

PLUVICTO® Epic® Tool Kit

The purpose of this tool kit is to provide a comprehensive guide for implementing radioligand therapy (RLT) using best practice standards within the Epic system. This tool kit addresses several build considerations and utilizes Epic's reporting tools specifically for prostate cancer patients receiving PLUVICTO.

Key Sections:



1

Referral Tracking

- Referral Reporting and Analytics
- Care Everywhere
- EpicCare Link Features Overview



2

Best Practice Workflows: Epic Beacon, Radiant, and MyChart

- Treatment Plan Build Guide
- PLUVICTO Therapy Ordering & Administration - Provider Workflow
- Beacon and Radiant Workflow Integration Considerations
- PLUVICTO Pre-Procedural Consult for RLT Evaluation

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

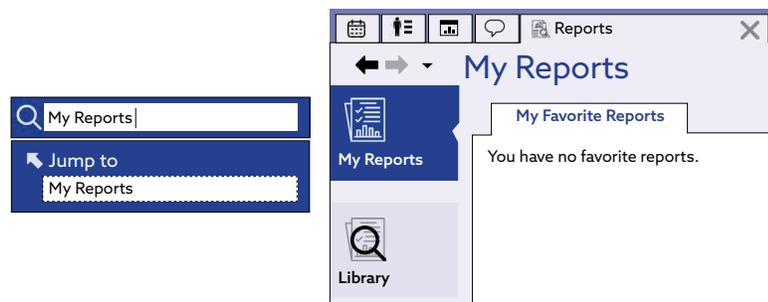
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Referral Tracking Tools

Instructions: The below instructions leverage Epic's referral tracking tools to help health care organizations manage and streamline the referral process. They are designed to track referral statuses, improve communication, and ensure patients receive timely care.

Steps for Using Reporting Workbench

1. Access **Reporting Workbench** (click the **Epic logo** > **Reports** > **My Reports**).



This image is intended for illustrative purposes only.

2. Navigate to the **Library** tab from the **Reports** menu.
3. Enter "**generic criteria**" or "**find patients**" in the search field and click **Search**.
4. Select the **Find My Patients – Generic Criteria** report and click **New** (note: a report template for Find Orders may be available. Consider entering the search term "Orders" to see if a report is available).
5. The **Report Settings** field will display. Click the **Criteria** tab in the toolbar.
6. Click **Add** new criterion and select a criterion. Enter "**diagnosis**" in the search field (**Filter Criteria**). Click **Finish**.
7. Select **Diagnosis by Code** in the search field and enter "**C61**", "**C79.51**", "**C77**", "**Z19.2**" as examples.
8. Add any other desired criteria.
9. Click **Add** new criterion and select a criterion. Enter "**Order Display Name**" in the search field (**Filter Criteria**). Click "**Finish**".
10. In Order Display Name, enter "**Ambulatory Referral to Nuclear Medicine or Radiation Oncology**."
11. Click the **Display** tab. Confirm the **Selected Columns** window (eg, First Name, Last Name, Primary Care Physician, Last Visit, Diagnoses, Order Description, Next Appointment Date).
12. In the **General** tab, enter the desired **Report Name** and a **Description**.

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Steps for Using Reporting Workbench *(continued)*

13. Click **Save and Run** to create the patient list. The list will display all patients matching the criteria.
14. Select the **Filters** tab to narrow down the results by filter (optional).

Referral Order	Patient	MRN	Date	Appt Time	Department	Prov/Res	Appt Stat	Type	Canc Date	Canc Reason	Rescheduled	Cancel Use
ONC RSH PROSTATE: 12345:12345678	Test, Beacon Two	12345	1/1/2025	8:00 AM	MED HEMATO OGY/ONCOLOGY	Name, Name	Sch	Return				
ONC RSH PROSTATE: 12345:12345678	Test, Beacon Two	34567	1/1/2025	8:00 PM	CLINICAL RESEARCH	Name, Name	Sch	CR INFUSION				

← [Icons] Beacon Treatment Plan [Icon] Research Study Enrollment

Treatment Plan Information

PLUVICTO 7.4 GBq (200 mCi)

Current Cycle	Treatment Dates	Line of Treatment	Treatment Goal	Treatment Plan Provider	Treatment Department	Status
1 of 17 cycles	3/1/2024 - 1/7/2025		Curative	Doctors Name	Comprehensive Cancer Dept	Active

Protocol
ONC: PROSTATE: MEDICATION • MEDICATION • As of 1/1/2025 8:25 AM

Reference Links
1. NCCN Guidelines

Treatment Plans Management
[Go to Treatment Plan Manager](#)

Created by: Name, Name on 1/1/2025 8:22 AM Created by: Name, Name on 1/1/2025 8:22 AM

Protocol Notes

** No Notes for this Protocol **

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Care Everywhere

Care Everywhere is a Health Information Exchange (HIE) platform that allows data to be securely exchanged between organizations using Epic, which include referral data, clinical notes, and other relevant information between institutions. In addition, organizations in different health systems using Epic can track referrals across the network using Care Everywhere, facilitating better continuity of care.

The screenshot displays the Care Everywhere interface. At the top, there are navigation tabs for Overview, Documents, and Results. Below the navigation, there are controls for Preview, Refresh (11:19 AM), Select All, Deselect All, and Review Selected. A Filters section includes Default Filter and Patient Summaries. The main area shows a table of referrals with columns for Date, Type, Specialty, Providers, Source, and Description. Below the table, a Clinical Summary is shown for a referral from Health System, dated 1/1/2025. The summary includes patient information, source comments, and a table of allergies.

Date	Type	Specialty	Providers	Source	Description
Yesterday	Clinical Su...			✓ Health System	
Yesterday	Care Plan			✓ Health System	
Yesterday	Dialysis Su...			✓ Health System	
Yesterday	Oncology...			✓ Health System	

Clinical Summary 1/1/2025

Health System
Source Organization

Patient Name - Age, Sex, Date of Birth Clinical Summary, generated on Jan. 1, 2025

Source Comments - Health System
Health System is live on ambulatory and inpatient applications.

Allergies Reconcile with Patient's Chart

Active Allergy	Reactions	Severity	Noted Date	Comments
Dogs	Rash, Itching		06/20/2015	Allergic to dog fur
Mushroom Extract Complex	Nausea and Vomiting		03/15/2005	
Olopatadine Hydrochloride	Palpitations	High	04/20/2011	Sever allergy

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EpicCare Link

EpicCare Link is a web-based portal that allows non-Epic health care providers and external organizations, such as independent physicians and referring providers, to securely access patient information stored in an Epic-hosted electronic health record (EHR). It is designed to enable better collaboration of patient care between treatment providers, streamline communication with specialists, and provide real-time tracking of patient care and referral status.

Key Features of EpicCare Link



Patient Search and Access

- After logging in, users can search for and select a patient in the health care organization's Epic system to create a referral order. They can access relevant patient demographics, medical history, lab results, and more.
- If the patient does not yet exist in the system, users may need to contact the organization to register them before placing the referral order.



Placing a Referral Order

- Once a patient is selected, the affiliate can initiate a referral order from within the patient's record.
- EpicCare Link provides options to refer patients to specialists or specific departments within the health care organization.
- The affiliate can select the desired specialty, enter notes or relevant clinical details, and submit the referral order electronically.



Tracking Referral Status

- After the referral order is placed, the affiliate can track its status through the EpicCare Link portal.
- Real-time updates on the referral order, such as appointment scheduling, referral acceptance, or feedback from specialists, are accessible through the system.
- The status and any updates or results associated with the referral (eg, specialist reports) can be reviewed without the need for phone calls or faxing.

Key Features of EpicCare Link *(continued)*



Viewing Test Results and Documentation

- Once the referral is complete, EpicCare Link allows the affiliate to view any resulting clinical documentation, such as lab results, imaging, or consultation notes, depending on the permissions granted by the health care organization.
- This helps affiliates stay informed about their patient's care throughout the referral process.



Referral Reporting and Analytics

- EpicCare Link can generate reports on referral orders, allowing affiliates to track referral outcomes and monitor patient follow-up.
- Some health care organizations provide tools to analyze referral patterns or ensure compliance with protocols, making it easier for the community practice to manage referrals effectively.

Step-by-Step Workflow to Enter Referral Orders From an Independent Physician Practice Into the Treating Health System's Epic EHR via EpicCare Link

STEP 1

EpicCare Link Login Screen

- **Appearance:** A simple login page with fields for Username and Password. It may include the health care organization's logo and contact information for technical support.
- **Action:** Users enter their credentials and log in to access the EpicCare Link portal.

Step-by-Step Workflow to Enter Referral Orders From an Independent Physician Practice Into the Treating Health System's Epic EHR via EpicCare Link *(continued)*

STEP 2

Dashboard (Home Page)

- **Appearance:** After logging in, users are taken to a dashboard that shows an overview of recent activity, such as referral orders, patient appointments, and notifications. There are multiple tabs and filters (eg, "New Orders," "Pending Referrals").
- **Common Tabs:**
 - Patients: A list of patients assigned to the affiliate's practice or recently referred patients.
 - Referrals: Active referrals, with the status of each referral displayed (eg, pending, scheduled, completed).
 - Messaging: A tab for secure communication with providers in the health care organization.
 - Action: Users can click on tabs to navigate to specific tasks, such as placing or reviewing referral orders.

STEP 3

Patient Search and Details Screen

- **Appearance:** A search bar at the top where users can type the patient's name, medical record number (MRN), or date of birth to locate the correct patient.
- **Patient List:** After a search, results are displayed in a list format, showing key identifiers like the patient's name, age, and MRN.
- **Patient Record:** Once selected, the screen shows a summary of the patient's record, with tabs for Demographics, Medical History, Results, and Documents. Information like the patient's primary care provider and recent visits may also be visible.
- **Action:** Select the patient to enter the referral order.

Step-by-Step Workflow to Enter Referral Orders From an Independent Physician Practice Into the Treating Health System's Epic EHR via EpicCare Link *(continued)*

STEP 4

Referral Order Entry Screen

- **Appearance:** A form with several sections to fill out:
- **Specialty or Department:** A dropdown list or search field where the user selects the department (eg, cardiology, orthopedics).
 - Referral Reason: A text box where the user can provide the reason for the referral or clinical notes.
 - Referral Priority: Options to select the urgency (eg, routine, urgent).
 - Preferred Appointment Date: Users may suggest a preferred date or range of dates for the specialist appointment.
- **Attachments:** If needed, users can upload documents (eg, lab results, imaging reports).
- **Action:** Fill out the required fields and submit the referral order.

STEP 5

Tracking Referral Orders Screen

- **Appearance:** A table listing all the referral orders made by the affiliate, with columns such as:
 - Patient Name
 - Referral Type
 - Status (eg, pending, accepted, scheduled)
 - Date of Request
 - Action Items: Links or buttons to view referral details or results.
- **Filter Options:** Users can filter by date, status, or provider to narrow the list.
- **Action:** Users click on specific referrals to check the status, make updates, or send additional information.

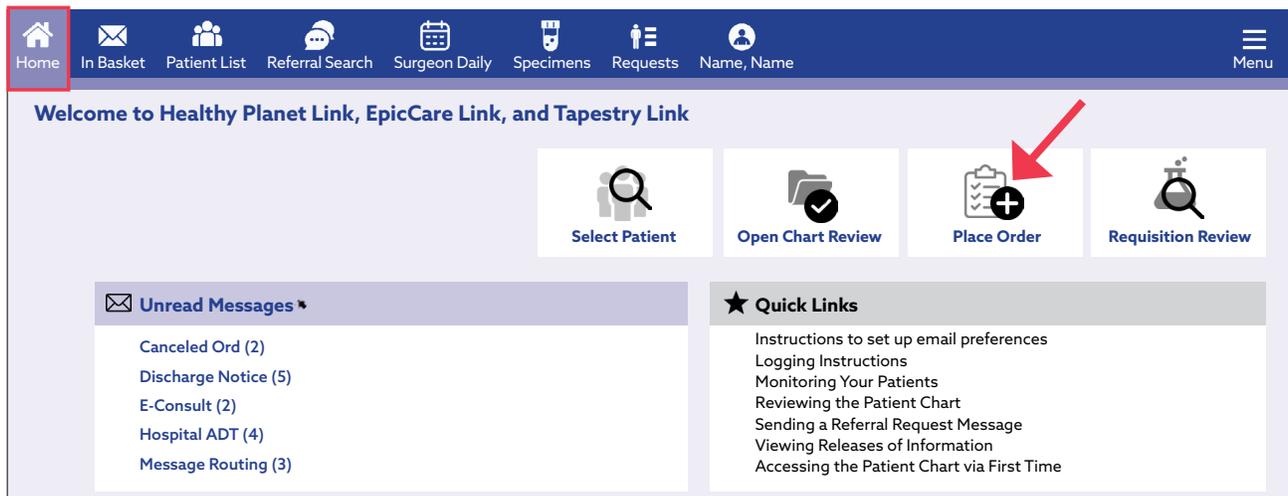
Step-by-Step Workflow to Enter Referral Orders From an Independent Physician Practice Into the Treating Health System's Epic EHR via EpicCare Link *(continued)*

STEP 6

Referral Status Update and Results View

- **Appearance:** A detailed view of the selected referral order, showing:
 - Specialist Appointment: The scheduled date and time (if available).
 - Specialist Notes: Documentation provided by the referred specialist (eg, consultation notes).
 - Results: Lab results, imaging, or other reports that have been completed after the referral.
- **Secure Messaging:** A section to send or receive messages related to the referral.
- **Action:** Users review the status or attach additional information as needed.

EpicCare Link Example Screenshots/User Experience



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Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

EpicCare Link Example Screenshots/User Experience *(continued)*

SnapShot Chart Review Care Everywhere Results Review Flowsheets Problem List Medications Histories Growth Charts Order Entry						
Patient List (2 patient records)						
Refresh						Filter by PCP: <input type="text"/>
PATIENT NAME	MRN	ID TYPE	Sex	DOB	Street Address	
Name, Name	000001234	HBOC	F	12/03/1995	1234 Drive, City, ST 12345	
Name, Name	000001234	HBOC	F	12/03/1995	1234 Drive, City, ST 12345	
Search All Patients						

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Search My Patients	Search All Patients	Create a New Chart
Please fill out the required fields to gain access to a patient/member. Enter the full name as Last, First (example: Doe, John), the date of birth and the patient's sex.		
Patients Select		
Name (Last, First)	Birth date (mm/dd/yyyy)	
<input type="text" value="TestLast, TestFirst"/>	<input type="text" value="8/27/1964"/>	
Sex		
<input type="text" value="Female"/>		
<input type="button" value="Search"/>		<input type="button" value="Clear"/>

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SnapShot Chart Review Care Everywhere Results Review Flowsheets Problem List Medications	
Order Entry	
Select a clinic and authorizing provider for this order.	
<div style="border: 1px solid #ccc; padding: 10px;"> <p>Select Ordering Clinic</p> <p>Patient currently associated with:</p> <p><input checked="" type="radio"/> FAMILY PRACTICE</p> <p><input type="radio"/> THYROID & ENDOCRINE CENTER</p> <p>Select Authorizing Provider</p> <p>Physicians Name <input type="text"/></p> <p><input type="button" value="Accept"/></p> </div>	

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EpicCare Link Example Screenshots/User Experience *(continued)*

Ambulatory Referral to Oncology

Referral: To dept: ONCOLOGY CLINIC [12345] 🔍

Comment: ? 📄 ⬅️ ➡️ 📋

Dx association: **Recent**

<input checked="" type="checkbox"/>	Secondary malignant neoplasm of bone	C79.51
Quick Picks		
<input type="checkbox"/>	Abdominal hematoma	S30.1XX
<input type="checkbox"/>	Body mass index (BMI) 50.0-59.9, adult (HCC)	Z68.43

Add a new diagnosis: 🔍

Status: Normal Standing Future

Expected Date: 📅 Today Tomorrow 1 Week 2 Weeks 1 Month 3 Months Approx.

Expires: 📅 6 Months 9 Months 1 Year

Expires: 📅 1 Month 2 Months 3 Months 4 Months 6 Months 1 Year 18 Months

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Referral Search

Referral Type	Referred By	Referral Status	Scheduling Status
Incoming <input checked="" type="checkbox"/> Outgoing	Incoming 1/2	<input checked="" type="checkbox"/> Select all 10/10	<input checked="" type="checkbox"/> Select all 19/19
Creation Dates	<input type="text"/> Physician Name	<input checked="" type="checkbox"/> Authorized	<input checked="" type="checkbox"/> All Visits Complete
From: <input type="text"/> 📅 To: <input type="text"/> 📅	<input checked="" type="checkbox"/> One Modelink	<input checked="" type="checkbox"/> Canceled	<input checked="" type="checkbox"/> All Visits Scheduled
<input type="text"/> 8/28/2024 📅 <input type="text"/> 2/28/2025 📅		<input checked="" type="checkbox"/> Closed	<input checked="" type="checkbox"/> Appointment Canceled
		<input checked="" type="checkbox"/> Denied	<input checked="" type="checkbox"/> Called 1x
		<input checked="" type="checkbox"/> Incomplete	<input checked="" type="checkbox"/> Called 2x
		<input checked="" type="checkbox"/> New Request	<input checked="" type="checkbox"/> Called 3x
		<input checked="" type="checkbox"/> Open	<input checked="" type="checkbox"/> Do not change
		<input checked="" type="checkbox"/> Pending Review	<input checked="" type="checkbox"/> Do Not Schedule
		<input checked="" type="checkbox"/> Prior Auth Conversation	<input checked="" type="checkbox"/> External - All Visits Comp...
		<input checked="" type="checkbox"/> (none)	<input checked="" type="checkbox"/> External - Ready to Sched...

🔍 Search

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Best Practice Workflows

PLUVICTO Treatment Plan Build Guide

Epic Beacon Module Suggested Implementation

This PLUVICTO EHR best practice guide provides an overview of workflows and associated configurations within Epic Beacon to support ordering and maintaining patients on PLUVICTO. Treatment plans are commonly used in the management of patients. After the initial release of a treatment plan, it may benefit from a clinical update.

Optimization of treatment plans is a common process and provides an opportunity to incorporate treatment updates. As treatment options such as PLUVICTO become available, it may be necessary to create a new treatment plan or update an existing one. Updating relevant treatment plans to include PLUVICTO communicates to the care team that they are available to order for appropriate patients and ensures ease of selection.

Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon

Prostate Radioligand Therapy Treatment Plan

- ▼ Documentation
 - ▼ Progress Note
 - Progress Note
- ▼ Diagnoses
 - ▼ Diagnoses

<input type="checkbox"/> C61 - Malignant neoplasm of prostate	<input type="checkbox"/> Secondary malignant neoplasm of other specified sites [C79.89]
<input type="checkbox"/> Secondary malignant neoplasm of bone [C79.51]	<input type="checkbox"/> Secondary malignant neoplasm of lung [C78.0]
<input type="checkbox"/> Secondary and unspecified malignant neoplasm of lymph nodes [C77]	<input type="checkbox"/> Secondary malignant neoplasm of liver and intrahepatic bile duct C78.7
<input type="checkbox"/> Hormone resistant malignancy status [Z19.2]	

Problem List + Care Coordination Note

Search for problem + Add

Past Problems Show: Past Problems

DxReference

Diagnosis	Priority		
Oncology			
Prostate Cancer	Unprioritized		
Cancer Staging			
Date	Classification	Stage	Status
7/24/2022	Clinical	Stage IIIc (T2, N1, M0)	Signed by Physician on 1/1/2025

+ Add New Staging Information

+ Create Oncology History

+ Create Oncology Treatment Summary Mark as Not Needed

Mark as Reviewed Last Reviewed by Physician Name Problem List Activity

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Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon *(continued)*

Treatment

Plan Summary Consents **Treatment Plan** Supportive Plan Therapy Plan Line Care Signed & Held Orders BMT Cell Therapy

Treatment Plan

PLUVICTO 7.4 GBq (200 mCi) Edit Plan ?

TP Height: 162.6 CM +0.0% 2 days ago (Sunday) TP Weight: 69.9 kg Δ +0.0% 2 days ago (Sunday) TP BSA: 1.78 m2 Δ +0.0% Schedule Orders

Rx External Outpatient Pharmacy

Calendar Day 1, Cycle 1 - Planned for 1/1/2025 Actions

Check Signed
 Check Unsigned
 Release Selected
 Sign Selected

Appointed Requests
 Infusion Appointment Request
 Expected: S, Expires: S+366, 180 minutes (calculated), Schedule appointment at most 0 days before or at most 0 days after

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Plan Creation · PLUVICTO 7.4 GBq (200 mCi)

Overview

Plan Name: PLUVICTO 7.4 GBq (200 mCi) Cycle 1 of 6

Start Date: 1/1/2025 Calendar

i Plan start date is for Day 1, Cycle 1

Line of Treatment: First Line Search

Treatment Goal: Warning Search

Plan Provider: Name, Name Search

Treatment Department: Nuclear Medicine Search

+ Add treatment note

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Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon *(continued)*

STEP 1

Create a New Beacon Protocol

- **Navigate to the Beacon Protocol Manager:**
 - Epic > Oncology > Beacon Protocol Manager or search for Beacon Protocol Manager in the search bar.
 - Click New to create a new protocol for Radioligand Therapy: PLUVICTO.

STEP 2

Define Protocol Settings

- **Protocol Name:** "PLUVICTO Radioligand Therapy."
- **Disease Group:** Select the appropriate oncology disease group (eg, **Adenocarcinoma of the prostate**).
- **Indications:** Include **prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC)** as the primary indication.
- **Treatment Setting:** Outpatient or Day Infusion (based on institutional protocol).

STEP 3

Add Medication Orders for PLUVICTO

- In the protocol setup, add the order for **PLUVICTO**.

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Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon *(continued)*

STEP 4

Order Medication Details:

- **Medication Name:** Search for “PLUVICTO” and select the appropriate National Drug Code (NDC).
- **Dose:** According to prescribing guidelines, PLUVICTO is typically dosed at **7.4 GBq (200 mCi)** per infusion.
- **Route:** Intravenous (IV) infusion.
- **Frequency:** Administer **every 6 weeks** for a total of up to 6 doses.
- **Duration of Infusion:** Specify the infusion time, depending on method of administration and institutional protocols.
- **Premedication Orders:** Add any orders for premedications, according to institutional protocols.

STEP 5

Monitoring and Safety Orders:

- **Radiation Safety Instructions:** Include orders for radiation safety protocols that need to be followed during and after administration (eg, patient isolation, dosimeter usage).
- **Pre- and Post-Therapy Labs:** Include lab orders for renal function (eg, **BUN/Creatinine**) and other relevant lab tests, such as **blood counts** (CBC) before each treatment cycle.
- **Vital Signs Monitoring:** Set orders for monitoring vital signs before, during, and after infusion.

Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon *(continued)*

STEP 6

Configure Scheduling for PLUVICTO Doses

- **Cycle Definition:** Create a cycle template for PLUVICTO.
 - Cycle 1 Day 1: Add the PLUVICTO infusion order.
 - Cycles 2, 3, 4, 5 and 6: Add PLUVICTO for subsequent cycles at 6-week intervals.
- **Total Cycles:** Set to 6 cycles, which is typical for PLUVICTO treatment.
- **Administration Instructions:** Include specific administration instructions in the treatment plan, depending on preferred method(s) of administration.
- **Scheduling Instructions:** Clearly define scheduling parameters for the nurses and scheduling team to ensure doses are administered **every 6 weeks**. Epic has standard functionality to address delays of adjustments to the treatment plan within The Treatment Plan Activity using the Shift Dates and Calculate Schedule functions. Once this is set, the system also reviews any dependencies and adjusts those.

STEP 7

Integrate Lab and Imaging Orders

- **Lab Orders:** Add necessary pretherapy labs, such as:
 - Renal Function Panel (BUN/Creatinine) for renal monitoring.
 - CBC With Differential to monitor for potential hematologic toxicity.
 - Standing lab orders can also be placed and released by the clinician on any visit between dosing cycles.
- **Imaging Orders:** Add necessary pre-therapy and post-therapy **imaging** orders, such as **CT** or **PET scans**.
- **Specify Timing for Imaging:** Imaging is ordered for monitoring based on the PLUVICTO Monitoring Guide and/or institutional protocols.

Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon *(continued)*

STEP 8

Administration Documentation and Medication Administration Record (MAR) Integration

- **Integrate With MAR:** Ensure the administration instructions for PLUVICTO are configured to flow into the MAR so that the infusion process is easily documented by nursing staff.
- **Administration Steps:**
 - Nursing staff should document the start time and end time of the infusion.
 - Include steps for documenting any vital signs, adverse reactions, and radiation safety measures during administration.

STEP 9

Build an Infusion Workflow in the Treatment Plan

- **Infusion Flowsheet:** Configure the infusion flowsheet to track and document the exact dose, time, and infusion details for each cycle.
 - Include specific fields for dose adjustments (if required due to renal or hematologic toxicity).
 - Add the ability to document vital signs at baseline, during infusion, and after infusion.
- **Radiation Safety Instructions:** Add a separate section in the infusion flowsheet for radiation safety instructions that staff must follow, including handling precautions and patient isolation protocols (if required).

Steps for Configuring a PLUVICTO Treatment Plan in Epic Beacon *(continued)*

STEP 10

Add Follow-Up Orders and Monitoring

- **Post-Therapy Monitoring:** Create any follow-up orders for applicable labs (eg, BUN/Creatinine).

STEP 11

Patient Education and Discharge Instructions

- Include standardized **patient education documents** in the protocol, covering:
 - Radiation safety precautions for patients after PLUVICTO infusion.
 - Symptom management and instructions for reporting adverse effects.
 - Follow-up appointment schedules.

STEP 12

Review and Finalize the Protocol

- **Test the Protocol:** Before finalizing, test the protocol in a **sandbox environment** to ensure it flows as expected from medication orders to scheduling and documentation.
- **Obtain Approvals:** Review the protocol with oncology pharmacists, radiation safety officers, and infusion nursing staff to ensure safety and compliance with institutional guidelines.
- **Publish the Protocol:** Once approved, publish the protocol so it is available for oncologists to select in the patient's treatment plan.

Epic Radioligand Therapy Ordering & Administration - Provider Workflow

Ordering PLUVICTO for RLT in Epic requires coordination across oncology and nuclear medicine to ensure accuracy and safety due to the specific handling and administration needs of radiopharmaceuticals. This structured workflow for ordering PLUVICTO in Epic helps maintain a high standard of care, optimizes interdepartmental communication, and enhances patient safety through standardized protocols.

Below is a recommended best practice workflow for ordering PLUVICTO in Epic:

1 Initiate the Treatment Plan in Epic Beacon (Oncology):

- **Order Entry:** Oncologists begin by selecting PLUVICTO as part of a treatment plan within Epic Beacon. This plan should include all specifics, such as dosage, administration intervals, and any preparatory steps required.
- **Pre-Order Checks:** Ensure that appropriate criteria (eg, confirmed diagnosis, patient eligibility, previous treatments) are met according to US Food and Drug Administration (FDA)-approved indications and institution protocols before PLUVICTO is ordered.



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1 Initiate the Treatment Plan in Epic Beacon (Oncology): *(continued)*

PLUVICTO Intravenous Infusion ✓ Accept ✗ Cancel

Status: Normal Standing Future

Expected Date: Today First Available Tomorrow 1 Week 2 Weeks 1 Month 3 Months 6 Months Approx.

Comment: After Procedure After Tests Before Next Visit Before Procedure Other (specify)

Expires: 1 Month 2 Months 3 Months 4 Months 6 Months 1 Year

Priority: Routine Routine STAT

Class: Clinic Administered Clinic Administered Historical

Medication Type: IV Infusion

This image is intended for illustrative purposes only.

2 Create Protocols and Order Sets:

- **Standardized Order Sets:** Build a specific order set for PLUVICTO in Beacon to standardize dosage, safety instructions, and administration details, which ensures consistency and compliance with protocols.
- **Radiopharmaceutical Specific Instructions:** Include applicable specific administration notes (eg, infusion time, radiation safety requirements, hydration protocols) to support Nuclear Medicine in Radiant.

PLUVICTO Intravenous Infusion Plan ✓ Accept ✗ Cancel

Order Instructions: **Radioligand Therapy**

Product: **PLUVICTO**

PLUVICTO **Dose:** 7.4 GBq (200 mCi)
Route: Intravenous

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3 Linking Orders to Nuclear Medicine (Epic Radiant):

- **Order Transmission:** Once the order is signed in Beacon, configure the workflow to automatically transfer the necessary details to Epic Radiant, notifying Nuclear Medicine of the scheduled therapy. The transfer should include specific requirements for radiopharmaceutical handling and patient safety protocols.
- **Order Transmittal Rule Configuration:**
 1. Navigation Path: Epic > Rules Engine > Order Transmittal Rules > New Rule
 2. Rule Name: Beacon to Radiant RLT Transmittal
 3. Trigger Event: Put what you'd like here, site dependent
 4. *Order Placement:* On Order Sign
 5. Source Application Filter:
 6. *Application:* Beacon Oncology
 7. *Encounter Type:* Oncology Treatment Encounter
 8. Orderable Item Filter:
 9. *Orderable Class:* Radioligand Therapy
 10. *Specific Orderables:* PLUVICTO or similar radiopharmaceuticals used in the organization.
 11. Destination Configuration:
 12. Destination Application: Radiant
 13. Destination Worklist: Radiology Scheduler Referral Worklist
- **Alert the Radiology/Radiation Oncology/Nuclear Medicine Team:** Best Practice Advisories (BPAs) or In Basket notifications can alert the Nuclear Medicine department of the need for radiopharmaceutical preparation and patient scheduling in Radiant.
- **Referral Rule Configuration:**
 1. Rule Name: Beacon RLT to Radiology Worklist
 2. Routing Criteria:
 3. *Source Application:* Beacon
 4. *Order Class:* Therapeutic Radiopharmaceutical
 5. *Order Type:* Referral
 6. *Procedure Codes:* Include Current Procedural Terminology (CPT), HCPCS codes, or internal procedure codes specific to radioligand therapies, (PLUVICTO administration code) if available.
 7. Routing Action:
 8. *Destination Worklist:* Radiology Scheduler Referral Worklist
 9. *Notification Type:* In Basket Message to notify Radiology schedulers and Nuclear Medicine team members.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

4 Scheduling and Preparation in Radiant:

- **Schedule the Appointment:** Nuclear Medicine staff schedule the patient's therapy in Epic Radiant, coordinating with the availability of the PLUVICTO dose and the patient's clinical needs.
- **Configure Radiant Worklist View:**
 1. Navigation Path: Radiant > Worklist Configuration > New Worklist View
 2. Worklist Name: Radioligand Therapy Orders From Beacon
 3. Worklist Filters:
 4. Order Source: Beacon Oncology
 5. Order Class: Radiopharmaceutical Therapy
 6. Order Status: Pending Scheduling
 7. Columns to Display:
 8. Patient Name
 9. MRN
 10. Order Date
 11. Treatment Type (eg, PLUVICTO)
 12. Radiation Safety Instructions
 13. Sort Order: Set to prioritize orders by Order Date for timely scheduling
- **Patient Preparation Protocols:** Nuclear Medicine technologists review all preparation requirements.
- **BPA & In-Basket Notification Configuration:** Configure this BPA alert as a safety net to catch missed patient orders/referrals:
 1. Navigation Path: Epic > BPA Builder > New BPA
 2. BPA Name: Notify Radiology of Pending RLT Order
 3. Trigger Condition: When a radioligand therapy order, such as PLUVICTO, is placed in Beacon
 4. Alert Target: Radiology Scheduling Team
 5. BPA Message:
 6. Text: "A new PLUVICTO radioligand therapy order has been placed for patient [Patient Name]. Please review and schedule in Radiant."
 7. Action Buttons: View Worklist, Mark as Reviewed
 8. Navigation Path: Epic > In Basket Setup > Routing Rules > New Rule
 9. Rule Name: RLT Order Notification
 10. Criteria:

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).



4 Scheduling and Preparation in Radiant:

11. Order Class: Radiopharmaceutical Therapy
12. Source Application: Beacon
13. Procedure Code: A9607 (example code for PLUVICTO)
14. Notification Recipients:
 - In Basket Pool: Radiology Scheduling Pool
 - Additional Recipients: Nuclear Medicine Team, Oncology Follow-up Coordinator
15. Message Template:
16. Subject: "Radioligand Therapy Order: [Patient Name]"
17. Body: "An order for PLUVICTO therapy has been placed in Beacon and requires scheduling. Please access the Radiology Scheduler Referral Worklist in Radiant to complete scheduling."

5 Documentation and Follow-Up:

- **Procedure Documentation:** During and after administration, Nuclear Medicine staff document all aspects of the PLUVICTO therapy in Radiant, noting any patient reactions or protocol deviations.
- **Procedure Documentation SmartForm (Option A):** Create a point-and-click SmartForm template to streamline PLUVICTO treatment documentation for Nuclear Medicine staff:
 1. Navigation Path: Epic > SmartTools > SmartForm Builder > New SmartForm
 2. SmartForm Name: PLUVICTO Administration Documentation
 3. Sections to Include: Put what you'd like here, site dependent
 - Patient Preparation: Put what you'd like here, site dependent
 - SmartText: Include fields for preadministration steps such as confirming patient hydration status, medication reconciliation, and preprocedure radiation safety counseling.
 4. Fields:
 - Preprocedure Hydration Status: (Dropdown: Adequate/Inadequate)
 - Medication Review Completed: (Checkbox)
 - Radiation Safety Counseling Provided: (Checkbox with date/time)
 - Medication Administration Details: Put what you'd like here, site dependent
 - SmartText: Document specific administration details of PLUVICTO, including dosage, infusion rate, and any observed patient response.

5 Documentation and Follow-Up: *(continued)*

5. Fields:
 - Medication Name: (Prefilled with "PLUVICTO")
 - Dose Administered: (Numeric field, eg, "7.4 GBq")
 - Infusion Start Time: (Date/Time field)
 - Infusion End Time: (Date/Time field)
 - IV Line Flush Performed Post-Administration: (Checkbox)
 - Patient Monitoring and Observations
 - SmartText: Provide fields for documenting any adverse reactions or notable observations during or immediately after administration.
6. Fields:
 - Vital Signs During Infusion: (Text box or linked to vitals module)
 - Observed Reactions: (Free text, eg, "None," "Nausea," "Mild fatigue")
 - Post-Procedure Instructions Provided: (Checkbox with a text a box for specific instructions if needed)
 - Radiation Safety and Post-Care Instructions
 - SmartText: Capture radiation safety instructions given to the patient, including recommendations for hydration and limiting contact with others.
7. Fields:
 - Radiation Safety Precautions Explained: (Checkbox)
 - Patient Advised to Increase Fluid Intake: (Checkbox)
 - Avoid Close Contact With Others for: (Dropdown options)

• **Procedure Documentation SmartText (Option B):** Create a SmartText or SmartPhrase for Nuclear Medicine staff to efficiently complete treatment documentation:

1. Navigation Path: Epic > SmartTools > SmartPhrase Builder > New SmartPhrase
2. SmartPhrase Name: .PLUVICTOADMIN
3. SmartPhrase Text:
4. ****Radioligand Therapy Administration Note****
 - ****Medication:**** PLUVICTO
 - ****Dose:**** [[7.4 GBq]]
 - ****Administration Date:**** [[DATE]]
 - ****Infusion Start Time:**** [[TIME]]
 - ****Infusion End Time:**** [[TIME]]
 - ****Pre-Procedure Patient Preparation:****
 - Patient hydrated adequately: [[Yes/No]]
 - Medication reconciliation completed: [[Yes/No]]
 - Radiation safety counseling provided: [[Yes/No]]

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

5 Documentation and Follow-Up: (continued)

- ****Vital Signs During Administration:****
 - Blood Pressure: [[BP]]
 - Heart Rate: [[HR]]
 - Respiratory Rate: [[RR]]
- ****Observed Reactions During Infusion:**** [[Free text: None, Mild, Severe reactions]]
- ****Post-Administration Instructions:****
 - Radiation safety instructions provided.
- **Oncology Follow-Up:** Following treatment, results and any post-therapy imaging are documented in Beacon and shared with the Oncology team to assess efficacy and plan further treatments.
- **Treatment Plan Manager:** Leverage the Treatment Plan Manager activity to review all relevant treatment plan information from Beacon, including Radioligand Therapy order and administration details, past and upcoming appointments, patient care team information, and other relevant details, such as a patient snapshot and the longitudinal plan of care.

Treatment Plan Manager · PLUVICTO

Save ◀ Restore + Add Future Plan ➔ Advanced Next Plan ✕ Discontinue Plan || Put Plan On Hold ✉ Send Plan ⚙ Add/Remember

TP Weight: **68 kg** Δ +0.0% ⌚ 3d ago

TP BSA: **1.83 m²** Δ +0.0% ⌚ Height: 3d ago

Rx Health Provider

+ Add
🔗 Modify Dose
👁 Show ▼

This image is intended for illustrative purposes only.

Visit Report

◀ ↻ 🖨 📄 📅 🔍

Name, Name MRN:12345 (66 y.o. M)

Treatment Plan Information

PLUVICTO 7.4 GBq (200 mCi) Cycle 1 of 6

Current Cycle	Treatment Dates	Line of Treatment	Treatment Goal	Treatment Plan Provider	Treatment Department	Status	Auth Status	Next Unauthorized Day
1 of 6 cycles	1/1/2025 to 1/1/2026	First Line	Curative	Physician Name	EMC Chemo Infusions	Active		Day 1, Cycle 1-1/1/2025

Protocol
PLUVICTO 7.4 GBq (200 mCi) Cycle 1 of 6

Treatment Plan Management	Created By	Created On	Updated By
Go to Treatment Plan Manager ▶ View ▶ Edit	Physician Name	1/1/2025 3:19 PM	Physician Name

Related Active Treatment Plan

Plan Name	Type
Name	Oncology Supportive Care
Name	Infusion Treatment

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Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

6 Post-Therapy Monitoring and Coordination:

- **Monitor for Adverse Effects:** Nuclear Medicine, Radiation Oncology, and/or Oncology teams should closely monitor for any adverse effects post-treatment, updating both Beacon and Radiant with relevant clinical information.
- **Billing and Coding:** Ensure that correct billing codes for RLT are used to streamline reimbursement processes.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).



Beacon Oncology and Radiant Radiology Workflow Integration Considerations

Integrating RLT orders within Epic's Beacon (Oncology) and Radiant (Radiology) applications requires a coordinated workflow to ensure patient safety and treatment efficacy. By considering this workflow and configuration, health care organizations can provide cohesive and effective RLT treatments, leveraging the strengths of both Epic Beacon and Radiant applications.



One recommended approach:

1 Order Placement in Epic Beacon:

- **Initiate a Treatment Plan:** Oncologists should begin by creating a treatment plan in Epic Beacon, selecting appropriate protocols that include RLT.
- **Enter Orders:** Within the treatment plan, place orders for the necessary RLT, ensuring all details—such as dosage, administration schedule, and specific instructions—are accurately documented.



This image is intended for illustrative purposes only.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

1 Order Placement in Epic Beacon: *(continued)*

PLUVICTO Intravenous Infusion ✓ Accept ✕ Cancel

Status: Normal Standing Future

Expected Date: Today First Available Tomorrow 1 Week 2 Weeks Approx.
 1 Month 3 Months 6 Months

Comment: After Procedure After Tests Before Next Visit Before Procedure
 Other (specify)

Expires: 1 Month 2 Months 3 Months 4 Months 6 Months 1 Year

Priority: Routine Routine STAT

Class: Clinic Administered Clinic Administered Historical

Medication Type: IV Infusion

This image is intended for illustrative purposes only.

2 Order Transmission to Epic Radiant:

- **Seamless Integration:** Once the order is signed in Beacon, it should automatically flow to Epic Radiant, notifying the Nuclear Medicine department of the pending procedure. This integration minimizes manual errors and ensures consistency across departments.

3 Scheduling in Epic Radiant:

- **Appointment Scheduling:** Nuclear Medicine staff use Epic Radiant to schedule the therapy session, coordinating with the patient's availability and preparing the necessary resources. It is also recommended to configure the Referrals module to track incoming internal/external referrals, authorization status, and other key referral details linked to the appointment and order. Worklists can then be generated to make sure the next appropriate workflow action is taken:

RLT Therapy Incoming Referrals Worklist								
MRN	Patient	DOB	Age	Sex	Referring Provider	Authorization Complete	Appointment Scheduled	Appointment Confirmed
12345	Last, First	12/12/1944	75	5	Male	Physicians Name	✕	 Authorization has not been complete This patient has an active referral order for Radioligand Therapy that requires authorization. Please complete the required authorization documentation in the referral record linked here
12345	Last, First	10/04/1975	44	5	Male	Physicians Name	✓	
12345	Last, First	01/01/1940	79	5	Male	Physicians Name	✕	
12345	Last, First	10/01/1969	50	5	Male	Physicians Name	✕	

This image is intended for illustrative purposes only.

- **Protocol Review:** Radiologists review the order details, confirm the appropriate protocol, and make any necessary adjustments before the procedure.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

4 Procedure Execution:

- **Patient Preparation:** On the day of the procedure, technologists prepare the patient according to the established protocols, ensuring all safety measures are in place.
- **Documentation:** Throughout the procedure, technologists document the process in Epic Radiant, noting any deviations or pertinent observations.

5 Postprocedure Care:

- **Immediate Review:** After the procedure, radiologists conduct a preliminary review of the results and document their findings.
- **Result Communication:** Findings are communicated to the oncologist, who then discusses the outcomes with the patient and adjusts the treatment plan as necessary.

Configuration Recommendations:

Standardized Order Sets:	Develop specific order sets within Beacon for radioligand therapies to streamline the ordering process and reduce variability.
Alerts and Reminders:	Implement BPAs to notify providers of critical steps or potential issues, enhancing patient safety.
Interdepartmental Communication:	Facilitate regular meetings between Oncology and Nuclear Medicine departments to review protocols, discuss cases, and ensure alignment in treatment approaches.
Training:	Nuclear Medicine staff may need to be cross-trained in Beacon and Radiant, as they will likely need to interact with Beacon ordering tools and reports during RLT therapy initiation or administration.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

RLT Therapy MyChart Patient Outreach Best Practices

1. Leverage Reporting Workbench Worklists (in this example, powered by Healthy Planet Registries) to drive efficient batch follow-up from a shared screen.

The screenshot displays the MyChart Patient Outreach interface. At the top, there are navigation options: Filters, Options, Re-run Report, Pt Outreach, Chart, Place Orders, Send Communication, Complete, Reassign, and Assign Me. Below this is a table of tasks with columns for Patient, Task, Due, Priority, Status, Care Gap, Next PCP Visit, and Last Visit Date. The tasks are:

Patient	Task	Due	Priority	Status	Care Gap	Next PCP Visit	Last Visit Date
? Patient Name	Nutritional Clearance	05/02/2023	Medium	○	5		
? Patient Name	wash/dry feet carefully daily	05/02/2023	Medium	○	4	1/1/2025	
- Patient Name	check 2 times/day, document	05/02/2023	Medium	○	3	1/1/2025	
Patient Name	schedule appointment	05/02/2023	Medium	○	3		

Below the task list is a 'Patient Task Info' section for a patient named 'Patient Name', 34 y.o. Male, DOB 3/4/1991. It includes contact information and PCP details. To the right is a 'Tasks To Do' section showing an overdue task for 'Nutritional Clearance' assigned to the first last name, due 5/2/2017.

On the far right is a 'Care Team' section listing a Physician Name, MD (PCP - General, Family Medicine, started 2 weeks ago) and a Nurse Name, RN (Care Manager, Family Medicine, started today, phone 123-456-7890).

At the bottom is an 'RLT Therapy' table:

MRN	Patient	DOB	Age	Sex	Current PCP	Admitted	RLT Therapy
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	6
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	13
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	6
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	6
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	6
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	1
100012345	Name	12/12/1951	68	Male	Physician Name, MD	Yes	1

A callout box highlights the '13 RLT Therapy Overdue' entry, stating: 'Details & Data Points (ex. missed appointment) displayed here'.

This image is intended for illustrative purposes only.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

RLT Therapy MyChart Patient Outreach Best Practices *(continued)*

2. Configure a Communications template to include the information you'd like to share with the patient, such as links to clinical literature, helpful videos, or embedded SmartLinks for missed and future appointments.

Bulk Communication

Outreach Details | Routing Details

Template Selection

Mail/Phone template: [dropdown]

MyChart template: [dropdown]

MRN	Patient	10/26/19	Name, MD
123456	Patient Name	10/26/1954	Male Physician Name, MD
123456	Patient Name	10/26/1990	Female Physician Name, MD

Send Bulk Communication
Generate Letters
Send Patients Messages
Send Staff Messages

Select a template or click in this area to compose your own.

Send Communication Cancel

Bulk Communication

Outreach Details | Routing Details

Template Selection

Mail/Phone template: POPCOM

MyChart template: POPCOM

Mail/Phone View | MyChart View

★ B [icons] Insert SmartText Insert SmartList

@TODAY DATE@

Dear @FNAME@

Our records indicate that you are overdue for a follow up visit. Regular physical exams are an important part of care and general wellness. Please contact the clinic to schedule an appointment.

See the attached information for tips on managing your care at home.

Sincerely,

Name Name, Clinic Manager

Outreach Tracking

Contacted about [dropdown] Add

Next contact [dropdown]

Any SmartData Elements configured in letter templates will not be filed.

Send Communication Cancel

This image is intended for illustrative purposes only.



Limitations

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

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

Physician Pre-Procedural Consult Template

Epic Clinical Documentation Template (ex. Epic SmartText) used to document requirements in a consultation note.

Patient Information

- **Name:** {Patient.Name}
- **MRN:** {Patient.MRN}
- **DOB:** {Patient.DOB}
- **Gender:** {Patient.Gender}

Reason for Consultation

- Evaluation for suitability to receive radioligand therapy.

Pre-Procedural Tests

1. **Laboratory Tests:** add any applicable lab tests based on institutional guidelines
2. **Imaging Studies:** add any applicable lab tests based on institutional guidelines

Physician Pre-Procedural Consult Template

(continued)

Patient Vitals

- **Date and Time of Vitals:** {Date/Time}
- **Heart Rate:** {Patient.HeartRate} bpm
- **Blood Pressure:** {Patient.BloodPressure} mmHg
- **Respiratory Rate:** {Patient.RespiratoryRate} breaths/min
- **Oxygen Saturation:** {Patient.OxygenSaturation}%
- **Temperature:** {Patient.Temperature} °F
- **Height:** {Patient.Height} inches or cm
- **Weight:** {Patient.Weight} lbs or kg
- **BMI:** {Patient.BMI}

Clinical Documentation

1. Patient History:

- Relevant medical history, including oncological history.
- Previous treatments and therapies.
- Allergies and medication history.

2. Physical Examination:

- General appearance
- **HEENT:** {PhysicalExam.HEENT}
- **Cardiovascular:** {PhysicalExam.Cardiovascular}
- **Pulmonary:** {PhysicalExam.Pulmonary}
- **Abdomen:** {PhysicalExam.Abdomen}
- **Extremities:** {PhysicalExam.Extremities}
- **Neurological:** {PhysicalExam.Neurological}

3. Assessment and Plan:

- Suitability for radioligand therapy.
- Additional tests or imaging required.
- Consultation with other specialists (if applicable).
- Next steps in the treatment plan.

4. Patient Education:

- Discuss the purpose, risks, and benefits of radioligand therapy.
- Address patient concerns and answer questions.
- Provide pre-procedural preparation instructions.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

Physician Pre-Procedural Consult Template

(continued)

Physician Attestation

- **Physician Name:** {Physician.Name}
- **Date/Time of Consultation:** {Consultation.DateTime}
- **Signature:** {Physician.Signature}

Additional Notes

- Ensure all results and documentation are reviewed prior to scheduling therapy.
- Obtain informed consent if the patient is deemed suitable for treatment.

Limitations

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

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.

Please see Indication and Important Safety Information on pages 35-36 and full [Prescribing Information](#).

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.

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 ($\geq 20\%$) 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](#).

