

## Iron Quantification with Magnetic Resonance Imaging

### Table of Content

[Purpose](#)  
[Description & Definitions](#)  
[Criteria](#)  
[Coding](#)  
[Document History](#)  
[References](#)  
[Special Notes](#)  
[Keywords](#)

<a href="#">Effective Date</a>	3/2013
<a href="#">Next Review Date</a>	3/15/2024
<a href="#">Coverage Policy</a>	Medical 174
<a href="#">Version</a>	5

**Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details \*.**

### Purpose:

This policy addresses the medical necessity of Iron Quantification with Magnetic Resonance Imaging.

### Description & Definitions:

Magnetic resonance iron quantification is a non-invasive imaging study that quantifies the concentration of iron within the liver and additional storage organs, a key indicator in the management of patients with hemochromatosis. Other names for Iron Quantification with Magnetic Resonance Imaging include but are not limited to, Liver iron concentration (LIC) imaging companion diagnostic, FerriScan, R2 MRI, liver iron concentration MRI, R2 Relaxometry, Liversmart, FerriSmart, Liver MRI T2 and LiverMultiScan.

### Criteria:

Iron Quantification with Magnetic Resonance Imaging is considered medically necessary with **1 or more** of the following:

- Individual is under 21 years of age with **ALL** of the following:
  - Individual is a candidate for chelation therapy.
  - Laboratory tests (e.g. serum ferritin, serum transferrin, etc.) are not sufficient to determine an appropriate treatment plan and the results of the scan will directly impact the treatment provided to the individual.
  - Individual has diagnosis of **1 or more** of the following:
    - Hereditary Hemochromatosis with **1 or more** of the following:
      - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
      - Individual's transferrin saturation (TSAT) level is greater than 45%.
    - Myelodysplastic Syndrome with **ALL** of the following:
      - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
      - Individual has received more than 20 units of packed red blood cells from long term transfusion therapy.
    - Porphyrin metabolism disorder in which the serum ferritin level is greater than 25 ng/ml (demonstrated within the last 12 months)
    - Sickle Cell Disease with **ALL** of the following:
      - Individual is over the age of 2 years old.

- Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
  - Individual has received more than 20 units of packed red blood cells from long term transfusion therapy.
- Thalassemia Major with **All** of the following:
  - Individual is over the age of 2 years old.
  - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
  - Individual has received more than 10 units of packed red blood cells from long term transfusion therapy.
- Thalassemia Intermedia with **All** of the Following:
  - Individual is over the age of 4 years old
  - Individual's serum ferritin level is greater than or equal to 400 ng/ml (demonstrated within the last 12 months).
- Individual is 21 years of age or older with **All of the following**:
  - Individual has a documented contraindication to liver biopsy.
  - Individual is a candidate for chelation therapy.
  - Laboratory tests (e.g. serum ferritin, serum transferrin, etc.) are not sufficient to determine an appropriate treatment plan and the results of the scan will directly impact the treatment provided to the individual.
  - Individual has **1 or more of the following**:
    - Hereditary Hemochromatosis with **1 or more** of the following:
      - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
      - Individual's transferrin saturation (TSAT) level is greater than 45%.
    - Myelodysplastic Syndrome with **ALL** of the following:
      - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
      - Individual has received more than 20 units of packed red blood cells from long term transfusion therapy.
    - Porphyrin metabolism disorder in which the serum ferritin level is greater than 25 ng/ml (demonstrated within the last 12 months).
    - Sickle Cell Disease with **ALL** of the following:
      - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
      - Individual has received more than 20 units of packed red blood cells from long term transfusion therapy.
    - Thalassemia Major with **ALL** of the following:
      - Individual's serum ferritin level is greater than or equal to 1000 ng/ml (demonstrated within the last 12 months).
      - Individual has received more than 10 units of packed red blood cells from long term transfusion therapy.
    - Thalassemia Intermedia with a serum ferritin level greater than or equal to 400 ng/ml (demonstrated within the last 12 months).

Iron Quantification with Magnetic Resonance Imaging is considered **not medically necessary** for any use other than those indicated in clinical criteria.

## Coding:

Medically necessary with criteria:

Coding	Description
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ

0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); single organ (List separately in addition to code for primary procedure)
0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs
0698T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (List separately in addition to code for primary procedure)
76498	Unlisted magnetic resonance procedure (eg, diagnostic, interventional)

**Considered Not Medically Necessary:**

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

**Document History:**

Revised Dates:

- 2022: April, May
- 2019: October
- 2015: December

Reviewed Dates:

- 2023: March
- 2021: May
- 2020: June
- 2019: January
- 2018: January
- 2017: February
- 2016: March
- 2015: November
- 2013: November

Effective Date:

- July 2013

**References:**

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2022, Aug 31). Retrieved Feb 13, 2023, from MCG: <https://careweb.careguidelines.com/ed26/index.html>

(2023). Retrieved Feb 09, 2023, from Hayes, Inc:

<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522hemochromatosis%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%2522%257B%2522page%2522:0,%2522size%2522:50%2522,%2522type%2522:%2522all%2522,%2522sources%2522:%2522>

(2023). Retrieved Feb 09, 2023, from Centers for Medicare and Medicaid Services: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=MRI&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance>

(2023). Retrieved Feb 09, 2023, from National Comprehensive Cancer Network: <https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=LiverMultiScan>

(2023). Retrieved Feb 13, 2023, from Department of Medical Assistance Services: <https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=LiverMultiScan&gsc.sort=>

ADVANCED IMAGING - Appropriate Use Criteria: Imaging of the Abdomen and Pelvis. (2022, Mar 13). Retrieved Feb 09, 2023, from AIM Specialty Health: [https://aimspecialtyhealth.com/wp-content/uploads/2021/09/RBM\\_abdomen-pelvis-imaging.pdf](https://aimspecialtyhealth.com/wp-content/uploads/2021/09/RBM_abdomen-pelvis-imaging.pdf)

ADVANCED IMAGING - Appropriate Use Criteria: Imaging of the Heart. (2022, Nov 06). Retrieved Feb 09, 2023, from AIM Specialty Health: <https://aimspecialtyhealth.com/wp-content/uploads/2022/08/Cardiac-Imaging-11-06-22.pdf>

Bacon, B., & Kwiatkowski, J. (2022, Jun 09). Approach to the patient with suspected iron overload. Retrieved Feb 09, 2023, from UpToDate: [https://www.uptodate.com/contents/approach-to-the-patient-with-suspected-iron-overload?sectionName=Noninvasive%20imaging%20\(MRI\)&search=FerriScan&topicRef=3614&anchor=H404538&source=see\\_link#H404538](https://www.uptodate.com/contents/approach-to-the-patient-with-suspected-iron-overload?sectionName=Noninvasive%20imaging%20(MRI)&search=FerriScan&topicRef=3614&anchor=H404538&source=see_link#H404538)

Bajre, M., Moawad, M., Shumbayawonda, E., Carolan, J., Hart, J., Culver, E., & Heneghan, M. (2022, Sep 08). LiverMultiScan as an alternative to liver biopsy to monitor autoimmune hepatitis in the National Health Service in England: an economic evaluation. Retrieved Feb 13, 2023, from PubMed: <https://pubmed.ncbi.nlm.nih.gov/36691214/>

Clinical Implementation of a Focused MRI Protocol for Hepatic Fat and Iron Quantification. (2019, Jul). Retrieved Feb 13, 2023, from American Journal of Roentgenology: <https://www.ajronline.org/doi/pdf/10.2214/AJR.18.20947>

MRI (Magnetic Resonance Imaging). (2018, Aug 29). Retrieved Feb 13, 2023, from Food and Drug Administration: <https://www.fda.gov/radiation-emitting-products/medical-imaging/mri-magnetic-resonance-imaging>

NCD: Magnetic Resonance Imaging (220.2). (2018, Apr 10). Retrieved Feb 13, 2023, from Centers for Medicare and Medicaid Services: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=177&ncdver=6&>

(2022). Retrieved Apr 12, 2022, from EncoderPro: <https://www.encoderpro.com>

(2022). Retrieved Apr 12, 2022, from FerriScan: <https://ferriscan.com/>

Comparison of liver MRI R2(FerriScan®) VS liver MRI T2\* as a measure of body iron load in a cohort of beta thalassemia major patients. (2020, Jan 22). Retrieved Apr 12, 2022, from Orphanet Journal of Rare Diseases: <https://ojrd.biomedcentral.com/articles/10.1186/s13023-020-1301-4>

FERRISCAN R2-MRI ANALYSIS SYSTEM: Liver iron concentration imaging. (2015). Retrieved Apr 12, 2022, from FDA: [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/K124065.pdf#:~:text=The%20FerriScan%20R2-MRI%20Analysis%20System%20is%20a%20post-processing,liver%20iron%20concentration%20measurements%20using%20a%20calibration%20curve.](https://www.accessdata.fda.gov/cdrh_docs/reviews/K124065.pdf#:~:text=The%20FerriScan%20R2-MRI%20Analysis%20System%20is%20a%20post-processing,liver%20iron%20concentration%20measurements%20using%20a%20calibration%20curve.)

GUIDELINES FOR THE MANAGEMENT OF TRANSFUSION DEPENDENT THALASSAEMIA (TDT). (2021). Retrieved Apr 12, 2022, from Thalassemia International Federation: <https://www.thalassemia.org/boduw/wp-content/uploads/2021/06/TIF-2021-Guidelines-for-Mgmt-of-TDT.pdf>

Guidelines Supporting the Use of FerriScan R2-MRI to Measure Liver Iron Concentration. (2017, June). Retrieved Apr 12, 2022, from FerriScan: MRI Measurement of Liver Iron Concentration: [https://www.resonancehealth.com/images/files/FerriScan/Guidelines\\_Supporting\\_The\\_Use\\_of\\_FerriScan\\_June\\_2017.pdf](https://www.resonancehealth.com/images/files/FerriScan/Guidelines_Supporting_The_Use_of_FerriScan_June_2017.pdf)

LiverMultiScan for liver disease. (2019, Apr 26). Retrieved Apr 12, 2022, from National Institute for Health and Care Excellence (NICE): <https://www.nice.org.uk/advice/mib181/resources/livermultiscan-for-liver-disease-pdf-2285963692990405>

Methods to determine hepatic iron content. (2022, Jan 24). Retrieved Apr 12, 2022, from UpToDate: [https://www.uptodate.com/contents/methods-to-determine-hepatic-iron-content?search=ferriscan&source=search\\_result&selectedTitle=1~2&usage\\_type=default&display\\_rank=1](https://www.uptodate.com/contents/methods-to-determine-hepatic-iron-content?search=ferriscan&source=search_result&selectedTitle=1~2&usage_type=default&display_rank=1)

Transfusional Iron Overload. (2018, Dec 3). Retrieved Apr 12, 2022, from DynaMed: [https://www.dynamed.com/condition/transfusional-iron-overload#LIVER\\_IRON\\_CONCENTRATION](https://www.dynamed.com/condition/transfusional-iron-overload#LIVER_IRON_CONCENTRATION)

### Special Notes: \*

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

### Keywords:

SHP Iron Quantification with Magnetic Resonance, SHP Imaging 16, MRI, chelation therapy, Hereditary Hemochromatosis, Myelodysplastic Syndrome, Porphyrin metabolism disorder, Sickle Cell Disease, Thalassemia Major, Thalassemia Intermedia, liver biopsy, serum ferritin, serum transferrin, Liver MRI T2, LiverMultiScan, FerriScan R2 Magnetic Resonance Imaging Analysis, Liver iron concentration (LIC) imaging companion diagnostic, FerriScan, R2 MRI, liver iron concentration MRI, R2 Relaxometry,