**Adverse Event Reporting can be found on page 11.**

[**Click here**](https://www.rlthub.co.uk/sites/rlthub.co.uk/files/NET-PI-reel.pdf) **to access Prescribing information for all Advanced Accelerator Applications and Novartis products mentioned in this material.**

LUTATHERA® (lutetium [177Lu] oxodotreotide) is indicated for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP NETs) in adults



**SERVICE MODEL FOR A BLENDED CARE “HUB AND SPOKE” INTEGRATED AND COMPREHENSIVE MOLECULAR RADIOTHERAPY SERVICE IN** **[*INSERT GEOGRAPHIC AREA*]**

Please note, any items in red are for completion by the service provider

1. **Introduction**

A hub and spoke (blended care) model for the provision of molecular radiotherapy may be appropriate in areas of the UK with a more dispersed population where cancer services have traditionally been delivered in a number of centres. The basis for this model should be based on the “Radiotherapy Networks” announced in 2019 by NHS England and the regional models of care in Wales, Scotland and Northern Ireland.

However, it must be understood that neuroendocrine tumours (NETs) are rare tumours and that any centre performing these treatments would need to reach a minimum level of service to justify the employment of trained individuals and maintaining expertise. Therefore, to run a devolved service may not be ideal if there were less than 40 treatments (10 patients) per year.

Also, it is important to fully understand the medical issues that can occur with patients suffering from NETs. Therefore, it may not be suitable for patients with severe, brittle carcinoid, syndromic pancreatic tumours or severe co-morbidities to be treated outside of a major and experienced centralised service.

The standard of service and clinical competence in a devolved blended care or hub and spoke model must be identical to that offered within a centralised major centre. Therefore, a significant quantity of the documentation provided will be identical.

Finally, it may be difficult to begin a blended care hub and spoke service immediately so it may be worth considering an iterative, evolutionary approach where some aspects of care including the work up of patients and follow up are devolved to the smaller centres first and as confidence and competence builds transfer the actual treatments to the local site. Therefore, parts of the following document may be useful at different time points.

The service aims to diagnose, treat and manage patients with neuroendocrine tumours (NETs)/ gastroenteropancreatic tumours (GEP-NETs) who require molecular radiotherapy according to national and European (ENETs) guidelines.

The service has been commissioned by NHS England. Referrals are accepted from [*insert geographical spread/relevant Trusts/STP/ICSs*].

1. **Objectives of the Service**

Improved survival and early diagnosis for patients with NETs can support the NHS in meeting key cancer policy objectives, national frameworks and performance metrics on cancer survivorship and quality of life. For example, therapies that provide improvement in progression-free survival have the potential to address NHS targets on cancer mortality and survivorship. Moreover, empowering patients to help manage their condition, including discussing choice of therapy and treatment setting, may contribute to improved patient quality of life.

Advantages/benefits to the patient, region, trust and staff are as follows:

* Providing care closer to home
* Improved patient experience and patient care/support
* Shorter treatment waiting times, reduced travel time, stress and financial burden
* Increased capacity to meet the anticipated growth/demand, with improved space/facilities for providing the necessary treatment, advice, and support
* Delivery of an enhanced model of medical care
* Improved confidence from treatment provided in an integrated, state of the art, easily identifiable and accessible ‘cancer centre’
1. **Composition and Location**

The molecular radiotherapy service will be led by the following [*clinic/NHS Trust*]: The lead ARSAC certificate holder for this service will be [*insert name, tel number and email*].

The contact person for this NET service will be [*insert name*]

[*insert name of Clinic/NHS Trust*]

[*insert address*]

Tel [*insert number*]

Email [*insert email*]

This molecular radiotherapy service will be delivered from the following location[*s*]:

[*insert name of Clinic/NHS Trust*]

[*insert address*]

Tel [*insert number*]

Email [*insert email*]

1. **Overview of NETs Service/Clinical Standard Operating Procedure**

The prevalence of NETs in the UK has recently been calculated by UKINETS to be 35/100,000 with about 60% of patients being female.1 The incidence of new cases is 9/100,000 1 [*insert number for this region*], this means that in this region of [*insert name*] with a population of [*insert population*] we are proposing to treat [*insert number*] of patients per year.

**Service delivery: overview of the service**

The molecular radiotherapy service is integrated into the NETs service and the role of nuclear medicine is vital for both diagnosis, following progression of the disease, and treatment. Molecular radiotherapy with Lutathera® (Lu177) involves extensive planning and co-ordination, and a multidisciplinary approach to treatment. The overall aim for the provision of molecular radiotherapy services is to provide an integrated care approach/patient-centric hospital setting for the management of patients with NETs involving a multidisciplinary team (MDT), allowing for the delivery of an effective treatment approach. The molecular radiotherapy service will provide local access to treatment with Lutathera® (Lu177) according to NICE guidance for patients with NETs. The service will offer diagnosis, clinical care/treatment and follow up. Additional information and resources for service can be found within the ‘NETs Starter Pack’ section of the toolkit.

**Testing/diagnosis**

Patients will be tested/diagnosed for the presence of somatostatin positive receptors on the tumour, as outlined in **Appendix 1.**

**Onward Referral/treatment**

Following confirmation of the presence of somatostatin positive receptors, the patient will be referred for treatment as outlined in **Appendix 1**.

**Follow up**

Patients will be followed up as outlined in **Appendix 1**.

**Our Multidisciplinary Team Approach**

Patients with NETs often present with long and complicated histories and may be polysymptomatic. They will need to be reviewed by a central regional multidisciplinary team based in the main NETs centre for that region. This should be linked to the nearest large NET treatment service with a wide experience of treating NETs with all treatments including Lutathera® (Lu177).

During the natural history of their illness patients may need a variety of treatments including surgery, somatostatin analogues, chemotherapy if indicated, external beam radiotherapy if indicated and molecular radiotherapy. It is important that the patient’s history and clinical picture is well known to the NET team to allow for the correct timing and sequencing of treatments.

The molecular radiotherapy service is delivered through a multi-professional approach, allowing the coordinated and integrated management of patients with NETs. The local molecular radiotherapy service will be comprised of a variety of healthcare professionals from various departments, all with specialist skills involved in the management of patients with NETs and the provision of molecular radiotherapy services. It may be worth considering different models to achieve this skill mix within small hospitals. Unless the smaller hospital has all the required skills on site it may be possible to look at models such as joint appointments with the local centralised provider or a service-based contract via a service level agreement. This may be a vital link in providing sufficient trained Medical Physics Expert (MPE) and clinicians with the appropriate administration of Radioactive Substances
Advisory Committee (ARSAC) license. This relationship can be dynamic and involve the training of local personnel to take over this role in due course.

Once a patient is diagnosed or referred into local molecular radiotherapy services at [*insert name of Clinic/NHS Trust*] the patient’s treatment course will continue to be managed by the regional MDT.

**Role and Composition of the Molecular Radiotherapy Clinical Team**

The role of the teams is to:

* Provide patients with diagnostic testing for somatostatin positive receptors to assess suitability/eligibility for treatment with Lutathera® (Lu177)
* Provide treatment with Lutathera® (Lu177) to patients who have somatostatin positive receptors
* Follow up patients treated with Lutathera® (Lu177)
* The care pathway for patients referred to the molecular radiotherapy service is mapped out in **Appendix 1**

The regional MDT will consist of [*some of/all of*] the following healthcare professionals involved in the provision of molecular radiotherapy services:

* **Lead NET clinician.** This person may be an oncologist, endocrinologist, gastroenterologist or nuclear medicine physician. Whatever their background they will have sufficient knowledge and training to be able to co-ordinate and direct the patient through their NET care pathway.

The other members of the team may include the following:

* Lead NET clinician: this person may be an oncologist, endocrinologist, gastroenterologist or nuclear medicine physician. Regardless of their background, they will have sufficient knowledge and training to be able to co-ordinate and direct the patient through their NET car pathway.
* Medical or Clinical Oncologist: this person will advise the patient on their overall oncological treatment and when treatment with chemotherapy, external beam radiotherapy or molecular radiotherapy. For molecular radiotherapy they will be responsible for assessing the patient to determine their suitability for treatment with PRRT/Lutathera, and patient follow-up post treatment.
* Consultant surgeons: who are responsible for assessing whether the patient is eligible for surgery.
* Physician endocrinologist/gastroenterologist: who often makes the initial diagnosis and is responsible for initial somatostatin analogue treatment. They may also be needed to advise timings for scan and treatment for those on long acting somatostatin analogues. Additionally, this doctor may be needed for care of syndromic patients during and in the few days after molecular radiotherapy especially for patients with severe carcinoid syndrome or insulinomas.
* Pathologist: this person establishes the diagnosis of NETs from tissue biopsy and assesses origin and grade of tumour to determine suitability for molecular radiotherapy.

The local molecular radiotherapy MDT will consist of:

* Nuclear Medicine Physician or radionuclide radiologist: this person will be responsible for the functional imaging of the tumour using somatostatin receptor scintigraphy using either SPECT or PET techniques.
* Diagnostic radiologist: this person will normally have special knowledge of liver imaging as the favoured site for metastases, to assess the extent and progression of the NET to determine when molecular radiotherapy is indicated.
* Nuclear Medicine Physician or ARSAC certificate holding clinical oncologist. This doctor has a legal responsibility to ensure the molecular radiotherapy is given in a way which is safe for the patient, the patients comforters and carers and staff. –They would also be the molecular radiotherapy service clinical lead and legally has a role in “prescribing” any molecular radiotherapy. Unless the lead NET clinician or Oncologist has obtained consent for treatment, they will also obtain informed consent for treatment.
* Medical Physics Expert (MPE): this person is legally responsible for preparing and dosing and the safe administration of the molecular radiotherapy, in addition to supervising radiation protection aspects of the treatment delivery. They will also be responsible for post discharge advice to be given to the patient, their comforters and carers.
* Radiopharmacy: the radiopharmacy would be responsible for ordering, receiving, unpacking, and checking the activity of the treatment and dispensing the therapy. They will enter into radioactive stock database. Responsibility for measurement and disposal of radioactive waste is shared with the MPE. They along with the Department managers may be responsible for correct billing and coding.
* Radiographer or nuclear medicine technologist: may have a role in administering the treatment and also for any radio-isotopic imaging either to determine if Lutathera should be given but post therapy imaging.
* Specialist neuroendocrine tumour nurse: this person is responsible for patient communication, preparation of the patient for treatment, provision of patient with treatment information, assistance with patient observation and patient follow-up, liaison between Oncology and Nuclear Medicine. They would be the first person a patient can contact regarding any issues arising before or after molecular radiotherapy and will coordinate any response.
* Administrative and Clerical: responsible for organising patient admission and appointment letters. They have a vital role in ensuring the patient, NET team and molecular radiotherapy dose all arrive at the same place at the same time. Will inform patient or NET care team of any issues which may cancel or delay treatment.

MDT meetings are required on a regular basis depending on patient numbers but normally once every week or every other week to discuss treatment options with progression and tumour grade as the primary determinants of treatment choice, to confirm the treatment scheme and to approve the overall treatment plan and see that it is reasonable for the patient to be treated locally.

1. **Patient Pathway**

For patients who are referred into the service and reviewed by the MDT, if there is evidence of an unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs), patients will be assessed for eligibility for Lutathera® (Lu177). This is delivered by the nuclear medicine physician and radiation oncologist (course of 4 treatments), with treatment responses assessed by a CT scan. The patient pathway is illustrated in Figure 1. Additional detail on the patient pathway is provided in Appendix 1.

**Access to Ga-68 DOTATOC PET scanning**

Ideally a patient’s eligibility for treatment with Lutathera® (Lu177) is assessed with a Ga-68 DOTATOC PET-CT scan. This should be carried out at [*insert centre*]. This may not be possible in every patient if such a service is not available within a reasonable travel time for that patient. In which case single photon somatostatin receptor scintigraphy with SPECT-CT is a suitable alternative. Noting that 11% of patients will have a positive Ga-68 DOTATOC PET-CT scan when their SPECT-CT is negative.2

**Pre-treatment (outpatient)**

This is one aspect of care which may be the easiest to devolve in a blended care hub and spoke model. Once considered eligible for treatment, the patient should be informed and will need to see one of the care team who will explain the Lutathera® (Lu177) treatment. The care team will explain why it is indicated and what to expect including any side effects. Any questions the patient have should be answered. Ideally this can be done in an outpatient setting and will include the lead NET clinician, the nuclear medicine physician or clinical oncologist in charge of the administration and the NET specialist nurse. During this consultation a clinical assessment is carried out if the patient is not well known to the NET care team or has not been seen recently, but the opportunity is also taken to inform the patient on treatment and potential side effects, and to answer any questions. If the patient has not had a CT or MRI scan to assess present tumour state within 3 months this should be arranged before treatment. This consultation should only be needed before the first cycle of treatment though the patient should be reassessed at each cycle of treatment.

**Treatment Regimen (inpatient)**

It may be that during the time that experience is gained the actual treatments should occur within the main centralised hub hospital. However, if that is the case key staff such as MPE and nursing staff should be with them during the active treatment with the molecular radiotherapy agent. This will promote continuity of care and will also be a learning exercise. We recommend that the first few patients are treated as inpatients for all their treatments and all patient have their first cycle of treatment as an inpatient. Likewise, if they are syndromic or have other co-morbidities in patient treatment is optimal. Please refer to the SPC for additional information on somatostatin analogue administration timing.

Patients are admitted to the hospital prior to their treatment for routine blood tests with treatment being administered on the second day, after which they may stay the night of their treatment depending on radiation levels. Patients are discharged once it is safe to do so by the nuclear medicine team. See Figure 1.

Patient referred into NET service

MDT treatment review and decision to treatment with PRRT

Cycle 1: DAY 1

Admission for PRRT treatment, bloods taken

DAY 2

Molecular radiotherapy administration (including antiemetic and amino acids delivery)

DAY 2/DAY 3

Radioactivity monitoring

DAY 2/DAY 3

Discharge

Patient Consultation and discussion

Patients receive Lutathera® (Lu177) treatment every 8 weeks (±1 week) for a total of 4 doses

Figure : Molecular Radiotherapy NETs Patient Centralised Treatment Pathway

A detailed protocol for the administration of Lutathera® (Lu177) is provided in Appendix A.

The following planner may help in determining how to use the treatment rooms. However, in a small unit it is likely that only 1-2 patients will be treated in any given week at least for the first 1-2 years.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Morning | Afternoon | Evening |
| **Sunday** |  |  |  |
| **Monday** |  |  |  |
| **Tuesday** |  |  |  |
| **Wednesday** |  |  |  |
| **Thursday** |  |  |  |
| **Friday** |  |  |  |
| **Saturday** |  |  |  |

An example for inpatient treatment is as follows:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Morning | Afternoon | Evening |
| **Sunday** |  |  | Admit patient 1 |
| **Monday** | Treat patient 1 | Treat patient 1 | Patient 1 resting |
| **Tuesday** | Discharge patient 1 | Room cleaning | Admit patient 2 |
| **Wednesday** | Treat patient 2 | Treat patient 2 | Patient 2 resting |
| **Thursday** | Discharge patient 2 | Room cleaning | Admit patient 3 |
| **Friday** | Treat patient 3 | Treat patient 3 | Patient 3 resting |
| **Saturday** | Discharge patient 3 | Room cleaning |  |

The provision of a well-established molecular radiotherapy service locally will allow other centres/clinics/NHS Trusts to cope with the anticipated growth and demand for such services in the near future, by reducing waiting times and optimising clinic time and pharmacy resource use.

1. **Referrals**

Referrals should be made using the referral form in **Appendix II**. (‘NETs Starter Pack’ section of this toolkit)

1. **Appointments and Approvals**

When patients are referred to the molecular radiotherapy service, they should normally be seen in the outpatient’s clinic run by the lead NET clinician who can see the patient and discuss treatment options. The patient may be discussed in an MDT before they are seen in clinic to try and streamline the referral system. Once it has been decided the patient will receive molecular radiotherapy, the lead NET clinician, if working in England, will apply for funding using the Blueteq system. In Wales, Scotland and Northern Ireland, prescribing should be in line with the Trust’s own prescribing guidelines. They will also normally formally request the treatment which will be authorised by the ARSAC certificate holder (though they may be the same individual). The NET nurse and the administration staff of nuclear medicine or oncology will arrange treatment, admission dates and times and ensure the patient is aware of these.

It is vital that if any part of the patient’s care is to occur locally that there is regular and full communication between the main centralised hospital and the local facility to ensure blended care and that all investigations and preparations are done in timely manner without repetition. It should be noted that there is a 11-day lead time (five days to cancel) on ordering the dosage required and is often only delivered on certain weekdays.

[*insert phone number*]

1. **Did not attend**

If a patient is unable to attend at short notice (up to 7 calendar days prior to the appointment) they will be offered one further appointment only if it is suitable for them to be treated. The appointment letter will state this. Due to the cost of treatment, a patient from any waiting list should be treated though this will need to be done under a new Blueteq number.

1. **Outcomes**

Suggested key performance indicators for the service are:

* 100% of patients are discussed at local and regional specialist MDTs
* [*90*]% of patients with NETs initiating treatment within [*4*] weeks of referral
* [*90*]% of patients with NETs accessing molecular radiotherapy services within 4 weeks when referred
* 100% of patients treated on planned day of treatment
* 100% of patients treated with prescribed activity of molecular radiotherapy
* 100% of patients requiring specialist care during treatment are referred to the main centre for that treatment.
1. **Evaluation and audit**

In order to assess the service, an audit should be undertaken.

All referrals should be entered on to the institutional cancer registry to define activity and case-mix. Also logged should be:

* Numbers taking up the service
* Failure to attend for treatment and unable to complete treatments
* Discharges
* Onward referrals to other services
* Re-referrals
* Side effect rate

For national audit purpose anonymised patient data should be uploaded into the national Lutathera® (Lu177) registry hosted on the British Nuclear Medicine Society web site. Patient consent should specifically state this.

1. **Clinical Governance**

Contracts of staff involved will need to be reviewed. Part time or honorary contracts will have to be offered to staff from the centralised hub if they are involved in treating or decision making concerning patients. This will need to be reflected in the clinical governance of these staff members. The Lead Practitioners will be accountable to [*insert name*] (Clinical Governance Lead) for delivery of clinical services and to [*insert name*] (Chief Executive) for contractual issues.

Professional Clinical Leads have been identified to establish a competency structure for each separate profession:

* Medical: [*insert name of clinical lead*]
* Nurse: [*insert name of clinical lead*]
* MPE: [*insert name of clinical lead*]

Annual Individual Performance Reviews (IPRs) will be established within the molecular radiotherapy service by the appropriate clinical lead and individual practitioners. Once all IPRs have been completed a training matrix will be carried out and costed and it is then the responsibility of [*insert name*] to allocate budget and approve expenditure.

Supervision of clinical staff will be carried out at intervals of [*insert number*] months and, where appropriate, more frequently by the [*insert date*].

Each healthcare professional working within the service will attend [*insert name/type of training*] education sessions at [*insert training location*]. Training sessions may include how to assemble equipment for Lutathera® (Lu177) delivery, delivering the treatment safely, radiation protection and risk mitigation and environmental impact.

Dr [*insert name*] of [*insert Trust*] Trust will be the primary point of secondary care consultant contact for the service.

Dr [*insert name*] of [*insert clinic*] Clinic will adopt the role of mentor to the Lead Practitioners leading the service.

A formal induction programme will be established for all new staff working within the service to include the following:

* Health and Safety
* Fire procedure
* CPR procedure
* Drugs procedure
* Lifting and handling policy
* Documentation standards
* Annual leave and sickness procedures
* Supervision structure
* Communication pathways
* Reporting procedures for incidents and accidents
* Complaints procedure

This will commence within the first [*insert number*] weeks of commencement of employment. Those staff offered an NHS Trust Contract will attend the induction course.

As the Lutathera® (Lu177) treatment will be a new treatment it may need to be approved by committees within the Trust. This could include the Drugs and Therapeutics Committee and the radiology interventional procedures committee. This will depend on the policies of each Trust.

1. **Health and Safety issues**

All staff will adhere to all protocols and the Health and Safety regulations of the site location they are working within.

It is the responsibility of the Lead Practitioners to ensure a copy of the documentation of all incidents/accidents reported at each site is sent to the Trust governance lead and, in the event of a radiation incident, the Care Quality Commission [*insert name*].

**References**

1. Genus T, Bouvier C, Wong K, Srirajaskanthan R, Rous B, Talbot D et al. Incidence and prevalence of neuroendocrine tumours in England. Endocrine Abstracts. 2017.
2. Srirajaskanthan R, Kayani I, Quigley A, Soh J, Caplin M, Bomanji J. The Role of 68Ga-DOTATATE PET in Patients with Neuroendocrine Tumors and Negative or Equivocal Findings on 111In-DTPA-Octreotide Scintigraphy. Journal of Nuclear Medicine. 2010;51(6):875-882.

**Adverse Event Reporting**

**Adverse events should be reported. Reporting forms and information can be found at** [**www.mhra.gov.uk/yellowcard**](http://www.mhra.gov.uk/yellowcard)**. Adverse events should also be reported to Novartis via** **uk.patientsafety@novartis.com** **or online through the pharmacovigilance intake (PVI) tool at** [**www.novartis.com/report**](http://www.novartis.com/report)

**If you have a question about the product, please contact Medical Information on 01276 698370 or
by email at** **medinfo.uk@novartis.com**

This material was developed by Advanced Accelerator Applications, a Novartis company. Advanced Accelerator Applications products are discussed herein.

**Appendix I: Patient Pathway – *Please adapt to your local requirements***

**Evolution of service**

It may be appropriate to devolve patient care in a stepwise fashion which is illustrated below:



This will allow for the development of local services but ensuring an optimal care pathway for the patient.

For the steps below it can be decided which should be done locally and which needs to be done at the central specialist centre. A review period may be appropriate, for example 6 monthly intervals for all parties involved to decide if any services can be devolved locally. At any time, it is possible to stop or reverse that process.

**Diagnosis**

A patient with a confirmed diagnosis of a NET/GEP-NET should undergo a scan to determine the presence of somatostatin positive receptors on the tumour, as this will determine a patient’s suitability for molecular radiotherapy treatment/treatment with Lutathera® (Lu177). The oncologist should refer the patient for either a 68-Gallium DOTATOC PET-CT scan or an Octreoscan to confirm the presence or absence of somatostatin positive receptors on the tumour. This should be carried out at [*insert Trust*], by[*department*]*.*  Please refer to the SMPC for a full list of contra-indications and considerations.

**Coordination with Nuclear Medicine**

After assessing suitability for treatment with molecular radiotherapy/treatment with Lutathera® (Lu177) the Lead NET Clinician will coordinate with the nuclear medicine department to review the patient’s case and proceed with a treatment plan. The patient and their proposed treatment plan will be assessed/discussed/reviewed during an MDT meeting. The MDT will consist of a number of healthcare professionals (see Section 4 for detailed information) who will be involved in delivering molecular radiotherapy treatment/treatment with Lutathera® (Lu177).

**Patient consent for treatment**

After a treatment plan is agreed with the MDT, informed consent is required from the patient to begin molecular radiotherapy treatment/treatment with Lutathera® (Lu177) before treatment commencement. The procedure is explained to the patient and informed consent is obtained from the patient to start molecular radiotherapy treatment/treatment with Lutathera® (Lu177). Once consent has been obtained from the patient and the patient agrees to treatment, an email must be sent to all staff involved in the patient’s care and delivery of treatment; this helps to ensure all relevant stakeholders are aware of the process. A tentative start date for treatment is agreed, which can be around 4-8 weeks depending on the patient’s last somatostatin analogue treatment and a scheduling process is initiated. The NET specialist nurse contacts all the relevant staff with a list of potential dates and times for molecular radiotherapy treatment in order to determine the best start date and time for the patient.

**177Lu-Dotatate (Lutathera®) Radiopharmaceutical Ordering**

Radiation safety requirements include an approved radiation safe inpatient room reserved for the day of the patient’s treatment, including leaded toilet facilities within the treatment and inpatient rooms.

The nuclear medicine pharmacy orders the required dosage of 177Lu-Dotatate and the hospital pharmacist orders an amino acid solution for renal protection (L-Arginine 2.5% /L-Lysine 2.5% in 1000 mL 0.9% NaCl).

For Lutathera® (Lu177) the nuclear medicine technicians set-up an efficient way of organising the 100mL saline bag, lead can of 177Lu-Dotatate, and radioactivity meter. It should be noted that there is a 11-day lead time (5 days cancellation) on ordering the dosage required and is often only delivered on certain weekdays.

**Day before treatment**

The patient is admitted to the hospital the day before their treatment. During this time, the oncologist will assess the patient. Before each administration and during the treatment, biological tests are required to re-assess the patient’s condition and adapt the therapeutic protocol if necessary. Please refer to the SMPC for a list of tests needed prior to each infusion.

If the patient is female and <55 years old, a pregnancy test will also be ordered. The oncologist will order anti-emetics or pre-medications as supportive care for the day of treatment in addition to somatostatin.

**Treatment Room**

All treatment will be delivered according to locally agreed protocols for molecular radiotherapy, in a treatment room which has been risk assessed as appropriate for a patient with Lutathera® (Lu177). Assessment normally falls under the responsibility of the hospital’s radiation protection team. The molecular radiotherapy room is located in[*insert infusion location*], within designated areas for therapy handling and administration of radionuclides as well as separate toilet and washing facilities deemed suitable for radioactive waste. The patient can be treated in a designated ward area or within nuclear medicine as deemed by risk assessment to be appropriate. Any toilet used by the patient cannot be used by anyone else until it has been decontaminated.

A full risk assessment should include methods to reduce the radiation burden to staff involved. This may include the use of mobile radiation shields, the wearing of correct PPE, the use of automated delivery systems where possible and having a group of staff who can be rotated through different administrations. Where there are infusion lines and pumps these should be shielded using Perspex sheets where possible. The staff involved in administering the treatment should distance themselves as far as possible from the patient both during and after administration.

The treatment room will normally need to be available for 5 hours per patient. Please refer to the SMPC for specific information on administration steps.

If they feel able the patient should continue to eat and drink normally. Unless they are medically unstable observations will only be needed every 6 hours. Any nurse or staff entering the room with the patient should have prior training and wear appropriate PPE.

Please refer to the SMPC for detailed information regarding dose adjustment and patient discharge.

The room in which they were staying will need to be checked and completely decontaminated before it is used by the next patient.

**Follow up post discharge**

Blood tests for bone marrow, liver and kidney function are collected every 2-4 weeks through the patient’s GP and results sent to and collated by the lead NET clinician and NET nurse. This should be for 8 to 10 weeks. If the patient has a significant reduction in haemoglobin, platelets or leukocytes they could be treated every 12 weeks instead of every 8 weeks to give time for recovery of the patient’s blood counts. About 4 weeks after the 2nd cycle of Lutathera® (Lu177) a repeat CT/MR scan would be considered good practice. If this scan shows progressive disease as defined by RECIST 1.1 the patient is unlikely to benefit from further cycles of treatment.

**Follow-up-longer term**

The lead NET clinician will follow-up with the patient as per the standard of care. The treating clinician will order an imaging study for the patient (CT, MRI, or 68-Gallium DOTATOC PET-CT) every 3 months for the first 6 months then 6-monthly. Chromogranin and if indicated fasting gut hormones can also be measured every 6 months.

**Treatment: 1 day protocol modifications to the above protocol**

Once the molecular radiotherapy team are experienced giving Lutathera® (Lu177) it may be possible to give the treatment as an outpatient if nuclear medicine or oncology have the correct facilities including the room the treatment can be given in and a dedicated toilet/wash hand basin. If this is to be done the patient may need to be in nuclear medicine from about 07.30 am to 17.00 pm on the treatment day. Clearly this is not suitable for patients who have significant co-morbidities or who would prefer an overnight stay or have severe side effects such as severe nausea not controlled by medication.

The patient will normally attend the nuclear medicine department the next day so their radiation levels can be checked, they can have a post therapy scan and can be asked if they have had any problems overnight. If indicated their monthly long acting somatostatin analogue can be given.

**Appendix II: Referral form and treatment record**

Affix patient identification label in box below or complete details

|  |
| --- |
| **Lutathera® (Lu177) Therapy for the treatment of Metastatic Neuroendocrine Tumours.** **Referral Form and Treatment Record**  |

|  |  |
| --- | --- |
| **Surname** | **Patient I.d.No.** |
| **Forename** | **D.O.B. DDMMYYYY** |
| **Address** | **NHS No.** |
|  | **Sex. Male/Female** |
|  |  |
|  |  |
| **Postcode** |  |

To ensure there is no delay in requests, *all criteria must be acknowledged* for patient selection and audit purposes, please encircle answers below;

1. Has the patient had a positive gallium PET or SPECT scan (Octreoscan or Tektrotyd) in the last 12 months? **YES/NO**

2. Is the patients GFR > 40ml/min? **YES/NO**

3. Current Performance Status: **0 1 2**

4. Current somatostatin analogue dosage and frequency?

……………………mg Every ……………… weeks

5. Has funding been approved for this patient? **YES/NO**

**If yes Blueteq/ reference number approval expiry date …/…./…..**

6. Has the patient received any prior PRRT? **YES/NO**

Indication for treatment:

Prescription **of Radioactive Isotope: Lutathera® (Lu177) 7.4GBq intravenous infusion *(Maximum of 4, 8-12-weekly treatments)***

**Name of clinician:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DECT: \_\_\_\_\_\_\_\_\_\_**

|  |
| --- |
|  **Lutathera® (Lu177) Therapy*****Treatment Record***   |
|  | **Treatment 1** | **Treatment 2** | **Treatment 3** | **Treatment 4** |
| **Treatment****Date** |  |  |  |  |
| **Amino Acid Lot number** |  |  |  |  |
| **Amino Acid expiry date** |  |  |  |  |
| **Dose (prescribed)** |  |  |  |  |
| **Lot number** |  |  |  |  |
| **Expiry date** |  |  |  |  |
| **Calibrator reading** |  |  |  |  |
| **Setting** |  |  |  |  |
| **Date** |  |  |  |  |
| **Time** |  |  |  |  |
| **Dispensed by** |  |  |  |  |
| **Checked** **By** |  |  |  |  |
| **Given** **by** |  |  |  |  |
| **Comments** |  |  |  |  |

**Appendix III: Permissions and approvals checklist**

|  |  |  |
| --- | --- | --- |
| Environment Agency Holding approval for Lutathera® (Lu177) | Limit/month: |  |
| Date Issued: |  |
| Environment Agency Disposal approval for Lutathera® (Lu177)  | Limit/month: |  |
| Date Issued:  |  |
| Trust site ARSAC certificate for 177Lu DOTATATE in treating NETs | Date of expiry:  |
| Two medical ARSAC certificate holders for 177Lu DOTATATE in treating NETs | Name 1:  | Certificate number:  | Date expiry: |
| Name 2: | Certificate number: | Date expiry: |
| Trust clinical governance approval  | Name of committee: |  |
| Date: |  |
| MPE responsible: |  |
| Name: |  |
| Registration number: |  |
| Risk assessments completed | By whom: |  |
| Date: |  |
| Staff training complete  | Date: |  |