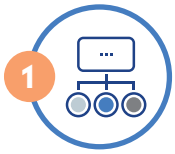
PLUVICTO® iKnowMed® Tool Kit

The purpose of this tool kit is to provide a workflow overview for the administration of PLUVICTO using best practice standards within iKnowMed.

Key Sections:



Integrate EHR Workflows for PLUVICTO Management

Monitor and Refine the Process

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is 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 pathway inhibition (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy

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

GLOBAL Clicking this hyperlink will take user to: https://www.novartis.com/us-en/sites/novartis_us/files/pluvicto.pdf

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

1. Integrate EHR Workflows for PLUVICTO Management

- **Treatment Plan/Order Set:** If your configuration of iKnowMed allows chemotherapy regimen templates, create a **PLUVICTO order set** including:
  - Pluvicto **7.4 GBq (200 mCi) IV every 6 weeks for up to 6 doses.**
  - Pre-medications (add any orders according to institutional protocols).
  - Lab monitoring (include any lab orders and relevant lab tests pre and post therapy).
- **Follow-Up Scheduling:** Use **calendar tools** to auto-schedule follow-ups (eg, renal function checks post-treatment).
- **Referral Coordination:** If PLUVICTO is administered at a specialized center, set up **referral order templates** with any applicable required documentation (eg, PSMA PET report, prior treatment summary).

2. Monitor and Refine the Process

- **Update Criteria:** If indications for PLUVICTO change, adjust filters accordingly.
- **Track Outcomes:** Generate reports on patients treated with PLUVICTO to monitor adherence to guidelines.

Limitations

These instructions are specific to setting up a PLUVICTO treatment plan for the iKnowMed EHR system and cannot be used for other conditions, treatments, or EHR systems. End users should be trained on the appropriate use of the new contents.

Notes

- The user (ie, physician, medical group, or integrated delivery network [IDN]) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each user's EHR system
- Capabilities, functionality, and set-up (customization) for each individual EHR system vary. Novartis shall not be responsible for revising the implementation instructions it provides to any user in the event that user's modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Novartis
- While Novartis tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and Novartis shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Novartis shall have no liability thereto
- The instructions have not been designed to and are not tools and/or solutions for meeting Meaningful Use, Advancing Care Information, and/or any other quality/accreditation requirement
-

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is 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 pathway inhibition (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy

Important Safety Information

Risk From Radiation Exposure

PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and others during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression. In the PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO. One death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of myelosuppression.

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

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

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Important Safety Information *(continued)*

Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, radioactive emissions, including those from PLUVICTO, can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

Infertility

The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

Adverse Reactions and Laboratory Abnormalities

In the pooled safety population for the PSMAfore and VISION studies (N=756), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%), nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back pain (21%).

Please see full Prescribing Information.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

4/25 FA-11404660