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 Cigna CPT code list for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2016 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.
<table>
<thead>
<tr>
<th>Preface to the Imaging Guidelines</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Preface-1~Guideline Development</td>
<td>3</td>
</tr>
<tr>
<td>Preface-2~Benefits, Coverage Policies, and Eligibility Issues</td>
<td>4</td>
</tr>
<tr>
<td>Preface-3~Clinical Information</td>
<td>5</td>
</tr>
<tr>
<td>Preface-4~Coding Issues</td>
<td>9</td>
</tr>
<tr>
<td>Preface-5~Whole Body Imaging</td>
<td>12</td>
</tr>
<tr>
<td>Preface-6~References</td>
<td>14</td>
</tr>
<tr>
<td>Preface-7~Copyright Information</td>
<td>14</td>
</tr>
<tr>
<td>Preface-8~Trademarks</td>
<td>14</td>
</tr>
</tbody>
</table>
Preface-1~Guideline Development

The cobranded Cigna- eviCore healthcare (eviCore) evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging and procedures, including CT, MRI, PET, and Cardiac interventions.

Cigna and eviCore reserves the right to change and update the guidelines. The guidelines undergo a formal review annually. The Cigna-eviCore cobranded guidelines are based upon major national and international association and society guidelines and criteria, peer-reviewed literature, major treatises and, input from health plans, 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 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.

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 support 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

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

**Medicare Coverage Policies**
For Medicare and Medicare Advantage enrollees, the coverage policies of CMS (Centers for Medicare and Medicaid Services) take precedence over these Cigna-eviCore cobranded guidelines.

**Investigational and Experimental Studies**
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**
Clinical trial imaging requests will be considered to determine whether they meet coverage.

**State and Federal Mandates**
State and federal legislations may need to be considered in the review of advanced imaging requests. For example:
- Various Breast Density Laws
- Digital Breast Tomosynthesis (3D mammography) coverage laws
- Texas HB 1290 Coronary Calcium CT Law
Preface-3~Clinical Information

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

✓ Clinical presentation of the individual, 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 the individual 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:
  o Lung nodule follow-up (CH-16.1 SPN – Imaging)
  o Thyroid nodule follow-up (Neck-9 Thyroid and Parathyroid)
  o Liver, pancreatic, and renal lesion follow-up (AB-29.1, AB-31.2, AB-35.1)
  o Annual breast MRI for High Risk (CH-25.6 Breast MRI Indications)
  o BI-RADS3 MRI or US follow-up (CH-25.5, CH-25.6)
  o Cardiac repeat testing (CD-1.4 Stress Testing with Imaging – Indications)
  o Oncology surveillance imaging
  o Abdominal or thoracic Aortic Aneurysm (CH-30.2 Thoracic Aortic Aneurysm)
  o Annual surveillance for multiple sclerosis
  o Follow up for brain tumors if consistent with applicable guideline (pituitary etc.)
  o Follow up for renal/ureteral stones (AB-4.2 Observation of Known Ureteral Stone and AB 4.3 Follow-up of Treated Renal Stone)
  o Fever can be considered in excess of normal range (oral 36.5–37.5C or 97.7–99.5F)
  o Childhood is often considered from birth through 18. This range is reflected in both the Medicaid program as well as many states legal ages of majority. Yet, childhood can be extended toward 21 years of age according to the American Academy of Pediatrics or less than 18 years, both depending on the individual’s anatomy, physiology or disease condition.*
PREFACE to the Imaging Guidelines

*References*

- This evaluation may include non-advanced imaging modalities (chest x-ray, EKG, EMG, etc.), prior patient medical 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 are 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 individuals 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 an individual 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). Individuals 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 individuals. 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 individuals may pump and discard breast milk for 12 to 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 individuals 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 individuals 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 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
- Adult CT settings used for smaller people and children

**Reference**

Preface-4~Coding Issues

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preface-4.1 3D Rendering CPT®76376 and CPT®76377</td>
<td>10</td>
</tr>
<tr>
<td>Preface-4.2 Unlisted Procedures/Therapy Treatment Planning</td>
<td>10</td>
</tr>
<tr>
<td>Preface-4.3 Unilateral versus Bilateral Breast MRI</td>
<td>11</td>
</tr>
<tr>
<td>Preface-4.4 CPT®76380 Limited or Follow-up CT</td>
<td>11</td>
</tr>
</tbody>
</table>
Preface-4.1 3D Rendering CPT®76376 and CPT®76377

✓ 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.

✓ CPT® 76376 does not require prior authorization.

✓ CPT®76377 DOES require prior authorization.

✓ 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 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>

✓ These unlisted codes should be reported whenever a diagnostic or interventional CT or MR study is performed for which an appropriate anatomic site-specific code is not available.
  o A Category III code that describes the procedure performed must be reported rather than an unlisted code if one is available.

✓ All requests for studies billed with these unlisted codes will be forwarded for Medical Director review.
Requests must be accompanied by detailed notes describing the procedure and the medical necessity indications for the study.

**Therapy Treatment Planning**

**Radiation Therapy Treatment Planning:**

- Imaging performed in support of radiation therapy treatment planning should be reported with the following codes: (CPT®76497 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).
  - CPT®78999 does not require prior authorization by eviCore

**Preface-4.3 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-4.4 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 clinical situation of the individual. Sometimes the protocols require more time and sometimes less.
Preface-5~Whole Body Imaging

Preface-5.1~Whole Body CT Imaging
✓ Whole body CT or LifeScan (CT of Brain, Chest, Abdomen, and Pelvis) for screening of asymptomatic individuals is not a covered benefit of any of the current health plans who have delegated utilization review to eviCore. The performance of whole body 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.

Preface-5.2~Whole Body MR Imaging
✓ Whole body MRI (WBMRI) is, generally, not covered due to lack of standardization in imaging technique and lack of evidence that WBMRI improves patient 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:
  - Separate diagnostic MRI codes for multiple individual body parts
  - MRI Bone Marrow Supply (CPT®77084)

Disease-specific considerations:
- Cancer screening:
  - WBMRI has not been shown to improve outcomes for cancer screening for any group of individuals, including Li-Fraumeni Syndrome. See: PACONC-2.2 Li-Fraumeni Syndrome (LFS) for additional information
  - The primary reference cited by providers to support requests for WBMRI in 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 individuals.
- 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 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, generally, is not covered 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.

Preface-7~Copyright Information

©2017 eviCore healthcare. All rights reserved. No part of these materials may be changed, reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying or recording, or in any information storage or retrieval system, without the prior express written permission of eviCore.

Preface-8~Trademarks

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2016 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.