**Adverse Event Reporting can be found on the last page.**

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**Business Case**

**Title: New service/expansion of existing molecular radiotherapy service for patients with neuroendocrine tumours (NETs)**

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| --- | --- |
| **Guidance information for using this business case template** | The ‘Guidance Section’ provides additional information on how to complete the business case. It can be found within the grey boxes at the start of each section. It includes instructions on the following topics:* Adaptation of the template to meet the needs of each centre
* Use of ‘Plain English’ language to explain how the current service works and what change is required
* Check all assumptions against benchmarks
* Conduct appropriate research to clarify facts

**The guidance instructions should be removed prior to submitting to the appropriate audience (e.g. Trust board).** Please note that this template is intended to guide your business case submission. It provides examples only and should be amended and localised as much as possible. In addition, it should not replace local Trust processes. Prior to developing your business case, it is important to identify the following: * Timelines – Ensure you are aware of deadlines for submission, or specified time periods for submission
* Templates – Ensure the business case is developed in line with your local/Trust’s template. If there are no standard templates, you may use this template for submission
* Stakeholder engagement and support – Reach out to your financial, performance and information teams for specialist support
 |
| **Name of Trust and contact person details** | **Name of Trust/Hospital:** *[Insert information]***Name of Division/Department:** *[Insert information]***Name of submitting person:** *[Insert information]***Job titles(s):** *[Insert information]***Organisation/Department:** *[Insert information]***E-mail:** *[Insert information]***Telephone:** *[Insert information]* |
| **Date of submission** | *[Insert date]* |
| **Section 1: Executive Summary** |
| **Guidance information** | The executive summary should be written last and needs to summarise the entire proposal so that the Trust board can see at a glance what the service proposes to do, demonstrate the cost/patient/NHS benefits, with the specific details around these topics addressed in the body of the business case.In this key section, the business case should set out the rationale for the new service/expansion or redesign of existing service.Start with an overarching statement outlining the aim of the proposal and summarising the business case.Keep the executive summary brief, but as a minimum, it must include content under the following headings: * An introduction to the current neuroendocrine tumours (NETs)/ gastroenteropancreatic neuroendocrine tumours (GEP-NETs) molecular radiotherapy service
* A description of the proposed new/expanded/redesigned NETs/GEP-NETs molecular radiotherapy service
* A summary of the financial information and investment proposed
* The benefit of the service and the risks if the service is not provided

Each of these sections should be no more than 2-3 paragraphs. Proposed content is included in this section and can be amended or deleted as appropriate.The recommended length of the executive summary is no more than one page. |
| **Introduction to the current neuroendocrine tumours (NETs)/gastroenteropancreatic neuroendocrine tumours (GEP-NETs) molecular radiotherapy service**This business case describes the need for a [*new/expanded]* service for the treatment of NETs patients with molecular radiotherapy. The provision of a molecular radiotherapy service requires trained staff in the administration of radiopharmaceuticals in a safe setting and multidisciplinary coordination. The objective of this proposal is to make a case for investment in a *[new service/additional trained staff/a dedicated treatment setting]*. Neuroendocrine tumours (NETs) are rare tumours that develop in the neuroendocrine cells. Around 4,000 people in the UK are diagnosed with NETs each year.1,2 However, the incidence and prevalence of NETs is steadily increasing as a result of greater awareness and earlier diagnosis.1,3 Surgery is the only curative treatment for NETs and is used as the first-line treatment of localised NETs. However, because most NETs are diagnosed at an advanced or metastatic disease stage, other treatment options are required.4 Somatostatin analogues are the first-line systemic treatment of NETs to inhibit tumour growth.5 However, if there is evidence of disease advancement on somatostatin analogue therapy molecularly targeted radiation therapy, such as lutetium (Lu177) DOTATATE (Lutathera®)- a peptide receptor radionuclide therapy (PRRT), is usually recommended.6 PRRT involves systemic administration of radiotherapy, which needs to be delivered by trained staff in a radiation controlled treatment room. ***Amend for service provision***Lutathera treatment is restricted to a small number of centres that offer specialist expertise and have the infrastructure in place to support the provision of treatment delivery7 and is currently not delivered in our centre. Within *[insert region covered by Trust]* there are *[insert number of NETs patients; If you do not know this number use the UKINETs guide of 35/100,0008]* NETs patients. Of these, *[insert number of PRRT eligible patients; there are about 7/100,000 new cases per year6 and between 33-50% will need PRRT9]* are eligible for Lutathera. This cohort is expected to grow to *[insert number of patients]* in the near future. *If these numbers are not available, an estimation of growth can be drawn from your local cancer registry. For example, ‘Over the past decade the number of patients with GEP NETs has increased by [insert percentage]*. These patients are currently referred for treatment to *[insert specialist centre/Trust]. [Insert impact of not providing the service within your centre, such as long patient travel times, any costs of referral and travel to your centre, etc.].****Amend for service development***There are currently *[insert number of patients]* with NETs in our centre, of these *[insert number of patients]* are treated with Lutathera. However, there are capacity constraints within the service *[insert a summary of specific constraint within your service, such as staff or space shortage, demand increases etc.].* These result in *[insert impact of constraints, such as increased wait times, decrease in quality of care etc.]*. The anticipated increase in patient numbers in the very near future, due to improved diagnosis and disease awareness, will compound this problem and add additional pressures on the current molecular radiotherapy service. As a result, the existing or current molecular radiotherapy service model will not be able to accommodate the increase in demand for molecular radiotherapy.10The proposed NETs/GEP-NETs molecular radiotherapy *[new service/expanded service]**[Insert summary of the proposed molecular radiotherapy service/change]*Financial information and investment proposed*[Insert summary financial information and investment needed]*The benefit of *[providing/developing]* the service and the risks if the service is not *[provided/developed]**[Insert summary benefits and risks]**[Insert metrics on relevant outputs including reducing diagnostics waits, staff recruitment and retention, reduction in complaints, income generation etc.]**[Insert your trust’s vision for its services and how the proposed service model achieves this]* |
| **Section 2: Background** |
| **Guidance information**This section sets the scene for GEP-NETs and the need for additional specialist/regional centres and service expansion within established NETs centres.This should be a clear introduction describing the background, context and purpose of the business case.The ‘Burden of disease and unmet need’ section should include a description of GEP-NETs, its prevalence and incidence rates nationally, a description of the unmet need and the effect on the patient. The ‘Current management guidelines (national and local)’ should describe any current national and local management guidelines for patients with NETs/GEP-NETs. Reference to any registry and GEP-NETs Network can also be included. The following information can be included and adapted as necessary.   |
| **Burden of disease** NETs rare tumours that develop in the neuroendocrine cells. There are various types of NETs depending on the type of cell from which the tumour started its development.1 The majority of the NETs develop slowly over some years and so may not cause symptoms during the early stages of the disease, with many patients presenting with metastatic disease without a known primary site.1,11 Most NETs express increased levels of somatostatin receptors; this helps when making a NET diagnosis and when staging the tumour.4Around 4,000 people in the UK are diagnosed with NETs each year.1,2 However, the incidence and prevalence of NETs is steadily increasing as a result of greater awareness and earlier diagnosis.1,3*[For additional information please refer to Appendix I]* |
| **Current management guidelines (national and local)**Surgery is the only curative treatment for NETs and is used as the first-line treatment of localised NETs. However, because most NETs are diagnosed at an advanced or metastatic disease stage, other treatment options are required.4 Somatostatin analogues are the first-line systemic treatment of NETs to inhibit tumour growth.5 However, if there is evidence of disease progression on somatostatin analogue therapy molecularly targeted radiation therapy, such as peptide receptor radionuclide therapy (PRRT), may be appropriate.6*[For additional information please refer to Appendix I]***Case for change*****Amend for service provision***In the UK there are currently 21 centres\* that use Lutathera for NETs, with some centres covering a catchment area of up to 3.6 million people, whereas others will take in patients referred from across the UK.17 The need to travel long distances results in unnecessary stress for patients many of whom are already experiencing reduced quality of life or significant symptoms that make long journeys difficult and incurs a huge expense to the patient or the NHS, depending on who is paying for travel. Within our catchment area *[insert number of eligible patients]* are eligible for Lutathera.In addition, the number of patients requiring treatment with Lutathera is anticipated to increase in the near future due to improved diagnosis and disease awareness. As a result, the existing or current molecular radiotherapy service model will not be able to accommodate the increase in demand for molecular radiotherapy.10 This may impact the goals set out in the NHS Long Term Plan, which aims to accelerate access to diagnosis and treatment. The NHS Long Term Plan also mentions that safer and more precise treatments, including advanced radiotherapy techniques, will help to improve cancer survival rates. In *[insert area name or Trust name]* there is currently a need for a [*new/expanded]* service to ensure that waiting times at current centres are reduced and patients receive care closer to home.***Amend for service development***Our centre currently covers *[insert geographical spread],* and currently delivers Lutathera to *[insert number of patients]* patients per year. This results in [*Please insert how specific constraints within the service are currently impacting outcomes such as patients wait times, quality standards not being met, resource gaps, clinical risks etc.]*. Our service is expecting an increase in patient numbers of *[insert number of patients]* over the course of the next *[insert time period]*. However, the current capacity constraints will affect the achievement of the goals set out in the NHS Long Term Plan. *[Insert specific service constraints and the impact this will have on achieving specific goals]*.The current service has examined the patient pathway in order to optimise efficiencies and resources within the current service, however, additional resources are still required. *[Insert a brief summary of specific actions and initiatives previously examined]*.In *[insert area name or Trust name]* there is currently a need for an expanded service to ensure that waiting times are reduced and patients receive care closer to home. |
| **Section 3: Current provision of care for GEP-NETs molecular radiotherapy**  |
| **Guidance information**The current service section should analyse and provide a concise picture of the local service and how it addresses the needs of patients with GEP-NETs/those requiring molecular radiotherapy. Describe how the current service works, patient numbers, region covered and unmet need.Content for this section would include:* Area demographics, including patient numbers, regional coverage, incidence rates for NETs/GEP-NETs
* Care pathway
* Discharge pathway
* Roles and responsibilities of the current multi-disciplinary team (MDT)
* Interdependency with other services
 |
| **Current Provision of care*****Amend for service provision***Given the rarity of NETs and the complexity of molecular radiotherapy treatment delivery, Lutathera treatment is restricted to a small number of centres that offer specialist expertise and have the infrastructure in place to support the provision of treatment delivery.7 Lutathera is currently not delivered within *[insert Trust name]*. Within *[insert region covered by Trust]* there are *[insert number of NET patients]* NETs patients. Of these, *[insert number of PRRT eligible patients]* are eligible for Lutathera). This cohort is expected to grow to *[insert number of patients]* in the near future. These patients are currently referred to treatment to *[insert specialist centre/Trust].* The average patient travel time to receive treatment is *[insert average time]*, with an overall cost of transport of £*[insert cost] to the patient/to the Trust*. In addition, patients may have to wait a considerable time to be treated due to capacity constraints at the centre of treatment. Patients may progress past PRRT treatable stage during wait, reducing outcomes significantly. In addition, if the patient is symptomatic, they may need multiple admissions for symptom control whist awaiting treatment. The risks associated with continuing the referral of patients to other sites would include potential loss of service upon specialist commissioning review, continued inconvenience of travel and boarding for unwell patients who are often in financial difficulties, and reputational damage to department and Trust. Some patients refuse treatment due to travel, leading to sub-optimal treatment and may suffer poor outcomes.***Amend for service development***Since setting up the service in *[insert date]*, *[insert total patient numbers]* NETs patients have undergone molecular radiotherapy at our centre. Once diagnosed, or referred into our service, the patient’s treatment course is discussed within our MDT *(please refer to Appendix II for additional information on MDT)* and patients receive Lutathera treatment every 8 weeks for a total of 4 doses *(please refer to the SmPC for additional information regarding Lutetium 177Lu delivery)*. The current pathway is complex and moving patient across it is challenging. It requires effective coordination to ensure that delays are minimised, steps are not missed or duplicated, and to ensure that the pathway is seamless.Lutathera must be delivered by specialist who has been trained to administer PRRT and hold the relevant ARSAC/IRMER certificate within a radiation protection compliant treatment room in a hospital that holds the relevant ARSAC/IRMER site certificate and appropriate Environment Agency permissions. *[Please refer to Appendix II for additional information on Lutathera treatment including access to Ga-68 DOTATATE PET-CT scanner, treatment room, and follow ups]*A review of the patient pathway and system solution has been carried out and discounted. *[Insert a summary of considerations of redesign and optimisation of current resources prior to request of additional resources]. Refer to STPs/ICS clinical service plans, priorities and the Trust’s operational plans.* **Resources**The service requires the following full-time staff equivalents: *[insert job titles using list in Appendix II]* The service currently requires a time commitment from the following additional staff: *[insert job title, % time required, numbers]*The service currently costs £*[insert total]*. This is made up of *[insert* *drug cost, staff costs, etc.]* The NHSE tariff for PRRT treatment is £ £2,083 *[insert amount if different in your centre]*.12 Current annual tariff revenue for *[insert Trust name]* is £*[insert total].* The additional tariffs paid for by the patient’s CCG are £[*agreed tariff for administration and for post therapy imaging - this would normally be a standard somatostatin imaging tariff*].For Scotland, Wales, and Northern Ireland please modify the above.However, there are significant pressures on the service, *[insert current pressures and challenges within the service],* which can result in longer waiting times for patients/the need for referral to *[insert other Trust name]*. Our current waiting time for NETs patients eligible for Lutathera is *[insert treatment waiting time].* This is currently *[lower than/higher than/in line with]* the national average. *[Insert any additional impacts of pressures and challenges, such as poor clinical outcomes, staff over time etc.].* Reasons include *limited treatment space, lack of trained staff, limited availability of current staff time, inefficient service model, etc.* The risks associated with not expanding the service would include potential loss of service upon specialist commissioning review, continued or worsening treatment wait times, low staff retention due to workload burden, loss of income, an impact on quality of care, an inability to manage increased demand and reputational damage to department and Trust.  |
| **Section 4: Proposal for the new service/expansion of the existing service** |
| **Guidance information**In this key section, the business case should set out the rationale for the new service or expansion of the existing service. There are three main topics which should be covered in this section and will provide the detail of the proposal:* Description of the service and what it will deliver
* Drivers for the service change
* Deliverable outcomes and activity

Populate detailed information explaining how the centre plans to deliver its new or expanded molecular radiotherapy service. The care pathway should be described, including the following:* Referral to the service
* Scanning requirements
* Admission
* Infusion therapy
* Post infusion care
* Assessment of treatment response
* Ongoing care and monitoring
* Discharge/follow-up

Include financial information for the care pathway, for example, staff costs, equipment costs and travel costs.Describe clearly what the proposal will deliver.Include the estimated number of patients the new or expanded service is likely to cover (minimum to maximum). |
| **Proposed new service/expanded service provision****Amend the below service provision**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. This requires an MDT led approach with appropriately trained clinical and technical staff and a suitable treatment setting. The provision of a well-established molecular radiotherapy service will also allow centres 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. The proposed service will provide treatment with Lutathera locally according to the NICE guidance, which will help avoid any associated stress and financial burden of travelling to other centres to receive treatment. Once the service is opened, it is expected to treat *[insert patient number]* NETs patients annually, delivering *[insert infusion number]* infusions per week. These calculations are based on *[insert assumptions]*.The new service requires [*Additional information and breakdown of treatment pathway and resources can be found in Appendix II and additional information on NETs MDT team can be found in Appendix III. Please note, the below is an example only and should be amended as per your service’s specific requirement. Please refer to the SmPC for additional information on treatment delivery]***:*** **A multidisciplinary team:** Once diagnosed or referred into our service the patient’s treatment course would be discussed within our MDT*. [Insert staff needed]. Some of the required healthcare professionals may already be employed by your Trust. Please add total hours needed of their time to be involved in the service. If these are not currently employed by your Trust, please insert the total cost expected to hire them.*
* **Access toGa-68 DOTATOC PET scanning:** *[Optional; Please detail where this will be carried out]*
* **Treatment:** *Including Lutathera [please detail any additional therapies such as anti-emetics, and equipment]*
* **Treatment room: *[****If this room is not available, please detail what will be required in terms of location and costs to develop one including building costs, non-works costs, fees, equipment and VAT]. [If this room is available, please detail how use will be co-ordinated across all departments with access to the room.]*
* **Follow up:** *[Insert any follow up requirements, examples include blood tests, nurses time and resource]*

**Resources assuming patient has had recent somatostatin receptor imaging (within 3 months)**Table 1. Once only set up costs

|  |  |  |
| --- | --- | --- |
| **Description** | Hours needed | Costs |
| ARSAC/IRMER site certificate | N/A |  |
| Environment Agency permissions | N/A |  |
| Training costs for staff*Please itemise* |  |  |
| Staff costs for above*Please itemise* |  |  |
| Risk assessment of service by Radiation Protection Advisor’s team |  |  |

Table 2. Expected Lutathera service resources and costs for full treatment course (4 cycles)

|  |  |  |
| --- | --- | --- |
| **Description** | **Hours needed per patient** | **Expected costs**  |
| *CT or MR scan pre-treatment and after 2nd cycle* | *[insert hours]* | *[insert expected cost]* |
| *Lutathera post therapy scans\*\*\** |  |  |
| *Treatment room*  | *[insert hours]* | *[insert expected cost]* |
| *Lutathera Drug cost\**  | *NA* | *[insert expected cost]* |
| *Lutathera Courier costs\*\**  | *NA* | *[insert expected cost]* |
| *Insert staff required to organise, prepare and deliver the infusion\*\*\** |  |  |
| *Other drugs and consumables* |  |  |
| *Clinical scientist costs (MPE) if service bought in* |  |  |

\*This cost is reimbursed by NHSE under the specialised commissioning budget\*\* Courier costs to have radioactive product delivered to the hospital. This is reclaimed on month end billing to NHSE\*\*\* This is covered by an agreed NHSE tariff but paid by the CCGNote you will need to find sources for Scotland, Wales and Northern Ireland. The service will require an upfront investment total of £[insert total], with annual running costs of [insert amount].The NHSE tariff for performing Lutathera infusions is £[insert total]. The actual cost of providing Lutathera therapy at [insert Trust name] is £[insert amount] which is adequately covered by the tariff. The net gain per patient is £[insert total]. With the expectation of treating [insert patient number] patients over the next 12 months, a total of £[insert total] can be anticipated by the Trust.*The above service description can be amended to address service expansion needs such as additional staff, more treatment rooms, change in treatment model. A few examples can be found below:**Additional staff Clinical Nurse Specialist:**New staff will only be needed if such a GEP-NET specialist nurse has not been appointed. If required, the number of hours dedicated to their work will need to be reviewed.* *The nursing team are at the centre of planning and execution of PRRT within our service and are currently working at maximum capacity. Once a specialist nurse (Band 5) has been hired at a total cost of £*[insert total]*, additional patients can be treated due to increased staff capacity. It is expected our service will treat [insert patient number] NETs patients weekly, delivering [insert infusion number] infusions per year. This is an increase of [insert infusion number].* *Additional Medical Staff requirements:**The ARSAC/IRMER certificate holders (minimum of 1) for Lutathera will need their job plans reviewed to ensure enough time to see patients, attend MDTs, supervise treatments etc. This may need additional PAs at a cost of £ [insert number of additional PAs and cost]**Additional staff Nuclear Medicine* *The technologist will be responsible for: the safe use of ionising for therapeutic purposes; instructing the patient regarding radiation before, during or following treatment; evaluating the satisfactory preparation of the patient before beginning treatment; recognising emergency patient conditions and initiating contingencies when appropriate. Hiring appropriate staff at a total cost of £*[insert total Please itemise the full time equivalent for each craft group you will be employing]*, will enable our service to treat multiple patients concurrently. Therefore, it is expected our service will treat [insert patient number] NETs patients weekly, delivering [insert infusion number] infusions per year. This is an increase of [insert infusion number]*.*Additional Administrative staff**The cost of these treatments mean it is imperative there is good co-ordination between the department staff, the GEP-NET team and the patient. This may require additional administration and clerical staff of [insert number] full time equivalents at cost [insert number].**Patient administration/recovery areas:* *Once patients have received treatment in one of our designated rooms, they may have to be moved to a different room for radiation monitoring. This room is compliant for molecular radiotherapy and located in [insert ward/location], which are designated for therapy handling and administration of radionuclides. This room is currently at capacity; however, additional recovery areas would allow for more patients to recover simultaneously, therefore removing unnecessary time spent in the lead lined treatment rooms. The room or suite of rooms will need a dedicated toilet and, if patients stay overnight, a shower as well. A room that would fit these requirements could be repurposed within our ward and would need to be available for [insert number of hours] hours per patient. These changes would result in £*[insert total] *being spent in renovations/set up. It is expected, that as a result patient throughput can be increased. Therefore, it is expected our service will treat [insert patient number] NETs patients weekly, delivering [insert infusion number] infusions per year. This is an increase of [insert infusion number]. This expense may only be needed once the service expands and therefore, may not need to be included in the first business plan.*As a result of this implementation, it is expected the treatment waiting time for NETs patients eligible for Lutathera will be *[insert treatment waiting time].* This is *[lower than, higher than, in line with]* the national average. With the expectation of treating [insert patient number] patients over the next 12 months, a total of £[insert total] would be returned into the Trust. *It is expected the treatment waiting time for NETs patients eligible for Lutathera will be [insert treatment waiting time]. This is [lower than, higher than, in line with] the national average.***Drivers for the service***Describe the benefit the service will have on:** National and local objectives
* Advantages/benefits to the patient, region, trust and staff
* The NHS Outcome Framework Domains and the key questions listed from the Care Quality Commission (CQC) in the table in section 4.2

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.18Potential advantages/benefits to the patient, region, trust and staff are as follows:* 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’
* The service is expandable as new molecular radiotherapy agents are licenced and funded by NHS England or the devolved nations it is more likely that those offering molecular radiotherapy services successfully will be commissioned to offer these new services

*The below is an example for an additional clinical nurse specialist:**Adding a specialist nurse to the service will benefit from the following:** *A more cohesive and streamlined NETs service*
* *Improved patient outcomes*
* *High level of job satisfaction*
* *Low staff turnover rate*

*The below is an example for additional Consultant PAS:**Adding 2 trained ARSAC/IRMER certificate holders would ensure:** Clear clinical governance pathways for molecular radiotherapy
* Higher likelihood of success in bidding for NHSE funding
* Ability to add new molecular radiotherapy services in other cancers as approved by NHS England/devolved nations

*The below is an example for an additional nuclear medicine staff:**Adding a nuclear medicine staff to the service will benefit from the following:** *A more cohesive and streamlined NETs service*
* *Improved patient outcomes*
* *Reduction in risk of treatment*

*The below is an example for additional treatment and recovery rooms:**Increasing patient’s treatment and recovery rooms will benefit from the following:** *A more cohesive and streamlined NETs service*
* *Ability to meet likely demand*
* *Spare capacity can be utilised for other populations if demand is less than expectations*

Deliverable outcomes and activityIt is estimated the service will treat a minimum of *[insert number of patients]* patients, and a maximum of *[insert number of patients]* patients per year. *Summarise key outcomes including increased revenue, reduced waiting times, reduced patient travel times, reduced costs.* *The below is an example for additional specialist nurses:**Investing in additional clinical nurse specialists will offer value for money as they maximise the use of existing resources and improve treatment waiting times.* With the expectation of treating [insert patient number] patients over the next 12 months, a total of £[insert total] would be returned into the Trust. *It is expected the treatment waiting time for NETs patients eligible for Lutathera will be [insert treatment waiting time]. This is [lower than, higher than, in line with] the national average.**The below is an example for additional nuclear medicine staff:**Investing in additional nuclear medicine staff will increase patient throughput and treatments, therefore improving treatment waiting times.* With the expectation of treating [insert patient number] patients over the next 12 months, a total of £[insert total] would be returned into the Trust. *It is expected the treatment waiting time for NETs patients eligible for Lutathera will be [insert treatment waiting time]. This is [lower than, higher than, in line with] the national average.**The below is an example for an additional treatment/recovery space:**Investing in additional treatment/recovery space will increase capacity, improve treatment waiting times and ensure demand for treatment can be met.* With the expectation of treating [insert patient number] patients over the next 12 months, a total of £[insert total] would be returned into the Trust. *It is expected the treatment waiting time for NETs patients eligible for Lutathera will be [insert treatment waiting time]. This is [lower than, higher than, in line with] the national average.* |
| **Section 5: Critical assumptions and risk mitigation** |
| **Guidance information**Document any assumptions made in the proposal which may affect the delivery.The risk assessment should be as comprehensive as possible, describing all possible risks that pertain to delivering the proposed service delivering against the NHSE service specification.Document the risks to the proposal, their likely impact and how they will be managed.Document any key dependencies that may affect the timeline. |
| Submit any critical assumptions within the risk assessment table and quantify the likelihood and impact of the possible risk.

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk** | **Likelihood (1 [low] to 5 [high])** | **Impact****(Low, Medium, High)** | **Mitigation** |
| *Examples: Potential loss of NET service to another centre*  |  |  |  |
| *Patient numbers are lower than the anticipated volume* |  |  |  |
| *Lack of suitably trained staff* |  |  |  |
|  |  |  |  |

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| **Section 6: Implementation timeline** |
| **Guidance information**In this section describe how you are going to implement the proposed service.The section has two sub-headings:1. The first should describe who is in the implementation team and their role and responsibility, including any additional team members who will need to be recruited
2. The second should describe deliverables and key milestones in a “what and when” format
 |
| Implementation team *– please note the below are examples only and should be amended to fit within your centre’s needs. Roles are more important than titles, however, ARSAC/IRMER certificate holder and MPE are legal requirements* * 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 care 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.
* 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.
* Pathologist: this person establishes the diagnosis of NETs from tissue biopsy and assesses origin and grade of tumour to determine suitability for molecular radiotherapy.
* 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.

*Describe the team member’s responsibilities for implementing the service and their role and responsibilities.* *The below is an example for an additional specialist nurse:** *The centre’s matron, with advice from the NETs lead, will be responsible for the appointment of a nurse specialist*
* *Current NETs nurse specialist will be responsible for any additional training required by the newly hired nurse*

*The below is an example for an additional nuclear medicine staff** *The Nuclear Medicine administration lead will be responsible for appointment of any new nuclear medicine staff*
* *The nuclear medicine training lead and the MPE will be responsible for any additional training required by the newly technologist*

Timeline/key Milestones and Accountability *Provide a timeline with implementation (task) details and milestones for delivery of the service, include any future development and who is responsible for each step. The below is an example for an additional specialist nurse.*

|  |  |  |
| --- | --- | --- |
| **Ref** | **Timeline/Milestone Example** | **Accountability**  |
| *1* | *Business case finalised by November 2020* | *NETs clinical lead* |
| *2* | *Presentation and approval by board December 2020* | *NETs clinical lead and Trust board*  |
| *3* | *Advertisement of post – January 2021* | *NETs clinical lead* |
| *4* | *Interview for post – March/April 2021* | *NETs clinical lead* |
| *5* | *Start date – May/June 2021* | *NETs clinical lead* |
| *6* | *Additional training June 2021* | *Senior NETs nurse specialist*  |

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| **Section 7: Workforce** |
| **Guidance information**Workforce planning is a continuous process used to align the needs and priorities of the Trust with those of its workforce to ensure it can meet the legislative, regulatory and delivery objectives of the molecular radiotherapy service. |
| Workforce planning*Provide information that describes the workforce planning requirements and how these will be met for the immediate and longer term. Please note the below are examples only and should be amended to fit within your centre’s needs** 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 care 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.
* 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.
* Pathologist: this person establishes the diagnosis of NETs from tissue biopsy and assesses origin and grade of tumour to determine suitability for molecular radiotherapy.
* 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.

Training requirements and considerations* Consider the specific competencies and training requirements for clinical staff; ensure senior nursing staff are included in your consultation
* All key competencies/training should aim to support optimal administration and management of adverse events (AEs). These will vary between hospital and outreach settings.

All staff that will be involved in delivering molecular radiotherapy services will have the appropriate training to fulfil their specific role. Staff will also have to ensure that they continue to maintain their competence and undertake any relevant activities relating to Continuing Professional Development. By modernizing the workforce, we can align to priorities outlined within the NHS people plan *[Insert local/Trust’s People Plan if applicable].*Example:

|  |  |  |
| --- | --- | --- |
| Task | Timeline | Accountability  |
| *Generate service wide workforce plan* | *End of June 2021* |  |
| *Implement initiative to recruit and retain workforce the service needs* | *Q2 2021* * *Implement Living Wage*
* *Review financial incentives for groups of staff*
 | *Director of Organizational Development & Workforce* |
| *Implement training*  | *Q3 2021* | *Senior Nurse specialist*  |

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*APPENDIX I: NETs disease burden and treatment approach*

**NETs Burden of disease**

Neuroendocrine tumours (NETs) are rare tumours that develop in the neuroendocrine cells. The incidence and prevalence of NETs is steadily increasing as a result of greater awareness and earlier diagnosis.1,3 There are various types of NETs depending on the type of cell from which the tumour started its development.6 The majority of the NETs develop slowly over some years and so may not cause symptoms during the early stages of the disease, with many patients presenting with metastatic disease without a known primary site.1,2 Most NETs express increased levels of somatostatin receptors; this helps when making a NET diagnosis and when staging the tumour.4

NETs are rare; however, the incidence and prevalence of NETs is steadily increasing as a result of greater awareness and earlier diagnosis.1,3

* Around 4,000 people in the UK are diagnosed with NETs each year.1,2
* In 2015 the incidence rate for NETs was estimated to be 8.84 per 100,000 (females: 9.30 per 100,000; males: 8.37 per 100,000) rising from 3.9 in 2001.8
* The prevalence in 2015 was estimated to be 19,268 (34.9 per 100,000; females: 10,525; males: 8,743).8

At *[insert Trust name]* the number of patients with NETs who are treated is *[insert number]* per year.

Over 50% of NETs originate from endocrine cells of the gastrointestinal tract and the pancreas; these NETs are referred to as gastroenteropancreatic NETs (GEP-NETs).4 Most often GEP-NETs are asymptomatic which can delay the diagnosis of GEP-NETs for a number of years; they are often discovered as an incidental finding during radiological assessment or surgery.11,13 GEP-NETs are a heterogeneous group of tumours that form in the neuroendocrine cells present in the gastrointestinal tract and the islets of Langerhans of the pancreas. 11,13 GEP-NETs can be classified as either functioning tumours, which cause symptoms due to the release of hormones and peptides, or non-functioning tumours, which have no hormone-related clinical features.4,11 GEP-NETs make up *[insert percentage]* of our NETs caseload.

**Current Management Guidelines (national and local)**

The aim of treatment should be curative, however, the treatment of NETs is challenging due to their marked heterogeneity. 4,11 To maximise patient prognosis and survival, a multidisciplinary approach is required when treating NETs.4,7 When planning a patient’s treatment, the size of the tumour, metastases, histological grade and its functional profile should be assessed.11

Surgery is the only curative treatment for NETs and is used as the first-line treatment of localised NETs. However, because most NETs are diagnosed at an advanced or metastatic disease stage, other treatment options are required.4 Somatostatin analogues are the first-line systemic treatment of NETs to inhibit tumour growth.5 However, if there is evidence of disease advancement on somatostatin analogue therapy, molecularly targeted radiation therapy is recommended, such as peptide receptor radionuclide therapy (PRRT).6 PRRT involves systemic administration of a radiolabelled peptide that targets specific receptors, such as somatostatin receptors, that are overexpressed in tumours.14

The National Institute for Health and Care Excellence (NICE) have recommended the use of Lutathera (oxodotreotide) as a treatment option for adult patients with unresectable or metastatic, progressive, well-differentiated (grade 1 or grade 2), somatostatin receptor-positive GEP-NETs.15 The clinical trial evidence that was submitted to NICE showed that Lutathera was an effective treatment option for treating somatostatin receptor-positive gastrointestinal and pancreatic NETs, in addition to having tolerable side effects, which allowed patients to live a relatively normal life.15 NHS England routinely commissions Lutathera, in line with the criteria for Blueteq approval, as of 27th November 2018.16 In the UK there are currently 21 centres (as of July 2020) that use Lutathera for NETs patients as part of their PRRT service.

*APPENDIX II: NETs Treatment Pathway*

**Molecular Radiotherapy Delivery Team**

*Please note these are examples only. Please amend for your individual service and needs. Please note additional information for treatment delivery can be found in the SmPC.*

* 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.
* 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.
* Pathologist: this person establishes the diagnosis of NETs from tissue biopsy and assesses origin and grade of tumour to determine suitability for molecular radiotherapy.
* 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 meeting is required once weekly to discuss treatment options with progression and tumour grade as the primary determinants of treatment choice. If there is evidence of disease progression on somatostatin analogue therapy, patients should be considered for eligibility for Lutathera®.

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

A patient’s eligibility for treatment with lutetium (177Lu) can be assessed with gallium PET or SPECT scans (Octreoscan or Tektrotyd). This should be carried out at *[insert centre]*, with an estimated cost of £*[insert cost].*

**Treatment Room**

All treatment will be delivered according to locally agreed protocols for molecular radiotherapy, in radioactive requirement compliant treatment room(s) in *[insert infusion location]*. The treatment room will be within a designated area for therapy handling and administration of radionuclides with toilet facilities for radioactive waste.

The treatment room will need to be available for *[insert number of hours]* hours per patient.

*If this room is not available, please detail what will be required in terms of location and costs to develop one including building costs, non-works costs, fees, equipment and VAT.*

**Follow up**

Blood test are collected and shared with the MDT on a regulate basis in line with the SmPC and extend to 3 months after the final infusion *[insert location, e.g centre, patient’s GP].*

*Appendix III:  NETs Multidisciplinary Team*

*Please note these are examples only. Please amend for your individual service and needs. Please note additional information for treatment delivery can be found in the SmCP.*

**MDT team:**

* 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.
* 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.
* Pathologist: this person establishes the diagnosis of NETs from tissue biopsy and assesses origin and grade of tumour to determine suitability for molecular radiotherapy.
* 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: he 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.

During the MDT meeting, treatment options for the patient are discussed, with progression and tumour grade as the primary determinants of treatment choice. Once the decision has been made to treat with PRRT there is a stringent process in place that requires a high level of co-ordination between the oncology and nuclear medicine departments. Patients are admitted to hospital prior to their treatment for routine blood tests. Treatment is generally administered on the second day, after which they may stay the night of their treatment, depending on radiation levels. Radioactivity levels are measured and patients discharged by the nuclear medicine team once it is safe to do so. Please refer to the SmPC for detailed information on Lutathera® administration.

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**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**

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