Subject: Magnetic Resonance Spectroscopy [MRS] (76390) *(re: MCP-063)*	Original Effective Date: 12/17/08
Policy Number: MCR-660	**Revision Date(s):** 6/27/12, 2/12/2015, 10/24/2018
Review Date: (re: MCP-063) 12/16/15, 9/15/16, 6/22/17, 12/13/18, 12/10/19	

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]

APPROVAL SUPPORT

- To distinguish between recurrent/residual brain tumor vs radiation tumor necrosis.
- To differentiate brain tumor from other non-tumor etiologies whereby the findings will allow for sparing of an invasive procedure.

MRS of the brain is considered investigational for all other indications.

ADDITIONAL INFORMATION

- The above medical necessity recommendations are used to determine the best diagnostic study based on a patient's specific clinical circumstances. The recommendations were developed using evidence based studies and current accepted clinical practices. Medical necessity will be determined using a combination of these recommendations as well as the patient's individual clinical or social circumstances.
- Tests that will not change treatment plans should not be recommended.
- Same or similar tests recently completed need a specific reason for repeat imaging.

SUMMARY OF MEDICAL EVIDENCE

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.

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	Description
76390	Magnetic resonance spectroscopy