<table>
<tr><td>Regimen</td><td colspan="4">Lutetium-177 Dotatate (Lutathera)</td></tr>
<tr><td>Indication</td><td colspan="4">SSTR positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs)</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 Dotatate</td><td>7.4 GBq (unless otherwise directed by ARSAC practitioner)</td><td>IV infusion</td></tr>
<tr><td>Administration</td><td colspan="4">Administered as an IV infusion gravity (via pump and giving set) method 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 minimize 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 minimize 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 8 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 4 cycles at the ARSAC practitioners request.</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">• Administer Dexamethasone 8 mg and Ondansetron 8 mg, orally 30 minutes before Lu-177 Lutathera injection.
• Amino Acids (25g lysine + 25g Arginine), in 1L saline administer 30 minutes before Lutathera and continue infusion for total 4 hours.</td></tr>
<tr><td>Emetogenicity</td><td colspan="4">Moderate to high</td></tr>
<tr><td>Additional recommended supportive medication (which may be given at ARSAC practitioners discretion)</td><td colspan="4">• Metoclopramide 10mg up to three times a day when required for nausea and sickness. Supplied at CYCLE 1.</td></tr>
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Pre-treatment evaluation	**Prior to day of treatment:** Gallium Dotatate PET/CT scan should be performed prior to treatment. FBC, LFT's, U&E's, eGFR 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). 99mTc-GFR results available. Baseline blood pressure, pulse, oxygen saturation levels, respiratory rate and 12-lead ECG reading. **On treatment day:** Baseline blood pressure, pulse, oxygen saturation levels, respiratory rate and temperature. Clinical assessment.
Regular investigations	FBC, LFT's, U&E's, eGFR two, six and eight weeks following each cycle.
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 80g/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 (formal renal clearance):** no lower than 45 mL/min. Treatment may be considered when eGFR range is between 30 – 40 mL/min if dose reduction is applied. Formal measurement of Creatinine clearance is mandatory prior to first treatment • Patient must have an **ECOG status** of 0-2.
Exclusion Criteria	• A. Concurrent illness, including severe infection that may jeopardise the ability of the participant to undergo the procedures with reasonable safety. • b. Progressive reduction in peripheral platelet counts particularly in the setting of prior cytotoxic therapy or extensive marrow infiltration or irradiation should be considered relative contraindication to treatment. • c. Suspected or unresolved obstruction of urinary tract either upper or lower; urinary incontinence (relative). • d. Relevant comorbidities resultant from previous therapies and incontinence.

	• e. Other significant comorbidities such as uncontrolled arrhythmia or severe left ventricular heart failure which renders patient potentially unable to tolerate fluid loading. • f. Pregnancy.
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	Pain, nausea, renal toxicity, bone marrow toxicity • Prolonged cutaneous flushing • Severe dyspnoea • Bronchospasm • Peripheral cyanosis • Tachycardia • Hypotension or Hypertension • Profound vomiting • Diarrhoea • Confusion • Collapse • Myocardial ischemia • Cardiomyopathy • Pulmonary oedema • Shock Carcinoid Crisis Informed consent to be taken prior to treatment.
Significant drug interactions – for full details consult product literature/ reference texts	• Avoid administration of long acting Somatostatin analogues within 4 weeks • Avoid short acting octreotide within 24 hours of the 177Lu Dotatate infusion
Comments	Consultant may prescribe Oramorph 10mg/5ml for Bone pain.
Cumulative Doses	Variable, usually individual dependent, monitored by FBC and followed up clinically.
References	1. NICE guideline Lutathera https://www.nice.org.uk/guidance/TA539 2. SPC Lutathera https://www.ema.europa.eu/en/documents/product-information/lutathera-epar-product-information_en.pdf

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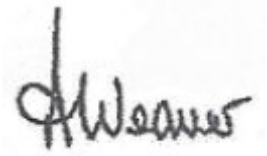
Approved by	Dr A Weaver & Dr Yong Du Consultants	 
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