Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Policy: CP67

Peptide Receptor Radionuclide Therapy (PRRT) for the Treatment of Neuroendocrine Tumours (NETs)

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Approved by:	Management Group
Issue Date:	01 July 2016
Review Date:	July 2019
Document No:	CP67

Document History

Revision History			
Version No.	Revision date	Summary of Changes	Updated to version no.:
0.1	23.06.12	Clinical criteria amended following consultation – somatostatin analogue therapy (SSAs) removed as this is currently being funded by Health Boards	0.2
0.2	03.07.12	Further refinements to clinical criteria as advised by Dr Aled Rees	0.3
0.3	30.08.12	Formatting and templating amendments as directed by WHSSC Execs	0.4
0.4	06.09.12	Formatting and templating amendments as directed by WHSSC Execs	0.5
1.0	January 2016	Updated the background information, name of therapy throughout document, definition, clinical indications, and criteria for treatment, referral pathway, exceptions and checklist annex i as advised by Dr Aled Rees. (note version control numbering issue at this point i.e. should be 1.1 but changed to 2.0)	2.0
1.0	January 2016	Updated the MDT section and referral criteria as advised by Dr Graeme Postron.	2.0
1.0	January 2016	Updated criteria and definitions as advised by Dr Mohid Khan.	2.0
2.0	21.04.16	Reference to guidelines added	2.1
2.1	13.05.16	Prior approval form added as annex	2.2
2.2	16.05.16	Change requested by Dr Mohid Khan	2.3
2.3	20.06.16	Template amendment as directed by WHSSC Corporate Directors Group	2.4
2.4	30.06.16	Approved by Management Group	3.0
Date of next revision		July 2019	

Consultation		
Name	Date of Issue	Version Number
Dr Aled Rees	22.06.12	0.1
Neuroendocrine MDT (Drs Tom Crosby, Dr Aled Rees, Dr Laura Moss)	02.07.12	0.2
Cancer Programme Team	27.06.12	0.2
WHSSC Execs	05.07.12	0.3
Cancer Programme Team	17.07.12	0.3
Cancer Programme Team	21.08.12	0.4
WHSSC Execs	04.09.12	0.4
Neuroendocrine MDT members (Dr Aled Rees, Dr Laura Moss, Dr Hilary Williams)		2.0
Cancer Network in Wales		2.0
Radiology Leads in Wales		2.0
Dr Aled Rees, Consultant Neuroendocrinologist, UHW		2.0
Dr Mohid Khan Consultant Gastroenterologist, UHW		2.0
NETs patient support groups		2.0
Management Group	30.06.16	2.4

Approvals		
Name	Date of Issue	Version No.
WHSSC Management Group	30.06.16	3.0

Policy Statement

Background	Peptide receptor radionuclide therapy (PRRT) is used as a therapy for patients with progressive neuroendocrine tumours.
Summary of Access Criteria	The use of radionuclide therapy is approved according to the criteria defined in this policy. Audited outcomes for the service will be sent to WHSSC on at least an annual basis.
Responsibilities	The policy will be managed under the gatekeeping arrangements with the Neuroendocrine Tumour MDT based at the University Hospital of Wales and The Royal Liverpool University Hospital. Clinicians considering treatment should: • Discuss all the alternative treatments with the patient • Advise the patient of any side effects and risks of the potential treatment • Inform the patient that the treatment is not routinely funded outside of the criteria in the policy • Confirm that there is contractual agreement with WHSSC for the treatment.

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1. Aim

1.1 Introduction

The document has been developed as the policy for treatment of patients with Neuroendocrine Tumours (NETs) using Peptide Receptor Radionuclide Therapy (PRRT).

The purpose of this document is to:

- clearly set out the circumstances under which patients will be able to access PRRT ;
- clarify the referral process to the designated Provider; and
- define the criteria that patients must meet in order to be referred.

1.2 Relationship with other Policies and Service Specifications

This document should be read in conjunction with the following documents:

- Specialised Services Policy CP50: Positron Emission Tomography (PET)
- Specialised Services Policy CP66: 68-gallium DOTATATE scanning for the Management of Neuroendocrine Tumours (NETs); and
- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR)

2. Scope

2.1 Definition

Neuroendocrine Tumours (NETs) are heterogeneous tumours which may be classified according to European Neuroendocrine Tumour Society (ENETS) and World Health Organisation (WHO) guidelines. Common sites of origin include gastroenteropancreatic and lung, but tumours can arise from almost any site in the body. Tumours are graded into low, intermediate or high grades based on histological review, and staged by a number of imaging techniques including octreotide scintigraphy (octreotide scan) or, where available, Gallium-68 PET scans. These techniques identify neuroendocrine tumours which express somatostatin receptors.

2.1.1 Peptide Receptor Radionuclide Therapy (PRRT)

A number of different types of PRRT have been employed. The radiolabels of choice include Yttrim-90 (90Y) and Lutetium-177 (177Lu). Available peptides include DOTATOC, DOTATATE, DOTA-lanreotide and DOTANOC, which exhibit

different affinities for individual somatostatin receptor populations. Optimal peptide selection in an individual patient is determined by diagnostic tracer imaging and availability. The main toxicities of radiopeptide treatment are temporary myelosuppression and radiation nephritis. Nausea and vomiting during and immediately after treatment are partly attributed to co-administration of amino acids for renal protection and are mitigated by prophylactic antiemetics[1]. The NETTER-1 trial recently confirmed a significant benefit of 177Lu-DOTATATE in improving progression-free survival compared to high dose octreotide in patients with progressive well-differentiated NETs.

2.2 Codes

ICD-10 Codes

2.2.1 Malignant neuroendocrine tumours C7A

Use Additional

- code to identify any associated endocrine syndrome, such as:
- carcinoid syndrome (E34.0)

Code Also

- any associated multiple endocrine neoplasia [MEN] syndromes (E31.2)

Type 2 Excludes

- malignant pancreatic islet cell tumors (C25.4)
- Merkel cell carcinoma (C4A.)

C7A Malignant neuroendocrine tumours
C7A.0 Malignant carcinoid tumours
C7A.00 Malignant carcinoid tumour of unspecified site
C7A.01 Malignant carcinoid tumours of the small intestine
C7A.010 Malignant carcinoid tumour of the duodenum
C7A.011 Malignant carcinoid tumour of the jejunum
C7A.012 Malignant carcinoid tumour of the ileum
C7A.019 Malignant carcinoid tumour of the small intestine, unspecified portion
C7A.02 Malignant carcinoid tumours of the appendix, large intestine, and rectum
C7A.020 Malignant carcinoid tumour of the appendix
C7A.021 Malignant carcinoid tumour of the cecum
C7A.022 Malignant carcinoid tumour of the ascending colon
C7A.023 Malignant carcinoid tumour of the transverse colon

[1] UKINETS Gut Guidelines

C7A.024 Malignant carcinoid tumour of the descending colon
C7A.025 Malignant carcinoid tumour of the sigmoid colon
C7A.026 Malignant carcinoid tumour of the rectum
C7A.029 Malignant carcinoid tumour of the large intestine, unspecified portion
C7A.09 Malignant carcinoid tumours of other sites
C7A.090 Malignant carcinoid tumour of the bronchus and lung
C7A.091 Malignant carcinoid tumour of the thymus
C7A.092 Malignant carcinoid tumour of the stomach
C7A.093 Malignant carcinoid tumour of the kidney
C7A.094 Malignant carcinoid tumour of the foregut NOS
C7A.095 Malignant carcinoid tumour of the midgut NOS
C7A.096 Malignant carcinoid tumour of the hindgut NOS
C7A.098 Malignant carcinoid tumours of other sites
C7A.1 Malignant poorly differentiated neuroendocrine tumours
C7A.8 Other malignant neuroendocrine tumours

3. Access Criteria

3.1 Clinical Indications

Peptide Receptor Radionuclide Therapy may be indicated for patients with inoperable NETs showing disease progression and who meet appropriate selection criteria to include demonstration of appropriate radiopharmaceutical uptake at all known tumour sites, on diagnostic imaging.

These clinical indications will be under the gatekeeping arrangements of the South Wales or Liverpool Neuroendocrine MDTs.

3.2 Criteria for Treatment

PRRT is funded for the management of NETs following review by Neuroendocrine MDTs in South Wales or Liverpool.

Response after two treatment cycles of Lu177 is assessed clinically and by CT or MRI scan. If there is clear progression then cycles 3 and 4 are not given.

3.3 Referral Pathway

Patients with NETs being considered for PRRT should be referred to the South Wales or Liverpool MDT depending on the patient's location, for access to treatment.

3.4 Exclusions

There are no exclusions to this policy.

3.5 Exceptions

If the patient does not meet the criteria for treatment, but the referring clinician believes that there are exceptional grounds for treatment, an Individual Patient Funding Request (IPFR) can be made to WHSSC under the All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR).

If the patient wishes to be referred to a provider out of the agreed pathway, an IPFR should be submitted.

Guidance on the IPFR process is available at www.whssc.wales.nhs.uk

3.6 Responsibilities

Clinical referrers should:

- Inform the patient that this treatment is not routinely funded outside the criteria in this policy
- Refer via the agreed pathway to the Neuroendocrine MDT for assessment.

Clinicians considering treatment should:

- Discuss all the alternative treatment with the patient
- Advise the patient of any side effect and risks of the potential treatment
- Inform the patient that treatment is not routinely funded outside of the criteria in the policy.
- Confirm that there is contractual agreement with WHSSC for the treatment

In all other circumstances submit an IPFR request.

4. Putting Things Right: Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided. The patient or their representative should be guided by the clinician, or the member of NHS staff

with whom the concern is raised, to the appropriate arrangements for management of their concern:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board;
- When a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (welsh).

This policy has been subjected to an Equality Impact Assessment. The Assessment has shown that there will be no impact.

Annex (i) Checklist

Specialised Services Policy: Peptide Receptor Radionuclide Therapy (PRRT) for the Treatment of Neuroendocrine Tumours (NETs)

The following checklist should be completed for ***all*** *patients to whom the policy applies*, before treatment, by the responsible clinician.

Please complete the appropriate boxes:

Patient NHS No:		
Patient is Welsh Resident	Post Code:	
Patient is English Resident registered with NHS Wales GP	GP Code:	

Patient meets following access criteria for treatment:	**Yes**	**No**
PRRT may be indicated for patients with inoperable NETs showing disease progression and who meet appropriate selection criteria to include demonstration of appropriate radiopharmaceutical uptake at all known tumour sites on diagnostic imaging.		
Patient wishes to be referred to non-contracted provider		
If the patient wishes to be referred to a non-contracted provider an Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided on the basis of exceptionality. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&id=181455		
Patient does not meet access criteria but is exceptional		
An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided as an exception. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&id=181455		

Name: _____ Designation: _____

Signature: _____ Date: _____

	Name (printed):	Signature:	Date:	Yes	No
Authorised by TRM Gatekeeper					
Authorised by WHSSC Patient Care Team					
Authorised by ???					
Patient Care Team/IPFR/TRM Reference number:					

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Welsh Health Specialised Services Committee (WHSSC)

Annex (ii) Neuroendocrine Tumour (NET) Prior Approval

1. Lead Clinician Details:			
Name:			
Job Title:			
Correspondence Address:			
E-mail Address:		Tel:	

2. Patient Details:			
Forename:		Surname:	
Address:		Postcode:	
NHS Number:			
Date of Birth:		M or F:	
GP Name & Address:			

3. Referral Details:	
What specific treatment is being requested: e.g. diagnostic, clinical intervention, drug therapy	
Provider and location of the intervention:	
Name of the clinician who will undertake the intervention:	

4. Checklist:	
Referral supported by MDT:	
Copy of clinical referral/relevant clinical information attached:	
Cost of treatment:	

Please send completed form to:
Patient Care Team, WHSSC, 3a, Caerphilly Business Park, Van Road, Caerphilly, CF83 3ED

E-mail: WHSSC.IPC@wales.nhs.uk or WHSSC.IPC@nhs.net