NCD - Serum Iron Studies (190.18)

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Tracking Information

Publication Number

100-3

Manual Section Number

190.18

Manual Section Title

Serum Iron Studies

Version Number

1

Effective Date of this Version

11/25/2002

Implementation Date

01/01/2003

Description Information

Benefit Category

Diagnostic Laboratory Tests

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

Item/Service Description

Serum iron studies are useful in the evaluation of disorders of iron metabolism, particularly iron deficiency and iron excess. Iron studies are best performed when the patient is fasting in the morning and has abstained from medications that may influence iron balance.

Iron deficiency is the most common cause of anemia. In young children on a milk diet, iron deficiency is often secondary to dietary deficiency. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary deficiency or malabsorption.

Following major surgery the patient may have iron deficient erythropoiesis for months or years if adequate iron replacement has not been given. High doses of supplemental iron may cause the serum iron to be elevated. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions.

Total iron binding capacity (TIBC) is an indirect measure of transferrin, a protein that binds and transports iron. TIBC quantifies transferrin by the amount of iron that it can bind. TIBC and transferrin are elevated in iron deficiency, and

with oral contraceptive use, and during pregnancy. TIBC and transferrin may be decreased in malabsorption syndromes or in those affected with chronic diseases. The percent saturation represents the ratio of iron to the TIBC.

Assays for ferritin are also useful in assessing iron balance. Low concentrations are associated with iron deficiency and are highly specific. High concentrations are found in hemosiderosis (iron overload without associated tissue injury) and hemochromatosis (iron overload with associated tissue injury). In these conditions the iron is elevated, the TIBC and transferrin are within the reference range or low, and the percent saturation is elevated. Serum ferritin can be useful for both initiating and monitoring treatment for iron overload.

Transferrin and ferritin belong to a group of serum proteins known as acute phase reactants, and are increased in response to stressful or inflammatory conditions and also can occur with infection and tissue injury due to surgery, trauma or necrosis. Ferritin and iron/TIBC (or transferrin) are affected by acute and chronic inflammatory conditions, and in patients with these disorders, tests of iron status may be difficult to interpret.

Indications and Limitations of Coverage

Indications

1. Ferritin, iron and either iron binding capacity or transferrin are useful in the differential diagnosis of iron deficiency, anemia, and for iron overload conditions.
    a. The following presentations are examples that may support the use of these studies for evaluating iron deficiency: certain abnormal blood count values (i.e., decreased mean corpuscular volume (MCV), decreased hemoglobin/hematocrit when the MCV is low or normal, or increased red cell distribution width (RDW) and low or normal MCV); abnormal appetite (pica); acute or chronic gastrointestinal blood loss; hematuria; menorrhagia; malabsorption; status post-gastrectomy; status post-gastrojejunostomy; malnutrition; preoperative autologous blood collection(s); malignant, chronic inflammatory and infectious conditions associated with anemia which may present in a similar manner to iron deficiency anemia; following a significant surgical procedure where blood loss had occurred and had not been repaired with adequate iron replacement.
    b. The following presentations are examples that may support the use of these studies for evaluating iron overload: chronic hepatitis; diabetes;
    hyperpigmentation of skin; arthropathy; cirrhosis; hypogonadism; hypopituitarism; impaired porphyrin metabolism; heart failure; multiple transfusions; sideroblastic anemia; thalassemia major; cardiomyopathy, cardiac dysrhythmias and conduction disturbances.
2. Follow-up testing may be appropriate to monitor response to therapy, e.g., oral or parenteral iron, ascorbic acid, and erythropoietin.
3. Iron studies may be appropriate in patients after treatment for other nutritional deficiency anemias, such as folate and vitamin B12, because iron deficiency may not be revealed until such a nutritional deficiency is treated.
4. Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.
5. Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (e.g., nickel, cadmium, aluminum, lead) whether due to accidental, intentional exposure or metabolic causes.

Limitations

1. Iron studies should be used to diagnose and manage iron deficiency or iron overload states. These tests are not to be used solely to assess acute phase reactants where disease management will be unchanged. For example, infections and malignancies are associated with elevations in acute phase reactants such as ferritin, and decreases in serum iron concentration, but iron studies would only be medically necessary if results of iron

studies might alter the management of the primary diagnosis or might warrant direct treatment of an iron disorder or condition.
2. If a normal serum ferritin level is documented, repeat testing would not ordinarily be medically necessary unless there is a change in the patient's condition, and ferritin assessment is needed for the ongoing management of the patient. For example, a patient presents with new onset insulin-dependent diabetes mellitus and has a serum ferritin level performed for the suspicion of hemochromatosis. If the ferritin level is normal, the repeat ferritin for diabetes mellitus would not be medically necessary.
3. When an End Stage Renal Disease (ESRD) patient is tested for ferritin, testing more frequently than every three months requires documentation of medical necessity (e.g., other than chronic renal failure or renal failure, unspecified).
4. It is ordinarily not necessary to measure both transferrin and TIBC at the same time because TIBC is an indirect measure of transferrin. When transferrin is ordered as part of the nutritional assessment for evaluating malnutrition, it is not necessary to order other iron studies unless iron deficiency or iron overload is suspected as well.
5. It is not ordinarily necessary to measure both iron/TIBC (or transferrin) and ferritin in initial patient testing. If clinically indicated after evaluation of the initial iron studies, it may be appropriate to perform additional iron studies either on the initial specimen or on a subsequently obtained specimen. After a diagnosis of iron deficiency or iron overload is established, either iron/TIBC (or transferrin) or ferritin may be medically necessary for monitoring, but not both.
6. It would not ordinarily be considered medically necessary to do a ferritin as a preoperative test except in the presence of anemia or recent autologous blood collections prior to the surgery.

Note: Scroll down for links to the quarterly Covered Code Lists (including narrative).

Cross Reference

Also see the Medicare Claims Processing Manual, Chapter 120, Clinical Laboratory Services Based on Negotiated Rulemaking.

Transmittal Information

Transmittal Number

17

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17ncd.pdf

Revision History

07/2002 - Implemented NCD. Effective date 11/25/02. Implementation date 1/01/03. (TN AB-02-110) (CR 2130)

07/2004 - Published NCD in the NCD Manual without change to narrative contained in PM AB-02-110. Coding guidance now published in Medicare Lab NCD Manual. Effective and Implementation dates NA. (TN 17) (CR 2130)

12/2019 - Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2020. This Change Request (CR) announces the changes that will be included in the April 2020 quarterly release of the edit module for clinical diagnostic laboratory services. This recurring update notification applies to chapter 16, section 120.2, publication 100-04. (TN 4475) (CR11593)

Other

Covered Code Lists (including narrative)

July 2022 (PDF) (ICD-10)
April 2022 (PDF) (ICD-10)
January 2022 (PDF) (ICD-10)
October 2021 (PDF) (ICD-10)
July 2021 (PDF) (ICD-10)
April 2021 (PDF) (ICD-10)
January 2021 (PDF) (ICD-10)
October 2020 (PDF) (ICD-10)
July 2020 (PDF) (ICD-10)
April 2020 (PDF) (ICD-10)
January 2020 (PDF) (ICD-10)
October 2019 (PDF) (ICD-10)
July 2019 (PDF) (ICD-10)
April 2019 (PDF) (ICD-10)
January 2019 (PDF) (ICD-10)
October 2018 (PDF) (ICD-10)
July 2018 (PDF) (ICD-10)
April 2018 (PDF) (ICD-10)
January 2018 (ICD-10)
October 2017 (ICD-10)
July 2017 (ICD-10)
April 2017 (ICD-10)
January 2017 (ICD-10)
October 2016 (ICD-10)
January 2016 (ICD-10)
October 2015 (ICD-10, ICD-9)
October 2014 (ICD-10, ICD-9)

Changes to Lab NCD Edit Software

April 2022
January 2022
October 2021
July 2021
October 2020
April 2020
January 2020
October 2019
July 2019
January 2019
October 2018
April 2018
January 2018
July 2017
April 2017
January 2017
January 2016

October 2014

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process.The following are existing associations with NCAs, from the National Coverage Analyses database.

- First reconsideration for Serum Iron Studies (Addition of Restless Leg Syndrome as a Covered Indication) (CAG-00263R)

Coding Analyses for Labs (CALs)

This NCD has been or is currently being reviewed under the National Coverage Determination process.The following are existing associations with CALs, from the Coding Analyses for Labs database.

- Original Consideration for Serum Iron Studies for Anemia Caused by Sickle Cell or End Stage Renal Disease (CAG-00172N)

- Original Consideration for Serum Iron Studies (Expansion of the Chronic Renal Failure Covered Codes to Include Hypertensive Renal Disease) (CAG-00194N)

- Original Consideration for Urine Culture (Bacterial) and Serum Iron Studies (Revision of ICD-9-CM Codes for Pre-operative Examinations) (CAG-00236N)

- Original Consideration for Serum Iron Studies NCD 190.18 (Addition of ICD-9-CM diagnosis code 285.22 Anemia of Malignancy and 285.29 Anemia of Other Chronic Condition) (CAG-00406N)

Additional Information

Other Versions

Title	Version	Effective Between
Serum Iron Studies	1	11/25/2002 - N/A