Select Health Medical Policies

Radiology Policies

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MEDICAL POLICY

AMYVID PET SCAN IN ALZHEIMER'S DISEASE

Policy # 546

Implementation Date: 1/3/14

Review Dates: 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/11/19, 2/20/20, 2/18/21, 1/18/22, 2/27/23, 2/21/24

Revision Dates:

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Description

Dementia is a disorder that is characterized by impairment of memory and at least one other cognitive domain (e.g., aphasia, apraxia, agnosia, executive function). These must represent a decline from previous levels of function and be severe enough to interfere with daily function and independence.

Alzheimer's disease (AD) is the most common form of dementia in the elderly, accounting for 60% to 80% of cases, and it is estimated to affect more than 4 million Americans. AD is a neurodegenerative disorder of uncertain cause and pathogenesis which primarily affects older adults. While treatments are available that can slow the course of the disease and/or ameliorate some symptoms, there are no disease modifying therapies, there is no cure, and the disease inevitably progresses in all patients.

Definitive diagnosis of AD requires histopathologic examination, which is rarely done except posthumously. The diagnosis of AD in practice depends on clinical criteria. The role of laboratory and imaging investigations is mainly to exclude other diagnoses. Neuropsychological testing may provide confirmatory information and aid in patient management. Clinicians should also consider potential contributors to the dementia syndrome such as adverse effects of medication, depression, and metabolic disorders and deficiencies.

Recently, amyloid PET tracers that measure amyloid lesion burden in the brain have been developed and are under investigation as a tool to positively diagnose AD in vivo, aid in prognosis, and differentiate AD from other causes of dementia. Amyvid (Florbetapir F18, Lilly, Indianapolis, IN) has been approved by the U.S. Food and Drug Administration for this purpose.

Amyvid is FDA approved for PET imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for AD and other causes of cognitive decline. A negative Amyvid scan indicates sparse-to-no neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Amyvid scan indicates moderate-to-frequent amyloid neuritic plaques. Neuropathological examinations have shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions, as well as older people with normal cognition; Amyvid is an adjunct to other diagnostic evaluations.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover Amyvid PET scans in the evaluation of Alzheimer's disease; this is considered not medically necessary as current therapies are not covered.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

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Summary of Medical Information

Two systematic reviews and nine primary literature articles met inclusion criteria for this report. Hayes noted what other authors have (see Johnson et al. or BCBS TEC, for example), that the clinical utility of ruling out beta amyloid remains to be proven. Earlier this year, BCBS TEC performed a review on florbetapir F18 PET tracing for Alzheimer's disease and concluded that there is insufficient evidence linking the test results to an improvement in patient outcomes. Hayes has only completed a Prognosis Report, which also supports the lack of defined clinical utility for Amyvid PET testing.

The nine primary articles demonstrated some degree of clinical validity in that they showed that the test can detect amyloid, which has been linked to Alzheimer's disease. However, none of the papers were able to demonstrate clinical utility and an improvement in outcomes. The most thorough analysis was published by Johnson et al., which illustrated a task forces' recommendation for when amyloid imaging is most appropriate. The task force did not demonstrate that after use of amyvid imaging the ability of a clinician to change treatment outcomes was improved.

In summary, little evidence exists pertaining to the clinical utility of Amyvid PET imaging in the diagnosis of Alzheimer's disease (GRADE 2C).

Billing/Coding Information

CPT CODES

78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation

HCPCS CODES

A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
A9586	Florbetapir F18, diagnostic, per study dose, up to 10 millicuries

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MEDICAL POLICY

BREAST THERMOGRAPHY

Policy # 451

Implementation Date: 8/9/10

Review Dates: 9/15/11, 7/18/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/20/18, 6/10/19, 6/18/20, 6/17/21, 5/19/22, 6/1/23

Revision Dates:

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Description

After skin cancer, breast cancer is the most common cancer diagnosed in women in the United States. Though breast cancer rates have fallen in recent years, for many women, breast cancer is a feared disease. Public support for breast cancer awareness and research funding has helped improve the diagnosis and treatment of breast cancer. It is thought this has led to improved breast cancer survival rates and a decline in the number of deaths due to earlier identification of less advanced disease.

In an effort to detect cancer early, prior to clinical presentation at a time when a cure of the disease is most likely, a variety of imaging modalities are currently employed. These include analog or digital mammography, breast ultrasound, breast MRI, and nuclear medicine. Mammography remains the mainstay of screening for breast cancer. Mammography may detect cancer one-and-a-half to four years before a cancer becomes clinically evident. Ultrasonography is commonly used for diagnostic follow-up of an abnormality seen on screening digital mammography, to clarify features of a potential lesion. Causes for an incomplete evaluation include technical factors such as suboptimal images due to either improper positioning or motion; or a questionable lesion not fully evaluated on the standard screening views; or unavailability of prior mammograms to confirm stability of a possible focal or diffuse abnormality. The role of magnetic resonance imaging (MRI) for breast cancer screening is emerging; currently MRI screening in combination with mammography is targeted to high-risk patients.

Thermography is an alternative diagnostic modality proposed by some as an alternative to mammography due to the lack of x-ray exposure and need for breast compression. It measures and maps the heat on the surface of the breast using a special heat-sensing camera. It is based on the idea that the temperature rises in areas with increased blood flow and metabolism, which could be a sign of a tumor.

Infrared rays are found in the electromagnetic spectrum within the wavelengths of 0.75 µm–1 mm. Human skin emits infrared radiation mainly, in the 2–20 µm wavelength range. As precancerous and malignant tissue types recruit existing and create new blood vessels to supply the tumor with nutrition, the temperature in that area increases. Digital infrared thermal imaging (DITI) is a means to detect the increased emission of heat from breast cancer cells.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover breast thermography as current evidence fails to demonstrate adequate sensitivity of breast thermography when used as a screening modality. Use of breast thermography meets the plan's definition of experimental/investigational.

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Summary of Medical Information

A technology assessment performed in May 2010 identified the issue of breast thermography vs. mammography as a screening tool for breast cancer as not being new. The issue was explored and seemingly answered in the 1970s and 1980s with a determination that mammography was the superior methodology. This is seemingly supported by the volume of studies related to each modality. Numerous papers on the use of mammography have been published in the last 5 years while only 3 peer-reviewed papers were found for DITI of breast cancer fitting our search criteria. Proponents of the technology advocate DITIs use for its lack of ionizing radiation, compression, and future risk of radiation-induced breast cancer. Arora et al. found DITI to have 97% sensitivity, 44% specificity, and 82% negative predictive value. This contrasts with Ng et al., who found an accuracy of 81%, 100% sensitivity, and 71% specificity in identifying breast cancer but is congruent with Li et al. who indicated 96% sensitivity and 52% specificity. One concern in the Ng paper is the extensive use of statistical modeling (i.e., artificial neural networks, regression and receiver operating characteristics, linear regression, and radial basis function network) to achieve data outcomes. The paper concludes that even with statistically significant outcomes, thermography should be adjunctive to mammography. In neither the 3 papers cited, nor the Adelaide Health Technology Assessment, is DITI advised as a replacement for mammography but only to be used in conjunction with ultrasound and mammography.

In summary, updated evidence does not support thermography as the preferred screening tool for breast cancer. Despite DITI's comparable sensitivity to mammography, this technology seems to lack specificity (10%–40% lower than mammography) particularly in detecting early breast cancer to warrant coverage, especially, given the alternative technologies available.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this condition

CPT CODES

93740 Temperature gradient studies

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

BREAST TOMOSYNTHESIS

Policy # 415
Implementation Date: 5/11/09
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Description

Breast cancer is the most common noncutaneous cancer in women. The National Cancer Institute indicates that in 2009, the estimated new cases of deaths from breast cancer in the United States were 192,370 in women and 1,910 in men.

Standard approaches to screening and diagnosis of breast cancer are analog or digital mammography, breast ultrasound, and breast MRI. Mammography or full-field digital mammography (FFDM) remains the mainstay of screening for breast cancer. Mammography may detect cancer one-and-a-half to four years before a cancer becomes clinically evident.

Ultrasonography is commonly used for diagnostic follow-up of an abnormality seen on screening digital mammography, to clarify features of a potential lesion. Ultrasound is used to further evaluate masses or asymmetries and can differentiate a solid mass from a cyst. Ultrasonography is also used to provide guidance for biopsies and other interventions. It is the first line of imaging in a woman who is pregnant or less than thirty years old with focal breast symptoms or findings.

The role of magnetic resonance imaging (MRI) for breast cancer screening is emerging; currently MRI screening, in combination with mammography is targeted to high-risk patients. Screening MRI is recommended for women with an approximately 20%–25% or greater lifetime risk of breast cancer, including women with a strong family history of breast or ovarian cancer and women who were treated for Hodgkin's disease.

The combination of MRI and mammography is recommended by the American Cancer Society in women at high risk of breast cancer (≥ 20% to 25% lifetime risk), as defined by risk prediction models based primarily on family history. The cancer mortality risk in this population is assumed to be high enough to justify the increased cost and numbers of follow-up procedures that would be generated because of low specificity.

Tomosynthesis is a tomographic application of digital mammography. The tomosynthesis acquisition mimics conventional mammography with regards to breast positioning and compression, but unlike conventional mammography, the x-ray tube takes multiple low-dose exposures as it moves through a limited (e.g., 30°) arc of motion. The individual images are then reconstructed into a series of thin high-resolution slices that can be displayed individually or in a dynamic ciné mode, with a total radiation dose similar to conventional mammography.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers breast tomosynthesis as a screening and diagnostic modality in the assessment and management of breast cancer.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

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Summary of Medical Information

Previous reviews of breast tomosynthesis (BT) in 2008 and 2011 failed to identify sufficient evidence for this technology to be considered proven. Since the previous review of this technology in 2011, two systematic reviews and thirteen primary literature articles have been published which met inclusion criteria for this review. The studies evaluated the results of more than 59,000 patients who underwent mammography and/or BT. Most of the articles report taking into consideration inter-rater reliability, recall rates, cancer detection rate, and study design.

Since the previous review, most of the primary literature articles assess similar endpoints. Both the systematic reviews and 11 of 13 (85%) of the primary literature articles used BT specifically for screening. With regards to their findings, several key endpoints are assessed—inter-rater reliability, recall rates, cancer detection, and comparative outcomes to digital mammography. The following summarizes these findings on several of these areas:

- **Inter-rater Reliability**: Kappa statistics (a statistical measure of inter-rater reliability with values between 0 and 1 where 0 is no agreement at all and 1 is complete agreement) were reported by two authors. Both these papers compared FFDM to BT and compared the conclusions of five radiologists when viewing each type of image. The average kappa statistic was 0.90. Where kappa statistics were not reported but where there were multiple readers, decreases in recall rates and increases in area under the curve were still identified with use of BT.
- **Recall Rates**: Ten of the thirteen papers (77%) addressed the potential for a decrease in recall rates with the use of BT. With the exception of the Rafferty et al. paper, which reported a recall reduction rate of 6–67%, from which reasonable conclusions cannot be drawn, the average recall reduction rate with the use of BT was 27.5% (range = 17.2-37%).
- **Cancer Detection**: There was an inherent inclusion bias against tomosynthesis with respect to cancer detection in a screening population. Many cancers were acquired in patients scheduled for biopsy and had been detected on conventional mammograms as part of standard screening evaluations. It is likely that studies underestimate the potential gains in sensitivity that might occur in clinical practice. For example, the study by Gennaro et al., both CC and MLO images were acquired with FFDM, but this information was compared to BT, which only assessed MLO images. This in turn will decrease the sensitivity of BT as it compares to FFDM. All studies that addressed cancer detection noted an increase in detection with the use of BT. Studies varied, however, in their ability to increase cancer detection to a statistically significant degree.

Specific to comparative sensitivity and specificity to FFDM, all 13 papers illustrated noninferiority to 2D mammography when used as either a screening tool or in follow-up imaging studies. These studies showed sensitivities for breast tomosynthesis, ranging from 76.2% to 100%, compared with 64.1% to 97.5% for full field digital mammography. Similarly, specificity for BT ranged from 74.2 to 92% in these studies compared with a range of 51% to 83% for FFDM. In those studies which looked at recall rates,

studies identified a reduction in recall rates ranging from 17.2% to 37%.

There is a degree of heterogeneity that exists between the papers that make clear and concise inferences regarding how BT will be used in routine practice difficult. Some studies used a combined technique comparing BT + FFDM to FFDM alone; some were prospective where others were retrospective; some papers assessed BT as a triage tool after FFDM had been done; some used BT as a screening tool and others used it as a diagnostic test.

In conclusion, based upon the updated published evidence, breast tomosynthesis appears to be a be a tool that is non-inferior to FFDM, decreases recall rates, identifies a statistically significant and non-significant number of breast cancers unidentifiable in FFDM, and has a better area under the curve statistic than does FFDM (GRADE 1B).

Billing/Coding Information

CPT CODES

77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed
77061	Digital breast tomosynthesis; unilateral
77062	Digital breast tomosynthesis; bilateral
77063	Screening Digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)

HCPCS CODES

G0202	Screening mammography, producing direct digital image, bilateral, all views
G0204	Diagnostic mammography, producing direct 2-d digital image, bilateral, all views
G0206	Diagnostic mammography, producing direct 2-d digital image, unilateral, all views
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206)
D24.9	Benign neoplasm of unspecified breast
D48.60	Neoplasm of uncertain behavior of unspecified breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
D49.3	Neoplasm of unspecified behavior of breast
N63	Unspecified lump in breast
R92.0	Mammographic microcalcification found on diagnostic imaging of breast
R92.1	Mammographic calcification found on diagnostic imaging of breast
R92.8	Other abnormal and inconclusive findings on diagnostic imaging of breast
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
Z12.39	Encounter for other screening for malignant neoplasm of breast

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MEDICAL POLICY

FUNCTIONAL MAGNETIC RESONANCE IMAGING

Policy # 628
Implementation Date: 9/18/18
Review Dates: 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/24/23
Revision Dates: 12/28/20

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Functional magnetic resonance imaging (fMRI) measures the small changes in blood flow that occur with brain activity. It may be used to examine the brain's functional anatomy (determine which parts of the brain are handling critical functions), evaluate the effects of stroke or other disease, or to guide brain treatment. fMRI may detect abnormalities within the brain that cannot be found with other imaging techniques.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

SelectHealth considers fMRI medically necessary to identify vulnerable cortex substrate in pre-surgical evaluation of individuals with any of the following chronic conditions:

- brain tumors
- epilepsy
- vascular malformations

Select Health considers fMRI experimental and investigational for the diagnosis, monitoring, prognosis, or surgical management of the following conditions/diseases (not an all-inclusive list), because its effectiveness for these indications has not been established:

- Alzheimer's disease
- Anoxic-ischemic brain injury
- Attention-deficit hyperactivity disorder
- Bipolar disorder
- Chronic pain (including fibromyalgia)
- Disorders of consciousness (e.g., locked-in syndrome, minimally conscious state (subacute/chronic; traumatic/non-traumatic), and coma/vegetative state)
- Multiple sclerosis
- Parkinson's disease
- Psychotic depression
- Schizophrenia
- Stroke/stroke rehabilitation
- Trauma (e.g., head injury)

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The attractions of fMRI have made it a popular tool for imaging normal brain function, especially for psychologists. Over the last decade it has provided several new insights, including further research into language, pain, learning, and emotion, as well as the investigation of how memories are formed.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

70554	Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration
70555	Magnetic resonance imaging, brain, functional MRI; requiring physician or psychologist administration of entire neurofunctional testing
96020	Neurofunctional testing selection and administration during noninvasive imaging functional brain mapping, with test administered entirely by a physician or other qualified health care professional (ie, psychologist), with review of test results and report

Key References

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Functional Magnetic Resonance Imaging, continued

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MEDICAL POLICY

MAGNETIC ENCEPHALOGRAPHY (MEG)/ MAGNETIC SOURCE IMAGING (MSI)

Policy # 279
Implementation Date: 8/18/05
Review Dates: 8/21/06, 8/23/07, 8/21/08, 8/13/09, 8/19/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 4/14/16, 4/27/17, 6/21/18, 4/12/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23
Revision Dates: 1/17/14

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Magnetic source imaging (MSI) has been used to evaluate brain function in patients with epilepsy, tumors, arteriovenous malformations (AVMs), trauma, stroke, and other neurological and psychiatric conditions. However, now the most common clinical applications of MSI are evaluation of patients with medically refractory epilepsy and for assessment of patients with brain masses such as tumors or AVMs.

Magnetic source imaging (MSI) is a noninvasive imaging technique that combines functional data obtained via magnetic encephalography (MEG) with structural data obtained via magnetic resonance imaging (MRI) to provide a detailed picture of the mapping of brain function onto brain structure. The procedure makes use of the fact that current flow within brain cells generates a surrounding neuromagnetic field. Changes in the spatial pattern of the summated neuromagnetic field generated by parts of the brain are monitored and recorded using MEG. This information is integrated with structural MRI data to identify the brain structures responsible for the observed currents. In this manner, MSI provides a spatiotemporal picture of the workings of the brain on a scale of millimeters and milliseconds.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers magnetic encephalography (MEG)/magnetic source imaging (MSI) in *limited circumstances:*

1. For preoperative surgical planning of individuals with intractable seizure disorders, which have failed to respond to multiple antiepileptic regimens, and in whom the seizure focus has not been adequately identified using traditional means.
2. For preoperative brain function mapping for individuals with intracranial tumors.
3. For preoperative brain function mapping for individuals undergoing surgery for AVMs.

Select Health does NOT cover other indications such as functional neurological or psychological testing. This meets the plan's definition of experimental/investigational.

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SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

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Summary of Medical Information

The recent Hayes review on MEG/MSI identifies the difficulties in sorting the evidence for a procedure such as this, which applied to only a small pool of potential patients. Sample sizes in the studies tend to be small, and thus, the studies are generally not powered to result in broad conclusions. However, the Hayes review identified multiple studies that were positive in their application of this technology when compared with standard testing methods. The issue of limited studies with small sample size is also the primary driver resulting in the negative conclusion of the Blue Cross TEC report. However, the body of the TEC review acknowledges that the limited studies still identify MEG/MSI testing may be as good, if not better in some instances, than standard EEG testing. It also recognizes MEG/MSI to be nearly equal to intracranial EEG testing.

The study by Bazil identifies the significant costs associated with uncontrolled epilepsy, while the study by Berg et al. identifies through retrospective analysis the limitations of current methods in adequately identifying appropriate surgical candidates. In their study published in the Journal of Clinical Neurophysiology, Barkley and Baumgartner identify the role MEG/MSI has in identifying patients who may otherwise not be deemed suitable for surgery. Pataria et al. further support this study's conclusion in their 2004 Neurology article, specifically looking at the role of MEG in epilepsy surgery; other small studies also support this conclusion. Though these studies are not powered to reach broad conclusions, they at least provide level II/III evidence of the benefit of MEG/MSI in selected patients with refractory seizure problems.

Similar studies by Bowyer et al. and Oishi have also identified the statistical reliability and clinical utility of MEG/MSI testing in patients with CNS tumors and cavernous hemangiomas, when compared to the current standard methods of testing.

The American Clinical MEG Society published a position statement in 2009 (Bagic et al.), in which it provided the following recommendation amongst several recommendations: The routine clinical use of MEG/MSI in obtaining noninvasive, nonredundant localizing information in presurgical evaluation of patients with medically intractable localization-related epilepsy.

A review from 2017 (Stefan et al.), noted problems with some of these studies (e.g., lack of long-term outcomes, small sample sizes, selection bias of non-lesional or unclear cases). The review notes that there are uses in presurgical planning, but larger prospective studies would be helpful.

Billing/Coding Information

CPT CODES

95965	Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)
95966	; for evoked magnetic fields, single modality (e.g., sensory, motor, language, or visual cortex localization)

95967	; for evoked magnetic fields, each additional modality (e.g., sensory, motor, language, or visual cortex localization) (List separately in addition to code for primary procedure)

HCPCS CODES

S8035	Magnetic source imaging

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MEDICAL POLICY

MAGNETIC RESONANCE-GUIDED FOCUSED ULTRASOUND FOR ESSENTIAL TREMOR

Policy # 560

Implementation Date: 12/3/14

Review Dates: 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/28/21, 1/18/23, 12/21/23

Revision Dates:

Description

Essential tremor (ET) is the most common type of tremor. ET is one of the most common neurological diseases, with a prevalence of approximately 4% in persons age forty and older, and considerably higher among persons in their sixties, seventies, eighties, and nineties.

Beta blockers are the most used medications for the treatment of ET. The efficacy of beta blockers has been demonstrated primarily for propranolol, and most of the studies evaluated short-term therapy. Anticonvulsants such as Gabapentin, Primidone, and Topiramate can also be used to reduce tremors. Alcohol, Benzodiazepines, and Botulinum Toxin are also sometimes used as well.

Surgical options are considered when conservative therapies fail. Common surgeries include thalamotomy, deep brain stimulation (DBS), radiofrequency, Gamma knife thalamotomy, or stereotactic radiosurgery.

Magnetic resonance-guided focused ultrasound (MRgFUS) is an alternative non-invasive procedure which uses focused ultrasound energy to ablate deep within the human body. It is typically performed under magnetic resonance image (MRI) guidance. The procedure begins with the acquisition of a planning image which captures the region of interest that will be treated. The clinician then manually identifies points on the reference image that indicate where ultrasound energy should be deposited to ablate the tissue. During the procedure, MR images are acquired in order to monitor target temperature changes as well as temperature of surrounding tissue.

In high-intensity focused ultrasound surgery, ultrasound waves are applied from different angles to the center of the region of interest. Induced temperature elevations up to 65–100°C result in coagulation necrosis with high spatial precision (approximately 1 mm). Changes in temperature are automatically registered by the MR system and are transmitted to the ultrasound transducer by a close-looped feedback controller. MRgFUS should preferably rely on high-field-strength MR scanners (three tesla or higher), as low-field scanners suffer from limited spatial resolution and impaired quantification of local tissue temperatures. With pulsed ultrasound and intermittent periods of cooling, the intervention times also depend on the volume of the area treated. Currently, MRgFUS treatment times, with the patient in the prone position within the scanner range, are between thirty and 150 minutes, possibly with a significant impairment of patient comfort.

During treatment, the patient lies in the MRI scanner with a novel helmet-like, multi-channel high power phased array transducer, used to destroy targeted tissue. The patient is awake the entire time and interacts with the treatment team.

The physician plans and conducts the procedure from a computer screen in the adjacent MRI control room. Immediately at the end of the treatment, the clinical effect of the MRgFUS lesioning can be evaluated. MRgFUS does not use ionizing radiation, so treatment may be repeated, may be staged as the disease progresses, and has no risks of toxicity and accumulated dose effects. Several clinical trials

have been initiated. In functional neurosurgery, the goal is to ameliorate symptoms by targeting specific neural pathways in patients with movement disorders.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover magnetic resonance-guided focused ultrasound in the management of essential tremor as it is considered experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Only three primary literature articles met inclusion criteria for this report. A paper by Elias et al. demonstrated that total tremor improved in all patients who underwent MRgFUS treatment for essential tremor. However, the study was an uncontrolled study in only 15 patients. The paper by Sperling et al. showed a statistically significant improvement in stop reaction time after treatment with MRgFUS.

In summary, as only three papers were identified, additional information is needed in order to draw meaningful conclusions regarding safety, efficacy, comparative effectiveness to standard treatments, durability of effect, and appropriate patient selection.

Billing/Coding Information

CPT CODES

0398T	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed

HCPCS CODES

C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

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MEDICAL POLICY

MAGNETIC RESONANCE (MR) NEUROGRAPHY

Policy # 491
Implementation Date: 10/11/11
Review Dates: 8/15/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/25/18, 6/10/19, 6/18/20, 6/17/21, 5/19/22, 6/1/23
Revision Dates: 5/1/12

Description

Traditionally, the diagnosis and management of disorders involving peripheral nerves has been undertaken without images of the nerves themselves, relying instead on information derived from the clinical history, physical examination, and electrodiagnostic studies. While radiological methods exist for generating tissue-specific images of bone, blood vessels, lymphatics, abdominal viscera, and the central nervous system, until recently, there has been no reliable method for producing a direct clinical image of a nerve. Ultrasonography and computed tomography, which allow soft tissues to be imaged directly, cannot distinguish structures as small as peripheral nerves from surrounding soft tissues and are useful mainly in detecting mass lesions or other large soft-tissue abnormalities in the region of peripheral nerves. Due to limitations in resolution and conspicuity, conventional MRI using standard body coils cannot be used reliably for directly visualizing most normal-sized peripheral nerves. Thus, the diagnosis and management of disorders involving peripheral nerves traditionally has relied upon information derived from the clinical history, neurological examination, and electrodiagnostic studies, including nerve conduction studies and electromyography (EMG), without images of the nerves themselves.

MR neurography is a new imaging modality, a modification of MRI using special software and hardware upgrades that has been proposed for the diagnosis of peripheral nerve disorders. The development of MR neurography has made possible direct, high-resolution longitudinal and cross-sectional images of peripheral nerves. Specially-designed, phased-array surface coils provide superior resolution of small structures so that normal-sized nerves can be distinguished from surrounding soft tissues, and the internal structure of the nerves can be visualized. Preliminary studies suggest a wide range of indications, including carpal tunnel syndrome, cubital tunnel syndrome or ulnar nerve entrapment at the elbow, cervical radiculopathy, brachial plexopathy or thoracic outlet syndrome, lumbosacral plexopathy, sciatica, traumatic peripheral nerve injuries, peripheral nerve tumors and cysts, or any other condition thought to be due to nerve compression or impingement.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover magnetic resonance (MR) neurography. Current evidence is limited and has not yet proven clinical validity for many conditions, nor has the clinical utility been defined. This meets the plan's definition of experimental/investigational.

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Summary of Medical Information

Filler et al. (2005) prospectively evaluated 239 consecutive patients with sciatica in whom standard diagnosis and treatment had failed to affect improvement. Patients without adequate lumbar spine imaging data obtained within the past 12 months underwent updated spinal radiography and MRI.

When a diagnosis could not be established by inspecting routine spine imaging, patients were referred for lumbar and pelvic soft-tissue MRI and MRN evaluation. Patients in whom physical examination findings and medical history were consistent with piriformis syndrome and in whom MRN did not rule out piriformis syndrome were considered to have probable piriformis syndrome and were referred for open MRI–guided piriformis muscle injection. The authors stated that when piriformis muscle asymmetry alone is used as a criterion to identify individuals with piriformis syndrome, MRN sensitivity was 64% and specificity was 93% in distinguishing patients with piriformis syndrome from those without, who had similar symptoms. With a new diagnosis identified, treatment (i.e., Marcaine injection into the piriformis muscle and piriformis surgery) was then pursued. Authors stated this study demonstrated an indication for MRN in patients with sciatica in whom an obvious spinal origin for this condition is absent. The authors noted that MRN and imaging-guided injection techniques can establish the correct diagnosis and guide management for both pelvic sciatic entrapment and nonstandard lumbar entrapment. The sensitivity of MRN (64%) compared with other MR imaging techniques or other diagnostic imaging modalities is not known, as MRN was not compared with other MR imaging techniques or other diagnostic imaging modalities.

Lewis et al. (2006) conducted a retrospective medical record review of 14 patients with unexplained sciatic distribution pain. In each patient, prior results of MRI of the lumbosacral spine were normal or demonstrated findings that were determined by the clinician to be incompatible with the patient's history and examination. Three other patients with sciatica and normal results on lumbar MRI who were diagnosed as having nonsciatic-related pelvic pathologic features on MRN were used as control subjects.

Results demonstrated focal signal abnormalities within the sciatic nerve in the buttock in almost all patients with unexplained sciatica. The authors stated that results of this study suggest MRN may have the ability to aid in the diagnosis of sciatic nerve entrapment by the piriformis muscle; however, the small sample size and case series from a retrospective medical record review design limits the ability to draw conclusions.

Raphael et al. (2005) performed MRN of the brachial plexus in ten volunteer subjects. Multiple software programs were explored for enhanced display and manipulation of the composite MRIs. Raphael and colleagues developed a frontal slab composite MRN approach. The authors concluded that image processed, three-dimensional, volume-rendered MRN scans, which allow visualization of the entire brachial plexus within a single composite image, have educational value in illustrating the complexity and individual variation of the plexus.

A prospective clinical trial of 30 carpal tunnel syndrome patients (plus eight controls) was conducted to evaluate the clinical, electrophysiological, and MRN findings before and three months after surgery (Cudlip, et al., 2002). The authors stated that MRN in patients with carpal tunnel syndrome demonstrated

proximal swelling and high signal change in the nerve, together with increased flattening ratios and loss of nerve signal in the distal carpal tunnel. Sagittal images were very effective in precisely demonstrating the site and severity of nerve compression. After surgery, division of the flexor retinaculum could be demonstrated in all cases. The authors concluded that MRN is an effective means of confirming both compression of the median nerve and its successful surgical decompression in patients with carpal tunnel syndrome. They noted that this modality may prove useful in the assessment of unconfirmed or complex cases of carpal tunnel syndrome, both before and after surgery.

Du et al. (2010) retrospectively compared MRN and NCS/EMG in 91 patients with spinal and/or peripheral nerve disorders. MRN was obtained, a median of twelve months after the onset of symptoms. The median interval from onset of symptoms to NCS/EMG was eight months. The most common diagnoses were radiculopathy (in 31% of patients), peripheral neuropathy (19%), and brachial plexopathy (in 12%). Radiculopathies were evaluated most frequently in the cervical and lumbar regions (58% and 38%, respectively). Peripheral mononeuropathies most commonly involved the sciatic nerve (in 61% of patients). Compared to NCS/EMG, MRN was found to give the same information in 29 patients (32%), additional diagnostic information in 41 (45%), less information in 15 (17%), and a different diagnosis in 6 (7%). The authors noted that cases in which MRN provides more diagnostic information than NCS/EMG are important in determining when MRNs can be expected to be helpful. For example, MRN was helpful when traditional MRI and NCS/EMG results were inconclusive, but not helpful, if the time from onset of symptoms was > 1 year.

A Medical Technology Assessment performed in April 2012 identified 1 systematic review and 19 published peer-reviewed studies, which were identified concerning MR neurography of peripheral nerves. Studies date from 2002–2011 and included 5,571 neuroimaging studies.

A Hayes Review from 2002, and last updated in 2007, noted proponents of MR neurography believe that the technology can safely add clinically useful diagnostic information where other testing measures fall short (i.e., nerve conduction studies, neurological examinations and conventional MRI). The group concluded though MR neurography is safe—with no complications have been reported up to the time of the publication of their review—current evidence was insufficient to provide proof that MRN was a useful clinical tool.

Similar to the Hayes review, the peer-reviewed studies identify multiple limitations including validation of statistical validity through multiple studies in similar anatomic regions, and lack of direct comparison to standard diagnostic modalities. Only 2 of the 19 studies evaluated the same disorder, ulnar neuropathy at the elbow. Only 1 paper addressed and championed MRNs use as a preoperative surgical planning tool. In this paper, Filler et al. noted that most of the 50,000 MRN studies they reviewed were ordered by neurosurgeons. This appears to represent its combined influence on diagnostics and surgical planning. The group gives no data comparing MRN to nerve conduction studies or EMG but concludes: "… with the elapsing of 15 years, tens of thousands of imaging studies and thousands of publications, these methods should no longer be considered experimental." Given the heterogeneity of the studies, evidence as to the clinical validity and clinical utility of MR neurography remains inconclusive.

An updated literature search of articles indexed in PubMed since 2015 shows more case series with MRN detecting abnormalities. Examples include conditions such as CMT (Chhabra, 2016), CIDP (Ishikawa, 2016), and diabetic polyneuropathy (Pharm, 2016). These all are cohort and observational studies on patients with known diagnoses. They do not compare MRN to other established diagnostic modalities (or even to routine physical exams and history) with regards to the ability of making a new diagnosis, and thus, do not demonstrate clinical utility of this modality in managing patients.

In summary, based upon available published evidence there appears to be inadequate data regarding the diagnostic performance of MR neurography, in terms of defining the normal range of morphologies able to be effectively studied with this technique, the sensitivity and specificity of identification of abnormalities in comparison to other diagnostic tests, and how the imaging data will affect the management of the individual.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

76498 Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

MRI OF THE BREAST FOR SCREENING AND DIAGNOSTIC PURPOSES

Policy # 267
Implementation Date: 1/13/05
Review Dates: 2/16/06, 12/18/08, 12/17/09, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/10/19, 6/18/20, 6/17/21, 5/19/22, 6/1/23
Revision Dates: 3/17/07, 6/17/07, 10/29/07

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description
Magnetic resonance imaging (MRI) of the breast can be performed using MR scanners and intravenous MR contrast agents; specialized breast coils are required. MRI computer-aided detection (CAD) systems are also available.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers diagnostic magnetic resonance imaging (MRI) of the breast for members who have had a previous conventional mammogram and/or breast sonogram, in any of the following circumstances where MRI of the breast is expected to affect the patient's clinical management:

1. To confirm, when necessary, rupture of breast implants in asymptomatic members whose screening ultrasonography shows rupture and whose implants are the result of a covered mastectomy; or

2. To detect implant rupture in symptomatic members whose ultrasonography shows no rupture and whose implants are the result of a covered mastectomy; or

3. To detect local tumor recurrence in breast cancer patients who have undergone mastectomy and breast reconstruction with an implant; or

4. To detect local tumor recurrence in individuals with breast cancer who have radiographically dense breasts or old scar tissue from previous breast surgery that compromises the ability of combined mammography and ultrasonography; or

5. To assess tumor location, size, and extent before and/or after neoadjuvant chemotherapy in persons with locally advanced breast cancer, for determination of eligibility for breast conservation therapy; or

6. To detect the extent of residual cancer in the recently postoperative breast with positive pathological margins after incomplete lumpectomy when the member still desires breast conservation, and local re-excision is planned; or

7. To localize the site of primary occult breast cancer in individuals with adeno-carcinoma suggestive of breast cancer discovered as axillary node metastasis or distant metastasis without focal findings on physical examination or on mammography/ultrasonography; or

8. To guide localization of breast lesions to perform needle biopsy when suspicious lesions exclusively detected by contrast-enhanced MRI cannot be visualized with mammography or ultrasonography.

Select Health covers MRI of the breast as a screening technique for breast cancer in patients who meet one of the following criteria:

1. Known BRCA1 or BRCA2 mutation in patient or relatives;

2. Pattern of breast cancer history in at least 2 first-degree relatives consistent with a high probability of harboring BRCA mutations, or another hereditary breast cancer;

3. In women 30 years of age and younger, with prior history of radiation therapy in childhood or adolescence to fields encompassing the supraclavicular, mediastinal, axillary, or pulmonary hilar lymph nodes.

Select Health does NOT cover MRI of the breast in the following circumstances as these are considered investigational:

1. To confirm implant rupture in symptomatic individuals whose ultrasonography shows rupture, especially with implants more than 10 years old (ultrasound is sufficient to proceed with removal); or

2. To screen for breast cancer in members with average risk of breast cancer; or

3. To evaluate breasts before biopsy, in an effort to reduce the number of surgical biopsies for benign lesions; or

4. To differentiate benign from malignant breast disease, especially clustered microcalcifications; or

5. To differentiate cysts from solid lesions (ultrasound indicated); or

6. To provide an early prediction of response to breast cancer chemotherapy in guiding choice of chemotherapy regimen; or

7. In women with “dense” breasts, but otherwise are at low/average risk for breast cancer.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit

their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Screening Uses

The policy regarding MRI as a screening tool in high-risk women is based on a 2003 TEC Assessment that offered the following observations and conclusions:

- When applied to high genetic-risk women, the evidence appears to show at least equivalent performance for MRI in terms of sensitivity in detecting breast cancer compared to mammography. In 2 published studies, however, there were only 15 cases of cancer. In both studies, MRI detected 100% of cancer cases, while mammography detected 33%. Recent abstracts show findings consistent with superior sensitivity of MRI and either equivalent or slightly inferior specificity.
- Although direct benefit of MRI screening among this population has not been proven, such a benefit might be inferred by knowledge of the sensitivity and specificity of this test, along with knowledge of the benefits of mammography developed through several lines of evidence including randomized clinical trials.

Kriege and colleagues, in a study published in July 2004, conducted surveillance of 1,952 women, ages 25–70 with a high genetic risk for breast cancer with clinical breast exam every 6 months, annual mammography, and annual dynamic MRI. Results of the imaging studies were blinded. When either mammography or MRI results were suspicious, further investigation with ultrasound, with or without biopsy, was performed. During the 2.9 years follow-up period, the overall detection rate for breast cancer was 9.5 per 1,000 women years at risk. Overall, 32 cancers were found on MRI (22 of these were not visible on mammography) whereas 13 were missed on MRI (8 of the 13 were visible on mammography). In this group of 45 breast cancers, mammography detected 18 tumors (10 were visible on MRI) and missed 27 tumors (including the 22 that were visible on MRI). Overall sensitivity for clinical breast exam, mammography, and MRI was 17.8%, 40%, and 71.1%, respectively. Specificity was 98.1% for clinical breast exam, 95% for mammography, and 89.9% for MRI.

A 2004 TEC Assessment assessed the evidence for MRI of the breast as a screening test for the detection of breast cancer in patients who have breast characteristics limiting the sensitivity of mammography (i.e., dense breasts, implants, scarring after treatment for breast cancer). The assessment offered the following observations and conclusions:

- In patients with or without a prior history of breast cancer, evidence is insufficient to draw conclusions on the effect of adjunctive breast MRI on health outcomes.
- In the average risk population, the incremental effects of adjunctive MRI screening are uncertain.
- When the sensitivity of mammography is limited in patients after breast conservation therapy, there may be improvements in sensitivity with MRI; however, additional prospective studies are needed to confirm this, and to identify the most useful subsets for MRI evaluation given the relatively low incidence of recurrence.

However, compared to mammography, the sensitivity and specificity of breast MRI are not affected by implants, dense breast tissue, or scars from prior breast surgery. MRI can be valuable in these settings if traditional mammography is limited or inadequate. In addition, large population-based studies have documented a subset of young women who are at risk for breast cancer at an early age due to prior lymph node irradiation for lymphoma in childhood or adolescence. It is recommended that these young women begin routine breast cancer screening at a younger age than the average risk population. In young women, generally under the age of 30 years, breast tissue may be dense. It is well documented that the sensitivity of mammography is diminished when imaging dense breast tissue. Therefore, in a population at risk with dense breast tissue breast MRI is the preferred imaging modality.

The policy regarding breast MRI as a technique for detection of a suspected occult breast primary tumor with axillary nodal adenocarcinoma when there is a negative mammography and physical exam is based on a 2004 TEC Assessment that offered the following observations and conclusions:

- In this small subgroup of patients, the adjunctive use of breast MRI allows patients to avoid the morbidity of mastectomy in a substantial portion of patients (approximately 25%–61%), while the risk of unnecessary biopsy is estimated to be 8%.
- The use of positive MRI findings to guide BCT instead of presumptive mastectomy appears to offer the substantive benefit of breast conservation in true-positive MRI cases.

The policy on MRI to detect breast cancer in the contralateral breast of patients with breast cancer is based on the following evidence:

- There are 5 studies (total n = 564) with a primary focus on screening the contralateral breast in women with breast cancer (8–12). Four of these 5 studies reported a 4%–9% prevalence of cancer in the contralateral breast on MRI, though 1 small study of 17 patients found a much higher prevalence at 24%. Positive predictive value (PPV) was quite variable, ranging from 20%–80%, and specificity ranged from 76%–97%.
- These studies conducted MRI exams at various times before, during and after treatment for breast cancer. Most studies reported that contralateral cancers detected on MRI were not detected by conventional testing; whereas in some cases, MRI was done to evaluate suspicious findings in the contralateral breast.
- Liberman et al. reported the largest study, including 212 subjects who had negative mammograms of the asymptomatic contralateral breast, and found 12 cancers (prevalence=5%) on MRI including 6 DCIS and 6 infiltrating carcinomas. However, the PPV of these findings was only 20%, with a specificity of 76%.
- These studies provide interesting preliminary findings that MRI may be able to detect cancers in the contralateral breast in women who have already been diagnosed with breast cancer; however, the degree of specificity and PPV for MRI in this context are not well established, and additional, prospective, confirmatory studies are necessary to support the use of MRI for screening the contralateral breast.
- An ongoing ACRIN-A6667 trial "MRI Evaluation of the Contralateral Breast in Women with a Recent Diagnosis of Breast Cancer" has enrolled 948 of 1,000 planned subjects as of May 25, 2004, and results are anticipated for release in early 2005.

Diagnostic Uses

The policy regarding MRI of the breast as a technique to further characterize otherwise indeterminate or suspicious breast lesions is based in part on TEC Assessments in February 2002 and 2004 that offered the following observations and conclusions:

- The available studies addressed a group of patients who have a lesion of sufficient suspicion to warrant recommendation to undergo biopsy diagnosis. Therefore, the MRI results would be assumed to have an impact on the decision whether to undergo definitive biopsy—considered the gold standard.
- The available evidence did not show that the use of MRI of the breast would improve health outcomes. Considering the relative ease of breast biopsy, the sensitivity of breast MRI would have to be virtually 100% to confidently avoid biopsy. While MRI performs well, it is clear that the sensitivity is not 100%. False negative results tend to occur, particularly in certain subcategories, such as ductal carcinoma in-situ, but invasive carcinomas fail to enhance on MRI, leading to false negative findings as well. The potential harm to health outcomes of failing to diagnose breast cancer or at least delaying the diagnosis is of significant concern. The TEC Assessment concluded that the potential benefit of sparing a fraction of patients from undergoing biopsy does not outweigh the potential harms, considering the current level of diagnostic performance of breast MRI.

The policy regarding MRI of the breast as a preoperative mapping technique to evaluate multicentric disease in patients with clinically localized breast cancer is based on a 2000 TEC Assessment and an update in 2004 that offered the following observations and conclusions:

- Breast MRI is primarily used to identify multicentric breast tumors that have not been detected by conventional testing using mammography, clinical exam, or ultrasound.

- Multiple studies confirm that MRI of the breast has a better sensitivity and specificity for identifying multicentric and multifocal breast tumors compared to mammography and/or ultrasound. Approximately 2%-15% of patients otherwise eligible for BCT may have multicentric disease seen on MRI.
- In studies that examined the effect of MRI on patient management, MRI led to mastectomy in 13/184 cases (7%), although 2 of these 13 mastectomy cases (15%) were MRI false-positives and did not have multicentric cancer. Preoperative imaging guided surgery (MRI or other) was not universally performed.
- The effect on health outcomes of multicentric disease detected only on MRI has not been firmly established. If MRI information is used to guide mastectomy, then the potential benefit of breast conservation will be decreased. The effects of multicentric disease on locoregional recurrence and survival have not been established after either BCT with whole-breast radiation or modified radical mastectomy.

BCT with radiation vs. mastectomy

- Multiple randomized controlled trials using mammography but not MRI for preoperative evaluation comparing outcomes after BCT with radiation or mastectomy have shown no significant difference in survival with follow-up to 20 years.
- Loco-regional recurrence rates during the first 10 years are not significantly different after BCT with radiation or mastectomy. Long-term follow-up reports from 3 trials have noted significantly increased locoregional recurrences after ten to twenty years among women treated with BCT radiation therapy compared with mastectomy. However, it is not known whether these late recurrences relate to failure at the surgical site, failure due to unresected multicentric disease, or development of a new primary tumor.
- BCT with radiation versus BCT without radiation.
- A recently published meta-analysis shows that women who receive BCT without radiation are at greater risk for locoregional recurrence and have a slightly lower survival compared with those who receive radiation after breast-conserving surgery. This provides some evidence linking recurrence and reduced survival and supports the use of radiation after breast-conserving surgery. However, this does not provide evidence that treatment of the breast by surgical resection is any better than treatment with radiation therapy.

Summary

There is insufficient evidence that modified radical mastectomy would add any benefit compared to breast-conserving therapy plus whole breast radiation with respect to risk of local or distant recurrence or survival of these patients. Information from MRI might change the decision from BCT in favor of mastectomy; however, it is not clear whether by doing so the patient receives a better trade-off of risk and benefit.

The policy on breast MRI for preoperative tumor mapping in patients with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy is based on a 2004 TEC Assessment that offered the following observations and conclusions:

- Compared with conventional methods of evaluating tumor size and extent (i.e., mammography, clinical exam, or ultrasound), MRI of the breast provides an estimation of tumor size and extent that is at least as good as or better than that based on alternatives. Drew and colleagues found MRI to be 100% sensitive and specific for defining residual tumor after chemotherapy. Conversely, mammography achieved 90% sensitivity and 57% specificity (mammography resulted considered equivocal), and clinical exam was only 50% sensitive and 86% specific. Similarly, Partridge and colleagues reported correlation of residual tumor on MRI of 0.89 and clinical exam of 0.60.
- MRI results were well-correlated with results of histopathological assessment (reference standard) with correlation coefficients of 0.72–0.98; however, MRI is not intended as a replacement for histopathological assessment.

- Using breast MRI instead of conventional methods to guide surgical decision-making regarding the use of BCT versus mastectomy would be at least as beneficial and more frequently lead to the appropriate surgical procedure.

The policy on breast MRI to evaluate response during neoadjuvant chemotherapy in patients with locally advanced breast cancer is based on a 2004 TEC Assessment that offered the following observations and conclusions:

- The most important use of MRI would be to reliably identify patients whose tumors are not responding to neoadjuvant chemotherapy to avoid the added morbidity of continued ineffective chemotherapy. Such chemotherapy may be discontinued or changed to an alternative and potentially effective regimen. MRI would be harmful when it falsely suggests a lack of response and leads to premature discontinuation of effective chemotherapy.
- High negative-predictive value (NPV) (i.e., ability to predict a non-responsive tumor) would be most important in association with high sensitivity for detecting tumor response and high specificity for nonresponsive tumors.
- A total of 6 studies, including a total of 206 patients, performed breast MRI during the course of chemotherapy. MRI outcomes for response to chemotherapy were based either on reduction in tumor size or contrast enhancement.
- Three studies report NPV results of 38%, 83%, and 100%; however, the 2 lower estimates were from prospective studies, while the highest estimate was from a retrospective study.
- The available body of evidence is limited to a few small studies with inconsistencies in outcome measures, reporting, and use of statistical comparisons. Results are not consistent, and there is insufficient evidence to determine whether breast MRI can reliably predict lack of response to neoadjuvant chemotherapy.

The policy on breast MRI to diagnose suspected chest wall involvement in posteriorly located tumors is based on the following evidence:

- Morris and colleagues prospectively studied 19 subjects with posteriorly located breast tumors suspected to involve the pectoralis major muscle based on either mammography or clinical exam. Thirteen of these tumors were thought to be fixed to the chest wall on clinical exam and 12 appeared to have pectoral muscle involvement on mammography. Results of MRI were compared with surgical and pathological findings. The presence of abnormal enhancement within the pectoralis major muscle on MRI was 100% sensitive and 100% specific for identifying the 5 tumors that actually involved the pectoralis major muscle.
- Two other retrospective studies reported 4 cases where MRI was able to determine involvement of the chest wall with 100% accuracy. Given the high level of diagnostic accuracy for MRI as compared with reference standard and conventional alternative techniques, the evidence is considered sufficient to permit conclusions that breast MRI improves net health outcomes.

The policy on breast MRI to evaluate residual tumor after lumpectomy with positive surgical margins is based on the following evidence:

- Seven studies evaluated the diagnostic performance of MRI to determine the presence of residual disease after prior biopsy or lumpectomy. Histopathology on re-excision was used as the reference standard. Most of these studies, including the single prospective study, report poor sensitivity and specificity of MRI for detection of residual disease, and the 2 studies that report more favorable results have methodologic concerns that limit the influence of reported results. Three of these studies were conducted at the same institution and accrued patients during similar time periods so overlap of reported patients exist. The available evidence is not sufficient to permit conclusions whether MRI improves net health outcomes when used to identify the presence and/or extent of residual disease after lumpectomy and prior to re-excision.
- Lee et al. prospectively studied 80 patients eligible for BCT who had close or positive margins on lumpectomy and were scheduled for re-excision lumpectomy. In this study, MRI was 81% sensitive and 70% specific for detection of residual tumor. The finding of extensive tumor on MRI led to mastectomy in 6 patients (7.5%), but it is difficult to determine from the publication what proportion of these cases had false-positive MRI results. Bedrosian et al. retrospectively studied 70 subjects prior to re-excision and found MRI had 57% sensitivity and 60% specificity. MRI

prompted wider than initially planned excision in 11 cases, but 10 of these turned out to be false-positive MRI results. Kawashima et al. studied 50 subjects and reported 66% sensitivity and 81% specificity. Orel et al. included 47 patients with questionable or positive margins after biopsy and found that MRI had 54% sensitivity and 62% specificity for residual tumor at the biopsy site. Similarly, sensitivity and specificity were low for identification of residual tumor anywhere in the breast (64% and 58%, respectively). Weinstein et al. reviewed 14 cases of invasive lobular carcinoma that had prior excisional biopsy and found that MRI had 57% sensitivity and 0% specificity for identifying residual disease.

- Frei et al. retrospectively studied 68 patients with positive margins and examined the relationship between when MRI was performed after initial surgery and diagnostic performance of MRI for residual disease. However, this study excluded 3 patients with technically inadequate MRI studies, and has discrepancies in reported results in the publication. Sensitivity of MRI ranged from 89%–95% with slight improvements noted with longer time intervals after initial surgery. Specificity was initially 52% for MRI performed at least 7 days after lumpectomy; whereas, when analysis was restricted to MRI conducted at least 28 days after lumpectomy, the specificity of MRI increased to 75%. Soderstrom and colleagues retrospectively examined 19 patients with various indications for MRI, including 11 patients with close or positive margins after surgery, and found MRI was 100% sensitive and 71% specific for identification of residual tumor. The authors note that MRI overestimated the extent of tumor in 1 patient that was counted as a true-positive in the results.

Billing/Coding Information

CPT CODES

77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral

HCPCS CODES

C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

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MEDICAL POLICY

MR GUIDED FOCUSED ULTRASOUND (MRgFUS) ABLATION OF UTERINE FIBROIDS

Policy # 280

Implementation Date: 8/15/05

Review Dates: 8/1/06, 8/23/07, 6/11/09, 6/17/10, 8/16/11, 8/16/12, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/19/18, 8/8/19, 8/20/20, 8/19/21, 7/14/22, 8/18/23

Revision Dates:7/14/08

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Uterine leiomyomas (i.e., fibroids or myomas) are benign tumors arising from the smooth muscle cells of the uterus. Most women with symptomatic fibroids are in their 30s or 40s. Fibroids are clinically apparent in approximately 25% of reproductive age women and noted on pathological examination in approximately 80% of surgically excised uteri. Relief of symptoms related to fibroids usually occurs at the time of menopause, when menstrual cyclicity and steroid hormone levels wane.

Multiple therapies currently exist to treat symptomatic uterine fibroids. Hysterectomy is the standard, permanent treatment for women who have symptomatic uterine fibroids and who do not want to retain their uterus. Myomectomy, another surgical treatment for fibroids, involves the removal of individual fibroids, while leaving the uterus in place. Several less invasive treatments are available to treat the symptoms of pressure or heavy bleeding, including uterine fibroid embolization (UFE), endometrial ablation, laparoscopic guided radiofrequency ablation, and drug therapy.

One method approved for the treatment of symptomatic uterine fibroids involves focused ultrasound energy to shrink/destroy the fibroids. The ExAblate 2000 uses magnetic resonance guidance to focus the ultrasound (MRgFUS) waves/energy in a manner similar to how a magnifying glass focuses light. The ultrasound waves are directed from a transducer (a device that converts electrical energy into ultrasound energy) into a small focal volume. During treatment, the beam of focused ultrasound energy penetrates through soft tissue and produces well defined regions of protein denaturation, irreversible cell damage, and coagulative necrosis, at specific target locations. A single exposure of focused ultrasound energy is called a "sonication." Multiple sonications are necessary to ablate the targeted tissue. Tight focusing is designed to limit the ablation to the targeted location.

Prior to the treatment, anatomical MR images, capable of showing the tumor and surrounding organs, are used to position the patient and plan the treatment. As the treatment is performed, the MR thermal mapping system displays the relative tissue temperature as a color map superimposed on an anatomical MR image. This allows the physician to observe temperature changes inside the body in real time during treatment. Based on these observed temperature changes, the physician can adjust treatment parameters accordingly to ensure safe and effective thermal ablation. Following the treatment, anatomical MR images are used to evaluate treatment outcome. T1 weighted images with Gadolinium contrast agent is often used to determine which regions have become ablated.

Each exposure of focused ultrasound, or "sonication," ablates a volume in the tumor of about 6x6x20 mm. Therefore, multiple sonications are usually required to ablate an entire fibroid, and the time required for a treatment depends on the tumor size. Treatments usually do not last longer than three hours, and multiple treatments may be required for large tumors.

Select Health

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover MRI guided ultrasound ablation of uterine fibroids. The published literature is limited and fails to answer questions regarding long-term efficacy and safety of this therapy. This meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Seventeen studies met criteria and multiple systematic reviews have been published. These studies are characterized by primarily prospective or retrospective cohort evaluations of women who underwent MRI guided ultrasound for symptomatic uterine fibroids. These studies mainly conclude that the procedure is effective in reducing fibroid volume and the severity of fibroid symptoms. For example, in 108 procedures evaluated by Hindley, et al. 79% of women reported improvement in fibroid symptoms at 6 months despite a mean reduction in fibroid volume of only 13.5%. Of 166 women followed by Fennessy, et al. who were treated with 2 different MRgFUS protocols, 79.2% of evaluable patients had a 10-point or greater symptom improvement at 3 months after treatment, which was sustained in 79.2% of patients at 6 months and in 78% of patients at 12 months. NPV was 59.4 cm^3 ± 65.1 in the original protocol group and 131.6 cm^3 ± 138.1 in the modified protocol group. When the NPV was calculated as a percentage of the total fibroid volume load, it was 16.65% ± 16.1 (n = 88) in the original protocol group and significantly increased to 25.79% ± 21.8 (n = 44) in the modified protocol group ($p < .001$, two-tailed t test). No serious adverse events were reported.

Stewart, et al.'s, 2007 evaluation of 359 women was the largest trial located for this review. This prospective study followed patients for 24 months, finding a statistical improvement in fibroid symptom severity compared with baseline. The authors also reported a statistical reduction in the number of women seeking further treatment for fibroids in women in the high non-perfused volume group. Mean shrinkage and non-perfused volume are significantly above 0 at 6 months in the high non-perfused group. For women with minimal treatment, however, risk for repeat treatments is high.

Zowall, et al., analyzed the cost-effectiveness of MRgFUS compared with current practice comprising UAE, myomectomy, and hysterectomy. The Markov model was based on a U.K. population, and National Health Service cost parameters. In the base case, the model started at age 39 and followed women until age 56. The model assumed no clinical or cost differences between treatments after menopause and a distribution across the three standard treatments: 25% to UAE, 25% to myomectomy, and 50% to hysterectomy. All outcomes, except quality of life, were tracked in cycles; for the initial procedures over 6 and 12 months, and yearly thereafter. Quality- of-life estimates were calculated monthly within the first year following the procedure and annually thereafter.

Of the many systematic reviews on the topic, the most recent technology review was a Blue Cross Blue Shield TEC completed in 2007. This review evaluated health outcomes from MRI guided ultrasound for uterine fibroids. The review concluded that the available evidence was insufficient to permit conclusions regarding the effect of the procedure on health outcomes. The report noted that the relatively few studies

on the technique considering the prevalence of uterine fibroids in the population raised concerns about the validity and reliability of published findings. The report further noted insufficient follow-up periods to permit measurement of regrowth rates for treated fibroids. The data are also insufficient to permit comparisons with established treatment alternatives such as hysterectomy.

In summary, available evidence suggests that MRgFUS may help to relieve pain and improve quality of life in women with uterine fibroids. However, small sample sizes, a lack of randomized and/or comparative trials with standard alternatives, and brief follow-up periods limit conclusions about the relative effectiveness of the procedure and its long-term safety and durability. Comparative studies assessing outcomes compared to hysterectomy and myomectomy are also lacking as are comparative long-term cost-effectiveness studies. Further research is needed to address this missing evidence in the literature.

A literature review performed in June 2010 did not identify randomized controlled studies in the literature where MRgFUS is compared to other accepted treatment for uterine fibroids, namely hysterectomy, myomectomy, or uterine artery embolization. However, there are some ongoing randomized controlled trials in progress. Until results of these and other studies become available and until more data is available regarding the safety and efficacy of MRgFUS, this technology remains investigational/experimental.

A literature review completed in 2014 found no new studies on this modality for the treatment of uterine fibroids. There remain no long-term prospective, controlled studies comparing any of the focused ultrasound ablative techniques with hysterectomy, myomectomy, or uterine artery embolization. And, to date, ACOG has still not given an official opinion on the treatment of uterine fibroids with MRgFUS.

A literature review completed in 2017 identified a recent evidence-based analysis by Pron, et al. (2015), which concluded: “The lack of comparative evidence between MRgHIFU and other, more established uterine-preserving treatments limits informed decision making among treatment options.” Another small study in 2016 (Jacoby, et al.) could not find a significant difference between the procedure and placebo as it related to the patient rated quality-of-life outcome.

Billing/Coding Information
CPT CODES

Not covered: Investigational/Experimental/Unproven for this indication

0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue

HCPCS CODES

No specific codes identified

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health

MR Guided Focused Ultrasound (MRgFUS) Ablation of Uterine Fibroids, continued

Select Health

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MEDICAL POLICY

PET SCANS IN THE EVALUATION OF ALZHEIMER'S DISEASE AND OTHER DEMENTIAS

Policy # 264
Implementation Date: 2/17/05
Review Dates: 1/23/06, 10/18/07, 10/23/08, 10/22/09, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 6/21/18, 4/14/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23
Revision Dates: 10/31/06, 5/10/16

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Description

Dementia is a disorder that is characterized by impairment of memory and at least one other cognitive domain (aphasia, apraxia, agnosia, executive function). The term dementia does not imply a specific cause or pathologic process. Clinically, multiple types of dementia are described. These include Alzheimer's disease (AD), vascular dementia, dementia with Lewy Bodies, and frontotemporal lobe dementia. Each dementia type has distinctive characteristics which suggest a clinical diagnosis of the condition. However, in many patients with dementia, the clinical manifestations can be obscure, causing a lack of clarity in the diagnosis as to the clinical type of dementia. Determining the dementia type assists in optimizing the therapeutic approach, avoiding certain medications of little or no effectiveness in some dementia types, and also, helping to allow accurate prognostication of the clinical course so that the patient and family can adequately prepare for future events.

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate glucose metabolism in dementia. This procedure begins with injection into the patient of 2- [F-18] fluoro-D-glucose (FDG), which is a radioactive tracer substance (radionuclide) that emits sub-atomic particles, known as positrons, as it decays. The operator then utilizes a positron camera (tomography) that measures the decay of the FDG radioisotopes in the patient. The rate of FDG decay provides biochemical information on glucose metabolism of the tissue being studied. The utility of FDG-PET in imaging relates to the ability to differentiate abnormalities based on metabolic function. The test involves the qualitative visual interpretation of the scan images where metabolically active areas of the body "light up" on an FDG-PET scan, more so than less active areas.

Functional neuroimaging, such as FDG-PET, has been proposed for the evaluation of elderly patients who may have early dementia and for whom the differential diagnosis includes one or more kinds of neurodegenerative diseases. FDG-PET may be able to diagnose AD by identifying anatomical patterns of brain hypometabolism, which typically occur bilaterally in the temporal and parietal lobes. FDG-PET scans typical of AD may be differentiated by visual inspection from scans suggestive of vascular dementia (asymmetric and focal abnormalities) and scans indicative of FTD (marked hypometabolism of frontal or temporal lobes with sparing of parietal lobes). An accurate distinction, for instance between AD and FTD, may prove helpful inpatient management given the variation during these 2 diseases.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health does NOT cover PET scans for the routine diagnosis of dementia and Alzheimer's disease as this testing has failed to demonstrate clinical utility and is considered not medically necessary; this meets the plan's definition of experimental/investigational.

Select Health covers FDG-PET scans in the evaluation of dementia only when frontal temporal lobe dementia is suspected, and other routine testing has failed to determine a definitive diagnosis as current evidence suggests clinical utility of this procedure in this circumstance.

To qualify for coverage of PET scanning, **ALL** the following conditions must be met:

1. The patient has seen a recognized expert in dementia (neurologist or neurology subspecialist).
2. The test is ordered by the neurologist or neurology subspecialist.
3. The patient has had a comprehensive clinical evaluation as defined by the American Academy of Neurology (AAN) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT).

Select Health does not cover other types of PET scans, including FBP-PET or PiB-PET, for this indication, based on very limited body of evidence pertaining to the comparative accuracy these tests relative to standard imaging procedures for AD (i.e., MRI, computed tomography) and the very limited evidence regarding the clinical utility for these indications.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A 2004 M-Tech review noted that the current evidence on PET was limited by numerous design limitations, failure to assess direct patient outcomes (e.g., mental state, quality of life, and functional status), inconsistent study results as a function of heterogeneity in study designs, patient selection, outcome measures, PET protocols, and other confounding variables. The report further observed a lack of consensus about the utility of PET scans in the published literature, specialty society guidelines, as well as by major coverage policies from third-party payers. The report concluded that it was not yet possible to determine whether coverage of PET would increase the likelihood of outcomes important to patients, their families, and providers.

It is noteworthy that none of the major North American or European technology assessment groups (e.g., AHRQ, Hayes, NHS) have published new or updated reviews of PET for dementia, nor have any new or updated clinical guidelines or position statements been released by academic or advocacy groups. The lack of new summary reports from any of these sources suggests that the level of empirical evidence, while it continues to improve, does not yet warrant a change to earlier conclusions about the utility of PET. From this standpoint, the evidence for PET scans' informing diagnostic decisions and altering patient outcomes remains scant.

PET Scans in the Evaluation of Alzheimer's Disease and Other Dementias, continued

Two review articles were published recently that summarized the extant research on PET for various indications, both concluding that PET improves diagnostic accuracy for AD. Silverman and Alvi's 2005 review reported sensitivity ranging from 88%−96% and specificity ranging from 63%−97% for detecting AD. These findings suggest that PET scanning can accurately identify dementing from non-dementing brains but that it is less accurate in differentiating between different forms of dementia. CMS concluded that PET is more effective in differentiating AD from frontotemporal dementia than over other dementias. However, this conclusion was based primarily on expert consensus as their review did not identify any new studies that had examined PET and FTD.

Since this last internal review in December 2004, most of the literature in this area has focused on using PET to distinguish mild cognitive impairment from Alzheimer's disease or other forms of dementia and to predict cognitive decline. In Kawachi et al., for example, 30 patients with very mild AD, 32 patients with mild AD, and 60 age- and sex-matched normal volunteers underwent voxel-based morphometry (VBM) on magnetic resonance imaging (MRI) and FDG-PET. ROC analysis revealed an area under the curve for VBM-MRI of 0.91 and 0.953 for FDG-PET. Combined, the 2 tests yielded a diagnostic accuracy of 93.5% and an area under the curve of 0.985.

Jagust et al. tracked 60 cognitively normal subjects over an average follow-up period of 3.8 years. Six developed dementia or cognitive impairment. Hippocampal and entorhinal cortical volumes as measured by PET at baseline predicted decline in delayed recall over time. Devan et al. followed 23 outpatients with mild cognitive impairment over an average of 48.8 months.

Drzezga et al. prospectively tracked 30 patients with mild cognitive impairment over 15 months. At baseline, patients underwent neuropsychological evaluation, routine blood screening, APOE genotyping, MRI, and FDG-PET. At follow-up, 40% of participants met criteria for AD. The authors compared the predictive value of each method of PET and APOE: Sensitivity 92% vs. 75%; Specificity 89% vs. 56%; Positive predictive value 85% vs. 53%; Negative predictive value 94% vs. 77%. Area under the ROC curve for PET was 0.90, 0.65 for APOE genotype, and 0.83 for the 2 approaches combined. The authors concluded that FDG-PET is superior to APOE genotype alone at predicting conversion from mild cognitive impairment to AD.

In a 2006 literature review, Modrego et al. concluded that PET in conjunction with memory scores or APOE4 genotype have the highest diagnostic accuracy for predicting conversion from mild cognitive impairment to MCI. Nevertheless, because of small sample sizes and the small number of studies conducted to that point, the authors could not recommend any single technique over another.

In 2013, Johnson et at. Published a consensus statement that gives instances where using amyloid PET in clinical practice may be useful. Helping the practitioner select appropriate test and treatments to avoid unnecessary ones, improving diagnostic accuracy, and advising families on clinical course and prognosis "the value of knowing". However, at several times the consensus statement also recognizes limitations with regards to proven clinical benefits of amyloid PET technology and that there is no proven economic benefit for using the technology, especially considering that disease modifying therapies are lacking. The paper notes that: "…most published studies to date have been designed to validate this technology and understand disease mechanisms rather than evaluate applications in clinical practice." Although the paper supports using amyloid imaging in patients with persistent or progressive unexplained mild cognitive impairment (the recent Cochrane review recommends against routine use of amyloid imaging in MCI patients), it acknowledges a limitation in this use in that amyloid positivity in such patients does not correlate with a future time point at which cognitive deterioration can be predicted, somewhat limiting the usefulness of this information to a particular patient. Differentiate it from other amyloid plaque disorders such as dementia with Lewy bodies or cerebral amyloid angiopathy. Limitations outlined in this consensus paper regarding use of amyloid in clinical practice, and limitations in what a positive test does or does not mean, suggest against widespread and routine use at this time.

In a 2016 review, results of the best available studies of PET for AD suggested that FDG PET often has moderate-to-high accuracy for discrimination of AD versus no impairment. However, this does not seem to be a common clinical application of this technique since PET is much more likely to be used during the early stages of disease when patients have MCI and symptoms that are suggestive of AD (but not conclusive), and when specific treatments for AD may be more effective. The best available studies of FDG PET for detection of MCI versus AD, MCI versus no impairment, and for prediction of progression

from MCI to AD, found that accuracy was widely scattered but primarily fell in the range of moderately accurate. Furthermore, almost all the reviewed studies that compared FDG PET with MRI for detection or prognosis of AD, found that the accuracy of these 2 techniques was similar.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

78608 Brain imaging, positron emission tomography (PET); metabolic evaluation

78609 ; perfusion evaluation

HCPCS CODES

No specific codes identified

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TOTAL BODY MRI FOR LI-FRAUMENI SYNDROME

Policy # 563
Implementation Date: 4/21/15
Review Dates: 10/20/16, 10/19/17, 10/2/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/24/23
Revision Dates:

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Description

Li-Fraumeni syndrome is an inherited autosomal dominant disorder that is manifested by a wide range of malignancies that appear at an unusually early age. Li-Fraumeni syndrome is also known as the Sarcoma, Breast, Leukemia and Adrenal Gland (SBLA) cancer syndrome. This cancer predisposition syndrome is inherited as an autosomal dominant disorder and is associated with abnormalities in the tumor protein p53 gene (TP53). The only gene that has been definitively associated with Li-Fraumeni syndrome is TP53. TP53 is a tumor suppressor gene that has a major role in determining the fate of cells that contain damaged DNA. The gene product, tumor protein p53, can delay cell cycle progression, permitting an opportunity for DNA repair or initiation of programmed cell death (apoptosis). In the absence of the normal activated p53 protein, cells containing damaged DNA can survive and proliferate, which contributes to malignant transformation.

A heightened level of surveillance for cancer is required for individuals who are considered at-risk, based upon a history of a Li-Fraumeni syndrome malignancy. This may be due to the presence of a known TP53 mutation, or the presence of increased risk in a family with Li-Fraumeni syndrome, even without an identifiable mutation or having not undergone mutation testing.

Whole body MRI is performed on scanners that have radiofrequency coils embedded in the patient table, which makes it possible to complete the entire scan without moving the patient. Images are acquired at multiple stations (sections) to scan the entire body, except for patients with lymphomas because this condition is less commonly associated with bone metastases and scanning the lower extremity station is not generally necessary. Because of their smaller size, pediatric patients can often be imaged in fewer stations, which shorten the total scan time; total imaging time is about 45 minutes. Pediatric patients under the age of 6 are not usually able to remain still during this time and will require sedation. Total imaging time for the 5 imaging stations necessary for adult imaging is only 15 minutes, if a short tau inversion recovery (STIR) pulse sequence is used.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers total body MRI for cancer surveillance in patients with Li-Fraumeni syndrome as clinically proven when billed using the unlisted CPT code 76498.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

One paper was identified which met inclusion criteria for this report. The study was well-conducted and prospective in construct. The study showed that active surveillance, which included, but was not exclusively limited to, whole-body MRI, increased survivability at 24 months by 80% and at 36 months by 79%, vis-à-vis patients who were not actively monitored. The authors were able to demonstrate a statistically significant decrease in mortality in the surveillance and treatment arm.

Billing/Coding Information

CPT CODES

76498 Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

TOTAL BODY MRI FOR THE STAGING AND DIAGNOSIS OF MULTIPLE MYELOMA

Policy # 427

Implementation Date: 11/9/09

Review Dates: 8/16/10, 4/21/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 7/20/18, 4/15/19, 4/15/20, 4/15/21, 3/18/22, 4/28/23

Revision Dates:

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Description

Multiple myeloma (MM) is the most common primary neoplasm of the skeletal system. The disease is a cancer of plasma cells producing a monoclonal immunoglobulin. This clone of plasma cells proliferates in the bone marrow and often results in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.

Monoclonal gammopathy of undetermined significance (MGUS) is an asymptomatic premalignant clonal plasma cell proliferative disorder. It occurs in over 3% of the general population over the age of 50. It is typically detected as an incidental finding when patients undergo a protein electrophoresis as part of a work-up for a wide variety of clinical symptoms and disorders (e.g., peripheral neuropathy, vasculitis, hemolytic anemia, skin rashes, hypercalcemia, and elevated sedimentation rate). The major reason for concern in the patient with MGUS is the risk of progression to multiple myeloma or other lymphoproliferative conditions.

In an effort to stage or diagnosis MM or MGUS, various technologies are employed. These include evaluation of the skeleton to assess for skin or soft tissue metastases. Focal skeletal survey has been determined to be the standard of care to assess for skeletal lesions. MRI has been proposed as a potentially useful tool for imaging multiple myeloma because of this modality's superior soft-tissue resolution. Among the first MR techniques for imaging, a larger field-of-view in a short time were a rolling platform with an extended field of view, which allowed whole body examinations without repositioning, and a 'moving-bed infusion-tracking MR angiography,' both of which are dependent on a rolling table platform. Today, commercially available scanners offer a table range of 200cm and up to several dozen simultaneous receiver channels. In addition, the patient can be covered with coils from 'head to toe' so the repositioning of a patient or coils is not required. The high number of simultaneous receiver channels additionally allows for 'parallel imaging,' which can, for example, be used for increased spatial resolution while keeping acquisition times constant.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers total body MRI in the assessment of multiple myeloma (MM) and monoclonal gammopathy of undetermined significance (MGUS) as a proven technology. Current evidence supports improved clinical validity for total body MRI over standard skeletal survey x-rays.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Eleven studies met criteria for the policy. Generally, these studies suggest that total body MRI (tb-MRI) is a reliable and accurate method for detecting myelomatous lesions. More importantly, the procedure appears to be more accurate than a skeletal survey. In Bauerle et al., for example, 100 patients with MGUS or MM underwent tb-MRI and MRI of the axial skeleton. The addition of tb-MRI revealed 37 patients with extra-axial lesions that were not detected through the standard procedure. Nine of these patients had no axial lesions at all and 13 patients had extra-axial lesions extending to cortical bone, thereby increasing fracture risk.

Goo et al. reported similar findings in 36 children with oncological diagnoses who underwent tb-MRI and bone scintigraphy to detect metastases. Tb-MRI was more sensitive (99%) and had a higher positive predictive value (94%) than bone scintigraphy (26 and 76%, respectively), and was more sensitive (100%) in detecting bone metastases than 123I-MIBG scintigraphy (25%) and CT (10%). In contrast, tb-MRI showed lower PPV in detecting skeletal and extraskeletal metastases (8 and 57%, respectively) than 123I-MIBG scintigraphy (100%), and lower sensitivity (60%) in detecting extraskeletal metastases than CT (100%). In 2 patients, TB-MRI findings led to a tumor being upgraded from stage 3 to 4 and TB-MRI revealed early treatment responses of skeletal metastases in 3 patients. In Shortt et al.'s study of 24 patients with multiple myeloma, all patients underwent FDG PET and tb-MRI with results verified by bone marrow biopsy. Relative to tb-MRI, PET had lower sensitivity (59% vs. 68%), specificity (75% and 83%), positive predictive value (81% and 88%), and negative predictive value (50% and 59%). In 62% of cases, PET and whole-body MRI findings were concordant.

In short, whole-body MRI appears to be an accurate and reliable method for detecting metastases in MM and MUGA. Compared with conventional procedures, tb-MRI is more sensitive and specific and has higher positive and negative predictive values.

Billing/Coding Information

Covered for the conditions outlined above

CPT CODES

76498 Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

TRANSCRANIAL DOPPLER ULTRASOUND

Policy # 181
Implementation Date: 12/9/02
Review Dates: 12/11/03, 11/16/04, 11/19/05, 12/21/06, 12/20/07, 12/18/08, 12/17/09, 12/16/10, 9/15/11, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/20/19, 6/18/20, 6/10/21, 5/19/22, 6/15/23
Revision Dates: 11/25/05, 10/21/10, 1/31/12, 7/8/12, 6/17/21

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Description

Transcranial Doppler ultrasound (TCD) is an ultrasound technology that measures physiological parameters of blood flow in the major intracranial arteries. Transcranial Doppler ultrasound uses a pulsed Doppler system with low frequencies that enables recording of blood velocities from intracranial arteries through selected cranial foramina and thin regions of the skull; it is a non-invasive test. Transcranial Doppler ultrasound is operator-dependent and requires training and experience to perform and interpret results. Transcranial Doppler ultrasound is performed by technologists, sonographers, and physicians, and is interpreted by neurologists and other specialists.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers transcranial Doppler (TCD) ultrasound in *limited circumstances*.

Specific clinical conditions for which TCD ultrasound is covered based upon the American Academy of Neurology (AAN) Type A or B level evidence include the following:

1. In the screening of children aged 2−16 years with sickle cell disease for stroke risk
2. For the detection and monitoring of angiographic vasospasm after spontaneous subarachnoid hemorrhage
3. For detection of intracranial steno-occlusive disease
4. Acute cerebral infarction
5. Extracranial internal carotid artery (ICA) stenosis
6. Vasomotor reactivity (VMR) testing
7. Detection of cerebral microembolic signals
8. Carotid endarterectomy (CEA)
9. For detection of cerebral circulatory arrest/brain death
10. Monitoring carotid endarterectomy
11. Monitoring cerebral thrombolysis
12. Monitoring coronary artery bypass graft (CABG) operations
13. Monitoring prosthetic heart valve operations
14. Monitoring cerebral thrombolysis operations
15. For the evaluation of right-to-left cardiac/extra cardiac shunts

16. For traumatic brain injury

Select Health does NOT cover transcranial Doppler (TCD) ultrasound after atrial septal defect (ASD) or patent foramen ovale (PFO) closures to assess the sufficiency of closure. This does not meet the standard of care, and therefore, meets the plan's definition of not medically necessary.

Select Health does NOT cover transcranial Doppler (TCD) ultrasound for any other indication including migraine or other headaches. These other indications meet the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Transcranial Doppler ultrasound has been an available technology for many years. There are numerous case reports and non-randomized studies demonstrating the clinical utility of this testing in varying situations. Since 2000, the advent of power mode TCD (pmTCD) has expanded the clinical utility of this testing as demonstrated in by Spencer and Moehring in their articles. However, it must be noted that Dr. Spencer is one of the developers of pmTCD and may have biases in his conclusions related to his position as principal owner of Spencer Technologies, which markets and sells the pmTCD devices.

However, the technology assessment completed for the American Academy of Neurology by Sloan et al., published in Neurology in October 2004 supports the efficacy of the use of this technology in multiple clinical circumstances. Additionally, multiple articles by individuals such as Markus and MacKinnon, and Droste et al., provide good evidence for the comparative clinical utility in settings demonstrating only type B evidence in the AAN technology assessment.

Billing/Coding Information

Covered: ONLY for the conditions above

CPT CODES

93886	Transcranial Doppler study of the intracranial arteries; complete study
93888	; limited study
93890	; vasoreactivity study
93892	; emboli detection without intravenous microbubble injection
93893	; emboli detection with intravenous microbubble injection

HCPCS CODES

No specific codes identified

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Select Health

MEDICAL POLICY

UPRIGHT/WEIGHT-BEARING, DYNAMIC KINETIC MRI

Policy # 312

Implementation Date: 6/30/06

Review Dates: 7/12/07, 6/19/08, 6/11/09, 6/17/10, 4/21/11, 6/21/12, 4/17/14, 4/14/16, 4/27/17, 7/20/18, 4/15/19, 4/15/20, 4/15/21, 3/18/22, 4/28/23

Revision Dates: 1/17/14

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Chronic back pain in the United States costs between $20 and $50 billion annually to treat. The patient complaining of back or neck pain may undergo any number of procedures to determine the cause, including MRI and computed tomography (CT)-myelography.

Conventional imaging techniques images are typically acquired with the patient lying down. Patients often experience signs and symptoms of back and neck pain during dynamic physiologic movement of the body; however, these are conditions that are not possible to assess if the patient is only imaged in a recumbent position. The FONAR Corporation (Melville, NY) has developed an MRI device that enables partial or full weight-bearing and simultaneous kinetic maneuvers of the patient's whole body, or any individual body part.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover upright/weight-bearing, dynamic kinetic magnetic resonance imaging. The medical literature has failed to prove clinical utility of this testing in the evaluation of chronic back and neck pain; this meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Select Health

Summary of Medical Information

Conclusions about the clinical utility of upright, dynamic MRI are limited by several weaknesses in the medical literature. First, 6 of the 14 studies identified for this report are descriptive case series examining the feasibility of this modality of MRI. Results in many cases were presented only as qualitative observations about the utility of upright MRI. In the four studies by Jinkins et al., it is even difficult to determine whether the data and conclusions are all from the same set of observations. All these authors concluded that upright MRI adds diagnostic information to that provided by conventional supine MRI in patients with spinal pain. However, without comparative data, the relative value of upright MRI images cannot be ascertained from these studies.

Seven studies compared upright with supine MRI images. None of these studies utilized evaluators who were blinded to patients' diagnoses or image source. Five of these obtained MRI scans of patients in standing, sitting, and sitting flexion and extension positions, and compared these images to supine images from the same open scanner. Because the magnetic field generated by open units, particularly the one most commonly used in these studies, is much weaker than that used by conventional MRI, one may expect differences between the two systems in the quality of the images they produce. Thus, while each of these studies concluded that non-supine MRI scans revealed spinal abnormalities that were not detected by supine scans, whether the lower resolution images result in missed abnormalities, cannot be determined from these studies.

Two studies compared upright MRI images with supine images derived from conventional MRI scanners. In Zamani et al., 30 patients were imaged in sitting positions while performing flexion and extension. The authors reported changes in disk bulge, central canal size, and foraminal size in the upright MRI that were not observed on the conventional images. Whether these observed differences would result in different therapeutic or diagnostic decisions cannot be determined, as these outcomes were not reported. The authors noted that, while diagnostically adequate, the resolution of the upright MRI images was inferior to those obtained from conventional MRI. Muhle et al. scanned 81 patients with degenerative disease of the cervical spine using a 1.5 Tesla strength scanner, which is not available commercially in the U.S. They compared these scans to images derived from conventional MRI, myelography, CT-myelography, and flexion/extension radiography. In 28% of patients, therapeutic management changed due to the additional information obtained by upright MRI. Therapeutic changes varied according to the severity of the cervical disease, however. Therapy changed in 87% of stage IV patients (13 of 15), 64% of stage III patients (7 of 11), 2% of stage II patients (1 of 42), and in no patients with stage I disease. However, the scanner used in this study was nearly three times stronger than the only commercially available upright scanner in the US made by FONAR, which scans at 0.6 Tesla. Whether this device would produce similar results in spinal patients is unknown.

None of the studies identified for this review calculated any statistics to evaluate the diagnostic accuracy of the upright MRI. Most studies simply provided percentages and raw numbers. A few studies made only qualitative statements about the benefits of upright MRI but provided no numbers to support those observations. Without these quantitative data, it is difficult to make strong conclusions about the relative accuracy of upright MRI or whether differences between upright and conventional MRI in terms of abnormality visualization are a result of random variability. In short, while one study (Mulhle et al.) suggests that upright MRI may improve detection of spinal abnormalities, this evidence is insufficient to conclude that the images from upright MRI are more accurate than those from conventional MRI or that they would impact diagnostic and therapy decisions. Additional studies are needed to replicate Muhle et al.'s findings using scanners that would be used clinically in the U.S. and that compare images to conventional MRI scans.

Billing/Coding Information

CPT CODES

76498	Unlisted magnetic resonance procedure (eg. diagnostic, interventional)

HCPCS CODES

No specific codes identified

Upright/Weight-Bearing, Dynamic Kinetic MRI, continued

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