497.8	78.6	
γ	71.6	0.15	
γ	112.9	6.40	
γ	136.7	0.05	
γ	208.4	11.0	
γ	249.7	0.21	
γ	321.3	0.22	

Table 2: Estimated Radiation Absorbed Dose for PLUVICTO in VISION

	Absorbed dose per unit activity (Gy/GBq) N = 29		Calculated absorbed dose for 7.4 GBq administration (Gy)		Calculated absorbed dose for 6 x 7.4 GBq (44.4 GBq cumulative activity) (Gy)	
Organ*	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Adrenals	0.033	0.025	0.24	0.19	1.5	1.1
Brain	0.007	0.005	0.049	0.035	0.30	0.22
Esophagus	0.025	0.026	0.18	0.19	1.1	1.1
Eyes	0.022	0.024	0.16	0.18	0.99	1.1
Gallbladder wall	0.028	0.026	0.20	0.19	1.2	1.1
Heart wall	0.17	0.12	1.2	0.83	7.8	5.2
Kidneys	0.43	0.16	3.1	1.2	19	7.3
Lacrimal glands	2.1	0.47	15	3.4	92	21
Left colon	0.58	0.14	4.1	1.0	26	6.0
Liver	0.090	0.044	0.64	0.32	4.0	2.0
Lungs	0.11	0.11	0.76	0.81	4.7	4.9
Pancreas	0.027	0.026	0.19	0.19	1.2	1.1
Prostate	0.027	0.026	0.19	0.19	1.2	1.1
Rectum	0.56	0.14	4.0	1.1	25	6.2
Right colon	0.32	0.078	2.3	0.58	14	3.4
Salivary glands	0.63	0.36	4.5	2.6	28	16
Small intestine	0.071	0.031	0.50	0.23	3.1	1.4
Spleen	0.067	0.027	0.48	0.20	3.0	1.2
Stomach wall	0.025	0.026	0.18	0.19	1.1	1.1
Testes	0.023	0.025	0.16	0.18	1.0	1.1
Thymus	0.025	0.026	0.18	0.19	1.1	1.1
Thyroid	0.26	0.37	1.8	2.7	11	16
Total body	0.037	0.027	0.27	0.20	1.6	1.2
Urinary bladder wall	0.32	0.025	2.3	0.19	14	1.1

*Estimated radiation absorbed dose for bone marrow is not included *[see Warnings and Precautions (5.2)]*.