<table>
<tr><td>Regimen</td><td colspan="4">Lutetium-177 PSMA</td></tr>
<tr><td>Indication</td><td colspan="4">METASTATIC CASTRATION RESISTANT PROSTATE CANCER</td></tr>
<tr><td>Regimen Details</td><td>Day</td><td>Drug</td><td>Dose</td><td>Route</td></tr>
<tr><td></td><td>Treatment Day</td><td>Lu-177 PSMA</td><td>7.4 GBq (unless otherwise directed by ARSAC practitioner)</td><td>IV injection.</td></tr>
<tr><td>Administration</td><td colspan="4">Administered IV via appropriate vein. See THE-SOP-001 for Cannulation Procedure Radionuclide Therapy.

Full administration procedure can be found in THE-SOP-011.

Lutetium is a radiopharmaceutical; handle with appropriate safety measures to minimise radiation exposure and always ensure appropriate PPE is worn.

See THE-WI-012 Radiation Safety for Staff – Radionuclide Therapy.

Radiation can be detected in the urine for up to 30 days following administration. Steps must be taken to minimise radiation exposure to patients, medical personnel, and household contacts during and after treatment consistent with good radiation safety practices and patient management procedures. Physicist to advise the patient appropriately.

Advise patients to hydrate and urinate frequently during and after administration. Patient will be instructed to double flush the toilet after each urination for a period of 7 days.</td></tr>
<tr><td>Frequency</td><td colspan="4">All cycles should be a minimum of 5 weeks apart.

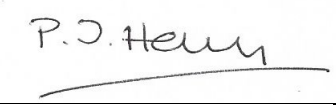
Consideration may be given by the ARSAC practitioner to adjust this time frame and such decisions and agreements should be duly documented on Mosaiq.
Patients may receive up to 6 cycles at the ARSAC practitioners request.

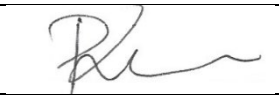
Patients can receive further cycles at discretion of ARSAC practitioner.</td></tr>
<tr><td>Extravasation</td><td colspan="4">Possible – refer to extravasation policy THE-SOP-002</td></tr>
<tr><td>Premedication</td><td colspan="4">• Consider Dexamethasone 8 mgs IV/orally 30 minutes before Lu-177 PSMA injection in patients with the following:
○ High volume disease
○ Extensive bony metastases
○ Liver disease
• Consider appropriate anti-emetic in low volume disease where this causes nausea.
• Sodium Chloride 0.9% 300mls – 1500mls as directed by ARSAC practitioner. (May be a Combination of IV infusion and oral intake)
• Consider Furosemide 40mg IV 30 minutes before Lu-177 PSMA injection in cases of renal impairment.</td></tr>
<tr><td>Emetogenicity</td><td colspan="4">Low to moderate</td></tr>
<tr><td>Additional recommended</td><td colspan="4">• Morphine Sulphate Oral Solution 10mg/5ml solution 10mg every 4 hours when required for pain. Supplied at CYCLE 1.</td></tr>
</table>

supportive medication (which may be given at ARSAC practitioners discretion)	• Co-amoxiclav 625mg THREE times a day. Supplied at CYCLE 1 To be used if advice for UTI. (check patient's allergy status) • Metoclopramide 10mg up to three times a day when required for nausea and sickness. Supplied at CYCLE 1. • Paracetamol 500mg take TWO tablets up to FOUR times a day when required supply 32 tablets. Supplied at CYCLE 1. • Dexamethasone 8mg od for 3 days, then 4mg od for 4 days, then stop. For the relief of bone pain. (Review if patient is already on steroid)
Pre-treatment evaluation	Gallium PSMA scan should be performed within approximately 4 weeks before treatment. FBC, LFT's, U&E's and PSA should be taken within 2 weeks of the planned treatment date. (Blood results can be accepted outside of this time frame with the specific agreement of the ARSAC practitioner) Clinical assessment.
Regular investigations	FBC, LFT's, U&E's and PSA should be taken every 2 weeks following treatment. If bloods results are outside of the agreed parameters, then weekly checks should be instigated. Gallium PSMA PET scan should be performed 4 weeks after 2 cycles to assess treatment response.
Standard limits for administration to go ahead – if blood results not within range, authorisation to administer must be given by prescriber/ Consultant	**Blood parameters should be no lower than the following**. (Decision to treat outside of these readings **will remain the responsibility of the treating ARSAC certificate holder** and must be clearly documented on Mosaiq) • **Haemoglobin** should be no lower than 8.0g g/L (blood transfusions may be considered at this level and ideally administered before Lu-177 PSMA therapy) • **Neutrophils** should be no lower than 1.5 x 10^9/L but treatment may be considered between 1.0 and 1.5 x 10^9/L if dose reduction is applied. • **Platelets** should be no lower than 100 x 10^9/L but treatment may be considered if they sit at 75 x 10^9/L with a favourable neutrophil profile. • **Albumin** no lower than 25g/L. • **eGFR** no lower than 40 mL/min. Treatment may be considered when eGFR range is between 30 – 40 mL/min if dose reduction is applied. Creatinine clearance is recommended in patients who fall into this category. • Patient must have an **ECOG status** of 0-2.
Dose modifications	May be made by the ARSAC practitioner. All modifications must be clearly documented in Mosaiq.
Haematological toxicity	Decision to proceed in these circumstances must be clearly documented by ARSAC practitioner in Mosaiq
Renal impairment	Dose modification should be considered in patients with renal impairment. This must be clearly documented in Mosaiq.
Hepatic impairment	Dose modification should be considered in patients with hepatic impairment. This must be clearly documented in Mosaiq.
NCI Common toxicity criteria	Thrombocytopenia Anaemia Neutropenia

	Renal toxicity Hepatotoxicity
Adverse effects – the contents of the table indicate the adverse effects that should be documented on the Treatment Consent form	1. Tiredness 2. Nausea 3. Pain Flare 4. Dry mouth 5. Low blood counts 6. Potential renal function impairment 7. Potential hepatic function impairment Informed consent to be taken prior to treatment.
Significant drug interactions – for full details consult product literature/ reference texts	See comments below.
Comments	Radiopharmaceuticals should be used by or be under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals. Their experience and training must be approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals. Advise patients to contact the treating physician and the referring oncologist for any signs or symptoms of myelosuppression or infection, such as fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. ARSAC practitioner may consider discontinuing myelosuppressive therapy 6 weeks before treatment if clinically appropriate.
Cumulative Doses	Variable, usually individual dependent, monitored by FBC and followed up clinically.
References	Fendler et al 177Lu-PSMA Radioligand Therapy for Prostate Cancer, Journal of Nuclear Medicine 2017 58(8) 1196-1200 Hofman et al 177Lu-PSMA-617 radionuclide treatment in patients with metastatic castration-resistant prostate cancer (Lu-PSMA trial): a single-centre, single-arm, phase 2 study, Lancet Oncology 2018 19 825-33

Revision History

Document Title	Clinical Protocol: Lu 177 PSMA in advanced Prostate Cancer	
Document number	THE-PRO-013	
Approval date	May 2020	
Written by	Penny Hickey Pharmacist	
Checked by	Titilayo Alagbe Principal Pharmacist	

Approved by	Penny Kechagioglou CMO	
Authorised by	Dr Yong Du - Clinical Director Theranostics	
Review date	TWO YEARS or if any significant changes:	
Document reviewed by	Medicine Management Committee	
Version Number	3.2	
Summary of changes	Reviewed and updated May 2020 by Theranostics team	