# Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

***Clinical Guidelines for Medical Necessity Review***

**Version:** 1
**Effective Date:** September 26, 2024

# 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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## Guideline Information:

**Specialty Area:** Diagnostic Imaging
**Guideline Name:** Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

**Date of last literature review**: 9/20/2024
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**Type:** [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

**Table of Contents**

# Medical Necessity Criteria

***Service: Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)***

## Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[41]

## Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- National Coverage Determination (NCD). Magnetic Resonance Imaging (MRI)(220.2).

## Recommended Clinical Approach

The use of contrast and the type of magnetic resonance (MR) contrast (e.g., extracellular or hepatobiliary-specific) should be at the request of the ordering provider with guidance from the radiologist. The MR field of view should be limited to the area of interest and, in some cases, may not be the preferred imaging study.

## 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 magnetic resonance imaging (MRI), abdomen and magnetic resonance cholangiopancreatography (MRCP). 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).
- 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.[1,42-44]
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.[1, 42-44]
- 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.
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.[44]

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. MRI is useful in obtaining images of any part of the body in any direction, as well as providing better soft tissue contrast compared to computed tomography.[45]
- Reduction in complications and adverse effects from unnecessary procedures. The absence of exposure of ionizing radiation compared to computed tomography use, and imaging quality when contrast is not used are several benefits of MRI use in abdominal evaluations.[46]
- Enhanced diagnostic accuracy for complex medical conditions. Per the American College of Radiology practice parameters for MRI of the abdomen and MRI of the liver, MRI imaging is useful for detection, characterization, and/or staging of abdominal neoplasms such as those in the pancreas, spleen, kidneys, and liver. Additionally, patients with traumatic abdominal injury , abdominal wall abnormalities, or vascular malformations may benefit from MRI.[47]
- 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

### Indications

- ➔ **Magnetic resonance imaging (MRI), abdomen** is considered appropriate if **ALL** of the following are **TRUE**[1]:
  - ◆ Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **AND**
  - ◆ **ANY** of the following is **TRUE**:
    - Suspected appendicitis in pregnant people; **OR**
    - Suspected appendicitis in a pediatric patient; **OR**
    - Unexplained abdominal pain in a pregnant person or pediatric patient with non-diagnostic ultrasound; **OR**
    - Suspected abdominal abscess, diverticulitis, complicated UTI in a pregnant person or pediatric patient; **OR**
    - Detection, screening, surveillance, and follow-up of malignancies or metastatic involvement in the abdomen for **ANY** of the following[2-4]:
      - ○ To further characterize a lesion previously identified on a CT scan when the CT result is inconclusive; **OR**
      - ○ Metastases, known or suspected, including preoperative mapping for liver resection; **OR**
      - ○ Known or suspected primary malignancies with an assessment of vascular and biliary invasion, including but not limited to **ANY** of the following[5]:
        - ◆ Rising alpha-fetoprotein (AFP) in a high-risk patient or patient with known hepatocellular carcinoma (HCC); **OR**
        - ◆ CA 19-9; **OR**
        - ◆ Painless jaundice; **OR**

        - Persistent hematuria; **OR**
        - Other biomarker/sign/symptom suggestive of underlying malignancy; **OR**
    - Neoplastic conditions for **ANY** of the following:
        - Initial staging; **OR**
        - Treatment planning; **OR**
        - Response assessment; **OR**
        - Surveillance, and **ANY** of the following is **TRUE**[2,9-11]:
            - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
            - Suspected recurrence/progression; **OR**
            - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
    - Annual screening of a patient with an increased risk of cancer due to **ANY** of the following:
        - Cirrhosis or chronic viral hepatitis where ultrasound or CT is nondiagnostic; **OR**
        - Primary sclerosing cholangitis after age 20[7]; **OR**
        - Known mutation that increases susceptibility (e.g., Von Hippel Lindai, Tuberous Sclerosis, BRCA-1/2); **OR**
        - The patient has two or more first-degree or second-degree relatives with the same or related cancer from the same side of the family; **OR**
- For evaluation of known benign or indeterminate adrenal masses with **ANY** of the following[8-9]:
    - Indeterminate adrenal mass found on initial imaging, and **ANY** of the following:
        - 1-4 cm with follow-up at 6-12 months[10]; **OR**
        - Potential metastatic involvement and less than 4 cm; **OR**

    - Adrenal adenoma, known or suspected based on clinical **AND** laboratory findings; **OR**
- Abdominal wall abnormalities, including hernias[11]; **OR**
- Peritoneal or mesenteric abnormalities such as carcinomatosis, internal hernias, or infarct; **OR**
- Characterization, and follow-up of intra-abdominal fluid collections; **OR**
- Gastrointestinal tract evaluation, as indicated by **ANY** of the following[12]:
    - Celiac disease with recurring symptoms despite maintaining a gluten-free diet for 12 months or more[13]; **OR**
    - Crohn's disease, known or suspected[14]; **OR**
    - Other autoimmune enteritis with small bowel involvement; **OR**
    - Volvulus, internal hernias, incarceration; **OR**
- Hepatobiliary system (liver, bile ducts, gallbladder, and associated structures) as indicated by **ANY** of the following[6]:
    - To further characterize a lesion previously identified on a CT scan when the CT result is inconclusive; **OR**
    - Infection/inflammation (e.g. cholangitis)[6]; **OR**
    - Pre-operative or post-operative evaluation (e.g., liver resection, donor or transplant, hepatic shunt placement); **OR**
    - Non-invasive quantification of iron, fat, and fibrosis in chronic liver disease (e.g., hemochromatosis, hemosiderosis, nonalcoholic steatohepatitis [NASH] hepatitis), includes hepatic elastography; **OR**
    - Gallbladder disease, including evaluation of indeterminate polyps/nodules detected with other imaging modalities[15]; **OR**
- Kidney and urinary system disease as indicated by **ANY** of the following[16-19]:
    - Renal cysts with classification of Bosniak IIF or above (up to annually); **OR**
    - Solid indeterminate renal masses (up to annually); **OR**

    - Renal angiomyolipomas more than 3 cm (up to annually); **OR**
    - Characterization of other indeterminate lesions detected with other imaging modalities; **OR**
    - Diagnostic evaluation of concerning signs/symptoms (e.g., pain, concern for rupture, infection, hemorrhage) in a patient with known polycystic kidney disease[20]; **OR**
    - Infectious of inflammatory disease (e.g., complicated pyelonephritis); **OR**
    - Anatomic abnormalities, congenital or acquired (e.g., horseshoe kidney, retroperitoneal fibrosis); **OR**
    - Evaluation of the ureters/collecting system (e.g., stones, tumors, or stricture); **OR**
- Pancreatic abnormalities as indicated by **ANY** of the following[21]:
    - Duct anomaly[22]; **OR**
    - Duct obstruction (e.g., calculi, stricture, or mass)[22]; **OR**
    - Fluid collections; **OR**
    - Pancreatic pseudocysts; **OR**
    - Indeterminate lesions; **OR**
    - Pancreatitis (acute or chronic) with **ANY** of the following [23-24]**:**
        - Concern for complications such as necrosis or abscess; **OR**
        - Lack of response to conservative treatment and management; **OR**
        - Ultrasound did not show clear etiology such as a stone; **OR**
    - Indeterminate cyst in an asymptomatic patient that requires follow-up, and **ANY** of the following is **TRUE**[22,25]:
        - One-year follow-up imaging when interval growth is present on the previous follow-up; **OR**
        - The cyst is less than 1.5 cm without interval growth, and **ANY** of the following is **TRUE**:
            - For patients less than 65 years of age, annually up to five years; **OR**

        - For patients from 65 to 79 years of age, every two years up to ten years; **OR**
        - For patients more than 80 years of age, every two years up to four years; **OR**
    - Cyst is greater than 1.5 cm without interval growth, and **ANY** of the following is **TRUE** :
        - The patient is less than 80 years old, and **ANY** of the following frequency limitations is **TRUE**:
            - Up to every 6 months for 2 years from diagnosis; **OR**
            - Up to annually for up to ten years from diagnosis; **OR**
        - The patient is greater or equal to 80 years old with a frequency limitation of every 2 years for 4 years; **OR**
- Splenic abnormalities as indicated by **ANY** of the following:
    - Characterization of indeterminate lesions detected with other imaging modalities; **OR**
    - Detection and characterization of suspected diffuse abnormalities of the spleen; **OR**
- Post-traumatic organ injury; **OR**
- Fever of unknown origin greater than 101°F for at least 3 weeks where laboratory and clinical workup has been performed and have not revealed a diagnosis[26-27]; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
    - Post-surgical complications involving the hepatobiliary system (bile ducts, gallbladder, and associated structures)[6]; **OR**
    - Post-treatment follow-up for **ANY** of the following:
        - Complications of pancreatitis; **OR**
        - Fluid collections; **OR**
        - Pancreatic duct anomalies; **OR**
- Characterization of complex congenital anomalies (e.g., genitourinary and pelvic organs)[16-19]; **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.

➔ **Magnetic resonance cholangiopancreatography (MRCP)** is considered appropriate if **ANY** of the following is **TRUE**:

- The patient has **ANY** of the following:
  - Evidence of biliary obstruction or involvement, including **ANY** of the following[28-30]:
    - Biliary duct dilation requiring further work-up; **OR**
    - Jaundice[31]; **OR**
    - Laboratory or biochemical markers, including increased alkaline phosphatase, gamma-glutamyl transpeptidase, or conjugated (direct) bilirubinemia; **OR**
    - Clinical suspicion of primary sclerosing cholangitis; **OR**
  - Known or suspected abnormalities of the pancreatic and biliary ducts, including **ANY** of the following[28-29,32-33]:
    - Acute pancreatitis[34]; **OR**
    - Chronic pancreatitis[34]; **OR**
    - Cystic lesions in the pancreas[22]; **OR**
    - Ductal stones; **OR**
    - Evaluation of bile duct dilation or stricture; **OR**
  - Unexplained right upper quadrant pain when ultrasound or CT are inconclusive[15,28-29]; **OR**
- Assessment of post-liver transplant biliary complications; **OR**
- When ERCP is unsuccessful or contraindicated, or therapeutic ERCP is unlikely to be needed[11,28-29,35]; **OR**
- Delineation of ductal anatomy before liver transplantation; **OR**
- Detection and anatomic delineation of bile leaks; **OR**
- Detection, staging, and post-treatment follow-up of bile duct and gallbladder cancer; **OR**

- Evaluation of suspected congenital abnormalities of the gallbladder or bile ducts; **OR**
- Follow-up after surgery or intervention; **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 imaging (MRI), abdomen or magnetic resonance cholangiopancreatography (MRCP)** is not considered appropriate if **ANY** of the following is **TRUE**:

- MRCP ordered with procedure code S8037; **OR**
- 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 Code | Code Description |
|---|---|

| | |
|---|---|
| 74181 | Magnetic resonance imaging (MRI) (e.g., proton), abdomen; without contrast material(s) |
| 74182 | Magnetic resonance imaging (MRI) (e.g., proton), abdomen; with contrast material(s) |
| 74183 | Magnetic resonance imaging (MRI) (e.g., proton), abdomen, without contrast material(s), followed by contrast material(s) and further sequences |
| S8037 | Magnetic resonance cholangiopancreatography (MRCP)(Not covered per CMS guidelines) |

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

# Medical Evidence

Hernando et al. (2022) reviewed quantitative diffusion MRI of the abdomen and pelvis, which involves employing multiple diffusion encodings and mapping diffusion parameters. Diffusion MRI allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring. Challenges include acquisition artifacts, limitations in signal modeling, and biological variability. Technical performance concerns include addressing physiologic motion (respiratory, peristaltic, and pulsatile), handling image distortions, and managing a low signal-to-noise ratio.[37]

The American Urological Association (AUA) published guidelines on renal mass and localized renal cancer. Based on recommendations from the American College of Radiology (ACR), cross-sectional nervous system imaging is the preferred diagnostic method for identifying or ruling out metastases in the brain and spine. While MRI may exhibit greater sensitivity in detecting small central nervous system (CNS) neoplasms, CT can be beneficial for promptly assessing acute neurological signs or symptoms. MRI benefits patients who cannot receive IV iodinated contrast before and after administering gadolinium. Cross-sectional MRI with diffusion-weighted imaging benefits for patients who cannot tolerate conventional contrast. If there is suspicion of a mass, contrast-enhanced ultrasound can be employed to assess for enhancement.[18-19]

Staubli et al. (2022) performed a randomized control trial (RCT) comparing intraoperative cholangiography (IOC) and magnetic resonance cholangiopancreatography (MRCP) in patients suspected of having common bile duct stones (CBDS). It was a multicenter randomized controlled trial conducted across five hospitals. Patients were randomly assigned to receive either IOC followed by laparoscopic cholecystectomy (LC) with potential endoscopic retrograde cholangiopancreatography (ERCP) or MRCP followed by ERCP and LC if deemed necessary. The primary focus was on the LOS, with secondary measures encompassing cost, stone detection, and complication rates. The findings indicated that IOC was more effective in diagnosing CBDS than MRCP. Although the median LOS was slightly shorter in the IOC group, this variance did not reach statistical significance. No significant cost difference was observed between the two approaches. However, CBDS were more frequently detected in the IOC group. Complication rates did not exhibit disparity between the two methods. The study concluded that while IOC and MRCP are viable options, IOC stands out for its notably higher diagnostic yield in detecting CBDS. (Clinicaltrials.gov Identifier: NCT02351492).[38]

Suzuki et al. conducted an RCT to evaluate the diagnostic precision of endoscopic ultrasound (EUS) and MRCP in detecting choledocholithiasis cases initially overlooked on CT scans. Patients suspected of having CBDS were divided into two groups: one receiving EUS and the other MRCP. Initially, those diagnosed with CBDS or sludge underwent ERCP, while CBDS-negative patients underwent a second diagnostic procedure, either MRCP or EUS, different from the initial one. The main focus was on the accuracy of diagnosis, with secondary interests in diagnostic capabilities, CBDS detection rates and characteristics during the second examination, and adverse event occurrence. Overall, EUS may provide higher diagnostic ability than MRCP; however, the authors did not note significant differences in recommending one procedure over the other.[39]

Timmerhuis et al. (2021) performed a systematic review of available guidelines for diagnosing a disrupted pancreatic duct in patients with acute pancreatitis. Eight studies with five distinct diagnostic modalities in 142 severe acute pancreatitis patients were included. Endoscopic ultrasound and ERCP reported a sensitivity of 100%. A sensitivity of 83% was reported with MRCP, with or without secretin. A combined cohort of secretin-enhanced MRCP and standard MRCP showed a sensitivity of 92%. Amylase measurements in drain fluid exhibited a sensitivity of 100% and specificity of 50% compared to ERCP. The authors concluded that various diagnostic modalities effectively diagnose disrupted pancreatic ducts in acute pancreatitis patients. Considering the invasiveness of alternative modalities, secretin-enhanced MRCP is recommended as the initial diagnostic approach.[40]

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# Clinical Guideline Revision History/Information

| Original Date: September 26, 2024 | | |
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| **Review History** | | |
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