Clinical Policy: Ferriscan R2-MRI

Reference Number: PA.CP.MP.53
Effective Date: 10/18
Last Review Date: 10/31/2021

Coding Implications
Revision Log

Description
FerriScan R2-MRI is a magnetic resonance imaging (MRI) -based solution for measuring liver iron concentration (LIC) in patients with iron overload.

Policy/Criteria
I. It is the policy of Pennsylvania Health and Wellness® (PHW), that the FerriScan® R2-MRI is **medically necessary** for the measurement of liver iron concentration in suspected cases of iron overload due to the following conditions:
- **A.** Hereditary hemochromatosis;
- **B.** Iron-loading anemias with or without multiple transfusions:
  1. Thalassemia major or thalassemia intermedia;
  2. Sideroblastic anemia;
  3. Chronic hemolytic anemias (e.g., sickle cell disease);
  4. Inherited or acquired aplastic anemia;
  5. Myelodysplastic syndromes;
- **C.** Dietary iron overload;
- **D.** Iron overload in liver diseases:
  1. Hepatitis C or B;
  2. Alcohol-induced liver disease;
  3. Porphyria cutanea tarda;
  4. Fatty liver disease;
  5. Gestational alloimmune liver disease
- **E.** Neonatal iron overload;
- **F.** Aceruloplasminemia;
- **G.** Repeated hemin infusions for acute porphyrias.

Background
FerriScan® is a non-invasive technology based on MRI. It has a high sensitivity and specificity for the measurement of LIC over the entire range encountered in clinical practice. It can be set up on most 1.5 Tesla MRI scanners (the most common type of clinical scanner). FerriScan makes a map of the liver iron concentration and calculates the mean LIC. The results are unaffected by the presence of fibrosis or cirrhosis. Image data is acquired on an MRI scanner and is electronically transmitted to a data analysis center. All data is analyzed to ensure correct acquisition and the LIC results are transmitted back to the originating MRI center.

The operational principle of the R2-MRI Analysis System is based on fitting signal decay curves to the image signal intensities (e.g. of the liver) at the different echo times for the MR data set on a voxel-by-voxel (3-D pixel) basis to determine transverse relaxation rate (R2) images. These may be further transformed by a defined calibration to provide a quantitative measure of liver iron concentrations.

Measurements have been shown to have a high degree of sensitivity and specificity for liver iron concentration measured by biopsy. FerriScan images give information on liver iron distribution. The mean LIC value given in the FerriScan report is then used to guide chelation therapy.

Magnetic resonance evaluation for hepatic iron concentration is improved compared with programs that were used several years ago. However, this type of imaging will not detect cellular liver damage due to iron overload.

The American College of Radiology's 2015 Practice Parameter for the performance of MRI of the liver states that indications for MRI of the liver include hemochromatosis, hemosiderosis, or steatosis. Additionally, multiple studies have confirmed the clinical utility of R2 MRI in the measurement of LIC for iron-overloading conditions such as thalassemia[7] and sickle cell anemia[8]. A study of R2 MRI results vs. simulated liver biopsy results found R2 MRI to be superior to liver biopsy for serial LIC observations[9]. Furthermore, a review of the current state of liver iron quantification by MRI states that R2 MRI provides validated measurement of LIC, and has advantages over liver biopsy, in that is in non-invasive.[10]

The R2-MRI Analysis System (Inner Vision Biometrics PTY LTD) received FDA 510(k) clearance (K043271) on January 21, 2005. In January 2013, the FDA authorized the FerriScan R2-MRI to be marketed as an imaging companion diagnostic device for the safe and effective use of Exjade in patients with non-transfusion-dependent thalassemia.

Coding Implications

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CPT® Codes	Description
76498	Unlisted MRI procedure

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
B16.0-B1.9	Acute hepatitis B
B17.10-B17.11	Acute hepatitis C
B18.0	Chronic viral hepatitis B, with delta -agent
B18.1	Chronic viral hepatitis B without delta-agent
B18.2	Chronic viral hepatitis C
B19.10-B19.11	Unspecified viral hepatitis B
B19.20-B19.21	Unspecified viral hepatitis C

ICD-10-CM Code	Description
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20-D46.22	Refractory anemia with excess of blasts
D56.1	Beta thalasemia
D61.01- D61.9	Other aplastic anemias and other bone marrow failure syndromes
D64.0	Hereditary sideroblastic anemia
D64.1	Secondary sideroblastic anemia due to disease
D64.2	Secondary sideroblastic anemia due to drugs and toxins
D64.3	Other sideroblastic anemia
D64.4	Congenital dyserythropoietic anemia
E80.1	Porphyria cutanea tarda
E83.10	Disorders of iron metabolism, unspecified
E83.110	Hereditary hemochromatosis
E83.111	Hemochromatosis due to repeated red blood cell transfusions
E83.118	Other hemochromatosis
K70.0-K70.9	Alcoholic liver disease
K76.0	Fatty (change of) liver, not elsewhere classified

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated. Codes reviewed and updated.	10/18	10/18
Changed "thalassemia major and thalassemia intermedia" to "thalassemia major or thalassemia intermedia." Changed "hepatitis C and B" to "hepatitis C or B"	01/19	02/19
Replaced codes D61.89 and D61.9 with expanded range of D61.01-D61.9. Replaced "member" with "member/enrollee/enrollee" in all instances. References reviewed and updated. Reviewed by specialist.	12/2020	1/18/2021
References reviewed and updated. Reviewed by specialist.	10/2021	

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