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Molecular Radiotherapy Services (MRT) All Ages

Service Specification: SS291

Document Information	
Document Name	Molecular Radiotherapy Services (MRT) All Ages
Document No	SS291
Document Purpose	Service Specification
Publication Date	March 2025
Version No	1.0
Commissioning Team Author	Cancer and Blood
Target Audience	Chief Executives, Medical Directors, Directors of Finance, Directors of Therapies and Health Science, Directors of Planning, Wales Cancer Network, Health Board Cancer leads
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy

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Abbreviations

AWMOL	All Wales Molecular Radiotherapy Group
HCC	Hepatocellular Carcinoma
HPB	Hepato-pancreatic Biliary
IPFR	Individual Patient Funding Request
MDT	Multi-disciplinary Team
MRT	Molecular Radiotherapy
NWJCC	NHS Wales Joint Commissioning Committee
PFS	Progression Free Survival
PRRT	Peptide Receptor Radionuclide Therapy
SIRT	Selective Internal Radiotherapy

Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission the service of Molecular Radiotherapy Treatments in accordance with the criteria outlined in this specification.

In creating this document NWJCC has reviewed the requirements and standards of care that are expected to deliver this service.

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language Act \(1993\)](#), the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment.

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to

the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This document has been developed as the Service Specification for the planning and delivery of Molecular Radiotherapy Treatments for people resident in Wales. This service will only be commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

1.1 Background

Molecular Radiotherapy (MRT) can be characterised as a form of unsealed source radiotherapy, utilising solutions or suspensions of radioactive substances that are injected or taken orally. These solutions can be termed therapeutic radiopharmaceuticals. Therapeutic radiopharmaceuticals should be regarded as distinct from diagnostic radiopharmaceuticals, commonly used in nuclear medicine and PET-CT, although there is an overlap in terms of specialist workforce, logistics and infrastructure.

For clarity, this specification does not apply to the use of sealed radiotherapy sources (such as seeds or wires) for brachytherapy, or external beam radiotherapy.

1.2 Aims and Objectives

The aim of this service specification is to define the requirements and standard of care essential for delivering Molecular Radiotherapy Treatments.

The objectives of this service specification are to:

- Detail the specifications required to deliver MRT services for people who are resident in Wales.
- Improve the outcomes from MRT and the experience of care by delivering best practice MRT treatments using appropriate technologies and holistic support in a safe culturally appropriate and inclusive way, enabling the diverse needs of service users to be met.
- Ensure equitable access to MRT for patients in Wales.
- Support disease specific multi-disciplinary teams to enable people requiring MRT to access high-quality care at the right time and in the right place and in a timely manner, giving regard to individual choice.
- Reduce variation in clinical practice through standardisation, audit and the adoption of best practice and dosimetry.
- Ensure minimum standards of care are set for the use of MRT.

1.3 Relationship with other documents

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

- **NHS Wales**
 - All Wales Policy: [Making Decisions in Individual Patient Funding requests \(IPFR\)](#).
- **NHS Wales Joint Commissioning Committee policies and service specifications**
 - CP50 Positron Emission Tomography (PET), Commissioning Policy, April 2024
 - PP195 Lutetium (177Lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours, Policy Position Statement, November 2023
 - CP266 Peptide Receptor Radionuclide Therapy (PRRT) for the Treatment of Neuroendocrine Tumours (NETs) in adults, Service Specification, March 2023
 - Specialist Services Commissioning Strategy 2023 – 2033
 - PPS227 Selective internal radiation therapies for treating adults with hepatocellular carcinoma, Policy Position Statement, November 2021
- **NHS England**
 - [2322 Radiotherapy Services \(Adults and Children\) Subspecialisation: Molecular Radiotherapy \(all ages\) September 2024](#)
- **Relevant Professional Guidance**
 - [Clinical Guideline for Administration of Molecular Radiotherapy Version 2 2019](#)
 - RCR molecular radiotherapy – guidance for clinicians [rcr-publications_molecular-radiotherapy-guidance-for-clinicians-second-edition_september-2019.pdf](#)
 - Nuclear Medicine Communications 44(11):p 927-936, November 2023. [Scientific support for nuclear medicine : Nuclear Medicine Communications \(lww.com\)](#)
 - Guidance on medical physics expert support for nuclear medicine (<https://doi.org/10.1259/bjr.20211393>)
 - ARSAC notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources (<https://assets.publishing.service.gov.uk/media/66588efa8f90ef31c23ebc64/Notes-for-guidance-on-the-clinical-administration-of-radiopharmaceuticals-and-use-of-sealed-radioactive-sources.pdf>)
 - Review of molecular radiotherapy services in the UK [rcr-publications_review-of-molecular-radiotherapy-services-in-the-uk_november-2021.pdf](#)
- **National Institute of Health and Care Excellence (NICE) guidance**

- Thyroid cancer: assessment and management, National Institute of Health and Care Excellence (NICE) Guideline 230 (NG 230) (<https://www.nice.org.uk/guidance/ng230>)
 - Thyroid disease: assessment and management NG 145 (<https://www.nice.org.uk/guidance/ng145>)
 - Brain tumours (primary) and brain metastases in over 16s NG 99 ([Overview | Brain tumours \(primary\) and brain metastases in over 16s | Guidance | NICE](#))
 - Colorectal cancer NG 151 ([Overview | Colorectal cancer | Guidance | NICE](#))
 - Non-Hodgkin's lymphoma: diagnosis and management NG 52 ([Overview | Non-Hodgkin's lymphoma: diagnosis and management | Guidance | NICE](#))
 - Lung cancer: diagnosis and management NG 122 ([Overview | Lung cancer: diagnosis and management | Guidance | NICE](#))
 - Lutetium (177Lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours NICE Technology Appraisal 539 (TA 539) ([Overview | Lutetium \(177Lu\) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours | Guidance | NICE](#))
 - Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases NICE TA 412 (<https://www.nice.org.uk/guidance/ta412/chapter/1-Recommendations>)
 - Selective internal radiation therapies for treating hepatocellular carcinoma NICE TA 688 ([Overview | Selective internal radiation therapies for treating hepatocellular carcinoma | Guidance | NICE](#))
- **Other published documents**
- ENETS 2017 Consensus Guidelines for the Standards of Care in Neuroendocrine Neoplasms: Peptide Receptor Radionuclide Therapy with Radiolabelled Somatostatin Analogues
 - The European Association of Nuclear Medicine (EANM) guideline on radioiodine therapy of benign thyroid disease (<https://doi.org/10.1007/s00259-023-06274-5>)
 - Joint SNMMI/EANM practice guideline for Nuclear Medicine Evaluation and Therapy of Differentiated Thyroid Cancer (<https://jnm.snmjournals.org/content/63/6/15N>)
 - EANM Procedure guidelines for 131I-meta-iodobenzylguanidine (131I-mIBG) therapy ([EANM procedure guidelines for 131I-meta-iodobenzylguanidine \(131I-mIBG\) therapy](#))
 - National Comprehensive Cancer Network (NCCN), Clinical practice guidelines in Oncology Neuroendocrine tumours (http://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf) ([Guidelines for the management of gastroenteropancreatic neuroendocrine \(including carcinoid\) tumours \(NETs\) | Gut \(bmj.com\)](#))

- EANM guidelines for radionuclide therapy of bone metastases with beta-emitting radionuclides
- (<https://doi.org/10.1007/s00259-018-3947-x>)https://www.eanm.org/publications/guidelines/gl_radio_ther_radioimmun.pdf
- EANM guideline for radionuclide therapy with radium-223 of metastatic castration-resistant prostate cancer
- (<https://doi.org/10.1007/s00259-017-3900-4>)
- SNMMI Procedure Standard/EANM Practice Guideline for Palliative Nuclear Medicine Therapies of Bone Metastases
- (<https://doi.org/10.2967/jnmt.123.265936>)
- EANM procedure guideline of radio-immunotherapy for B-cell lymphoma with 90Y-radiolabeled ibritumomab tiuxetan (https://www.eanm.org/publications/guidelines/gl_radio_ther_radioimmun.pdf)
- The joint IAEA, EANM, and SNMMI practical guidance on peptide receptor radionuclide therapy (PRRT) in neuroendocrine tumours
- (<https://doi.org/10.1007/s00259-012-2330-6>)
- EANM procedure guideline for 32P phosphate treatment of myeloproliferative diseases (https://www.eanm.org/publications/guidelines/gl_radio_ther_32p.pdf)
- EANM procedure guideline for the treatment of liver cancer and liver metastases with intra-arterial radioactive compounds (<https://doi.org/10.1007/s00259-021-05600-z>)
- Management of thyroid cancer: United Kingdom National Multidisciplinary Guidelines (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4873931/>)
- Suddle A, Reeves H, Hubner R, et al [British Society of Gastroenterology guidelines for the management of hepatocellular carcinoma in adults](#) Gut 2024;73:1235-1268

2. Service Delivery

The NHS Wales Joint Commissioning Committee will commission the service of Molecular Radiotherapy Treatments in line with the criteria identified in this specification.

2.1 Service description

Each Service provider must be configured so that there is sufficient patient volume for each MRT treatment to ensure workforce sustainability, maintain professional expertise and should serve a population sufficient to support a critical mass of infrastructure required to deliver the service.

2.2 Population Size

Each Service must meet any relevant volume requirements relating to specific treatments, for example:

- Lutetium (^{177}Lu) oxodotreotide – a minimum of 5 patients per year
- Radium (^{223}Ra) dichloride – a minimum of 5 patients per year
- Selective Internal Radiation Therapy (SIRT) – a minimum of 10 patients per year

2.3 Clinical Model

The Service clinical model for MRT is set out in **Table 1**.

Table 1: The Welsh MRT Service Clinical Model

Level 1 – single administration MRT in pill or capsule	MRT treatments offered by Level 1 Services are of lower complexity. This includes single administration MRT in capsule form for benign disease in an outpatient setting. Service provision will be linked to relevant disease-specific multi-disciplinary teams, with access to appropriate facilities to receipt, store, unpack and assay.
Level 2 – intravenous administration for cancer	Includes oral or intravenous MRT for localised or metastatic cancers. It is expected that Level 2 services will also have the capability to deliver Level 1 services. Service provision will be anchored around multi-disciplinary teams and cancer pathways and requires integration of nuclear medicine and oncology, with access to appropriate facilities to receipt, store, unpack and assay.
Level 3 – selective internal radiation therapy (SIRT)	The delivery of SIRT is anchored around the specialist hepato-pancreatic biliary (HPB) or HCC multi-disciplinary team and requires integration of nuclear medicine, oncology and interventional radiology.

Paediatric MRT (0-15, up to 16th Birthday)	MRT administered to paediatric service users for benign or malignant disease. To deliver paediatric MRT, the Service will also need to be a Level 2 Service.
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2.3.1 Core Requirements of a Level 1 Service

The Service Provider will deliver the service in centres with appropriate levels of expertise relevant to the treatments being administered and must ensure that the Service:

- operates within a clinically safe environment ensuring safe practice and adequate levels of staffing and equipment to deal effectively with medical emergencies
- must be delivered in facilities that ensure the integrity of radiopharmaceuticals by preventing contamination and maintaining appropriate environmental controls. These facilities should comply with all regulatory and safety standards, be designed to minimize contamination risks, and provide safe handling of radioactive materials in designated areas to protect both the product and personnel
- ensures that unsealed radioactive sources are handled in safe designated areas that meet statutory and licensing requirements
- provides good care within a stringent clinical governance framework
- ensures adequate precautionary measures to comply with relevant legislation and to ensure that the radiation dose to the patient is optimised and radiation risks are minimised for staff, other workers, relatives, carers and the general public
- has the capability to undertake dosimetry in accordance with regulatory and licensing requirements. Where this is not available on sites, arrangements underpinned by agreed protocols must be put in place with other MRT services where required dosimetry can be undertaken.

The Service must ensure that:

- MRT is administered by an Administration of Radioactive Substances Advisory Committee (ARSAC) Licensed institution and Practitioner or by another appropriately trained and registered healthcare professional (HCP) (doctor, nurse, radiographer, clinical scientist or technologist)
- all medicines and radiopharmaceutical products are managed safely and securely, in accordance with environmental permits and defined local radiological rules, NHS Resolution and relevant consents and law. Legislation and Regulations that must be complied with are, as follows:
 - [The Environmental Permitting \(England and Wales\) Regulations 2016 \(as amended\)\[EPR\]](#)
 - Medicines Act 1968 (as amended)
 - [Ionising Radiation \(Medical Exposure\) \(Amendment\) Regulations 2024](#)
 - The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended)

- Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) 2023
- The Ionising Radiations Regulations 2017 (as amended).
- there are contingency plans in place to deal with the following circumstances:
 - Adverse reactions
 - Extravasation
 - Clinical issues not related to MRT
 - Medical emergencies, i.e., a deteriorating service user
 - Re-admission to a healthcare establishment
 - Reasonably foreseeable accidents involving radioactive materials.

The Provider must work in close alignment with the appropriate referring specialist multi-disciplinary teams (MDTs), and have agreed and documented protocols and associated clinical and referral pathways detailing that the Service can only be accessed by tertiary referral from an appropriate specialist MDT. The Service must:

- develop local protocols to facilitate close collaboration and clear communication pathways between members of the MRT team and the referring specialists
- ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload
- ensure that the shared care between the referring specialist and clinician responsible for administering the MRT are underpinned by written protocols that specify the responsibilities of individual specialists involved in the delivery of treatment, aftercare and follow-up
- ensure that service users receive both written and verbal information about the procedure prior to therapy and are advised about minimising radiation exposure and contamination after discharge
- ensure that service users receive clear and verbal information about their care and management between MRT administrations and after discharge from the MRT service
- implement new technologies that are recommended by the National Institute for Health and Care Excellence (NICE) and give due regard to national clinical guidelines and guidance (Section 8).

Where the Provider delivers services for oncology indications, the Provider must work closely with Local Health Board(s) and Multidisciplinary Teams to ensure effective service planning and pathway integration of the Service.

2.3.2 Core Requirements of a Level 2 Service

The Service must meet the Level 1 service requirements and:

- operate as part of fully constituted Welsh cancer MDT(s)

- schedule and integrate treatment appropriately to meet the needs of service users where MRT is used concurrently with other treatments (such as external beam radiotherapy or chemotherapy)
- ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.

2.3.3 Core Requirements of a Level 3 Service

At present, the only potential Level 3 service is Selective Internal Radiation Therapy (SIRT). SIRT should be in a specialist liver centre, which is part of a specialist HPB or HCC MDT. The Service must also meet the Level 1 and Level 2 service requirements and:

- through the specialist HPB or HCC MDT, ensure appropriate case selection and ensure that service users are offered the full range of treatment options appropriate to their clinical circumstances
- service users must have access to a healthcare professional with experience in SIRT able to co-ordinate care and provide individual expert advice and support for the whole SIRT pathway
- service users must receive detailed radiation protection advice from an appointed Radiation Protection Adviser, Radioactive Waste Adviser and Medical Physics Experts
- ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.

2.3.4 Core Requirements of a Paediatric Service

Paediatric MRT must only be delivered by a level 2 MRT provider at a designated paediatric centre working as part of a Children's Principal Treatment Centre and specialist paediatric cancer MDTs. The Service must:

- have the appropriate MRT expertise, staffing and facilities for the treatment of children
- ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.

2.4 Essential Staff Groups

The Provider must ensure that the service has sufficient appropriately trained staff to deliver a safe and effective MRT service that meets, regulatory and legislative requirements as well as activity. This includes ensuring the availability of multiple supervisory and specialist staff in the following roles and as defined by regulatory requirements, set out in Section 2.2, including:

- a minimum of two ARSAC Licensed Practitioners
- Radiation Protection Advisor (RPA)

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- Radiation Protection Supervisor (RPS)
- Medical Physics Expert (MPE) with radionuclide therapy
- Radioactive Waste Advisor (RWA)
- Radiographers (diagnostic and therapeutic)
- Nuclear medicine clinical technologists
- Nuclear medicine clinical scientists
- Oncologists/endocrinologists or Nuclear medicine physicians
- Surgeons, where required
- Radiologists or Nuclear medicine physicians
- Consultation with Pharmacy and Radio/Pharmacy when appropriate.
- Coordinator of care

Note: MRT Service Providers would be expected to work with local operational colleagues to ensure that more complex workforce planning is undertaken, so that future MRT services can be “manned” with a resilient workforce. Collaboration with Health Education and Improvement Wales (HEIW), AWMOL and Health Board Workforce Directors is essential.

Service providers must ensure the following duty holders are appointed at the appropriate staffing level¹:

Key Duty Holder	Responsible for	Knowledge and skills/certification	On site during MRT
Practitioner* (ARSAC licence holder)	The clinical aspects of the treatment including justifying the administration	ARSAC Practitioner Licence for therapies being performed	Contactable for all ² . Present for research, complex or novel therapies
Radiation Protection Adviser(RPA)	Advising the employer on compliance with IRR2017 (amended)	RPA Certificate of Competence issued by an assessing body recognised by the HSE e.g. RPA2000	Contactable
Radiation Protection Supervisor* (RPS)	Overseeing the Local rules, radiation safety culture, procedures under IRR2017 (amended)	Relevant training. Formal appointment	Present during any procedures within a controlled area and contactable thereafter.

¹ Based on [Clinical Guideline for Administration of Molecular Radiotherapy Version 2 2019](#)

² For newly established services, it may desirable that there is an ARSAC licence holder on site.

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Medical Physics Expert* (MPE)	Optimisation, dosimetry, patient risk assessments, advising on equipment QA, and compliance with IRMER2017	MPE with appropriate radionuclide experience. Certificate of Competence issued by RPA2000	Contactable for all. Closely involved for research, complex or novel therapies as defined in regulations
Radioactive Waste Adviser (RWA)	Advising on the accumulation, storage and disposal of radioactive materials <u>in accordance with EPR2016 and the environmental permits issued under EPR2016</u>	RWA Certificate of Competence issued by RPA2000	Contactable
Operators	Administering the radiopharmaceutical and patient safety checks defined in IRMER2017. The operator will also work within procedures that ensure adherence to IRR 2017 and EPR 2016.	Local training that meets the requirements of employer's procedures and radiation safety.	Yes

*Some procedures may involve a combination of imaging and MRT. There needs to be clear identification of duty holders and lines of accountability for each function. Duty holders should be appointed in writing by the employer.

Where delivering Level 3 Services, the Provider must also ensure that the Service has access to:

- a minimum of two interventional radiology operators
- a minimum of two ARSAC licensed practitioners able to deliver SIRT
- a SIRT co-ordinator.

Where delivering Paediatric MRT, the Provider must also ensure that the Service has access to:

- paediatric clinical oncologists

- therapeutic radiographers with special expertise in paediatrics
- play specialists.

2.5 Essential Equipment and/or Facilities

All sites must have access to equipment and facilities sufficient to meet the requirements of ARSAC licensing, Environmental Permitting, and IRR 2017 (amended) regulations for the MRT procedures undertaken, ensuring the integrity of radiopharmaceuticals used during the procedures. This will also include, but is not limited to:

- radiation monitors
- spill kits
- where necessary, dedicated controlled areas, uptake rooms, hot toilets and waiting areas
- designated outpatient facilities with shielded rooms and hot toilets where appropriate
- radiation source transport, accumulation, storage and disposal facilities
- where appropriate, dedicated dispensing cabinet
- diagnostic imaging.

Additional requirements for services delivering Level 2 activity:

- full resuscitation equipment including oxygen and suction
- designated inpatient facilities with shielded rooms and hot toilets where appropriate.

Additional requirements for services delivering Level 3 activity:

- Interventional Radiology, appropriately equipped, with capacity to support 10-20 cases per annum
- cone beam computed tomography (CBCT)
- day case accommodation and inpatient facilities for all service users
- specialised software for dose planning.

Additional requirements for delivering paediatric MRT:

- age-appropriate facilities for associated imaging under general anaesthetic, where required
- age-appropriate accommodation
- paediatric anaesthetic service
- on-site paediatric resuscitation

2.6 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.7 Patient Pathway (Annex i)

Patient pathways are detailed at Annex i.

2.8 Interdependent Service Components – Links with other NHS Services

Interdependent Service	Relevant Service Specification/Standards	Proximity to service (not applicable/co-located/same town/city)
PET-CT	PET-CT Service Specification	Not applicable
Children's Cancer Services	Children's cancer services: Principal treatment centres service specification - 1746-principal-treatment-centres-service-specification-.pdf (england.nhs.uk)	Same town/city – if delivering paediatric MRT
Paediatric Anaesthesia	Guidelines for the Provision of Paediatric Anaesthesia Services 2020. GPAS-2020-10-PAEDIATRICALS.pdf (rcoa.ac.uk)	Co-located – if delivering paediatric MRT
Teenage and Young Adult Cancer Services	Specialist cancer services for children and young people: teenage and young adults principal treatment centre services NHS England » Specialist cancer services for children and young people: teenage and young adults principal treatment centre services NHS England » Specialist cancer services for children and young people: teenage and young adults designated hospitals	Not applicable
Paediatric Endocrinology	E03/S/e - Paediatric Medicine: Endocrinology & Diabetes.	Same town/city

	Paediatric Medicine: Endocrinology and Diabetes	
Dosimetry services		Not applicable

2.9 Service Defined Outcomes / Outputs

There are currently no quality outcomes for this service, however, a range of quality metrics are provided with regular data collections which support an enhanced understanding of the quality of the service delivered.

2.10 Transition Arrangements

Transition arrangements should be in line with [Transition from children's to adults' services for young people using health or social care services NICE guidance NG43 and the Welsh Government Transition and Handover Guidance.](#)

Transition involves a process of preparation for young people and their families for their transition to adulthood and their transition to adult services. This preparation should start from early adolescence 12-13 year olds. The exact timing of this will ideally be dependent on the wishes of the young person but will need to comply with local resources and arrangements.

The transition process should be a flexible and collaborative process involving the young person and their family as appropriate and the service.

The manner in which this process is managed will vary on an individual case basis with multidisciplinary input often required and patient and family choice taken into account together with individual health board and environmental circumstances factored in.

2.11 Service providers/Designated Centres

Level 2

NWJCC commissions Peptide Receptor Radionuclide Therapy (PRRT) for Neuroendocrine Tumours from the following centres:

The Royal Liverpool University Hospital
Mount Vernon Street
Liverpool
L7 8XP

The Royal Free Hospital
Pond Street
London

NW3 2QG

Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
CF14 2TL

Level 3

NWJCC commissions Selective Internal Radiotherapy (SIRT) for hepatocellular carcinoma from:

The Christie NHS Foundation Trust
Wilmslow Road
Manchester
M20 4BX
United Kingdom

3. Quality and Patient Safety

The provider must work to written quality standards and provide monitoring information to the lead commissioner. The quality management systems must be externally audited and accredited.

There should be compliance with the radiation safety and protection legislation and regulations referred to in section 2.2.1.

There should be risk assessments and contingency plans in place in the event of a recently discharged patient becoming unwell and requiring emergency admission to another hospital or in the unfortunate event of the patient's death.

The centre must enable the patients, carers and advocates informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

3.1 Quality Indicators (Standards)

- The provider will have a recognised system to demonstrate service quality and standards.
- The service will have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site.
- The quality system and its treatment protocols will be subject to regular clinical and management audit.
- The provider is required to undertake regular patient surveys and develop and implement an action plan based on findings.
- The provider is required to submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. (RTDS V6 has Radioisotope therapy as a Treatment modality option).
- The provider will keep records of patients' disease response, overall survival, complication rate, progression free survival (PFS) and quality of life.
- All patients should be offered a Macmillan Holistic Needs Assessment and PROMs.

4. Performance Monitoring and Information Requirement

4.1 Performance Monitoring

NWJCC will be responsible for commissioning services in line with this policy. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this policy the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care

NWJCC will conduct performance and quality reviews on an annual basis

4.2 Key Performance Indicators

The providers will be expected to monitor against the full list of Quality Indicators derived from the service description components described in Section 2.2.

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

In particular, the provider will be expected to monitor against the following target outcomes:

- Time from receipt of referral for MRT to first treatment – target within 4 weeks.

4.3 Date of Review

This document is scheduled for review every three years, unless information is received which indicates that the policy requires revision.

If an update is carried out, this version of the policy will remain extant until the revised policy is published.

5. Equality Impact and Assessment

The Equality Impact Assessment (EIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning 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 demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

6. Putting Things Right

6.1 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.

If 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 NWJCC.

6.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

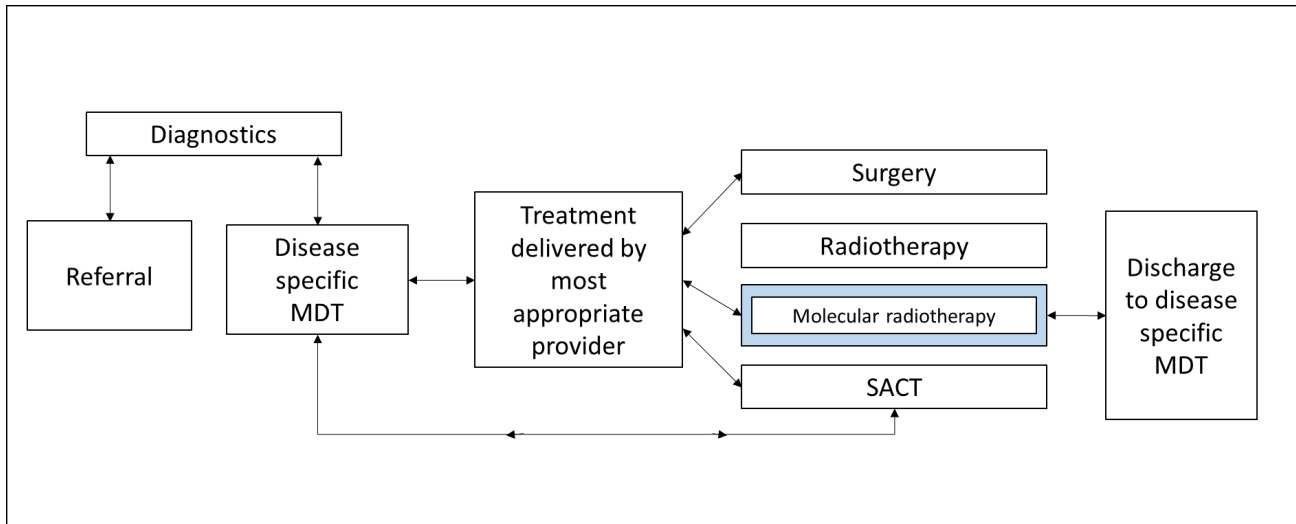
If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated.

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

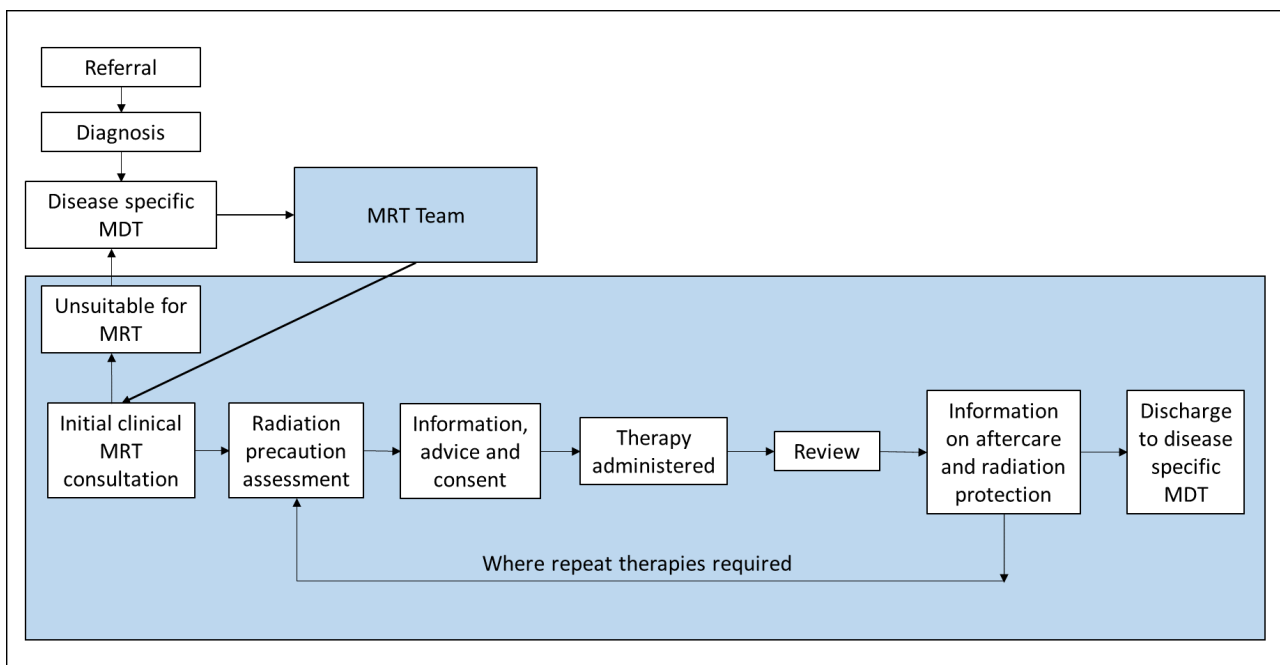
Further information on making IPFR requests can be found at: [Individual Patient Funding Requests](#).

Annex i Patient Pathway

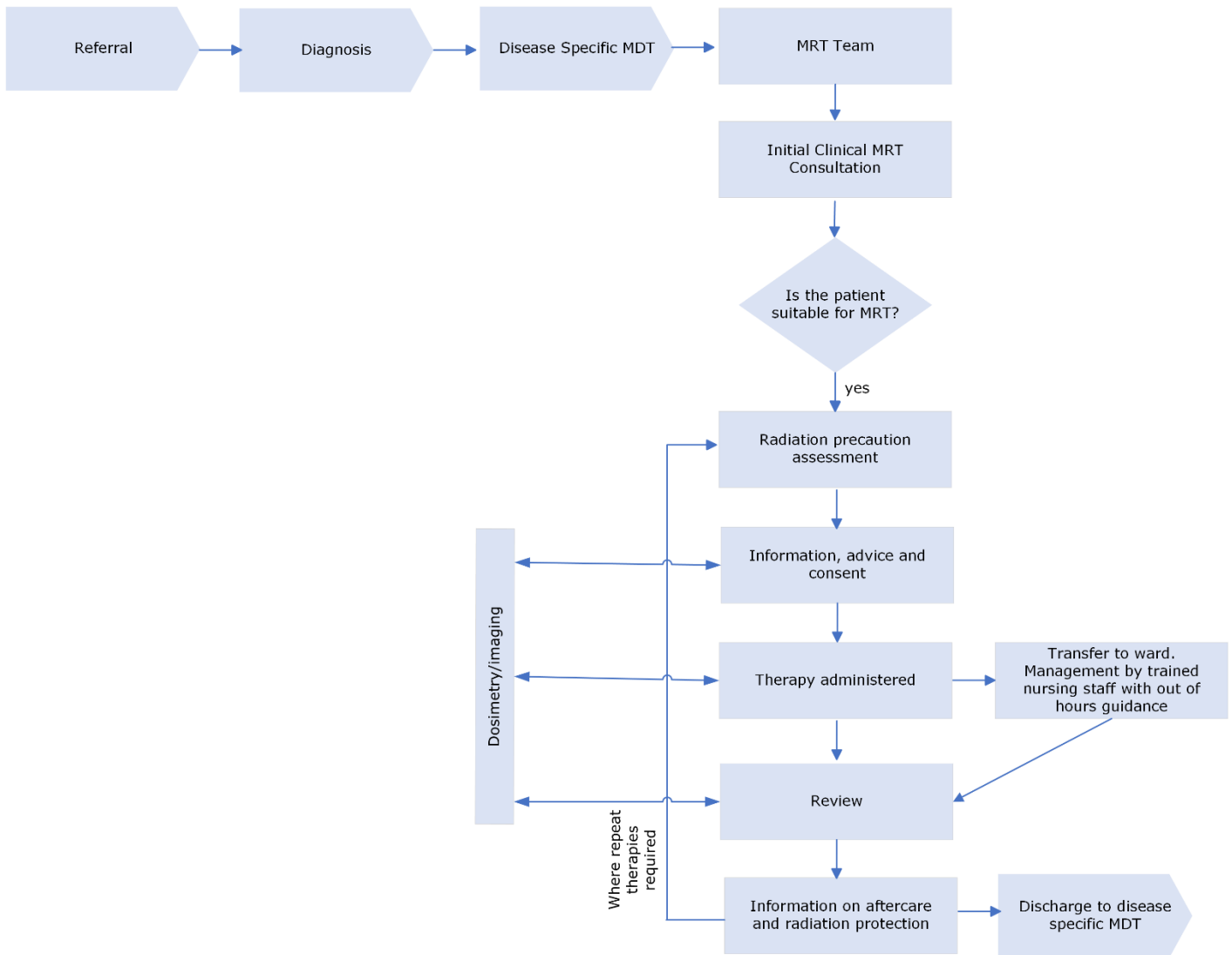
Overall patient pathway for Level 1 and Level 2 services



Specific patient pathway Level 1 services



Specific patient pathway level 2, 3 and paediatric services



Annex ii Codes

The list of ICD codes is indicative and is not exhaustive. Additional codes may be used for contract monitoring purposes, furthermore some codes may cover indications not included within this policy.

Code Category	Code	Description
OPCS	J12.3	Selective internal radiotherapy with microspheres to lesion of liver

Annex iii Glossary

All Wales Molecular Radiotherapy Group (AWMOL)

AWMOL is a subgroup of the Clinical Oncology Subcommittee (COSC) of the Welsh Scientific Advisory Committee (WSAC) and was set up to advise Welsh Government and the Welsh Health Specialised Services Committee (WHSSC) (now NHS Wales Joint Commissioning Committee (NWJCC)) on the provision of Molecular Radiotherapy services for the people of Wales.

Individual Patient Funding Request (IPFR)

An IPFR is a request to NHS Wales Joint Commissioning Committee (NWJCC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Molecular radiotherapy (MRT)

An umbrella term for the use of therapeutic radiopharmaceuticals, given either orally or by injection.

NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Radioligands

Compounds where a radionuclide is conjugated to a complex organic molecule such as an antibody, which is subsequently taken up selectively by a specific cellular target. This permits novel targeting of the radioligand which is not dependent on the chemistry of the radionuclide. Radioligand therapy is a field that is currently expanding rapidly.

Therapeutic radionuclides

These are basic radioactive molecules, or inorganic salts containing the radionuclide used for treating cancer and other diseases. Examples in common use include Sodium Iodide-131 (radioiodine) or Radium-223 Dichloride. These molecules are selectively taken up by certain human tissues by virtue of the radionuclide's chemical properties, allowing the radiotherapeutic effect to be localised. Some of these therapies, in particular the treatment of thyroid cancer with radioiodine, have been used routinely for decades.

Therapeutic radiopharmaceuticals

Therapeutic radiopharmaceuticals should be regarded as distinct from *diagnostic* radiopharmaceuticals, commonly used in nuclear medicine and PET-CT, although there is an overlap in terms of specialist workforce, logistics and infrastructure. There are several definitions used for therapeutic radiopharmaceuticals.

Contact Us

If you have a question related to this document you can contact us using one of the methods outlined below.

If you would like this document in an alternative format and/or language, please contact us for assistance.

Email:

NWJCC consultation mailbox – nwjccconsultation@wales.nhs.uk

Telephone:

General Enquiries – 01443 433112

Website:

[Contact us - NHS Wales Joint Commissioning Committee](#)

Writing:

If you wish to contact the NHS Wales Joint Commissioning Committee, you can write to us at one of our locations below, we welcome correspondence in Welsh or English:

South Wales Offices

Unit 1, Charnwood Court, Heol Billingsley, Nantgarw, CF15 7QZ

Unit G1 The Willowford, Main Avenue, Treforest Industrial Estate, Pontypridd, CF37 5YL

North Wales Offices

Unit 3, Media Point - Unit 3, Mold Business Park, Mold, CH7 1XY

Preswylfa, Hendy Road, Mold, CH7 1PZ