

## References

### R-5006

1. Food and Drug Administration (FDA). PET Drugs - Current Good Manufacturing Practice (CGMP). 2009; <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070306.pdf>. Accessed August 29, 2022.
2. Food and Drug Administration (FDA). PET Drugs - Current Good Manufacturing Practice (CGMP) Small Entity Compliance Guide. 2011; <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM266640.pdf>. Accessed August 30, 2022.
3. Food and Drug Administration (FDA). Guidance: Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs. 2012; <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291573.pdf>. Accessed August 31, 2022.
4. Food and Drug Administration (FDA). Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications. Federal Register. 2000;65(48):12999-13010.
5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Positron Emission Tomography (PET) of Central Nervous System Diseases. TEC Assessments. 1992;Volume 7:Tab 3.
6. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT) for the Assessment of Cerebrovascular Disease. TEC Assessments. 1996;Volume 11:Tab 35.
7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT) in the Management of Seizure Disorders. TEC Assessments. 1996;Volume 11:Tab 33.
8. Kwan P, Schachter SC, Brodie MJ. Drug-resistant epilepsy. N Engl J Med. Sep 08 2011; 365(10): 919-26. PMID 21899452
9. Mishra AM, Bai H, Gribizis A, et al. Neuroimaging biomarkers of epileptogenesis. Neurosci Lett. Jun 27 2011; 497(3): 194-204. PMID 21303682
10. Engel J, Cascino G, Ness P, et al. Outcome with respect to epileptic seizures. In: Engel J, ed. Surgical Treatment of the Epilepsies. New York, NY: Raven Press; 1993:609-621.
11. Niu N, Xing H, Wu M, et al. Performance of PET imaging for the localization of epileptogenic zone in patients with epilepsy: a meta-analysis. Eur Radiol. Aug 2021; 31(8): 6353-6366. PMID 33523306

12. Jones AL, Cascino GD. Evidence on Use of Neuroimaging for Surgical Treatment of Temporal Lobe Epilepsy: A Systematic Review. *JAMA Neurol.* Apr 2016; 73(4): 464-70. PMID 26926529
13. Wang X, Zhang C, Wang Y, et al. Prognostic factors for seizure outcome in patients with MRI-negative temporal lobe epilepsy: A meta-analysis and systematic review. *Seizure.* May 2016; 38: 54-62. PMID 27182689
14. Burneo JG, Poon R, Kellett S, et al. The Utility of Positron Emission Tomography in Epilepsy. *Can J Neurol Sci.* Nov 2015; 42(6): 360-71. PMID 26437611
15. Englot DJ, Wang DD, Rolston JD, et al. Rates and predictors of long-term seizure freedom after frontal lobe epilepsy surgery: a systematic review and meta-analysis. *J Neurosurg.* May 2012; 116(5): 1042-8. PMID 22304450
16. Willmann O, Wennberg R, May T, et al. The contribution of 18F-FDG PET in preoperative epilepsy surgery evaluation for patients with temporal lobe epilepsy A meta-analysis. *Seizure.* Sep 2007; 16(6): 509-20. PMID 17532231
17. Traub-Weidinger T, Weidinger P, Groppe G, et al. Presurgical evaluation of pediatric epilepsy patients prior to hemispherotomy: the prognostic value of 18 F-FDG PET. *J Neurosurg Pediatr.* Dec 2016; 25(6): 683-688. PMID 27611898
18. Lipsky BA, Berendt AR, Deery HG, et al. Diagnosis and treatment of diabetic foot infections. *Clin Infect Dis.* Oct 01 2004; 39(7): 885-910. PMID 15472838
19. Dinh MT, Abad CL, Safdar N. Diagnostic accuracy of the physical examination and imaging tests for osteomyelitis underlying diabetic foot ulcers: meta-analysis. *Clin Infect Dis.* Aug 15 2008; 47(4): 519-27. PMID 18611152
20. Llewellyn A, Kraft J, Holton C, et al. Imaging for detection of osteomyelitis in people with diabetic foot ulcers: A systematic review and meta-analysis. *Eur J Radiol.* Oct 2020; 131: 109215. PMID 32862106
21. Lauri C, Tamminga M, Glaudemans AWJM, et al. Detection of Osteomyelitis in the Diabetic Foot by Imaging Techniques: A Systematic Review and Meta-analysis Comparing MRI, White Blood Cell Scintigraphy, and FDG-PET. *Diabetes Care.* Aug 2017; 40(8): 1111-1120. PMID 28733376
22. Treglia G, Sadeghi R, Annunziata S, et al. Diagnostic performance of Fluorine-18-Fluorodeoxyglucose positron emission tomography for the diagnosis of osteomyelitis related to diabetic foot: a systematic review and a meta-analysis. *Foot (Edinb).* Dec 2013; 23(4): 140-8. PMID 23906976
23. Termaat MF, Raijmakers PG, Scholten HJ, et al. The accuracy of diagnostic imaging for the assessment of chronic osteomyelitis: a systematic review and meta-analysis. *J Bone Joint Surg Am.* Nov 2005; 87(11): 2464-71. PMID 16264122
24. de Winter F, van de Wiele C, Vogelaers D, et al. Fluorine-18 fluorodeoxyglucose-positron emission tomography: a highly accurate imaging

- modality for the diagnosis of chronic musculoskeletal infections. *J Bone Joint Surg Am.* May 2001; 83(5): 651-60. PMID 11379733
25. Schiesser M, Stumpe KD, Trentz O, et al. Detection of metallic implant-associated infections with FDG PET in patients with trauma: correlation with microbiologic results. *Radiology.* Feb 2003; 226(2): 391-8. PMID 12563131
  26. Guhlmann A, Brecht-Krauss D, Suger G, et al. Fluorine-18-FDG PET and technetium-99m antigranulocyte antibody scintigraphy in chronic osteomyelitis. *J Nucl Med.* Dec 1998; 39(12): 2145-52. PMID 9867159
  27. Meller J, Koster G, Liersch T, et al. Chronic bacterial osteomyelitis: prospective comparison of (18)F-FDG imaging with a dual-head coincidence camera and (111)In-labelled autologous leucocyte scintigraphy. *Eur J Nucl Med Mol Imaging.* Jan 2002; 29(1): 53-60. PMID 11807607
  28. Rastogi A, Bhattacharya A, Prakash M, et al. Utility of PET/CT with fluorine-18-fluorodeoxyglucose-labeled autologous leukocytes for diagnosing diabetic foot osteomyelitis in patients with Charcot's neuroarthropathy. *Nucl Med Commun.* Dec 2016; 37(12): 1253-1259. PMID 27749777
  29. Gulati A, Bagga A. Large vessel vasculitis. *Pediatr Nephrol.* Jun 2010; 25(6): 1037-48. PMID 19844748
  30. Arend WP, Michel BA, Bloch DA, et al. The American College of Rheumatology 1990 criteria for the classification of Takayasu arteritis. *Arthritis Rheum.* Aug 1990; 33(8): 1129-34. PMID 1975175
  31. Hunder GG, Bloch DA, Michel BA, et al. The American College of Rheumatology 1990 criteria for the classification of giant cell arteritis. *Arthritis Rheum.* Aug 1990; 33(8): 1122-8. PMID 2202311
  32. Jennette JC, Falk RJ, Bacon PA, et al. 2012 revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. *Arthritis Rheum.* Jan 2013; 65(1): 1-11. PMID 23045170
  33. Mukhtyar C, Guillevin L, Cid MC, et al. EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis.* Mar 2009; 68(3): 318-23. PMID 18413441
  34. van der Geest KSM, Treglia G, Glaudemans AWJM, et al. Diagnostic value of [18F]FDG-PET/CT for treatment monitoring in large vessel vasculitis: a systematic review and meta-analysis. *Eur J Nucl Med Mol Imaging.* Nov 2021; 48(12): 3886-3902. PMID 33942141
  35. Lee YH, Choi SJ, Ji JD, et al. Diagnostic accuracy of 18F-FDG PET or PET/CT for large vessel vasculitis : A meta-analysis. *Z Rheumatol.* Nov 2016; 75(9): 924-931. PMID 26704559
  36. Soussan M, Nicolas P, Schramm C, et al. Management of large-vessel vasculitis with FDG-PET: a systematic literature review and meta-analysis. *Medicine (Baltimore).* Apr 2015; 94(14): e622. PMID 25860208

37. Puppo C, Massollo M, Paparo F, et al. Giant cell arteritis: a systematic review of the qualitative and semiquantitative methods to assess vasculitis with 18F-fluorodeoxyglucose positron emission tomography. *Biomed Res Int*. 2014; 2014: 574248. PMID 25254211
38. Treglia G, Mattoli MV, Leccisotti L, et al. Usefulness of whole-body fluorine-18-fluorodeoxyglucose positron emission tomography in patients with large-vessel vasculitis: a systematic review. *Clin Rheumatol*. Oct 2011; 30(10): 1265-75. PMID 21833685
39. Besson FL, Parienti JJ, Bienvenu B, et al. Diagnostic performance of F-fluorodeoxyglucose positron emission tomography in giant cell arteritis: a systematic review and meta-analysis. *Eur J Nucl Med Mol Imaging*. Sep 2011; 38(9): 1764-72. PMID 21559981
40. Kerr GS, Hallahan CW, Giordano J, et al. Takayasu arteritis. *Ann Intern Med*. Jun 01 1994; 120(11): 919-29. PMID 7909656
41. Sammel AM, Hsiao E, Schembri G, et al. Diagnostic Accuracy of Positron Emission Tomography/Computed Tomography of the Head, Neck, and Chest for Giant Cell Arteritis: A Prospective, Double-Blind, Cross-Sectional Study. *Arthritis Rheumatol*. Aug 2019; 71(8): 1319-1328. PMID 30848549
42. Gupta A, Baradaran H, Schweitzer AD, et al. Oxygen extraction fraction and stroke risk in patients with carotid stenosis or occlusion: a systematic review and meta-analysis. *AJNR Am J Neuroradiol*. Feb 2014; 35(2): 250-5. PMID 23945227
43. Kim SJ, Pak K, Kim K, et al. Comparing the Diagnostic Accuracies of F-18 Fluorodeoxyglucose Positron Emission Tomography and Magnetic Resonance Imaging for the Detection of Spondylodiscitis: A Meta-analysis. *Spine (Phila Pa 1976)*. Apr 01 2019; 44(7): E414-E422. PMID 30889146
44. Yan J, Zhang C, Niu Y, et al. The role of 18F-FDG PET/CT in infectious endocarditis: a systematic review and meta-analysis. *Int J Clin Pharmacol Ther*. May 2016; 54(5): 337-42. PMID 27008000
45. Mackie SL, Koduri G, Hill CL, et al. Accuracy of musculoskeletal imaging for the diagnosis of polymyalgia rheumatica: systematic review. *RMD Open*. 2015; 1(1): e000100. PMID 26535139
46. Treglia G, Taralli S, Giordano A. Emerging role of whole-body 18F-fluorodeoxyglucose positron emission tomography as a marker of disease activity in patients with sarcoidosis: a systematic review. *Sarcoidosis Vasc Diffuse Lung Dis*. Oct 2011; 28(2): 87-94. PMID 22117499
47. Yin Y, Liu X, Yang X, et al. Diagnostic value of FDG-PET versus magnetic resonance imaging for detecting spondylitis: a systematic review and meta-analysis. *Spine J*. Dec 2018; 18(12): 2323-2332. PMID 30121323

48. Hao R, Yuan L, Kan Y, et al. Diagnostic performance of 18F-FDG PET/CT in patients with fever of unknown origin: a meta-analysis. *Nucl Med Commun.* Jul 2013; 34(7): 682-8. PMID 23636293
49. Besson FL, Chaumet-Riffaud P, Playe M, et al. Contribution of (18)F-FDG PET in the diagnostic assessment of fever of unknown origin (FUO): a stratification-based meta-analysis. *Eur J Nucl Med Mol Imaging.* Sep 2016; 43(10): 1887-95. PMID 27037917
50. Bharucha T, Rutherford A, Skeoch S, et al. Diagnostic yield of FDG-PET/CT in fever of unknown origin: a systematic review, meta-analysis, and Delphi exercise. *Clin Radiol.* Sep 2017; 72(9): 764-771. PMID 28600002
51. Li Q, Tian R, Wang H, et al. Quantifying the contribution of 18 F-FDG PET to the diagnostic assessment of pediatric patients with fever of unknown origin: a systematic review and meta-analysis. *Pediatr Radiol.* Jul 2022; 52(8): 1500-1511. PMID 35348809
52. Kapoor RR, James C, Hussain K. Advances in the diagnosis and management of hyperinsulinemic hypoglycemia. *Nat Clin Pract Endocrinol Metab.* Feb 2009; 5(2): 101-12. PMID 19165222
53. Yang J, Hao R, Zhu X. Diagnostic role of 18F-dihydroxyphenylalanine positron emission tomography in patients with congenital hyperinsulinism: a meta-analysis. *Nucl Med Commun.* Apr 2013; 34(4): 347-53. PMID 23376859
54. Prodromou ML, Ziakas PD, Poulou LS, et al. FDG PET is a robust tool for the diagnosis of spondylodiscitis: a meta-analysis of diagnostic data. *Clin Nucl Med.* Apr 2014; 39(4): 330-5. PMID 24445277
55. Treglia G, Pascale M, Lazzeri E, et al. Diagnostic performance of 18 F-FDG PET/CT in patients with spinal infection: a systematic review and a bivariate meta-analysis. *Eur J Nucl Med Mol Imaging.* May 2020; 47(5): 1287-1301. PMID 31729539
56. Treglia G, Taralli S, Calcagni ML, et al. Is there a role for fluorine 18 fluorodeoxyglucose-positron emission tomography and positron emission tomography/computed tomography in evaluating patients with mycobacteriosis? A systematic review. *J Comput Assist Tomogr.* May-Jun 2011; 35(3): 387-93. PMID 21586936
57. Caobelli F, Cobelli M, Pizzocaro C, et al. The role of neuroimaging in evaluating patients affected by Creutzfeldt-Jakob disease: a systematic review of the literature. *J Neuroimaging.* Jan-Feb 2015; 25(1): 2-13. PMID 24593302
58. Saleem BR, Pol RA, Slart RH, et al. 18F-Fluorodeoxyglucose positron emission tomography/CT scanning in diagnosing vascular prosthetic graft infection. *Biomed Res Int.* 2014; 2014: 471971. PMID 25210712
59. Kim SJ, Lee SW, Jeong SY, et al. A systematic review and meta-analysis of 18 F-fluorodeoxyglucose positron emission tomography or positron emission

- tomography/computed tomography for detection of infected prosthetic vascular grafts. *J Vasc Surg*. Jul 2019; 70(1): 307-313. PMID 30922755
60. Mahmoodi Z, Salarzai M, Sheikh M. Prosthetic vascular graft infection: A systematic review and meta-analysis on diagnostic accuracy of 18FDG PET/CT. *Gen Thorac Cardiovasc Surg*. Mar 2022; 70(3): 219-229. PMID 34309812
61. Jin H, Yuan L, Li C, et al. Diagnostic performance of FDG PET or PET/CT in prosthetic infection after arthroplasty: a meta-analysis. *Q J Nucl Med Mol Imaging*. Mar 2014; 58(1): 85-93. PMID 24469570
62. Kwee TC, Kwee RM, Alavi A. FDG-PET for diagnosing prosthetic joint infection: systematic review and metaanalysis. *Eur J Nucl Med Mol Imaging*. Nov 2008; 35(11): 2122-32. PMID 18704405
63. Zhang J, Li LF, Zhu YJ, et al. Diagnostic performance of 18F-FDG-PET versus scintigraphy in patients with inflammatory bowel disease: a meta-analysis of prospective literature. *Nucl Med Commun*. Dec 2014; 35(12): 1233-46. PMID 25192191
64. Niccolini F, Politis M. A systematic review of lessons learned from PET molecular imaging research in atypical parkinsonism. *Eur J Nucl Med Mol Imaging*. Nov 2016; 43(12): 2244-2254. PMID 27470326
65. Pagano G, Niccolini F, Politis M. Current status of PET imaging in Huntington's disease. *Eur J Nucl Med Mol Imaging*. Jun 2016; 43(6): 1171-82. PMID 26899245
66. American Academy of Orthopaedic Surgeons (AAOS). The diagnosis of periprosthetic joint infections of the hip and knee: guideline and evidence report. 2019; <https://aaos.org/globalassets/quality-and-practice-resources/pji/diagnosisandpreventionofperiprostheticjointinfections-7-24-19.pdf>. Accessed September 6, 2022.
67. American College of Radiology (ACR). ACR appropriateness criteria: Suspected Osteomyelitis, Septic Arthritis, or Soft Tissue Infection (Excluding Spine and Diabetic Foot). 2022; <https://acsearch.acr.org/docs/3094201/Narrative/>. Accessed September 6, 2022.
68. American College of Radiology (ACR). ACR appropriateness criteria: imaging after total knee arthroplasty. 2017; <https://acsearch.acr.org/docs/69430/Narrative/> Accessed August 27, 2022.
69. Frey KA, Lodge MA, Meltzer CC, et al. ACR-ASNR Practice Parameter for Brain PET/CT Imaging Dementia. *Clin Nucl Med*. Feb 2016; 41(2): 118-25. PMID 26646994

70. American College of Radiology (ACR). ACR appropriateness criteria: seizures and epilepsy. 2019; <https://acsearch.acr.org/docs/69479/Narrative/> Accessed August 26, 2022.
71. American College of Radiology (ACR). ACR appropriateness criteria: Crohn disease. 2019; <https://acsearch.acr.org/docs/69470/Narrative/> Accessed August 31, 2022.
72. American College of Radiology (ACR). ACR appropriateness criteria: suspected osteomyelitis of the foot in patients with diabetes mellitus: 2019. <https://acsearch.acr.org/docs/69340/Narrative/>. Accessed August 25, 2022.
73. American College of Radiology. ACR appropriateness criteria: Noncerebral Vasculitis. 2021; <https://acsearch.acr.org/docs/3158180/Narrative/>. Accessed August 24, 2022.
74. Woods CR, Bradley JS, Chatterjee A, et al. Clinical Practice Guideline by the Pediatric Infectious Diseases Society and the Infectious Diseases Society of America: 2021 Guideline on Diagnosis and Management of Acute Hematogenous Osteomyelitis in Pediatrics. *J Pediatric Infect Dis Soc*. Sep 23 2021; 10(8): 801-844. PMID 34350458
75. Berbari EF, Kanj SS, Kowalski TJ, et al. 2015 Infectious Diseases Society of America (IDSA) Clinical Practice Guidelines for the Diagnosis and Treatment of Native Vertebral Osteomyelitis in Adults. *Clin Infect Dis*. Sep 15 2015; 61(6): e26-46. PMID 26229122
76. Osmon DR, Berbari EF, Berendt AR, et al. Diagnosis and management of prosthetic joint infection: clinical practice guidelines by the Infectious Diseases Society of America. *Clin Infect Dis*. Jan 2013; 56(1): e1-e25. PMID 23223583
77. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clin Infect Dis*. Jun 2012; 54(12): e132-73. PMID 22619242
78. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination for FDG PET for Infection and Inflammation (220.6.16). 2008; [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=323&ncdver=1&DocID=220.6.16&ncd\\_id=220.6.16&ncd\\_version=1&basket=ncd%25253A220%25252E6%25252E16%25253A1%25253AFDG+PET+for+Infection+and+Inflammation&bc=gAAAAAgAAAAAA%3D%3D&](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=323&ncdver=1&DocID=220.6.16&ncd_id=220.6.16&ncd_version=1&basket=ncd%25253A220%25252E6%25252E16%25253A1%25253AFDG+PET+for+Infection+and+Inflammation&bc=gAAAAAgAAAAAA%3D%3D&). Accessed August 29, 2022.