NHS England

Clinical Commissioning Policy Statement: Positron Emission Tomography-Computed Tomography (PET-CT) Guidelines (all ages)

Reference: NHS England B02/PS/b

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Publications Gateway Reference:	**03713**
Document Purpose	Policy
Document Name	B02/P/a Positron Emission Tomography - Computed Tomography Guidelines
Author	Specialised Commissioning Team, NHS England
Publication Date	July 2015
Target Audience	Local Team Assistant Directors of Specialised Commissioning; Regional Team IFR Leads; Finance Leads; Local Team Pharmacists; Chairs of Clinical Reference Groups; Members of Clinical Reference Groups and registered stakeholders; Acute Trust Chief Executives; Acute Trust Medical Directors; Acute Trust Chief Pharmacists
Additional Circulation List	Regional Medical Directors; Regional Directors of Specialised Commissioning; Regional Clinical Directors of Specialised Commissioning; Regional Directors of Nursing
Description	NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	
Superseded Docs (if applicable)	B02/PS/a
Action Required	
Timing / Deadlines (if applicable)	
Contact Details for further information	jeremyglyde@nhs.net for policy issues

Document Status

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POLICY STATEMENT: Positron Emission Tomography- Computed Tomography (PET-CT) Guidelines (all ages)	**Reference:** **NHS England B02/PS/b**

Background:	Positron Emission Tomography- Computed Tomography (PET-CT) is a unique imaging tool which shows pathology by using PET to detect derangement in tissue metabolism and CT to show structural changes. PET-CT is a key diagnostic service which provides information to allow informed clinical management decisions and more effective targeted care. This contributes to more individualised care and treatment of patients. The appropriate use of the examination in the patient pathway optimises the efficiency of the subsequent clinical interventions and treatment regimens. PET-CT is a directly commissioned service within NHS England. The service is delivered through a variety of providers mainly NHS Trusts, the independent sector, research institutes and charitable organisations. Contractual arrangements are made by area teams on behalf of NHS England directly with providers or through subcontracting arrangements with NHS Trusts. The commissioning policy has been developed because: • The existing PET-CT clinical policy statement allows for commissioning of oncology PET-CT indications stated in the Evidence Based Indications for the use of

	PET-CT in the UK 2012 guidelines (Evidence based Indications for the use of PET CT in the UK 2012, Clinical Commissioning Policy Statement: Positron Emission Tomography-Computerised Tomography). In addition, the existing policy statement allows for the delivery of PET-CT scans for non-oncology indications listed in Evidence Based Indications for the use of PET-CT in the UK 2012 guidelines up to a threshold equal to 10% of total oncology activity. The 10% discretionary criterion is used in selected patients at the Administration of Radioactive Substances Advisory Committee (ARSAC) certificate holder's discretion. It enables ARSAC certificate holders to undertake additional PET-CT scans and particularly non-oncology PET-CT scans. • There is need to normalise the commissioning of the non-oncology PET-CT indications, to ensure usage of PET-CT where there is good evidence that patients will benefit from improved disease assessment resulting in altered management and improved outcomes.
Commissioning position:	NHS England will commission oncology PET-CT using [18F]-fluoro-deoxy-glucose (FDG PET-CT) and non-FDG PET-CT radioactive tracers as expressed in the 'Evidence based indications for the use of PET-CT in the UK 2013' (Evidence based indications for the use of PET CT 2013). NHS England will commission non-oncology FDG PET-CT for indications that are expressed in the 'Evidence based indications for the use of PET-CT in the UK 2013' and which are currently funded as part of service delivery by NHS England. As such, FDG PET-CT will be commissioned for the investigation of selected patients with infection, pyrexia of

	unknown origin, suspected large vessel vasculitis, sarcoidosis, cardiac and neurological conditions. It should be noted that, based on audit data, the ratio of oncology to non-oncology activity is expected to be between 10:1 and 30:1. Area Teams are expected to work with providers and the Clinical Reference Group to monitor this over time. NHS England will not commission the use of amyloid radioactive tracers for brain imaging. This is because there is insufficient evidence available to demonstrate benefit. Because the evidence base is still emerging in this field, the policy recommends that this area should be reviewed no later than 2016/17. Specifically NHS England will commission the following FDG PET –CT non-cancer indications: **Large Vessel Vasculitis** • Evaluation of suspected vasculitis in selected cases; 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 • PET-CT would not be indicated in all patients with giant cell arteritis, but is of use in patients where conventional investigations are unhelpful and treatment would be altered if ongoing inflammatory disease is confirmed. **Sarcoidosis** • Assessment of activity and distribution of disease at baseline in highly selected cases where there is diagnostic uncertainty using conventional imaging

	(e.g. suspected cardiac sarcoidosis) • Assessment of disease response where other measures to monitor response are unhelpful and/or in patients with disease resistant to treatment. **Infection imaging** • Detection of site of focal infection in immuno-compromised patients or problematic cases of infection • Evaluation of vascular graft infection in selected cases provided sufficient time has elapsed since surgery. **Pyrexia of unknown origin (PUO)** • To identify the cause of a PUO where conventional investigations have not revealed a source. **Neurological applications** • Pre-surgical assessment of medically refractory complex partial seizures where MR is normal, equivocal or conflicts with EEG localisation • Evaluation of memory loss/neurological signs suggestive of dementia and differentiation of types of dementia in selected patients. **Cardiological indications** • Assessment of myocardial viability in patients with ischaemic heart failure and poor left ventricular function being considered for revascularisation, usually in combination with perfusion imaging with sestamibi/tetrofosmin or ammonia/rubidium. • The current interim arrangement, enabling the use of PET-CT scans using the radioactive tracer Rubidium from the two centres in England (Manchester and London) where Rubidium PET-CT is firmly established as part of a comprehensive NHS England cardiac imaging service, remains unaltered.

	This policy statement follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).
Effective from:	July 2015
Evidence summary:	The proposed PET-CT policy is supported by published peer-reviewed literature and is justified by national and international guidelines on the use of PET-CT including the Evidence-based Indications for PET-CT in the UK 2013 document, a joint Royal Colleges of Physicians, Royal Colleges of Radiologists, British Nuclear Medicine Society and Administration of Radioactive Substances Committee (ARSAC) document which specifies the use of FDG and non-FDG radioactive tracers for oncology and non-oncology indications in PET-CT. The policy, and specifically the non-oncology recommendations, is also supported by a recent national audit of the use of PET-CT which included FDG PET-CT and non FDG PET-CT for non-oncology indications. The audit was commissioned by the PET-CT CRG and coordinated by the British Nuclear Medicine Society. Inter alia, the audit provides evidence that within an NHS England setting the non-oncology PET-CT indications proposed in the policy is part of established investigative pathways and benefits patients when used appropriately as part of the imaging pathway. The study was undertaken between 18th June 2013 and 17th December 2013. Participating centres were asked to record non FDG and FDG PET-CT scans for non-oncology

	indications that were performed, to provide details of information sought from PET-CT and the impact of the PET-CT scan on clinical management. Returns were submitted by 52 centres throughout England. Seven hundred and seventy six PET-CT data sets were returned, including 616 for non-oncology indications during the 6-month period. Two hundred and sixty seven patients underwent FDG PET-CT for assessment of suspected infection/inflammation, 50 for assessment of pyrexia of unknown origin, 51 for extent of granulomatous inflammation, 82 for suspected large vessel vasculitis and 84 for other inflammatory disorders. Unexpected sites of disease were identified in 169 patients (63.3%) and influenced management in 239 (89.5%) of patients. Two hundred and seventy four cardiology PET-CT studies were undertaken, 260 for assessment of myocardial perfusion using Rubidium chloride and 14 for the assessment of myocardial viability using FDG. Following the scan, disease was categorised as less extensive in 136 patients, and more extensive in 73 patients, in other words having a direct impact on management in 209 (76.3%) of patients. Fifty-three patients underwent PET CT scans for assessment of dementia and 22 for refractory epilepsy. The outcome of the PET-CT prevented the patient requiring further tests in 54/75 (72.0%) patients. In total, of the 616 non-oncology PET-CT studies carried out between June and December 2013, 502 studies (81.5%) were reported to have directly influenced patient management.

	Amyloid PET-CT radioactive tracers An in-depth rapid review of the evidence was commissioned from 'Solutions for Public Health' to evaluate the current evidence for the use of amyloid radioactive tracers in patients with cognitive impairment. Overall the review concluded that there is evidence that amyloid PET-CT can contribute to the diagnosis of Alzheimer's disease and some other types of dementia with studies reporting change in diagnosis and resolution of dilemmas (Sanchez-Juan et al 2014, Ossenkoppele et al 2013, Frederiksen et al 2012, Grundman et al 2013, Schipke et al 2012). However, due to differences in study populations and differences in outcomes reported it is not clear what the degree of benefit obtained would be. There was evidence from one study suggesting that the proportion of diagnoses that change is greater when diagnostic certainty in the initial diagnosis is lower (Schipke et al 2012). There is evidence that amyloid PET-CT has a reasonable sensitivity and specificity to distinguish people with Alzheimer's disease from healthy controls (Hatashita et al 2014, Clark et al 2012, Camus et al 2012, Barthel et al 2011). However the sensitivity and specificity of amyloid PET-CT to confirm or exclude the diagnosis of Alzheimer's disease in adults suspected of having dementia but in whom the diagnosis is inconclusive using current diagnostic tools is essentially unknown. No studies assessing the impact of amyloid PET-CT on any change in patient outcomes were identified. Two studies reported changes in the intended plans for patient

	management and treatment following amyloid PET CT (Grundman et al 2013, Schipke et al 2012). However, no studies addressed actual changes as opposed to anticipated changes in treatment and patient management and assessed outcomes for patients. No studies assessed the cost-effectiveness of amyloid PET CT were identified. Future studies following-up patients whose diagnosis changed or was confirmed following PET-CT would be beneficial to assess impact on treatment and patient management and effect on outcomes for patients. A phase IV study evaluating the effectiveness of florbetapir PET-CT imaging in changes patient management [expected n=600] is in progress with an estimated completion date of December 2014 (Effectiveness of Florbetapir (18F) PET Imaging in Changing Patient Management and the Relationship Between Scan Status and Cognitive Decline NCT01703702).
Equality impact:	NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Responsible CRG:	PET-CT
Mechanism for Funding:	NHS England – Regional and Hub Commissioning Teams
Date Approved:	July 2015
Policy review date:	2016/17

References

NHS Commissioning Board. Clinical Commissioning Policy Statement: Positron Emission Tomography-Computerised Tomography. December 2012. NHSCB/B02. Available at: www.**england**.**nhs**.uk/wp-content/uploads/2013/09/b02-ps-a.pdf

Royal College of Physicians, The Royal College of Radiologists. Evidence based Indications for the use of PET CT in the UK. 2012. Available at: www.rcr.ac.uk/publications.aspx

Royal College of Physicians, The Royal College of Radiologists. Evidence based Indications for the use of PET CT in the UK. 2013. Available at: www.rcr.ac.uk/publications.aspx

Amyloid Radioactive Tracers:

Sanchez-Juan P, Ghost PM, Hagan J, et al. Practical utility of amyloid and FDG PET in an academic dementia centre. Neurology 2014; 82: 230-238.

Ossenkoppele R, Prins NS, Pijnenburg YA, et al. Impact of molecular imaging on the diagnostic process in a memory clinic. Alzheimer's and Dementia 2013; 9: 414-421.

Frederiksen KS, Hasselbalch SG, Hejl AM, et al. Added diagnostic value of [11]C-PIB-PET in memory clinic patients with uncertain diagnosis. Dementia and Geriatric Cognitive Disorders 2012; 2: 610-621.

Grundman M, Pontecorvo MJ, Salloway SP, et al. Potential impact of amyloid imaging on diagnosis and intended management in patients with progressive cognitive decline. Alzheimer's Disease and Associated Disorders 2013; 27(1): 4-15.

Schipke CG, Peters O, Heuser I, et al. Impact of beta-amyloid-specific florbetaben PET imaging on confidence in early diagnosis of Alzheimer's disease. Dementia and Geriatric Cognitive Disorders 2012; 33: 416-422.

Hatashita S, Yamasaki H, Suzuku Y, et al. [18F] flutemetamol amyloid-beta PET imaging compared with [11C] PIB across the spectrum in Alzheimer's disease. European Journal of Nuclear Medicine and Molecular Imaging 2014; 41: 290-300.

Clarke CM, Pontercorvo MJ, Beach TG, et al. Cerebral PET with florbetapir compared with neuropathology at autopsy for detection of neuritic amyloid-beta plaques: a prospective cohort study. Lancet Neurology 2012; 11: 669-678.

Camus V, Payoux P, Barre L. Using PET with [18F]-AV-45 (fluorbetapir) to quantify brain amyloid load in a clinical environment. European Journal of Nuclear Medicine and Molecular Imaging 2012; 39: 621-631.

Barthel H, Gertz HJ, Dresel S, et al. Cerebral amyloid beta PET with florbetaben (18F) in patients with Alzheimer's disease an healthy controls: a multicentre phase II diagnostic study. Lancet Neurology 2011; 10: 424-435.

National Institute in Aging (NIA). Effectiveness of Florbetapir (18F) PET Imaging in Changing Patient Management and the Relationship Between Scan Status and Cognitive Decline. NCT01703702. 2014. Available at: www.nia.nih.gov/alzheimers/clinical-trials/florbetapir-18f-pet