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Medicare Advantage Medical Coverage Policy

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Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT[®] codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Fusion Imaging for Noncancer Indications

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type Tit	e ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services	§80 -Requirementsfor DiagnosticX-Ray,DiagnosticLaboratory,and OtherDiagnosticTests
	Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 4	<u>§220 -</u> <u>Radiology</u>
Internet- Only Manuals (IOMs)	Pub. 100-04, Medicare Claims Processing Manual, Chapter 1 (General Billing Requirements) & 35 (Independent Diagnostic Testing Facility [IDTF])	§30 - ProviderParticipation§10 - GeneralCoverage andPaymentPolicies
	Pub. 100-08, Medicare Program Integrity Manual, Chapter 3 (Verifying Potential Errors and Taking Corrective Actions), 10 (Medicare Enrollment) & 13 (Local Coverage Determination)	§3.2 - Overview of Prepayment and Postpayment Reviews§10.2.4 - Other Medicare Part B Services§13.2 LCD Process
NCD	Positron Emission Tomography (FDG) for Oncologic Conditions	<u>220.6.17</u>
NCD	Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer	220.6.19

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LCA	Independent Diagnostic Testing Facilities- physician supervision and technician requirements	<u>A54953</u>	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE IN, MI
LCA	Billing and Coding: Positron Emission Tomography Scans Coverage	<u>A54666</u>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Positron Emission Tomography Scans Coverage	<u>A54668</u>	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Independent Diagnostic Testing Facility (IDTF)	<u>L35448</u> <u>A53252</u>	JH - Novitas Solutions, Inc. (Part A/B MAC) JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, D.C., MD, NJ, PA
LCD LCA	Multiple Imaging in Oncology	<u>L35391</u> <u>A56848</u>	JH - Novitas Solutions, Inc. (Part A/B MAC) JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, D.C., MD, NJ, PA
LCA	Billing and Coding: Independent Diagnostic Testing Facilities (IDTF)	<u>A58559</u>	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Independent Diagnostic Testing Facility (IDTF)	<u>L33910</u> <u>A57807</u>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

Fusion imaging combines two different imaging scans to create a more detailed picture for screening or diagnosis than either individual scan. The following are examples of fusion imaging for cancer indications:

Positron emission tomography with concurrent computed tomography (PET/CT) – PET assesses the function of tissues and organs by monitoring the metabolic or biochemical activity while tracking the movement and concentration of a radioactive contrast agent. The technique uses special computerized imaging equipment and rings of detectors surrounding the individual to record gamma radiation produced when positrons (positively charged particles) emitted by the radioactive agent collide with electrons. CT combines digital computing with a rotating x-ray device to generate detailed cross-sectional pictures of the imaged body area. Integrated PET/CT imaging is a technique in which both PET and CT are performed during a single visit on a hybrid PET/CT scanner (eg, Biograph mCT). The CT and PET images are then coregistered using fusion software, enabling the physiologic data obtained on PET to be localized according to the anatomic CT images. When PET/CT is performed, a low radiation dose CT without contrast is typically used to keep the radiation dose as low as possible and to limit adverse events. A higher resolution CT requires a higher dose of radiation and intravenous (IV) contrast. PET/CT scanning is frequently utilized in oncology for diagnosis, staging, restaging and monitoring cancer treatment response.

The uEXPLORER is an example of a total-body PET/CT scanner which captures three-dimensional (3D) images of the entire body while using less radiation than other methods.

Prostate-specific membrane antigen PET/CT (PSMA PET/CT) – PSMA PET/CT imaging enables detection of prostate cancer cells in an individual with recurrent or metastatic castration-resistant prostate cancer by using radiotracers that bind specifically to the PSMA proteins that are overexpressed in prostate cancer tissue. A PSMA PET/CT scan is used to localize and direct treatment for an individual at high risk for metastasis or recurrence following surgery or radiation therapy.

Computer aided detection (CAD) is used in conjunction with magnetic resonance imaging (MRI) or ultrasound to purportedly define the location or position of the area requiring biopsy. Examples of CAD used for prostate biopsies include, but may not be limited to, DynaCAD (CAD with magnetic resonance imaging [MRI]) and Fusion Bx 2.0 (CAD with ultrasound).

MRI/CT – MRI uses nuclear magnetic resonance to detect atomic nuclei or electron particle energy absorption when exposed to electromagnetic radiation. The images produced are used to diagnose disorders of body structures (eg, soft tissues) that are not easily visualized on standard x-rays. Fusing MRI with CT generates detailed cross-sectional images of the targeted body areas.

MRI/transrectal ultrasound (MRI/TRUS) fusion imaging for biopsy of the prostate – MRI/TRUS uses software to combine detailed images obtained from a previously performed multiparametric MRI (mpMRI) with the less detailed real-time TRUS, through an overlaid 3D view. The fused images guide the placement of the biopsy needle to suspicious lesions identified from the MRI for prostate biopsy. An example of a US Food & Drug Administration (FDA)-approved MRI/TRUS fusion biopsy platform system is UroNav.

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PET/MRI – PET/MRI combines PET functional imaging simultaneously with MRI soft-tissue morphological imaging to reportedly produce enhanced image quality with a reduced radiation dose and prevention of fusion software image mismatch. A PET/MRI using a hybrid imaging system is suggested for imaging anatomical, biochemical and functional characteristics of disease. The Biograph mMR is an example of a PET/MRI device.

SeeFactor CT3 is a **high-definition 3D volumetric imaging (HDVI)** platform that uses HDVI CT, fluoroscopy and digital radiography. It is proposed for diagnostic, interventional and intraoperative imaging of the head, neck, upper spine, upper and lower extremities.

Single photon emission computed tomography with concurrently acquired CT (SPECT/CT) – SPECT/CT uses radioactive contrast agents and a scanner to record data that a computer constructs into 2D or 3D images. A small amount of radioactive agent is introduced (intravenously or orally) while a scanner measures the emission of single photons to make detailed images of areas inside the body where the radioactive material is taken up by the cells. SPECT provides information about blood flow to tissues and chemical reactions (metabolism) in the body. SPECT and CT images can be fused by software or processed by combined SPECT/CT scanners. It is suggested that incorporating CT data with SPECT images allows improved views of the location and changes in tissue. The Symbia Intevo is an example of a SPECT/CT device.

SPECT/MRI – Simultaneous SPECT and MRI images are fused by software which is suggested to provide improved views of anatomical structures.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **fusion imaging for cancer indications**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria.

Fusion Imaging for Cancer Indications

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 -</u> Particular services excluded from coverage

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
70450	Computed tomography, head or brain; without contrast material	
70460	Computed tomography, head or brain; with contrast material(s)	
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections	
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material	
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)	
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections	
70486	Computed tomography, maxillofacial area; without contrast material	
70487	Computed tomography, maxillofacial area; with contrast material(s)	
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections	
70490	Computed tomography, soft tissue neck; without contrast material	
70491	Computed tomography, soft tissue neck; with contrast material(s)	
70492	Computed tomography, soft tissue neck; without contrast material followed by contrast material(s) and further sections	
71250	Computed tomography, thorax, diagnostic; without contrast material	
71260	Computed tomography, thorax, diagnostic; with contrast material(s)	
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections	
72125	Computed tomography, cervical spine; without contrast material	

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72126	Computed tomography, cervical spine; with contrast material	
72127	Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections	
72128	Computed tomography, thoracic spine; without contrast material	
72129	Computed tomography, thoracic spine; with contrast material	
72130	Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections	
72131	Computed tomography, lumbar spine; without contrast material	
72132	Computed tomography, lumbar spine; with contrast material	
72133	Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections	
72192	Computed tomography, pelvis; without contrast material	
72193	Computed tomography, pelvis; with contrast material(s)	
72194	Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections	
73200	Computed tomography, upper extremity; without contrast material	
73201	Computed tomography, upper extremity; with contrast material(s)	
73202	Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections	
73700	Computed tomography, lower extremity; without contrast material	
73701	Computed tomography, lower extremity; with contrast material(s)	
73702	Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections	
74150	Computed tomography, abdomen; without contrast material	
74160	Computed tomography, abdomen; with contrast material(s)	
74170	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections	
74176	Computed tomography, abdomen and pelvis; without contrast material	
74177	Computed tomography, abdomen and pelvis; with contrast material(s)	
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions	
76380	Computed tomography, limited or localized follow-up study	

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Code(s)	lentified	
HCPCS	Description	Comments
lo code(s) ic	lentified	
Category III Code(s)	Description	Comments
CPT®		
78999	Unlisted miscellaneous procedure, diagnostic nuclear medicine	
78832	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day imaging, or single area imaging over 2 or more days	
78830	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day imaging	
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body	
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh	
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)	
78072	Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization	
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)	
76498	Unlisted magnetic resonance procedure (eg, diagnostic, interventional)	
76497	Unlisted computed tomography procedure (eg, diagnostic, interventional)	

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Change Summary

- 01/01/2024 New Policy.