Blood Counts *(CBC)*

CPT: 85004, 85007, 85008, 85013, 85014, 85018, 85025, 85027, 85032, 85048, 85049

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Blood counts are used to evaluate and diagnose diseases relating to abnormalities of the blood or bone marrow. These include primary disorders such as anemia, leukemia, polycythemia, thrombocytosis and thrombocytopenia. Many other conditions secondarily affect the blood or bone marrow, including reaction to inflammation and infections, coagulopathies, neoplasms and exposure to toxic substances. Many treatments and therapies affect the blood or bone marrow, and blood counts may be used to monitor treatment effects.

The complete blood count (CBC) includes a hemogram and differential white blood count (WBC). The hemogram includes enumeration of red blood cells, white blood cells, and platelets, as well as the determination of hemoglobin, hematocrit, and indices.

The symptoms of hematological disorders are often nonspecific and are commonly encountered in patients who may or may not prove to have a disorder of the blood or bone marrow. Furthermore, many medical conditions that are not primarily due to abnormalities of blood or bone marrow may have hematological manifestations that result from the disease or its treatment. As a result, the CBC is one of the most commonly indicated laboratory tests.

In patients with possible hematological abnormalities, it may be necessary to determine the hemoglobin and hematocrit, to calculate the red cell indices, and to measure the concentration of white blood cells and platelets. These measurements are usually performed on a multichannel analyzer that measures all of the parameters on every sample. Therefore, laboratory assessments routinely include these measurements.

Indications

Indications for a CBC or hemogram include red cell, platelet, and white cell disorders. Examples of these indications are enumerated individually below.

1. Indications for a CBC generally include the evaluation of bone marrow dysfunction as a result of neoplasms, therapeutic agents, exposure to toxic substances, or pregnancy. The CBC is also useful in assessing peripheral destruction of blood cells, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic, or lymphoproliferative processes, and immune disorders.
2. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with anemia or other red blood cell disorder (e.g., pallor, weakness, fatigue, weight loss, bleeding, acute injury associated with blood loss or suspected blood loss, abnormal menstrual bleeding, hematuria, hematemesis, hematochezia, positive fecal occult blood test, malnutrition, vitamin deficiency, malabsorption, neuropathy, known malignancy, presence of acute or chronic disease that may have associated anemia, coagulation or hemostatic disorders, postural dizziness, syncope, abdominal pain, change in bowel habits, chronic marrow hypoplasia or decreased RBC production, tachycardia, systolic heart murmur, congestive heart failure, dyspnea, angina, nailbed deformities, growth retardation, jaundice, hepatomegaly, splenomegaly, lymphadenopathy, ulcers on the lower extremities). Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with polycythemia (for example, fever, chills, ruddy skin, conjunctival redness, cough, wheezing, cyanosis, clubbing of the fingers, orthopnea, heart murmur, headache, vague cognitive changes including memory changes, sleep apnea, weakness, pruritus, dizziness, excessive sweating, visual symptoms, weight loss, massive obesity, gastrointestinal bleeding, paresthesias, dyspnea, joint symptoms, epigastric distress, pain and erythema of the fingers or toes, venous or arterial thrombosis, thromboembolism, myocardial infarction, stroke, transient ischemic

Blood Counts *(CBC)*

CPT: 85004, 85007, 85008, 85013, 85014, 85018, 85025, 85027, 85032, 85048, 85049

Summary of CMS National Coverage Policies* (continued)

attacks, congenital heart disease, chronic obstructive pulmonary disease, increased erythropoietin production associated with neoplastic, renal or hepatic disorders, androgen or diuretic use, splenomegaly, hepatomegaly, diastolic hypertension.

3. Specific indications for CBC with differential count related to the WBC include signs, symptoms, test results, illness, or disease associated with leukemia, infections or inflammatory processes, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic or lymphoproliferative disorder, use of drugs that may cause leukopenia, and immune disorders (e.g., fever, chills, sweats, shock, fatigue, malaise, tachycardia, tachypnea, heart murmur, seizures, alterations of consciousness, meningismus, pain such as headache, abdominal pain, arthralgia, odynophagia, or dysuria, redness or swelling of skin, soft tissue bone, or joint, ulcers of the skin or mucous membranes, gangrene, mucous membrane discharge, bleeding, thrombosis, respiratory failure, pulmonary infiltrate, jaundice, diarrhea, vomiting, hepatomegaly, splenomegaly, lymphadenopathy, opportunistic infection, such as oral candidiasis.)
4. Specific indications for CBC related to the platelet count include signs, symptoms, test results, illness, or disease associated with increased or decreased platelet production and destruction, or platelet dysfunction (e.g., gastrointestinal bleeding, genitourinary tract bleeding, bilateral epistaxis, thrombosis, ecchymosis, purpura, jaundice, petechiae, fever, heparin therapy, suspected DIC, shock, pre-eclampsia, neonate with maternal ITP, massive transfusion, recent platelet transfusion, cardiopulmonary bypass, hemolytic uremic syndrome, renal diseases, lymphadenopathy, hepatomegaly, splenomegaly, hypersplenism, neurologic abnormalities, viral or other infection, myeloproliferative, myelodysplastic, or lymphoproliferative disorder, thrombosis, exposure to toxic agents, excessive alcohol ingestion, autoimmune disorder (SLE, RA).
5. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include, in addition to those already listed, thalassemia, suspected hemoglobinopathy, lead poisoning, arsenic poisoning, and spherocytosis.
6. Specific indications for CBC with differential count related to the WBC include, in addition to those already listed, storage diseases; mucopolysaccharidoses, and use of drugs that cause leukocytosis such as G-CSF or CM-CSF.
7. Specific indications for CBC related to platelet count include, in addition to those already listed, May-Hegglin syndrome and Wiskott-Aldrich syndrome.

Limitations

1. Testing of patients who are asymptomatic, or who do not have a condition that could be expected to result in a hematological abnormality, is screening and is not a covered service.

2. In some circumstances it may be appropriate to perform only a hemoglobin or hematocrit to assess the oxygen carrying capacity of the blood. When the ordering provider requests only a hemoglobin or hematocrit, the remaining components of the CBC are not covered.

3. When a blood count is performed for an end-stage renal disease (ESRD) patient, and is billed outside the ESRD rate, documentation of the medical necessity for the blood count must be submitted with the claim.

4. In some patients presenting with certain signs, symptoms or diseases, a single CBC may be appropriate. Repeat testing may not be indicated unless abnormal results are found, or unless there is a change in clinical condition. If repeat testing is performed, a more descriptive diagnosis code (e.g., anemia) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a continued risk for the development of hematologic abnormality.

Medicare National Coverage Determination Policy

Blood Counts *(CBC)*

CPT: 85004, 85007, 85008, 85013, 85014, 85018, 85025, 85027, 85032, 85048, 85049

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
D50.9	Iron deficiency anemia, unspecified
D64.9	Anemia, unspecified
E03.9	Hypothyroidism, unspecified
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.9	Type 2 diabetes mellitus without complications
E53.8	Deficiency of other specified B group vitamins
E55.9	Vitamin D deficiency, unspecified
E78.00	Pure hypercholesterolemia, unspecified
E78.2	Mixed hyperlipidemia
E78.5	Hyperlipidemia, unspecified I10 Essential (primary) hypertension
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
N39.0	Urinary tract infection, site not specified
R53.83	Other fatigue
R73.01	Impaired fasting glucose
R73.03	Prediabetes
R73.09	Other abnormal glucose
R73.9	Hyperglycemia, unspecified
R79.89	Other specified abnormal findings of blood chemistry
Z79.899	Other long term (current) drug therapy

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Blood Glucose Testing

CPT: 82947, 82948, 82962

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

This policy is intended to apply to blood samples used to determine glucose levels. Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. The method for assay may be by color comparison of an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

Indications

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in patient with impaired fasting glucose (FPG 110-125 mg/dL), patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose/glucose sources of food), in patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to conditions listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (i.e.: pruritis, skin infections, ulceration and gangrene without cause). Many medical conditions may be a consequence of a sustained elevated or depressed glucose level, including comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may be indicated in patients on medications known to affect carbohydrate metabolism.

Effective January 1, 2005, the Medicare law expanded coverage to diabetic screening services. Some forms of blood glucose testing covered under this NCD may be covered for screening purposes subject to specified frequencies. See 42 CFR410.18, sec. 90 ch.18 Claims Processing Manual for screening benefit description.

Limitations

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients unable or unwilling to do home monitoring, it may necessary to measure quantitative blood glucose up to 4 times a year. Depending upon patient's age, type of diabetes, complications, degree of control, and other co-morbid conditions, more frequent testing than 4 times a year may be reasonable and necessary. In patients presenting nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary. Repeat testing may not be indicated unless abnormal results are found or there is a change in clinical condition. If repeat testing is performed, a diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions of a continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

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Medicare National Coverage Determination Policy

Blood Glucose Testing

CPT: 82947, 82948, 82962

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.9	Type 2 diabetes mellitus without complications
E78.00	Pure hypercholesterolemia, unspecified
E78.2	Mixed hyperlipidemia
E78.5	Hyperlipidemia, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
N39.0	Urinary tract infection, site not specified
R53.83	Other fatigue
R73.01	Impaired fasting glucose
R73.03	Prediabetes
R73.09	Other abnormal glucose
R73.9	Hyperglycemia, unspecified
R79.89	Other specified abnormal findings of blood chemistry
R79.9	Abnormal finding of blood chemistry, unspecified
R80.9	Proteinuria, unspecified
Z13.1	Encounter for screening for diabetes mellitus
Z79.4	Long term (current) use of insulin
Z79.899	Other long term (current) drug therapy

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Gamma Glutamyl Transferase *(GGT)*

CPT: 82977

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Gamma glutamyl transferase (GGT) is an intracellular enzyme that appears in blood following leakage from cells. Renal tubules, liver, and pancreas contain high amounts, although the measurement of GGT in serum is almost always used for assessment of Hepatobiliary function. Unlike other enzymes which are found in heart, skeletal muscle, and intestinal mucosa as well as liver, the appearance of an elevated level of GGT in serum is almost always the result of liver disease or injury.

It is specifically useful to differentiate elevated alkaline phosphatase levels when the source of the alkaline phosphatase increase (bone, liver, or placenta) is unclear. The combination of high alkaline phosphatase and a normal GGT does not, however, rule out liver disease completely. As well as being a very specific marker of Hepatobiliary function, GGT is also a very sensitive marker for hepatocellular damage. Abnormal concentrations typically appear before elevations of other liver enzymes or biliuria are evident. Obstruction of the biliary tract, viral infection (e.g., hepatitis, mononucleosis), metastatic cancer, exposure to hepatotoxins (e.g., organic solvents, drugs, alcohol), and use of drugs that induce microsomal enzymes in the liver (e.g., cimetidine, barbiturates, phenytoin, and carbamazepine) all can cause a moderate to marked increase in GGT serum concentration. In addition, some drugs can cause or exacerbate liver dysfunction (e.g., atorvastatin, troglitazone, and others as noted in FDA Contraindications and Warnings.)

GGT is useful for diagnosis of liver disease or injury, exclusion of hepatobiliary involvement related to other diseases, and patient management during the resolution of existing disease or following injury.

Indications

1. To provide information about known or suspected hepatobiliary disease, for example:
   a. Following chronic alcohol or drug ingestion
   b. Following exposure to hepatotoxins
   c. When using medication known to have a potential for causing liver toxicity (e.g., following the drug manufacturer's recommendations)
   d. Following infection (e.g., viral hepatitis and other specific infections such as amebiasis, tuberculosis, psittacosis, and similar infections)
2. To assess liver injury/function following diagnosis of primary or secondary malignant neoplasms
3. To assess liver injury/function in a wide variety of disorders and diseases known to cause liver involvement (e.g., diabetes mellitus, malnutrition, disorders of iron and mineral metabolism, sarcoidosis, amyloidosis, lupus, and hypertension)
4. To assess liver function related to gastrointestinal disease
5. To assess liver function related to pancreatic disease
6. To assess liver function in patients subsequent to liver transplantation
7. To differentiate between the different sources of elevated alkaline phosphatase activity

Limitations

When used to assess liver dysfunction secondary to existing non-hepatobiliary disease with no change in signs, symptoms, or treatment, it is generally not necessary to repeat a GGT determination after a normal result has been obtained unless new indications are present. If the GGT is the only "liver" enzyme abnormally high, it is generally not necessary to pursue further evaluation for liver disease for this specific indication.

When used to determine if other abnormal enzyme tests reflect liver abnormality rather than other tissue, it generally is not necessary to repeat a GGT more than one time per week.

Because of the extreme sensitivity of GGT as a marker for cytochrome oxidase induction or cell membrane permeability, it is generally not useful in monitoring patients with known liver disease.

Medicare National Coverage Determination Policy

Gamma Glutamyl Transferase *(GGT)*

CPT: 82977

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
C61	Malignant neoplasm of prostate
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.9	Type 2 diabetes mellitus without complications
E78.00	Pure hypercholesterolemia, unspecified
E78.2	Mixed hyperlipidemia
E78.49	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified
E78.9	Disorder of lipoprotein metabolism, unspecified
E83.40	Disorders of magnesium metabolism, unspecified
E83.42	Hypomagnesemia
K74.60	Unspecified cirrhosis of liver
K75.81	Nonalcoholic steatohepatitis (NASH)
K76.0	Fatty (change of) liver, not elsewhere classified
K76.89	Other specified diseases of liver
K76.9	Liver disease, unspecified
R74.01	Elevation of levels of liver transaminase levels
R74.8	Abnormal levels of other serum enzymes
Z79.899	Other long term (current) drug therapy
Z94.4	Liver transplant status

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Glycated Hemoglobin/Glycated Protein *(Hemoglobin A1C)*

CPT: 82985, 83036

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

The management of diabetes mellitus requires regular determinations of blood glucose levels. Glycated hemoglobin/protein levels are used to assess long-term glucose control in diabetes. Alternative names for these tests include glycated or glycosylated hemoglobin or Hgb, hemoglobin glycated or glycosylated protein, and fructosamine.

Glycated hemoglobin (equivalent to hemoglobin A1) refers to total glycosylated hemoglobin present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. Hemoglobin A1c refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis. Fructosamine or glycated protein refers to glycosylated protein present in a serum or plasma sample. Glycated protein refers to measurement of the component of the specific protein that is glycated usually by colorimetric method or affinity chromatography.

Glycated hemoglobin in whole blood assesses glycemic control over a period of 4-8 weeks and appears to be the more appropriate test for monitoring a patient who is capable of maintaining long-term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient's metabolic control has been on average within the target range. More frequent assessments, every 1-2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). Glycated protein in serum/plasma assesses glycemic control over a period of 1-2 weeks. It may be reasonable and necessary to monitor glycated protein monthly in pregnant diabetic women. Glycated hemoglobin/protein test results may be low, indicating significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the patient's hypoglycemic state in those conditions.

Indications

Glycated hemoglobin/protein testing is accepted as medically necessary for management and control of diabetes and to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. Glycated protein testing may be used in place of glycated hemoglobin in the management of diabetic patients, and is useful in patients with abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

Limitations

It is not reasonable and necessary to perform glycated hemoglobin tests more often than every three months on a controlled diabetic patient to determine if the patient's metabolic control has been on average within the target range. It is not reasonable and necessary for these tests to be performed more frequently than once a month for diabetic pregnant women. Testing for uncontrolled type one or two diabetes mellitus may require testing more than four times a year. The above Description Section provides the clinical basis for those situations in which testing more frequently than four times per annum is indicated, and medical necessity documentation must support such testing in excess of the above guidelines.

Many analytical methods of glycated hemoglobin show interference from elevated levels of fetal hemoglobin or by variant hemoglobin molecules. When the glycated hemoglobin assay is initially performed in these patients, the laboratory may inform the ordering physician of a possible analytical interference. Alternative testing, including glycated protein, for example, fructosamine, may be indicated for monitoring the degree of glycemic control. It is therefore conceivable that a patient will have both a glycated hemoglobin and glycated protein ordered on the same day. This should be limited to the initial assay of glycated hemoglobin, with subsequent exclusive use of glycated protein. These tests are not considered to be medically necessary for the diagnosis of diabetes.

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Medicare National Coverage Determination Policy

Glycated Hemoglobin/Glycated Protein *(Hemoglobin A1C)*

CPT: 82985, 83036

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
E11.21*	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.40*	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69*	Type 2 diabetes mellitus with other specified complication
E11.8*	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E79.0	Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
R73.01*	Impaired fasting glucose
R73.02*	Impaired glucose tolerance (oral)
R73.03*	Prediabetes
R73.09*	Other abnormal glucose
R73.9*	Hyperglycemia, unspecified
R79.89*	Other specified abnormal findings of blood chemistry
R79.9*	Abnormal finding of blood chemistry, unspecified
Z79.4	Long term (current) use of insulin
Z79.899	Other long term (current) drug therapy

The current Palmetto GBA local coverage determination indicates the asterisked codes do not, in and of themselves, indicate uncontrolled diabetes and must be used in conjunction with one of the following codes: **E08.01, E08.10, E08.11, E08.65, E09.01, E09.10, E09.11, E09.65, E10.10, E10.11, E10.65. E11.00, E11.01, E11.22, E11.65, E11.9, E13.00, E13.01 or E13.10.**

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Hepatitis Panel/Acute Hepatitis Panel

CPT: 80074

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

This panel consists of the following tests: Hepatitis A antibody (HAAb), IgM antibody; Hepatitis B core antibody (HBcAb), IgM antibody; Hepatitis B surface antigen (HBsAg); and Hepatitis C antibody.

Hepatitis is an inflammation of the liver resulting from viruses, drugs, toxins, and other etiologies. Viral hepatitis can be due to one of at least five different viruses, designated hepatitis A, B, C, and E. Most cases are caused by hepatitis A virus (HAV), hepatitis B virus (HBV), or hepatitis C virus (HCV). HAV is the most common cause of hepatitis in children and adolescents in the United States. Prior exposure is indicated by a positive IgG anti-HAV. Acute HAV is diagnosed by IgM anti-HAV, which typically appears within four weeks of exposure, and which disappears within three months of its appearance. IgG anti-HAV is similar in the timing of its appearance, but it persists indefinitely. Its detection indicates prior effective immunization or recovery from infection. Although HAV is spread most commonly by fecal-oral exposure, standard immune globulin may be effective as a prophylaxis.

HBV produces three separate antigens (surface, core, and e (envelope) antigens) when it infects the liver, although only hepatitis B surface antigen (HBsAg) is included as part of this panel. Following exposure, the body normally responds by producing antibodies to each of these antigens; one of which is included in this panel: hepatitis B surface antibody (HBsAb)-IgM antibody. HBsAg is the earlier marker, appearing in serum four to eight weeks after exposure, and typically disappearing within six months after its appearance. If HBsAg remains detectable for greater than six months, this indicates chronic HBV infection. HBcAb, in the form of both IgG and IgM antibodies, are next to appear in serum, typically becoming detectable two to three months following exposure. The IgM antibody gradually declines or disappears entirely one to two years following exposure, but the IgG usually remains detectable for life. Because HBsAg is present for a relatively short period and usually displays a low titer, a negative result does not exclude an HBV diagnosis. HBcAb, on the other hand, rises to a much higher titer and remains elevated for a longer period of time, but a positive result is not diagnostic of acute disease, since it may be the result of a prior infection. The last marker to appear in the course of a typical infection is HBsAb, which appears in serum four to six months following exposure to infected blood or body fluids; in the U.S., sexual transmission accounts for 30% to 60% of new cases of HBV infection.

The diagnosis of acute HBV infection is best established by documentation of positive IgM antibody against the core antigen (HBcAb-IgM) and by identification of a positive hepatitis B surface antigen (HBsAg). The diagnosis of chronic HBV infection is established primarily by identifying a positive hepatitis B surface antigen (HBsAg) and demonstrating positive IgG antibody directed against the core antigen (HBcAb-IgG). Additional tests such as hepatitis B e antigen (HBeAg) and hepatitis B e antibody (HBeAb), the envelope antigen and antibody, are not included in the hepatitis panel, but may be of importance in assessing the infectivity of patients with HBV. Following completion of a HBV vaccination series, HBsAb alone may be used monthly for up to six months, or until a positive result is obtained, to verify an adequate antibody response.

HCV is the most common cause of post-transfusion hepatitis; overall HCV is responsible for 15% to 20% of all cases of acute hepatitis, and is the most common cause of chronic liver disease. The test most commonly used to identify HCV measures HCV antibodies, which appear in blood two to four months after infection. False positive HCV results can occur. For example, a patient with a recent yeast infection may produce a false positive anti-HCV result. For this reason, at present positive results usually are confirmed by a more specific technique. Like HBV, HCV is spread exclusively through exposure to infected blood or body fluids.

This panel of tests is used for differential diagnosis in a patient with symptoms of liver disease or injury. When the time of exposure or the stage of the disease is not known, a patient with continued symptoms of liver disease despite a completely negative hepatitis panel may need a repeat panel approximately two weeks to two months later to exclude the possibility of hepatitis. Once a diagnosis is established, specific tests can be used to monitor the course of the disease.

Indications

1. To detect viral hepatitis infection when there are abnormal liver function test results, with or without signs or symptoms of hepatitis.
2. Prior to and subsequent to liver transplantation. Limitations After a hepatitis diagnosis is established, only individual tests are needed.

Limitations

After a hepatitis diagnosis is established, only individual tests are needed.

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Hepatitis Panel/Acute Hepatitis Panel

CPT: 80074

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
B17.9	Acute viral hepatitis, unspecified
B18.2	Chronic viral hepatitis C
B18.9	Chronic viral hepatitis, unspecified
B19.20	Unspecified viral hepatitis C without hepatic coma
B19.9	Unspecified viral hepatitis without hepatic coma
K74.60	Unspecified cirrhosis of liver
K75.9	Inflammatory liver disease, unspecified
R10.13	Epigastric pain
R10.84	Generalized abdominal pain
R10.9	Unspecified abdominal pain
R16.0	Hepatomegaly, not elsewhere classified
R17	Unspecified jaundice
R53.1	Weakness
R53.81	Other malaise
R53.82	Chronic fatigue, unspecified
R53.83	Other fatigue
R63.4	Abnormal weight loss
R74.01	Elevation of levels of liver transaminase levels
R94.5	Abnormal results of liver function studies
Z01.89	Encounter for other specified special examinations

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Human Chronic Gonadotropin *(hCG)*

CPT: 84702

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Human Chorionic Gonadotropin (hCG) is useful for monitoring and diagnosis of germ cell neoplasms of the ovary, testis, mediastinum, retroperitoneum, and central nervous system. In addition, hCG is useful for monitoring pregnant patients with vaginal bleeding, hypertension and/or suspected fetal loss.

Limitations

It is not reasonable and necessary to perform hCG testing more than once per month for diagnostic purposes. It may be performed as needed for monitoring of patient progress and treatment. Qualitative hCG assays are not appropriate for medically managing patients with known or suspected germ cell neoplasms.

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Human Chronic Gonadotropin *(hCG)*

CPT: 84702

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
C56.9	Malignant neoplasm of unspecified ovary
C62.10	Malignant neoplasm of unspecified descended testis
C62.11	Malignant neoplasm of descended right testis
C62.12	Malignant neoplasm of descended left testis
C62.90	Malignant neoplasm of unspecified testis, unspecified whether descended or undescended
C62.92	Malignant neoplasm of left testis, unspecified whether descended or undescended
D49.59	Neoplasm of unspecified behavior of other genitourinary organ
G89.3	Neoplasm related pain (acute) (chronic)
J98.59	Other diseases of mediastinum, not elsewhere classified
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
O02.1	Missed abortion
O02.81	Inappropriate change in quantitative human chorionic gonadotropin (hCG) in early pregnancy
O02.89	Other abnormal products of conception
R10.2	Pelvic and perineal pain
R93.49	Abnormal radiologic findings on diagnostic imaging of other urinary organs
R97.8	Other abnormal tumor markers
Z34.81	Encounter for supervision of other normal pregnancy, first trimester
Z34.90	Encounter for supervision of normal pregnancy, unspecified, unspecified trimester
Z34.91	Encounter for supervision of normal pregnancy, unspecified, first trimester
Z85.47	Personal history of malignant neoplasm of testis

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Human Immunodeficiency Virus *(HIV)*

CPT: 87536, 87539

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

HIV quantification is achieved through the use of a number of different assays which measure the amount of circulating viral RNA. Assays vary both in methods used to detect viral RNA as well as in ability to detect viral levels at lower limits. However, all employ some type of nucleic acid amplification technique to enhance sensitivity, and results are expressed as the HIV copy number.

Quantification assays of HIV plasma RNA are used prognostically to assess relative risk for disease progression and predict time to death, as well as to assess efficacy of anti-retroviral therapies over time.

HIV quantification is often performed together with CD4+ T cell counts which provide information on extent of HIV induced immune system damage already incurred.

Indications

1. A plasma HIV RNA baseline level may be medically necessary in any patient with confirmed HIV infection.
2. Regular periodic measurement of plasma HIV RNA levels may be medically necessary to determine risk for disease progression in an HIV-infected individual and to determine when to initiate anti-retroviral treatment regimens.
3. In clinical situations where risk of HIV infection is significant and initiation of therapy is anticipated, a baseline HIV quantification may be performed. These situations include:
    a. Persistence of borderline or equivocal serologic reactivity in an at-risk individual.
    b. Signs and symptoms of acute retroviral syndrome characterized by fever, malaise, lymphadenopathy and rash in an at-risk individual.

Limitations

1. Viral quantification may be appropriate for prognostic use including baseline determination, periodic monitoring, and monitoring of response to therapy. Use as a diagnostic test method is not indicated.
2. Measurement of plasma HIV RNA levels should be performed at the time of establishment of an HIV infection diagnosis. For an accurate baseline, 2 specimens in a 2-week period are appropriate.
3. For prognosis including anti-retroviral therapy monitoring, regular, periodic measurements are appropriate. The frequency of viral load testing should be consistent with the most current Centers for Disease Control and Prevention guidelines for use of anti-retroviral agents in adults and adolescents or pediatrics.
4. Because differences in absolute HIV copy number are known to occur using different assays, plasma HIV RNA levels should be measured by the same analytical method. A change in assay method may necessitate re-establishment of a baseline.
5. Nucleic acid quantification techniques are representative of rapidly emerging & evolving new technologies. Users advised to remain current on FDA-approval status.

Last Updated: 11/30/2023

Human Immunodeficiency Virus *(HIV)*

CPT: 87536, 87539

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
B20	Human immunodeficiency virus [HIV] disease
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
O98.719	Human immunodeficiency virus [HIV] disease complicating pregnancy, unspecified trimester
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Human Immunodeficiency Virus *(HIV)* testing (Diagnosis)

CPT: 86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Diagnosis of Human Immunodeficiency Virus (HIV) infection is primarily made through the use of serologic assays. These assays take one of two forms: antibody detection assays and specific HIV antigen (p24) procedures. The antibody assays are usually enzyme immunoassays (EIA) which are used to confirm exposure of an individual's immune system to specific viral antigens. These assays may be formatted to detect HIV-1, HIV-2, or HIV-1 and 2 simultaneously and to detect both IgM and IgG. When the initial EIA test is repeatedly positive or indeterminate, an alternative test is used to confirm the specificity of the antibodies to individual viral components. The most commonly used method is the Western Blot.

The HIV-1 core antigen (p24) test detects circulating viral antigen which may be found prior to the development of antibodies and may also be present in later stages of illness in the form of recurrent or persistent antigenemia. Its prognostic utility in HIV infection has been diminished as a result of development of sensitive viral RNA assays, and its primary use today is as a routine screening tool in potential blood donors.

In several unique situations, serologic testing alone may not reliably establish an HIV infection. This may occur because the antibody response (particularly the IgG response detected by Western Blot) has not yet developed (that is, acute retroviral syndrome), or is persistently equivocal because of inherent viral antigen variability. It is also an issue in perinatal HIV infection due to transplacental passage of maternal HIV antibody. In these situations, laboratory evidence of HIV in blood by culture, antigen assays, or proviral DNA or viral RNA assays, is required to establish a definitive determination of HIV infection.

Indications

Diagnostic testing to establish HIV infection may be indicated when there is a strong clinical suspicion supported by one or more of the following clinical findings:

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.
2. The patient has another documented sexually transmitted disease which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.
3. The patient has documented acute or chronic hepatitis B or C infection that identifies a significant risk of exposure to HIV and the potential for an early or subclinical infection.
4. The patient has a documented AIDS-defining or AIDS-associated neoplasm.
5. The patient has a documented AIDS-associated neurologic disorder or otherwise unexplained dementia.
6. The patient has another documented AIDS-defining clinical condition, or a history of other severe, recurrent, or persistent conditions which suggest an underlying immune deficiency (for example, cutaneous or mucosal disorders).
7. The patient has otherwise unexplained generalized signs and symptoms suggestive of a chronic process with an underlying immune deficiency (for example, fever, weight loss, malaise, fatigue, chronic diarrhea, failure to thrive, chronic cough, hemoptysis, shortness of breath, or lymphadenopathy).
8. The patient has otherwise unexplained laboratory evidence of a chronic disease process with an underlying immune deficiency (for example, anemia, leukopenia, pancytopenia, lymphopenia, or low CD4+ lymphocyte count).
9. The patient has signs and symptoms of acute retroviral syndrome with fever, malaise, lymphadenopathy, and skin rash
10. The patient has documented exposure to blood or body fluids known to be capable of transmitting HIV (for example, needlesticks and other significant blood exposures) and antiviral therapy is initiated or anticipated to be initiated.
11. The patient is undergoing treatment for rape. (HIV testing is part of the rape treatment protocol.)

Immunodeficiency Virus *(HIV)* testing (Diagnosis)

CPT: 86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538

Summary of CMS National Coverage Policies* (continued)

Limitations

1. HIV antibody testing in the United States is usually performed using HIV-1 or HIV-½ combination tests. HIV-2 testing is indicated if clinical circumstances suggest HIV-2 is likely (that is compatible clinical findings and HIV-1 test negative). HIV-2 testing may be indicated in areas of the country where there is greater prevalence of HIV-2 infections.
2. The Western Blot test should be performed only after documentation that the initial EIA tests are repeatedly positive or equivocal on a single sample.
3. The HIV antigen tests currently have no defined diagnostic usage.
4. Direct viral RNA detection may be performed in those situations where serologic testing does not establish a diagnosis but strong clinical suspicion persists (for example, acute retroviral syndrome, nonspecific serologic evidence of HIV, or perinatal HIV infection).
5. If initial serologic tests confirm an HIV infection, repeat testing is not indicated.
6. If initial serologic tests are HIV EIA negative and there is no indication for confirmation of infection by viral RNA detection, the interval prior to retesting is 3-6 months.
7. Testing for evidence of HIV infection using serologic methods may be medically appropriate in situations where there is a risk of exposure to HIV. However, in the absence of a documented AIDS defining or HIV-associated disease, an HIV-associated sign or symptom, or documented exposure to a known HIV-infected source, the testing is considered by Medicare to be screening and thus is not covered by Medicare (for example, history of multiple blood component transfusions, exposure to blood or body fluids not resulting in consideration of therapy, history of transplant, history of illicit drug use, multiple sexual partners, same-sex encounters, prostitution, or contact with prostitutes).
8. The CPT Editorial Panel has issued a number of codes for infectious agent detection by direct antigen or nucleic acid probe techniques that have not yet been developed or are only being used on an investigational basis. Laboratory providers are advised to remain current on FDA-approval status for these tests.

Human Immunodeficiency Virus *(HIV)* testing (Diagnosis)

CPT: 86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
A64	Unspecified sexually transmitted disease
B20	Human immunodeficiency virus [HIV] disease
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D64.9	Anemia, unspecified
D69.6	Thrombocytopenia, unspecified
D72.810	Lymphocytopenia
D72.819	Decreased white blood cell count, unspecified
G62.9	Polyneuropathy, unspecified
L03.327	Acute lymphangitis of buttock
N17.9	Acute kidney failure, unspecified
N18.2	Chronic kidney disease, stage 2 (mild)
N18.31	Chronic kidney disease, stage 3a
N25.81	Secondary hyperparathyroidism of renal origin
R19.7	Diarrhea, unspecified
R53.83	Other fatigue
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.820	Contact with and (suspected) exposure to varicella

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Lipid Testing

CPT: 80061, 82465, 83700, 83701, 83704, 83718, 83721, 84478

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins. Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise, genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease (including diabetes), and kidney disease. In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol (LDL -C) and high density lipoprotein cholesterol (HDL-C) are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Blood levels of the above cholesterol components including triglyceride have been separated into desirable, borderline and high-risk categories by the National Heart, Lung, and Blood Institute in their report in 1993. These categories form a useful basis for evaluation and treatment of patients with hyperlipidemia. Therapy to reduce these risk parameters includes diet, exercise and medication, and fat weight loss, which is particularly powerful when combined with diet and exercise.

Indications

The medical community recognizes lipid testing as appropriate for evaluating atherosclerotic cardiovascular disease. Conditions in which lipid testing may be indicated include:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease, or any disease leading to the formation of atherosclerotic disease
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure
- Signs or symptoms of dyslipidemias, such as skin lesions
- As follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200-240 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol.

To monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for the treatment of elevated blood lipid disorders, total cholesterol, HDL cholesterol and LDL cholesterol may be used. Triglycerides may be obtained if this lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.

When monitoring long-term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel at a yearly interval will usually be adequate while measurement of the serum total cholesterol or a measured LDL should suffice for interim visits if the patient does not have hypertriglyceridemia.

Lipid Testing

CPT: 80061, 82465, 83700, 83701, 83704, 83718, 83721, 84478

Summary of CMS National Coverage Policies* (continued)

Any one component of the panel or a measured LDL may be reasonable and necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.
Electrophoretic or other quantitation of lipoproteins may be indicated if the patient has a primary disorder of lipoid metabolism.

Effective January 1, 2005, the Medicare law expanded coverage to cardiovascular screening services. Several of the procedures included in this NCD may be covered for screening purposes subject to specified frequencies. See 42 CFR 410.17 and section 100, chapter 18, of the Claims Processing Manual, for a full description of this benefit.

Limitations
Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid etretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis. Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc.

Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

When monitoring long-term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it is reasonable to perform the lipid panel annually. A lipid panel at a yearly interval will usually be adequate while measurement of the serum total cholesterol or a measured LDL should suffice for interim visits if the patient does not have hypertriglyceridemia.

Any one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved. If no dietary or pharmacological therapy is advised, monitoring is not necessary.

When evaluating non-specific chronic abnormalities of the liver (for example, elevations of transaminase, alkaline phosphatase, abnormal imaging studies, etc.), a lipid panel would generally not be indicated more than twice per year.

Lipid Testing

CPT: 80061, 82465, 83700, 83701, 83704, 83718, 83721, 84478

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
E03.8	Other specified hypothyroidism
E03.9	Hypothyroidism, unspecified
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.9	Type 2 diabetes mellitus without complications
E66.9	Obesity, unspecified
E78.00	Pure hypercholesterolemia, unspecified
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.49	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified
I10	Essential (primary) hypertension
I11.9	Hypertensive heart disease without heart failure
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
R79.89	Other specified abnormal findings of blood chemistry
R79.9	Abnormal finding of blood chemistry, unspecified
Z13.6	Encounter for screening for cardiovascular disorders
Z79.899	Other long term (current) drug therapy

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Prostate Specific Antigen

CPT: 84153

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Prostate Specific Antigen (PSA), a tumor marker for adenocarcinoma of the prostate, can predict residual tumor in the post-operative phase of prostate cancer. Three to 6 months after radical prostatectomy, PSA is reported to provide a sensitive indicator of persistent disease. Six months following introduction of antiandrogen therapy, PSA is reported of distinguishing patients with favorable response from those in whom limited response is anticipated.

PSA when used in conjunction with other prostate cancer tests, such as digital rectal examination, may assist in the decision-making process for diagnosing prostate cancer. PSA also serves as a marker in following the progress of most prostate tumors once a diagnosis has been established. This test is also an aid in the management of prostate cancer patients and in detecting metastatic or persistent disease in patients following treatment.

Indications

PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs & symptoms (e.g., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia & incontinence) as well as with patients with palpably abnormal prostate glands on physician exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder. PSA is also a marker used to follow the progress of prostate cancer once a diagnosis has been established, such as detecting metastatic or persistent disease in patients who may require additional treatment. PSA testing may also be useful in the differential diagnosis of men presenting with yet undiagnosed disseminated metastatic disease.

Limitations

Generally, for patients with lower urinary tract signs or symptoms, the test is performed only once per year unless there is a change in the patient’s medical condition.

Testing with a diagnosis of in situ carcinoma is not reasonably done more frequently than once, unless the result is abnormal, in which case the test may be repeated once.

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Medicare National Coverage Determination Policy

Prostate Specific Antigen

CPT: 84153

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
C61	Malignant neoplasm of prostate
C79.51	Secondary malignant neoplasm of bone
N40.0	Benign prostatic hyperplasia without lower urinary tract symp
N40.1	Benign prostatic hyperplasia with lower urinary tract symp
N40.2	Nodular prostate without lower urinary tract symptoms
N41.9	Inflammatory disease of prostate, unspecified
N42.9	Disorder of prostate, unspecified
R31.0	Gross hematuria
R31.29	Other microscopic hematuria
R31.9	Hematuria, unspecified
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R35.1	Nocturia
R39.11	Hesitancy of micturition
R39.12	Poor urinary stream
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination
R97.20	Elevated prostate specific antigen [PSA]
R97.21	Rising PSA fol treatment for malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Serum Iron Studies

CPT: 82728, 83540, 83550, 84466

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

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 erythropoietin 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 transferring, a protein that binds and transports iron. TIBC quantifies transferring by the amount of iron that it can bind. TIBC and transferring are elevated in iron deficiency, and with oral contraceptive use, and during pregnancy. TIBC and transferring 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 ferreting 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

Serum Iron Studies

CPT: 82728, 83540, 83550, 84466

Summary of CMS National Coverage Policies* (continued)

- 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, and 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 either 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.

Medicare National Coverage Determination Policy

Serum Iron Studies

CPT: 82728, 83540, 83550, 84466

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D51.0	Vitamin B12 deficiency anemia due to intrinsic factor deficiency
D51.8	Other vitamin B12 deficiency anemias
D51.9	Vitamin B12 deficiency anemia, unspecified
D52.9	Folate deficiency anemia, unspecified
D53.9	Nutritional anemia, unspecified
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic diseases classified elsewhere
D64.9	Anemia, unspecified
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.9	Type 2 diabetes mellitus without complications
E61.1	Iron deficiency M25.50 Pain in unspecified joint
N18.4	Chronic kidney disease, stage 4 (severe) N18.9 Chronic kidney disease, unspecified
R79.89	Other specified abnormal findings of blood chemistry
R79.9	Abnormal finding of blood chemistry, unspecified

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Medicare National Coverage Determination Policy

Thyroid Testing

CPT: 84436, 84439, 84443, 84479

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

Thyroid function studies are used to delineate the presence or absence of hormonal abnormalities of the thyroid and pituitary glands. These abnormalities may be either primary or secondary and often but not always accompany clinically defined signs and symptoms indicative of thyroid dysfunction.

Laboratory evaluation of thyroid function has become more scientifically defined. Tests can be done with increased specificity, thereby reducing the number of tests needed to diagnose and follow treatment of most thyroid disease. Measurements of serum sensitive thyroidstimulating hormone (TSH) levels, complemented by determination of thyroid hormone levels [free thyroxine (fT-4) or total thyroxine (T4) with Triiodothyronine (T3) uptake] are used for diagnosis and follow-up of patients with thyroid disorders. Additional tests may be necessary to evaluate certain complex diagnostic problems or on hospitalized patients, where many circumstances can skew tests results. When a test for total thyroxine (total T4 or T4 radioimmunoassay) or T3 uptake is performed, calculation of the free thyroxine index (FTI) is useful to correct for abnormal results for either total T4 or T3 uptake due to protein binding effects.

Indications

Thyroid function tests are used to define hyper function, euthyroidism, or hypofunction of thyroid disease. Thyroid testing may be reasonable and necessary to:

- Distinguish between primary and secondary hypothyroidism
- Confirm or rule out primary hypothyroidism
- Monitor thyroid hormone levels (for example, patients with goiter, thyroid nodules, or thyroid cancer)
- Monitor drug therapy in patients with primary hypothyroidism
- Confirm or rule out primary hyperthyroidism
- Monitor therapy in patients with hyperthyroidism

Thyroid function testing may be medically necessary in patients with disease or neoplasm of the thyroid and other endocrine glands. Thyroid function testing may also be medically necessary in patients with metabolic disorders; malnutrition; hyperlipidemia; certain types of anemia; psychosis and non-psychotic personality disorders; unexplained depression; ophthalmologic disorders; various cardiac arrhythmias; disorders of menstruation; skin conditions; myalgias; and a wide array of signs and symptoms, including alterations in consciousness; malaise; hypothermia; symptoms of the nervous and musculoskeletal system; skin and integumentary system; nutrition and metabolism; cardiovascular; and gastrointestinal system.

It may be medically necessary to do follow-up thyroid testing in patients with a history of malignant neoplasm of the endocrine system and in patients on long-term thyroid drug therapy.

Limitations

Testing may be covered up to two times a year in clinically stable patients; more frequent testing may be reasonable and necessary for patients whose thyroid therapy has been altered or in whom symptoms or signs of hyperthyroidism or hypothyroidism are noted.

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Medicare National Coverage Determination Policy

Thyroid Testing

CPT: 84436, 84439, 84443, 84479

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Please refer to the Limitations or Utilization Guidelines section on previous page(s).

CODE	DESCRIPTION
D64.9	Anemia, unspecified
E03.8	Other specified hypothyroidism
E03.9	Hypothyroidism, unspecified
E04.2	Nontoxic multinodular goiter
E05.90	Thyrotoxicosis, unspecified without thyrotoxic crisis or storm
E06.3	Autoimmune thyroiditis
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.9	Type 2 diabetes mellitus without complications
E78.00	Pure hypercholesterolemia, unspecified
E78.2	Mixed hyperlipidemia
E78.49	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified
E89.0	Postprocedural hypothyroidism
I10	Essential (primary) hypertension
R53.82	Chronic fatigue, unspecified
R53.83	Other fatigue
R73.03	Prediabetes
R94.6	Abnormal results of thyroid function studies
Z79.899	Other long term (current) drug therapy

To view the complete policy and the full list of codes, please refer to the CMS website Home - Centers for Medicare & Medicaid Services | CMS

Last Updated: 11/30/2023

Medicare National Coverage Determination Policy

Urine Culture, Bacterial

CPT: 87086, 87088

Summary of CMS National Coverage Policies*

Coverage Indications, Limitations, and/or Medical Necessity

A bacterial urine culture is a laboratory test service performed on a urine specimen to establish the probable etiology of a presumed urinary tract infection. It is common practice to do a urinalysis prior to a urine culture. A urine culture for bacteria might also be used as part of the evaluation and management of another related condition. The procedure includes aerobic agarbased isolation of bacteria or other cultivable organisms present, and quantitation of types present based on morphologic criteria. Isolates deemed significant may be subjected to additional identification and susceptibility procedures as requested by the ordering physician. The physician's request may be through clearly documented and communicated laboratory protocols

Indications

1. A beneficiary's urinalysis is abnormal suggesting urinary tract infection, for example, abnormal microscopic (hematuria, pyuria, bacteriuria); abnormal biochemical urinalysis (positive leukocyte esterase, nitrite, protein, blood); a Gram's stain positive for microorganisms; positive bacteriuria screen by a non-culture technique; or other significant abnormality of a urinalysis. While it is not essential to evaluate a urine specimen by one of these methods before a urine culture is performed, certain clinical presentations with highly suggestive signs and symptoms may lend themselves to an antecedent urinalysis procedure where follow-up culture depends upon an initial positive or abnormal test result

2. A beneficiary has clinical signs and symptoms indicative of a possible urinary tract infection (UTI). Acute lower UTI may present with urgency, frequency, nocturia, dysuria, discharge or incontinence. These findings might also be noted in upper UTI with additional systemic symptoms (for example, fever, chills, lethargy); or pain in the costovertebral, abdominal, or pelvic areas. Signs and symptoms might overlap considerably with other inflammatory conditions of the genitourinary tract (for example, prostatitis, urethritis, vaginitis, or cervicitis). Elderly or immunocompromised beneficiaries or those with neurologic disorders might present atypically (for example, general debility, acute mental status changes, declining functional status).

3. The beneficiary is being evaluated for suspected urosepsis, fever of unknown origin, or other systemic manifestations of infection but without a known source. Signs and symptoms used to define sepsis have been well established.

4. A test of cure is generally not indicated in an uncomplicated infection. However, it may be indicated if the beneficiary is being evaluated for response to therapy and there is a complicating co-existing urinary abnormality including structural or functional abnormalities, calculi, foreign bodies, or ureteral/renal stents or there is clinical or laboratory evidence of failure to respond as described in Indications 1 and 2. 5. In surgical procedures involving major manipulations of the genitourinary tract, preoperative examination to detect occult infection may be indicated in selected cases (for example, prior to renal transplantation, manipulation or removal of kidney stones, or transurethral surgery of the bladder or prostate). 6. Urine culture may be indicated to detect occult infection in renal transplant recipients on immunosuppressive therapy.

Limitations

1. CPT© code 87086 may be used one time per encounter.
2. Colony count restrictions on coverage of CPT© code 87088 do not apply as they may be highly variable according to syndrome or other clinical circumstances (for example, antecedent therapy, collection time, and degree of hydration).
3. CPT© code 87088 may be used multiple times in association with or independent of87086, as urinary tract infections may be polymicrobial.
4. Testing for asymptomatic bacteriuria as part of a prenatal evaluation may be medically appropriate but is considered screening and therefore not covered by Medicare. The U.S. Preventive Services Task Force has concluded that screening for asymptomatic bacteriuria outside of the narrow indication for pregnant women is generally not indicated. There are insufficient data to recommend screening in ambulatory elderly beneficiaries including those with diabetes. Testing may be clinically indicated on other grounds including likelihood of recurrence or potential adverse effects of antibiotics, but is considered screening in the absence of clinical or laboratory evidence of infection.
5. To detect a clinically significant post-transplant occult infection in a renal allograft recipient on long-term immunosuppressive therapy, use code Z79.899.

Medicare National Coverage Determination Policy

Urine Culture, Bacterial

CPT: 87086, 87088

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CODE	DESCRIPTION
N30.00	Acute cystitis without hematuria
N30.01	Acute cystitis with hematuria
N39.0	Urinary tract infection, site not specified
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms
R10.9	Unspecified abdominal pain
R30.0	Dysuria
R30.9	Painful micturition, unspecified
R31.0	Gross hematuria
R31.29	Other microscopic hematuria
R31.9	Hematuria, unspecified
R35.0	Frequency of micturition
R39.15	Urgency of urination
R39.9	Unspecified symptoms and signs involving the genitourinary system
R53.83	Other fatigue
R73.03	Prediabetes
R80.9	Proteinuria, unspecified
R82.79	Other abnormal findings on microbiological examination of urine
R82.90	Unspecified abnormal findings in urine
R82.998	Other abnormal findings in urine
Z79.899	Other long term (current) drug therapy

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