

Specialised Services Commissioning Policy: CP50a

Positron Emission Tomography

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Update information

This policy is an update to the previous published Commissioning policy published in 2022. New and updated indications have been included for gastric cancer, lymphoma, oesophageal / oesophago-gastric cancer and some rare rheumatological conditions.

Indications are marked to indicate the year of the last evidence review:

[2015] No change made since the original evidence review. [2018] Indications added after updated evidence review. [2019] Indications added after updated evidence review. [2020] Indications has been added after updated evidence review. [2021] Indications added after updated evidence review. [2022] Indications added after updated evidence review. [New 2023] Indications added after updated evidence review.

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission positron emission tomography - computed tomography (PET-CT) services in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed each relevant clinical condition and the options for its treatment. It has considered the place of positron emission tomography - computed tomography (PET-CT) in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Welsh Language

WHSSC 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 WHSSC 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

WHSSC 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 WHSSC commitment.

Disclaimer

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

This policy 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.

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

1. Introduction

This policy has been developed for the planning and delivery of positron emission tomography - computed tomography (PET-CT) for people resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

This updated policy (2023) has been developed in collaboration with the All Wales PET Advisory Group (AWPET). This Group is tasked with reviewing the evidence base for PET-CT and advising WHSSC on the introduction of new indications, ensuring that all decisions are made following a systematic review and appraisal of all the available evidence.

This policy presents an up to date summary of relevant indications for the use of PET-CT, where there is good evidence that patients will benefit from improved disease assessment resulting in altered management and improved outcomes.

The indications in this policy are divided into oncological and non-oncological and then by body site/system.

The purpose of this document is to:

- set out the circumstances under which patients will be able to access PET-CT services
- clarify the referral process and pathways
- define the clinical criteria that patients must meet in order to access treatment
- enable all patients in Wales to have equity of access to PET-CT services

1.1 Plain Language Summary

A PET-CT scan is a nuclear medicine imaging technique that produces a three dimensional image or picture of functional processes in the body. The purpose of a PET scan is to improve diagnosis and treatment planning for both cancer and non-cancer indications.

PET-CT is a non-invasive imaging technique that combines information from two different modalities. PET provides information about functional and metabolic cellular activity, while a CT scanner gives precise anatomical localisation.

The procedure usually involves injecting a radio-labelled tracer into the body. The radio-labelled tracer can be a sugar (glucose), an amino acid, or a vitamin. The tracer is taken up and accumulates in metabolically active cells (such as malignant cells), and emits gamma rays detected by the PET scanner to produce colour-coded images of the body demonstrating the

cellular activity of both normal and malignant tissue. The CT scanner detects the X-rays emitted by the X-ray tube during exposures.

Images acquired from both PET and CT devices can be combined into a single superimposed image (PET-CT). This image provides important diagnostic information as well as assessing the effectiveness of treatment in cancer. The radio-labelled tracers are then passed out of the body in the urine or bowel movement.

1.2 Aims and Objectives

This policy defines the commissioning position of WHSSC on the use of positron emission tomography - computed tomography (PET-CT). It includes an up to date list of all PET-CT indications currently commissioned and funded by WHSSC for Welsh residents.

The objectives of this policy are to:

- ensure the commissioning of PET-CT for Welsh residents
- ensure equitable access to PET-CT
- define criteria for people to access PET-CT
- describe evidence based indications (see section 2.2) that will improve disease assessment, resulting in altered management and improved outcomes.

1.3 Epidemiology

Positron emission tomography (PET) has become a central diagnostic tool in the management of patients with cancer and many other non-cancer conditions, and its role continues to evolve. PET influences clinical decision making, and there is an increasing body of high quality evidence to demonstrate the contribution of PET to improved patient outcomes in a number of disease areas^{1,2}. All recent indications added to this policy in 2018, 2019, 2020, 2021 and 2022 are supported by the best available evidence and this is presented separately in Appendix 1.

The Welsh PET service is currently delivered across three sites: an analogue, fixed scanner in Cardiff (PETIC; since 2010), a mobile PET scanner located at Wrexham Hospital in North Wales (since 2015) and more recently, a mobile scanner at Singleton Hospital in Swansea (since 2020).

Welsh Health Specialised Services Committee (WHSSC) April 2023

¹ Relationship Between Cancer Type and Impact of PET and PET/CT on Intended Management: Findings of the National Oncologic PET Registry Hillner, B. Et al., <u>Journal of Nuclear Medicine</u> 49(12):1928-35 December 2008

² Evidence-based indications for the use of PET-CT in the United Kingdom 2022. Royal College of Radiology and Royal College of Physicians

Clinical demand for PET scanning is growing worldwide, with an 18.9% year on year growth reported in England in 2019-203. Wales is clearly realising this increase in demand with 5,327 PET scans performed in 2021-22 (PETIC - 2,624; North Wales - 1,296 and Swansea - 1,407). This represents an increase of 38% compared to 2020-21, when 3,865 PET scans were performed. Based on current activity, a projected 5,940 PET scans are expected to be performed in 2022/23, an 11.5% growth on the previous year's activity.

According to the NCRI⁴ there are 1.05 PET scanners per million population in England. The Royal College of Radiology recommendations suggest an allowance of approximately 1 scanner per million population. In Wales, there are currently 0.73 PET scanners per million population, which is significantly lower than the rest of the UK and many countries in Europe.

Following publication of the Imaging Statement of Intent (Welsh Government, 2018) in November 2018⁵, the All Wales PET Advisory Group (AWPET) and the Welsh Scientific Advisory Committee (WSAC) produced a report "Positron Emission Tomography (PET) in Wales - Overview and Strategic Recommendations"6. One of its five key recommendations was that WHSSC should be commissioned to produce a Programme Business Case (PBC) for PET-CT capacity in Wales that considers increased demand projections, estates, staffing requirements and research for the next 10 years.

Following support and scrutiny from all Health Boards (HBs), the All Wales PET Programme Business Case (PBC) was endorsed by Welsh Government (WG) in August 2021. Subsequently, WG requested that WHSSC continue to "hold the ring" for this national Programme⁷, with Dr Sian Lewis appointed as Programme SRO and a small Programme Management Office (PMO) set up at WHSSC to oversee and facilitate the Programme in April 2022.

The nationally directed Programme formally started in March 2022 and oversees a range of work that is focused on delivering sustainable and high quality PET services across Wales, including four fixed, digital PET scanners. Features of the service in a business as usual end-state will show responsive demand and capacity planning, and will deliver clear quality outcomes through modern facilities, optimally configured workforce in fully accredited units and an assured supply of radiopharmaceuticals. Ultimately, this Programme will ensure that the population of Wales has equitable

³ Professor Sir Mike Richards, Diagnostics: Recovery and Renewal – Report of the Independent Review of Diagnostic Services for NHS England (Dec 2020)

⁴ UK PET Core Lab - Home Page

⁵ https://gov.wales/written-statement-statement-intent-diagnostic-imaging-services

⁶ WHSSC, 2018

⁷ Goodall, A. 2021. Letter to Sian Lewis. 28 October 2021

access to high quality PET scanning and research, in line with best practice across the UK and Europe.

Radiation dose

Patients referred for a PET-CT scan will receive a dose of radiation. The total dose is a combination of the PET emission scan dose and the CT transmission scan dose.

Scanning routinely extends from the base of brain to top of thighs unless there is a clinical reason to include imaging of the brain and/or lower limbs.

The typical injected activities for 18F labelled radiopharmaceuticals are between 150 to 400 MBq. This relates to an adult, whole-body, effective dose range of around 3–8 mSv.

The CT component of the study enables attenuation correction and anatomic localisation of the radiopharmaceutical uptake. It is usually performed without enhancement by iodinated contrast administration and at a lower dose than conventional diagnostic CT, typically equating to an approximate effective dose of 5 mSv. The CT can therefore account for a significant proportion of the combined PET-CT patient dose.

It may on occasion be deemed necessary to incorporate contrast-enhanced CT, in order to provide more detailed anatomical information. This would typically equate to an approximate effective dose of 16 mSv, although techniques such as automatic exposure control may be used to considerably reduce diagnostic CT doses (~ 8 mSv).

Accordingly, protocol-dependent effective doses arising from whole-body PET-CT scanning may be represented typically in the range of 8-24 mSv. Efforts are of course made to minimise radiation dose without compromising diagnostic quality.

The radiation burden from multiple radiological investigations can be substantial, leading to an increased risk of potentially fatal interval cancers compared with the rest of the population. Referrals for the clinical indications listed in this document are though justified as showing a sufficient net benefit to patients, considering the risks from exposure to ionising radiation.

1.4 What NHS Wales has decided

WHSSC has carefully reviewed the evidence of positron emission tomography - computed tomography (PET-CT). We have concluded that there is enough evidence to fund the use of positron emission tomography - computed tomography (PET-CT) within the criteria set out in section 2.1.

1.5 Relationship with other documents

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

NHS Wales

 All Wales Policy: <u>Making Decisions in Individual Patient Funding</u> <u>requests</u> (IPFR).

WHSSC policies and service specifications

- WHSCC commissioning of the Epilepsy Surgery Programme. (Some brain FDG PET scans are performed as part of the pre-surgical evaluation of epilepsy and within the costs of the Epilepsy Surgery Programme).
- <u>CP50b, Positron Emission Tomography</u>, Service Specification, August 2020.

National Institute of Health and Care Excellence (NICE) guidance

- <u>Epilepsies in children, young people and adults</u>, NICE Clinical Guideline (NG217) April 2022
- <u>Colorectal Cancer: diagnosis and management</u>, NICE Guideline (NG151). NICE, December 2021.
- Prostate Cancer: diagnosis and management, NICE Guideline (NG131), December 2021
- o <u>Early and locally advanced breast cancer: diagnosis and management</u>, NICE Guideline (NG101), July 2018.
- Myeloma: diagnosis and management, NICE Guideline (NG35), October 2018.
- o <u>Pancreatic cancer in adults: diagnosis and management</u>, NICE Guideline (NG85), February 2018.
- Oesophago-gastric cancer: assessment and management in adults, NICE Guideline (NG83), January 2018.
- Advanced Breast Cancer: diagnosis and management, Clinical Guideline (CG81) NICE, August 2017.
- o <u>Non-Hodgkin's lymphoma: diagnosis and management</u>, Clinical Guideline (NG52). NICE, July 2016.
- <u>Bladder cancer: diagnosis and management</u>, NICE guideline (NG2), February 2015.
- <u>Lung Cancer: diagnosis and management</u>, NICE Guideline (NG122).
 NICE, September 2022.
- Ovarian Cancer: recognition and initial management, NICE Clinical Guideline (CG122), April 2011
- Metastatic malignant disease of unknown primary origin in adults: diagnosis and management, Clinical Guideline (CG104) NICE, July 2010.

- Improving Outcomes for people with Sarcoma, Cancer Service Guideline (CSG9) NICE, March 2006.
- Improving Outcomes in head and neck cancers, Cancer Service Guideline (CSG6) NICE, November 2004.

• Relevant Scottish Medicine Consortium (SMC) policies

- o <u>PET-CT Guidelines Scottish Clinical Imaging Network</u> Scottish Clinical Imaging Network (SCIN), NHS Scotland.
- <u>PET-CT Review of Indications report V2.0</u>, Scottish Clinical Imaging Network (SCIN), NHS Scotland, July 2017.

Relevant NHS England policies

 Positron Emission Tomography – Computed Tomography (PET-CT) Scanning (All Ages), 2013/14 NHS Standard Contract, NHS England, Service Specification, 2013.

Other published documents

- <u>Evidence-based indications for the use of PET-CT in the United Kingdom, 2022</u>. The Royal College of Radiologists.
- PET-CT in the UK. A strategy for development and integration of a leading-edge technology within routine clinical practice. The Royal College of Radiologists. (August 2005).

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of PET-CT in line with the criteria identified in this policy.

2.1 Referral Criteria

Clinicians are requested to consider the contents of this policy when discussing management options with patients.

It is expected that in all cases, PET-CT will influence management and that the patient will have been discussed at a multidisciplinary team (MDT) meeting.

The referral for PET-CT should include the clinical review of the patient by a member of the referring MDT. The role of PET-CT in the various indications will be subject to prospective and retrospective audit by the Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC) and the North Wales service on behalf of WHSSC.

2.2 Criteria for Treatment

2.2.1 Oncological Indications

Adrenocortical carcinoma

 Assessment of selected patients with adrenocortical carcinoma being considered for invasive treatment where cross-sectional imaging is inconclusive. [2018]

Anal Cancer

- Staging of selected patients considered for radical treatment with equivocal imaging. [2015]
- Restaging of proven or strongly suspected recurrent or locally persistent anal cancer in whom radical salvage therapy is being planned. This includes prior to extensive pelvic surgery or groin node dissection. [2022]

Bladder cancer

Consider fluorodeoxyglucose (FDG) PET-CT for people with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer before radical treatment if there are indeterminate findings on CT or MRI, or a high risk of metastatic disease (for example, T3b disease). [2019]

Breast Cancer

- Assessment of extent of disease in selected patients with disseminated or high suspicion of disseminated breast cancer (both primary and recurrent) when the appropriate conventional examination(s) are negative or equivocal. [2018]
- In limited circumstances when regional nodal involvement outside axillary levels I and II is suspected on conventional imaging (i.e.: level III infraclavicular or extra-axillary locoregional nodessupraclavicular/internal mammary) and not amenable to biopsy.
 [2018]
- Differentiation of treatment induced brachial plexopathy from tumour infiltration in symptomatic patients with an equivocal or normal MR.
 [2018]
- Assessment of response to chemotherapy in patients when disease is not well demonstrated using other techniques including tumour markers. [2018]

Cancer of Unknown Primary (CUP)

- Detection of the primary site in biopsy proven malignancy where imaging and histopathology have failed to show a primary site and in whom radical management is proposed. [2015]
- Prior to referral the patient should have been discussed in an MDT, conventional imaging and diagnostic investigations should have been undertaken as recommended in NICE clinical guideline 104, Metastatic malignant disease of unknown primary origin and identification of the primary site should be viewed as pivotal to proceeding with radical management. [2015]

Cervical cancer

- Staging or restaging of patients with carcinoma of the uterine cervix being considered for exenterative surgery. [2015]
- Staging of patients with carcinoma of the uterine cervix FIGO stage <IB2 with suspicious pelvic nodes on MRI or FIGO stage IB2-IVB with the exception of those patients with stage IVB who have disease outside of a radically-treatable radiotherapy field. [2015]
- Suspected recurrence of cervical or endometrial cancer where other imaging is equivocal and where there is a potential radical treatment option such as para-aortic radiotherapy or stereotactic radiotherapy for in-field lymph node recurrences. [2015]
- PET-CT for response assessment of locally advanced cervical cancer after chemoradiotherapy. **[2020]**

Cholangiocarcinoma

• Staging of potentially operable primary hepatobiliary malignancies (cholangiocarcinoma, gall bladder carcinoma), where the patient is fit for resection and a positive PET-CT would lead to a decision not to operate. [2021]

Colorectal cancer

Selected patients with colorectal cancer at staging/first presentation

- Those with suspected liver or lung metastases which might subsequently be amenable for radical therapy/surgical removal. [2021]
- Patients with locally extensive tumours in whom extensive surgery for the primary tumour may subsequently be an option (for example those who might require extensive pelvic surgery). [2021]
- Highly selected patients being considered for radical therapy with equivocal imaging findings outside the standard surgical field. This might in particular include patients with equivocal pelvic nodes outside a standard resection margin, equivocal upper abdominal lymph nodes or other equivocal lesions e.g. bone in which characterisation would be pivotal to management. [2021]

In these patients there is often initial treatment with chemotherapy or radiotherapy prior to radical surgery. In this scenario it is recommended that PET is performed prior to the chemotherapy or radiotherapy treatment. [2021]

Known or suspected recurrence of colorectal cancer

- Restaging of proven or strongly suspected recurrent CRC in whom radical salvage therapy is being planned. This includes prior to resection of lung and liver metastases and extensive pelvic surgery. It also includes any other site of limited disease in which there is a radical salvage option either surgical or with radiotherapy. [2021]
- Restaging of known colorectal cancer where conventional imaging has failed to show the cause of rising tumour markers. [2021]

Endometrial cancer

- Staging or restaging of patients with carcinoma of the endometrium being considered for exenterative surgery. [2015]
- Suspected recurrence of endometrial cancer where other imaging is equivocal where there is a potential radical treatment option. [2015]

Gastric Cancer

• Staging of patients with gastric carcinoma who are suitable for radical treatment. **[New 2023]**

Gastrointestinal Stromal Tumours (GIST)

- Staging prior to treatment in patients who are likely to require extensive surgery +/-systemic therapy. [2021]
- Baseline and response assessment to systemic therapy. [2021]

Head and neck cancer

- To identify the primary site in patients presenting with metastatic squamous cell carcinoma in cervical lymph nodes, with no primary site identified on other imaging. [2015]
- To differentiate relapse from treatment effects in patients suspected to have tumour recurrence where magnetic resonance imaging (MRI) is uncertain or equivocal. [2015]
- As part of the initial clinical staging of patients with N3 cancer of the upper aerodigestive tract. [2018]
- Response assessment at 3-6 months following completion of radical chemo-radiotherapy. [2018]
- As part of the initial clinical staging of patients with T4 nasopharyngeal of hypopharyngeal squamous cell carcinoma.
 [2018]
- Include PET-CT imaging as part of the initial clinical staging of patients with T4 oropharyngeal cancer. [2020]

Lung Cancer

- Investigation of solitary pulmonary nodule in cases where a biopsy is not possible or has failed, depending on nodule size, position and CT characterisation. [2015]
- Investigation of patients with non-small cell lung cancer who are staged as candidates for surgery on CT, to look for involved intrathoracic lymph nodes and distant metastases. [2015]
- Investigation of patients with non-small cell lung cancer who are otherwise surgical candidates and have, on CT, limited N2/3 disease of uncertain pathological significance. [2015]
- Investigation of patients with non-small cell lung cancer who are candidates for radical radiotherapy on CT. [2015]
- Assessment of possible recurrent non-small cell lung cancer when radical treatment is being contemplated. [2015]
- Assessment of the extent of disease in mesothelioma prior to planned radical decortication. [2015]
- PET-CT is indicated in staging of patients with small-cell lung cancer with limited disease on CT being considered for radical therapy [2018].

Lymphoma

- Staging of FDG avid lymphomas (this should include follicular lymphoma and mantle cell lymphoma). [2021]
- Remission assessment for FDG avid lymphomas (this should include follicular lymphoma and mantle cell lymphoma) after completion of treatment using the 5 point scale (Deauville criteria). [2021]
- Interim assessment to guide response adapted treatment in selected patients with Hodgkin lymphoma. [2021]
- Assessment of response to second line treatment and subsequent treatments for FDG avid lymphomas (this should include follicular lymphoma and mantle cell lymphoma where patients are candidates for autologous stem cell transplant). [2021]
- Staging of confirmed post-transplant lymphoproliferative disorders (PTLD). [2021]
- Prior to stem cell transplant to assess remission status and suitability for transplant. [2021]
- In patients being treated with CAR-T therapy, imaging immediately before cell reinfusion and at 3 months after cell reinfusion. [2021]
- To demonstrate metabolically active disease and potentially guide biopsy in cases of strongly suspected new, relapsed or transformed lymphoma when a haematology MDT (including a consultant radiologist) determines that:
 - a watchful waiting approach +/- radiological surveillance is inappropriate, and
 - conventional imaging has failed to confirm a suitable biopsy site.

This does NOT allow for the routine use of PET to assess undiagnosed masses or lymphadenopathy. The usual expectation/ practice in lymphoma is that histology should be obtained prior to PET imaging. These highly selected cases should have been reviewed in a haematology clinic prior to referral for PET imaging. [New 2023]

Myeloma

- MRI is considered the primary imaging modality for myeloma. FDG PET may be considered in certain specific situations. [2022]
- The following apply to patients with confirmed plasmacytoma or myeloma. Other clinical classifications are not included (apart from the specific instance of Smouldering Myeloma and a contraindication to MRI as set out in the penultimate clause). There must also be a plan for subsequent further potentially definitive therapy:
 - Baseline assessment in patients with non-secretory and oligosecretory myeloma and patients with predominantly extramedullary myeloma as a baseline for subsequent response assessment.

- Assessment of patients with apparently solitary plasmacytoma to exclude other sites of disease.
- To assess response or suspected relapse in patients with oligo-secretory or non-secretory myeloma, patients with predominantly extramedullary disease and patients with solitary plasmacytoma.
- Assessment of patients with monoclonal gammopathy associated neuropathies (MGAN) to identify plasmacytomas which may be amenable to radiotherapy.
- Assessment of patients with a contraindication to MRI (e.g. non compatible pacemaker).
- In patients with smouldering myeloma in whom there is a concern as regards progression to myeloma and a contraindication to MRI.
- Assessment of patients with indeterminate MRI findings.
 [2022]

Neuroendocrine tumours (Ga DOTA and/or FDG PET)

- FDG-PET: Staging or restaging of selected patients with higher grade tumours prior to treatment. [2021]
- Ga-DOTA: The staging of patients with neuroendocrine tumours and the assessment of suspected recurrence, following discussion at the neuroendocrine tumours MDT meeting where imaging is pivotal to patient management. [2015]

Oesophageal / oesophago -gastric cancer

- Staging of patients with oesophageal or oesophago-gastric cancer prior to radical treatment e.g. surgery or radical chemoradiotherapy.
 [2015]
- PET-CT for the restaging of locally advanced oesophageal and oesophagogastric junctional tumours following neoadjuvant treatment. [2020]
- Re-staging of patients with local recurrence of oesophageal or oesophago-gastric carcinoma who are suitable for salvage treatment following previous curative treatment. [New 2023]
- Evaluation of suspected recurrence of oesophago-gastric tumours when other imaging is negative or equivocal. [New 2023]

Prior to radical SABR in oligometastatic disease

- Prior to referral, the patient should have been discussed in an appropriately constituted MDT [2022]
- Restaging of patients with cancer recurrence being considered for SABR to confirm oligometastatic status. [2019]

 Restaging of patients being considered for SABR with equivocal findings on other imaging modalities. [2019]

Other Cancer Sites

 Other cancer sites including melanoma and testicular where there is particular difficulty in staging, restaging or the assessment of possible recurrence. [2015]

Ovarian, fallopian tube and primary peritoneal cancer

- Detection of tumour in selected patients with ovarian, fallopian tube and primary peritoneal carcinoma who have rising CA125 levels and equivocal or negative imaging. [2019]
- Suspected recurrence of ovarian, fallopian tube and primary peritoneal carcinoma where other imaging is equivocal and where there is a potential radical treatment option. [2019]

Paraneoplastic disease

• Detection of occult primary tumour in patients with neurological non-metastatic manifestations of neoplastic disease, where imaging is negative or equivocal. [2021]

Parathyroid Adenomas (18F-Choline)

 18F-Fluorocholine PET for Parathyroid tumour localisation after failed surgery or for recurrent hyperparathyroidism, where the tumour has not been found using conventional anatomical and functional techniques, including Sestamibi scans, ultrasound and 4D CT. [2020]

Pancreatic cancer

- People with obstructive jaundice. If the diagnosis is still unclear after pancreatic protocol CT, offer fluorodeoxyglucose-positron emission tomography/CT (FDG-PET-CT) and/or endoscopic ultrasound (EUS) with EUS-quided tissue sampling. [2019]
- People without jaundice who have pancreatic abnormalities on imaging. If the diagnosis is still unclear after pancreatic protocol CT, offer FDG-PET-CT and/or EUS with EUS-guided tissue sampling.
 [2019]
- Offer fluorodeoxyglucose-positron emission tomography/CT (FDG-PET-CT) to people with localised disease on CT who will be having radical cancer treatment (surgery, radiotherapy or systemic therapy). [2019]

Prostate Cancer (18 F-Choline PET/CT or 18F-PSMA PET)

- Staging of high-risk patients (clinical T3 or above or PSA > 20 or Gleason 8 or above) who are considered suitable for curative treatment following conventional imaging. [2021]
- Suspected recurrence in patients with a rapidly rising prostatespecific antigen (PSA) and negative or equivocal conventional imaging where the results would directly influence patient management. [2021]

Sarcoma

- Assessment of suspected malignant transformation with plexiform neurofibromas in patients with neurofibromatosis type 1. [2018]
- Staging of high grade sarcomas, unless already proven to have metastatic disease, especially Ewing's sarcoma, rhabdomyosarcoma, leiomyosarcoma, osteosarcoma, malignant fibrous histiocytoma, synovial sarcoma and myxoid liposarcoma. [2018]
- Pre-amputation in the setting of a high grade sarcoma where the detection of distant disease will alter the surgical management.
 [2018]
- To stage patients with metastatic sarcoma considered for liver or lung metastasectomy where anatomical imaging has not identified any extra-thoracic or extra-hepatic disease which could preclude surgery. [2018]

Thyroid cancer

- Assessment of patients with elevated thyroglobulin levels and negative iodine scintigraphy with suspected recurrent disease.
 [2018]
- To evaluate disease in treated medullary thyroid carcinoma associated with elevated calcitonin levels with equivocal or normal cross-sectional imaging, bone and octreotide scintigraphy. [2018]

Vaginal cancer

- Staging or restaging of patients with vaginal carcinoma being considered for exenterative surgery. [2018]
- Suspected recurrence of vaginal cancer where other imaging is equivocal and where there is a potential radical treatment option.
 [2018]

Vulval cancer

- Staging or restaging of patients with vulval carcinoma being considered for exenterative surgery. [2018]
- Suspected recurrence of vulval cancer where other imaging is equivocal and where there is a potential radical treatment option.
 [2018]

2.2.2 Non-oncological indications

Cardiac

 Referrals to Guy's and St Thomas's NHS Foundation Hospital for cardiac PET for the assessment of myocardial viability and hibernation will be considered on a named patient basis only.
 [2015]

Dementia (FDG)

- Evaluation of memory loss/neurological signs suggestive of dementia and differentiation of types of dementia in selected patients where there is diagnostic uncertainty. This includes patients with:
 - o mild cognitive impairment
 - a dementia of early onset (<65 years)
 - o an atypical presentation of dementia
 - multiple established psychiatric co-morbidities (depression, schizophrenia, bipolar illness, alcohol-related, learning difficulties) with co-existing and/or new-onset cognitive impairment
 - o inconclusive formal neuropsychological assessment [2021].
- Before referral for a PET the patient needs to have:
 - been assessed by a dementia specialist (with appropriate neurological examination and cognitive testing performed) and been discussed by the dementia MDT
 - had conventional cross-sectional imaging of the brain (i.e. at least 1 CT or MRI)
 - o had a negative or equivocal DaTSCAN, if a high pre-test probability of Lewy Body Dementia. [2021].

Epilepsy

 FDG PET is available for the pre-surgical evaluation of epilepsy, referrals come through the South Wales Epilepsy Surgery MDT.
 [2021]

Known or suspected cardiac sarcoidosis

- Assessment of activity and distribution of disease at baseline in those cases where there is diagnostic uncertainty despite conventional assessments and where treatment would be altered if ongoing cardiac inflammation is confirmed. [2019]
- Assessment of disease response where other measures to monitor response are unhelpful and/or in patients with disease resistant to treatment. [2019]

Infection and pyrexia of unknown origin (PUO)

- To identify the cause of pyrexia of unknown origin where conventional investigations have not revealed a source. [2019]
- Detection of site of focal infection in immunocompromised patients or problematic cases of infection. [2019]
- Evaluation of vascular graft or cardiac implantable device related infection in selected cases provided sufficient time has elapsed since surgery. [2019]

Rheumatology

- Detection of occult malignancy in Idiopathic Inflammatory Myopathies (IIMs) i.e. Polymyositis (PM), Dermatomyositis (DM) especially treatment resistant and/or with high-risk clinical phenotype. [New 2023]
- Detection of occult malignancy in patients with rare rheumatological conditions, such as, Relapsing Polychondritis and RS3PE⁸ when high clinical suspicion of underlying malignancy. [New 2023]

Vasculitis

 Evaluation of suspected vasculitis in selected cases, where conventional imaging has proved inconclusive; for example, to determine the extent and distribution of the disease activity or to exclude underlying malignancy which may be a paraneoplastic phenomenon, resulting in atypical presentations of vasculitis.
 [2019]

2.3 Treatment

Treatment and clinical management plans are expected to be affected by the results of PET (including upstaging or down staging of patients). This will be subject to prospective audit.

⁸ Remitting seronegative symmetrical synovitis with pitting oedema

2.4 Exclusion Criteria

PET-CT is only commissioned for those indications listed in section 2.2.

2.5 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.6 Acceptance Criteria

The service outlined in this policy 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)

Clinicians in South East Wales (excluding Swansea Bay, Hywel Dda and West Bridgend) and parts of Mid Wales should refer their patients to the Wales Research and Diagnostic PET Imaging Centre (PETIC) Cardiff.

Clinicians in South West Wales, and parts of Mid Wales should refer their patients to the mobile PET-CT service at Singleton Hospital, Swansea.

Clinicians in North Wales and parts of Mid Wales should refer their patients to Nuclear Medicine, Wrexham Maelor Hospital, Wrexham.

The patient flow for mid Wales should generally follow the pattern for cancer referral to the north and south Wales specialist centres. Patients from mid Wales who would otherwise be referred to the Royal Shrewsbury Hospital for specialist treatment should be referred to north Wales for PET scans.

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

2.8 Designated Centres

Refer patients resident in South East Wales and parts of Mid Wales to:

Wales Research and Diagnostic PET Imaging Centre (PETIC)
 University Hospital of Wales
 Heath Park
 Cardiff
 CF14 4XN

[Referral forms, contact details and further information on PETIC can be found on the PETIC website at <u>Wales Research and Diagnostic PET Imaging</u> Centre - Cardiff University]

Refer patients resident in South West Wales, and parts of Mid Wales to:

Nuclear Medicine
 Singleton Hospital
 Swansea Bay University Health Board
 Sketty Lane
 Swansea
 SA2 8QA

[Referral forms, contact details and further information can be found on the PETCT Swansea Website at: <a href="https://example.com/hemospheres/bullet-bulle

Refer patients resident in North Wales and parts of Mid Wales to:

Nuclear Medicine
 Wrexham Maelor Hospital
 Croesnewydd Road
 Wrexham
 LL13 7TD

2.9 Exceptions

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

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

2.10 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's 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.

2.11 Responsibilities

For South Wales and parts of Mid Wales, clinicians should refer all PET scan requests to PETIC, Heath Park, Cardiff or Singleton Hospital, Swansea. Clinicians in North Wales and parts of Mid Wales should refer their patients to Wrexham Maelor Hospital.

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all alternative treatments with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Evidence

WHSSC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

Evidence to support the indications marked [2018], [2019], [2020], [2021], [2022] or [2023] is presented in Appendix 1 (which is a separate document).

3.1 Date of Review

This policy will be reviewed by WHSSC and the All Wales PET Advisory Group (AWPET) on an annual basis. AWPET, a subgroup of the Clinical Oncology Sub-Committee (COSC) of the Welsh Scientific Advisory Committee (WSAC), will be asked to scrutinise any new evidence of clinical and cost effectiveness to help inform WHSSC of any change to the list of indications included in this document.

4. 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 reassignment, 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.

5. Putting Things Right: Raising a Concern

5.1 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 WHSSC.

5.2 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: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Annex i Codes

Code Category	Code	Description
OPCS	U10.4	Myocardial positron emission tomography
OPCS	U21.3	Positron tomography NEC
OPCS	U36.2	Positron emission tomography with computed tomography NEC

Annex ii Abbreviations and Glossary

Abbreviations

AWMSG All Wales Medicines Strategy Group

FDG Fluorodeoxyglucose

IPFR Individual Patient Funding Request

PET Positron Emission Tomography

SMC Scottish Medicines Consortium

WHSSC Welsh Health Specialised Services

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services 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.