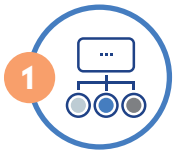
# PLUVICTO® Meditech® Tool Kit

The purpose of this tool kit is to provide a workflow overview for implementing radioligand therapy (RLT) referrals as well as PLUVICTO administration using best practice standards within the Meditech Expanse system.

## Key Sections:




**Best Practices for Workflow Efficiency**

## 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 5-6 and full Prescribing Information.

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## Update Patient Status

- **Action:** Mark patients as "Eligible," "Pending Further Review," or "Not Eligible" directly in the worklist

# 1. Referral Order Placement for Radioligand Therapy

**STEP 1**

### Provider Places a Referral Order

- **User Role:** Ordering Provider (Oncologist, Specialist)
- **Action:** Navigate to Orders and select the Radioligand Therapy Referral order
- **Details to Include in Order:** Patient diagnosis, relevant history, and justification for Radioligand Therapy

**STEP 2**

### Order Routing

- **User Role:** Referral Coordinator or Nuclear Medicine/Radiology/Radiation Oncology Scheduling Team
- **Action:** Review referral order for completeness and route it to Nuclear Medicine/Radiology/Radiation Oncology
- **Communication Tool:** Utilize Referrals Worklist to ensure the referral is sent to the appropriate department for review

# 2. Nuclear Medicine/Radiology/Radiation Oncology Department: Reviewing the Referral

**STEP 3**

### Nuclear Medicine/Radiology/Radiation Oncology Receives and Reviews Referral

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Specialist or Scheduling Coordinator
- **Action:** Navigate to Worklist to access incoming referrals and review patient details
- **Details to Verify:** Confirm patient eligibility, appropriateness for therapy, and any contraindications

# 2. Nuclear Medicine/Radiology/Radiation Oncology Department: Reviewing the Referral *(continued)*

## STEP 4

### Patient Scheduling

- **Action:** Use the Scheduling Module to book a consultation and treatment date for the patient
- **Documentation:** Update the appointment details in the Scheduling Notes

# 3. Ordering and Administering PLUVICTO

## STEP 5

### Placing Order for PLUVICTO

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Specialist or Pharmacist
- **Action:** Navigate to Orders and place an order for PLUVICTO. Ensure proper dose and administration instructions are provided
- **Details to Include:** Dosage, route of administration, and intended therapy date

## STEP 6

### Pharmacy Verification

- **User Role:** Pharmacist
- **Action:** Pharmacist verifies the PLUVICTO order, checking dosage accuracy and potential drug interactions
- **Clinical Decision Support (CDS):** Utilize CDS rules to highlight any contraindications or warnings

## STEP 7

### Medication Preparation and Dispensation

- **User Role:** Pharmacist or Nuclear Medicine/Radiology/Radiation Oncology Technician
- **Action:** Prepare the medication for administration. Document preparation details in the **Medication Preparation Log**

# 3. Ordering and Administering PLUVICTO *(continued)*

**STEP 8**

## Medication Administration

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Nurse or Specialist
- **Action:** Administer PLUVICTO and document in the **MAR (Medication Administration Record)**
- **Details to Include:** Dosage, route, time of administration, and any immediate patient reactions

# 4. Clinical Documentation

**STEP 9**

## Documenting Procedure Notes

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Specialist
- **Action:** Complete a **Procedure Note** in the patient's chart after administering PLUVICTO
  - Include patient condition before and after treatment, details of medication administration, any observed reactions, and follow-up instructions

# 5. Charge Capture

**STEP 10**

## Billing and Charge Capture

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Specialist or Billing Coordinator
- **Action:** Ensure accurate **Charge Capture** by entering relevant **CPT codes** and medication charges
- **Workflow Tool:** Use the Charge Capture Module to record all billing details for PLUVICTO administration and Radioligand Therapy

## Best Practices for Workflow Efficiency

- **Order Sets:** Create **Order Sets** for Radioligand Therapy to ensure that all necessary orders (eg, referral, medication order, follow-up) are included
- **Clinical Decision Support (CDS):** Configure CDS alerts for allergies or contraindications during the ordering process
- **Communication Tools:** Use **In-system Messaging** to communicate seamlessly between departments about patient status or task completion

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## Limitations

These instructions are specific to setting up a PLUVICTO treatment plan for the Meditech 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
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# Indication

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# 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.

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# 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



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