Cigna Medical Coverage Policies – Radiology Preface to the Imaging Guidelines

Effective February 01, 2024





Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

- 1. The terms of the applicable benefit plan document in effect on the date of service
- 2. Any applicable laws and regulations
- 3. Any relevant collateral source materials including coverage policies
- 4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the <u>Cigna CPT</u> <u>code list</u> for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

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Guideline Development (Preface-1.1)

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- The co-branded Cigna-eviCore healthcare (eviCore) evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging and procedures, including CT, MRI, PET, Gastrointestinal Endoscopy, as well as Cardiac, and musculoskeletal interventions.
- Cigna and eviCore reserve the right to change and update the guidelines. The guidelines undergo a formal review annually. Cigna-eviCore's co-branded guidelines are based on current evidence supported by major national and international association and society guidelines and criteria, peer-reviewed literature, major treatises as well as practicing academic and community-based physicians.
- These guidelines are not intended to supersede or replace sound medical judgment, but instead, should facilitate the identification of the most appropriate imaging or other designated procedure given the individual's clinical condition. These guidelines are written to cover medical conditions as experienced by the majority of individuals. However, these guidelines may not be applicable in certain clinical circumstances, and physician judgment can override the guidelines.
- These guidelines provide evidence-based, clinical benefits with a focus on health care quality and patient safety.
- Clinical decisions, including treatment decisions, are the responsibility of the individual and his/her provider. Clinicians are expected to use independent medical judgment, which takes into account the clinical circumstances to determine individual management decisions.
- Cigna and eviCore supports the Choosing Wisely initiative

 (<u>https://www.choosingwisely.org/</u>) by the American Board of Internal Medicine
 (ABIM) Foundation and many national physician organizations, to reduce the
 overuse of diagnostic tests that are low value, no value, or whose risks are greater
 than the benefits.

Benefits and Coverage Policies (Preface-2)

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• Medical Benefit Plan coverage and eligibility issues may take precedence over these co-branded Cigna-eviCore guidelines.

Medicare Coverage

 See the co-branded Cigna-eviCore Medicaid and Medicare Hierarchy and Application document

Investigational, Experimental, or Unproven Studies

 Certain advanced imaging studies, or other procedures, may be considered investigational, experimental, or unproven if there is a paucity of supporting evidence; if the evidence has not matured to exhibit improved health parameters or; the advanced imaging study/procedure lacks a collective opinion of support.

Clinical and Research Trials

- Clinical trial imaging requests will be considered to determine whether they meet coverage.
- Imaging studies which are inconsistent with established clinical standards, or are requested for data collection and not used in direct clinical management are not supported.

Legislative Mandates

- State and federal legislations may need to be considered in the review of advanced imaging requests. For example:
 - Various State and Federal Breast Density Laws
 - Texas HB 1290 Coronary Calcium CT Law

References (Preface-2)

- Prospective Payment Systems General Information. CMS. https://www.cms.gov/medicare/payment/prospective-payment-systems#:~:text=A%20Prospective %20Payment%20System%20(PPS,on%20a%20predetermined%2C%20fixed%20amount.
- 2. Medicares Coverage With Evidence Development: A Policy-Making Tool in Evolution. *J Oncol Pract.* 2007;3(6):296-301. doi: 10.1200/jop.0763501.
- 3. Coverage of Clinical Trials under the Patient Protection and Affordable Care Act; 42 U.S.C.A. § 300gg-8.

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Clinical Documentation and Age Considerations

- Cigna-eviCore co-branded guidelines use an evidence-based approach to determine the most appropriate procedure for each individual, at the most appropriate time in the diagnostic and treatment cycle. eviCore guidelines are framed by:
 - \circ Clinical presentation of the individual, rather than the studies requested
 - Adequate clinical information that must be submitted to eviCore in order to establish medical necessity for advanced imaging or other designated procedures includes, but is not limited to, the following:
 - Pertinent clinical evaluation should include a recent detailed history, physical examination²⁰ since the onset or change in symptoms, and/or laboratory and prior imaging studies.
 - Condition-specific guideline sections may describe additional clinical information which is required for a pertinent clinical evaluation.
 - The Spine and Musculoskeletal guidelines require x-ray studies from when the current episode of symptoms has started or changed; x-ray imaging does not have to be within the past 60 days.
 - Advanced imaging or other designated procedures should not be ordered prior to clinical evaluation of an individual by the physician treating the individual. This may include referral to a consultant specialist who will make further treatment decisions.
 - Other meaningful technological contact (telehealth visit, telephone or video call, electronic mail or messaging) since the onset or change in symptoms by an established individual can serve as a pertinent clinical evaluation.
 - Some conditions may require a face-to-face evaluation as discussed in the applicable condition-specific guideline sections.
 - A recent clinical evaluation may be unnecessary if the individual is undergoing a guideline-supported, scheduled follow-up imaging or other designated procedural evaluation. Exceptions due to routine surveillance indications are addressed in the applicable condition-specific guideline sections.
 - eviCore's evidence-based approach to determine the most appropriate procedure for each individual requires submission of medical records pertinent to the requested imaging or other designated procedures.
- Many conditions affecting the pediatric population are different diagnoses than those occurring in the adult population. For those diseases which occur in both pediatric and adult populations, minor differences may exist in management due to

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individual age, comorbidities, and differences in disease natural history between children and adults.

- Individuals who are 18 years old or younger¹⁹ should be imaged according to the Pediatric Imaging Guidelines if discussed in the condition-specific guideline sections. Any conditions not specifically discussed in the Pediatric Imaging Guidelines should be imaged according to the General Imaging Guidelines. Individuals who are >18 years old should be imaged according to the General Imaging Guidelines, except where directed otherwise by a specific guideline section.
- The terms "male" and "female" used in these guidelines refer to anatomic-specific diseases and disease predispositions associated with the individual's sex assigned at birth rather than their gender identity. It should be noted that gender identity and anatomic-specific diseases as well as disease predispositions are not always linked. As such, these guidelines should be applied to the individual's corresponding known or suspected anatomic-specific disease or disease predisposition. At eviCore, we believe that it is important to understand how all individuals, including those who are gender-diverse, choose to identify themselves. To ensure that gender-diverse individuals are treated with respect and that decisions impacting their healthcare are made correctly and with sensitivity, eviCore recognizes all individuals with the following gender marker options: Male, Female, Transgender Male, Transgender Female, "X", and "Not Specified."

General Imaging Information

- "Standard" or "conventional" imaging is most often performed in the initial and subsequent evaluations of malignancy. Standard or conventional imaging includes plain film, CT, MRI, or US.
 - Often, further advanced imaging is needed when initial imaging, such as ultrasound, CT, or MRI does not answer the clinical question. Uncertain, indeterminate, inconclusive, or equivocal may describe these situations.
- Appropriate use of contrast is a very important component of evidence-based advanced imaging use.
 - The appropriate levels of contrast for an examination (i.e., without contrast, with contrast, without and with contrast) is determined by the evidence-based guidance reflected in the condition-specific guideline sections.
 - If, during the performance of a non-contrast imaging study, there is the unexpected need to use contrast in order to evaluate a possible abnormality, then that is appropriate.¹

<u>Ultrasound</u>

- Diagnostic ultrasound uses high-frequency sound waves to evaluate soft tissue structures and vascular structures utilizing grey scale and Doppler techniques.
- Ultrasound allows for dynamic real-time imaging at the bedside.
 - \circ Ultrasound is limited in areas where there is dense bone or other calcification.
 - Ultrasound also has a relatively limited imaging window so may be of limited value in evaluating very large abnormalities.

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- In general, ultrasound is highly operator-dependent, and proper training and experience are required to perform consistent, high quality evaluations.
- Indications for ultrasound may include, but are not limited to, the following:
 - o Obstetric and gynecologic imaging
 - \circ Soft tissue and visceral imaging of the chest, abdomen, pelvis, and extremities
 - Brain and spine imaging when not obscured by dense bony structures
 - \circ $\,$ Vascular imaging when not obscured by dense bony structures
 - Procedural guidance when not obscured by dense bony structures
 - Initial evaluation of ill-defined soft tissue masses or fullness and differentiating adenopathy from mass or cyst. Prior to advanced imaging, ultrasound can be very beneficial in selecting the proper modality, body area, image sequences, and contrast level that will provide the most definitive information for the individual.
- More specific guidance for ultrasound usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Computed Tomography (CT)

- The AMA CPT[®] manual does not describe nor assign any minimum or maximum number of sequences for any CT study. CT imaging protocols are often influenced by the individual's clinical situation and additional sequences are not uncommon. There are numerous CT protocols that may be performed to evaluate specific clinical questions, and this technology is constantly undergoing development.
- CT utilizes ionizing radiation to create cross-sectional and volumetric images of the body.
 - Advantages over ultrasound include a much larger field of view and faster completion time in general. Disadvantages compared to ultrasound include lack of portability and exposure to ionizing radiation.
 - Advantages over MRI include faster imaging and a more spacious scanner area limiting claustrophobia. Disadvantages compared to MRI include decreased soft tissue definition, especially with non-contrast imaging, and exposure to ionizing radiation.
- CT can be performed without, with, or without and with intravenous (IV) contrast depending on the clinical indication and body area.
 - In general, non-contrast imaging is appropriate for evaluating structures with significant tissue density differences such as lung parenchyma and bony structures, or when there is a contraindication to contrast.
 - In general, CT with contrast is the most common level of contrast, and can be used when there is need for improved vascular or soft tissue resolution, including better characterization of known or suspected malignancy, as well as infectious and inflammatory conditions.
 - CT without and with contrast has a limited role as the risks of doubling the ionizing radiation exposure rarely outweigh the benefits of multiphasic imaging, though there are some exceptions which include, but are not limited to, the following:

- Characterization of a mass
- Characterization of arterial and venous anatomy
- CT with contrast may be used to better characterize findings on a very recent (within two weeks) inconclusive non-contrast CT where the guidelines would support CT without and with contrast.
- More specific guidance for CT contrast usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.
- Shellfish allergy:
 - It is commonly assumed that an allergy to shellfish indicates iodine allergy, and that this implies an allergy to iodinated contrast media used with CT. However, this is NOT true. Shellfish allergy is due to tropomyosins. Iodine plays no role in these allergic reactions. Allergies to shellfish do not increase the risk of reaction to iodinated contrast media any more than that of other allergens.¹
- Enteric contrast (oral or rectal) is sometimes used in abdominal imaging. There is no specific CPT[®] code which refers to enteric contrast.
- The appropriate contrast level and anatomic region in CT imaging is specific to the clinical indication, as listed in the condition-specific guideline sections.
- CT should not be used to replace MRI in an attempt to avoid sedation, unless it is listed as a recommended study the appropriate condition-specific guideline.
- There are significant potential adverse effects associated with the use of iodinated contrast media. These include hypersensitivity reactions, thyroid dysfunction, and contrast-induced nephropathy (CIN). Individuals with impaired renal function are at increased risk for CIN.²
- Both contrast CT and MRI may be considered to have the same risk profile with renal failure (GFR <30 mL/min).
- The use of CT contrast should proceed with caution in pregnant and breastfeeding individuals. There is a theoretical risk of contrast toxicity to the fetal and infant thyroid. The procedure can be performed if the specific need for that contrast-enhanced procedure outweighs risk to the fetus. Breastfeeding individuals may reduce this risk by choosing to pump and discard breast milk for 12-24 hours after the contrast injection.
- CT without contrast may be appropriate if clinical criteria for CT with contrast are met AND the individual has:
 - o Elevated blood urea nitrogen (BUN) and/or creatinine
 - Renal insufficiency
 - o Allergies to iodinated contrast
 - Thyroid disease which could be treated with I-131
 - o Diabetes
 - Very elderly
 - o Urgent or emergent settings due to availability
 - \circ Trauma
- CT is superior to other imaging modalities in certain conditions including, but not limited to, the following:

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- Screening following trauma
- Imaging pulmonary disease
- \circ $\,$ Imaging abdominal and pelvic viscera
- Imaging of complex fractures
- Evaluation of inconclusive findings on Ultrasound or MRI, or if there is a contraindication to MRI
- More specific guidance for CT usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Magnetic Resonance Imaging (MRI)

- The AMA CPT[®] manual does not describe nor assign any minimum or maximum number of sequences for any MRI study. MRI protocols are often influenced by the individual's clinical situation and additional sequences are not uncommon. There are numerous MRI sequences that may be performed to evaluate specific clinical questions, and this technology is constantly undergoing development.
- Magnetic Resonance Imaging (MRI) utilizes the interaction between the intrinsic radiofrequency of certain Molecules in the body (hydrogen in most cases) and a strong external magnetic field.
 - MRI is often superior for advanced imaging of soft tissues, and can also define physiological processes in some instances (e.g., edema, loss of circulation [AVN], and increased vascularity [tumors]).
 - MRI does not use ionizing radiation, and even non-contrast images have much higher soft tissue definition than CT or Ultrasound.
 - MRI typically takes much longer than either CT or Ultrasound, and for some individuals may require sedation. It is also much more sensitive to individual motion that can degrade image quality than either CT or Ultrasound.
- MRI Breast and MRI Chest are not interchangeable, as they focus detailed sequences on different adjacent body parts.
- MRI may be utilized either as the primary advanced imaging modality, or when further definition is needed based on CT or ultrasound imaging.
- Most orthopedic and dental implants are not magnetic. These include hip and knee replacements; plates, screws, and rods used to treat fractures; and cavity fillings. Yet, all of these metal implants can distort the MRI image if near the part of the body being scanned.
 - Other implants, however, may have contraindications to MRI. These include the following:
 - Pacemakers
 - ICD or heart valves
 - Metal implants in the brain
 - Metal implants in the eyes or ears
 - Infusion catheters and bullets or shrapnel
 - $\circ~$ CT can therefore be an alternative study to MRI in these scenarios.

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- The contrast level and anatomic region in MRI imaging is specific to the clinical indication, as listed in the specific guideline sections.
- MRI utilizing Xenon Xe 129 for contrast is considered investigational and experimental at this time. MRI with or with and without contrast in these guidelines refers to MRI utilizing gadolinium for contrast.
- MRI is commonly performed without, without and with contrast.
 - Non-contrast imaging offers excellent tissue definition.
 - Imaging without and with contrast is commonly used when needed to better characterize tissue perfusion and vascularization.
 - Most contrast is gadolinium based and causes T2 brightening of the vascular and extracellular spaces.
 - Some specialized gadolinium and non-gadolinium contrast agents are available, and most commonly used for characterizing liver lesions.
 - MRI with contrast only is rarely appropriate and is usually used to better characterize findings on a recent inconclusive non-contrast MRI, commonly called a completion study.
 - o MRI contrast is contraindicated in pregnant individuals.
 - More specific guidance for MRI contrast usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.
- MRI may be preferred in individuals with renal failure and in individuals allergic to intravenous CT contrast.
 - $\circ~$ Both contrast CT and MRI may be considered to have the same risk profile with renal failure (GFR <30 mL/min).²
 - Gadolinium can cause Nephrogenic Systemic Fibrosis (NSF). The greater the exposure to gadolinium in individuals with a low GFR (especially if on dialysis), the greater the chance of individuals developing NSF.
 - Multiple studies have demonstrated potential for gadolinium deposition following the use of gadolinium-based contrast agents (GBCAs) for MRI studies.^{3,4,5,6,7} The U.S. Food and Drug Administration (FDA) has noted that there is currently no evidence to suggest that gadolinium retention in the brain is harmful and restricting gadolinium-based contrast agents (GBCAs) use is not warranted at this time. It has been recommended that GBCA use should be limited to circumstances in which additional information provided by the contrast agent is necessary and the necessity of repetitive MRIs with GBCAs should be assessed.⁸
- A CT may be approved in place of an MRI when clinical criteria are met for MRI AND there is a contraindication to having an MRI (pacemaker, ICD, insulin pump, neurostimulator, etc.).
 - \circ $\,$ When replacing MRI with CT, contrast level matching should occur as follows:
 - MRI without contrast → CT without contrast
 - MRI without and with contrast \rightarrow CT with contrast or CT without and with contrast
- The following situations may impact the appropriateness for MRI and or MR contrast:

- \circ Caution should be taken in the use of gadolinium in individuals with renal failure.
- The use of gadolinium contrast agents is contraindicated during pregnancy unless the specific need for that procedure outweighs risk to the fetus.
- MRI can be performed for non-ferromagnetic body metals (i.e., titanium), although some imaging facilities will consider it contraindicated if recent surgery, regardless of the metal type.
- MRI should not be used as a replacement for CT for the sole reason of avoidance of ionizing radiation when MRI is not supported in the condition based guidelines, since it does not solve the problem of overutilization.
- MRI is superior to other imaging modalities in certain conditions including, but not limited to, the following:
 - o Imaging the brain and spinal cord
 - o Characterizing visceral and musculoskeletal soft tissue masses
 - o Evaluating musculoskeletal soft tissues including ligaments and tendons
 - o Evaluating inconclusive findings on ultrasound or CT
 - o Individuals who are pregnant or have high radiation sensitivity
 - o Suspicion, diagnosis, or surveillance of infections
- More specific guidance for MRI usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Positron Emission Tomography (PET)

- PET is a nuclear medicine study that uses a positron emitting radiotracer to create cross-sectional and volumetric images based on tissue metabolism.
- Conventional imaging (frequently CT, sometimes MRI or bone scan) of the affected area(s) drives much of initial and restaging and surveillance imaging for malignancy and other chronic conditions. PET is not indicated for surveillance imaging unless specifically stated in the condition-specific guideline sections.
- PET/MRI is generally not supported, see <u>PET-MRI (Preface-5.3)</u>.
- PET is rarely performed as a single modality, but is typically performed as a combined PET/CT.
 - The unbundling of PET/CT into separate PET and diagnostic CT CPT[®] codes is not supported, because PET/CT is done as a single study.
- PET/CT lacks the tissue definition of CT or MRI, but is fairly specific for metabolic activity based on the radiotracer used.
- Indications for PET/CT may include the following:
 - Oncologic Imaging for evaluation of tumor metabolic activity
 - o Cardiac Imaging for evaluation of myocardial metabolic activity
 - o Brain Imaging for evaluation of metabolic activity for procedural planning
- More specific guidance for PET usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Overutilization of Advanced Imaging

- A number of recent reports describe overutilization in many areas of advanced imaging and other procedures, which may include the following:
 - High-level testing without consideration of less invasive, lower cost options which may adequately address the clinical question at hand
 - \circ $\,$ Excessive radiation and costs with unnecessary testing
 - o Defensive medical practice
 - CT without and with contrast (so called "double contrast studies") requests, which have few current indications
 - MRI requested in place of CT to avoid radiation without considering the primary indication for imaging
 - o Adult CT settings and protocols used for smaller people and children
 - Unnecessary imaging procedures when the same or similar studies have already been conducted
- A review of the imaging or other relevant procedural histories of all individuals presenting for studies has been recognized as one of the more important processes that can be significantly improved. By recognizing that a duplicate or questionably indicated examination has been ordered for individuals, it may be possible to avoid exposing them to unnecessary risks.^{9,10} To avoid these unnecessary risks, the precautions below should be considered:
 - The results of initial diagnostic tests or radiologic studies to narrow the differential diagnosis should be obtained prior to performing further tests or radiologic studies.
 - The clinical history should include a potential indication such as a known or suspected abnormality involving the body part for which the imaging study is being requested. These potential indications are addressed in greater detail within the applicable guidelines.
 - The results of the requested imaging procedures should be expected to have an impact on individual management or treatment decisions.
 - Repeat imaging studies are not generally necessary unless there is evidence of disease progression, recurrence of disease, and/or the repeat imaging will affect an individual's clinical management.
- Pre-operative imaging/pre-surgical planning imaging/pre-procedure imaging is considered not medically necessary if the surgery/procedure is not considered medically necessary. Once the procedure has been approved or if the procedure does not require prior authorization, the appropriate pre-procedural imaging may be approved.

References (Preface-3)

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- 1. Bettmann MA. Frequently Asked Questions: Iodinated Contrast Agents. *RadioGraphics*. 2004;24(suppl_1):S3-S10. doi: 10.1148/rg.24si045519.
- 2. Andreucci M, Solomon R, Tasanarong A. Side Effects of Radiographic Contrast Media: Pathogenesis, Risk Factors, and Prevention. *BioMed Res Int.* 2014;2014:1-20. doi: 10.1155/2014/741018.
- McDonald RJ, McDonald JS, Kallmes DF, et al. Intracranial Gadolinium Deposition after Contrastenhanced MR Imaging. *Radiology*. 2015;275(3):772-782. doi: 10.1148/radiol.15150025.
- 4. Kanda T, Ishii K, Kawaguchi H, Kitajima K, Takenaka D. High Signal Intensity in the Dentate Nucleus and Globus Pallidus on Unenhanced T1-weighted MR Images: Relationship with Increasing Cumulative Dose of a Gadolinium-based Contrast Material. *Radiology*. 2014;270(3):834-841. doi: 10.1148/radiol.13131669.
- 5. Olchowy C, Cebulski K, Łasecki M, et al. The presence of the gadolinium-based contrast agent depositions in the brain and symptoms of gadolinium neurotoxicity A systematic review. Mohapatra S, ed. *PLOS ONE*. 2017;12(2):e0171704. doi: 10.1371/journal.pone.0171704.
- 6. Ramalho J, Castillo M, AlObaidy M, et al. High Signal Intensity in Globus Pallidus and Dentate Nucleus on Unenhanced T1-weighted MR Images: Evaluation of Two Linear Gadolinium-based Contrast Agents. *Radiology*. 2015;276(3):836-844. doi:10.1148/radiol.2015150872.
- Radbruch A, Weberling LD, Kieslich PJ, et al. Intraindividual Analysis of Signal Intensity Changes in the Dentate Nucleus After Consecutive Serial Applications of Linear and Macrocyclic Gadolinium-Based Contrast Agents. *Invest Radiol.* 2016;51(11):683-690. doi: 10.1097/rli.000000000000308.
- 8. FDA Warns That Gadolinium-Based Contrast Agents (GBCAs) Are Retained in the Body; Requires New Class Warnings. https://www.fda.gov/media/109825/download.
- 9. Amis ES, Butler PF, Applegate KE, et al. American College of Radiology White Paper on Radiation Dose in Medicine. *J Am Coll Radiol*. 2007;4(5):272-284. doi: 10.1016/j.jacr.2007.03.002.
- 10. Powell AC, Long JW, Kren EM, Gupta AK, Levin DC. Evaluation of a Program for Improving Advanced Imaging Interpretation. *J Patient Saf.* 2019;15(1):69-75. doi: 10.1097/PTS.000000000034.5.
- 11. FDA. White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. Page Last Updated: 06/14/2019. https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ RadiationDoseReduction/ucm199994.htm.
- 12. Update on FDA approach to safety issue of gadolinium retention after administration of gadolinium-based contrast agents. https://www.fda.gov/media/116492/download.
- Blumfield E, Swenson DW, Iyer RS, Stanescu AL. Gadolinium-based contrast agents review of recent literature on magnetic resonance imaging signal intensity changes and tissue deposits, with emphasis on pediatric patients. *Pediatr Radiol*. 2019;49(4):448-457. doi: 10.1007/s00247-018-4304-8.
- American College of Radiology. ACR SPR SRU Parameter for the Performing and Interpreting Diagnostic Ultrasound Examinations. Revised 2017. (Resolution 32). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Perf-Interpret.pdf.
- American College of Radiology. ACR–SPR Practice Parameter for Performing FDG-PET/CT in Oncology. Revised 2021. (Resolution 20). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/ FDG-PET-CT.pdf.
- 16. American College of Radiology. ACR PRACTICE Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI). Revised 2017. (Resolution 10). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Perf-Interpret.pdf.
- American College of Radiology. ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT). Revised 2017. (Resolution 22). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CT-Perf-Interpret.pdf.
- Lohrke J, Frenzel T, Endrikat J, et al. 25 Years of Contrast-Enhanced MRI: Developments, Current Challenges and Future Perspectives. Adv Ther. 2016;33(1):1-28. doi: 10.1007/s12325-015-0275-4.
- 19. Implementation Guide: Medicaid State Plan Eligibility Eligibility Groups Mandatory Coverage Infants and Children under Age 19. Available at: https://www.hhs.gov/guidance/document/implementation-guide-medicaid-state-plan-eligibility-eligibility-groups-aeu-mandatory-2.
- 20. History and Physicals Understanding the Requirements. Available at: https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/provision-of-caretreatment-and-services-pc/000002272/.
- 21. Mammarappallil JG, Rankine L, Wild JM, Driehuys B. New Developments in Imaging Idiopathic Pulmonary Fibrosis With Hyperpolarized Xenon Magnetic Resonance Imaging. *J Thorac Imaging*. 2019;34(2):136-150. doi: 10.1097/rti.000000000000392.
- 22. Wang JM, Robertson SH, Wang Z, et al. Using hyperpolarized 129Xe MRI to quantify regional gas transfer in idiopathic pulmonary fibrosis. *Thorax*. 2017;73(1):21-28. doi: 10.1136/thoraxjnl-2017-210070.

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3D Rendering (Preface-4.1)

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CPT[®] 76376 and CPT[®] 76377:

- CPT® 76376 and CPT® 76377 do not require prior authorization through eviCore.
- Both codes require concurrent supervision of the image post-processing 3D manipulation of the volumetric data set and image rendering.
 - Concurrent supervision is defined as active physician participation in and monitoring of the reconstruction process including design of the anatomic region that is to be reconstructed; determination of the tissue types and actual structures to be displayed (e.g., bone, organs, and vessels); determination of the images or cine loops that are to be archived; and monitoring and adjustment of the 3D work product. The American College of Radiology (ACR) recommends that it is best to document the physician's supervision or participation in the 3D reconstruction of images.
- These two codes differ in the need for and use of an independent workstation for post-processing.
 - CPT[®] 76376 reports procedures not requiring image post-processing on an independent workstation.
 - CPT[®] 76377 reports procedures that require image post-processing on an independent workstation.
- These 3D rendering codes should not be used for 2D reformatting.
- Two-dimensional reconstruction (e.g. reformatting an axial scan into the coronal plane) is now included in all cross-sectional imaging base codes and is not separately reimbursable.
- CPT[®] codes for 3D rendering should not be billed in conjunction with computeraided detection (CAD), MRA, CTA, nuclear medicine SPECT studies, PET, PET/CT, Mammogram, MRI Breast, US Breast, CT Colonography (virtual colonoscopy), Cardiac MRI, Cardiac CT, or Coronary CTA studies.
- CPT® 76377 (3D rendering requiring image post-processing on an independent workstation) can be considered in the following clinical scenarios:
 - Bony conditions: 0
 - Evaluation of congenital skull abnormalities in newborns, infants, and • toddlers (usually for preoperative planning)
 - Complex fractures (comminuted or displaced)/dislocations of any joint (For preoperative planning when conventional imaging is insufficient)
 - Spine fractures, pelvic/acetabulum fractures, intra-articular fractures (For preoperative planning when conventional imaging is insufficient)
 - Preoperative planning for other complex surgical cases
 - Complex facial fractures
 - Preoperative planning for other complex surgical cases

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- Cerebral angiography
- Pelvis conditions:
 - Uterine intra-cavitary lesion when initial US is equivocal (See <u>Abnormal</u> <u>Uterine Bleeding (AUB) (PV-2.1)</u> and <u>Leiomyoma/Uterine Fibroids (PV-12.1)</u> in the Pelvis Imaging Guidelines)
 - Hydrosalpinxes or peritoneal cysts when initial US is indeterminate (See <u>Complex Adnexal Masses (PV-5.3)</u> in the Pelvis Imaging Guidelines)
 - Lost IUD (inability to feel or see IUD string) with initial US (See <u>Intrauterine</u> <u>Device (PV-10.1)</u> in the Pelvis Imaging Guidelines)
 - Uterine anomalies with initial US (See <u>Uterine Anomalies (PV-14.1)</u> in the Pelvis Imaging Guidelines)
 - Infertility (See <u>Initial Infertility Evaluation, Female (PV-9.1)</u> in the Pelvis Imaging Guidelines)
- Abdomen conditions:
 - CT Urogram (See <u>Hematuria and Hydronephrosis (AB-39)</u> in the Abdomen Imaging Guidelines)
 - MRCP (See <u>MR Cholangiopancreatography (MRCP) (AB-27)</u> in the Abdomen Imaging Guidelines)

Unlisted Procedures/Therapy Treatment Planning (Preface-4.3)

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CPT®	Description
76497	Unlisted CT procedure (e.g., diagnostic or interventional)
76498	Unlisted MR procedure (e.g., diagnostic or interventional)
78999	Unlisted procedure, diagnostic nuclear medicine

- These unlisted codes should be reported whenever a diagnostic or interventional CT or MR study is performed in which an appropriate anatomic site-specific code is not available.
 - A Category III code that describes the procedure performed must be reported rather than an unlisted code if one is available.
- CPT[®] 76497 or CPT[®] 76498 (Unlisted CT or MRI procedure) can be considered in the following clinical scenarios:
 - Studies done for navigation and planning for neurosurgical procedures (i.e., Stealth or Brain Lab Imaging)^{1,2}
 - Custom joint arthroplasty planning (not as an alternative recommendation: See Osteoarthritis (MS-12.1) in the Musculoskeletal Imaging Guidelines.
 - Any procedure/surgical planning if thinner cuts or different positional acquisition (than those on the completed diagnostic study) are needed. These could include navigational bronchoscopy. See <u>Navigational Bronchoscopy (CH-1.7)</u> in the Chest Imaging Guidelines.

Therapy Treatment Planning

 Radiation Therapy Treatment Planning: See <u>Unlisted Procedure Codes in</u> <u>Oncology (ONC-1.5)</u> In the Oncology Imaging Guidelines.

Unilateral Versus Bilateral Breast MRI (Preface-4.4)

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 Diagnostic MRI of both breasts should be coded as CPT[®] 77049 regardless of whether both breasts are imaged simultaneously or whether unilateral breast MRI is performed in two separate imaging sessions.

CPT[®] 76380 Limited or Follow-up CT (Preface-4.5)

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- CPT[®] 76380 describes a limited or follow-up CT scan. The code is used to report any CT scan, for any given area of the body, in which the work of a full diagnostic code is not performed.
- Common examples include, but are not limited to, the following:
 - Limited sinus CT imaging protocol
 - o Limited or follow-up slices through a known pulmonary nodule
 - Limited slices to assess a non-healing fracture (such as the clavicle)
- Limited CT (CPT[®] 76380) is not indicated for treatment planning purposes. See <u>Unlisted Procedure Codes in Oncology (ONC-1.5)</u> in the Oncology Imaging Guidelines.
- It is inappropriate to report CPT[®] 76380, in conjunction with other diagnostic CT codes, to cover 'extra slices' in certain imaging protocols.
 - There is no specific number of sequences or slices defined in any CT CPT[®] code definition.
 - The AMA, in *CPT*[®] 2019, does not describe nor assign any minimum or maximum number of sequences or slices for any CT study.
 - A few additional slices or sequences are not uncommon.
 - CT imaging protocols are often influenced by the individual's clinical situation. Sometimes the protocols require more time and sometimes less.

CPT[®] 76140 Interpretation of an Outside Study (Preface-4.7)

PRF.CD.0004.7.A v1.0.2024

- It is inappropriate to use diagnostic imaging codes for interpretation of a previously performed exam that was completed at another facility.
 - If the outside exam is being used for comparison with a current exam, the diagnostic code for the current examination includes comparison to the prior study.⁴
 - CPT[®] 76140 is the appropriate code to use for an exam which was completed elsewhere and a secondary interpretation of the images is requested.⁵
 - Medicare, as well as many other payors do not reimburse CPT[®] 76140 and their coverage policies take precedence over eviCore's guidelines.

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Quantitative MR Analysis of Tissue Composition (Preface-4.8)

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- Category III CPT[®] codes for quantitative analysis of multiparametric-MR (mp-MRI) data with and without an associated diagnostic MRI have been established. Quantitative mp-MRI uses software to analyze tissue physiology of visceral organs and other anatomic structures non-invasively. At present, these procedures are primarily being used in clinical trials and there is no widely recommended indications in clinical practice. As such, these procedures are considered to be investigational and experimental for coverage purposes.
 - CPT[®] 0648T (without diagnostic MRI) and CPT[®] 0649T (with diagnostic MRI) refer to data analysis with and without associate imaging of a single organ, with its most common use being LiverMultiScan (LMS).
 - See <u>Fatty Liver (AB-29.2)</u> in the Abdomen Imaging Guidelines.
 - CPT[®] 0697T (without diagnostic MRI) and CPT[®] 0698T (with diagnostic MRI) refer to data analysis with and without associate imaging of a multiple organs, with its most common use being CoverScan.

HCPCS Codes (Preface-4.9)

PRF.CD.0004.9.A

- Healthcare Common Procedure Coding System (HCPCS) codes are utilized by some hospitals in favor of the typical Level-III CPT[®] codes. These codes are typically 4 digits preceded by a C or S.⁶
 - Many of these codes have similar code descriptions to Level-III CPT[®] codes (i.e., C8931 – MRA with dye, Spinal Canal; and, CPT[®] 72159 – MRA Spinal Canal).
 - If cases are submitted with HCPCS codes with similar code descriptions to the typical Level-III CPT[®] codes, those procedures should be managed in the same manner as the typical CPT[®] codes.
 - $\circ~$ Medicare does not support approval of "S" HCPCS codes.
 - HCPCS code management is discussed further in the applicable guideline sections.
- Requests for many Healthcare Common Procedure Coding System (HCPCS) codes, including non-specific codes such as S8042 (Magnetic resonance imaging [MRI], low-field), should be redirected to a more appropriate and specific CPT[®] code. Exceptions are noted in the applicable guideline sections.

References (Preface-4)

- Society of Nuclear Medicine and Molecular Imaging Coding Corner. Available at: http://www.snmmi.org/ClinicalPractice/CodingCornerPT.aspx?ItemNumber=1786.
- 2. Intraoperative MR. Brainlab. Available at: https://www.brainlab.com/surgery-products/overview-neurosurgery-products/intraoperative-mr/
- 3. Experience the Advanced 3D Sinus Surgery Planning with Scopis Building Blocks planning software. Scopis Planning. Available at: http://planning.scopis.com/.
- 4. ACR Radiology Coding Source[™] March-April 2007 Q and A. Available at: https://www.acr.org/Advocacyand-Economics/Coding-Source/ACR-Radiology-Coding-Source-March-April-2007-Q-and-A.
- 5. Chung CY, Alson MD, Duszak R, Degnan AJ. From imaging to reimbursement: what the pediatric radiologist needs to know about health care payers, documentation, coding and billing. *Pediatr Radiol.* 2018;48(7):904-914. doi: 10.1007/s00247-018-4104-1.
- 6. HCPCS General Information from CMS.gov. Available at: www.cms.gov/medicare/coding/medhcpcsgeninfo.

Whole-Body Imaging (Preface-5)

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Whole-Body CT Imaging (Preface-5.1)

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- Whole-body CT or LifeScan (CT Brain, Chest, Abdomen, and Pelvis) for screening of asymptomatic individuals is not a covered benefit. The performance of wholebody screening CT examinations in healthy individuals does not meet any of the current validity criteria for screening studies and there is no clear documentation of benefit versus radiation risk.
- Whole-body low-dose CT is supported for oncologic staging in Multiple Myeloma. See <u>Multiple Myeloma and Plasmacytomas (ONC-25)</u> in the Oncology Imaging Guidelines.

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Whole-Body MR Imaging (Preface-5.2)

PRF.WB.0005.2.A

- Whole-body MRI (WBMRI) is, with the exception of select cancer predisposition syndromes and autoimmune conditions discussed below, generally not supported at this time due to lack of standardization in imaging technique and lack of evidence that WBMRI improves outcome for any individual disease state.
 - While WBMRI has the benefit of whole-body imaging and lack of radiation exposure, substantial variation still exists in the number of images, type of sequences (STIR vs. diffusion weighting, for example), and contrast agent(s) used.
- Coding considerations:
 - There are no established CPT[®] or HCPCS codes for reporting WBMRI.
 - WBMRI is at present only reportable using CPT[®] 76498. All other methods of reporting whole-body MRI are inappropriate including the following:
 - Separate diagnostic MRI codes for multiple individual body parts
 - MRI Bone Marrow Supply (CPT[®] 77084)
- Disease-specific considerations:
 - \circ $\,$ Cancer screening:
 - Interval WBMRI is recommended for cancer screening in individuals with select cancer predisposition syndromes. Otherwise, WBMRI has not been shown to improve outcomes for cancer screening.
 - For additional information, see <u>Li-Fraumeni Syndrome (LFS)</u> (PEDONC-2.2), <u>Hereditary Paraganglioma-Pheochromocytoma</u> (HPP) Syndromes (PEDONC-2.13), or <u>Constitutional Mismatch</u> <u>Repair Deficiency (CMMRD or Turcot Syndrome) (PEDONC-2.15)</u> in the Pediatric Oncology Imaging Guidelines.
 - Cancer staging and restaging:
 - While the feasibility of WBMRI has been established, data remain conflicting on whether WBMRI is of equivalent diagnostic accuracy compared with standard imaging modalities such as CT, scintigraphy, and PET imaging. Evidence has not been published establishing WBMRI as a standard evaluation for any type of cancer.
 - Autoimmune disease:
 - WBMRI can be approved in some situations for individuals with chronic recurrent multifocal osteomyelitis.
 - For additional information, see <u>Chronic Recurrent Multifocal</u> <u>Osteomyelitis (PEDMS-10.2)</u> in the Pediatric Musculoskeletal Imaging Guidelines.

PET-MRI (Preface-5.3)

PRF.WB.0005.3.A

- PET-MRI is generally not supported for a vast majority of oncologic and neurologic conditions due to lack of standardization in imaging technique and interpretation. However, it may be appropriate in select circumstances when the following criteria are met:
 - $\circ~$ The individual meets guideline criteria for PET-CT, AND
 - o PET-CT is not available at the treating institution, AND
 - The provider requests PET-MRI in lieu of PET-CT
- When the above criteria are met, PET-MRI may be reported using the code combination of PET Whole-Body (CPT[®] 78813) and MRI Unlisted (CPT[®] 76498). All other methods of reporting PET-MRI are inappropriate.
 - When clinically appropriate, diagnostic MRI codes may be indicated at the same time as the PET-MRI code combination.
- For more information, see <u>PET Imaging in Pediatric Oncology (PEDONC-1.4)</u> in the Pediatric Oncology Imaging Guidelines, and <u>PET Brain Imaging (PEDHD-2.3)</u> and <u>Special Imaging Studies in Evaluation for Epilepsy Surgery (PEDHD-6.3)</u> in the Pediatric Head Imaging Guidelines.

References (Preface-5)

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- 1. Villani A, Tabori U, Schiffman J, et al. Biochemical and imaging surveillance in germline TP53 mutation carriers with Li-Fraumeni syndrome: a prospective observational study. *Lancet Oncol.* 2011;12(6):559-567. doi: 10.1016/S1470-2045(11)70119-X.
- Siegel MJ, Acharyya S, Hoffer FA, et al. Whole-Body MR Imaging for Staging of Malignant Tumors in Pediatric Patients: Results of the American College of Radiology Imaging Network 6660 Trial. *Radiology*. 2013;266(2):599-609. doi: 10.1148/radiol.12112531.
- 3. Antoch G. Whole-Body Dual-Modality PET/CT and Whole-Body MRI for Tumor Staging in Oncology. *JAMA*. 2003;290(24):3199. doi: 10.1001/jama.290.24.3199.
- 4. Lauenstein TC, Semelka RC. Emerging techniques: Whole-body screening and staging with MRI. *J Magn Reson Imaging*. 2006;24(3):489-498. doi: 10.1002/jmri.20666.
- 5. Khanna G, Sato TSP, Ferguson P. Imaging of Chronic Recurrent Multifocal Osteomyelitis. *RadioGraphics*. 2009;29(4):1159-1177. doi: 10.1148/rg.294085244.
- Ferguson PJ, Sandu M. Current Understanding of the Pathogenesis and Management of Chronic Recurrent Multifocal Osteomyelitis. *Curr Rheumatol Rep.* 2012;14(2):130-141. doi: 10.1007/s11926-012-0239-5.
- 7. National Comprehensive Cancer Network[®] (NCCN[®]). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]): Genetic/Familial High Risk Assessment: Breast, Ovarian, and Pancreatic. Version 3.2023. February 13, 2023. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic V.3.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed July 10, 2023. The NCCN Guidelines[®] and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines[®] go online to NCCN.org.

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- Complete reference citations for the journal articles are embedded within the body of the guidelines and/or may be found on the Reference pages at the end of some guideline sections.
- The website addresses for certain references are included in the body of the guidelines but are not hyperlinked to the actual website.
- The website address for the American College of Radiology (ACR) Appropriateness Criteria[®] is <u>http://www.acr.org</u>.

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