PLUVICTO® Oracle Cerner® Millennium Tool Kit

The purpose of this tool kit is to provide an overview of workflow configuration best practices in the Oracle Health Cerner Millennium EHR system. The tool kit is intended to assist organizations with the configuration of standard tools to streamline the identification and care coordination for patients receiving PLUVICTO.

Key Sections:

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 9-10 and full Prescribing Information.

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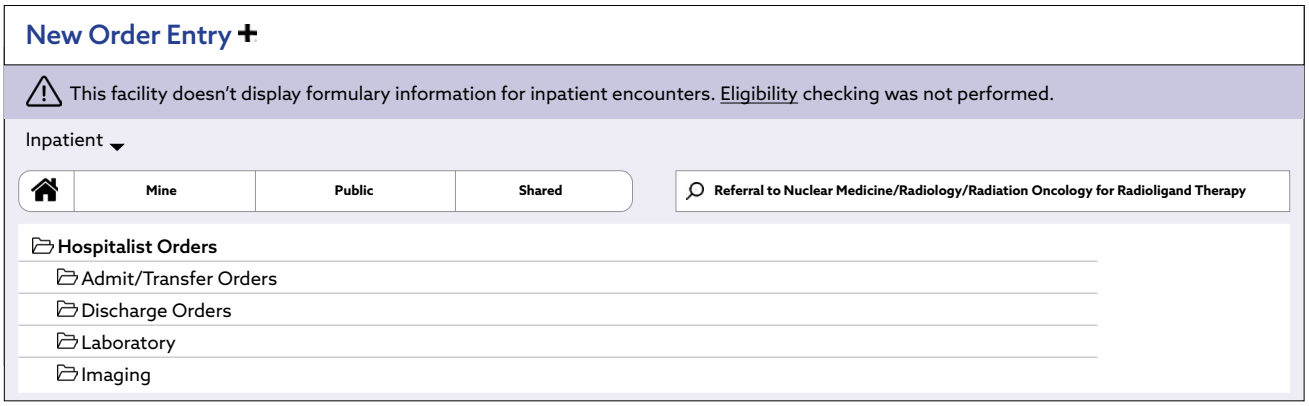
1. Referral Order

STEP 1

Provider Places a Referral Order

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



Configuration Example:

- Configure the Order Catalog to include the Radioligand Therapy Referral order, ensuring it is easily searchable for providers
- Set up Orderables with appropriate attributes, including required fields such as diagnosis and clinical justification

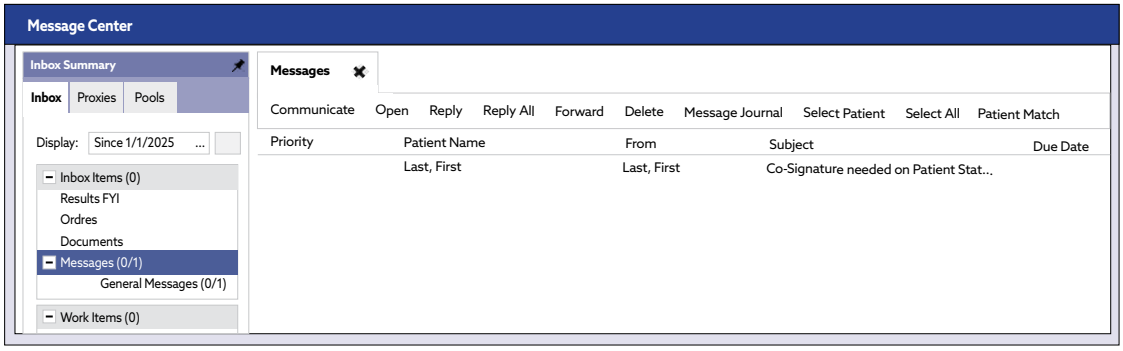
STEP 2

Order Verification and Routing

- **User Role:** Referral Coordinator or Nuclear Medicine/Radiology/Radiation Oncology Scheduling Team
- **Action:** Review referral order for completeness, then route it to Nuclear Medicine/Radiology/Radiation Oncology
- **Note:** Utilize the Message Center or Tasks to flag Nuclear Medicine/Radiology/Radiation Oncology regarding pending referral orders

Configuration Example:

- Create a Message Center Workflow for order routing to Nuclear Medicine/Radiology/Radiation Oncology, including task generation for incomplete referrals



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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 Chart Review or Referral Worklist to access the incoming referral
- **Details to Verify:** Patient eligibility, clinical appropriateness, and any contraindications

Configuration Example:

- Configure a Referral Worklist specific to Nuclear Medicine/Radiology/Radiation Oncology to display pending referrals for Radioligand Therapy

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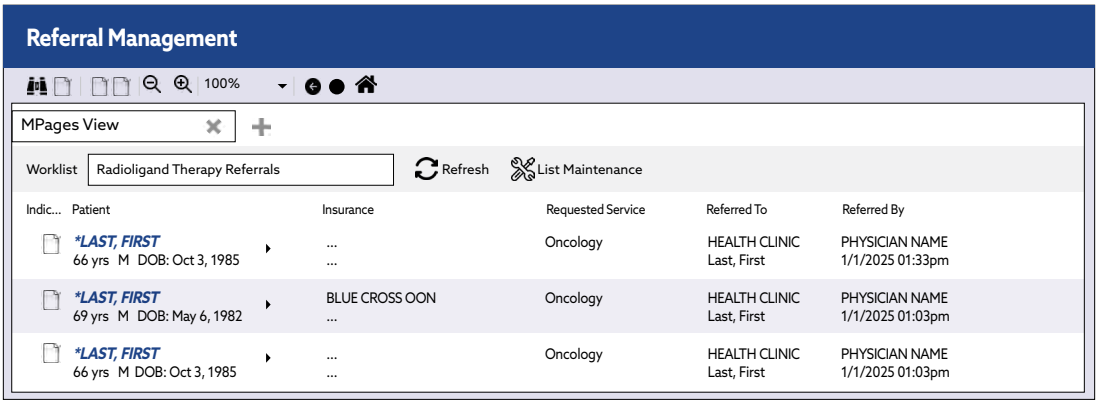
STEP 3

Nuclear Medicine/Radiology/Radiation Oncology Receives and Reviews Referral *(continued)*



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STEP 4

Patient Scheduling

- **Action:** Use Scheduling System to book a consultation and potential therapy date with the patient
- **Communication:** Document the patient appointment details in the Scheduling Notes

Configuration Example:

- Integrate Scheduling Templates for Radioligand Therapy consultations and treatments to streamline patient appointment booking

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3. Ordering and Administering PLUVICTO

STEP 5

Place Order for PLUVICTO

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

Configuration Example:

- Add Order Sentences for PLUVICTO with predefined dosing options to facilitate accuracy and speed in ordering

STEP 6

Pharmacy Verification

- **User Role:** Pharmacist
- **Action:** The pharmacist verifies the PLUVICTO order for dosing accuracy and any potential drug interactions. They use Medication Order Verification workflow

Configuration Example:

- Set up Clinical Decision Support (CDS) rules for medication verification to flag potential interactions or dosage errors

STEP 7

Medication Preparation and Dispensation

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

Configuration Example:

- Create a Preparation Log Template in the system for Nuclear Medicine/Radiology/Radiation Oncology to document PLUVICTO preparation details efficiently

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STEP 8

Medication Administration

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Nurse or Specialist
- **Action:** Administer PLUVICTO to the patient. Record the administration details in the MAR (Medication Administration Record)
- **Documentation Details:** Include dose, route, date/time of administration, and any observations or adverse reactions

Configuration Example:

- Configure the MAR to include specific fields for Radioligand Therapies, ensuring comprehensive documentation

4. Clinical Documentation

STEP 9

Clinical Notes Documentation

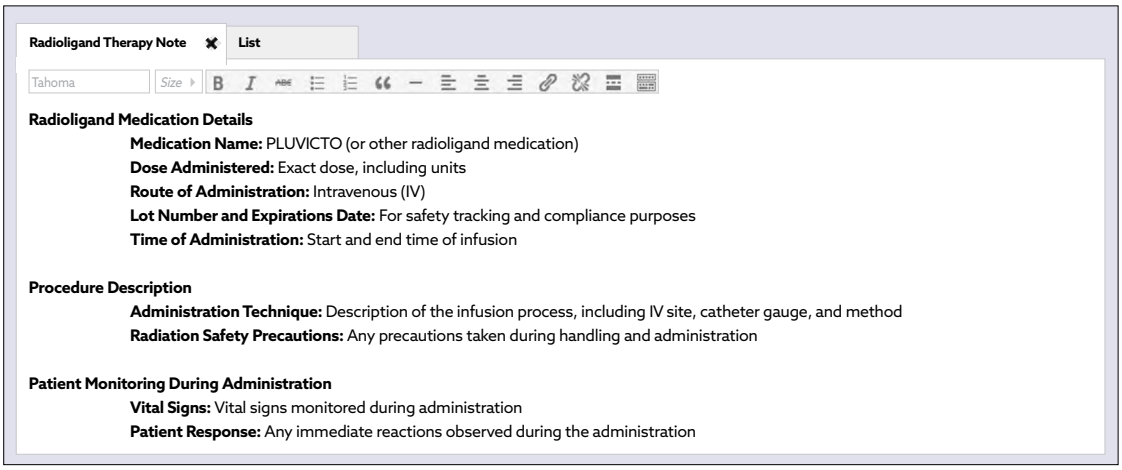
- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Specialist
- **Action:** Complete a Procedure Note in the patient's chart. Include:
  - Patient status pre- and post-administration
  - Details of PLUVICTO administration
  - Any side effects or follow-up care instructions

Configuration Example:

- Develop a Procedure Note Template for Nuclear Medicine/Radiology/Radiation Oncology that auto-populates key data elements and ensures consistent documentation

STEP 9

Clinical Notes Documentation *(continued)*



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5. Charge Capture

STEP 10

Billing and Charge Capture

- **User Role:** Nuclear Medicine/Radiology/Radiation Oncology Specialist or Billing Coordinator
- **Action:** Ensure that the Procedure Code (CPT) and Medication Administration Charges are accurately captured
- **Workflow:** Utilize the Charge Capture Tool within Oracle Cerner Millennium to record the appropriate codes for PLUVICTO administration and Radioligand Therapy

Configuration Example:

- Configure the Charge Capture Tool to include specific CPT codes for Radioligand Therapy and PLUVICTO, with logic to ensure accurate billing based on administration details

Please see Indication and Important Safety Information on pages 9-10 and full Prescribing Information.

STEP 10

Billing and Charge Capture *(continued)*

Best Practices for Workflow Efficiency

- **Order Sets:** Develop an Order Set for Radioligand Therapy to ensure all necessary steps (eg, referral, medication order, follow-up) are included
- **Clinical Decision Support (CDS):** Enable CDS Alerts for contraindications or allergies that may be relevant during the order verification of PLUVICTO
- **Communication Tools:** Use Message Center for seamless communication between departments and to notify key personnel when a task is complete

Configuration Example:

- Create an Order Set Configuration that includes all orders required for Radioligand Therapy, streamlining the ordering process
- Set up CDS Alerts that are triggered when contraindications are detected for patients being considered for PLUVICTO

Limitations

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

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