

RADIOFARMACI E DIAGNOSTICI CON USO CONSOLIDATO PER INDICAZIONI ANCHE DIFFERENTI DA QUELLE PREVISTE DAL PROVVEDIMENTO DI AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

Medicinale	Estensione di indicazione relativa ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura
Acetilcolina cloruro	Test farmacologico per la valutazione della funzione vascolare coronarica limitatamente all'uso durante le procedure di cateterismo/coronarografia. Knuuti J. et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J. 2020; 41(3):407-477.
Fluorocolina (18F) cloruro	Localizzazione preoperatoria di adenomi della paratiroide in caso di iperparatiroidismo primario dopo una diagnostica per immagini convenzionale negativa o non conclusiva (scintigrafia con 99mTc-sestamibi o SPECT/TC). Quak E. et al. F18-choline PET/CT guided surgery in primary hyperparathyroidism when ultrasound and MIBI SPECT/CT are negative or inconclusive: the APACH1 study. Eur J Nucl Med Mol Imaging. 2018; 45(4):658-666. Hope TA et al. Accuracy of 18F-fluorocholine PET for the detection of parathyroid adenomas: prospective single center study. J Nucl Med. 2021 2021;jnumed.120.256735. doi: 10.2967/jnumed.120.256735
Fluorodesossiglucosio (18F)	Neurologia Il Fluorodesossiglucosio (18F) è consigliato nella diagnosi differenziale tra malattia di Alzheimer (AD) e altre forme di demenza, in particolare la demenza vascolare (VD) e la demenza frontotemporale (FTD), limitatamente alla risoluzione di casi dubbi, in cui la diagnosi clinica è incerta. Linea guida 19 “Impiego delle tecniche di imaging delle demenze” a cura dell’ISS (settembre 2010) (http://www.iss.it/binary/pres/cont/LG_demenze_08_09_10.pdf) Silverman DH. J Nucl Med. 2004; 45:594-607. Yuan Y, Z.-X. Gu Z-X, Wie W-S. AJNR 2009 ;30 :404-410. Nobili F, Salmaso D, Morbelli S, Girtler N, Piccardo A, Brugnolo A, Dessi B, Larsson SA, Rodriguez G, Pagani M. Eur J Nucl Med Mol Imaging 2008;35:2191–2202. Hoffman JM, Welsh-Bohmer KA, Hanson M, Crain B, Hulette C, Earl N, Coleman RE. J Nucl Med. 2000;41:1920-1928.
Furosemide	Valutazione della funzionalità renale nella scintigrafia renale sequenziale.

	O'Reilly PH, Testa HJ, Lawson RS, Farrar DJ, Charlton Edwards E. Diuresis renography in equivocal urinary tract obstruction. Br J Urol. 1978;50;76-80.
Sodio ossidronato (idrossi-metilene difosfonato o HMDP) radiomarcato con Sodio pertecnetato (99mTc)	Identificazione dei depositi di amiloide da transtiretina (ATTR) in pazienti con sospetto clinico di interessamento cardiaco da amiloidosi Perugini E, et al. Noninvasive etiologic diagnosis of cardiac amyloidosis using 99mTc-3,3-diphosphono-1,2-propanodicarboxylic acid scintigraphy. J Am Coll Cardiol 2005;4 6:1076-84. Valsamaki PN, Zissimopoulos A. Cardiac amyloidosis. Two main subtypes and diagnosis by Nuclear Medicine: SPET tracer revival. Hell J Nucl Med. 2019; 22(3):161–4. Galat A, et al. Early Phase 99Tc-HMDP Scintigraphy for the Diagnosis and Typing of Cardiac Amyloidosis. JACC Cardiovasc Imaging. 2017; 10(5):601-603. Glaudemans AW. et al. Bone scintigraphy with 99mtechnetium-hydroxymethylene diphosphonate allows early diagnosis of cardiac involvement in patients with transthyretin-derived systemic amyloidosis. Amyloid 2014; 21: 35-44. Cappelli F, et al. Accuracy of 99mTc-hydroxymethylene diphosphonate scintigraphy for diagnosis of transthyretin cardiac amyloidosis. J Nucl Cardiol 2019; 26: 497–504.
SonoVue	Diagnosi ed il follow-up del reflusso vescico-ureterale (RVU) nei pazienti pediatrici mediante l'indagine di cistosonografia. • Darge K. Voiding urosonography with US contrast agent for the diagnosis of vesicoureteric reflux in children: an update. Pediatr Radiol. 2010; 40:956-962. Duran C et al Voiding urosonography including urethrosoneography: high-quality examinations with an optimised procedure using a secondgeneration US contrast agent. Pediatr Radiol. 2012; 42:660-660-7. Riccabona M. Application of a second-generation US contrast agent in infants and children- a European questionnaire-based survey. Pediatr Radiol 2021.;42:1471-80. Papadopoulou F et al. Harmonic voiding urosonography with a second-generation contrast agent for the diagnosis of vesicoureteral reflux. Radiol . 2009; 39:239-44. Kis E. et al. Voiding urosonography with the second-generation contrast agent versus voiding cystourethrography. Pediatr Nephrol. 2010; 25:2289-2293. Piscaglia F. et al. The EFSUMB Guidelines and Recommendations on the Clinical Practice of Contrast Enhanced Ultrasound (CEUS): Update 2011 on non-hepatic applications. Ultraschall in Med. 2012; 33:33- 59.
Verde indocianina	Identificazione del linfonodo sentinella negli interventi chirurgici mammari. Ballardini B. The indocyanine green method is equivalent to the 99m Tc-labeled radiotracer method for identifying the sentinel node in breast

cancer: a concordance and validation study. Eur J Surg Oncol. 2013; 39:1332-6.

Samorani D. et al. Comment to: The indocyanine green method is equivalent to the 99mTc-labeled radiotracer method for identifying the sentinel node in breast cancer: A concordance and validation study. Eur J Surg Oncol 2013. Eur J Surg Oncol. 2014; 40(6):782-3.

Verbeek F.P.R. et al. Near-infrared fluorescence sentinel lymph node mapping in breast cancer: a multicenter experience. Breast Cancer Research and Treatment. 2014; 143:333–42.

Identificazione del linfonodo sentinella nei pazienti affetti da carcinoma dell'endometrio e della cervice uterina, stadio I FIGO.

Frumovitz M, et al. Near-infrared fluorescence for detection of sentinel lymph nodes in women with cervical and uterine cancers (FILM): a randomised, phase 3, multicentre, non-inferiority trial. Lancet Oncol 2018;19: 1394–403.

Rossi EC, Kowalski LD, Scalici J, et al. A comparison of sentinel lymph node biopsy to lymphadenectomy for endometrial cancer staging (FIRES trial): a multicentre, prospective, cohort study. Lancet Oncol 2017; 18: 384–92.

Identificazione intraoperatoria del linfonodo sentinella in pazienti affette da carcinoma invasivo e microinvasivo della vulva, candidabili a stadiazione linfonodale mediante tecnica del linfonodo sentinella.

Oonk M.H.M. et al., European Society of Gynaecological Oncology Guidelines for the Management of Patients with Vulvar Cancer - Update 2023. Int J Gynecol Cancer. 2023. 33(7):1023-1043.

Deken M.M. et al., Near-infrared fluorescence imaging compared to standard sentinel lymph node detection with blue dye in patients with vulvar cancer - a randomized controlled trial. Gynecol Oncol. 2020; 159(3):672-680.

Soergel P. et al., Sentinel Lymphadenectomy in Vulvar Cancer Using Near-Infrared Fluorescence From Indocyanine Green Compared With Technetium 99m Nanocolloid. Int J Gynecol Cancer. 2017; 27(4):805-812.