PLUVICTO (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN)

Date: Click or tap to enter a date. ☐ **Initial Consult** ☐ **Follow Up**

Identity Verified: ☐ Full Name ☐ Electronic Data Interchange Personnel Identifier (EDIPI)/Full Social Security ☐ Date of Birth

☐ **Medication Reconciled** ☐ **Allergies Reviewed**

Diagnosis: Click or tap here to enter text.

Staging AJCC: _____ Pathology: _____ ECOG PS: _____

Indication: Prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

Mechanism of Action: Lutetium Lu 177 vipivotide tetraxetan is a radioligand therapeutic agent. The active moiety of lutetium Lu 177 vipivotide tetraxetan is the radionuclide lutetium-177 which is linked to a moiety that binds to PSMA, a transmembrane protein that is expressed in prostate cancer, including mCRPC. Upon binding of lutetium Lu 177 vipivotide tetraxetan to PSMA-expressing cells, the beta-minus emission from lutetium-177 delivers radiation to PSMA-expressing cells, as well as to surrounding cells, and induces DNA damage which can lead to cell death.

Elimination: Lutetium Lu 177 vipivotide tetraxetan terminal elimination half-life is 41.6 hours (68.8%) and clearance is 2.04 L/h (31.5%).

Half Life: 6.647 days **Excretion:** Urine excretion

Response Rate: Median Overall Survival improved by 4 months; Radiographic progression-free survival increased by 5.3 months

Last Chemotherapy: Click or tap to enter a date. (Should not be within 4 weeks)

Patient Selection: ☐ PSMA PETClick or tap to enter a date. ☐ FDG PETClick or tap to enter a date.

☐ >1 PSMA+ lesion ☐ Metastatic disease predominantly PSMA+ ☐ No dominant PSMA- lesions.

☐ Patient reviewed at tumor board ☐ Consider corticosteroids 1 day prior and up to 7-14 days post treatment

☐ Cerebral/spinal or other metastases that risk painful or obstructive swelling/inflammation

Possible Exclusion:

☐ Life expectancy < 6 months (ECOG performance status >2)

☐ Main objective is alleviating suffering from disease-related symptoms.

☐ Unmanageable urinary tract obstruction, hydronephroses or incontinence

☐ Diagnosed, or high risk of urinary retention:

☐ Consider Tc99m-MAG3 renal scintigraphy as a baseline exam

☐ Progressive deterioration of organ function:

☐ GFR <30 mL/min ☐ Creatinine > 2x ULN ☐ Liver enzymes >5x ULN

☐ Myelosuppression:

☐ Total WBC < 2.5 x 10^9/L ☐ PLT count < 75 x 10^9/L

☐ Condition requiring time sensitive intervention (Consider after resolution of acute concern)

☐ Radiation therapy ☐ Surgery for imminent spinal cord compromise ☐ Unstable fracture

Contraindications: Pregnancy ☐ None☐

Adverse Reactions:

☐ ≥20% Fatigue ☐ Dry mouth ☐ Nausea ☐ Anemia ☐ Decreased appetite ☐ Constipation

Laboratory Abnormalities: ≥30% Decreased: Lymphocytes ☐ Hgb ☐ Leukocytes ☐ PLT ☐ Ca ☐ Na ☐

Dose: 7.4 GBq (200mCi) every 6 weeks for 6 doses (May be extended up to 10 weeks but no longer)

Dose Reduction: 5.9 GBq (160mCi) (do not re-escalate dose and discontinue if further reaction)

☐ First Dose ☐ Second Dose ☐ Third Dose ☐ Fourth Dose ☐ Fifth Dose ☐ Sixth Dose

Labs checked within 8 weeks of first dose and 1 week of subsequent doses:Click or tap to enter a date.

CBC should be checked every 2-3 weeks for up to 12 weeks from last treatment

CBC with diff: Hgb ≥ 8g/dl	**PLT > 75,000/mm3**	**ANC > 1000**	**Creatinine < 1.5 X ULN**	**Creatinine Clearance > 40**	**ALT < 3X ULN**	**AST < 3 X ULN**	**Bilirubin < 1.5 X ULN**
Calcium	**Sodium**	**Potassium**	**ALP**	**PSA**			

Post Treatment Scan: Scheduled 48hr post treatment ☐Click or tap to enter a date.

Patient Education:

☐ Use contraception: During and up to 14 weeks post treatment

☐ Urinary Incontinence, reminded to bring extra supplies

☐ Instructed to hydrate pre and post ☐ Environment ensures ability to maintain precautions

Radiation Safety Precautions:

☐ When urinating, sit, and flush 2 times for 3 days

☐ Follow good hygiene practices to minimize radiation exposure to household 1 week

☐ Wash clothing soiled in urine or feces promptly and separately for 1 week

☐ Promptly clean up spills and discard of trash by double bagging prior to discarding with the other trash. Keep trash separate and away from children and animals.

☐ Family assisting in care should use universal precautions gloves when handling bodily fluids (urine, feces, vomit) for 1 week

☐ Limit close contact (less than 3 feet) with household contacts for 2 days.
☐ Limit close contact with women and children for 7 days and pregnant women for 15 days.
☐ Sleep in a separate room from household contacts for 3 days.

TREATMENT SCHEDULE

Week1 : Treatment 1 Click or tap to enter a date.

Post Treatment Emission Scan 48hr post Click or tap to enter a date.

Week 5

Labs: CBC, CMP, PSAClick or tap to enter a date.

Week 6: Treatment 2 Click or tap to enter a date.

Post Treatment Emission scan 48hr post Click or tap to enter a date.

Week 8-10

Follow Up PSMA PET ScanClick or tap to enter a date.

Week 11

Labs: CBC, CMP, PSA Click or tap to enter a date.

Week 12: Treatment 3 Click or tap to enter a date.

Post Treatment Emission Scan 48hr post Click or tap to enter a date.

Week 17

Labs: CBC, CMP, PSAClick or tap to enter a date.

Week 18: Treatment 4 Click or tap to enter a date.

Post Treatment Emission Scan 48hr post Click or tap to enter a date.

Week 20-22

Follow Up PSMA PET Scan Click or tap to enter a date.

Week 23

Labs: CBC, CMP, PSA Click or tap to enter a date.

Week 24: Treatment 5 Click or tap to enter a date.

Post Treatment Emission Scan 48hr post Click or tap to enter a date.

Week 29

Labs: CBC, CMP, PSA Click or tap to enter a date.

Week 30: Treatment 6 Click or tap to enter a date.

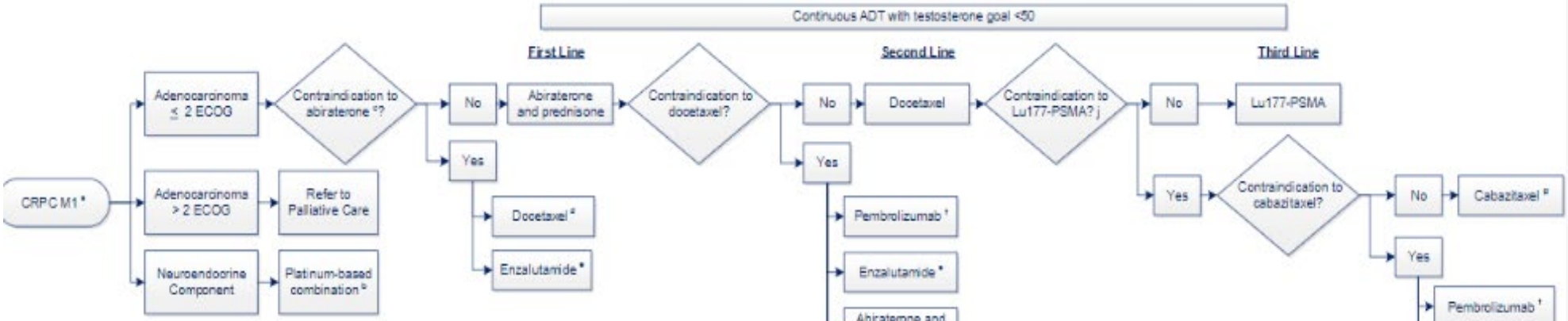
Post Treatment Emission Scan 48hr post Click or tap to enter a date.

Week 32-34

Follow Up PSMA PET Scan Click or tap to enter a date.

Labs: Every 2-3 weeks for 12 weeks

Prostate Cancer – Castrate Resistant Prostate Cancer (CRPC) M1



Clinical trial(s) always considered on pathway.

a Consider biopsy in setting of visceral disease or atypical progression (scan worsening without overt PSA progression)

b Platinum-based Combination No regimen proven more effective than another

c Abiraterone contraindications include hepatic dysfunction, significant cardiovascular disease, uncontrolled hypertension, or the inability to tolerate prednisone

d Docetaxel prescribe for relatively rapidly progressing symptomatic disease

e Enzalutamide contraindications include severe renal impairment (CrCl <30 ml/min), seizure history, and/or brain metastases/active epidural disease

f Pembrolizumab prescribe if patient has MSI-H (microsatellite instability-high), dMMR (deficient mismatch repair) or TMB high in tumor agnostic fashion

g Cabazitaxel favored for use after previous failure of one ART (enzalutamide/abiraterone); avoid repeat of previously used therapies

h Radium 223 prescribe if patient has symptomatic bone metastases and no visceral disease

i Olaparib prescribe if patient has HRRm (Homologous Recombination Repair mutation)

j Contraindications cannot be given with radium 223, cabaztaxel, or investigational product; patient can continue standard care i.e., AR-directed therapy