PLUVICTO® OncoEMR® Tool Kit

The purpose of this tool kit is to provide a step-by-step guide for configuring and implementing the Radioligand Therapy workflow in OncoEMR. It includes detailed steps for each phase with guidance for workflow configurations.

Key Sections:

Referrals and Placing PLUVICTO Orders

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 6-7 and full Prescribing Information.

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Referrals and Placing PLUVICTO Orders

STEP 1

Referral Order Placement

Workflow: Providers place a Radioligand Therapy Referral order.

- **Configuration Steps for IT Analysts:**
  - Create a custom order template in OncoEMR's "Orders" module
  - Include required fields for:
    - Patient diagnosis
    - Relevant history
    - Clinical justification
  - Ensure the template is easily searchable for providers

Additional Notes: Train providers to use this referral template and emphasize the importance of completing all required fields for streamlined workflow.

STEP 2

Order Verification and Routing

Workflow: Verify and route orders to the appropriate team.

- **Configuration Steps for IT Analysts:**
  - Utilize the task management system in OncoEMR to:
    - Notify the Nuclear Medicine/Radiology/Radiation Oncology team of pending referrals
    - Assign tasks for incomplete orders

Additional Notes: Ensure all notifications are HIPAA-compliant and routed to the correct roles.

STEP 3

Referral Review by Nuclear Medicine/Radiology/Radiation Oncology

Workflow: Review patient referrals for eligibility and appropriateness.

- **Configuration Steps for IT Analysts:**
  - Customize referral views in OncoEMR to display pending referrals
  - Add options for documenting eligibility and contraindications directly in the patient chart

Additional Notes: Standardize eligibility criteria to ensure consistent decision-making across cases.

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STEP 4

Patient Scheduling

Workflow: Schedule consultations and therapy sessions.

- **Configuration Steps for IT Analysts:**
  - Develop scheduling templates for:
    - Consultations
    - Therapy sessions
  - Automate notifications for appointment confirmations

Additional Notes: Integrate appointment reminders via email or SMS to reduce no-shows.

STEP 5

PLUVICTO Order Placement

Workflow: Place orders for PLUVICTO with predefined details.

- **Configuration Steps for IT Analysts:**
  - Build medication order templates with:
    - Predefined dosing options
    - Administration routes
  - Enable error-checking features during order entry

Additional Notes: Provide training for Nuclear Medicine/Radiology/Radiation Oncology Specialists on using the predefined templates.

STEP 6

Pharmacy Verification

Workflow: Verify medication orders for accuracy.

- **Configuration Steps for IT Analysts:**
  - Configure Clinical Decision Support (CDS) rules for:
    - Dosage checks
    - Drug interaction alerts

Additional Notes: Ensure CDS rules are regularly updated based on the latest clinical guidelines.

STEP 7

Medication Preparation and Dispensation

Workflow: Prepare and document medication details.

- **Configuration Steps for IT Analysts:**
  - Create a Medication Preparation Log template for:
    - Tracking preparation details
    - Recording batch and lot numbers

Additional Notes: Integrate barcoding for accurate tracking of prepared medications.

STEP 8

Medication Administration

Workflow: Administer medication and document details.

- **Configuration Steps for IT Analysts:**
  - Enable nursing documentation modules to capture:
    - Dose
    - Time
    - Route
    - Observations

Additional Notes: Include fields for documenting adverse reactions or side effects.

STEP 9

Clinical Notes Documentation

Workflow: Document procedure details in patient charts.

- **Configuration Steps for IT Analysts:**
  - Develop standardized Procedure Note templates with auto-population of:
    - Patient details & procedure specifics
    - Patient instructions for pre-therapy and post-therapy

Additional Notes: Ensure all mandatory fields are completed before allowing note submission.

STEP 10

Billing and Charge Capture

Workflow: Record procedure and medication charges.

- **Configuration Steps for IT Analysts:**
  - Configure CPT codes for:
    - Radioligand therapy
    - Medication administration
  - Automate charge capture based on documented procedures

Additional Notes: Conduct periodic audits to ensure billing accuracy.

Best Practices for Workflow Efficiency

1. Order Sets: Develop comprehensive Order Sets for Radioligand Therapy.
2. CDS Alerts: Enable alerts for contraindications or incomplete documentation.
3. Communication Tools: Use secure messaging for interdepartmental collaboration.

IT Analyst Notes

- Regularly review system configurations to align with organizational policies
- Provide ongoing training to users to maximize system efficiency
- Monitor workflow performance and gather feedback for continuous improvement

Limitations

These instructions are specific to setting up a PLUVICTO treatment plan for the OncoEMR 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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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.

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