Schedule for radiolabelled somatostatin analogue (Lu-177) treatment for metastatic neuroendocrine tumours

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Clinician's duties

Purpose of outpatient review in M30 clinic prior to treatment is to ensure that patients meet the inclusion criteria for treatment and re-treatment.
This proforma is to be printed out for each patient and filed in the notes, with clinical parameters and blood results filled in the appropriate column (page 6) prior to each treatment cycle.
Patient's written voluntary informed consent for treatment must be documented in the medical notes. This should be done by a Nuclear Medicine consultant or SpR either in M30 prior to the onset of therapy or in the Nuclear Medicine department prior to the first treatment cycle.

Eligibility for therapy for all patients will be discussed in a multidisciplinary setting.

Inclusion criteria	**Contraindications to treatment**
Somatostatin-receptors on tumour lesions demonstrated by octreotide scan or 68 Ga-DOTATATE PET CT scan within 6 months of first dose. Tumour uptake using this imaging should be at least as high as normal liver uptake on planar imaging.	Pregnancy and lactation.
Metastatic disease	Renal impairment; creatinine clearance (eGFR) <40 mL/min.
Life expectancy at least 3-6 months.	Impaired haematological function; Hb < 8 g/dL, WCC < 2 x 10^9/L, platelets <75 x 10^9/L
ECOG Performance Status 2 or above (see page 3) or	Severe hepatic impairment; bilirubin >3 x ULN, ALT/AST >3 x ULN *or* albumin <30g/L *with* increased prothrombin time.
	Severe cardiac impairment*

* In patients where this may be a concern, particularly those with metastatic carcinoid syndrome, a baseline echocardiogram should be performed pre-treatment prior to discussion about patient eligibility for Lu-177 treatment.

ECOG PERFORMANCE STATUS*	
Grade	**ECOG**
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

* As published in Am. J. Clin. Oncol.:
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.

Assessment TWO weeks prior to each treatment cycle

The nuclear medicine (NM)/ENDO F2 doctor running M30 clinic should be informed by the NM department about patients awaiting lutetium treatment. The ENDO team will then:

1) Arrange an appointment for the patient in M30 clinic (Tuesday afternoon) for review 2 weeks prior to therapy.
2) Perform baseline bloods (FBC, clotting, U and Es, LFTs, CgA) and complete assessment visit in this proforma. Blood results to be reviewed and documented on page 6 of this proforma by doctor reviewing patient in M30 clinic. Any concerns about patient eligibility should be discussed with referring physician or a senior clinician in M30 clinic. QoL questionnaire is available for download at http://www.imperialendo.com
3) Ensure that if a patient is taking a depot somatostatin analogue preparation this is stopped 6 weeks before lutetium treatment. Patients may require subcutaneous octreotide (100mg tds and increase according to symptom control) in the interim, so Endocrine Specialist Nurse (Debbie Papadopoulou bleep 7934) input may be needed to teach patients to self-inject octreotide.
4) Book patient transport if required.
5) Inform NM department immediately if the patient is unable to proceed with treatment (a minimum notice period of 10 days is required to cancel the dose from Radiopharmacy otherwise the department will be billed).

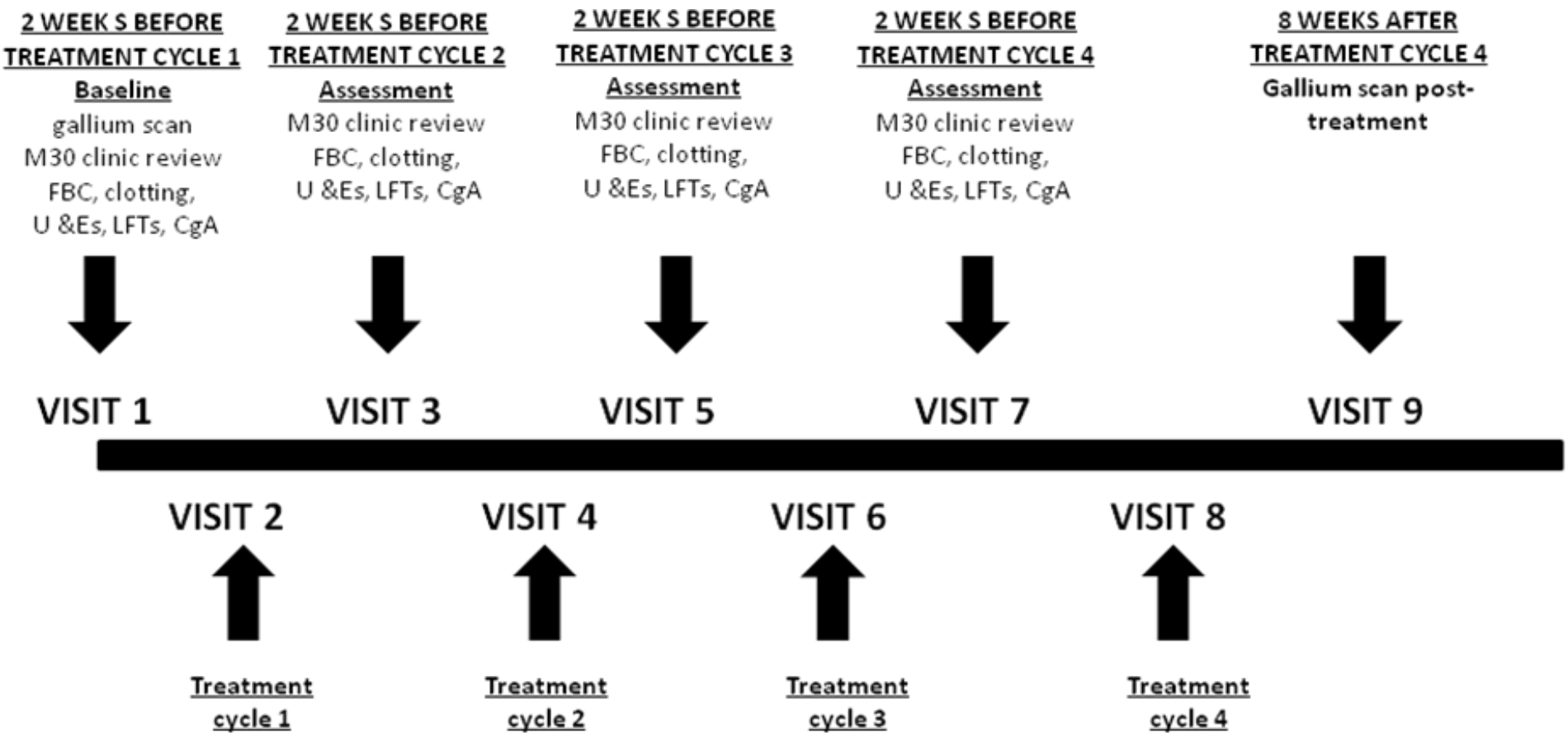
Treatment cycles: patient arrives on ward 6N

Admitting endocrine team doctor (AIM TO HAVE PATIENT READY IE POINTS 1 – 5 COMPLETED BY 9AM ON MORNING OF THERAPY) :

1) Clerks patient using this proforma (patient and blood results will have been assessed in M30 prior to this admission to ensure patient fits criteria for therapy).
2) Writes up drug chart
    a. intravenous ondansetron 8mg stat dose
    b. oral ondansetron 4 mg bd for 3 days
    c. intravenous 1L amino acid solution over 4h (provided by NM department).
3) Informs NM dept that patient is able to proceed with treatment.
4) Inserts 2 venflons in both antecubital fossae.
5) Administers intravenous bolus of anti-emetic ondansetron 8mg 30 min prior to therapy.
6) Patient discharged later the same day with discharge summary/TTA summarising treatment for GP. Discharge summary includes bleep number of medical SpR on call if patient becomes significantly unwell at home eg severe vomiting, diarrhoea, flushing (NB this is most likely to occur in patients with extensive metastatic disease).
7) Subsequent M30 clinic assessment (including bloods) also required 2 weeks prior to next treatment cycle. For patients originally referred to M30 via other specialties, please ensure that referring consultant (eg Dr Rohini Sharma, Oncology) is informed that patient has undergone a treatment cycle so that follow-up plans in other specialty clinics can be made if necessary. Otherwise, patients must have a follow up clinic appointment (M30 clinic) approximately 6 weeks after treatment.

Follow-up

Patients attend M30 clinic 2 weeks before each treatment cycle to ensure that they meet the criteria for subsequent treatment. Treatment cycles are approximately every 12-16 weeks for 3 - 4 cycles.



Treatment cycles approximately 12-16 weeks apart

Treatment protocol for lutetium therapy for metastatic neuroendocrine tumours

Version 2 NMM 06062011

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Summary of blood test results during lutetium therapy

	Baseline	**2 weeks before treatment cycle 1**	**2 weeks before treatment cycle 2**	**2 weeks before treatment cycle 3**	**2 weeks before treatment cycle 4**
Date of blood test					
FBC **Hb** **WCC** **Platelets**					
Clotting **PT**					
U & Es **Cr** **eGFR**					
LFTs **Bilirubin** **ALT** **AST** **Alk phos** **Albumin**					
CgA					
Other NET marker*					

*NET marker = eg gastrin for gastrinoma, VIP for VIPoma, urine 5HIAA for carcinoid, urine metanephrines for phaeochromocytoma/paraganglioma

VISIT 1. Baseline assessment prior to treatment cycle 1. Clinical details

PATIENT STICKER OR

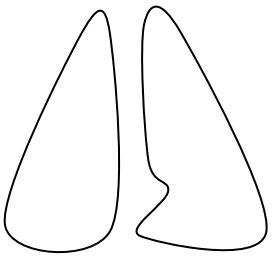
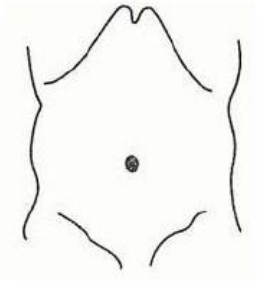
PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
PMH	
Drugs	
ECOG performance score	
Quality of life score	

VISIT 1. Baseline assessment prior to treatment cycle 1. Examination

PATIENT STICKER OR

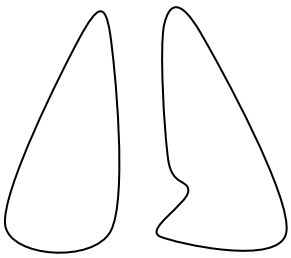
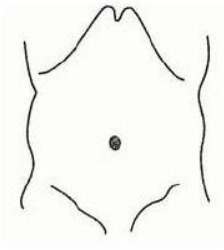
PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Pulse **BP**	
CVS	
Chest	
Abdomen	

VISIT 2. Day case admission for treatment cycle 1.

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Temperature O2 saturation	
CVS	**Pulse** **BP**
Chest	
Abdomen	

Checklist

- **Insert 2 venflons,**
- **Prescribe antiemetics and amino acid solution (see page 4)**
- **TTA/discharge summary for GP**

VISIT 3. Assessment 2 weeks prior to treatment cycle 2

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Side effects of treatment eg nausea, hair loss	
Relevant examination findings	

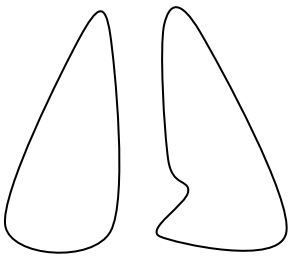
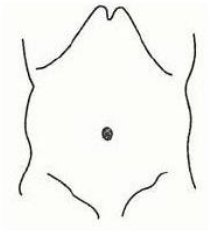
Checklist

- **ECOG score**
- **QoL score from questionnaire**
- **Send off bloods for FBC, clotting, U and Es, LFTS, CgA**

VISIT 4. Day case admission for treatment cycle 2.

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Temperature O2 saturation	
CVS	**Pulse** **BP**
Chest	
Abdomen	

Checklist

- **Insert 2 venflons,**
- **Prescribe antiemetics and amino acid solution (see page 4)**
- **TTA/discharge summary for GP**

VISIT 5. Assessment 2 weeks prior to treatment cycle 3

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Side effects of treatment eg nausea, hair loss	
Relevant examination findings	

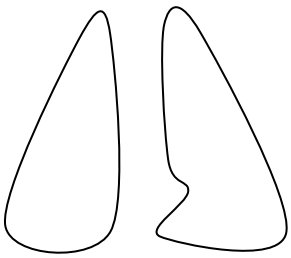
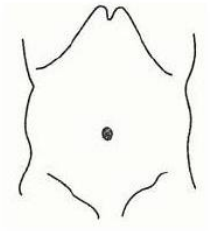
Checklist

- **ECOG score**
- **QoL score from questionnaire**
- **Send off bloods for FBC, clotting, U and Es, LFTS, CgA**

VISIT 6. Day case admission for treatment cycle 3.

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Temperature O2 saturation	
CVS	**Pulse** **BP**
Chest	
Abdomen	

Checklist

- **Insert 2 venflons,**
- **Prescribe antiemetics and amino acid solution (see page 4)**
- **TTA/discharge summary for GP**

VISIT 7. Assessment 2 weeks prior to treatment cycle 4

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Side effects of treatment eg nausea, hair loss	
Relevant examination findings	

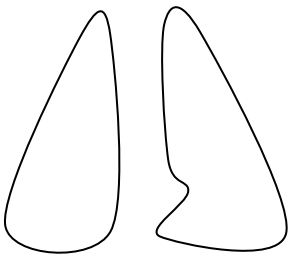
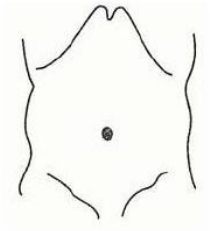
Checklist

- **ECOG score**
- **QoL score from questionnaire**
- **Send off bloods for FBC, clotting, U and Es, LFTS, CgA**

VISIT 8. Day case admission for treatment cycle 4.

PATIENT STICKER OR

PATIENT NAME, HOSPITAL NUMBER AND DATE OF BIRTH

Diagnosis	
Current symptoms	
Temperature O2 saturation	
CVS	**Pulse** **BP**
Chest	
Abdomen	

Checklist

- **Insert 2 venflons,**
- **Prescribe antiemetics and amino acid solution (see page 4)**
- **TTA/discharge summary for GP**

NB BOOK GALLIUM SCAN FOR 8 WEEKS POST TREATMENT CYCLE 4