Summary: National Coverage Determination for Serum Iron Studies

NCD 190.18

The terms of Medicare National Coverage Determinations (NCDs) are binding on all fee-for-service (Part A/B) Medicare Administrative Contractors (MACs) and Medicare Advantage (MA) plans. NCDs are not binding, however, on Medicaid and other governmental payers, nor are they binding on commercial payers in their non-MA lines of business.

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*

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.

*This language is a direct quote from the NCD.

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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

Representative List of Covered ICD-10-CM Diagnosis Codes

The following diagnosis codes are among those identified as "ICD-10-CM Codes Covered by Medicare Program" in the CMS "National Coverage Determinations (NCD) Coding Policy Manual and Change Report (ICD-10-CM)" section that identifies covered diagnosis codes for the above-described NCD.

ICD-10 Code	Description
D50.9	Iron deficiency anemia, unspecified
D51.0	Vitamin B12 deficiency anemia due to intrinsic factor deficiency
D51.1	Vitamin B12 deficiency anemia due to selective vitamin B12 malabsorption with proteinuria
D51.8	Other vitamin B12 deficiency anemias
D51.9	Vitamin B12 deficiency anemia, unspecified
D52.9	Folate deficiency anemia, unspecified
D63.1	Anemia in chronic kidney disease
D64.9	Anemia, unspecified
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.9	Type 2 diabetes mellitus without complications
E61.1	Iron deficiency
E83.10	Disorder of iron metabolism, unspecified

ICD-10 Code	Description
E83.19	Other disorders of iron metabolism
K75.9	Inflammatory liver disease, unspecified
K76.9	Liver disease, unspecified
K77	Liver disorders in diseases classified elsewhere
M25.50	Pain in unspecified joint
R74.0	Nonspecific elevation of levels of transaminase and lactic acid dehydrogenase [LDH]
R74.8	Abnormal levels of other serum enzymes
R78.89	Finding of other specified substances, not normally found in blood
R79.0	Abnormal level of blood mineral
R79.89	Other specified abnormal findings of blood chemistry
R79.9	Abnormal finding of blood chemistry, unspecified

To view a full list of codes covered by Medicare and the complete NCD, please refer to the CMS website reference, www.cms.gov.