Subject: Magnetic Resonance Spectroscopy (MRS)		Original Effective Date: 12/17/08
Policy Number: MCP-063	**Revision Date(s):** 6/27/12, 2/12/2015	
Review Date: 12/16/15, 9/15/16		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[2]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Magnetic resonance spectroscopy is a noninvasive diagnostic test that is conducted to measure and analyze the chemical composition of human tissues.[1] MRS is similar to MRI with the exception of using radiofrequency waves that are translated into biochemical composition of the scanned tissue rather than anatomical images. MRS relies on chemicals in the body that emit radiofrequency signals when stimulated by a strong magnetic field. MRS has the potential to provide information to assist in diagnosing pathological states by analyzing the different chemical compounds or metabolites in diseased tissue and comparing these with normal metabolite composition of corresponding tissue. MRS has been most widely studied in identifying brain tumors; specifically in differentiating neoplastic from non-neoplastic, malignant from benign, primary from metastatic, and radiation injury from recurrence. It has also been used as a method for grading tumors and in guiding biopsy to the area of greatest malignancy. Other uses for MRS include chronic pain syndrome, encephalopathy's, neurodegenerative disorders such as Alzheimer's disease, amyotrophic lateral sclerosis, parkinson's disease, and Huntington's disease; seizure disorder, traumatic brain injury, inherited disorders and neuropsychiatric disorders among many other oncological and non-oncological conditions.

Magnetic Resonance Spectroscopy Systems are approved by the FDA as magnetic resonance diagnostic devices (MRDDs). MRDDs are Class II devices regulated by the FDA. Several have been approved via the FDA 510(k) process. MRS devices are intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. [1]

RECOMMENDATION

MRS of the brain is considered experimental, investigational and unproven for any indication including but not limited to all of the following: [ALL]

- Acute brain ischemia or infarction, including birth asphyxia
- Brain developmental abnormality and cerebral palsy
- Brain infection, especially cerebral abscess (pretreatment and post-treatment) and HIV-related infections.
- Cerebral vasculitis, systemic lupus erythematosus (sle), and neuropsychiatric systemic lupus erythematosus
- Chromosomal and inherited neurocutaneous disorders such as neurofibromatosis and tuberous sclerosis.
- Chronic pain syndromes
- Demyelination or dysmyelination disorder
- Differentiation between recurrent tumor and treatment related changes or radiation injury
- Differentiation of cystic lesions, e.g., abscess versus cystic metastasis or cystic primary neoplasm
- Evaluation of response to treatment of neurological disorders, e.g., tumor evaluation.
- Grading of primary glial neoplasm, particularly high-grade versus low-grade glioma
- Hepatic encephalopathy
- Hypoxic ischemic encephalopathy
- Inherited metabolic disorder such as canavan's disease, mitochondrial encephalopathy's, and other leukodystrophies
- Neurodegenerative disease: Alzheimer's disease, amyotrophic lateral sclerosis, parkinson's disease, and Huntington's disease
- Neuropsychiatric disorders such as depression, post-traumatic stress syndrome, and schizophrenia
- Neurotoxicity, such as misuse of medications, exposure to environmental hazards such as carbon monoxide and inhalants
- Primary or secondary neoplasm (pretreatment and post-treatment)
- Prostate cancer
- Seizures, especially temporal lobe epilepsy

- Spinal cord disorders such as tumors, demyelination, infection, and trauma
- Traumatic brain injury

SUMMARY OF MEDICAL EVIDENCE

Brain Tumors [3-18 37]

There is insufficient clinical evidence to determine the clinical roles of MRS and to establish its impact on health outcomes for patients undergoing MRS. To date, no randomized controlled trials have been published on the use of MRS in the evaluation of suspected brain tumors. The literature on the use of MRS in patients with suspected or known malignant tumors of the brain consists of a technology assessment, a systematic review and the remaining are small prospective studies. The current evidence is limited by retrospective analysis, small sample size, lack of uniform criteria for result interpretation and a heterogeneous study population. It remains unproven whether MRS can be used to modify treatment decisions in patients suspected with brain tumors or exclude the need for biopsy. Comparative analysis of data with conventional imaging techniques (e.g., MRI, PET) have varying results and do not provide results indicating superiority of outcomes. There is paucity of peer reviewed literature to confirm the efficacy of MRS use as a complement to conventional imaging techniques for the identification of neoplastic lesions, differentiation of low-grade tumors from high-grade tumors, diagnosing glioblastomas from metastases, discriminating tumor recurrence from radiation injury, determining treatment response and grading tumors.

Neurodegenerative Diseases [19-24 38]

There is paucity of peer reviewed literature to confirm the efficacy of MRS use as a diagnostic tool for neurodegenerative disease. To date, no randomized controlled trials have been published on the use of MRS in the evaluation of neurodegenerative disease (i.e. Alzheimer's disease, amyotrophic lateral sclerosis, Parkinson's disease, and Huntington's disease). The evidence consists of controlled comparison studies and prospective studies involving a small number of participants that evaluated MRS in patients with neurodegenerative diseases and compared results with another population, which included healthy controls. There is insufficient clinical evidence to determine the clinical roles of MRS and to establish its impact on health outcomes for patients undergoing MRS with neurodegenerative disease. Further clinical trials demonstrating the clinical benefits of MRS are necessary before it can be considered proven for these conditions.

Other Conditions [25-36]

There is paucity of peer reviewed literature to confirm the efficacy of MRS in the evaluation of any other disease. To date, no randomized controlled trials have been published and the available evidence consists of small comparison studies most with heterogeneous study populations that do not confirm the efficacy of MRS in other conditions. There is no published research data indicating how MRS affects patient management compared to standard clinical assessment, including use of magnetic resonance imaging. There is insufficient clinical evidence to determine the clinical roles of MRS and to establish its impact on health outcomes for patients undergoing MRS with any other clinical condition including but not limited to epilepsy, psychiatric disorders, chronic pain syndromes, encephalopathy, spinal cord injury, traumatic brain disorder, neurotoxicity, inherited metabolic disorders and prostate cancer. Further clinical trials demonstrating the clinical benefits of MRS are necessary before it can be considered proven for these conditions.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
76390	Magnetic resonance spectroscopy

HCPCS	Description
	N/A

ICD-9	Description
	Any/All

ICD-10	Description
	Any/All

RESOURCE REFERENCES

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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

CMS considers Magnetic Resonance Spectroscopy an investigational procedure and issued a national coverage determination of non-coverage for all indications of MRS following an updated review of evidence in September of 2004. [3]