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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Magnetic Resonance Enterography (MR per OS) for the Diagnosis and Monitoring of Crohn's and Celiac Diseases

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (MRI) (220.2)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Kaiser Permanente considers magnetic resonance enterography medically necessary to evaluate and monitor Crohn's disease and other small bowel disorders and does not require medical necessity review.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract. In 80% of cases it involves the small bowel, more specifically the ileum, and is characterized by luminal, transmural and mesenteric abnormalities. Crohn's usually manifests in early adulthood and typically runs a relapsing and remitting course. Initial diagnosis aims at establishing and characterizing the disease including the location, extent of inflammation, and the presence of stenosis, fistulae or abscesses. Several modalities such as radiology, endoscopy, and serologic markers are being used to diagnose and assess the disease activity. None is recognized as a gold standard, but radiological procedures including small bowel series and fluoroscopic enteroclysis continue to lead the diagnostic tools that examine the small bowel in its entirety. Because there is no known cure, and the condition is typically relapsing, patients with Crohn's disease normally undergo several radiological investigations during the course of the disease to monitor the treatment response, recurrence, and /or development of complications (Negaard 2007, 2008, Masselli 2006, Lin 2008).

Celiac disease is a gluten-sensitive enteropathy of the gastrointestinal tract that affects the small intestine in genetically susceptible individuals at any age. The disease is relatively common in European countries and occurs less frequently in the US. Celiac disease has a wide range of nonspecific clinical manifestations which make it challenging to diagnose. Its may be silent and go clinically undetected or present with symptoms that range from fatigue and abdominal pain to weight loss, diarrhea, and malabsorption with steatorrhea. In children it may be associated with apathy, anorexia, and muscle wasting. It is reported that a small-intestine biopsy is mandatory to confirm the diagnosis of celiac disease. Imaging plays a role in suggesting celiac disease in adults with intestinal disorders, and in ruling out complicating lesions in patients with known disease (Paolantonio 2007).

The traditional imaging techniques used to evaluate the small bowel are the conventional barium studies e.g. small bowel follow-through or conventional enteroclysis (CE) Historically CE has been the radiological method of

Back to Top

choice. It was found to be highly accurate for diagnosing Crohn's disease and detecting partially or non-obstructive lesions that may not be demonstrated by cross-sectional imaging techniques. The procedure involves distension of the entire small bowel with barium suspension which when adequate, would allow the radiological demonstration of mucosal abnormalities and provide functional information on the ability of the small bowel to distend. CE, however, exposes the patient to ionizing radiation, may be hindered by the overlapping bowel loops, and does not provide information on the transmural and extramural extension, or other complications of the disease such as fistulae and abscesses (Schreyer 2004, Bernstein 2005, Masselli 2008).

Computed tomographic (CT) enterography, magnetic resonance (MR) enterography, and MR enteroclysis are emerging techniques for small bowel imaging. They have a benefit over traditional barium fluoroscopic techniques in their ability to visualize superimposed bowel loops and extraluminal extensions, and complications. CT provides excellent temporal and spatial high-resolution images of the small bowel, and is less susceptible to motion artifacts than MRI, but at the cost of radiation exposure. MRI on the other hand, has several advantages over CT, such as its superior tissue contrast, ability to provide direct cross-sectional imaging in multiple planes, functional or real-time examination of the bowel, and lack of ionizing radiation exposure which is particularly important in Crohn's patients who need repeated evaluation. The real-time imaging can be helpful in evaluating the progress of bowel filling with contrast agents during enteroclysis, determining the ability of the narrowed areas to distend, and improving differentiation of contractions from strictures. In addition, the gadolinium contrast agents used in MRI are known to have an excellent safety profile and can be used in patients with iodine contrast allergies, renal insufficiency, or during pregnancy. MRI, however, has inferior spatial and temporal resolution compared to CT, and its image quality may be degraded by artifacts from bowel peristalsis. Other reported constraints for MRI use include the limited number and access to MR scanners as well as its high cost (Rieber 2000, Bruining 2006, Fidler 2007).

MRI for small bowel disease may be performed by MR enteroclysis (luminal contrast) or MR enterography (MRI per OS, oral contrast). MR enteroclysis requires the fluoroscopic passage of a nasojejunal catheter and controlled administration of significant volumes (up to 3 liters) of enteric contrast agents. The small bowel can be filled with manual injection or hand-held infusion pumps while the patient is in the scanner. The procedure is associated with significant patient discomfort particularly due to the catheter introduction and manipulation, as well as the profuse diarrhea which results from the infused contrast medium. Moreover, the continuous infusion of the contrast agent may result in gastro-esophageal reflux especially in the obstructed patient, leading to potential vomiting and aspiration (Negaard 2007, Lohan 2007).

To achieve a compromise between patient tolerability and reproducible diagnostic image acquisition, MRI techniques with oral contrast (MR enterography) have been introduced. For this procedure, the patient is required to ingest a large amount of fluid (1.5-2 liters) to distend the stomach and small bowel in continuity. Various substances and volumes have been added to the oral solutions to increase the bowel distension. It is reported that there is no agreement on the optimal oral contrast, but investigators found that high osmolarity of the contrast e.g. mannitol, improves the bowel distension. MR enterography may be associated with adverse effects such as diarrhea, nausea, abdominal pain, ileus due to the increased fluid content, and other side effects (Masselli 2006, Lohan 2007).

Medical Technology Assessment Committee (MTAC)

Magnetic Resonance Enterography (MR per OS)

02/02/2009: MTAC REVIEW

Evidence Conclusion: Most of the published studies on MR imaging of the small bowel used the enteroclysis technique that requires intubation of the proximal small bowel followed by the administration of contrast agent. Few studies performed MR enterography where the contrast material is ingested orally. Different modalities for the diagnosis of Crohn's disease were used as reference standards, as there is no non-surgical gold standard to date.

In the studies reviewed, MR imaging was used for patients with suspected or confirmed Crohn's disease to characterize the disease, assess the extent and severity of bowel inflammation, and detect any stenosis, fistula, or other associated lesions. In both MR techniques, good distension of the small bowel loops during examination is essential to accurately evaluate the bowel wall pathology because collapsed loops may hide the disease or falsely identify a collapsed segment as a thickened wall. Negaard et al's study (2007) included 40 participants with known or suspected Crohn's. All participants were examined with both MR techniques, and the diagnosis of the disease was based on clinical evaluation, ileoscopy with histopathology, capsule endoscopy, or surgery. The study had several limitations, no comparison was made to with conventional enteroclysis, and lesions in jejunum and proximal ileum were not evaluated. Moreover, the reference standards were performed 2-3 months after the

 Back to Top

MR imaging, which may affect the presence or absence of some disease-related findings. The overall results of the study show that bowel distension was statistically significantly inferior in MR enterography compared to MR enteroclysis at both the jejunal and ileal levels. The difference was, however, insignificant for the terminal ileum. The accuracy of the two MR imaging techniques had similar sensitivity in assessing the intestinal wall thickness, enhancement and ulcer detection, when compared to reference standards used in the study. MR enteroclysis was more sensitive and specific than MR enterography in detecting intestinal stenosis, but less specific for the three other measures. MR enterography was associated with bowel obstruction in two patients one of which required abdominal surgery to treat the condition. Masselli and colleagues' study (2008) compared the diagnostic accuracy of MR enterography, with MR enteroclysis, and conventional enteroclysis as a reference standard in 40 patients with histologically proven Crohn's disease. All participants underwent conventional enteroclysis and either the MR enteroclysis or enterography on an alternating basis. The study was small and had several limitations. Its overall results show that conventional enteroclysis detected significantly more mucosal and mural abnormalities, but less mesenteric findings vs. MR enteroclysis and MR enterography. There was no significant difference between the two MR imaging techniques in the image quality, or assessment of mural stenosis and fistulae. However, MR enterography was statistically significantly inferior in bowel distension vs. MR or conventional enteroclysis. It was also inferior to MR enteroclysis in detecting the involved affected segments, superficial erosions, and deep ulcers. Conclusions: The published studies indicate that MR enterography may be inferior to conventional and MR enteroclysis in bowel distension, and detection of some associated lesions. There is insufficient evidence to determine the role of MR enterography in the diagnosis or assessment of celiac disease. There is insufficient evidence to determine the role of MR enterography in monitoring patients with Crohn's or celiac disease. There is insufficient evidence to determine the safety of the MR enterography in patients with Crohn's or celiac disease.
Articles: The literature search revealed over three hundred publications. The majority was reviews, articles that dealt with the technical aspects of the tests, or that were unrelated to the current review. The studies on the use of MR imaging for the evaluation of small bowel diseases mainly included patients with Crohn's disease; only one small retrospective case series evaluated the test for patients with celiac disease. The literature on MR enterography was very limited compared to MR enteroclysis. One study compared both MR techniques (enteroclysis and enterography) to conventional enteroclysis, and one to a combination of reference standards. The technology was also compared to capsule endoscopy or CT enterography in two small studies. The test was mainly used for the initial assessment of known or suspected Crohn's. Only one small study that included patients with recurrent disease was identified, but there were no published studies on the use of MR enterography for monitoring treatment response. The studies that compared MR enterography of the small bowel to conventional enteroclysis and/or MR enteroclysis, and that had more valid methodology and data analysis, were selected for critical appraisal. Negaard A, Paulson V, Sandvick L, et al. A prospective randomized comparison between two MRI studies of the small bowel in Crohn's disease, the oral contrast methods and MR enteroclysis. Eur Radiol 2007;17:2294-2301. See Evidence Table. Masselli G, Casciani E, Polettini E, et al. Comparison of MR enteroclysis with MR enterography and conventional enteroclysis in patients with Crohn's disease. Eur Radiol. 2008;18:438-47. See Evidence Table.

The use of Magnetic Resonance Enterography (MR per OS) for the diagnosis and monitoring of Crohn's and celiac diseases does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medical Necessity Review not required:

CPT® or HCPC Codes	Description
No Specific Codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised

Back to Top

03/12/2009	05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
06/06/2017	MPC approved criteria for medical necessity
05/04/2021	MPC approved to remove the medical necessity review requirement for Magnetic Resonance Enterography. Requires 60-day notice, effective date 10/1/2021.

Back to Top