Cohere Medicare Advantage Policy - MR Spectroscopy

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Cohere Medicare Advantage Policy - MR Spectroscopy

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: MR Spectroscopy

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 the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for MR Spectroscopy.

Recommended Clinical Approach

Magnetic resonance spectroscopy (MRS) is a non-invasive diagnostic test that measures biochemical changes in the brain, muscles, and other organs. It primarily evaluates metabolic disorders, tumors, and other lesions. MRS provides additional information to conventional MRI by measuring the concentration of specific metabolites, such as N-acetylaspartate (NAA), choline (Cho), creatine (Cr), and myoinositol (mI).[1-2]

MRS is particularly valuable in grading and assessing types of brain tumors and in assessing metabolic changes associated with tumor progression or response to therapy. For example, high choline levels can indicate increased cell membrane turnover associated with tumor growth, while reduced NAA levels may suggest neuronal loss or dysfunction.[2] Additionally, MRS can help differentiate between tumor recurrence, abscess, and radiation necrosis, aiding in treatment planning and monitoring.[2]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MR spectroscopy. This process helps to prevent both 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 malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- 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 uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.[11]
- Increased healthcare costs and complications from the inappropriate use of additional interventions.[12]

The clinical benefits of using these criteria include:

- Specificity: MRS is uniquely able to differentiate between primary brain tumors and clinical mimics; it can also predict the clinical course of a brain tumor by diagnosing high-grade versus low-grade tumors.[2] In addition, MRS plays a unique role following treatment by serving as one of the few imaging modalities that can delineate radiation necrosis from tumor tissue, thereby allaying a common diagnostic challenge.[2]
- Noninvasive: As an imaging modality, MR spectroscopy is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent and no ionizing radiation, conferring an inherent safety benefit.
- 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, ensuring 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, the use of 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

- ➔ **Magnetic resonance spectroscopy (MRS)** is considered appropriate when **ALL** of the following are **TRUE**:
  - ◆ Conventional imaging by magnetic resonance imaging (MRI) or computed tomography (CT) is inconclusive; **AND**
  - ◆ **ANY** of the following is **TRUE**:
    - Neoplastic conditions (including masses or mass-like conditions) and **ANY** of the following is **TRUE**:
      - Grading of primary glial neoplasm, particularly high-grade versus low-grade glioma[2]; **OR**
      - Evaluation of brain tumors, including differentiation between tumor recurrence and radiation necrosis[2-4]; **OR**
    - Vascular conditions, known or suspected, including **ANY** of the following:
      - Neonatal hypoxic ischemic encephalopathy[5]; **OR**
    - Congenital condition as indicated by **ANY** of the following:
      - Diagnosis and evaluation of metabolic disorders such as mitochondrial diseases and inborn errors of metabolism[6]; **OR**
      - Inherited metabolic disorders (e.g., Canavan disease, mitochondrial encephalopathies, and other leukodystrophies)[7]; **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

- ➔ **Magnetic resonance spectroscopy (MRS)** is not considered appropriate if **ANY** of the following is **TRUE**:
  - The patient has metallic clips on vascular aneurysms; **OR**
  - Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
  - Presence of metallic implants or devices such as pacemakers that are not MRI-compatible; **OR**
  - Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
76390	Magnetic resonance spectroscopy

Medical Evidence

Weinberg et al. (2021) conducted a systematic review of the literature regarding the clinical applications of magnetic resonance spectroscopy (MRS) in brain tumors. The writers state that MRS is utilized in clinical practice as well as research applications. The diagnostic clinical relevance of MRS includes its use as a type of virtual biopsy, as well as distinguishing gliomas from other types of diagnoses such as edema, necrosis, infection, or lymphoma. It is recommended by the group to use MRS in conjunction with conventional MRI due to occasional overlap in the appearance of different conditions. In tumor grading, the distinction between high and low-grade gliomas can be achieved with MRS. Limitations of MRS use in brain tumor imaging include similarities in the appearance of different diseases despite the differentiation of tissue types. Image quality may be affected by equipment variability and artifacts.[2]

In a 2022 systematic review of the literature, Germano et al. updated the 2014 Congress of Neurological Surgeons evidence-based guidelines on the management of progressive glioblastoma (pGBM) in adults. The literature search range was between 2012 to 2019, with 237 full-text articles extracted from 8786 total abstracts. The group made two new level II recommendations based on this review, with an additional 21 level III recommendations. The level II recommendations included the use of diffusion-weighted images included with magnetic resonance images with and without contrast in the diagnosis of patients with GBM as well as for surveillance. The other new level II recommendation is related to surgical procedures.[4]

Feldmann and colleagues (2022) examined MR-spectroscopy in metachromatic leukodystrophy (MLD) in a controlled cohort study consisting of 29 patients (10 infants, 19 juveniles) and 12 controls in 53 MRS datasets. MLD spectra were found to differ from the control group. White matter revealed the greatest differences compared to gray matter. Infant patients were found to have more severe changes when compared to later-onset patients in *N*-acetylaspartate (NAA), aspartate, glutamine, and choline intervals. It was concluded that NAA seemed to be the most clinically meaningful biomarker correlating with urine measurements obtained during the study.[7]

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