Code	Description
999.2	Other vascular complications
999.8	Other transfusion reactions
V08	Asymptomatic HIV infection
V12.1	History of nutritional deficiency
V12.3	Personal history of diseases of blood and blood-forming organs
V12.50–V12.59	Diseases of circulatory system
V15.1	Personal history of surgery to heart and great vessels
V15.2	Personal history of surgery of other major organs
V42.0	Kidney replaced by transplant
V42.1	Heart replaced by transplant
V42.2	Heart valve replaced by transplant
V42.6	Lung replaced by transplant
V42.7	Liver replaced by transplant
V42.8	Other specified organ or tissue replaced by transplant
V43.2	Heart replaced by other means
V43.3	Heart valve replaced by other means
V43.4	Blood vessel replaced by other means
V43.60	Unspecified joint replaced by other means
V58.2	Transfusion of blood products
V58.61	Long-term (current) use of anticoagulants
V72.84	Pre-operative examination, unspecified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons

Code	Description
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

CMD Clinical Laboratory Workgroup.

1999 CPT Physicians' Current Procedural Terminology, American Medical Association.

Wintrobe's Clinical Hematology 9th Ed. Lea and Febinger.

Harrison's Principles of Internal Medicine, McGraw Hill, 14th Ed., 1997.

Diagnostic Tests Handbook, Springhouse Corporation, 1987.

Hemostasis and Thrombosis: Basic Principles and Clinical Practice. Colman, et al editors, J.B. Lippincott, 3rd Edition, 1994, pp 896–898 and 1045–1046.

Disorders of Hemostasis, Ratnoff, Oscar D. and Forbes, Charles D., W.B. Saunders Company, 1996.

Merck Manual of Diagnosis and Therapy, 16th Edition (should be replaced with 17th Edition when available in 1999.)

''Performance of the Coumatrak System at a Large Anticoagulation Clinic''. Coagulation and Transfusion Medicine. January 1995. p98–102.

''Monitoring Oral Anticoagulation Therapy with Point-of-Care Devices. Correlation and Caveats''. Clinical Chemistry: No. 9, 1997, p1785–1786.

''College of Americal Pathologists Conference XXXI on Laboratory Monitoring of Anticoagulant Therapy''. Arch.Pathol.Lab.Med. Vol.122. September 1998. p768–780.

''A Structured Teaching and Self-management Program for Patients Receiving Oral Anti-coagulation''. JAMA; 1999; 281: 145–150.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. If a specific condition is known and is the reason for a pre-operative test, submit the text description or ICD–9–CM code describing the condition with the order/referral. If a specific condition or disease is not known, and the pre-operative test is for pre-operative clearance only, assign code V72.84.

7. Assign codes 289.8—other specified disease of blood and blood-forming organs only when a specific disease exists and is indexed to 289.8 (for example, myelofibrosis). Do not assign code 289.8 to report a patient on long term use of anticoagulant therapy (e.g. to report a PT value or re-check need for medication adjustment.) Assign code V58.61 to referrals for PT checks or re-checks. (Reference AHA's Coding Clinic, March-April, pg 12—1987, 2nd quarter pg 8—1989)

Medicare National Coverage Decision for Serum Iron Studies

Other Names/Abbreviations

Description

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

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

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

Total iron binding capacity (TIBC) is an indirect measure of transferrin, a protein that binds and transports iron. TIBC quantifies transferrin by the amount of iron that it can bind. TIBC and transferrin are elevated in iron deficiency, and with oral contraceptive use, and during pregnancy. TIBC and transferrin may be decreased in malabsorption syndromes or in those affected with chronic diseases. The percent saturation represents the ratio of iron to the TIBC.

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

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82728	Ferritin
83540	Iron
83550	Iron Binding capacity
84466	Transferrin

Indications

1. Ferritin (82728), iron (83540) and either iron binding capacity (83550) or transferrin (84466) are useful in the differential diagnosis of iron deficiency, anemia, and for iron overload conditions.

A. The following presentations are examples that may support the use of these studies for evaluating iron deficiency:

- Certain abnormal blood count values (i.e., decreased mean corpuscular volume (MCV), decreased hemoglobin/hematocrit when the MCV is low or normal, or increased red cell distribution width (RDW) and low or normal MCV).
- Abnormal appetite (pica)
- Acute or chronic gastrointestinal blood loss
- Hematuria
- Menorrhagia
- Malabsorption
- Status post-gastrectomy
- Status post-gastrojejunostomy
- Malnutrition
- Preoperative autologous blood collection(s)
- Malignant, chronic inflammatory and infectious conditions Associated with anemia which may present in a similar manner to iron deficiency anemia
- Following a significant surgical procedure where blood loss had occurred and had not been repaired with adequate iron replacement.

B. The following presentations are examples that may support the use of these studies for evaluating iron overload:

- Chronic Hepatitis
- Diabetes
- Hyperpigmentation of skin
- Arthropathy
- Cirrhosis
- Hypogonadism
- Hypopituitarism
- Impaired porphyrin metabolism
- Heart failure
- Multiple transfusions
- Sideroblastic anemia
- Thalassemia major
- Cardiomyopathy, cardiac dysrhythmias and conduction distrubances

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

3. Iron studies may be appropriate in patients after treatment for other nutritional deficiency anemias, such as folate and vitamin B12, because iron deficiency may not be revealed until such a nutritional deficiency is treated.

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

5. Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (e.g., nickel, cadmium, aluminum, lead) whether due to accidental, intentional exposure or metabolic causes.

Limitations

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

2. If a normal serum ferritin level is documented, repeat testing would not ordinarily be medically necessary unless there is a change in the patient's condition, and ferritin assessment is needed for the ongoing management of the patient. For example, a patient presents with new onset insulin-dependent diabetes mellitus and has a serum ferritin level performed for the suspicion of hemochromatosis. If the ferritin level is normal, the repeat ferritin for diabetes mellitus would not be medically necessary.

3. When an End Stage Renal Disease (ESRD) patient is tested for ferritin, testing more frequently than every three months (the frequency authorized by 3167.3, Fiscal Intermediary manual) requires documentation of medical necessity [e.g., other than ''Chronic Renal Failure'' (ICD–9–CM 585) or ''Renal Failure, Unspecified'' (ICD–9–CM 586)].

4. It is ordinarily not necessary to measure both transferrin and TIBC at the same time because TIBC is an indirect measure of transferrin. When transferrin is ordered as part of the nutritional assessment for evaluating malnutrition, it is not necessary to order

other iron studies unless iron deficiency or iron overload is suspected as well.

5. It is not ordinarily necessary to measure both iron/TIBC (or transferrin) and ferritin in initial patient testing. If clinically indicated after evaluation of the initial iron studies, it may be appropriate to perform additional iron studies either on the initial specimen or on a subsequently obtained specimen. After a diagnosis of iron deficiency or iron overload is established, either iron/TIBC (or transferrin) or ferritin may be medically necessary for monitoring, but not both.

6. It would not ordinarily be considered medically necessary to do a ferritin as a preoperative test except in the presence of anemia or recent autologous blood collections prior to the surgery.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
002.0–002.9	Typhoid and paratyphoid fevers
003.0–003.9	Other salmonella infections
006.0–006.9	Amebiasis
007.0–007.9	Other protozoal intestinal diseases
008.00–008.8	Intestinal infections due to other organisms
009.0–009.3	Ill-defined intestinal infections
011.50–011.56	Tuberculous bronchiectasis
014.00–014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands
015.00–015.96	Tuberculosis of bones and joints
016.00–016.06	Tuberculosis of kidney
016.10–016.16	Tuberculosis of bladder
016.20–016.26	Tuberculosis of ureter
016.30–016.36	Tuberculosis of other urinary organs
042	Human Immunodeficiency virus (HIV) disease
070.0–070.9	Viral hepatitis
140.0–149.9	Malignant neoplasm of lip oral cavity and pharynx
150.0–159.9	Malignant neoplasm of digestive organs and peritoneum
160.0–165.9	Malignant neoplasm of respiratory and intrathoracic organs
170.0–176.9	Malignant neoplasm of bone, connective tissue, skin and breast
179–189.9	Malignant neoplasm of genitourinary organs
190.0–199.1	Malignant neoplasm of other and unspecified sites
200.0–208.91	Malignant neoplasm of lymphatic and hematopoietic tissue
210.0–229.9	Benign neoplasms
230.0–234.9	Carcinoma in situ
235.0–238.9	Neoplasms of uncertain behavior
239.0–239.9	Neoplasms of unspecified nature
250.00–250.93	Diabetes mellitus
253.2	Panhypopituitarism
253.7	Iatrogenic pituitary disorders
253.8	Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin
256.3	Other ovarian failure
257.2	Other testicular hypofunction
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe protein-calorie malnutrition
263.0–263.9	Other and unspecified protein-calorie malnutrition
275.0	Disorders of iron metabolism
277.1	Disorders of porphyrin metabolism
280.0–280.9	Iron deficiency anemias
281.0–281.9	Other deficiency anemias
282.4	Thalassemias
285.0	Sideroblastic anemia (includes hemochromatosis with refractory anemia)
285.1	Acute post-hemorrhagic anemia
285.9	Anemia, unspecified
286.0–286.9	Coagulation defects (congenital factor disorders)
287.0–287.9	Purpura and other hemorrhagic conditions
306.4	Physiological malfunction arising from mental factors, gastrointestinal
307.1	Anexoria nervosa
307.50–307.59	Other and unspecified disorders of eating
425.4	Other primary cardiomyopathies
425.5	Alcoholic cardiomyopathy
425.7	Nutritional and metabolic cardiomyopathy
425.8	Cardiomyopathy in other diseases classified elsewhere
425.9	Secondary cardiomyopathy, unspecified
426.0–426.9	Conduction disorders
427.0–427.9	Cardiac dysrhythmias
428.0–428.9	Heart Failure
530.7	Gastroesophageal laceration-hemorrhage syndrome
530.82	Esophageal hemorrhage
531.00–531.91	Gastric ulcer
532.00–532.91	Duodenal ulcer
533.00–533.91	Peptic ulcer, site unspecified

Code	Description
534.00–534.91	Gastrojejunal ulcer
535.00–535.61	Gastritis and duodenitis
536.0–536.9	Disorders of function of stomach
537.83	Angiodysplasia of stomach and duodenum with hemorrhage
555.0–555.9	Regional enteritis
556.0–556.9	Ulcerative colitis
557.0	Acute vascular insufficiency of intestine
557.1	Chronic vascular insufficiency of intestine
562.02	Diverticulosis of small intestine without hemorrhage
562.03	Diverticulitis of small intestine without hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon with hemorrhage
569.3	Hemorrhage of rectum and anus
569.85	Angiodysplasia of intestine with hemorrhage
570	Acute and subacute necrosis of liver
571.0–571.9	Chronic liver disease and cirrhosis
572.0–572.8	Liver abscess and sequelae of chronic liver disease
573.0–573.9	Other disorders of liver
578.0–578.9	Gastrointestinal hemorrhage
579.0–579.3	Intestinal malabsorption
579.8–579.9	Other specified and unspecified intestinal malabsorption
581.0–581.9	Nephrotic syndrome
585	Chronic renal failure
586	Renal failure, unspecified
608.3	Atrophy of testis
626.0–626.9	Disorders of menstruation and other abnormal bleeding from female genital tract
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
648.20–648.24	Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium: Anemia
698.0–698.9	Pruritis and related conditions
704.00–704.09	Alopecia
709.00–709.09	Dyschromia
713.0	Arthropathy associated with other endocrine and matabolic disorders
716.40–716.99	Other and unspecified arthropathies
719.40–719.49	Pain in joint
773.2	Hemolytic disease due to other and unspecified isoimmunization
773.3	Hydrops fetalis due to isoimmunization
773.4	Kernicterus due to isoimmunization
773.5	Late anemia due to isoimmunization
783.9	Other symptoms concerning nutrition, metabolism and development
790.0	Abnormality of red blood cells
790.4	Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase [LDH]
790.5	Other nonspecific abnormal serum enzyme levels
790.6	Other abnormal blood chemistry
799.4	Cachexia
964.0	Poisoning by agents primarily affecting blood constituents, iron compounds
984.0–984.9	Toxic effect of lead and its compounds (including fumes)
996.85	Complications of transplanted organ, bone marrow
999.8	Other transfusion reaction
V08	Asymptomatic HIV infection
V12.1	Personal history of nutritional deficiency
V12.3	Personal history of diseases of blood and blood forming organs
V15.1	Personal history of surgery to heart and great vessels
V15.2	Personal history of surgery to other major organs
V43.2	Heart replaced by other means
V43.3	Heart valve replaced by other means
V43.4	Blood vessel replaced by other means
V43.60	Unspecified joint replaced by other means
V56.0	Extracorporeal dialysis
V56.8	Other dialysis
V72.84	Pre-operative examination, unspecified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result

in denial of claims. Such 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 may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

CDC. Recommendations to prevent and control iron deficiency in the United States. MMWR 1998; 47(RR–3):1–29.

Powell LW, George DK, McDonnell SM, Kowdley KV. Diagnosis of hemochromatosis. Ann.Intern.Med. 1998;129:925–931.

Spiekerman AM. Proteins used in nutritional assessment. Clin.Lab.Med. 1993;13:353–369.

Wallach JB. Handbook of Interpretation of Diagnostic Tests. Lippincott-Raven Publishers (Philadelphia) 1998, pp. 170–180.

Van Walraven C, Goel V, Chan B. Effect of Population-Based Interventions on Laboratory Utilization. JAMA. 1998; 280:2028–2033.

Guyatt GH, Patterson C, Ali M, Singer J, Levine M, Turpie I, Meyer R. Diagnosis of Iron-Deficiency Anemia in the Elderly. AmJMed. 1990; 88:205–209.

Burns ER, Goldberg SN, Lawrence C, Wenz B. AJCP. 1990; 3: 240–245.

Burns ER, et al. Brief Clinical Observations. AmJMed. 1991; 90:653–654.

Yang Q, et al. Hemochromatosis-associated Mortality in the United States from 1979 to 1992: An Analysis of Multiple-Cause Mortality Data. AnIntMed. 1998; 129:946–953.

Coding Guidelines

1. Any claim for a test listed in AHCPCS CODES@ above must be submitted with an ICD–9–CM diagnosis

code or comparable narrative. ICD–9–CM code V82.9 (special screening of other conditions, unspecified condition), or comparable narratives should be used to indicate screening tests performed in the absence of a specific sign, symptom, or complaint. Use of V82.9 or comparable narrative will result in the denial of claims as non covered screening services. (**Note:** this language may be inappropriate for screening tests that are specifically covered by statute, such as pap smears.) All ICD–9–CM diagnosis codes must be coded to the highest level of specificity.

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit or fifth-digit classifications are provided, they must be assigned. From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Collagen Crosslinks, Any Method

Other Names/Abbreviations

Description

Collagen crosslinks, part of the matrix of bone upon which bone mineral is deposited, are biochemical markers the excretion of which provide 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, such as three months, when compared to bone mass density. If bone resorption is not elevated, repeat testing is not medically necessary.

HCPCS Codes (Alpha numeric, CPT © AMA)

Code	Descriptor
82523	Collagen cross links, any method

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 antiresorptive 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 antiresorptive 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 three months after starting anti-resorptive therapy; followed by a repeat assay in 12 months after the three-month assay; and thereafter not more than annually, unless there is a change in therapy in which circumstance an additional test may be indicated three 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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
242.00–242.91	Thyrotoxicosis
245.2	Chronic lymphocytic thyroiditis (only if thyrotoxic)
246.9	Unspecified disorder of thyroid
252.0	Hyperparathyroidism
256.2	Postablative ovarian failure
256.3	Other ovarian failure
256.8	Other ovarian dysfunction
256.9	Unspecified ovarian dysfunction
268.9	Unspecified vitamin D deficiency
269.3	Mineral deficiency, not elsewhere classified
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
627.2	Menopausal or female climacteric state
627.4	States associated with artificial menopause
627.8	Other specified menopausal and postmenopausal disorders
627.9	Unspecified menopausal & postmenopausal disorder
731.0	Osteitis deformans without mention of bone tumor (Paget's disease of bone)
733.00–733.09	Osteoporosis
733.10–733.19	Pathological fracture
733.90	Disorder of bone and cartilage, unspecified
805.8	Fracture of vertebral column without mention of spiral cord injury, unspecified, closed
V58.69	Long-term (current) use of other medications

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs

Code	Description
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections.

Sources of Information

Arnaud CD. Osteoporosis: Using 'bone markers' for diagnosis and monitoring. Geriatrics 1996; 51:24–30.

Chesnut CH, III, Bell NH, Clark G, et al. Hormone replacement therapy in postmenopausal women: urinary N-telopeptide of type I collagen monitors therapeutic effect and predicts response of bone mineral density. Am. J. Med. 1997;102:29–37.

Garnero P, Delmas PD. Clinical usefulness of markers of bone remodelling in osteoporosis. In: Meunier PJ (ed). Osteoporosis:diagnosis and management. London:Martin Dunitz Ltd. 1998:79–101.

Garnero P, Shih WJ, Gineyts E, et al. Comparison of new biochemical markers of bone turnover in late postmenopausal osteoporotic women in response to alendronate treatment. J. Clin. Endocrinol. Metab.1994;79:1693–700.

Harper KD, Weber TJ. Secondary osteoporosis—Diagnostic considerations.

Endocrinol. Metab.Clin. North Am. 1998;27:325–48.

Hesley RP, Shepard KA, Jenkins DK, Riggs BL. Monitoring estrogen replacement therapy and identifying rapid bone losers with an immunoassay for deoxypyridinoline. Osteoporos.Int. 1998;8:159–64.

Melton LJ, III, Khosla S, Atkinson EJ, et al. Relationship of bone turnover to bone density and fractures. J.Bone Miner.Res.1997;12:1083–91.

Millard PS. Prevention of osteoporosis: making sense of the published evidence. In: Rosen CJ (ed). Osteoporosis: diagnostic and therapeutic principles. Totowa: Humana Press Inc. 1996:275–85.

Rosen CJ. Biochemical markers of bone turnover. In: Rosen CJ(ed). Osteoporosis: diagnostic and therapeutic principles. Totowa: Humana Press Inc. 1996:129–41.

Schneider DL, Barrett-Connor EL. Urinary N-Telopeptide levels discriminate normal, osteopenic, and osteoporotic bone mineral density. Arch. Intern. Med. 1997;157:1241–5.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it

has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. When the indication for the test is long-term administration of glucocorticosteroids, use ICD–9–CM code V58.69.

Medicare National Coverage Decision for Blood Glucose Testing

Description

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.

HCPCS Codes (Alpha numeric, CPT–AMA)

Code	Descriptor
82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose; blood, reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use.

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 the patient with impaired fasting glucose (FPG 110–125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to those conditions already 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 (including pruritis, local skin infections, ulceration and gangrene without an established cause). Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

Limitations

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually.

Depending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with 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 unless there is a change in clinical condition. If repeat testing is performed, a specific 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 where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

ICD–9–CM Codes Covered by Medicare Program

Code	Description
011.00–011.96	Tuberculosis
038.0–038.9	Septicemia
112.1	Recurrent vaginal candidiasis
112.3	Interdigital candidiasis
118	Opportunistic mycoses
157.4	Malignant neoplasm of Islets of Langerhans
158.0	Malignant neoplasm of retroperitoneum
211.7	Benign neoplasm of Islets of Langerhans
242.00–242.91	Thyrotoxicosis
250.00–250.93	Diabetes mellitus
251.0–251.9	Disorders of pancreatic internal secretion
253.0–253.9	Disorders of the pituitary gland
255.0	Cushing syndrome

Code	Description
263.0–263.9	Malnutrition
271.0–271.9	Disorders of carbohydrate transport and metabolism
272.0–272–4	Disorders of lipoid metabolism
275.0	Hemochromotosis
276.0–276.9	Disorders of fluid, electrolyte and acid-base balance
278.3	Hypercarotinemia
293.0	Acute delirium
294.9	Unspecified organic brain syndrome
298.9	Unspecified psychosis
300.9	Unspecified neurotic disorder
310.1	Organic personality syndrome
337.9	Autonomic nervous system neuropathy
345.10–345.11	Generalized convulsive epilepsy
348.3	Encephalopathy, unspecified
355.9	Neuropathy, not otherwise specified
356.9	Unspecified hereditary and idiopathic peripheral neuropathy
357.9	Unspecified inflammatory and toxic neuropathy
362.10	Background retinopathy
362.18	Retinal vasculitis
362.29	Nondiabetic proliferative retinopathy
362.50–362.57	Degeneration of macular posterior pole
362.60–362.66	Peripherial retinal degeneration
362.81–362.89	Other retinal disorders
362.0	Unspecified retinal disorders
365.04	Borderline glaucoma, ocular hypertension
365.32	Corticosteriod-induced glaucoma residual
366.00–366.09	Presenile cataract
366.10–366.19	Senile cataract
367.1	Acute myopia
368.8	Other specified visual disturbance
373.00	Blepharitis
377.24	Pseudopapilledema
377.9	Autonomic nervous system neuropathy
378.50–378.55	Paralytic strabiamus
379.45	Argyll-Robertson pupils
410.00–410.92	Acute myocardial infarctions
414.00–414.19	Coronary atherosclerosis and aneurysm of heart
425.9	Secondary cardiomyopathy, unspecified
440.23	Arteriosclerosis of extremities with ulceration
440.24	Arteriosclerosis of extremities with gangrene
440.9	Arteriosclerosis, not otherwise specified
458.0	Postural hypotension
462	Acute pharyngitis
466.0	Acute bronchitis
480.0–486	Pneumonia
490	Recurrent bronchitis, not specified as acute or chronic
491.0–491.9	Chronic bronchitis
527.7	Disturbance of salivory secretion (drymouth)
528.0	Stomatitis
535.50–535.51	Gastritis
536.8	Dyspepsia
571.8	Other chronic nonalcoholic liver disease
572.0–572.8	Liver abscess and sequelae of chronic liver disease
574.50–574.51	Choledocholitiasis
575.0–575.12	Cholecystitis
576.1	Cholangitis
577.0	Acute pancreatitis
577.1	Chronic pancreatitis
577.8	Pancreatic multiple calculi
590.00–590.9	Infections of the kidney
595.9	Recurrent cystitis
596.4	Bladder atony
596.53	Bladder paresis
599.0	Urinary tract infection, recurrent
607.84	Impotence of organic origin
608.89	Other disorders male genital organs
616.10	Vulvovaginitis
626.0	Amenorrhea
626.4	Irregular menses
628.9	Infertility—female
648.00	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable
648.03	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antipartum condition or complication

Code	Description
648.04	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication
648.80	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable
648.83	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antipartum condition or complication
648.84	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication
656.60–656.63	Fetal problems affecting management of mother—large for-date of fetus
657.00–657.03	Polyhydramnios
680.0–680.9	Carbuncle and furuncle
686.00–686.9	Infections of skin and subcutaneous tissue
698.0	Pruritis ani
698.1	Pruritis of genital organs
704.1	Hirsutism
705.0	Anhidrosis
707.0–707.9	Chronic ulcer of skin
709.3	Degenerative skin disorders
729.1	Myalgia
730.07–730.27	Osteomyelitis of tarsal bones
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.2	Syncope and collapse
780.31	Febrile convulsions
780.39	Seizures, not otherwise specified
780.4	Dizziness and giddiness
780.71–780.79	Malaise and fatigue
780.8	Hyperhidrosis
781.0	Abnormal involuntary movements
782.0	Loss of vibratory sensation
783.1	Abnormal weight gain
783.2	Abnormal loss of weight
783.5	Polydipsia
783.6	Polyphagia
785.0	Tachycardia
785.4	Gangrene
786.01	Hyperventilation
786.09	Dyspnea,
786.50	Chest pain, unspecified
787.6	Fecal incontinence
787.91	Diarrhea
788.41–788.43	Frequency of urination and polyuria
789.1	Hepatomegaly
790.2	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry (hyperglycemia)
791.0	Proteinuria
791.5	Glycosuria
796.1	Abnormal reflex
799.4	Cachexia
V23.0–.9	Supervision of high risk pregnancy
V67.2	Follow-up examination, following chemotherapy
V67.51	Follow up examination with high-risk medication not elsewhere classified
V58.69	Long term current use of other medication

Reasons for Denial:

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

AACE Guidelines for the Management of Diabetes Mellitus, Endocrine Practice (1995)1:149–157.

Bower, Bruce F. and Robert E. Moore, Endocrine Function and Carbohydrates.

Clinical Laboratory Medicine, Kenneth D. McClatchy, editor. Baltimore/Williams & Wilkins, 1994. pp 321–323.

Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, Diabetes Care, Volume 20, Number 7, July 1997, pages 1183 *et seq.*

Roberts, H.J., Difficult Diagnoses. W. B. Saunders Co., pp 69–70.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided.

Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44).

4. Diagnoses documented as ''probable,'' ''suspected,' questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD–9–CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6—other abnormal blood chemistry. If the provider bases the diagnostic statement of impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2—normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

7. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD–9–CM code that best describes the condition is most frequently listed as the reason for the test.

8. When laboratory testing is done solely to monitor response to medication, the most accurate ICD–9–CM code to describe the reason for the test would be V58.69—long term use of medication.

9. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category—follow-up examination.

10. According to ICD–9–CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD–9–CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement, ''thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0–242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD–9–CM must be expanded to include the underlying disease in order to accurately code the condition.

Documentation Requirements

The ordering physician must include evidence in the patient's clinical record that an evaluation of history and physical preceded the ordering of glucose testing and that manifestations of abnormal glucose levels were present to warrant the testing.

Medicare National Coverage Decision for Glycated Hemoglobin/glycated Protein

Description

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.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82985	Glycated protein
83036	Hemoglobin; glycated

Indications

Glycated hemoglobin/protein testing is widely accepted as medically necessary for the management and control of diabetes. It is also valuable 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 particularly useful in patients who have abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

Limitations

It is not considered reasonable and necessary to perform glycated hemoglobin tests more often than every

three months on a controlled diabetic patient to determine whether the patient's metabolic control has been on average within the target range. It is not considered 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 methods for the analysis of glycated hemoglobin show significant 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 the monitoring of the degree of glycemic control in this situation. 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.

ICD–9–CM Codes Covered by the Medicare Program

Code	Description
211.7	Benign neoplasm of islets of Langerhans
250.00–250.93	Diabetes mellitus & various related codes
251.0	Hypoglycemic coma
251.1	Other specified hypoglycemia
251.2	Hypoglycemia unspecified
251.3	Post-surgical hypoinsulinemia
251.4	Abnormality of secretion of glucagon
251.8	Other specified disorders of pancreatic internal secretion
251.9	Unspecified disorder of pancreatic internal secretion
258.0–258.9	Polyglandular dysfunction
271.4	Renal glycosuria
275.0	Hemochromatosis
577.1	Chronic pancreatitis
579.3	Other and unspecified postsurgical nonabsorption
648.00	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable
648.03	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antepartum condition or complication
648.04	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication
648.80	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable
648.83	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antepartum condition or complication
648.84	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication
790.2	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry (hyperglycemia)
962.3	Poisoning by insulin and antidiabetic agents
V12.2	Personal history of endocrine, metabolic, and immunity disorders
V58.69	Long-term use of other medication

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical

Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

Bower, Bruce F. and Robert E. Moore, Endocrine Function and Carbohydrates. Clinical Laboratory Medicine, Kenneth D. McClatchy, editor. Baltimore/ Williams & Wilkins, 1994. pp. 321–323.

Tests of Glycemia in Diabetes. Diabetes Care. 1/98, 21:Supp. 1:S69–S71.

American Association of Clinical Endocrinologists Guidelines for the Management of Diabetes Mellitus

Dons, Robert F., Endocrine and Metabolic Testing Manual, Third Edition. Expert Committee on Glycated Hb. Diabetes Care,. 11/84, 7:6:602–606. Evaluation of Glycated Hb in Diabetes, Diabetes. 7/91, 30:613–617.

Foster, Daniel W., Diabetes Mellitus, Harrison's Principles of Internal Medicine. 13th ed., Kurt J. Isselbacher et al. Editors, New York/McGraw-Hill, 1994, pg. 1990.

Management of Diabetes in Older Patients. Practical Therapeutics. 1991, Drugs 41:4:548–565.

Koch, David D., Fructosamine: How Useful Is It?, Laboratory Medicine, Volume 21, No. 8, August 1990, pp. 497–503.

Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, Diabetes Care, Volume 20, Number 7, July 1997, pp. 1183 et seq.

Sacks, David B., Carbohydrates. In Tietz Textbook of Clinical Chemistry, 2nd Ed., Carl A. Burtis and Edward R. Ashwood, editors. Philadelphia, W.B. Saunders Co., 1994. pp. 980–988.

Tests of Glycemia in Diabetes, American Diabetes Association, Diabetes Care, Volume 20, Supplement I, January 1997, pp. 518–520.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43).

2. Screening is the testing for disease or disease precursors in seemingly well individuals so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no related sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or

exposure to communicable diseases, should be assigned, not a screening code. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52).

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD–9–CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6—other abnormal blood chemistry. If the provider bases the diagnostic statement of impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2—normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

Medicare National Coverage Decision For Thyroid Testing

Other Names/Abbreviations

Description

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.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
84436	Thyroxine; total
84439	Thyroxine; free
84443	Thyroid stimulating hormone (TSH)
84479	Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)

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; and
- 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 personal 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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
017.50–017.56	Tuberculosis of the thyroid gland
183.0	Malignant neoplasm of ovary
193	Malignant neoplasm of thyroid gland

Code	Description
194.8	Malignant neoplasm of other endocrine glands and related structures, other
198.89	Secondary malignant neoplasm of the thyroid
220	Benign neoplasm of ovary
226	Benign neoplasm of thyroid gland
227.3	Benign neoplasm of pituitary gland and craniopharyngeal duct
234.8	Carcinoma in situ of other and unspecified sites
237.4	Neoplasm of uncertain behavior of other and unspecified endocrine glands
239.7	Neoplasm of unspecified nature, thyroid gland
240.0–240.9	Goiter specified and unspecified
241.0–241.9	Nontoxic nodular goiter
242.00–242.91	Thyrotoxicosis with or without goiter
243	Congenital hypothyroidism
244.0–244.9	Acquired hypothyroidism
245.0–245.9	Thyroiditis
246.0–246.9	Other disorders of thyroid
250.00–250.93	Diabetes mellitus
252.1	Hypoparathyroidism
253.1	Other and unspecified anterior pituitary hyper function
253.2	Panhypopituitarism
253.3–253.4	Pituitary dwarfism
253.4	Other anterior pituitary disorders
253.7	Iatrogenic pituitary disorders
255.2	Adrenogenital disorders
255.4	Corticoadrenal insufficiency
256.3	Ovarian failure
257.2	Testicular hypofunction
258.0–258.9	Polyglandular dysfunction
262	Malnutrition, severe
263.0–263.9	Malnutrition, other and unspecified
266.0	Ariboflavinosis
272.0	Pure hypercholesterolemia
272.2	Mixed hyperlipidemia
272.4	Other and unspecified hyperlipidemia
275.40–275.49	Calcium disorders
276.0	Hyposmolality and/or hypernatremia
276.1	Hyposmolality and/or hyponatremia
278.3	Hypercarotinemia
279.4	Autoimmune disorder, not classified elsewhere
281.0	Pernicious anemia
281.9	Unspecified deficiency anemia
283.0	Autoimmune hemolytic anemia
285.9	Anemia, unspecified
290.0	Senile dementia, uncomplicated
290.10–290.13	Presenile dementia
290.20–290.21	Senile dementia with delusional or depressive features
290.3	Senile dementia with delirium
293.0–293.1	Delirium
293.81–293.89	Transient organic mental disorders
294.8	Other specified organic brain syndromes
296.00–296.99	Affective psychoses
297.0	Paranoid state, simple
297.1	Paranoia
297.9	Unspecified paranoid state
298.3	Acute paranoid reaction
300.00–300.09	Anxiety states
307.9	Agitation—other and unspecified special symptoms or syndromes, not elsewhere classified
310.1	Organic personality syndrome
311	Depressive disorder, not elsewhere classified
331.0–331.2	Alzheimer's, pick's disease, Senile degeneration of brain
333.1	Essential and other specified forms of tremor
333.99	Other extrapyramidao diseases and abnormal movement disorders
354.0	Carpal Tunnel syndrome
356.9	Idiopathic peripheral neuropathy, unspecified polyneuropathy
358.1	Myasthenic syndromes in diseases classified elsewhere
359.5	Myopathy in endocrine diseases classified elsewhere
359.9	Myopathy, unspecified
368.2	Diplopia
372.71	Conjunctival hyperemia
372.73	Conjunctival edema
374.41	Lid retraction or lag
374.82	Eyelid edema
376.21	Thyrotoxic exophthalmos
376.22	Exophthalmic ophthlmoplegia
376.30–376.31	Exophthalmic conditions, unspecified and constant

Code	Description
376.33–376.34	Orbital edema or congestion, intermittent exophthalmos
378.50–378.55	Paralytic strabismus
401.0–401.9	Essential hypertension
403.00–403.91	Hypertensive renal disease
404.00–404.93	Hypertensive heart and renal disease
423.9	Unspecified disease of pericardium
425.7	Nutritional and metabolic cardiomyopathy
427.0	Paroxysmal supraventricular tachycardia
427.2	Paroxysmal tachycardia, unspecified
427.31	Atrial fibrillation
427.89	Other specified cardiac dysrhythmia
427.9	Cardiac dysrhythmia, unspecified
428.0	Congestive heart failure
428.1	Left heart failure
429.3	Cardiomegaly
511.9	Unspecified pleural effusion
518.81	Acute respiratory failure
529.8	Other specified conditions of the tongue
560.1	Paralytic ileus
564.0	Constipation
564.7	Megacolon, other than Hirschsprung's
568.82	Peritoneal effusion (chronic)
625.3	Dysmenorrhea
626.0–626.2	Disorders of menstruation
626.4	Irregular menstrual cycle
648.10–648.14	Other current conditions in the mother, classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium, thyroid dysfunction
676.20–676.24	Engorgement of breast associated with childbirth and disorders of lactation
698.9	Unspecified pruritic disorder
701.1	Keratoderma, acquired (dry skin)
703.8	Other specified diseases of nail (Brittle nails)
704.00–704.09	Alopecia
709.01	Vitiligo
710.0–710.9	Diffuse disease of connective tissue
728.2	Muscle wasting
728.9	Unspecified disorder of muscle, ligament, and fascia
729.1	Myalgia and myositis, unspecified
729.82	Musculoskeletal cramp
730.30–730.39	Periostitis without osteomyelitis
733.09	Osteoporosis, drug induced
750.15	Macroglossia, congenital
759.2	Anomaly of other endocrine glands
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.50–780.52	Insomnia
780.6	Fever
780.71–780.79	Malaise and fatigue
780.8	Hyperhidrosis
780.9	Other general symptoms (hyperthermia)
781.0	Abnormal involuntary movements
781.3	Lack of coordination, ataxia
782.0	Disturbance of skin sensation
782.3	Localized edema
782.8	Changes in skin texture
782.9	Other symptoms involving skin and integumentary tissues
783.1	Abnormal weight gain
783.2	Abnormal loss of weight
783.6	Polyphagia
784.1	Throat pain
784.49	Voice disturbance
784.5	Other speech disturbance
785.0	Tachycardia, unspecified
785.1	Palpitations
785.9	Other symptoms involving cardiovascular system
786.09	Other symptoms involving respiratory system
786.1	Stridor
787.2	Dysphagia
787.91–787.99	Other symptoms involving digestive system
789.5	Ascites
793.9	Nonspecific abnormal findings on radiological and other examination, other (neck)
794.5	Thyroid, abnormal scan or uptake
796.1	Other nonspecific abnormal findings, abnormal reflex
799.2	Nervousness

Code	Description
990	Effects of radiation, unspecified
V10.87	Personal history of malignant neoplasm of the thyroid
V10.88	Personal history of malignant neoplasm of other endocrine gland
V12.2	Personal history of endocrine, metabolic and immunity disorders
V58.69	Long term (current) use of other medications
V67.0-V67.9	Follow-up examination

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for routine 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
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- 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases

Code	Description
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

AACE Clinical Practice Guidelines for the Diagnosis and Management of Thyroid Nodules, Endocrine Practice (1996) 2:1, pp. 78–84.

AACE Clinical Practice Guidelines for the Evaluation and Treatment of Hyperthyroidism and Hypothyroidism, Endocrine Practice (1995) 1:1, pp. 54–62.

AACE Clinical Practice Guidelines for the Management of Thyroid Carcinoma, Endocrine Practice (1997) 3:1, pp. 60–71.

Cooper DS. Treatment of thyrotoxicosis. In Braverman LE, Utiger RD, eds. Werner and Ingbar's The Thyroid: A Fundamental and Clinical Text. 6th ed. Philadelphia, Pa: JB Lippincott Co; 1991: 887–916.

Endocrinology. DeGroot LJ, et. al. Eds. 3rd ed. Philadelphia, Pa: W.B. Saunders Co.; 1995.

Endocrinology and Metabolism. Felig, P, Baxter, JD, Frohman, LA, eds.3rd ed. McGraw-Hill, Inc.: 1995.

Franklyn JA. The Management of Hyperthyroidism. N Engl J Med. 1994; 330(24):1731–1738.

Glenn GC and the Laboratory Testing Strategy Task Force of the College of American Pathologists. Practice parameter on laboratory panel testing for screening and case finding in asymptomatic adults. Arch Pathol LabMed. 1996:120:929–43.

Larsen PR, Ingbar SH. The Thyroid Gland. In: Wilson JD, Foster DW, eds. Williams Textbook of Endocrinology. 9th ed. Philadelphia, Pa: WB Saunders Co; 1992:357–487.

The Merck Manual, 16th Edition, pp. 1072–1081.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD–9–CM code that best describes the condition is most frequently listed as the reason for the test.

7. When laboratory testing is done solely to monitor response to medication, the most accurate ICD–9–CM code to describe the reason for the test would be V58.69—long term use of medication.

8. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category—follow-up examination.

9. According to ICD–9–CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD–9–CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement ''thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0–242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD–9–CM must be expanded to include the underlying disease in order to accurately code the condition.

10. Use code 728.9 to report muscle weakness as the indication for the test. Other diagnoses included in 728.9 do not support medical necessity.

11. Use code 194.8 (Malignant neoplasm of other endocrine glands and related structures, Other) to report multiple endocrine neoplasia syndromes (MEN–1 and MEN–2). Other diagnoses included in 194.8 do not support medical necessity.

Documentation Requirements

When these tests are billed at a greater frequency than the norm (two per year), the ordering physician's documentation must support the medical necessity of this frequency.

Medicare National Coverage Decision for Lipids

Other Names/Abbreviations

Description

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 (See Reference). 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.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
80061	Lipid panel
82465	Cholesterol, serum, total
83715	Lipoprotein, blood; electrophoretic separation and quantitation
83716	Lipoprotein, blood: high resolution fractionation and quantitation of lipoprotein cholesterols (for example, electrophoretic, nuclear magnetic resonance, ultracentrifugation)
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721	Lipoprotein, direct measurement, LDL cholesterol
84478	Triglycerides

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 dyslipidemias;
- Any form of atherosclerotic disease;
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism;
- Secondary dyslipidemias, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure; and
- 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 (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD–9–CM code 272.1, Pure hyperglyceridemia).

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 (CPT codes 83715 and 83716) may be indicated if the patient has a primary disorder of lipoid metabolism (ICD–9–CM codes 272.0 to 272.9).

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 estretinate 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 (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD–9–CM code 272.1, Pure hyperglyceridemia).

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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
242.00–245.9	Disorders of the thyroid gland with hormonal dysfunction
250.00–250.93	Diabetes mellitus
255.0	Cushing's syndrome
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe, protein-calorie malnutrition
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.8	Other protein-calorie malnutrition
263.9	Unspecified protein-calorie malnutrition
270.0	Disturbances of amino-acid transport
271.1	Galactosemia
272.0	Pure hypercholesterolemia
272.1	Hyperglyceridemia
272.2	Mixed hyperlipidemia (tuberous xanthoma)
272.3	Hyperchylomicronemia
272.4	Other and unspecified hyperlipidemia (unspecified xanthoma)
272.5	Lipoprotein deficiencies
272.6	Lipodystrophy
272.7	Lipidoses
272.8	Other disorders of lipoid metabolism
272.9	Unspecified disorders of lipoid metabolism
277.3	Amyloidosis
278.00	Obesity
278.01	Morbid obesity
303.90–303.92	Alcoholism
362.10–362.16	Other background retinopathy and retinal vascular change
362.30–362.34	Retinal vascular occlusion
362.82	Retinal exudates and deposits
371.41	Corneal arcus, juvenile
374.51	Xanthelasma
379.22	Crystalline deposits in vitreous
388.00	Degenerative & vascular disorder of ear, unspecified
388.02	Transient ischemic deafness
401.0, 401.9	Essential hypertension
402.00–402.91	Hypertensive heart disease
403.00–403.91	Hypertensive renal disease
404.00–404.93	Hypertensive heart and renal disease
405.01–405.99	Secondary hypertension
410.00–410.92	Acute myocardial infarction
411.0–411.1	Other acute & subacute forms of ischemic heart disease
411.81	Coronary occlusion without myocardial infarction
411.89	Other acute and subacute ischemic heart disease
412	Old myocardial infarction
413.0–413.1	Angina pectoris
413.9	Other and unspecified angina pectoris
414.00–414.03	Coronary atherosclerosis
414.04	Coronary athrscl-artery bypass graft
414.05	Coronary athrscl-unspec graft
414.10	Aneurysm, heart (wall)
414.11	Coronary vessel aneurysm
414.19	Other aneurysm of heart
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
428.0–428.9	Heart failure
429.2	Arteriosclerotic cardiovascular disease
429.9	Heart disease NOS
431	Intracerebral hemorrhage
433.00–433.91	Occlusion & stenosis of precerebral arteries
434.00–434.91	Occlusion of cerebral arteries
435.0–435.9	Transient cerebral ischemia
437.0	Other & ill-defined cerebrovascular disease
437.1	Other generalized ischemic cerebrovascular disease
437.5	Moyamoya disease

Code	Description
438.0–438.9	Late effects of cerebrovascular disease
440.0–440.9	Arteriosclerosis
441.00–441.9	Aortic aneurysms
442.0	Upper extremity aneurysm
442.1	Renal artery aneurysm
442.2	Iliac artery aneurysm
444.0–444.9	Arterial embolism & thrombosis
557.1	Chronic vascular insufficiency of intestine
571.8	Other chronic non-alcoholic liver disease
571.9	Unspecified chronic liver disease without mention of alcohol
573.8	Other specified disorders of liver
573.9	Unspecified disorders of liver
577.0–577.9	Pancreatic disease
579.3	Other & unspecified postsurgical nonabsorption
579.8	Other specified intestinal malabsorption
581.0–581.9	Nephrotic syndrome
584.5	Acute renal failure with lesion of tubular necrosis
585	Chronic renal failure
588.0	Renal osteodystrophy
588.1	Nephrogenic diabetes insipidus
588.8	Other specified disorders resulting from impaired renal function
588.9	Unspecified disorder resulting from impaired renal function
607.84	Impotence of organic origin, penis disorder
646.70–646.71	Liver disorders in pregnancy
646.73	Liver disorder antepartum
648.10–648.14	Thyroid disfunction in pregnancy and the puerperium
696.0	Psoriatic arthropathy
696.1	Other psoriasis
751.61	Biliary atresia
764.10–764.19	''Light for dates'' with signs of fetal malnutrition
786.50	Chest pain unspecified
786.51	Precordial pain
786.59	Chest pain, other
789.1	Hepatomegaly
790.4	Abnormal transaminase
790.5	Abnormal alkaline phosphatase
790.6	Other abnormal blood chemistry
793.4	Abnormal imaging study
987.9	Toxic effect of unspecified gas or vapor
996.81	Complication of transplanted organ, kidney
V42.0	Transplanted organ, kidney
V42.7	Organ replacement by transplant, liver
V58.69	Long term (current) use of other medications

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

American Diabetes Association. Management of Dyslipidemia in Adults with Diabetes. J. Florida M.A. 1998, 85:2 30–34.

Jialal, I. Evolving lipoprotein risk factors: lipoprotein (a) and oxidizing low-density lipoprotein. Clin Chem 1998; 44:8(B) 1827–1832.

McMorrow, ME, Malarkey, L. Laboratory and Diagnostic Tests: A Pocket Guide. W.B. Saunders Company. 206–207.

U.S. Department of Health and Human Services. National Cholesterol Education Program. Recommendations for Improving Cholesterol Measurement. NIH Publication 90–2964. February 1990.

National Institutes of Health. Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. NIH Publication 93–3095. September 1993.

Bierman EL. Atherosclerosis and other forms of arteriosclerosis. Harrison's Principles of Internal Medicine. Eds. Isselbacher KJ, Braunwald E, Wilson JD, et al. McGraw-Hill. New York. 1994; 2058–2069.

Brown MS and Goldstein JL. The hyperlipoproteinemias and other disorders of lipid metabolism. Harrison's Principles of Internal Medicine. Eds. Isselbacher KJ, Braunwald E, Wilson JD, et al. McGraw-Hill. New York. 1994; 1106–1116.

Coding Guidelines

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has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Digoxin Therapeutic Drug Assay

Other Names/Abbreviations

Description

A digoxin therapeutic drug assay is useful for diagnosis and prevention of digoxin toxicity, and/or prevention for under dosage of digoxin.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
80162	Digoxin (Therapeutic Drug Assay)

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; or
- 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; or
- 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 for the treatment of other supraventricular arrhythmias, particularly in the presence of heart failure.

Limitations

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

ICD–9–CM Codes Covered by Medicare Program

Code	Description
242.00–242.91	Thyrotoxicosis with or without goiter
243	Congenital hypothyroidism
244.0–244.9	Acquired hypothyroidism
245.0–245.9	Thyroiditis
275.2	Disorders of magnesium metabolism
275.40–275.49	Disorders of calcium metabolism
276.0	Hyperosmolality
276.1	Hyposmolality
276.2	Acidosis
276.3	Alkalosis
276.4	Mixed acid-base balance disorder
276.5	Volume depletion
276.6	Fluid Overload
276.7	Hyperpotassemia
276.8	Hypopotassemia
276.9	Electrolyte and fluid Disorder (not elsewhere classified)
293.0	Acute delirium
293.1	Subacute delirium
307.47	Other dysfunctions of sleep stages or arousal from sleep
368.16	Psychophysical visual disturbances
368.8	Other specified visual disturbances
368.9	Unspecified visual disturbances
397.9	Rheumatic diseases of endocardium
398.0	Rheumatic Myocarditis

Code	Description
398.91	Rheumatic Heart Failure
402.01	Hypertensive heart disease, malignant with CHF
402.11	Hypertensive heart disease, benign with CHF
402.91	Hypertensive heart disease, unspecified with CHF
403.00–403.91	Hypertensive renal disease
404.00–404.93	Hypertensive heart & renal disease
410.00–410.92	Acute myocardial infarction
411.0–411.89	Other acute & subacute forms of ischemic heart disease
413.0–413.9	Angina pectoris
422.0–422.99	Acute myocarditis
425.0–425.9	Cardiomyopathy
426.0–426.9	Conduction disorders
427.0–427.9	Cardiac dysrhythmias
428.0–428.9	Heart failure
429.2	Cardiovascular disease, unspecified
429.4	Heart Disturbances Postcardiac Surgery
429.5	Rupture chordae tendinae
429.6	Rupture papillary muscle
429.71	Acquired cardiac septal defect
514	Pulmonary congestion & hypostasis
579.9	Unspecified Intestinal malabsorption
584.5–584.9	Acute renal failure
585	Chronic renal failure
586	Renal Failure, unspecified
587	Renal sclerosis, unspecified
588.0	Renal osteodystrophy
588.1	Nephrogenic Diabetes Insipidus
588.8	Impaired renal function (not elsewhere classified)
588.9	Unspecified disorder resulting from impaired renal function
780.01	Coma
780.02	Transient alteration of awareness
780.09	Other ill-defined general symptoms (drowsiness, semicoma, somnolence, stupor, unconsciousness)
780.1	Hallucinations
780.2	Syncope & collapse
780.4	Dizziness and giddiness
780.71–.79	Malaise & fatigue
783.0	Anorexia
784.0	Headache
787.01–787.03	Nausea & vomiting
787.91	Diarrhea
794.31	Abnormal electrocardiogram
799.2	Nervousness
972.0	Poisoning by cardiac rhythm regulators
972.1	Poisoning by cardiotonic glycosides & drugs of similar action
995.2	Unspecified adverse effect of drug, medicinal and biological substance
*E942.1	Adverse effect of cardiotonic glycosides and drugs of similar action
V58.69	Encounter long term—Medication Use (not elsewhere classified)

*Code may not be reported as a stand-alone or first-listed code on the claim.

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
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- 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing

performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0—V17.8	Family history of certain chronic disabling diseases
V18.0—V18.8	Family history of certain other specific conditions
V19.0—V19.8	Family history of other conditions
V20.0—V20.2	Health supervision of infant or child
V28.0—V28.9	Antenatal screenings
V50.0—V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0—V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0—V68.9	Encounters for administrative purposes
V70.0—V70.9	General medical examinations
V73.0—V73.99	Special screening examinations for viral and chlamydia diseases
V74.0—V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0—V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42—V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0—V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0—V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0—V79.9	Special screening for mental disorders
V80.0—V80.3	Special screening for neurological, eye, and ear diseases
V81.0—V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0—V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

Doherty JE. Digitalis serum levels: clinical use. Ann Intern Med 1971 May; 74(5):787–789.

Duhme DW, Greenblatt DJ, Koch-Weser J. Reduction of digoxin toxicity associated with measurement of serum levels. A report from the Boston Collaborative Drug Surveillance Program. Ann Intern Med 1974 Apr; 80(4):516–519

Goldman RH. The use of serum digoxin levels in clinical practice. JAMA 1974, Jul 15; 229(3):331–332.

Howanitz PJ, Steindel SJ. Digoxin therapeutic drug monitoring practices. A College of American Pathologists Q-Probes study of 666 institutions and 18,679 toxic levels. Arch Pathol Lab Med 1993 Jul; 117(7):684–690.

Marcus FI. Pharmacokinetic interactions between digoxin and other drugs. J Am Coll Cardiol 1985 May; 5(5 Suppl A):82A–90A.

Rodin SM, Johnson BF. Pharmacokinetic interactions with digoxin. Clin Pharmaco-kinet 1988 Oct; 15(4):227–244.

Smith TW, Butler VP Jr, Haber E. Determination of therapeutic and toxic serum digoxin concentrations by radioimmunoassay. N Engl J Med 1969 Nov 27; 281(22):1212–1216.

Smith TW, Haber E. Digoxin intoxication: the relationship of clinical presentation to serum digoxin concentration. J Clin Invest 1970, Dec; 49 (12):2377–2386.

Valdes R Jr, Jortani SA, Gheorghiade M. Standards of laboratory practice: cardiac drug monitoring. National Academy of Clinical Biochemistry. Clin Chem 1998 May; 44(5): 1096–1109.

Konstam M, Dracup K, Baker D, et al. Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction. Clinical Practice Guideline No. 11. AHCPR Publication No. 94–0612. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. June 1994.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom

is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Alpha-fetoprotein
Other Names/Abbreviations: Afp

Description

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.

HCPCS Codes (alpha numeric CPT © AMA)

Code	Descriptor
82105	Alpha-fetoprotein; serum

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.

Limitations

ICD–9–CM Codes Covered by Medicare Program

Code	Description
070.22–070.23	Chronic viral hepatitis B with hepatic coma, with or without mention of hepatitis delta
070.32–070.33	Chronic viral hepatitis B without mention of hepatic coma, with or without mention of hepatitis delta
070.44	Chronic hepatitis C with hepatic coma
070.54	Chronic hepatitis C without mention of hepatic coma
095.3	Syphilis of liver
121.1	Clonorchiasis
121.3	Fascioliasis
155.0–155.2	Malignant neoplasm of the liver and intrahepatic bile ducts
164.2–164.9	Malignant neoplasm of the mediastinum
183.0	Malignant neoplasm, ovary
186.0	Malignant neoplasm of undescended testis
186.9	Malignant neoplasm, other and unspecific testis
197.1	Secondary malignant neoplasm of mediastinum
197.7	Secondary malignant neoplasm of liver
198.6	Secondary malignant neoplasm of ovary
198.82	Secondary malignant neoplasm, genital organs
211.5	Benign neoplasm of liver and biliary passages
235.3	Neoplasm of uncertain behavior of liver and biliary passages
272.2	Mixed hyperlipidemia
275.0	Disorder of iron metabolites
275.1	Disorder of copper metabolism
277.00	Cystic Fibrosis without mention of meconium ileus
277.6	Other deficiencies of circulating enzymes
285.0	Sideroblastic Anemia
571.2	Alcoholic cirrhosis of liver
571.40	Chronic hepatitis, unspecified
571.41	Chronic persistent hepatitis
571.49	Other chronic hepatitis
571.5	Cirrhosis of liver without mention of alcohol
608.89	Other specified disorders of male genital organs
793.1	Non-specific abnormal findings of lung field
793.2	Non-specific abnormal findings of other intrathoracic organs
793.3	Non-specific abnormal findings of biliary tract
793.6	Non-specific abnormal findings of abdominal area, including retro peritoneum
V10.07	Personal history of malignant neoplasm, liver

Code	Description
V10.43	Personal history of malignant neoplasm, ovary
V10.47	Personal history of malignant neoplasm, testis

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

Tatsuta M. Yamamura H. Iishi H. Kasugai H. Okuda S.Value of serum alpha-fetoprotein and ferritin in the diagnosis of hepatocellular carcinoma. Oncology. 43(5):306–10, 1986.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition described by that code must be related to the above indications for the test.

Medicare National Coverage Decision for Carcinoembryonic Antigen

Other Names/Abbreviations: CEA

Description

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.

HCPCS Codes (Alpha numeric, CPT © AMA)

Code	Descriptor
82378	Carcinoembryonic antigen (CEA)

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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
150.0–150.9	Malignant neoplasm of the esophagus
151.0–151.9	Malignant neoplasm of stomach
152.0–154.8	Malignant neoplasm of small intestine, including duodenum, rectum, rectosigmoid junction and anus.
157.0–157.9	Primary malignancy of pancreas
159.0	Malignant neoplasm of intestinal tract, part unspecified

Code	Description
162.0–162.9	Malignant neoplasm of trachea, bronchus, lung
174.0–174.9	Malignant neoplasm of female breast
175.0–175.9	Malignant neoplasm of male breast
183.0	Malignant neoplasm of ovary
197.0	Secondary malignant neoplasm of neoplasm of lung
197.4	Secondary malignant neoplasm of small intestine
197.5	Secondary malignant neoplasm of large intestine and rectum
230.3	Carcinoma in situ of colon
230.4	Carcinoma in situ of rectum
230.7	Carcinoma in situ of other/unspecified parts of intestine
230.9	Carcinoma in situ other and unspecified digestive organs
235.2	Neoplasm of uncertain behavior of stomach, intestines, rectum
790.99	Other nonspecific findings on examination of blood
V10.00	Personal history of malignant neoplasm of gastro-intestinal tract, unspecified
V10.3	Personal history of malignant neoplasm, breast
V10.05	Personal history of malignant neoplasm, large intestine
V10.06	Personal history of malignant neoplasm, rectum, rectosigmoid junction, anus
V10.11	Personal history of malignant neoplasm, bronchus, and lung
V10.43	Personal history of malignant neoplasm, ovary
V67.2	Follow-up examination following chemotherapy

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person

Code	Description
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

Journal Clinical Oncol: 14 (10:2843–2877), 1996

Vauthey JN. Dudrick PS. Lind DS. Copeland EM 3rd. Management of recurrent colorectal cancer: another look at carcinoembryonic antigen©detected recurrence [see comments]. [Review] Digestive Diseases. 14(1):5–13, 1996 Jan–Feb.

Grem J. The prognostic importance of tumor markers in adenocarcinomas of the gastrointestinal tract. [Review] [38 refs] Current Opinion in Oncology. 9(4):380–7, 1997 Jul.

Bergamaschi R. Arnaud JP. Routine compared with nonscheduled follow-up of patients with ''curative'' surgery for colorectal cancer. Annals of Surgical Oncology. 3(5):464–9, 1996 Sep.

Kim YH. Ajani JA. Ota DM. Lynch P. Roth JA. Value of serial carcinoembryonic antigen levels in patients with resectable adenocarcinoma of the esophagus and stomach Cancer. 75(2):451–6, 1995 Jan 15.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected, ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. To show elevated CEA, use ICD–9–CM 790.99 (Other nonspecific findings on examination of blood) only if a more specific diagnosis has not been made. If a more specific diagnosis has been made, use the code for that diagnosis.

Medicare National Coverage Decision for Human Chorionic Gonadotropin

Other Names/Abbreviations: hCG

Description

Human chorionic gonadotropin.

HCPCS Codes (Alpha numeric, CPT © AMA)

Code	Descriptor
84702	Gonodotropin, chorionic (hCG); quantitative

Indications

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, hyperension and/or suspected fetal loss.

Limitations

Not more than once per month for diagnostic purposes. As needed for monitoring of patient progress and treatment. Qualitative hCG assays (CPT

84703) are not appropriate for medically managing patients with known or suspected germ cell neoplasms.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
158.0	Malignant neoplasm of retroperitoneum
158.8	Malignant neoplasm of specified parts of peritoneum
164.2	Malignant neoplasm of anterior mediastinum
164.3	Malignant neoplasm of posterior mediastinum
164.8	Malignant neoplasm, other (includes malignant neoplasm of contiguous overlapping sites of thymus, heart, and mediastinum whose point of origin cannot be determined
164.9	Malignant neoplasm of mediastinum, part unspecified
181	Malignant neoplasm of placenta
183.0	Malignant neoplasm of ovary
183.8	Other specified sites of uterine adnexas
186.0	Malignant neoplasm of undescended testes
186.9	Malignant neoplasm of other and unspecified testis
194.4	Malignant neoplasm of pineal gland
197.1	Secondary malignant neoplasm of mediastinum
197.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
198.6	Secondary malignant neoplasm of ovary
198.82	Secondary malignant neoplasm of other genital organs
236.1	Neoplasm of uncertain behavior, placenta
623.8	Vaginal bleeding
625.9	Pelvic pain
630	Hydatidiform mole
631	Pregnancy, molar
632	Missed abortion
633.9	Ectopic pregnancy
634.00–634.02	Spontaneous abortion, complicated by genital tract and pelvic infection
640.00–640.03	Threatened abortion
642.30–642.34	Transient hypertension of pregnancy
642.40–642.74	Pre-eclampsia or eclampsia
642.90–642.94	Unspecified hypertension complicating pregnancy, childbirth, or the proerperium
V10.09	Personal history of malignant neoplasm, other gastrointestinal sites
V10.29	Personal history of malignant neoplasm of other respiratory and intrathoracic organs
V10.43	Personal history of malignant neoplasm, ovary
V10.47	Personal history of malignant neoplasm, testis
V22.0–V22.1	Pregnancy

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids

Code	Description
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

O'Callaghan A. Mead GM. Testicular carcinoma. [Review] [23 Refs] Postgraduate Medical Journal. 73(862):4816, 1997 Aug.

Sawamura Y. Current diagnosis and treatment of central nervous system germ cell tumours. [Review] [47 Refs] Current Opinion in Neurology. 9(6):41923, 1996 Dec.

Wilkins M. Horwich A. Diagnosis and treatment of urological malignancy: The testes. [Review] [23 Refs] British Journal of Hospital Medicine. 55(4): 199203, 1996. Feb 21, Mar 5.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Tumor Antigen by Immunoassay—CA125

Other Names/Abbreviations

Description

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 CA125.

HCPCS Codes (alpha numeric, CPT ©AMA)

Code	Descriptor
86304	Immunoassay for tumor antigen, quantitative, 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.

A CA125 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.

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.

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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
180.0	Malignant neoplasm, endocervix
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm,ovary
183.2	Malignant neoplasm, fallopian tube
183.8	Malignant neoplasm, other specified sites of uterine adnexa
184.8	Malignant neoplasm, other specified sites of female genital organs
198.6	Secondary malignant neoplasm, ovary
198.82	Secondary malignancy of genital organs
236.0–236.3	Neoplasm of uncertain behavior of female genital organs
V10.43–V10.44	Personal history of malignant neoplasm of female genital organs

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Chan DW, Beveridge RA, Muss H, et al. Use of Triquant BR Radioimmunoassay for Early Detection of Breast Cancer Recurrence in Patients with Stage II and Stage III Disease. J Clin Oncol 1977, 15(6):2322–2328.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Documentation Requirements

Indicated if service request for CA125 is requested more frequently than stipulated.

Medicare National Coverage Decision for Tumor Antigen by Immunoassay CA 15–3/CA 27.29

Other Names/Abbreviations

Description

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 antigens: CA 15–3 and CA 27.29

HCPCS Codes (Alpha Numeric, CPT–AMA)

Code	Descriptor
86300	Immunoassay for tumor antigen, quantitative; CA 15–3 (27.29)

Indications

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether 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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
174.0–174.9	Breast, primary (female)—malignant neoplasm of female breast
175.0–175.9	Breast, primary (male)—malignant neoplasm of male breast
198.2	Secondary malignant neoplasm (male breast)
198.81	Secondary malignant neoplasm (female breast)
V10.3	Personal history of malignant neoplasm, breast

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemi
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms

Code	Description
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0—V17.8	Family history of certain chronic disabling diseases
V18.0—V18.8	Family history of certain other specific conditions
V19.0—V19.8	Family history of other conditions
V20.0—V20.2	Health supervision of infant or child
V28.0—V28.9	Antenatal screenings
V50.0—V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0—V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0—V68.9	Encounters for administrative purposes
V70.0—V70.9	General medical examinations
V73.0—V73.99	Special screening examinations for viral and chlamydia diseases
V74.0—V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0—V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42—V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0—V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0—V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0—V79.9	Special screening for mental disorders
V80.0—V80.3	Special screening for neurological, eye, and ear diseases
V81.0—V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0—V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Chan DW, Beveridge RA, Muss H, et al. Use of Triquant BR Radioimmunoassay for Early Detection of Breast Cancer Recurrence in Patients with Stage II and Stage III Disease. J Clin Oncol 1977, 15(6):2322–2328.

Bone GG, von Mensdorff-Pouilly S, Kenemans P, van Kamp GJ, et al. Clinical and Technical Evaluation of ACS BR Serum Assay of MUC–1 Gene Derived Glycoprotein in Breast Cancer, and Compared with CA15–3 Assays. Clin Chem 1997, 43(4):585–593.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Tumor Antigen by Immunoassay CA 19–9

Other Names/Abbreviations:

Description

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.

HCPCS Codes (Alpha Numeric, CPT © AMA)

Code	Descriptor
86301	Immunoassay for tumor antigen, quantitative; CA 19–9

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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
155.1	Malignant neoplasm, intrahepatic bile ducts
156.1	Malignant neoplasm, extrahepatic bile ducts
156.8	Malignant neoplasm, other specified sites of gallbladder and extrahepatic bile ducts
156.9	Malignant neoplasm, unspecified part of biliary tract
157.0–157.9	Malignant neoplasm, pancreas
197.8	Secondary malignant neoplasm, other digestive organs and spleen
235.3	Neoplasm of uncertain behavior, liver and biliary passages
235.5	Neoplasm of uncertain behavior, other and unspecified digestive organs
V10.09	Other personal history of cancer

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions

Code	Description
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Richter JM, Christensen MR, Rustgi AK, and Silverstein MD. The Clinical Utility of the CA19–9 Radioimmunoassay for the Diagnosis of Pancreatic Cancer Presenting as Pain or Weight Loss: A Cost Effective Analysis. Arch Intern Med 1989, 149:2292–2297.

Safi F, SchlosseW, Falkenreck S, et. al. Prognostic Value of CA 19–9 Serum Course in Pancreatic Cancer. Hepaetogastroenterology 1998 Jan–Feb; 45(19):253–9.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Prostate Specific Antigen

Other Names/Abbreviations: Total PSA

Description

PSA, a tumor marker for adenocarcinoma of the prostate, can predict residual tumor in the post-operative phase of prostate cancer. Three to six 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 as capable 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.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
84153	Prostate Specific Antigen (PSA), total

Indications

PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms (e.g., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and 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 in 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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
185	Malignant neoplasm of prostate
188.5	Malignant neoplasm of bladder neck
196.5	Secondary malignant neoplasm, lymph nodes inguinal region and lower limb
196.6	Secondary malignant neoplasm, intrapelvic lymph nodes
196.8	Secondary malignant neoplasm, lymph nodes of multiple sites
198.5	Secondary malignant neoplasm, bone and bone marrow
198.82	Secondary malignant neoplasm, genital organs
233.4	Carcinoma in situ, prostate
236.5	Neoplasm of uncertain behavior of prostate
239.5	Neoplasm of unspecified nature, other genitourinary organs
596.0	Bladder neck obstruction
599.6	Urinary obstruction, unspecified
599.7	Hematuria
601.9	Unspecified prostatitis
602.9	Unspecified disorder of prostate
788.20	Retention of urine, unspecified
788.21	Incomplete bladder emptying
788.30	Urinary incontinence, unspecified
788.41	Urinary frequency
788.43	Nocturia
788.62	Slowing of urinary stream
790.93	Elevated prostate specific antigen
793.6/793.7	Non-specific abnormal result of radiologic examination, evidence of malignancy
794.9	Bone scan evidence of malignancy
V10.46	Personal history of malignant neoplasm; prostate

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing

performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Laboratory Test Handbook, 3rd edition, pp. 338–340.

Cooner WH, Mosley BR, Rutherford CL, et al. Prostate Cancer Detection in a Clinical Urological Practice by Ultrasonography, Digital Rectal Examination and Prostate Specific Antigen. J.Urol.1990;143: 1146–1154.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign,

symptom or condition must be related to the indications for the test above.

6. To show elevated PSA, use ICD–9–CM code 790.93 (Elevated prostate specific antigen). If a more specific diagnosis code has been made, use the code for that diagnosis.

Medicare National Coverage Decision for Gamma Glutamyl Transferase

Other Names/Abbreviations: GGT

Description

Gamma glutamyltransferase (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 bilirubin 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.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82977	Glutamyltransferase, gamma (GGT)

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); or
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.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
003.1	Salmonella septicemia
006.0–006.9	Amebiasis
014.00–014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands
017.90–017.96	Tuberculosis of other specified organs
018.90–018.96	Miliary tuberculosis, unspecified
020.0–020.9	Plague
022.3	Anthrax septicemia
027.0	Listeriosis
027.1	Erysipelothrix infection
030.1	Tuberculoid leprosy [Type T]
032.83	Diphtheritic peritonitis
036.1	Meningococcal encephalitis
036.2	Meningococcemia
038.0–038.9	Septicemia
039.2	Actinomycotic infections, abdominal
040.0	Gas gangrene

Code	Description
042	Human immunodeficiency virus (HIV) disease
054.0	Eczema herpeticum
054.5	Herpetic septicemia
060.0–060.1	Yellow fever
070.0–070.9	Viral hepatitis
072.71	Mumps hepatitis
073.0	Ornithosis, with pneumonia
074.8	Other specified diseases due to Coxsackie virus
075	Infectious mononucleosis
078.5	Cytomegaloviral disease
079.99	Unspecified viral infection
082.0–082.9	Tick-borne rickettsioses, stet
084.9	Other pernicious complications of malaria
086.1	Chagas disease with organ involvement other than heart
088.81	Lyme disease
091.62	Secondary syphilitic hepatitis
095.3	Syphilis of liver
100.0	Leptospirosis icterohemorrhagica
112.5	Candidiasis, disseminated
115.00	Infection by Histoplasma capsulatum without mention of manifestation
120.9	Schistosomiasis, unspecified
121.1	Clonorchiasis
121.3	Fascioliasis
122.0	Echinococcus granulosus infection of liver
122.5	Echinococcus multilocularis infection of liver
122.8	Echinococcosis, unspecified, of liver
122.9	Echinococcus, other and unspecified
130.5	Hepatitis due to toxoplasmosis
135	Sarcoidosis
150.0–159.9	Malignant neoplasm of digestive organs and peritoneum
160.0–165.9	Malignant neoplasm of respiratory and intrathoracic organs
170.0–176.9	Malignant neoplasm of bone, connective tissue, skin, and breast
179–189.9	Malignant neoplasm of genitourinary organs
200.00–208.91	Malignant neoplasm of lymphatic and hematopoietic tissue
211.5	Benign neoplasm of liver and biliary passages
211.6	Benign neoplasm of pancreas, except islets of Langerhans
211.7	Benign neoplasm of islets of Langerhans
228.04	Hemangioma of intra-abdominal structures
230.7	Carcinoma in situ of other and unspecified parts of intestine
230.8	Carcinoma in situ of liver and biliary system
230.9	Carcinoma in situ other and unspecified digestive organs
235.0–238.9	Neoplasms of uncertain behavior
239.0	Neoplasm of unspecified nature of digestive system
250.00–250.93	Diabetes mellitus
252.0	Hyperparathyroidism
263.1	Malnutrition of mild degree
263.9	Unspecified protein-calorie malnutrition
268.0	Rickets, active
268.2	Osteomalacia, unspecified
269.0	Deficiency of vitamin K
270.2	Other disturbances of aromatic amino acid metabolism
270.9	Unspecified disorder of amino acid metabolism
271.0	Glycogenosis
272.0	Pure hypercholesterolemia
272.1	Pure hyperglyceridemia
272.2	Mixed hyperlipidemia
272.4	Other and unspecified hyperlipidemia
272.7	Lipidoses
272.9	Unspecified disorder of lipoid metabolism
275.0	Disorders of iron metabolism
275.1	Disorders of copper metabolism
275.3	Disorders of phosphorus metabolism
275.40–275.49	Disorders of calcium metabolism
277.1	Disorders of porphyrin metabolism
277.3	Amyloidosis
277.4	Disorders of bilirubin excretion
277.6	Other deficiencies of circulating enzymes
282.60–282.69	Sickle cell anemia
286.6	Defibrination syndrome
286.7	Acquired coagulation factor deficiency
289.4	Hypersplenism
291.0–291.9	Alcoholic psychoses
303.00–303.03	Acute alcoholic intoxication
303.90–303.93	Other and unspecified alcohol dependence

Code	Description
304.0–304.9	Drug dependence
305.00–305.93	Non-dependent abuse of drugs
357.5	Alcoholic polyneuropathy
359.2	Myotonic disorders
452	Portal vein thrombosis
453.0–453.9	Other vein embolism and thrombosis
456.0–456.21	Esophageal varices
555.0–555.9	Regional enteritis
556.0–556.9	Ulcerative colitis
557.0	Acute vascular insufficiency of intestine
558.1–558.9	Other noninfectious gastroenteritis and colitis
560.0–560.9	Intestinal obstruction without mention of hernia
562.01	Diverticulitis of small intestine (without mention of hemorrhage)
562.03	Diverticulitis of small intestine with hemorrhage
562.11	Diverticulitis of colon (without mention of hemorrhage)
562.13	Diverticulitis of colon with hemorrhage
567.0–567.9	Peritonitis
569.83	Perforation of intestine
570	Acute and subacute necrosis of liver
571.0–571.9	Chronic liver disease and cirrhosis
572.0–572.8	Liver abscess and sequelae of chronic liver disease
573.0–573.9	Other disorders of liver
574.00–574.91	Cholelithiasis
575.0–575.9	Other disorders of gallbladder
576.0–576.9	Other disorders of biliary tract
581.0–581.9	Nephrotic syndrome
582.0–582.9	Chronic glomerulonephritis
583.0–583.9	Nephritis and nephropathy not specified as acute or chronic
584.5–584.9	Acute renal failure
585	Chronic renal failure
586	Renal failure, unspecified
587	Renal sclerosis, unspecified
588.0–588.9	Disorders resulting from impaired renal function
590.00–590.9	Infections of kidney
642.5	Severe pre-eclampsia
646.7	Liver disorders in pregnancy
782.4	Jaundice, unspecified, not of newborn
789.1	Hepatomegaly
790.4	Nonspecific elevation of levels of transaminase or lactic acid dehydrgenase
790.5	Other nonspecific abnormal serum enzyme levels
960.0–979.9	Poisoning by drugs, medicinal, and biological substances
980.0–989.89	Toxic effects of substances chiefly nonmedical as to source
V42.7	Organ replaced by transplant, liver
V58.61–V58.69	Long term (current) drug use
V67.1	Follow-up examination, radiotherapy
V67.2	Follow-up examination, chemotherapy
V67.51	Follow-up examination after completed treatment with high-risk medications, not elsewhere classified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing

performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Ockner, R.K., ''Clinical approach to liver disease,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 808–809.

Ockner, R.K., ''Laboratory tests in liver disease,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 814–817.

Gornall, A.G., and Goldberg, D.M., ''Hepatobiliary Disorders,'' in Gornall, A.G. (ed.)., *Applied Biochemistry of Clinical Disorders* (2nd ed.), 1986, J.B. Lippincott, pp. 211–246.

Scharschmidt, B.F., ''Parasitic, bacterial, fungal, and granulomatous liver disease,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 834–838.

Pincus, M.R., and Schaffner, J.A., ''Assessment of liver function,'' in Henry, J.B. (ed.), *Clinical Diagnosis and Management by Laboratory Methods* (19th ed.), 1996, W.B. Saunders, pp. 253–267.

Bordley, D.R., Nattinger, A.B., *et al.,* ''Gastrointestinal, Hepatobiliary, and Pancreatic Problems,'' in Panzer, R.J., Black, E.R., and Griner, P.F. (eds.), *Diagnostic Strategies for Common Medical Problems,* 1991, American College of Physicians, pp. 94–185.

Tietz, N.W. (ed.), *Clinical guide to Laboratory Tests* (3rd ed.), 1995, pp. 286–287.

Zakim, D., and Boyer, T.D., *Hepatology* (2nd ed.), 1990, W.B. Saunders.

Dufour, D.R., Clinical Use of Laboratory Data: A Practical Guide, 1998, Williams and Wilkins, pp. 142–155.

Harrison's Principles of Internal Medicine (14th ed.), 1998, McGraw Hill

Wallach, J., *Interpretation of Diagnostic Tests,* 1996, Little Brown and Co.

Illustrated Guide to Diagnostic Tests (2nd ed.), 1997, Springhouse Corporation.

Sleisenger and Fordtrans's Gastrointestinal and Liver Disease (6th ed.), 1997, W.B. Saunders.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Hepatitis Panel

Description

This panel consists of the following tests:

Hepatitis B surface antigen (HBsAg) (CPT 87340)
Hepatitis C antibody (CPT 86803)
Hepatitis B core antibody (HBcAb), IgM Antibody (CPT 86705)
Hepatitis A antibody (HAAb), IgM Antibody (CPT 86709)

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, D, 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, parenteral infection is possible during the acute viremia stage of the disease. After 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, remains positive indefinitely, and confers immunity. HBV is spread exclusively by 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 a 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 0responsible 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 of 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.

HCPCS Codes (Alpha Numeric, CPT © AMA)

Code	Descriptor
80074	Acute Hepatitis Panel

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 has been established, only individual tests, rather than the entire panel, are needed.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
070.0–070.9	Viral hepatitis
456.0–456.21	Esophageal varices with or without mention of bleeding
570	Acute and subacute necrosis of liver
571.5	Cirrhosis of liver without mention of alcohol
572.0–572.8	Liver abscess and sequelae of chronic liver disease
573.3	Hepatitis, unspecified
780.31	Febrile convulsions
780.71	Chronic fatigue syndrome
780.79	Other malaise and fatigue
782.4	Jaundice, unspecified, not of newborn
783.0–783.6	Symptoms concerning nutrition, metabolism, and development
784.69	Other symbolic dysfunction
787.01–787.03	Nausea and vomiting
789.00–789.09	Abdominal pain
789.1	Hepatomegaly
789.6	Localized abdominal tenderness (RUQ)
794.8	Nonspecific abnormal results of function
999.3	Other infection following infusion
996.82	Complications of transplanted organ, liver
V72.85	Liver transplant recipient evaluation

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies 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. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such 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 may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–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 or local 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 laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs

Code	Description
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Ockner, R.K., ''Approaches to the diagnosis of jaundice,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 817–818.

Ockner, R.K., ''Acute viral hepatitis,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 818–826.

Ockner, R.K., ''Chronic hepatitis,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 830–834.

Arvan, D.A., ''Acute viral hepatitis,'' in Panzer, R.J., Black, E.R., and Griner, P.F. (eds.), *Diagnostic Strategies for Common Medical Problems,* 1991, American College of Physicians, pp. 141–151.

Goldberg, D.M., ''Diagnostic Enzymology,'' in Gornall, A.G. (ed.), *Applied Biochemistry of Clinical Disorders* (2nd ed.), 1986, J.B. Lippincott, pp. 33–51.

Pincus, M.R., and Schaffner, J.A., ''Assessment of liver function,'' in Henry, J.B. (ed.), *Clinical Diagnosis and Management by Laboratory Methods* (19th ed.), 1996, W.B. Saunders, pp. 253–267.

Tietz, N.W. (ed.), *Clinical Guide to Laboratory Tests* (3rd ed.), 1995, pp. 320–327.

Zakim, D., and Boyer, T.D., *Hepatology* (2nd ed.), 1990, W.B. Saunders.

Harrison's Principles of Internal Medicine (14th ed.), 1998, McGraw Hill.

Wallach, J., *Interpretation of Diagnostic Tests,* 1996, Little Brown and Co.

Illustrated Guide to Diagnostic Tests (2nd ed.), 1997, Springhouse Corporation.

Sleisenger and Fordtrans's Gastrointestinal and Liver Disease (6th ed.), 1997, W.B. Saunders.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the 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 patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of