Preface to the Imaging Guidelines

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Clinical Decision Support Tool
for Advanced Diagnostic Imaging

Common symptoms and symptom complexes are addressed by this tool. Imaging requests for patients with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician may provide additional insight.

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Preface-1~Guideline Development

The Medical Guidelines Institute (MGI) evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging procedures, including CT, MRI, PET, and other Cardiac imaging procedures.

The MGI reserves the right to change and update these guidelines. The guidelines undergo a formal review annually. These MGI guidelines are based upon major national and international association and society guidelines and criteria, peer-reviewed literature, major treatises as well as input from 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 procedure given the patient’s clinical condition. These guidelines are written to cover medical conditions as experienced by the majority of patients. However, these guidelines may not be applicable in certain clinical circumstances, and physician judgment can override the guidelines.

Clinical decisions, including treatment decisions, are the responsibility of the patient and his/her provider. Clinicians are expected to use independent medical judgment which takes into account the clinical circumstances to determine patient management decisions.

The MGI supports the Choosing Wisely initiative (www.choosingwisely.org) 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.

Preface-2~Benefits, Coverage Policies, and Eligibility Issues

For Medicare and Medicare Advantage enrollees, the benefits, eligibility issues and coverage policies of CMS (Centers for Medicare and Medicaid Services), including National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) may take precedence over the MGI guidelines.

Investigational and Experimental Studies
Certain imaging studies described in these guidelines may be considered investigational by CMS and those coverage policies may take precedence over the MGI guidelines. Certain advanced imaging studies, or other procedures, may be considered investigational and experimental 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
Some investigational and experimental imaging studies which are being performed in a CMS approved clinical trial may meet the CMS requirements for coverage.
Preface-3~Clinical Information

The MGI guidelines use an evidence-based approach to determine the most appropriate imaging procedure for each patient, at the most appropriate time in the diagnostic and treatment cycle. The MGI guidelines direct by:

- Clinical presentation of the patient, not by the studies requested
- Current evaluation (within 60 days), to include any of the following: a recent detailed history, physical examination, or appropriate laboratory studies. 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 should not be ordered prior to clinical evaluation of a patient by the physician treating the individual. This may include referral to Consultant Specialist who will make further treatment decisions.
- Other meaningful contact (telephone call, electronic mail or messaging) by an established patient can substitute for a face-to-face clinical evaluation.
- Certain routine indications can be considered without documented contact, which include:
  - Lung nodule follow-up (CH-16.1 SPN – Imaging)
  - Annual breast MRI for High Risk (CH-25.5 Breast MRI Indications)
  - Cardiac repeat testing (CD-1.4 Stress Testing with Imaging – Indications)
  - Oncology surveillance imaging
  - Thoracic Aortic Aneurysm (CH-30.2 Thoracic Aortic Aneurysm)
- Fever can be considered in excess of normal range (oral 36.5–37.5°C or 97.7–99.5°F)
- This evaluation may include non-advanced imaging modalities (chest x-ray, EKG, EMG, etc.), prior patient records and be through other means on meaningful contact (telephone call, electronic mail or messaging) in an established patient.
- Reference is made to a potential indication and an abnormality of that body part for the requested imaging study(ies).
- Patient management or treatment decisions is affected by the requested imaging study(ies)
- Sequential approach to obtaining imaging studies, that is, awaiting the results of initial tests or radiologic studies to rule in or out an entity on the differential diagnosis prior to obtaining further tests or radiologic studies
  - Often, further advanced imaging is needed when initial imaging, such as ultrasound or CT does not answer the clinical question. Uncertain, indeterminate, inconclusive or equivocal may describe these situations.
  - Except, decisions for advanced imaging of patients requiring anesthesia or sedation should take into account risks of that anesthesia or sedation and
therefore consider more expansive imaging needs in order to avoid a secondary imaging session(s).

- Repeat advanced imaging study(ies) are not generally needed unless there is evidence for progression of disease, new onset of disease, and/or how repeat imaging will affect patient management or treatment decisions.

**Imaging – General Process**

Standard” or “conventional” imaging is most often performed in the initial and subsequent evaluations of malignancy. Standard or conventional imaging includes plain film, CT, MR or US.

**Imaging Contrast Media**

Contrast is the second important component, along with the advanced imaging modality (refer to specific guideline contrast section)

If, during the performance of a non-contrast imaging study, there is the need to use contrast in order to evaluate a possible abnormality, then that is appropriate.¹

**Imaging – Metal devices or implants**

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 be contraindications to MRI. These include pacemakers, ICD or heart valves; metal implants in the brain; metal implants in the eyes or ears; infusion catheters and bullets or shrapnel. CT can therefore be an alternative study to MRI in these scenarios.

**Computed Tomography (CT):**

- CT can be performed without contrast, with contrast or without and with contrast depending on the clinical indication and body part.
- CT without contrast maybe appropriate if clinical criteria are met AND if a patient has elevated BUN and/or creatinine, renal insufficiency, renal failure, and allergies to iodinated CT contrast or thyroid disease.
  - CT contrast can cause contrast induced nephropathy (defined as contrast induced renal failure). Patients with impaired renal function are at increased risk.
  - 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 breast feeding patients. There is a theoretical risk of contrast to the fetal and infant thyroid. The procedure can be performed if the specific need for that procedure outweighs risk to the fetus. Breast feeding patients may pump and discard breast milk for 12-24 hours after the contrast injection.

**Magnetic Resonance Imaging (MRI):**
MR imaging may be utilized through these guidelines, when further definition is needed based on CT imaging.

MRI imaging may be preferred in cases of renal failure, and in patients allergic to intravenous CT contrast.

- Both contrast CT and MRI may be considered to have the same risk profile with renal failure (GFR < 30 mL/min).
- Gadolinium can cause Nephrogenic Systemic Fibrosis (NSF). The greater the number exposure of gadolinium in patients with a low GFR (especially if on dialysis), the greater the chance of NSF.

- A CT (contrast mirrors what is appropriate for MRI) 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.)
  - Caution should be taken in the use of gadolinium in clients 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 not ferromagnetic body metals, although and some imaging facilities will consider if recent surgery regardless of the metal type.

- MRI should not be used as a replacement for CT, for the reason of lack of ionizing radiation, especially when the indication does not meet these Guidelines. Since it does not solve the problem of over-utilization.

**Overutilization of Advanced Imaging:**
An increasing number of current reports describe over-utilization in all areas of advanced imaging, which may include:

- High level testing without consideration of lesser invasive, lesser cost and low technology options
- Excessive radiation and costs with unnecessary testing
- Defensive medical practice
- CT without and with contrast (so called “double contrast studies) requesting, which are needed less often
- MRI trading in place of CT scanning to avoid radiation without considering the primary need for imaging
- Standard adult CT settings used for smaller people

**Reference**
Preface-4~Coding Issues

Preface-4.1 3D Rendering

CPT®76376 and CPT®76377:
✓ Both of these codes share the following text in their definitions: “3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound or other tomographic modality.”
✓ Both codes require concurrent supervision of the image post-processing 3D manipulation of the volumetric data set and image rendering.
✓ These two codes differ in the need for and use of an independent workstation for post-processing.
  o CPT®76376 reports procedures not requiring image post-processing on an independent workstation.
  o 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.
✓ The codes used to report 3D rendering for ultrasound and echocardiography are also used to report the 3D post processing work on CT, MRI, and other tomographic modalities.
✓ CPT® codes for 3D rendering should not be billed in conjunction with computer-aided detection (CAD), MRA, CTA, nuclear medicine SPECT studies, PET, PET/CT, CT colonography (virtual colonoscopy), cardiac MRI, cardiac CT, or coronary CTA studies.
  o **NOTE:** Specifically, providers performing CAD, in conjunction with breast MRI, should report the service with Category III code 0159T, not one of the 3D codes.
✓ In general, the MGI maintains that CPT®76376 (3D rendering not requiring image post-processing on an independent workstation) should not be separately reimbursed, since this function is built into the imaging software and generally takes less than 15 minutes to perform.
✓ The routine use of 3D and 4D rendering (post-processing) in conjunction with ultrasound is considered investigational.
✓ CPT®76377 (3D rendering requiring image post-processing on an independent workstation) can be considered in the following clinical scenarios:
  o Evaluation of congenital skull abnormalities in babies/toddlers (usually for preoperative planning)
  o Complex joint fractures or pelvis fractures
  o Spine fractures (usually for preoperative planning)
  o Complex facial fractures
  o Preoperative planning for other complex surgical cases
Preface-4.2 CT-, MR-, or Ultrasound-Guided Procedures

✓ CT, MR, and Ultrasound guidance procedure codes contain all the imaging necessary to guide a needle or catheter. It is inappropriate to routinely bill a diagnostic procedure code in conjunction with a guidance procedure code.
  ○ For example, a diagnostic breast MRI code (CPT®77058 or CPT®77059) should not be billed in conjunction with an MR guidance code CPT®77021) unless a separate diagnostic breast MRI was ordered by the referring physician, medically necessary, and the findings are clearly documented on a separate radiology report (or in a separate section).

✓ Imaging studies performed as part of a CT-, MR-, or Ultrasound-guided procedure should be reported using the CPT® codes in the following table.
  ○ For example, MR-guided breast biopsy should be coded as CPT®77021 and not as CPT®77058 or CPT®77059

<table>
<thead>
<tr>
<th>CPT®</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>75989</td>
<td>Imaging guidance for percutaneous drainage with placement of catheter (all modalities)</td>
</tr>
<tr>
<td>77011</td>
<td>CT guidance for stereotactic localization</td>
</tr>
<tr>
<td>77012</td>
<td>CT guidance for needle placement</td>
</tr>
<tr>
<td>77013</td>
<td>CT guidance for, and monitoring of parenchymal tissue ablation</td>
</tr>
<tr>
<td>77021</td>
<td>MR guidance for needle placement</td>
</tr>
<tr>
<td>77022</td>
<td>MR guidance for, and monitoring of parenchymal tissue ablation</td>
</tr>
<tr>
<td>76942</td>
<td>Ultrasonic guidance for needle placement</td>
</tr>
</tbody>
</table>

CPT®75989:
✓ This code is used to report imaging guidance for a percutaneous drainage procedure in which a catheter is left in place.
✓ This code can be used to report whether the drainage catheter is placed under fluoroscopy, ultrasound, CT, or MR guidance modality.

CPT®77011:
A stereotactic CT localization scan is frequently obtained prior to sinus surgery. The dataset is then loaded into the navigational workstation in the operating room for use during the surgical procedure. The information provides exact positioning of surgical instruments with regard to the patient’s 3D CT images.
✓ In most cases, the preoperative CT is a technical-only service that does not require interpretation by a radiologist.
  ○ The imaging facility should report CPT®77011 when performing a scan not requiring interpretation by a radiologist.
  ○ If a diagnostic scan is performed and interpreted by a radiologist, the appropriate diagnostic CT code (e.g., CPT®70486) should be used.
It is not appropriate to report both CPT®70486 and CPT®77011 for the same CT stereotactic localization imaging session.

3D Rendering (CPT®76376 or CPT®76377) should not be reported in conjunction with CPT®77011 (or CPT®70486 if used). The procedure inherently generates a 3D dataset.

CPT®77012 (CT) and CPT®77021 (MR):
These codes are used to report imaging guidance for needle placement during biopsy, aspiration, and other percutaneous procedures.

✓ They represent the radiological supervision and interpretation of the procedure and are often billed in conjunction with surgical procedure codes.

○ For example, CPT®77012 is reported when CT guidance is used to place the needle for a conventional arthrogram.

○ Only codes representing percutaneous surgical procedures should be billed with CPT®77012 and CPT®77021. It is inappropriate to use with surgical codes for open, excisional, or incisional procedures.

CPT®77013 (CT) and CPT®77022 (MR):

✓ These codes include the initial guidance to direct a needle electrode to the tumor(s), monitoring for needle electrode repositioning within the lesion, and as necessary for multiple ablations to coagulate the lesion and confirmation of satisfactory coagulative necrosis of the lesion(s) and comparison to pre-ablation images.

○ **NOTE:** CPT®77013 should only be used for non-bone ablation procedures.

○ CPT®20982 includes CT guidance for bone tumor ablations.

○ Only codes representing percutaneous surgical procedures should be billed with CPT®77013 and CPT®77022. It is inappropriate to use with surgical codes for open, excisional, or incisional procedures.

✓ CPT®77012 and CPT®77021 (as well as guidance codes CPT®76942 [US], and CPT®77002-CPT®77003 [fluoroscopy]) describe radiologic guidance by different modalities.

○ Only one unit of any of these codes should be reported per patient encounter (date of service). The unit of service is considered to be the patient encounter, not the number of lesions, aspirations, biopsies, injections, or localizations.

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**Preface-4.3 Unlisted Procedures/Therapy Treatment Planning**

<table>
<thead>
<tr>
<th>CPT®</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>76497</td>
<td>Unlisted CT procedure (e.g., diagnostic or interventional)</td>
</tr>
<tr>
<td>76498</td>
<td>Unlisted MR procedure (e.g., diagnostic or interventional)</td>
</tr>
<tr>
<td>78999</td>
<td>Unlisted procedure, diagnostic nuclear medicine</td>
</tr>
</tbody>
</table>

✓ In the absence of written payor instructions, 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.

**Therapy Treatment Planning**

**Radiation Therapy Treatment Planning:**

- In the absence of written payer guidelines, imaging performed in support of radiation therapy treatment planning should be reported with the following codes: (CPT®76497 or CPT®77014 for CT, CPT®76498 for MRI, or CPT®78999 for PET), not with diagnostic imaging codes.
- PET being performed for radiation therapy treatment planning should be coded as CPT®78999 (unlisted procedure, diagnostic nuclear medicine) and **not** as diagnostic PET (CPT®78812, CPT®78815, or CPT®78816).

**Preface-4.4 Unilateral versus Bilateral Breast MRI**

- Diagnostic MRI of both breasts should be coded as CPT®77059 regardless of whether both breasts are imaged simultaneously or whether unilateral breast MRI is performed in two separate imaging sessions.

**Preface-4.5 CPT®76380 Limited or Follow-up CT**

- 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):
  - Limited sinus CT imaging protocol
  - Limited or follow-up slices through a known pulmonary nodule
  - Limited slices to assess a non-healing fracture (such as the clavicle)
- 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® 2015*, 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 clinical situation of the patient. Sometimes the protocols require more time and sometimes less.
Preface-4.6 SPECT/CT Imaging

✓ SPECT/CT involves SPECT (Single Photon Emission Computed Tomography) nuclear medicine imaging and CT for optimizing location, accuracy, and attenuation correction and combines functional and anatomic information.
  o Common studies using this modality include $^{123}$I- or $^{131}$I-Metaiodobenzylguanidine (MIBG) and octreotide scintigraphy for neuroendocrine tumors.
✓ There is currently no evidence-based data to formulate appropriateness criteria for these hybrid scans.
✓ A procedure code for SPECT/CT parathyroid nuclear imaging, (CPT® 78072), became effective January 1, 2013. No other unique codes have yet been established to specifically report these imaging procedures.
✓ It is not appropriate to separately report any CT, performed only for localization and/or attenuation correction purposes, with any diagnostic CT code, including CPT® 76380).

References:

Preface-5~WHOLE BODY IMAGING

Preface-5.1~Whole Body CT Imaging

✓ The performance of whole body screening CT examinations in healthy patients does not meet any of the current validity criteria for screening studies and there is no clear documentation of benefit versus radiation risk.

Preface-5.2~Whole Body MR Imaging

✓ Whole body MRI (WBMRI) is, generally, not supported by the MGI at this time due to lack of standardization in imaging technique and lack of evidence that WBMRI improves patient outcome for any individual disease state.
  o 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:
  o There are no established CPT® or HCPCS codes for reporting WBMRI.
  o WBMRI is at present only reportable using CPT® 76498. All other methods of reporting whole body MRI are inappropriate, including:
    • Separate diagnostic MRI codes for multiple individual body parts
• MRI Bone Marrow Supply (CPT® 77084)

✓ Disease-specific considerations:
  o Cancer screening:
    • WBMRI has not been shown to improve outcomes for cancer screening for any group of patients.
    • The primary reference cited to support requests for WBMRI in Li-Fraumeni Syndrome (LFS) is Villani et al, Lancet Oncol 2011. In this study, the overall screening program was feasible and successful. However, the WBMRI component only detected a single malignancy which was concurrently detectable on clinical examination. This article does not provide sufficient scientific rationale to justify WBMRI use in Li-Fraumeni patients.
  o 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.
  o Autoimmune disease
    • WBMRI has been shown to increase the number of detected lesions in chronic multifocal osteomyelitis and other inflammatory arthridities, but no improvement in outcomes from the use of WBMRI has yet been shown.

Preface-5.3~PET-MRI

✓ PET-MRI is, generally, not supported by the MGI at this time due to lack of standardization in imaging technique and lack of evidence that PET-MRI improves patient outcome for any individual disease state.

References:


Preface-6~References

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 http://www.acr.org.

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