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Cohere Medicare Advantage Policy -Magnetic Resonance Imaging (MRI), Brain Functional

Clinical Guidelines for Medical Necessity Review

Version: 1 Effective Date: October 17, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging **Guideline Name:** Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Brain Functional

Date of last literature review: 10/15/2024 Document last updated: 10/16/2024 Type: [X] Adult (18+ yo) | [X] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Brain Functional

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.

• There are no related National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Recommended Clinical Approach

Functional magnetic resonance imaging (fMRI) localizes areas for critical functions such as thought, speech, movement, and sensation, typically in relation to a focal brain lesion, such as a neoplasm or vascular malformation. fMRI is a non-invasive alternative to other invasive methods to identify eloquent brain areas, including the intracarotid amobarbital procedure (IAP), known as a Wada test, and electrocortical stimulation mapping (ESM). During fMRI, the patient is asked to conduct specific language, memory, or motor activities while sequential MRI images are collected. The activities cause an increase in blood flow to the areas of the brain being used, allowing for their identification and location.¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of functional magnetic resonance imaging (fMRI) of the brain. This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary

procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunctioning implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²⁻⁴
- Using gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²⁻⁴
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is an uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁵
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁶

The clinical benefits of using these criteria include:

- Resting-state blood oxygen level-dependent fMRI provides a task-free method of measuring cerebrovascular reserve (the potential capacity of brain tissue to receive more blood flow when needed), which is an effective marker in evaluating ischemic risk.²
- A meta-analysis shows the benefit of preoperative fMRI planning for the resection of brain tumors in reducing post-surgical morbidity, particularly when used with other advanced imaging techniques like diffusion-tensor imaging (DTI), intraoperative MRI, or cortical stimulation.⁸
- In patients with medial temporal lobe, temporal, or extratemporal epilepsy, fMRI can determine lateralization of language functions instead of the intracarotid amobarbital procedure (IAP). The use of fMRI may be considered for lateralizing memory functions in place of IAP in

patients with medial temporal lobe epilepsy (Level C) but is of unclear utility in other types of epilepsy types.⁹

• Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, using these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- → Functional magnetic resonance imaging (fMRI) of the brain is considered appropriate if ALL of the following are TRUE:
 - Ultrasound and computed tomography (CT)/ computed tomography angiography (CTA) are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to intravenous [IV] contrast reaction, pregnancy, pediatric); AND
 - **ANY** of the following:
 - Evaluation of cerebral vascular reactivity when considering revascularization procedures¹; OR
 - Evaluation of eloquent cortex and language lateralization for epilepsy surgery¹; OR
 - Evaluation of preserved eloquent cortex^{1.9}; OR
 - Failure or poor response to 2 or more anticonvulsant medications (maximal dose) - includes refractory or drug-resistant epilepsy³; OR
 - Radiation treatment planning of eloquent cortex^{1.9}; OR
 - Radiation post-treatment evaluation of eloquent cortex^{1.9};
 OR

- Targeted lesions (including intracranial neoplasms, and vascular formations) for **ANY** of the following¹:
 - Presurgical planning and operative risk assessment;
 OR
 - Assessment of eloquent cortex (e.g, language, sensory, motor, visual centers) in relation to a tumor or another focal lesion; **OR**
 - Surgical planning (biopsy or resection); **OR**
 - Therapeutic follow-up; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; OR
 - One-time clarifying follow-up of a prior indeterminate finding; OR
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- → Functional magnetic resonance imaging (fMRI) of the brain may not be considered appropriate if ANY of the following is TRUE:
 - If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; OR
 - The patient has metallic clips on vascular aneurysms; OR
 - Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); OR
 - Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Codes	Code Description/Definition
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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Kaptan et al. (2024) discuss current developments in functional MRI (fMRI) and the impact on facilitating the creation of clinically significant biomarkers for disorders impacting sensorimotor processing in the central nervous system (CNS). Research has focused on corticospinal fMRI to evaluate sensorimotor projections at various hierarchical levels of the neuraxis. This includes the cervical spinal cord, brainstem, cerebellum, subcortical structures, and cortical regions. Unlike imaging the brain or spinal cord separately, corticospinal fMRI can identify neural activity in important CNS areas related to upper limb sensorimotor processing. The authors note that the technique requires further research as it applies to neural activity from lower limb stimulations or tasks.¹¹

Luna et al. (2021) performed a meta-analysis to evaluate the comparative postoperative morbidity in patients with brain tumors undergoing surgery with preoperative fMRI guidance versus those undergoing surgery without fMRI guidance or with the use of standard (non-functional) neuronavigation. A total of 68 observational studies and existing data demonstrate a decrease in postoperative morbidity when utilizing preoperative fMRI for planning brain resections. This benefit is particularly notable when combined with other advanced imaging modalities like diffusion-tensor imaging, intraoperative MRI, or cortical stimulation.⁸

Liu et al. (2021) conducted a study to refine and assess resting-state (RS) cerebrovascular reactivity (CVR) MRI methodology and its correlation to neurosurgical intervention outcomes. Data from 170 health controls identify the optimal frequency range of temporal filtering based on spatial correlation with the reference standard CVR map obtained with CO_2 inhalation. The refined RS approach was implemented in a new cohort with 50 individuals diagnosed with Moyamoya disease. Comparative analysis of CVR values between cerebral hemispheres with and without revascularization surgery was conducted using the Mann-Whitney U test. The authors conclude that utilizing RS blood oxygen level-dependent (BOLD) fMRI, CVR mapping offered a non-task-based approach for quantifying cerebrovascular reserve. This method effectively illustrated the therapeutic impact of revascularization surgery in Moyamoya disease patients, demonstrating comparable results to the established CO_2 inhalation MRI reference standard.²

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024			
Review History			