MEDICAL POLICY	Serum Iron Studies (All Lines of Business Except Medicare)
Effective Date: 11/1/2021  11/1/2021 Medical Officer Date	Medical Policy Number: 321 Medical Policy Committee Approved Date: 09/2021

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: The following policy criteria are based on the Centers for Medicare & Medicaid (CMS) National Coverage Determination (NCD) for Serum Iron Studies (190.18) and the Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM).[1,2]

I. Ferritin, iron and either iron binding capacity or transferrin studies may be considered **medically necessary and covered** for differential diagnosis of iron deficiency, anemia, and for iron overload conditions (see Policy Guidelines for indication guidance).

II. Ferritin, iron and either iron binding capacity or transferrin studies are considered **not medically necessary and not covered** when Criterion I. is not met, including but not limited to the diagnosis and management of iron deficiency or iron overload states.

Link to Policy Summary

POLICY GUIDELINES

Appropriate, Medically Necessary Testing

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.

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.

Follow-up testing may be appropriate to monitor response to therapy, e.g., oral or parenteral iron, ascorbic acid, and erythropoietin.

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.

Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.

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, frequent testing may require 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.

BILLING GUIDELINES

The following CPT/HCPCS codes may be covered when billed with one of the ICD-10 codes that Medicare has included as medically necessary in the most recent *Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report (ICD-10-CM)*. Available for download at: Lab NCDs – ICD-10. Select the "Lab Code List ICD10 (ZIP)" file option that aligns with the date services were or will be rendered from the Downloads section. Open a spreadsheet and look for NCD 190.18 in column A. This resource can also be accessed directly from the NCD noted above, under "Revision History" and by selecting the applicable "Covered Code List" version. While these services do not require prior authorization, utilization may be subject to audit and all criteria from NCD 190.18 must be met. Thus, inclusion of a diagnosis (ICD-10) code on this list may not warrant automatic coverage.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
No Prior Authorization Required	
82728	Ferritin
83540	Iron
83550	Iron binding capacity

84466	Transferrin

DESCRIPTION

Serum Iron Studies

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.

POLICY SUMMARY

Serum iron studies are widely accepted as medically necessary for the management and control of disorders of iron metabolism, particularly iron deficiency and iron excess. 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. Therefore, serum iron studies may be considered medically necessary and covered when policy criteria are met.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Centers for Medicare & Medicaid (CMS). National Coverage Determination (NCD) for Serum Iron Studies (190.18). Effective Date of this Version: 11/25/2002. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=100. Accessed 08/26/2021.
2. Centers for Medicare & Medicaid Services. Lab NCDs - ICD-10. July 2021 Lab Code List ICD-10 (ZIP). https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10. Accessed 08/30/2021.