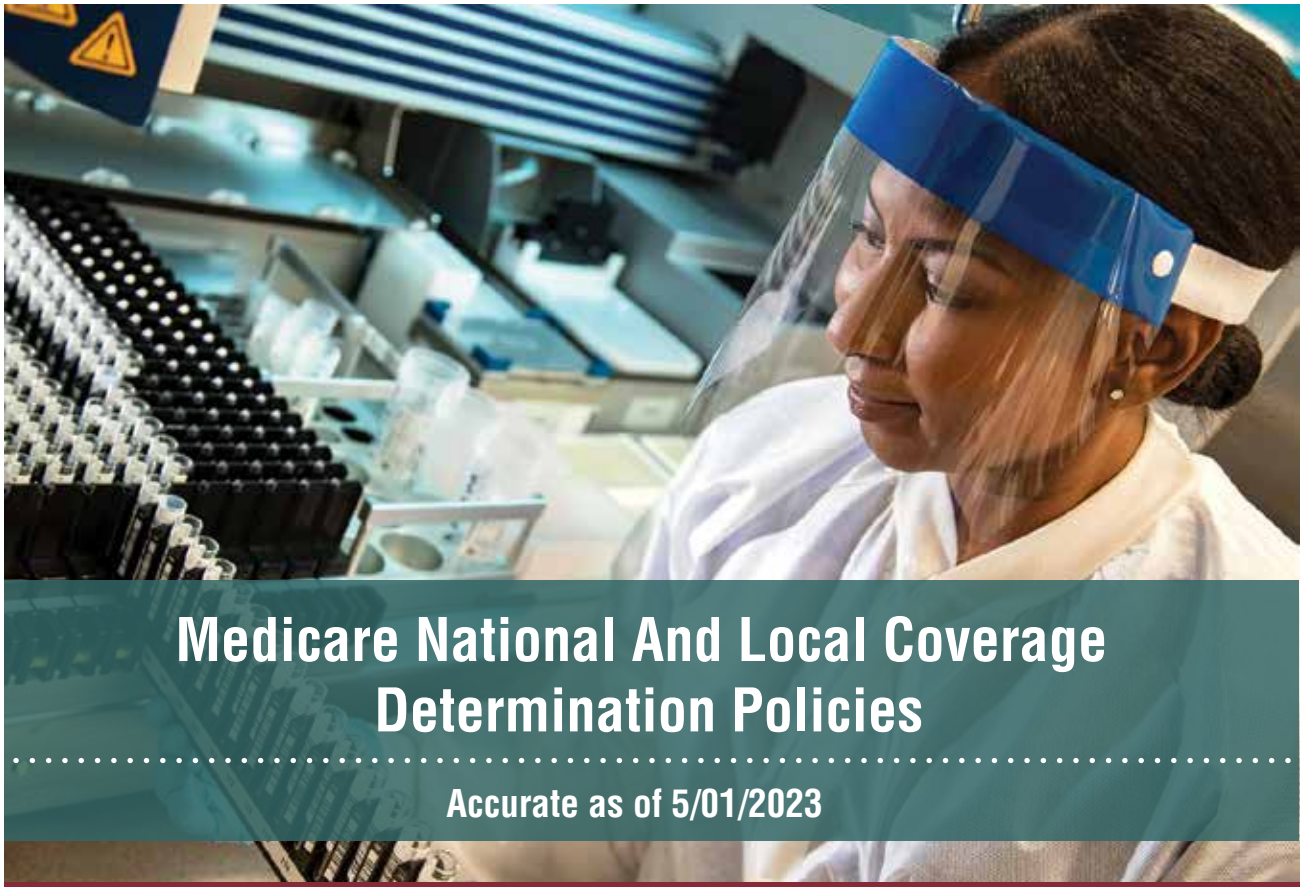

Medicare National And Local Coverage Determination Policies

Accurate as of 5/01/2023

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Alpha-fetoprotein

CPT: 82105

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Alpha-fetoprotein (AFP) is a polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

Indications
AFP is useful for the diagnosis of hepatocellular carcinoma in high-risk patients (such as alcoholic cirrhosis, cirrhosis of viral etiology, hemochromatosis, and alpha 1-antitrypsin deficiency) and in separating patients with benign hepatocellular neoplasms or metastases from those with hepatocellular carcinoma and, as a non-specific tumor associated antigen, serves in marking germ cell neoplasms of the testis, ovary, retro peritoneum, and mediastinum.

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Alpha-fetoprotein

CPT: 82105

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
B18.1	**Chronic viral hepatitis B without delta-agent**
B18.2	**Chronic viral hepatitis C**
C22.0	**Liver cell carcinoma**
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
E78.2	Mixed hyperlipidemia
E83.110	Hereditary hemochromatosis
E83.119	Hemochromatosis, unspecified
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K73.9	Chronic hepatitis, unspecified
K74.00	Hepatic fibrosis
K74.02	Hepatic fibrosis, advanced fibrosis
K74.60	**Unspecified cirrhosis of liver**
K74.69	**Other cirrhosis of liver**
K75.4	Autoimmune hepatitis
R93.2	Abnormal findings on diagnostic imaging of liver and biliary tract
R93.5	Abnormal findings on diagnostic imaging of other abdominal regions, including retroperitoneum
R97.8	Other abnormal tumor markers
Z85.05	Personal history of malignant neoplasm of liver

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

Blood Counts

CBC

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

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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).
3. 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 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.)

Blood Counts

CBC

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

CMS National Coverage Policy (continued)

4. 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.)
5. 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).
6. 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.
7. 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.
8. 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.
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, amore descriptive diagnosis code (e.g., anemia) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal inpatients with conditions where there is a continued risk for the development of hematologic abnormality.

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Blood Counts

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.**
Note—Bolded diagnoses below have the highest utilization

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**

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

Tumor Antigen by Immunoassay CA15-3/CA 27.29

CPT: 86300

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of markers may reflect tumor size & grade.

This policy specifically addresses the following tumor antigens: CA 15-3 and CA 27.29

Indications
Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether a residual tumor exists post-surgical therapy. CA 15-3 is often medically necessary to aid in the management of patients with breast cancer. Serial testing must be used in conjunction with other clinical methods for monitoring breast cancer. For monitoring, if medically necessary, use consistently either CA 15-3 or CA 27.29, not both. CA 27.29 is equivalent to CA 15-3 in its usage in management of patients with breast cancer.

Limitations
These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

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Tumor Antigen by Immunoassay CA 15-3/CA 27.29

CPT: 86300

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.411	**Malignant neoplasm of upper-outer quadrant of right female breast**
C50.412	**Malignant neoplasm of upper-outer quadrant of left female breast**
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.911	**Malignant neoplasm of unspecified site of right female breast**
C50.912	**Malignant neoplasm of unspecified site of left female breast**
C50.919	**Malignant neoplasm of unspecified site of unspecified female breast**
R97.8	Other abnormal tumor markers
Z85.3	Personal history of malignant neoplasm of breast

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

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Tumor Antigen by Immunoassay CA 19-9

CPT: 86301

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade. This policy specifically addresses the following tumor antigen: CA19-9.

Indications
Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy.

Levels are useful in following the course of patients with established diagnosis of pancreatic and biliary ductal carcinoma. The test is not indicated for diagnosing these two diseases.

Limitations
These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

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Tumor Antigen by Immunoassay CA 19-9

CPT: 86301

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.**
Note—Bolded diagnoses below have the highest utilization

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Code	Description
C22.1	**Intrahepatic bile duct carcinoma**
C23	Malignant neoplasm of gallbladder
C24.1	Malignant neoplasm of ampulla of Vater
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	**Malignant neoplasm of head of pancreas**
C25.1	**Malignant neoplasm of body of pancreas**
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	**Malignant neoplasm of pancreas, unspecified**
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.89	Secondary malignant neoplasm of other digestive organs
D37.6	Neoplasm of uncertain behavior of liver, gallbladder and bile ducts
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
G89.3	Neoplasm related pain (acute) (chronic)
R97.8	**Other abnormal tumor markers**
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs

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Last updated: 05/01/23

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Tumor Antigen by Immunoassay CA 125

CPT: 86304

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade. This policy specifically addresses tumor antigen CA 125.

Indications
CA 125 is a high molecular weight serum tumor marker elevated in 80% of patients who present with epithelial ovarian carcinoma. It is also elevated in carcinomas of the fallopian tube, endometrium, and endocervix. An elevated level may also be associated with the presence of a malignant mesothelioma or primary peritoneal carcinoma.

A CA 125 level may be obtained as part of the initial pre-operative work-up for women presenting with a suspicious pelvic mass to be used as a baseline for purposes of post-operative monitoring. Initial declines in CA 125 after initial surgery and/or chemotherapy for ovarian carcinoma are also measured by obtaining three serum levels during the first month post treatment to determine the patient's CA 125 half-life, which has significant prognostic implications.

The CA 125 levels are again obtained at the completion of chemotherapy as an index of residual disease. Surveillance CA 125 measurements are generally obtained every 3 months for 2 years, every 6 months for the next 3 years, and yearly thereafter. CA 125 levels are also an important indicator of a patient's response to therapy in the presence of advanced or recurrent disease. In this setting, CA 125 levels may be obtained prior to each treatment cycle.

Limitations
These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

The CA 125 is specifically not covered for aiding in the differential diagnosis of patients with a pelvic mass as the sensitivity and specificity of the test is not sufficient. In general, a single "tumor marker" will suffice in following a patient with one of these malignancies.

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Tumor Antigen by Immunoassay CA 125

CPT: 86304

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C53.0	Malignant neoplasm of endocervix
C54.1	**Malignant neoplasm of endometrium**
C54.9	Malignant neoplasm of corpus uteri, unspecified
C56.1	**Malignant neoplasm of right ovary**
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	**Malignant neoplasm of unspecified ovary**
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
D39.10	Neoplasm of uncertain behavior of unspecified ovary
D39.11	Neoplasm of uncertain behavior of right ovary
D39.12	Neoplasm of uncertain behavior of left ovary
G89.3	Neoplasm related pain (acute) (chronic)
R19.09	Other intra-abdominal and pelvic swelling, mass and lump
R97.1	**Elevated cancer antigen 125 [CA 125]**
R97.8	**Other abnormal tumor markers**
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary

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Last updated: 05/01/23

Sonora Quest Laboratories™
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Carcinoembryonic Antigen

CEA

CPT: 82378

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Carcinoembryonic antigen (CEA) is a protein polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

Indications
CEA may be medically necessary for follow-up of patients with colorectal carcinoma. It would however only be medically necessary at treatment decision-making points. In some clinical situations (e.g. adenocarcinoma of the lung, small cell carcinoma of the lung, and some gastrointestinal carcinomas) when a more specific marker is not expressed by the tumor, CEA may be a medically necessary alternative marker for monitoring. Preoperative CEA may also be helpful in determining the post-operative adequacy of surgical resection and subsequent medical management. In general, a single tumor marker will suffice in following patients with colorectal carcinoma or other malignancies that express such tumor markers.

In following patients who have had treatment for colorectal carcinoma, ASCO guideline suggests that if resection of liver metastasis would be indicated, it is recommended that post-operative CEA testing be performed every two to three months in patients with initial stage II or stage III disease for at least two years after diagnosis.

For patients with metastatic solid tumors which express CEA, CEA may be measured at the start of the treatment and with subsequent treatment cycles to assess the tumor's response to therapy.

Limitations
Serum CEA determinations are generally not indicated more frequently than once per chemotherapy treatment cycle for patients with metastatic solid tumors which express CEA or every two months post-surgical treatment for patients who have had colorectal carcinoma. However, it may be proper to order the test more frequently in certain situations, for example, when there has been a significant change from prior CEA level or a significant change in patient status which could reflect disease progression or recurrence.

Testing with a diagnosis of an 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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Carcinoembryonic Antigen

CPT: 82378

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
C18.0	Malignant neoplasm of cecum
C18.2	**Malignant neoplasm of ascending colon**
C18.4	Malignant neoplasm of transverse colon
C18.7	Malignant neoplasm of sigmoid colon
C18.9	**Malignant neoplasm of colon, unspecified**
C19	Malignant neoplasm of rectosigmoid junction
C20	**Malignant neoplasm of rectum**
C25.9	Malignant neoplasm of pancreas, unspecified
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C56.9	Malignant neoplasm of unspecified ovary
R79.89	Other specified abnormal findings of blood chemistry
R97.0	**Elevated carcinoembryonic antigen [CEA]**
R97.8	**Other abnormal tumor markers**
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.3	Personal history of malignant neoplasm of breast

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Last updated: 05/01/23

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Collagen Crosslinks (Any Method)

CPT: 82523

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity

Collagen crosslinks, part of the matrix of bone upon which bone mineral is deposited, are biochemical markers the excretion of which provides a quantitative measurement of bone resorption. Elevated levels of urinary collagen crosslinks indicate elevated bone resorption. Elevated bone resorption contributes to age-related and postmenopausal loss of bone leading to osteoporosis and increased risk of fracture. The collagen crosslinks assay can be performed by immunoassay or by high performance liquid chromatography (HPLC). Collagen crosslink immunoassays measure the pyridinoline crosslinks and associated telopeptides in urine.

Bone is constantly undergoing a metabolic process called turnover or remodeling. This includes a degradation process, bone resorption, mediated by the action of osteoclasts, and a building process, bone formation, mediated by the action of osteoblasts. Remodeling is required for the maintenance and overall health of bone and is tightly coupled; that is, resorption and formation must be in balance. In abnormal states of bone remodeling, when resorption exceeds formation, it results in a net loss of bone. The measurement of specific, bone-derived resorption products provides analytical data about the rate of bone resorption.

Osteoporosis is a condition characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. The term primary osteoporosis is applied where the causal factor in the disease is menopause or aging. The term secondary osteoporosis is applied where the causal factor is something other than menopause or aging, such as long-term administration of glucocorticosteroids, endocrine-related disorders (other than loss of estrogen due to menopause), and certain bone diseases such as cancer of the bone.

With respect to quantifying bone resorption, collagen crosslink tests can provide adjunct diagnostic information in concert with bone mass measurements. Bone mass measurements and biochemical markers may have complementary roles to play in assessing effectiveness of osteoporosis treatment. Proper management of osteoporosis patients, who are on long-term therapeutic regimens, may include laboratory testing of biochemical markers of bone turnover, such as collagen crosslinks, that provide a profile of bone turnover responses within weeks of therapy. Changes in collagen crosslinks are determined following commencement of antiresorptive therapy. These can be measured over a shorter time interval when compared to bone mass density. If bone resorption is not elevated, repeat testing is not medically necessary.

Indications

Generally speaking, collagen crosslink testing is useful mostly in “fast losers” of bone. The age when these bone markers can help direct therapy is often pre-Medicare. By the time a fast loser of bone reaches age 65, she will most likely have been stabilized by appropriate therapy or have lost so much bone mass that further testing is useless. Coverage for bone marker assays may be established, however, for younger Medicare beneficiaries and for those men and women who might become fast losers because of some other therapy such as glucocorticoids. Safeguards should be incorporated to prevent excessive use of tests in patients for whom they have no clinical relevance.

Collagen crosslinks testing is used to:

- Identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored.
- Predict response (as assessed by bone mass measurements) to FDA approved anti-resorptive therapy in postmenopausal women.
- Assess response to treatment of patients with osteoporosis, Paget’s disease of the bone, or risk for osteoporosis where treatment may include FDA approved anti-resorptive agents, anti-estrogens or selective estrogen receptor moderators.

Limitations

Because of significant specimen to specimen collagen crosslink physiologic variability (15-20%), current recommendations for appropriate utilization include: one or two base-line assays from specified urine collections on separate days; followed by a repeat assay about 3 months after starting anti-resorptive therapy; followed by a repeat assay in 12 months after the 3-month assay; and thereafter not more than annually, unless there is a change in therapy in which circumstance an additional test may be indicated 3 months after the initiation of new therapy.

Some collagen crosslink assays may not be appropriate for use in some disorders, according to FDA labeling restrictions.

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Collagen Crosslinks (Any Method)

CPT: 82523

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E06.3	Autoimmune thyroiditis
E07.9	Disorder of thyroid, unspecified
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E21.3	Hyperparathyroidism, unspecified
E55.9	**Vitamin D deficiency, unspecified**
E61.1	Iron deficiency
E61.2	Magnesium deficiency
M80.00XA	Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for fracture
M81.0	**Age-related osteoporosis without current pathological fracture**
M81.8	**Other osteoporosis without current pathological fracture**
M85.80	**Other specified disorders of bone density and structure, unspecified site**
M85.88	Other specified disorders of bone density and structure, other site
M85.89	Other specified disorders of bone density and structure, multiple sites
M85.9	Disorder of bone density and structure, unspecified
M89.9	Disorder of bone, unspecified
N95.1	Menopausal and female climacteric states
N95.9	Unspecified menopausal and perimenopausal disorder
Z79.899	**Other long term (current) drug therapy**

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

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Cytogenetic Studies

CPT: 88230, 88235, 88237, 88249, 88262, 88263, 88264, 88269, 88271, 88273, 88274, 88275, 88280, 88289, 88291

Medically Supportive ICD Codes are listed
on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
The term cytogenetic studies is used to describe the microscopic examination of the physical appearance of human chromosomes.

Indications and Limitations of Coverage Medicare covers these tests when they are reasonable and necessary for the diagnosis or treatment of the following conditions:

- Genetic disorders (e.g., mongolism) in a fetus; (See the Medicare Benefit Policy Chapter 15, "Covered Medical and Other Health Services," §20.1)
- Failure of sexual development;
- Chronic myelogenous leukemia;
- Acute leukemias lymphoid (FAB L1-L3), myeloid (FAB M0-M7), and unclassified; or
- Mylodysplasia

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Cytogenetic Studies

CPT: 88230, 88235, 88237, 88249, 88262, 88263, 88264, 88269, 88271, 88273, 88274, 88275, 88280, 88289, 88291

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C92.10	**Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission**
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.20	Refractory anemia with excess of blasts, unspecified
D46.4	Refractory anemia, unspecified
D46.9	**Myelodysplastic syndrome, unspecified**
D72.0	**Genetic anomalies of leukocytes**
E28.39	Other primary ovarian failure
E29.1	**Testicular hypofunction**
Q90.9	Down syndrome, unspecified
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z13.79	**Encounter for other screening for genetic and chromosomal anomalies**
Z31.448	Encounter for other genetic testing of male for procreative management

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Last updated: 05/01/23

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Digoxin Therapeutic Drug Assay

CPT: 80162

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
A digoxin therapeutic drug assay is useful for diagnosis and prevention of digoxin toxicity, and/or prevention for under dosage of digoxin.

Indications
Digoxin levels may be performed to monitor drug levels of individuals receiving digoxin therapy because the margin of safety between side effects and toxicity is narrow or because the blood level may not be high enough to achieve the desired clinical effect.
Clinical indications may include individuals on digoxin:

- With symptoms, signs or electrocardiogram (ECG) suggestive of digoxin toxicity
- Taking medications that influence absorption, bioavailability, distribution, and/or elimination of digoxin
- With impaired renal, hepatic, gastrointestinal, or thyroid function
- With pH and/or electrolyte abnormalities
- With unstable cardiovascular status, including myocarditis
- Requiring monitoring of patient compliance

Clinical indications may include individuals:

- Suspected of accidental or intended overdose
- Who have an acceptable cardiac diagnosis (as listed) and for whom an accurate history of use of digoxin is unobtainable

The value of obtaining regular serum digoxin levels is uncertain, but it may be reasonable to check levels once yearly after a steady state is achieved. In addition, it may be reasonable to check the level if:

- Heart failure status worsens
- Renal function deteriorates
- Additional medications are added that could affect the digoxin level
- Signs or symptoms of toxicity develop

Steady state will be reached in approximately 1 week in patients with normal renal function, although 2-3 weeks may be needed in patients with renal impairment. After changes in dosages or the addition of a medication that could affect the digoxin level, it is reasonable to check the digoxin level one week after the change or addition. Based on the clinical situation, in cases of digoxin toxicity, testing may need to be done more than once a week.

Digoxin is indicated for the treatment of patients with heart failure due to systolic dysfunction and for reduction of the ventricular response in patients with atrial fibrillation or flutter. Digoxin may also be indicated to treat other supraventricular arrhythmias, particularly with heart failure.

Limitations
This test is not appropriate for patients on digitoxin or treated with digoxin FAB (fragment antigen binding) antibody.

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Digoxin Therapeutic Drug Assay

CPT: 80162

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.**
Note—Bolded diagnoses below have the highest utilization

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

Code	Description
E03.9	**Hypothyroidism, unspecified**
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I42.0	Dilated cardiomyopathy
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I47.1	Supraventricular tachycardia
I48.0	**Paroxysmal atrial fibrillation**
I48.11	Longstanding persistent atrial fibrillation
I48.19	Paroxysmal atrial fibrillation
I48.20	**Chronic atrial fibrillation**
I48.21	Permanent atrial fibrillation
I48.91	**Unspecified atrial fibrillation**
I49.9	Cardiac arrhythmia, unspecified
I50.22	Chronic systolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.9	**Heart failure, unspecified**
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
R53.83	Other fatigue
Z79.899	**Other long term (current) drug therapy**

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Last updated: 050/1/23

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Fecal Occult Blood Test

CPT: 82272

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity

The Fecal Occult Blood Test (FOBT) detects the presence of trace amounts of blood in stool. The procedure is performed by testing one or several small samples of one, two or three different stool specimens.

This test may be performed with or without evidence of iron deficiency anemia, which may be related to gastrointestinal blood loss. The range of causes for blood loss include inflammatory causes, including acid-peptic disease, non-steroidal anti-inflammatory drug use, hiatal hernia, Crohn's disease, ulcerative colitis, gastroenteritis, and colon ulcers. It is also seen with infectious causes, including hookworm, strongyloides, ascariasis, tuberculosis, and enteroamebiasis. Vascular causes include angiodysplasia, hemangiomas, varices, blue rubber bleb nevus syndrome, and watermelon stomach. Tumors and neoplastic causes include lymphoma, leiomyosarcoma, lipomas, adenocarcinoma and primary and secondary metastases to the GI tract. Drugs such as nonsteroidal anti-inflammatory drugs also cause bleeding. There are extra gastrointestinal causes such as hemoptysis, epistaxis, and oropharyngeal bleeding. Artifactual causes include hematuria, and menstrual bleeding. In addition, there may be other causes such as coagulopathies, gastrostomy tubes or other appliances, factitial causes, and long distance running.

Three basic types of fecal hemoglobin assays exist, each directed at a different component of the hemoglobin molecule.

1. Immunoassays recognize antigenic sites on the globin portion and are least affected by diet or proximal gut bleeding, but the antigen may be destroyed by fecal flora.
2. The heme-porphyrin assay measures heme-derived porphyrin and is least influenced by enterocolic metabolism or fecal storage. This assay does not discriminate dietary from endogenous heme. The capacity to detect proximal gut bleeding reduces its specificity for colorectal cancer screening but makes it more useful for evaluating overall GI bleeding in case finding for iron deficiency anemia.
3. The guaiac-based test is the most widely used. It requires the peroxidase activity of an intact heme moiety to be reactive. Positivity rates fall with storage. Fecal hydration such as adding a drop of water increases the test reactivity but also increases false positivity.

Of these three tests, the guaiac-based test is the most sensitive for detecting lower bowel bleeding. Because of this sensitivity, it is advisable, when it is used for screening, to defer the guaiac-based test if other studies of the colon are performed prior to the test. Similarly, this test's sensitivity may result in a false positive if the patient has recently ingested meat. Both of these cautions are appropriate when the test is used for screening, but when appropriate indications are present, the test should be done despite its limitations.

Indications

1. To evaluate known or suspected alimentary tract conditions that might cause bleeding into the intestinal tract.
2. To evaluate unexpected anemia.
3. To evaluate abnormal signs, symptoms, or complaints that might be associated with loss of blood.
4. To evaluate patient complaints of black or red-tinged stools.

Limitations

1. The FOBT is reported once for the testing of up to three separate specimens (comprising either one or two tests per specimen).
2. In patients who are taking non-steroidal anti-inflammatory drugs and have a history of gastrointestinal bleeding but no other signs, symptoms, or complaints associated with gastrointestinal blood loss, testing for occult blood may generally be appropriate no more than once every three months.

When testing is done for the purpose of screening for colorectal cancer in the absence of signs, symptoms, conditions, or complaints associated with gastrointestinal blood loss, report the HCPCS code for colorectal cancer screening; fecal-occult blood test, 1-3 simultaneous determinations should be used.

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Fecal Occult Blood Test

CPT: 82272

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.**
Note—Bolded diagnoses below have the highest utilization

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
K92.2	**Gastrointestinal hemorrhage, unspecified**
R10.30	Lower abdominal pain, unspecified
R10.32	Left lower quadrant pain
R11.0	Nausea
R19.4	Change in bowel habit
R19.7	**Diarrhea, unspecified**
R63.4	Abnormal weight loss
Z79.01	Long term (current) use of anticoagulants
Z79.899	Other long term (current) drug therapy

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Last updated: 05/01/23

Gamma Glutamyl Transferase

GGT

CPT: 82977

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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.

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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.**
Note—Bolded diagnoses below have the highest utilization

There is a frequency associated with this test. 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**

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Last updated: 05/01/23

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Blood Glucose Testing

CPT: 82947, 82948, 82962

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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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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.**
Note—Bolded diagnoses below have the highest utilization

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

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**

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Hemoglobin A1c

Glycated Hemoglobin/Glycated Protein

CPT: 82985, 83036

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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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Hemoglobin A1c

Glycated Hemoglobin/Glycated Protein

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.**
Note—Bolded diagnoses below have the highest utilization

There is a frequency associated with this test. 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**

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Last updated: 05/01/23

Human Chorionic Gonadotropin

hCG

CPT: 84702

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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.

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Human Chorionic Gonadotropin

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.**
Note—Bolded diagnoses below have the highest utilization

There is a frequency associated with this test. 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
N89.8	Other specified noninflammatory disorders of vagina
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

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To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

Sonora Quest Laboratories™
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Hepatitis Panel/Acute Hepatitis Panel

CPT: 80074

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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.

Sonora Quest Laboratories™
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Hepatitis Panel/Acute Hepatitis Panel

CPT: 80074

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Note—Bolded diagnoses below have the highest utilization

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

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**

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Last updated: 05/01/23

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Histocompatibility Testing

CPT: 86812, 86816

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Histocompatibility testing involves the matching or typing of the human leucocyte antigen (HLA).

Indications and Limitations of Coverage
This testing is safe and effective when it is performed on patients:

A. In preparation for a kidney transplant;

B. In preparation for bone marrow transplantation;

C. In preparation for blood platelet transfusions (particularly where multiple infusions are involved); or

D. Who are suspected of having ankylosing spondylitis.

This testing is covered under Medicare when used for any of the indications listed in A, B, and C and if it is reasonable and necessary for the patient.

It is covered for ankylosing spondylitis in cases where other methods of diagnosis would not be appropriate or have yielded inconclusive results. Request documentation supporting the medical necessity of the test from the physician in all cases where ankylosing spondylitis is indicated as the reason for the test.

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Histocompatibility Testing

CPT: 86812, 86816

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

Code	Description
M08.1	Juvenile ankylosing spondylitis
M45.0	**Ankylosing spondylitis of multiple sites in spine**
M45.2	Ankylosing spondylitis of cervical region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	**Ankylosing spondylitis of thoracolumbar region**
M45.6	**Ankylosing spondylitis lumbar region**
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	**Ankylosing spondylitis sacral and sacrococcygeal region**
M45.9	**Ankylosing spondylitis of unspecified sites in spine**
N18.4	Chronic kidney disease, stage 4 (severe)
N18.6	End stage renal disease
Z52.008	Unspecified donor, other blood
Z52.098	Other blood donor, other blood
Z76.82	Awaiting organ transplant status

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Last updated: 05/01/23

Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

Sonora Quest Laboratories™
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CPT: 86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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).

Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

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

CMS National Coverage Policy (continued)

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.)

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.

Medicare National Coverage Determination Policy

Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

Sonora Quest Laboratories™
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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.**
Note—Bolded diagnoses below have the highest utilization

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

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)
N17.0	Acute kidney failure with tubular necrosis
N18.31	Chronic kidney disease, stage 3a
N25.81	Secondary hyperparathyroidism of renal
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

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Last updated: 05/01/23

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Human Immunodeficiency Virus (HIV)

Prognosis Including Monitoring

CPT: 87536, 87539

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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.

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Human Immunodeficiency Virus (HIV)

Prognosis Including Monitoring

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.**
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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**

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Lipid Testing

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

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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 <35 mg/dL.

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.

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Lipid Testing

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

CMS National Coverage Policy (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.

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Lipid Testing

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

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There is a frequency associated with this test. 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

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Partial Thromboplastin Time (PTT)

CPT: 85730

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity
Basic plasma coagulation function is readily assessed with a few simple laboratory tests: The Partial Thromboplastin Time (PTT), Prothrombin Time (PT), Thrombin Time (TT), or a quantitative fibrinogen determination. The PTT test is an in vitro laboratory test used to assess the intrinsic coagulation pathway and monitor heparin therapy.

Indications

1. The PTT is most commonly used to quantitate the effect of therapeutic unfractionated heparin and to regulate its dosing. Except during transitions between heparin and warfarin therapy, in general both the PTT and PT are not necessary together to assess the effect of anticoagulation therapy. PT and PTT must be justified separately.
2. A PTT may be used to assess patients with signs or symptoms of hemorrhage orthrombosis. For example:
   - Abnormal bleeding, hemorrhage or hematoma petechiae or other signs ofthrombocytopenia that could be due to Disseminated Intravascular Coagulation
   - Swollen extremity with or without prior trauma
3. A PTT may be useful in evaluating patients who have a history of a condition known tobe associated with the risk of hemorrhage or thrombosis that is related to the intrinsiccoagulation pathway. Such abnormalities may be genetic or acquired. For example:
   - Dysfibrinogenemia; Afibrinogenemia (complete)
   - Acute or chronic liver dysfunction or failure, including Wilson's disease
   - Hemophilia
   - Liver disease and failure;
   - Infectious processes
   - Bleeding disorders
   - Disseminated intravascular coagulation
   - Lupus erythematosus or other conditions associated with circulating inhibitors, e.g., factor VIII Inhibitor, lupus-like anticoagulant
   - Sepsis
   - Von Willebrand's disease
   - Arterial and venous thrombosis, including the evaluation of hypercoagulable states
   - Clinical conditions associated with nephrosis or renal failure
   - Other acquired and congenital coagulopathies as well as thrombotic states
4. A PTT may be used to assess the risk of thrombosis or hemorrhage in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. An example is as follows: evaluation prior to invasive procedures or operations of patients with personal or family history of bleeding or who are on heparin therapy.

Limitations

1. The PTT is not useful in monitoring the effects of warfarin on a patient's coagulation routinely. However, a PTT may be ordered on a patient being treated with warfarin as heparin therapy is being discontinued. A PTT may also be indicated when the PT is markedly prolonged due to warfarin toxicity.
2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of heparin.
3. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

Sonora Quest Laboratories™
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Partial Thromboplastin Time (PTT)

CPT: 85730

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Note—Bolded diagnoses below have the highest utilization

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

Code	Description
D47.2	Monoclonal gammopathy
D68.59	Other primary thrombophilia
D68.8	Other specified coagulation defects
D68.9	**Coagulation defect, unspecified**
D69.6	Thrombocytopenia, unspecified
E11.65	Type 2 diabetes mellitus with hyperglycemia
I48.0	Paroxysmal atrial fibrillation
I48.91	**Unspecified atrial fibrillation**
I50.9	Heart failure, unspecified
I82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
K74.60	Unspecified cirrhosis of liver
M32.9	Systemic lupus erythematosus, unspecified
M79.609	Pain in unspecified limb
N18.9	Chronic kidney disease, unspecified
R06.02	Shortness of breath
R10.9	Unspecified abdominal pain
R23.3	**Spontaneous ecchymoses**
R79.1	**Abnormal coagulation profile**
Z51.81	Encounter for therapeutic drug level monitoring
Z79.01	**Long term (current) use of anticoagulants**

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

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Prostate Specific Antigen

PSA

CPT: 84153

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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 as 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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Prostate Specific Antigen

CPT: 84153

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Note—Bolded diagnoses below have the highest utilization

There is a frequency associated with this test. 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 symptoms**
N40.1	**Benign prostatic hyperplasia with lower urinary tract symptoms**
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**
R39.12	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 following treatment for malignant neoplasm of prostate
Z12.5	Encounter for screening for malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

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Prothrombin Time (PT)

CPT: 85610

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: the Partial Thromboplastin Time (PTT), Prothrombin Time (PT), Thrombin Time (TT), or a quantitative fibrinogen determination. The PT test is one in-vitro laboratory test used to assess coagulation. While the PTT assesses the intrinsic limb of the coagulation system, the PT assesses the extrinsic or tissue factor dependent pathway. Both tests also evaluate the common coagulation pathway involving all the reactions that occur after the activation of factor X. Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of factors may be related to decreased production or increased consumption of coagulation factors. The PT/INR is most commonly used to measure the effect of warfarin and regulate its dosing. Warfarin blocks the effect of vitamin K on hepatic production of extrinsic pathway factors.

A PT is expressed in seconds and/or as an international normalized ratio (INR). The INR is the PT ratio that would result if the WHO reference thromboplastin was used in performing the test.

Current medical information does not clarify the role of laboratory PT testing in patients who are self monitoring. Therefore, the indications for testing apply regardless of whether or not the patient is also PT self-testing.

Indications

1. A PT may be used to assess patients taking warfarin. The PT is generally not useful in monitoring patients receiving heparin who are not taking warfarin.
2. A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example:
   - Swollen extremity with or without prior trauma
   - Unexplained bruising
   - Abnormal bleeding, hemorrhage or hematoma
   - Petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation

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Prothrombin Time (PT)

CPT: 85610

CMS National Coverage Policy (continued)

3. A PT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example:

   - Dysfibrinogenemia
   - Afibrinogenemia (complete)
   - Acute or chronic liver dysfunction or failure, including Wilson's disease and Hemochromatosis
   - Disseminated intravascular coagulation (DIC)
   - Congenital and acquired deficiencies of factors II, V, VII, X
   - Vitamin K deficiency
   - Lupus erythematosus
   - Hypercoagulable state
   - Paraproteinemia
   - Lymphoma
   - Amyloidosis
   - Acute and chronic leukemias
   - Plasma cell dyscrasia
   - HIV infection
   - Malignant neoplasms
   - Hemorrhagic fever
   - Salicylate poisoning
   - Obstructive jaundice
   - Intestinal fistula
   - Malabsorption syndrome
   - Colitis
   - Chronic diarrhea
   - Presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction
   - Patients with bleeding or clotting tendencies
   - Organ transplantation
   - Presence of circulating coagulation inhibitors

4. A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example:
   - Evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy.
   - Prior to the use of thrombolytic medication

Limitations

1. When an ESRD patient is tested for PT, testing more frequently than weekly requires documentation of medical necessity, e.g., other than chronic renal failure or renal failure unspecified.

2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of warfarin. In a patient on stable warfarin therapy, it is ordinarily not necessary to repeat testing more than every two to three weeks. When testing is performed to evaluate a patient with signs or symptoms of abnormal bleeding or thrombosis and the initial test result is normal, it is ordinarily not necessary to repeat testing unless there is a change in the patient's medical status.

3. Since the INR is a calculation, it will not be paid in addition to the PT when expressed in seconds, and is considered part of the conventional PT test.

4. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

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Prothrombin Time (PT)

CPT: 85610

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Note—Bolded diagnoses below have the highest utilization

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
D68.9	Coagulation defect, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I26.99	Other pulmonary embolism without acute cor pulmonale
I48.0	**Paroxysmal atrial fibrillation**
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.21	Permanent atrial fibrillation
I48.91	**Unspecified atrial fibrillation**
I73.9	Peripheral vascular disease, unspecified
I82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
K74.60	Unspecified cirrhosis of liver
R06.02	Shortness of breath
R79.1	**Abnormal coagulation profile**
Z51.81	Encounter for therapeutic drug level monitoring
Z79.01	**Long term (current) use of anticoagulants**
Z86.711	Personal history of pulmonary embolism
Z86.718	Personal history of other venous thrombosis and embolism
Z95.2	Presence of prosthetic heart valve

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Serum Iron Studies

CPT: 82728, 83540, 83550, 84466

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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

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

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Serum Iron Studies

CPT: 82728, 83540, 83550, 84466

CMS National Coverage Policy (continued)

b. The following presentations are examples that may support the use of these studies for evaluating iron overload:
   - Chronic Hepatitis
   - Diabetes
   - Hyperpigmentation of skin
   - Arthropathy
   - Cirrhosis
   - Hypogonadism
   - Hypopituitarism
   - Impaired porphyrin metabolism
   - Heart failure
   - Multiple transfusions
   - Sideroblastic anemia
   - Thalassemia major
   - Cardiomyopathy, cardiac dysrhythmias and conduction disturbances

2. Follow-up testing may be appropriate to monitor response to therapy, e.g., oral or parenteral iron, ascorbic acid, and erythropoietin.
3. Iron studies may be appropriate in patients after treatment for other nutritional deficiency anemias, such as folate and vitamin B12, because iron deficiency may not be revealed until such a nutritional deficiency is treated.
4. Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.
5. Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (e.g., nickel, cadmium, aluminum, 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.

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Serum Iron Studies

CPT: 82728, 83540, 83550, 84466

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Note—Bolded diagnoses below have the highest utilization

There is a frequency associated with this test. 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

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Thyroid Testing

CPT: 84436, 84439, 84443, 84479

Medically Supportive ICD Codes are listed
on subsequent page(s) of this document

CMS National Coverage Policy

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 thyroid-stimulating 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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Thyroid Testing

CPT: 84436, 84439, 84443, 84479

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Note—Bolded diagnoses below have the highest utilization

There is a frequency associated with this test. 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

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Urine Culture, Bacterial

CPT: 87086, 87088

Medically Supportive ICD Codes are listed on subsequent page(s) of this document

CMS National Coverage Policy

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 agar based 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 maybe 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 of 87086, 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.

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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
R82.90	**Unspecified abnormal findings in urine**
R82.998	Other abnormal findings in urine
Z79.899	Other long term (current) drug therapy

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Non-covered ICD-10-CM Codes for All Lab NCDs

This section lists codes that are never covered by Medicare for a diagnostic lab testing service. If a code from this section is given as the reason for the test, the test may be billed to the Medicare beneficiary without billing Medicare first because the service is not covered by statute, in most instances because it is performed for screening purposes and is not within an exception. The beneficiary, however, does have a right to have the claim submitted to Medicare, upon request.

The ICD-10-CM codes in the table below can be viewed on CMS' website as part of Downloads: Lab Code List, at
http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10.html

Code	Description
R99	Ill-defined and unknown cause of mortality
Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.01	Encounter for general adult medical examination with abnormal findings
Z00.110	Health examination for newborn under 8 days old
Z00.111	Health examination for newborn 8 to 28 days old
Z00.121	Encounter for routine child health examination with abnormal findings
Z00.129	Encounter for routine child health examination without abnormal findings
Z00.5	Encounter for examination of potential donor of organ and tissue
Z00.6	Encounter for examination for normal comparison and control in clinical research program
Z00.70	Encounter for examination for period of delayed growth in childhood without abnormal findings
Z00.71	Encounter for examination for period of delayed growth in childhood with abnormal findings
Z00.8	Encounter for other general examination
Z02.0	Encounter for examination for admission to educational institution
Z02.1	Encounter for pre-employment examination
Z02.2	Encounter for examination for admission to residential institution
Z02.3	Encounter for examination for recruitment to armed forces
Z02.4	Encounter for examination for driving license
Z02.5	Encounter for examination for participation in sport
Z02.6	Encounter for examination for insurance purposes
Z02.71	Encounter for disability determination
Z02.79	Encounter for issue of other medical certificate
Z02.81	Encounter for paternity testing
Z02.82	Encounter for adoption services

***January 2023 Changes**
ICD-10-CM Version – Red

Code	Description
Z02.83	Encounter for blood-alcohol and blood-drug test
Z02.89	Encounter for other administrative examinations
Z02.9	Encounter for administrative examinations, unspecified
Z04.6	Encounter for general psychiatric examination, requested by authority
Z04.81	Encounter for examination and observation of victim following forced sexual exploitation
Z04.82	Encounter for examination and observation of victim following forced labor exploitation
Z04.89	Encounter for examination and observation for other specified reasons
Z04.9	Encounter for examination and observation for unspecified reason
Z11.0	Encounter for screening for intestinal infectious diseases
Z11.1	Encounter for screening for respiratory tuberculosis
Z11.2	Encounter for screening for other bacterial diseases
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]
Z11.51	Encounter for screening for human papillomavirus (HPV)
Z11.52	Encounter for screening for COVID-19
Z11.59	Encounter for screening for other viral diseases
Z11.6	Encounter for screening for other protozoal diseases and helminthiases
Z11.7	Encounter for testing for latent tuberculosis infection
Z11.8	Encounter for screening for other infectious and parasitic diseases
Z11.9	Encounter for screening for infectious and parasitic diseases, unspecified
Z12.0	Encounter for screening for malignant neoplasm of stomach
Z12.10	Encounter for screening for malignant neoplasm of intestinal tract, unspecified
Z12.13	Encounter for screening for malignant neoplasm of small intestine
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs
Z12.6	Encounter for screening for malignant neoplasm of bladder
Z12.71	Encounter for screening for malignant neoplasm of testis
Z12.72	Encounter for screening for malignant neoplasm of vagina
Z12.73	Encounter for screening for malignant neoplasm of ovary
Z12.79	Encounter for screening for malignant neoplasm of other genitourinary organs
Z12.81	Encounter for screening for malignant neoplasm of oral cavity
Z12.82	Encounter for screening for malignant neoplasm of nervous system
Z12.83	Encounter for screening for malignant neoplasm of skin
Z12.89	Encounter for screening for malignant neoplasm of other sites
Z12.9	Encounter for screening for malignant neoplasm, site unspecified

Code	Description
Z13.0	Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z13.21	Encounter for screening for nutritional disorder
Z13.220	Encounter for screening for lipoid disorders
Z13.228	Encounter for screening for other metabolic disorders
Z13.29	Encounter for screening for other suspected endocrine disorder
Z13.30	Encounter for screening examination for mental health and behavioral disorders, unspecified
Z13.31	Encounter for screening for depression
Z13.32	Encounter for screening for maternal depression
Z13.39	Encounter for screening examination for other mental health and behavioral disorders
Z13.40	Encounter for screening for unspecified developmental delays
Z13.41	Encounter for autism screening
Z13.42	Encounter for screening for global developmental delays (milestones)
Z13.49	Encounter for screening for other developmental delays
Z13.5	Encounter for screening for eye and ear disorders
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z13.79	Encounter for other screening for genetic and chromosomal anomalies
Z13.810	Encounter for screening for upper gastrointestinal disorder
Z13.811	Encounter for screening for lower gastrointestinal disorder
Z13.818	Encounter for screening for other digestive system disorders
Z13.820	Encounter for screening for osteoporosis
Z13.828	Encounter for screening for other musculoskeletal disorder
Z13.83	Encounter for screening for respiratory disorder NEC
Z13.84	Encounter for screening for dental disorders
Z13.850	Encounter for screening for traumatic brain injury
Z13.858	Encounter for screening for other nervous system disorders
Z13.88	Encounter for screening for disorder due to exposure to contaminants
Z13.89	Encounter for screening for other disorder
Z13.9	Encounter for screening, unspecified
Z36.0	Encounter for antenatal screening for chromosomal anomalies
Z36.1	Encounter for antenatal screening for raised alphafetoprotein level
Z36.2	Encounter for other antenatal screening follow-up
Z36.3	Encounter for antenatal screening for malformations

Code	Description
Z36.4	Encounter for antenatal screening for fetal growth retardation
Z36.5	Encounter for antenatal screening for isoimmunization
Z36.81	Encounter for antenatal screening for hydrops fetalis
Z36.82	Encounter for antenatal screening for nuchal translucency
Z36.83	Encounter for fetal screening for congenital cardiac abnormalities
Z36.84	Encounter for antenatal screening for fetal lung maturity
Z36.85	Encounter for antenatal screening for Streptococcus B
Z36.86	Encounter for antenatal screening for cervical length
Z36.87	Encounter for antenatal screening for uncertain dates
Z36.88	Encounter for antenatal screening for fetal macrosomia
Z36.89	Encounter for other specified antenatal screening
Z36.8A	Encounter for antenatal screening for other genetic defects
Z36.9	Encounter for antenatal screening, unspecified
Z40.00	Encounter for prophylactic removal of unspecified organ
Z40.01	Encounter for prophylactic removal of breast
Z40.02	Encounter for prophylactic removal of ovary(s)
Z40.09	Encounter for prophylactic removal of other organ
Z40.8	Encounter for other prophylactic surgery
Z40.9	Encounter for prophylactic surgery, unspecified
Z41.1	Encounter for cosmetic surgery
Z41.2	Encounter for routine and ritual male circumcision
Z41.3	Encounter for ear piercing
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z41.9	Encounter for procedure for purposes other than remedying health state, unspecified
Z46.1	Encounter for fitting and adjustment of hearing aid
Z56.0	Unemployment, unspecified
Z56.2	Threat of job loss
Z56.3	Stressful work schedule
Z56.4	Discord with boss and workmates
Z56.5	Uncongenial work environment
Z56.6	Other physical and mental strain related to work
Z56.81	Sexual harassment on the job
Z56.82	Military deployment status
Z56.89	Other problems related to employment

Code	Description
Z56.9	Unspecified problems related to employment
Z57.0	Occupational exposure to noise
Z57.1	Occupational exposure to radiation
Z57.2	Occupational exposure to dust
Z57.31	Occupational exposure to environmental tobacco smoke
Z57.39	Occupational exposure to other air contaminants
Z57.4	Occupational exposure to toxic agents in agriculture
Z57.5	Occupational exposure to toxic agents in other industries
Z57.6	Occupational exposure to extreme temperature
Z57.7	Occupational exposure to vibration
Z57.8	Occupational exposure to other risk factors
Z57.9	Occupational exposure to unspecified risk factor
Z58.6	Inadequate drinking-water supply
Z59.00	Homelessness unspecified
Z59.01	Sheltered homelessness
Z59.02	Unsheltered homelessness
Z59.1	Inadequate housing
Z59.2	Discord with neighbors, lodgers and landlord
Z59.3	Problems related to living in residential institution
Z59.41	Food insecurity
Z59.48	Other specified lack of adequate food
Z59.5	Extreme poverty
Z59.6	Low income
Z59.7	Insufficient social insurance and welfare support
Z59.811	Housing instability, housed, with risk of homelessness
Z59.812	Housing instability, housed, homelessness in past 12 months
Z59.819	Housing instability, housed unspecified
***Z59.82**	***Transportation insecurity**
***Z59.86**	***Financial insecurity**
***Z59.87**	***Material hardship**
Z59.89	Other problems related to housing and economic circumstances
Z59.9	Problem related to housing and economic circumstances, unspecified
Z60.2	Problems related to living alone
Z62.21	Child in welfare custody

***January 2023 Changes**
ICD-10-CM Version – Red

Code	Description
Z71.0	Person encountering health services to consult on behalf of another person
Z74.1	Need for assistance with personal care
Z74.2	Need for assistance at home and no other household member able to render care
Z74.3	Need for continuous supervision
Z74.8	Other problems related to care provider dependency
Z74.9	Problem related to care provider dependency, unspecified
Z75.5	Holiday relief care
Z76.0	Encounter for issue of repeat prescription
Z76.1	Encounter for health supervision and care of foundling
Z76.2	Encounter for health supervision and care of other healthy infant and child
Z76.3	Healthy person accompanying sick person
Z76.4	Other boarder to healthcare facility
Z76.81	Expectant parent(s) prebirth pediatrician visit
Z80.1	Family history of malignant neoplasm of trachea, bronchus and lung
Z80.2	Family history of malignant neoplasm of other respiratory and intrathoracic organs
Z80.49	Family history of malignant neoplasm of other genital organs
Z80.51	Family history of malignant neoplasm of kidney
Z80.52	Family history of malignant neoplasm of bladder
Z80.59	Family history of malignant neoplasm of other urinary tract organ
Z80.6	Family history of leukemia
Z80.7	Family history of other malignant neoplasms of lymphoid, hematopoietic and related tissues
Z80.8	Family history of malignant neoplasm of other organs or systems
Z80.9	Family history of malignant neoplasm, unspecified
Z81.0	Family history of intellectual disabilities
Z81.1	Family history of alcohol abuse and dependence
Z81.2	Family history of tobacco abuse and dependence
Z81.3	Family history of other psychoactive substance abuse and dependence
Z81.4	Family history of other substance abuse and dependence
Z81.8	Family history of other mental and behavioral disorders
Z82.0	Family history of epilepsy and other diseases of the nervous system
Z82.1	Family history of blindness and visual loss
Z82.2	Family history of deafness and hearing loss
Z82.3	Family history of stroke

Code	Description
Z82.41	Family history of sudden cardiac death
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system
Z82.5	Family history of asthma and other chronic lower respiratory diseases
Z82.61	Family history of arthritis
Z82.62	Family history of osteoporosis
Z82.69	Family history of other diseases of the musculoskeletal system and connective tissue
Z82.71	Family history of polycystic kidney
Z82.79	Family history of other congenital malformations, deformations and chromosomal abnormalities
Z82.8	Family history of other disabilities and chronic diseases leading to disablement, not elsewhere classified
Z83.0	Family history of human immunodeficiency virus [HIV] disease
Z83.1	Family history of other infectious and parasitic diseases
Z83.2	Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z83.3	Family history of diabetes mellitus
Z83.41	Family history of multiple endocrine neoplasia [MEN] syndrome
Z83.49	Family history of other endocrine, nutritional and metabolic diseases
Z83.511	Family history of glaucoma
Z83.518	Family history of other specified eye disorder
Z83.52	Family history of ear disorders
Z83.6	Family history of other diseases of the respiratory system
Z83.71	Family history of colonic polyps
Z83.79	Family history of other diseases of the digestive system
Z84.0	Family history of diseases of the skin and subcutaneous tissue
Z84.1	Family history of disorders of kidney and ureter
Z84.2	Family history of other diseases of the genitourinary system
Z84.3	Family history of consanguinity
Z84.81	Family history of carrier of genetic disease
Z84.89	Family history of other specified conditions

Reasons for Denial for All Lab NCDs

NOTE: This section includes CMS's interpretation of its longstanding policies pertaining to nationally covered laboratory services, and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute.
- Tests for administrative purposes, including exams required by insurance companies, business establishments, government agencies, or other third parties, are not covered.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered by statute.
- Failure to provide documentation of the medical necessity of tests might result in denial of claims. The documentation may include notes documenting relevant signs, symptoms, or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office might result in denial.
- A claim for a test for which there is a national coverage policy will be denied as not reasonable and necessary if the claim is submitted without an ICD-10-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national coverage policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the clinical laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate will result in denial of claims.

Coding Guidelines for All Lab NCDs

1. On and after the implementation date for ICD-10-CM coding of Medicare billing claims, a claim for a clinical diagnostic laboratory service must include a valid ICD-10-CM diagnosis code. When a diagnosis has not been established by the physician, codes that describe symptoms and signs, as opposed to diagnoses, should be provided (see also bullet #5 below).

   Please note that ICD-10-CM codes for diagnoses are not required (and will not be effective) for Medicare billing transactions prior to October 1, 2015. Please use ICD-9-CM codes for diagnoses prior to that date.

   Please check the CMS website www.cms.gov/ICD10 for more information on the implementation of ICD-10-CM codes.

2. Medicare distinguishes 'screening' from 'diagnostic uses' of tests. 'Screening' is testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the beneficiary has not been exposed to a disease.

   In contrast, 'diagnostic' testing is testing to rule out or to confirm a suspected diagnosis because of a sign and/or symptom in the beneficiary. In these cases, the sign or symptom should be used to explain the reason for the test.

   Some laboratory tests are covered by the Medicare program for screening purposes (for example, NCD # 210.1, Prostate Cancer Screening Tests). However, this manual focuses only on coding policies for diagnostic uses of laboratory services (for example, the test for prostate specific antigen (PSA)).

3. When the reason for performing a test is because the beneficiary has had contact with, or exposure to, a communicable disease, the appropriate code from category Z20, 'Contact with or exposure to communicable diseases', should be assigned. However, on review, the test might still be considered screening and not covered by Medicare.

4. All digits required by ICD-10-CM coding conventions must be used. A code is invalid if it has not been coded with all digits/characters required for that code.

5. The beneficiary's condition(s) and/or diseases should be coded in ICD-10-CM to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, or other reasons for the visit. When a non-specific ICD-10-CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

Additional Coding Guideline(s)

Note: For any additional guideline(s) about ICD-10-CM coding for a specific diagnostic test service, please see the section “Limitations” in each NCD following the code list table.

Medicare Local Coverage Determination Policy

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

Aspirin Resistance (11-Dehydrothromboxane B2)

CPT: 84431

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

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

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Aspirin Resistance (11-Dehydrothromboxane B2). The Aspirin Resistance (11-Dehydrothromboxane B2) is not considered reasonable and necessary and is not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

Visit **SonoraQuest.Com/Medicare** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ►

Last updated: 05/01/23

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

B-type Natriuretic Peptide (BNP) Testing

CPT: 83880

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

B-type natriuretic peptide (BNP) is a cardiac neurohormone produced mainly in the left ventricle. It is secreted in response to ventricular volume expansion and pressure overload, conditions often present in congestive heart failure (CHF). Used in conjunction with other clinical information, measurement of BNP levels (either total or N-terminal) is useful in rapidly establishing or excluding the diagnosis or worsening of CHF in patients with acute exacerbation of dyspnea. Also, BNP levels determined in the first few days after an acute coronary syndrome or event (ACS) may be useful in the prediction of longer-term cardiovascular risk but this risk assessment does not change the management of ACS and is non-covered by regulation. BNP measurements may be considered reasonable and necessary when used in combination with other medical data such as medical history, physical examination, laboratory studies, and chest x-ray.to diagnose or to differentiate heart failure from other potential clinical conditions if the patient's signs and/or symptoms are consistent with both heart failure and one or more other conditions, e.g., acute dyspnea in a patient with known or suspected pulmonary disease.to diagnose or differentiate worsening heart failure if use of the test replaces other diagnostic tests, such as chest film; and/or to confirm the diagnosis when other diagnostic tests are equivocal.

Indications

BNP measurements must be assessed in conjunction with standard diagnostic tests, medical history and clinical findings. The efficacy of BNP measurement as a stand-alone test has not been established yet. BNP measurements for monitoring and management of CHF are non-covered. Treatment guided by BNP has not been shown to be superior to symptom-guided treatment in either clinical or quality-of-life outcomes. The efficacy but not the utility of BNP as a risk stratification tool (to assess risk of death, myocardial infarction or congestive heart failure) among patients with acute coronary syndrome (myocardial infarction with or without T-wave elevation and unstable angina) has been established. However, the assessment of BNP level has not been shown to alter patient management. The BNP is not sufficiently sensitive to either preclude or necessitate any other evaluation or treatment in this group of patients. Screening examinations are statutorily non-covered.

Medicare Local Coverage Determination Policy

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

B-type Natriuretic Peptide (BNP) Testing

CPT: 83880

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

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

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.**
Note—Bolded diagnoses below have the highest utilization

Code	Description
I11.0	Hypertensive heart disease with heart failure
I42.0	Dilated cardiomyopathy
I42.8	Other cardiomyopathies
I50.1	Left ventricular failure
I50.21	Acute systolic (congestive) heart failure
I50.22	**Chronic systolic (congestive) heart failure**
I50.23	Acute on chronic systolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	**Chronic diastolic (congestive) heart failure**
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	**Heart failure, unspecified**
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
R06.00	Dyspnea, unspecified
R06.01	Orthopnea
R06.02	**Shortness of breath**
R06.09	**Other forms of dyspnea**
R06.2	Wheezing

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

Last updated: 05/01/23

Medicare Local Coverage Determination Policy

Controlled Substance Monitoring and Drugs of Abuse Testing

CPT: 80305, 80306, 80307, G0480, G0481, G0482, G0483, G0659

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

Purpose

Urine drug testing (UDT) provides objective information to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions.

This policy details:
• The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders.
• Designates documentation, by the clinician caring for the beneficiary in the beneficiary's medical record, of medical necessity for, and testing ordered on an individual patient basis;
• Provides an overview of presumptive urine drug testing (UDT) and definitive UDT testing by various methodologies.

This policy addresses UDT for Medicare patients only.

Definitions

As used in this document, the following terminology relates to the basic forms of UDT:

1. **Presumptive/Qualitative Drug Testing (hereafter called "presumptive" UDT)** - Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample; results expressed as negative or positive or as a numerical result; includes competitive immunoassays (IA) and thin layer chromatography.
2. **Definitive/Quantitative/Confirmation (hereafter called "definitive" UDT)** - Used when medically necessary to identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL; definitive methods include, but are not limited to GC-MS and LC-MS/MS testing methods.
3. **Specimen Validity Testing** - Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted, may include, but is not limited to pH, specific gravity, oxidants and creatinine.
4. **Immunoassay (IA)** - Ordered by clinicians primarily to identify the presence or absence of drug classes and some specific drugs; biochemical tests that measure the presence above a cutoff level of a substance (drug) with the use of an antibody; read by photometric technology.
5. **Point of Care Testing (POCT)** - Used when medically necessary by clinicians caring for the beneficiary for immediate test results for the immediate management of the beneficiary; available when the beneficiary and physician are in the same location; IA test method that primarily identifies drug classes and a few specific drugs; platform consists of cups, dipsticks, cassettes, or strips; read by the human eye, or read by instrument assisted direct optical observation.
6. **Standing Orders** - Test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles; clinician can alter the standing order.

Note: A "profile" differs from a "panel" in that a profile responds to the clinical risks of a particular patient, whereas a panel may encourage unnecessary or excessive testing when no clinical cause exists for many of the tests.

Controlled Substance Monitoring and Drugs of Abuse Testing

CPT: 80305, 80306, 80307, G0480, G0481, G0482, G0483, G0659

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming (continued)

7. Blanket Orders - Test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician's practice without individualized decision making at every visit.
8. Reflex Testing - Laboratory testing that is performed "reflexively" after initial test results to identify further diagnostic information essential to patient care. This testing is not based on a specific physician's order. Testing performed as a step necessary to complete a physician's order is not considered reflex testing.

Drug Test Methods

The Clinical Laboratory Improvement Amendments (CLIA) regulates laboratory testing and requires clinical labs to be certified by their State as well as the CMS before they can accept human samples for diagnostic testing. Multiple types of CLIA certificates may be obtained based on the complexity of testing a lab conducts. CLIA levels of complexity (CLIA-waived, moderate complexity and high complexity) are addressed only as they relate to the HCPCS code description and the coding/billing guidance to be attached to this document.

A. Presumptive Testing Methods:

1. Presumptive UDT:
Presumptive UDT consist of various platforms including cards, dipsticks, cassettes and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test. A presumptive IA test detects the presence of the amount of drug/substance present in urine above a predetermined "cut-off" value and may be read by direct optical observation or by instrument assisted direct optical observation.
A positive test result is reported when the concentration of drug is above the cutoff; a negative is reported when the concentration of drug is below the cut-off. Positive test results are presumptive but not necessarily definitive due to sensitivity and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen. The accuracy of the results of a presumptive UDT will depend on the testing environment, type of test, and training of the individual conducting the test.
This type of test should only be used when results are needed immediately.

2. Presumptive UDT by Instrumented Chemistry Analyzers:
Chemistry analyzers with IA UDT technology can be used in an office or clinical laboratory setting. This test may be used when less immediate test results are required. At no time is IA technology by chemistry analyzer analysis considered confirmatory (definitive) testing.
A presumptive positive IA test detects the presence of a drug/substance in urine at or above the "cut-off" value. If the concentration of the drug is below the cut-off, the result will be negative. Presumptive positive tests are not always true positives due to sensitivity, specificity, and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.
FDA approved/cleared test platforms are available in the marketplace as well as, laboratory developed tests (LDTs) such as modified FDA approved/ cleared and non-FDA approved/cleared platforms and/or reagents. LDTs generally have been modified to test at a lower cutoff in order to detect substances that would have been missed at a higher cutoff. For example, a FDA labeled cutoff may be 300 ng/mL and the LDT cutoff for the same drug may be a 100 ng/mL.
Presumptive UDT can be carried out at any validated cut-off concentration. Lowering of the cut-off concentration provides more stringent cutoffs for illicit drugs. LDTs may include non-FDA cleared tests not available in CLIA-waived or moderate complexity tests (e.g. tramadol, tapentadol, carisoprodol, fentanyl, zolpidem). Lowering the cutoff increases the possibility of detecting a drug when the test has been modified from the recipe of the manufacturer.

Controlled Substance Monitoring and Drugs of Abuse Testing

CPT: 80305, 80306, 80307, G0480, G0481, G0482, G0483, G0659

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming (continued)

3. Limitations of Presumptive UDT:

Presumptive UDT testing is limited due to:
◦ Primarily screens for drug classes rather than specific drugs, and therefore, the practitioner may not be able to determine if a different drug within the same class is causing the positive result;
◦ Produces erroneous results due to cross-reactivity with other compounds or does not detect all drugs within a drug class;
◦ Given that not all prescription medications or synthetic/analog drugs are detectable and/or have assays available, it is unclear as to whether other drugs are present when some tests are reported as positive;
◦ Cut-off may be too high to detect presence of a drug
This information could cause a practitioner to make an erroneous assumption or clinical decision.
An IA involves an antibody that reacts best with the stimulating drug, and reacts to a lesser extent (cross-reactive) or not at all with other drugs in the drug class. While presumptive tests vary in their ability to detect illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4-methylenedioxy-N-methylamphetamine (MDMA; "ecstasy"), and phencyclidine (PCP), they may not be optimal tests for many prescription drugs, such as: opiates, barbiturates, benzodiazepines and opioids.
For example, opiate reagents are formulated from morphine. Consequently, the cross-reactivity for other opioids and opiates varies based on the manufacturer and lot number. The semisynthetic opioids, hydromorphone and hydrocodone, may contribute to a positive presumptive result, while the semisynthetic opioids, oxycodone and oxymorphone, will not typically be detected even at 300 ng/mL cutoff. Synthetic opioids, such as fentanyl, meperidine and methadone, will not be detected by current opiate IA testing. Consequently, a positive opiate result by IA normally necessitates more specific identification of the substance(s) that account for the positive result, and a negative result does not rule out the presence of opiates or opioids.
Presumptive UDT reagents for benzodiazepine are typically formulated for oxazepam, a metabolite of diazepam (Valium®) and chlordiazepoxide (Librium®), the main benzodiazepines prescribed twenty years ago. However, many of the more than 10 benzodiazepines that are currently available do not cross-react with IA benzodiazepine reagents. In particular, clonazepam and lorazepam give false negative results with presumptive IA tests and may necessitate more specific identification to account for the negative result. Similarly, a positive screening test result may require definitive UDT to identify the specific drug(s).
Synthetic/analog or "designer" drugs manufactured to elude law enforcement require definitive testing for detection. Most commercially available IA reagents fail to detect designer drugs, such as psychedelic phenethylamines even at very high concentrations.
In summary, presumptive IA UDT is often unable to identify specific drugs within many drug classes, particularly within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and opiate/opioid drug classes. Drugs such as buprenorphine, amphetamines, benzodiazepines, and cocaine/heroin yield false negative IA results due to low cross-reactivity or non-reactivity and drugs such as fentanyl, carisoprodol, tramadol, tapentadol and synthetic designer drugs cannot be detected by presumptive IA. Therefore, it may be medically necessary for clinicians to utilize definitive UDT when the presumptive tests for these drugs are negative.

B. Definitive UDT:

Gas Chromatography coupled with Mass Spectrometry (GC-MS) and Liquid Chromatography coupled with Mass Spectrometry (LC-MS/MS) are complex technologies that use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry. These methodologies require the competency of on-site highly trained experts in this technology and interpretation of results. While these tests require different sample preparation and analytical runs, they identify specific drugs, metabolites, and most illicit substances and report the results as absent or present typically in concentrations of ng/mL.
Quantification should not be used to determine adherence with a specific dosage or time of dose of a pain medication or illicit drug for clinical purposes. Rather, the use of quantitative drug data may be important for many reasons such as in a differential patient assessment. For example, when several opioids are present in the urine of a patient prescribed a single opioid, quantification may help the clinician decide whether the presence of the other opioids is consistent with metabolism of the prescribed opioid, opioid contamination during manufacturing, or if more than one drug within a class is being used.

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Quantification may also provide information in the setting of illicit drug use. Serial creatinine-corrected quantitative values may assist in the differential assessment of ongoing drug use or cessation of drug use with continued drug excretion.

1. GC-MS

GC-MS can only be performed on molecules that are volatile. If the test drug is not volatile in its own right, it must be modified or derivatized to a volatile form. To derivatize, the test drug must be extracted from the urine, eluted from the extraction device, concentrated, and then reacted with a chemical reagent to make a volatile product. Each drug class may require a different derivatizing agent. For patients on multiple classes of medications, laboratories using GC procedures must make different volatile derivatives in order to perform comprehensive testing. Since a GC column may not be able to separate more than one class of compounds, multiple chromatographic runs on different column types may be required to monitor multiple drug classes. Newer GC-MS instruments often use tandem systems. GC-MS methodology allows for the testing of multiple substances but differs in ease of run.

2. LC-MS/MS

LC-MS/MS is roughly 100 times more sensitive and selective, involves less human steps, provides quicker turn-around time, uses less specimen volume and can test for a larger number of substances simultaneously when compared to GC-MS. After sample preparation, it is injected into the LC-MS/MS. The sample has to undergo hydrolysis to break the glucuronide bond that frees the drug and drug metabolites. Hydrolysis is followed by multiple additional steps including protein precipitation, centrifugation and purification. Deuterium-labeled isotopic internal standards are added to quantify the drugs and drug metabolites.

The sample is injected when the mobile phase is flowing through the chromatographic column. Each drug and drug metabolite interacts with the mobile phase and stationary phase differently and moves at different speeds depending on their chemical properties. In other words, each analyte elutes at different times. Specific drugs and metabolites are identified by their retention time and quantified against isotopic internal standards for each drug and metabolite. Each drug peak has to be compared to drug standards (calibrators) in order to ensure identification.

CLIA-Certified Laboratories

CLIA specifies quality standards for proficiency testing, facility administration, general laboratory systems, pre-analytic, analytic and post-analytic systems, onsite supervision requirements, personnel qualifications and responsibilities, quality control, and quality assessment. High complexity laboratories must ensure that testing is carried out by onsite qualified, trained personnel using validated reliable methods compliant with regulatory procedures (42 CFR Part 493). Both GC-MS and LC-MS/MS require a quality program to monitor the quality and audit the competency of the staff. LC-MS/MS instrument maintenance must be performed daily as well as the validation of instrument performance prior to patient specimens. Final review and approval of GC-MS and LC-MS/MS results must be performed by a qualified clinical laboratory scientist as defined in 42 CFR Part 493.1489 (Testing Personnel Qualifications). A GC-MS or LC-MS/MS laboratory must have a qualified laboratory director, qualified physician, or qualified clinical laboratory scientist, as provided in 42 CFR 493.1443 (Laboratory Director Qualifications).

Assay validation must be consistent with FDA guidelines. Laboratories that use “application notes” from vendors to establish drug validation do not comply with federal standards, and put patients and providers at risk by potentially reporting inaccurate test results. Only FDA 510K cleared test methods may be distributed by vendors.

Purpose of UDT:

Presumptive UDT may be ordered by the clinician caring for a beneficiary when it is necessary to rapidly obtain and/or integrate results into clinical assessment and treatment decisions.

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Definitive UDT is reasonable and necessary for the following circumstances:
• Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT; • Definitively identify specific drugs in a large family of drugs; • Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs; • Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan); • Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
• Rule out an error as the cause of a presumptive UDT result; •Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and • Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions
Definitive UDT may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions. The clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record.

Drug Testing Panels

A. Presumptive UDT Panels
Presumptive UDT testing typically involves testing for multiple analytes based on the beneficiary's clinical history and risk assessment, and must be documented in the medical record.

B. Definitive UDT Panels
Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record.

Specimen Type
Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness. UDT cannot detect the dosage of drug ingested/used, the time of use, or the means of delivery (intravenous vs. oral vs. inhaled). Detection time of a substance in urine is typically 1-3 days depending on the drug, rate of metabolism, and rate of excretion. Lipid-soluble drugs, such as marijuana, may remain in body fat and be detected upwards of a week or more.

Parent Drugs and Metabolite

The following chart illustrates parent drugs and their metabolites but may not be totally inclusive of all drugs and metabolites.
Note: Ethanol is a significant drug of abuse. Alcohol metabolites of ethyl glucuronide and ethyl sulfate are typically detected by definitive (GC-MS or LC-MS/MS) UDT, and should only be performed based on clinician's documentation of medical necessity.

Parent Drugs and Metabolite Chart

Drug Class/Drugs	Common Names	General Monitoring Possibilities Subject to Medical Necessity
Alcohol/Alcohol Metabolites Ethyl Glucuronide Ethyl Sulfate	Alcohol	Ethyl Glucuronide Ethyl Sulfate

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Barbiturates		
Amobarbital	Amytal Sodium®	Amobarbital
Butabarbital	Butisol Sodium®, Butibel	Butabarbital
Butalbital	Fiorinal®, Fioricet®	Butalbital
Pentobarbital	Nembutal®	Pentobarbital
Phenobarbital	Belladona, Luminal®	Phenobarbital
Secobarbital	Seconal®	Secobarbital
Benzodiazepines		
Alprazolam	Xanax®, Niravam®, Xanor	Alprazolam, Alpha-hydroxyalprazolam
Chlordiazepoxide	Librax®, Libritabs	Nordiazepam, Oxazepam
Clonazepam	Klonopin®	7-Aminoclonazepam
Clorazepate	Tranxene®	Nordiazepam, Oxazepam
Diazepam	Valium®	Diazepam, Nordiazepam, Temazepam, Oxazepam
Lorazepam	Ativan®, Lorax	Lorazepam
Oxazepam	Adumbran, Alepam, Murelax, Serax, Serepax	Oxazepam
Temazepam	Restoril®, Tenox, Euhypnos	Temazepam, Oxazepam
Illicit Drugs		
Cocaine	Blow, Coke, Crack, Snow	Benzoylecgonine
Heroin	Black Tar, Brown Sugar, Dragon, H, Horse, Tar	6-MAM, Morphine
Marijuana	Marinol, Pot, Reefer, Weed	THC-COOH
MDA	Ecstasy, X	Methylenedioxyamphetamine
MDMA	Ecstasy, X	Methylenedioxymethamphetamine, Methylenedioxyamphetamine
Methamphetamine	Crank, Crystal Meth, Didrex®, Eldepryl®, Ice	Methamphetamine, Amphetamine
Phencylclidine (PCP)	Angel Dust	Phencyclidine
Synthetic Cannabinoids	"K2"/"Spice"	
Cathinones	"Bath Salts" Kratom	
General Anesthetic	Ketamine	
Ketamine	Norketamine	

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General Anesthetic Ketamine	Ketamine Norketamine	
Muscle Relaxants Carisoprodol Meprobamate	Soma®, Soprodoal Equinal, Miltown®, Meprospan	Carisoprodol, Meprobamate Meprobamate
Neuroleptics Gabapentin Pregabalin	Neurontin® Lyrica®	
Opiates Codeine Hydrocodone Hydromorphone Morphine Oxycodone Oxymorphone	Tylenol® 3 Hycodan®, Lorcet®, Lortab®, Norco® Vicodin®, Vicoprofen® Dilaudid®, Exalgo®, Hymorphan Avinza®, Kadian®, MS Contin®, MSER, MSIR, Roxanol OxyContin®, OxyIR®, Percocet®, Percodan®, Roxicodone®, Tylox® Numorphan®, Opana® ER, Opana®	Codeine, Morphine Hydrocodone, Hydromorphone, Norhydrocodone Hydromorphone Morphine Oxycodone, Oxymorphone, Noroxycodone Oxymorphone
Opioids Buprenorphine Fentanyl Meperidine Methadone Propoxyphene Tapentadol Tramadol	Buprenex®, Butrans®, Suboxone®, Subutex® Actiq®, Duragesic®, Fentora®, Onsolis® Sublimaze Demerol®, Mepergan® Dolophine®, Methadose® Darvocet®, Darvon® Nucynta® Ryzolt®, Ultracet®, Ultram®, Tramadol	Buprenorphine, Norbuprenorphine Fentanyl, Norfentanyl Meperidine, Normeperidine Methadone, EDDP Propoxyphene, Norpropoxyphene Tapentadol, N-Desmethyltapentadol Tramadol, O-Desmethyltramadol
Stimulants Amphetamine Methylphenidate Nicotine	Adderall®, Benzedrine, Dexedrine®, Vyvanse® Concerta®, Focalin®, Methylin®, Ritalin® Nicoderm®, Nicorette®	Amphetamine Methylphenidate, Ritalinic Acid Cotinine

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Covered Indications for UDT

Group A – Symptomatic patients, Multiple drug ingestion and/or Patients with unreliable history

A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting rapid, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon rapid test findings, responses to medical interventions, and treatment plan.

A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an urgent care setting with any one of the following: • Coma • Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome • Severe or unexplained cardiovascular instability (cardiotoxicity) • Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome • Seizures with an undetermined history • To provide antagonist to specific drug

The presumptive findings, definitive drug tests ordered and reasons for the testing must be documented in the patient's medical record.

Group B - Diagnosis and treatment for substance abuse or dependence

A patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions. A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected. The risk of drug-drug interactions is inherent to the patient, and may be compounded by prescribed medications.

UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis. For patients with no known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT.

For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria: • Patient history, physical examination, and previous laboratory findings • Stage of treatment or recovery; • Suspected abused substance; • Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care.

1. Frequency of Presumptive UDT for SUD:

The testing frequency must meet medical necessity and be documented in the clinician's medical record.

a. For patients with 0 to 30 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 presumptive UDT per week. More than 3 presumptive panels in one week is not reasonable and necessary and is not covered by Medicare.

b. For patients with 31 to 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT per week. More than 3 presumptive UDT in one week is not reasonable and necessary and is not be covered by Medicare.

c. For patients with > 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT in one month. More than 3 physician-directed UDT in one month is not reasonable and necessary and is not covered by Medicare.

2. Frequency of Definitive UDT for SUD:

Depending on the patient's specific substance use history, definitive UDT to accurately determine the specific drugs in the patient's system may be necessary. Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment. The frequency and the rational for definitive UDT must be documented in the patient's medical record.

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a. For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week. More than 1 physician-directed testing profile in one week is not reasonable and necessary and is not covered by Medicare.
b. For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month. More than 3 UDT in one month is not reasonable and necessary and is not covered by Medicare.
c. For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

Group C - Treatment for patients on chronic opioid therapy (COT).
A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general.

1. COT UDT Testing Objectives:
a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
b. Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
c. Identifies substances that contribute to adverse events or drug-drug interactions;
d. Provides objectivity to the treatment plan;
e. Reinforces therapeutic compliance with the patient;
f. Provides additional documentation demonstrating compliance with patient evaluation and monitoring;
g. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

2. Medical Necessity Guidance:
Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements: ◦ Patient history, physical examination and previous laboratory findings; ◦ Current treatment plan; ◦ Prescribed medication(s) ◦ Risk assessment plan
National pain organizations, physician societies, and the Federation of State Medical Boards recommend a practical approach to definitive UDT for COT. Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:
a. COT Baseline Testing:
Initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.
b. COT Monitoring Testing:
Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern. The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications.
The clinician should perform random UDT at random intervals, in order to properly monitor a patient. UDT testing does not have to be associated with an office visit.

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Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

3. UDT Frequency Based on Validated Risk Assessment and Stratification*:
Testing must be based on clinician's documented medical necessity and reviewed by the clinician in the management of prescribing/renewing a controlled substance for every risk group outlined below.

Risk Group	Baseline	Frequency of Testing
Low Risk	Prior to Initiation of COT	Random testing 1-2 times every 12 months for prescribed medications, non-prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage.
Moderate Risk	Prior to Initiation of COT	Random testing 1-2 times every 6 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Random testing performed 1-3 times every 3 months for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

*Note: Any additional definitive UDT beyond recommendations above must be justified by the clinician in the medical record in situations in which changes in prescribed medications may be needed, such as: ◦ Patient response to prescribed medication suddenly changes ◦ Patient side effect profile changes ◦ To assess for possible drug-drug interactions ◦ Sudden change in patient's medical condition ◦ Patient admits to use of illicit or non-prescribed controlled substance.

Other Covered Services
1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:
a.To verify a presumptive positive UDT using definitive methods that include, but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
b.To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.

2.Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient.

3.Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
a.The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
b.Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
c.To rule out an error as the cause of a negative presumptive UDT result.

4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

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Non-Covered Services

1. Blanket Orders

2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).

3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.

4. It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.

5. It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory with or without reflex testing. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.

6. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.

7. IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification and/or quantification typically by GC-MS or LC-MS/MS.

8. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.

9. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.

10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

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Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

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.**
Note—Bolded diagnoses below have the highest utilization

Code	Description
F10.20	Alcohol dependence, uncomplicated
F11.20	**Opioid dependence, uncomplicated**
F19.20	Other psychoactive substance dependence, uncomplicated
G89.29	**Other chronic pain**
G89.4	**Chronic pain syndrome**
I47.1	Supraventricular tachycardia
M25.50	Pain in unspecified joint
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.2	Cervicalgia
M54.5	Low back pain
M79.1	Myalgia
Z51.81	Encounter for therapeutic drug level monitoring
Z79.891	**Long term (current) use of opiate analgesic**
Z79.899	**Other long term (current) drug therapy**

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ►

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Cystic Fibrosis Screen
CFvantage® Cystic Fibrosis Expanded Screen

CPT: 81220

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

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

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Cystic Fibrosis Screen and CFvantage® Cystic Fibrosis Expanded Screen. The Cystic Fibrosis Screen and CFvantage® Cystic Fibrosis Expanded Screen are not considered reasonable and necessary and are not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

Visit **SonoraQuest.Com/Medicare** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ►

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Factor V Leiden Mutation

CPT: 81241

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

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

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Factor V Leiden Mutation. The Factor V Leiden Mutation is not considered reasonable and necessary and is not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

Visit **SonoraQuest.Com/Medicare** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ►

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Flow Cytometry

CPT: 88182, 88184, 88185, 88187, 88188, 88189, 86355, 86356, 86357, 86359, 86360, 86361, 86367

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

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Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

Flow cytometry (FCM) is a complex process to examine blood, body fluids, CSF, bone marrow, lymph node, tonsil, spleen and other solid tissues. The use of peripheral blood and fine needle aspirate material avoids more invasive procedures for diagnosis.

A flow cytometer evaluates the physical and/or chemical characteristics of single cells as the cells pass individually in a fluid stream through a measuring device. Surface receptors, intracellular molecules, and DNA bind with fluorescent dyes that allow detection and evaluation.

When light of one wave length excites electrons of certain chemicals to energy levels above their ground state and upon return to ground state emits light of a longer wavelength, fluorescence is produced. A flow cytometer detects cell characteristics by measuring the fluorescence produced by fluorochromes conjugated either directly with cell components or conjugated to antibodies directed against cell components.

Indications

Cytopenias and Hypercellular Hematolymphoid Disorders

Hematolymphoid neoplasia can present with cytopenias (anemia, leucopenia and/or thrombocytopenia) or elevated leukocyte counts. If medical review and preliminary laboratory testing fails to reveal a cause, bone marrow aspiration and biopsy are indicated to rule out an infiltrative process or a stem cell disorder. FCM is essential to evaluate hematolymphoid lineages. Although anemia commonly occurs in nonneoplastic diseases, anemia alone should not automatically trigger FCM.

FCM may be useful in hypercellular hematolymphoid disorders to differentiate reactive conditions from neoplastic conditions. In the absence of blasts, neutrophilic leukocytosis is not generally an indication for FCM. Isolated polycythemia and basophilia are not sufficient to warrant FCM.

Lymphomas

In the current WHO classification, all non-Hodgkin lymphomas (NHLs) are distinct clinicopathologic entities defined by their clinical features, morpholology, immunophenotype and, where appropriate, their genetic abnormalities. Immunophenotyping by FCM allows multiparameter evaluation of single cells and the ability to work on very small samples.

Most new cases of suspected NHL undergo initial immunophenotypic analysis as part of the routine handling of a specimen. A standard lymphoma panel is designed to identify abnormal populations of B cells, T cells and/or NK cells. A standard lymphoma panel might include a combination of markers from the following categories: T cells (CD2, CD3, CD4, CD5, CD7, CD8); B cells (CD19, CD20, CD23); Kappa and lambda surface immunoglobulins light chains; plasma cells (CD38 and CD138); CALLA (CD10); CD45; CD56: FMC-7, CD103, CD11b, CD13, CD14, CD15, CD16 and CD34.

The immunophenotypes of lymphomas are widely known and FCM allows appropriate classification of most cases. However, atypical patterns occur and pose significant diagnostic difficulties where aberrant antigen expression patterns must be reconciled with morphology. Additional markers may be required to characterize the abnormal population of cells including markers of immature cells (HLA-DR), B cells (CD22) and myeloid cells (CD14, CD15, CD33, CD64, CD117).

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Acute Leukemia

The diagnosis and management of acute leukemia depend on the detection, identification and characterization of leukemic cells. The identification of leukemic cells is straightforward in most occasions. However, each acute leukemia subgroup has heterogeneous biologic characteristics, many of which are associated with a different response to therapy.

As part of a routine diagnostic workup, most suspected acute leukemia cases undergo initial multiparameter immunophenotypic analysis, combined with morphology, cytochemistry, cytogenetics, and molecular biology.

A standard acute leukemia FCM panel is designed to determine whether leukemic blasts are of myeloid or lymphoid origin, and then to further classify the neoplastic cells (myeloid blasts, B lymphoblasts, abnormal promyelocytes, monoblasts, etc). An acute leukemia panel might include a combination of cell markers from the following categories: stem cell lineage (CD34), immature cell lineage (HLA-DR, CD 10); T cell (CD2, CD3, CD4, CD5, CD7 and CD8); B cell (CD19, CD20); myeloid cell (CD13, CD14, CD15, CD 33, CD 64 and CD17); CD38, CD45, and CD56.

When the routine panel is insufficient to characterize the leukemic cells, additional antibodies including erythroid markers (CD71 and glycophorin A), megakaryocytic markers (CD41, CD61) or cytoplasmic markers may be indicated.

Chronic Lymphocytic Leukemia (CLL) & Other Chronic Lymphoproliferative Diseases (CLPD)

The history, physical exam (lymphadenopathy, splenomegaly and/or hepatomegaly) laboratory findings (lymphocytosis, granulocytopenia, anemia, thrombocytopena), and lymphocyte morphology are suggestive of CLL. The diagnosis is established by paradoxical co-expression of CD5 on peripheral lymphocytes that express B cell markers (CD19, CD20, CD21 and CD 23) with Kappa or lambda immunoglobulin light chain restriction. Additional markers such as CD38 and ZAP70 may provide important prognostic information.

FCM can distinguish CLL, the peripheral counterpart of small lymphocytic lymphoma, often diagnosed in lymph node biopsies, from other indolent lymphocytic malignancies including prolymphocytic leukemia, Waldenstrom's macroglobulinemia, leukemic phase of lymphomas, hairy cell leukemia, T-cell CLL, adult T-cell leukemia, large granulocytic leukemia and cutaneous T-cell lymphoma and natural killer (NK) disorders including KIR expression.

Plasma Cell Disorders

Plasma cell disorders are often identified through a combination of clinical, laboratory studies (urine or serum gamma globulins), morphologic, and radiologic findings. FCM immunophenotyping is useful to identify abnormal plasma cells, and the distinction between lymphoid and plasma cell neoplasms, and between reactive plasma cells and neoplastic plasma cells.

The initial FCM workup for a plasma cell disorder may include the basic lymphoma panel markers with additional markers such as CD28 and CD117.

Myelodysplastic Syndromes (MDS)

The gold standard for an MDS diagnosis is assessment of bone marrow smears for dysplastic changes. FCM may assist in MDS determination through the identification of abnormal maturing myeloid cells. An abnormal phenotype by FCM is a minimal diagnostic MDS criteria to establish a definitive diagnosis.

MDS has a definite risk and rate of progression to acute leukemia. Standard FCM leukemia panels are indicated to evaluate progression and onset of leukemia.

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Chronic Myeloproliferative Disorders (CMPD)
Although genetic (Philadelphia chromosome and BCR/abl) and molecular studies (Jak 2) are the accepted cornerstone for the identification and classification of CMPDs, FCM may assist in the distinction from reactive hematopoietic proliferations and is important in the enumeration of blasts in the distinction from acute leukemia and an accelerated phase of CMPD.

CMPD also has a definite risk and rate of progression to acute leukemia. Standard FCM leukemia panels are indicated to evaluate progression and onset of leukemia.

Mast Cell Neoplasms
Mast cell neoplasms are uncommon disorders. Mast cells coexpress multiple markers including CD9, CD33, CD45, CD68, CD117, but also lack several myelomonocytic antigens including CD14, CD15, CD16 and most T- and B- cells antigens. Neoplastic mast cells have a similar antigen profile, but also can coexpress CD2 and CD25, which helps in distinguishing malignant mast cells from mastocytosis.

Paroxysmal hemoglobinuria (PNH)
PNH is a rare clonal hematopoietic disorder of stem cells. This condition is caused by genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. FCM can diagnose PNH by assessing both the red and white blood cells for the absence of these antigens.

Minimal Residual Disease (MRD)
FCM analysis for MRD must identify phenotypic features characteristic of the disease of interest. The MRD flow analysis should not rely on an exact match between the phenotype of the residual disease and the original diagnostic specimen because phenotypes can change over time and with treatment. The antibody combinations should be chosen to maximize detection of disease, limit the impact of phenotypic variation, and permit detection of disease following antibody directed therapy.

HIV Infection
HIV-1 infection causes significant changes in the number of CD4 and CD8 positive lymphocytes. CD4 count falls roughly 30% while CD8 count increases within 6 months after seroconversion, causing a decrease in the CD4/CD8 ratio

Following HIV-1 diagnosis, FCM should include enumeration of mature T cells (CD3), helper T cells (CD4) and suppressor T cells (CD8) to ensure all major T cell subsets are accounted for (the sum of helper CD4 and suppressor CD8 T cells is roughly close to the total number of CD3 positive T cells). This ensures that the absolute CD4 is not artificially decreased due to sample degradation or other artifact.

A WBC count with differential also needs to be performed to calculate the absolute CD4 count (absolute lymphocyte count times CD4%).

Organ Transplants
In order to differentiate early rejection, immunosuppressive therapy toxicity or infection, FCM may be indicated to monitor postoperative organ transplants. CD3 is useful to monitor the effectiveness of certain immunosuppressive therapies. When the transplant patient demonstrates symptoms for the above conditions, repeated analysis may be required.

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DNA Analysis

Carcinoma, Non-hematolymphoid Tumors
DNA analysis of tumor for ploidy and percent S-phase cells may be necessary for a few selective patients with carcinomas. When the obtained prognostic information will affect treatment decisions in patients with low stage (localized) disease, FCM results are useful.

Molar Pregnancy
FCM is useful to evaluate molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles (triploid), can be distinguished from normal placenta and complete molar (diploid) pregnancies.

Primary Immunodeficiencies (PIDS)
PIDs are rare disorders that reflect inherited abnormalities in the development and maturation of cells responsible for immune function. More than 120 inherited immunodeficiency disorders are currently recognized. Affected individuals are prone to repeated infections, allergies, autoimmune disorders, and malignancies. Diagnosis typically occurs at an early age.

FCM may be indicated for diagnostic purposes and is usually limited to T (CD3, CD4, CD8), B (CD20) and NK cell (CD56) markers. Additional disease specific markers may be indicated.

Primary Platelet Disorders, Non-neoplastic
FCM is used for platelet analysis in quantitative and qualitative disorders such as Glanzmann Thrombasthenia (GT) and Bernard-Soulier Disease (B-S). GT is a rare inherited or acquired platelet disorder. Hereditary GT is defined by platelets with decreased expression or absence of the GPIIa/GPIIIb receptor. This receptor is responsible for the initial platelet plug at the site of endothelial injury. Absence if the receptor may result in increased bleeding.

Acquired GT is likely an autoimmune phenomenon with the presence of GPIIb/GPIIIa blocking antibodies. FCM may be used to determine the functional effect and identity the molecular targets of these antibodies.

B-S is another rare inherited disorder that prevents the initial binding of platelets at the site of endothelial injury by absence of or presence of abnormal surface GPIa/V/IX receptor. Abnormalities of this receptor prevent attachment of platelets to subendothelial or free von Willebrand's factor with subsequent tendency to bleed.

FCM may be used to measure antibodies directed at specific loci of the GPIa/V/IX receptor, which include GPIb (CD42b), GPIX (CD42a), and GPV (CD42d). FCM is also used to assess the size of platelets in the initial evaluation of B-S disease. In B-S disease, platelets are generally larger than normal. FCM can distinguish B-S platelets from fragmented RBCs and debris by antibodies directed to the GPIb/IX/V receptor.

Red Cell and White Cell Disorders, Non-neoplastic
FCM is a valuable tool to establish abnormal or defective red blood cell, leukocyte and lymphocyte surface receptors, transmembrane molecules, and intracellular DNA.
It may be used in acquired and congenital red cell conditions such as in quantifying fetomaternal hemorrhage and hereditary spherocytosis, hereditary elliptocytosis, and hereditary persistence of fetal hemoglobin in the context of compound hemoglobinopathy syndromes.

FCM is a sensitive and specific method to identify leukocyte receptor abnormalities for the diagnosis of chronic granulomatous disease and CD11b deficiency.

It is an efficient method to identify lymphocytes HLA B27 associated with uveitis, ankylosing spondylitis, Reiter's syndrome and sacroiliitis.

Limitations
Since FCM immunophenotypes for most common lymphomas and leukemias are well characterized, Noridian does NOT consider it "reasonable and necessary" to perform more than 24 markers in a panel. When atypical or unusual FCM results are obtained, the selective addition of more markers may be indicated.

The flow report must document the specific indication for each marker over the 24 marker limit.

The FCM report must document the specific indication for each marker over the 24-marker limit. FCM reports without clear justification for each marker over 24 will be denied.

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Note—Bolded diagnoses below have the highest utilization

Code	Description
B20	**Human immunodeficiency virus [HIV] disease**
C32.1	Malignant neoplasm of supraglottis
C61	Malignant neoplasm of prostate
C73	**Malignant neoplasm of thyroid gland**
C76.0	Malignant neoplasm of head, face and neck
C79.51	Secondary malignant neoplasm of bone
C90.00	**Multiple myeloma not having achieved remission**
D64.9	**Anemia, unspecified**
D69.3	Immune thrombocytopenic purpura
D69.6	Thrombocytopenia, unspecified
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	**Decreased white blood cell count, unspecified**
D72.829	Elevated white blood cell count, unspecified
D80.1	Nonfamilial hypogammaglobulinemia
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D84.821	Immunodeficiency due to drugs
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

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GlycoMark Testing for Glycemic Control

CPT: 84378

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

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Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the GlycoMark® assay. The GlycoMark assay is not considered reasonable and necessary for the management of diabetes or the prevention of diabetic complications and is not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

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To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ►

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HE4, Ovarian Cancer Monitoring

CPT: 86305

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

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the HE4, Ovarian Cancer Monitoring. The HE4, Ovarian Cancer Monitoring is not considered reasonable and necessary and is not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

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Helicobacter Pylori Infection Testing

CPT: 83013, 83014, 87338

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Coverage Indications, Limitations, and/or Medical Necessity

This policy provides limited coverage for Helicobacter pylori (H. pylori) infection testing by carbon isotope (^{13}C or ^{14}C) urea breath testing or stool antigen testing. This policy also denies coverage for H. pylori serology testing, TZAM H. pylori multiplex PCR testing, plasma pepsinogen II testing, tonsillar H. pylori colonization, IL1B-31>T polymorphism testing for H. pylori, tumor necrosis factor-alpha (TNFα), and AmHPR Helicobacter antibiotic resistance next generation sequencing panel testing.

Summary of Evidence

This policy is consistent with guidelines of the American Gastroenterological Association and the American College of Gastroenterology.[3,4] in younger patients without “alarm” symptoms (e.g., weight loss, progressive dysphagia, recurrent vomiting, evidence of GI bleeding, or family history of UGI cancer)[20]. Endoscopy with biopsy is recommended for patients >55 years of age and younger patients with alarm symptoms.[2,5]

Multiple Food and Drug Administration (FDA) cleared urea place.[6,8] (Halyard Health, Alpharetta, GA).

A stool antigen test, cleared by the FDA, may be used for initial diagnosis, therapeutic monitoring and eradication confirmation in adults and children. The HpSA® test (Meridian Bioscience, Cincinnati, OH) is the only FDA cleared stool antigen test in the US. All others use analyte specific reagents (ASR) or are laboratory developed tests (LDTs). The stool antigen test is based on the passage of H. pylori bacteria and H. pylori antigens in the GI tract, and their detection by immunoassay which translates into the detection of an active infection. The test does not require fasting or an instrument for analysis, does not have adverse effects, nor does it depend on a by-product of H. pylori and, has the additional advantage that testing can be performed while patients are on proton pump inhibitor (PPI), bismuth or H2 blockers.

Confirmation of the presence of H. pylori bacterium can be determined invasively on endoscopic biopsy followed by rapid urease testing (CLOtest™ PyloriTek™, Hpfast™), by histology which on occasion may require special stains or immunohistochemistry, or culture.

More than 90% of gastroduodenal ulcers are associated with H. pylori infection. The ACG guidelines recommend that all person suspected of having peptic ulcer disease should be tested for H. pylori regardless of whether they are concurrently taking non-steroidal anti-inflammatory drugs (NSAIDS), as H. pylori and NSAIDs are independent risk factors for the development of peptic ulcer disease. Antibiotic therapy is indicated for all H. pylori infected ulcer patients together with acid-suppressing drugs to facilitate symptom relief and healing. The ACG also recommend post-treatment testing, by the stool antigen test or the urea breath test, in ALL patients treated for H. pylori infection[3].

With an H. pylori prevalence of up to 30-40% in the US, it is not surprising that 30-40% of patients undergoing bariatric surgery are infected with H. pylori.[9] Because H. pylori infection may increase the risk of post-operative marginal ulcers, noninvasive H. pylori infection testing is recommended as part of the routine pre-operative evaluation of patients before bariatric surgery.

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Helicobacter Pylori Infection Testing

CPT: 83013, 83014, 87338

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming (continued)

The AGA and ACG no longer recommend H. pylori serology testing because it is not a test of active infection. Although a negative serology for H. pylori antibody can be used to rule out infection, a positive serology indicates H. pylori exposure at some time in the past, not whether the patient has current infection. Studies suggest that nearly 50% of person with positive H. pylori serology do not have active infection.3 Furthermore, serology cannot be used to show that H. pylori infection has been successfully eradicated after treatment. Antibody levels commonly remain elevated for months to years after treatment.

A reliable diagnosis is mandatory for the identification of infection and to confirm eradication of infection. Although bacterial culture from the gastric biopsy is the “gold” standard technique for H. pylori identification, and is recommended for antibiotic susceptibility testing, it is not practical for all patients. Although infrequently indicated, quantitative polymerase chain reaction (PCR) on gastric biopsies can be used to detect low bacterial loads, the use of the testing is limited by its high cost.[10] Others have suggested the measurement of decreased plasma pepsinogen II may be a reliable biomarker to confirm successful eradiation of H. pylori infection.[11] However, studies are with limited numbers of patients, and inconclusive findings.

Others have suggested that H. pylori infection plays a role in the development of other conditions. Hwang et al[12], in a systematic review and meta-analysis, found no evidence that H. pylori infection plays a role in the pathogenesis or development of chronic tonsillitis. Gomes et al[13] concluded that recurrent aphthous stomatitis (RAS) ulcers are not associated with the presence of bacteria in the oral cavity and there is no evidence that H. pylori infection drives RAS development. Sun et al[14] hypothesized that host genetic factors that control the production of cytokines, including interleukin -1ß, which affect susceptibility to many H. pylori-related diseases. The authors concluded that the findings of their meta-analysis showed that IL1ß-31C>T polymorphism might increase H. pylori risk in Asian and Latin American populations, that TNFa-308G>A and -1031T>C polymorphisms may be protective factors against H. pylori infection[15], and that -863C>A may be a risk factor in Asian populations. However, they indicate further studies with different ethnicities and larger samples size are needed to validate their findings.

AmHPR H. pylori antibiotic resistance panel testing examines antibiotic resistance to 6 antibiotic types that are currently used in H. pylori treatment by means of NGS: 23S rRNA for clarithromycin; gyrA for fluoroquinolones; rdxA for metronidazole; pbp1 for amoxicillin; 16S rRNA for tetracycline, and rpoB for rifabutin. Binh et al[16] stated that metronidazole resistance is a key factor associated with H. pylori failure. The authors confirmed that the mutations in rdxA were mainly associated with metronidazole resistance, and mutations in frxA were able to enhance H. pylori resistance only in the presence of rdxA mutations. These authors conclude that further work is needed to identify the role of mutations associated with treatment failure. In a large pilot study by[17] and colleagues on 849 Indonesian dyspeptic patients, authors showed a high prevalence of metronidazole and levofloxacin resistance with low prevalence of clarithromycin, amoxicillin and tetracycline resistance, largely related to local antibiotic consumption. They noted that resistance is primarily due to the H. pylori genotype, rather than the human genotype.

Multiple regimens are available for treating H. pylori infection. The first-line regimen for H. pylori eradication includes proton pump inhibitor (PPI), clarithromycin (CAM), and amoxicillin (AMX), or metronidazole. Proton pump inhibitors (PPIs) suppress acid production in combination with antibiotic treatment. However, the failure rate of triple anti-H. pylori therapies has increased up to 30%. The known factors for therapy failure include antibiotic resistance, poor compliance, high gastric acidity, and high bacterial load.

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Helicobacter Pylori Infection Testing

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Studies suggest that cytochrome P450 CYP2C19 polymorphism may also play a role in therapy failure. CYP2C19 is implicated in the metabolism of PPIs. What is known is that differences in PPI metabolism lead to variability in gastric acid suppression, with associated variability in gastric pH, and that CYP2C19 polymorphism is highly varied among different ethnic populations. Observational studies suggest that extensive metabolizers (EM) of PPIs have lower eradication rates following standard treatment for H. pylori compared to poor metabolizers (PM). Studies suggest that CTP2C19 genotype is a cardinal factor for H. pylori eradication in patients taking omeprazole-based or lansoprazole-based triple therapies. In contrast, this polymorphism has no significant effect on the rabeprazole-based or esomeprazole-based triple therapies. However, overall there is conflicting data and meta-analyses that conflict with one another. At the current time, the existing scientific data is insufficient to demonstrate a causal effect.

Analysis of Evidence (Rationale for Determination)

Level of Evidence

Quality of evidence: Mixed

Strength of evidence: Strong

Weight of evidence: Sufficient

Based upon the American College of Gastroenterology 2017 Guidelines, Noridian establishes the following Criteria for coverage for urea breath testing **or** stool antigen testing for active H pylori infection are:

- Evaluation of new onset, uninvestigated dyspepsia in persons younger than 60 years of age without alarm symptoms; or
- All patients with active peptic ulcer disease (PUD), a past history of PUD (unless previous cure of H. Pylori infection is documented); or
- Patients with low grade gastric mucosa-associated lymphoid tissue (MALT); or
- Patients with a history of endoscopic resection of early gastric cancer; or
- Patients taking long term low dose aspirin may be considered for testing to reduce the risk of ulcer bleeding; or
- Patients initiating chronic treatment with nonsteroidal anti-inflammatory drugs; or
- Patients with unexplained iron deficiency despite an appropriate workup; or
- Adults with idiopathic thrombocytopenic purpura; or
- Recurrent dyspeptic symptoms suggest reinfection with H. pylori; or
- Re-evaluation to assess success of eradication of H. pylori infection (no sooner than 4 weeks post-treatment and after PPI threapy has been withheld for 1-2 weeks).

All other H. pylori testing for any other etiology is not reasonable and necessary, and not a Medicare benefit. Some non-covered etiologies including but not limited to the risk of developing dementia, dyspepsia associated with “alarm” markers, recurrent aphthous stomatitis (RAS), onset of new dyspepsia in person aged 55 years or older, and screening of asymptomatic person for H. pylori infection. Upper GI endoscopy is indicated for persons aged 55 years or older because of increased concern for gastric neoplasia.

Note: Either urea breath testing or stool antigen testing for H. pylori is medically indicated; not both tests. Serology is no longer an acceptable non-invasive test H. pylori infection.

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Code	Description
B96.81	**Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere**
E66.01	Morbid (severe) obesity due to excess calories
E66.9	Obesity, unspecified
K25.0	Acute gastric ulcer with hemorrhage
K25.4	Chronic or unspecified gastric ulcer with hemorrhage
K25.9	Gastric ulcer, unspecified as acute or chronic, without hemorrhage or perforation
K26.2	Acute duodenal ulcer with both hemorrhage and perforation
K26.3	Acute duodenal ulcer without hemorrhage or perforation
K27.3	Acute peptic ulcer, site unspecified, without hemorrhage or perforation
K27.4	Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage
K27.9	Peptic ulcer, site unspecified, unspecified as acute or chronic, without hemorrhage or perforation
K29.00	Acute gastritis without bleeding
K29.50	**Unspecified chronic gastritis without bleeding**
K29.70	**Gastritis, unspecified, without bleeding**
K29.80	Duodenitis without bleeding
K30	**Functional dyspepsia**
K31.89	Other diseases of stomach and duodenum
R10.13	**Epigastric pain**
Z87.11	Personal history of peptic ulcer disease

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Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation

CPT: 81291

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Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation. The Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation is not considered reasonable and necessary and is not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

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MolDX: Pigmented Lesion Assay

CPT: 0089U, ZB6L6

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Coverage Indications, Limitations, and/or Medical Necessity

This Medicare contractor will provide limited coverage for the Pigmented Lesion Assay / PLA (DermTech, Inc., La Jolla, CA), an RNA gene expression test conducted on skin samples obtained non-invasively via adhesive patches.

The PLA is indicated only for use on pigmented skin lesions, for which a diagnosis of melanoma is being considered. **The test may only be ordered by clinicians who evaluate pigmented skin lesions and perform biopsies. The test is covered for use as a source of information on whether or not to perform a biopsy.**

The specific characteristics that the lesion must have are as follows:

- The lesion must meet one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving)
- Primary melanocytic skin lesions between 5mm and 19mm
- Lesions where the skin is intact (i.e., non-ulcerated or non-bleeding lesions)
- Lesions that do not contain a scar or were previously biopsied
- Lesions not located in areas of psoriasis, eczema or similar skin conditions
- Lesions not already clinically diagnosed as melanoma or for which the clinical suspicion is sufficiently high that the treating clinician believes melanoma is a more likely diagnosis than not
- Lesions in areas other than palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed

Additional coverage requirements:

- The ordering clinician must also have a plan at the time of ordering the test to continue to monitor the skin lesion for changes if the test is negative. **The record must also contain a photograph of the lesion at the time that the PLA is ordered to allow for appropriate evaluation in subsequent follow-up.**
- **Records must clearly support that the ordering clinician has the knowledge, skills, and experience to evaluate and biopsy pigmented skin lesions. If this information is not contained with the chart of the beneficiary to whom a service is being rendered, it must be supported by other readily available documentation, such as credentialing documentation, or documentation of training in the performance of such tasks. Such documentation should be provided if there are documentation requests.**
- The ordering physician must clearly document the lesion site on the patient's body
- The test may not be ordered for the same lesion a second time.
- Only one test may be used per patient per clinical encounter in most cases. **In roughly 10% of patients, a second test may be indicated for the same clinical encounter. For rare cases where more than 2 tests are indicated in a single clinical encounter, an appeal with supporting documentation may be submitted for additional tests.**

The PLA is not intended to be used as a screening test in patients without melanocytic skin lesions. It is also not covered as an adjunctive test in lesions that are considered to already warrant a biopsy. The PLA is a decision tool for atypical melanocytic lesions prior to the decision to biopsy.

Medicare Local Coverage Determination Policy

MolDX: Pigmented Lesion Assay

CPT: 0089U, ZB6L6

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CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

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Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Specific Coverage Criteria

The Pigmented Lesion Assay (PLA) is indicated for use on melanocytic skin lesions with one or more clinical or historical characteristics suggestive of melanoma, including one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving) when a clinician trained in the clinical diagnosis of skin cancer is considering the need for biopsy to rule out melanoma. The PLA should not be used on clinically obvious melanoma. The PLA result is one element of the overall clinical assessment and should be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to biopsy.

(PLA positive lesions (LINC and/or PRAME detected) should be considered for biopsy. The biopsy decision of a PLA negative lesion should be based on the remainder of the entire clinical context.)

The PLA is indicated only for use on:
- Primary melanocytic skin lesions between 5mm and 19mm
- Lesions where the skin is intact (i.e. non-ulcerated or non-bleeding lesions)
- Lesions that do not contain a scar or were previously biopsied
- Lesions not located in areas of psoriasis, eczema or similar skin conditions
- Lesions not clinically diagnosed as melanoma
- Lesions in areas other than palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed

The PLA is not intended to be used as a screening test in patients without melanocytic skin lesions. It is also not covered as an adjunctive test in lesions that are considered to already warrant a biopsy. The PLA is a decision tool for atypical melanocytic lesions prior to the decision to biopsy.

The evaluation with the PLA is limited to order by a physician or other qualified healthcare professional.

Medicare Local Coverage Determination Policy

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Prothrombin (Factor II) 20210G>A Mutation Analysis

CPT: 81240

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

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

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Prothrombin (Factor II) 20210G>A Mutation Analysis. The Prothrombin (Factor II) 20210G>A Mutation Analysis is not considered reasonable and necessary and is not covered by Medicare.

There are NO ICD-10 Codes that support medical necessity.

Visit **SonoraQuest.Com/Medicare** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ►

Last updated: 05/01/23

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Serum Magnesium

CPT: 83735

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

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Coverage Indications, Limitations, and/or Medical Necessity

Magnesium is a mineral required by the body for the use of adenosine triphosphate (ATP) as a source of energy. It is also necessary for neuromuscular irritability and blood clotting. Magnesium deficiency produces neuromuscular disorders. It may cause weakness, tremors, tetany, and convulsions. Hypomagnesemia is associated with hypocalcemia, hypokalemia, long-term hyperalimentation, intravenous therapy, diabetes mellitus (especially during treatment of ketoacidosis); alcoholism and other types of malnutrition; malabsorption; hyperparathyroidism; dialysis; pregnancy; and hyperaldosteronism. The following are other conditions that may cause magnesium deficiencies.

- Renal loss of magnesium occurs with cis-platinum therapy.
- Hypomagnesemia may also be induced by amphotericin or anti-EGFR (some monoclonal antibodies) toxicity.
- Magnesium deficiency is described with cardiac arrhythmias. There is evidence that magnesium may cause arrhythmias.

Indications

- Utilization of certain cardiac drugs which cause adverse effects in the presence of low magnesium (i.e., quinidine, procainamide, and disopyramide phosphate or Norpace). Patients taking these drugs should have their magnesium checked approximately once every six months.
- Long term parenteral nutrition. Patients on long term parenteral nutrition that are otherwise asymptomatic should have their serum magnesium checked monthly.
- Malabsorption syndrome. The frequency should depend on the severity of the syndrome, but once the patient's level is stabilized, a monthly check should be adequate.
- Renal loss secondary to diuretic use.
- Chronic alcoholism, diabetic acidosis, and renal tubular acidosis. These patients should be followed on an as needed basis according to their symptomatology. Without symptoms, they should be checked no more than annually.
- Chronic diarrhea, otherwise unexplained and persistent.
- Prolonged nasogastric suction greater than five days. These patients should have a magnesium check every two to three weeks.
- Cisplatin treatment.
- Amphotericin treatment
- EGFR monoclonal antibodies
- Patients receiving IV magnesium therapy for a low serum level. Serum level should be monitored appropriately.
- Patients with hypocalcemia. If the hypocalcemia persists, the level should probably be checked on a six-month basis as long as the patient does not have symptoms of arrhythmias that would warrant closer follow up.
- Lethargy and confusion that are not otherwise explained. Once a patient has been diagnosed with mental health processes such as Alzheimer or psychotic depression, etc., there is no indication to follow their magnesium level on a regular basis.
- Patients receiving oral magnesium in the face of impaired renal function should have their magnesium level checked on a monthly basis.

Other clinical situations:

- Pre-eclampsia
- Unexplained muscular paralysis
- Neuromuscular irritability
- Blood clotting abnormalities
- Evidence (mixed) that magnesium levels are low and increased magnesium may benefit patients with sickle cell anemia, beta thalassemia and hypersplenism– more recent articles dispute this.
- Long Q-T syndrome, torsades de pointes and ventricular arrhythmias.

Medicare Local Coverage Determination Policy

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Serum Magnesium

CPT: 83735

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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.**
Note—Bolded diagnoses below have the highest utilization

Code	Description
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.9	**Type 2 diabetes mellitus without complications**
E83.42	**Hypomagnesemia**
E83.51	Hypocalcemia
E87.6	Hypokalemia
I10	**Essential (primary) hypertension**
I48.0	Paroxysmal atrial fibrillation
I50.22	Chronic systolic (congestive) heart failure
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N25.81	Secondary hyperparathyroidism of renal origin
R25.2	Cramp and spasm
R53.1	Weakness
R53.83	Other fatigue
R79.89	Other specified abnormal findings of blood chemistry
Z51.11	Encounter for antineoplastic chemotherapy
Z79.899	**Other long term (current) drug therapy**
Z94.0	**Kidney transplant status**
Z94.4	Liver transplant status

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Last updated: 05/01/23

Medicare Local Coverage Determination Policy

Vitamin D Assay Testing

Vitamin D; 1, 25 dihydroxy

CPT: 82652

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Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

Vitamin D is called a "vitamin" because of its exogenous source, predominately from oily fish in the form of vitamin D 2 and vitamin D 3. It is more accurate to consider fat-soluble Vitamin D as a steroid hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol. Clinical disorders related to vitamin D may arise because of altered availability of the parent vitamin D, altered conversion of vitamin D to its predominant metabolites, altered organ responsiveness to dihydroxylated metabolites and disturbances in the interactions of the vitamin D metabolites with PTH and calcitonin. Normal levels of Vitamin D range from 20 – 50 ng/dl. This LCD identifies the indications and limitations of Medicare coverage and reimbursement for the lab assay.

Indications

Measurement of 25-OH Vitamin D, CPT 82306, level is indicated for patients with: chronic kidney disease stage III or greater; cirrhosis; hypocalcemia; hypercalcemia; hypercalciuria; hypervitaminosis D; parathyroid disorders; malabsorption states; obstructive jaundice; osteomalacia; osteoporosis if:

i. T score on DEXA scan <-2.5 or

ii. History of fragility fractures or

iii. FRAX > 3% 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture or

iv. FRAX > 3% (any fracture) with T-score <-1.5 or

v. Initiating bisphosphanate therapy (Vit D level should be determined and managed as necessary before bisphosphonate is initiated); osteosclerosis/petrosis; rickets; vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.

Measurement of 1, 25-OH Vitamin D, CPT 82652, level is indicated for patients with:

unexplained hypercalcemia (suspected granulomatous disease or lymphoma), unexplained hypercalciuria (suspected granulomatous disease or lymphoma), suspected genetic childhood rickets, suspected tumor-induced osteomalacia, nephrolithiasis or hypercalciuria.

Limitations

Testing may not be used for routine or other screening. Both assays of vitamin D need not be performed for each of the above conditions. Often, one type is more appropriate for a certain disease state than another. The most common type of vitamin D deficiency is 25-OH vitamin D. A much smaller percentage of 1,25 dihydroxy vitamin D deficiency exists; mostly, in those with renal disease. Documentation must justify the test(s) chosen for a particular disease entity. Various component sources of 25-OH vitamin D, such as stored D or diet-derived D, should not be billed separately.

Once a beneficiary has been shown to be vitamin D deficient, further testing may be medically necessary only to ensure adequate replacement has been accomplished. If Vitamin D level is between 20 and 50 ng/dl and patient is clinically stable, repeat testing is often unnecessary; if performed, documentation most clearly indicate the necessity of the test. If level <20 ng/dl or > 60 ng/dl, a subsequent level(s) may be reimbursed until the level is within the normal range.

Medicare Local Coverage Determination Policy

Vitamin D Assay Testing

Vitamin D; 1, 25 dihydroxy

CPT: 82652

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Note—Bolded diagnoses below have the highest utilization

Code	Description
E55.0	Rickets, active
E55.9	Vitamin D deficiency, unspecified
E83.50	Unspecified disorder of calcium metabolism
E83.52	Hypercalcemia
M83.0	Puerperal osteomalacia
M83.1	Senile osteomalacia
M83.2	Adult osteomalacia due to malabsorption
M83.3	Adult osteomalacia due to malnutrition
M83.4	Aluminum bone disease
M83.5	Other drug-induced osteomalacia in adults
M83.8	Other adult osteomalacia
M83.9	Adult osteomalacia, unspecified
N20.0	Calculus of kidney
N20.1	Calculus of ureter
N20.2	Calculus of kidney with calculus of ureter
N20.9	Urinary calculus, unspecified
N22	Calculus of urinary tract in diseases classified elsewhere

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Last updated: 05/01/23

Disclaimer:
This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with documentation in the patient's medical record. Sonora Quest Laboratories does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Medicare Local Coverage Determination Policy

Vitamin D Assay Testing

Vitamin D; 25 hydroxy

CPT: 82306

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Indications

Measurement of 25-OH Vitamin D, CPT 82306, level is indicated for patients with: chronic kidney disease stage III or greater; cirrhosis; hypocalcemia; hypercalcemia; hypercalciuria; hypervitaminosis D; parathyroid disorders; malabsorption states; obstructive jaundice; osteomalacia; osteoporosis if:

i. T score on DEXA scan <-2.5 or

ii. History of fragility fractures or

iii. FRAX > 3% 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture or

iv. FRAX > 3% (any fracture) with T-score <-1.5 or

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Measurement of 1, 25-OH Vitamin D, CPT 82652, level is indicated for patients with:

unexplained hypercalcemia (suspected granulomatous disease or lymphoma), unexplained hypercalciuria (suspected granulomatous disease or lymphoma), suspected genetic childhood rickets, suspected tumor-induced osteomalacia, nephrolithiasis or hypercalciuria.

Limitations

Testing may not be used for routine or other screening. Both assays of vitamin D need not be performed for each of the above conditions. Often, one type is more appropriate for a certain disease state than another. The most common type of vitamin D deficiency is 25-OH vitamin D. A much smaller percentage of 1,25 dihydroxy vitamin D deficiency exists; mostly, in those with renal disease. Documentation must justify the test(s) chosen for a particular disease entity. Various component sources of 25-OH vitamin D, such as stored D or diet-derived D, should not be billed separately.

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Medicare Local Coverage Determination Policy

Vitamin D Assay Testing

Vitamin D; 25 hydroxy

CPT: 82306

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Note—Bolded diagnoses below have the highest utilization

Code	Description
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E21.2	Other hyperparathyroidism
E21.3	Hyperparathyroidism, unspecified
E55.9	**Vitamin D deficiency, unspecified**
E67.3	Hypervitaminosis D
E83.50	Unspecified disorder of calcium metabolism
E83.51	Hypocalcemia
E83.52	Hypercalcemia
K90.9	Intestinal malabsorption, unspecified
M81.0	**Age-related osteoporosis without current pathological fracture**
M81.8	Other osteoporosis without current pathological fracture
M85.80	**Other specified disorders of bone density and structure, unspecified site**
N18.30	**Chronic kidney disease**
N18.31	Chronic kidney disease
N18.32	Chronic kidney disease
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N25.81	Secondary hyperparathyroidism of renal origin
Z79.899	**Other long term (current) drug therapy**

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