CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare National Coverage Determinations (NCD) Manual
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Clinical Diagnostic Laboratory Services

MEDICARE NATIONAL COVERAGE DETERMINATIONS

Clinical Diagnostic Laboratory Services

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INTRODUCTION

Background

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Public Law 105-33, mandated the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. This provision requires that these national coverage policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services in connection with the following:
Beneficiary information required to be submitted with each claim or order for laboratory services;
The medical condition for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Social Security Act);
The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services;
The medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test (in accordance with section 1833(e) of the Act);
Record keeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding these requirements;
Procedures for filing claims and for providing remittances by electronic media; and
Limitations on frequency of coverage for the same services performed on the same individual.

On March 10, 2000, a proposed rule was published in the Federal Register (65 FR 13082) that set forth uniform national coverage and administrative policies for clinical diagnostic laboratory

services. These proposed policies reflected the consensus of the Negotiated Rulemaking Committee. The final rule, published in the Federal Register on November 23, 2001 (66 FR 58788), addresses the public comments received on the proposed rule. The final rule established the national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. It promotes Medicare program integrity and national uniformity, and simplifies administrative requirements for clinical diagnostic services. There are 23 national coverage determinations included in the final rule. Those determinations are listed below:

Culture, Bacterial, Urine
Human Immunodeficiency Virus Testing (Prognosis including monitoring)
Human Immunodeficiency Virus Testing (Diagnosis)
Blood Counts
Partial Thromboplastin Time
Prothrombin Time
Serum Iron Studies
Collagen Crosslinks, Any Method
Blood Glucose Testing
Glycated Hemoglobin/ Glycated Protein
Thyroid Testing
Lipids
Digoxin Therapeutic Drug Assay
Alpha-fetoprotein
Carcinoembryonic Antigen
Human Chorionic Gonadotropin
Tumor Antigen by Immunoassay - CA125
Tumor Antigen by Immunoassay CA 15-3/CA 27.29
Tumor Antigen by Immunoassay CA 19-9
Prostate Specific Antigen
Gamma Glutamyl Transferase
Hepatitis Panel/Acute Hepatitis Panel
Fecal Occult Blood

What Is a National Coverage Policy?

Part B of title XVIII of the Social Security Act (the Act) provides for Supplementary Medical Insurance (SMI) for certain Medicare beneficiaries, specifying what health care items or services will be covered by the Medicare Part B program. Diagnostic laboratory tests are generally covered under Part B, unless excluded from coverage by the Act. Services that are generally excluded from coverage include routine physical examinations and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute. A test may be considered medically appropriate, but nonetheless be excluded from Medicare coverage by statute. A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide. A national coverage policy is neither a practice parameter nor a statement of the accepted standard of medical practice. Words such as ''may be indicated'' or ''may be considered medically necessary'' are used for this reason. Where a policy gives a general description and then lists examples (following words like ''for example'' or ''including''), the list of examples is not meant to be all-inclusive but merely to provide some guidance.

What Is the Effect of a National Coverage Policy?

A national coverage policy to which this introduction applies is a National Coverage Decision (NCD) under section 1862(a)(1) of the Social Security Act. Regulations on National Coverage Decisions are codified at 42 CFR 405.732(b)-(d). A Medicare contractor may not develop a local policy that conflicts with a national coverage policy.

What Is the Format for These National Coverage Policies?
Below are the headings for national coverage policies, developed by the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests.

Other Names/Abbreviations
This section identifies other names for the policy. It generally reflects more colloquial terminology.

Description
This section includes a description of the test(s) addressed by the policy and provides a general description of the appropriate uses of the test(s).

HCPCS Codes
The descriptor(s) used in this section is (are) the Current Procedural Terminology (CPT) or other CMS Common Procedure Coding System (HCPCS). The CPT is developed and copyrighted by the American Medical Association (AMA). If a descriptor does not accurately or fully describe the test, a more complete description may be included elsewhere in the policy, such as in the *Indications* section.

ICD–9–CM Codes Covered by Medicare Program
This section includes covered codes—those where there is a presumption of medical necessity, but the claim is subject to review to determine whether the test was in fact reasonable and necessary. The diagnosis codes are from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). Where the policy takes an ''exclusionary'' approach, as described below, this section states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM code sections below.''

Indications
This section lists detailed clinical indications for Medicare coverage of the test(s).

Limitations
This section lists any national frequency expectations, as well as other limitations on Medicare coverage of the specific test(s) addressed in the policy—for example, if it would be unnecessary to perform a particular test with a particular combination of diagnoses.

ICD–9–CM Codes That Do Not Support Medical Necessity
This section lists/describes generally non-covered codes for which there are only limited exceptions. However, additional documentation could support a determination of medical necessity in certain circumstances. Subject to section 1879 of the Social Security Act (the Act), 42 CFR 411, subpart K, section 7330 of the Medicare Carriers Manual section 3440–3446.9 of the Medicare Fiscal Intermediary Manual and any applicable rulings, it would be appropriate for the ordering physician or the laboratory to obtain an advance beneficiary notice from the beneficiary. Where the policy takes an ''inclusionary'' approach, as described below, this section states: ''Any ICD–9–CM code not listed in either of the
ICD–9–CM sections above.''

Other Comments
This section may contain any other relevant comments that are not addressed in the sections described above.

Documentation Requirements
This section refers to documentation requirements for clinical diagnostic laboratory tests at 42 CFR 410.32(d) and includes any specific documentation requirements related to the test(s) addressed in the policy.

Sources of Information
Relevant sources of information used in developing the policy are listed in this section.

NON-COVERED ICD-9-CM CODES

FOR ALL NCD EDITS

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

Code:	**Descriptor:**
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
V16.40	Family history of malignant neoplasm, genital organs
V16.51-V16.59	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 - V77.99	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

REASONS FOR DENIAL

FOR ALL NCD EDITS

Note: This section has not been negotiated by the Negotiated Rulemaking Committee. It includes CMS'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. The documentation may include notes documenting relevant signs, symptoms, or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office 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 notreasonable 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 Amendments of 1988

(CLIA) certificate for the testing performed will result in denial of claims.

CODING GUIDELINES

FOR ALL NCD EDITS

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 sub-classifications 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.

ADDITIONAL CODING GUIDELINES

EDIT 1

1. In the case of pre-operative examination (V72.84), the following codes may support medical necessity: 585, 586, 592.0-592.9, 594.0-594.9, 600.0-600.9, 602.0-602.9, 939.0, 939.3.

2. Specific coding guidelines:

a. Use CPT 87086 Culture, bacterial, urine; quantitative, colony count where a urine culture colony count is performed to determine the approximate number of bacteria present per milliliter of urine. The number of units of service is determined by the number of specimens.

b. Use CPT 87088 where a commercial kit uses manufacturer defined media for isolation, presumptive identification, and quantitation of morphotypes present. The number of units of service is determined by the number of specimens.

c. Use CPT 87088 where identification of morphotypes recovered by quantitative culture or commercial kits and deemed to represent significant bacteriuria requires the use of additional testing, for example, biochemical test procedures on colonies. Identification based solely on visual observation of the primary media is usually not adequate to justify use of this code. The number of units of service is determined by the number of isolates.

d. Use CPT 87184 or 87186 where susceptibility testing of isolates deemed to be significant is performed concurrently with identification. The number of units of service is determined by the number of isolates. These codes are not exclusively used for urine cultures but are appropriate for isolates from other sources as well.

e. Appropriate combinations are as follows: CPT 87086, 1 per specimen with 87088, 1 per isolate and 87184 or 87186 where appropriate.

f. Culture for other specific organism groups not ordinarily recovered by media used for aerobic urine culture may require use of additional CPT codes (for example, anaerobes from suprapubic samples).

g. Identification of isolates by non-routine, nonbiochemical methods may be coded appropriately (for example,

immunologic identification of streptococci, nucleic acid techniques for identification of N. gonorrhoeae).

h. While infrequently used, sensitivity studies by methods other than CPT 87184 or 87186 are appropriate. CPT 87181, agar dilution method, each antibiotic or CPT 87188, macrotube dilution method, each antibiotic may be used. The number of units of service is the number of antibiotics multiplied by the number of unique isolates.

3. ICD-9-CM code 780.02, 780.9 or 799.3 should be used only in the situation of an elderly patient, immunocompromised patient or patient with neurologic disorder who presents without typical manifestations of a urinary tract infection but who presents with one of the following signs or symptoms, not otherwise explained by another co-existing condition: increasing debility; declining functional status; acute mental changes; changes in awareness; or hypothermia.

4. In cases of post renal-transplant urine culture used to detect clinically significant occult infection in patients on long term immunosuppressive therapy, use code V58.69.

EDIT 2

1. Specific coding guidelines:

a. Temporary code G0100 has been superseded by code 87536 effective January 1, 1998.

b. CPT codes for quantification should not be used simultaneously with other nucleic acid detection codes for HIV-1 (that is, 87534, 87535) or HIV-2 (that is, 87537, 87538).

2. Codes 647.60-647.64 should only be used for HIV infections complicating pregnancy.

EDIT 3

1. Specific coding guidelines:

a. CPT 86701 or 86703 is performed initially. CPT 86702 is performed when 86701 is negative and clinical suspicion of HIV-2 exists.

b. CPT 86689 is performed only on samples repeatedly positive by 86701, 86702, or 86703.

c. CPT 87534 or 87535 is used to detect HIV-1 RNA where indicated. CPT 87537 or 87538 is used to detect HIV-2 RNA where indicated.

EDIT 5

1. When patients are being converted from heparin therapy to warfarin therapy, use code V58.61 to document the medical necessity of the PTT.

2. When coding for Disseminated Intravascular Coagulation (DIC), use 286.6 or code for the signs and symptoms clinically indicating DIC.

3. If a specific condition is known and is the reason for a pre-operative test, submit the clinical 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.

4. 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 (for example, to report a PTT value or re-check need for medication adjustment.) Assign code V58.61 to referrals for PTT checks or re-checks. (Reference AHA's Coding Clinic, March-April, pg 12 – 1987, 2nd quarter pg 8 – 1989)

EDIT 6

1. 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.

2. 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)

EDIT 8

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

EDIT 9

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

EDIT 10

1. 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.

EDIT 11

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

EDIT 15

1. 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.

EDIT 20

1. 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

DETERMINATIONS EDITS

EDIT 1

Culture
Bacterial, Urine

Other Names/Abbreviations: Urine culture

Description:

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

HCPCS Codes: (alpha numeric, CPT © AMA):

Codes:	Descriptor:
87086	Culture, bacterial; quantitative, colony count, urine.
87088	Culture, bacterial; with isolation and presumptive identification of isolates, urine.

ICD-9-CM Codes Covered by Medicare Program

Code:	Descriptor:
003.1	Salmonella septicemia
038.0-038.9	Septicemia
276.2	Acidosis
276.4	Metabolic acidosis/alkalosis
286.6	Defibrination syndrome/disseminated intravascular coagulation
288.0	Agranulocytosis/neutropenia
288.8	Other specified disease of white blood cells including leukemoid reaction/ leukocytosis
306.53	Psychogenic dysuria
306.59	Other psychogenic genitourinary malfunction
518.82	Other pulmonary insufficiency, not elsewhere classified
570	Acute and subacute necrosis of liver
580.0-580.9	Acute glomerulonephritis
583.0-583.9	Nephritis and Nephropathy, not specified as acute or chronic
584.5	Acute renal failure, with lesion of tubular necrosis
584.9	Acute renal failure, unspecified
585	Chronic renal failure
586	Renal failure, unspecified
590.00-590.9	Infections of kidney/pyelonephritis acute and chronic
592.0-592.9	Calculus of kidney and ureter
593.0-593.9	Other disorders of kidney and ureter (cyst, stricture, obstruction, reflux, etc.)
594.0-594.9	Calculus of lower urinary tract
595.0-595.9	Cystitis
597.0	Urethritis, not sexually transmitted and urethral syndrome
597.80-597.89	Other urethritis
598.00-598.01	Urethral stricture due to infection
599.0	Urinary tract infection, site not specified
599.7	Hematuria
600.0-600.9	Hyperplasia of prostate
601.0-601.9	Inflammatory diseases of prostate

602.0-602.9	Other disorders of prostate (calculus, congestion, atrophy, etc.)
604.0-604.99	Orchitis and epididymitis
608.0-608.9	Other disorders of male genital organs (seminal vesiculitis, spermatocele, etc.)
614.0-614.9	Inflammatory disease of ovary, fallopian tube, pelvic cellular tissue, and peritoneum
615.0-615.9	Inflammatory disease of uterus, except cervix
616.0	Cervicitis and endocervicitis
616.10-616.11	Vaginitis and vulvovaginitis
616.2-616.9	Other inflammatory conditions of cervix, vagina and vulva
619.0-619.9	Fistula involving female genital tract
625.6	Stress incontinence, female
639.0	Genital tract and pelvic infection complicating abortion, ectopic or molar pregnancies
639.5	Shock complicating abortion, ectopic or molar pregnancies
646.60-646.64	Infections of genitourinary tract in pregnancy
670.00-670.04	Major puerperal infection
672.00-672.04	Pyrexia of unknown origin during the puerperium
724.5	Backache, unspecified
771.81	Septicemia (sepsis) of newborn
771.82	Urinary tract infection of newborn
771.83	Bacteremia of newborn
780.02	General symptoms, transient alteration of awareness
780.6	Fever (Hyperthermia)
780.79	Other malaise and fatigue
780.99	Other general symptoms
785.0	Tachycardia, unspecified
785.50-785.59	Shock without mention of trauma
788.0-788.9	Symptoms involving urinary system (renal colic, dysuria, retention of urine, incontinence of urine, frequency, polyuria, nocturia, oliguria, anuria, other abnormality of urination, urethral discharge, extravasation of urine, other symptoms of urinary system)

789.00-789.09	Abdominal pain
789.60-789.69	Abdominal tenderness
790.7	Bacteremia
791.0-791.9	Nonspecific findings on examination of urine (proteinuria, chyluria, hemoglobinuria, myoglobinuria, biliuria, glycosuria, acetonuria, other cells and casts in urine, other nonspecific findings on examination of urine)
799.3	Debility, unspecified (only for declining functional status)
939.0	Foreign body in genitourinary tract, bladder and urethra
939.3	Foreign body in genitourinary tract, penis
V44.50-V44.6	Artificial cystostomy or other artificial opening of urinary tract status
V55.5-V55.6	Attention to cystostomy or other artificial opening of urinary tract
V58.69	Long-term (current) use of other medications
V72.84	Pre-operative examination, unspecified

Indications

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

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

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

4. A test-of cure is generally not indicated in an uncomplicated infection. However, it may be indicated if the patient is being evaluated for response to therapy and there is a complicating co-existing urinary abnormality including structural or functional abnormalities, calculi, foreign bodies, or ureteral/renal stents or there is clinical or laboratory evidence of failure to respond as described in Indications 1 and 2.

5. In surgical procedures involving major manipulations of the genitourinary tract, preoperative examination to detect occult infection may be indicated in selected cases (for example, prior to renal transplantation, manipulation or removal of kidney stones, or transurethral surgery of the bladder or prostate).

6. Urine culture may be indicated to detect occult infection in renal transplant recipients on immunosuppressive therapy.

Limitations

1. CPT 87086 may be used one time per encounter.

2. Colony count restrictions on coverage of CPT 87088 do not apply as they may be highly variable according to syndrome or other clinical circumstances(for example, antecedent therapy, collection time, degree of hydration).

3. CPT 87088, 87184, and 87186 may be used multiple times in association with or independent of 87086, as urinary tract infections may be polymicrobial.

4. Testing for asymptomatic bacteriuria as part of a prenatal evaluation may be medically appropriate but is considered screening and therefore not covered by Medicare. The US Preventive Services Task Force has concluded that screening for asymptomatic bacteriuria outside of the narrow indication for pregnant women is generally not indicated. There are insufficient data to recommend screening in ambulatory elderly patients including those with diabetes. Testing may be clinically indicated on other grounds including likelihood of recurrence or potential adverse effects of antibiotics, but is considered screening in the absence of clinical or laboratory evidence of infection.

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

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Documentation Requirements

Appropriate HCPCS/CPT code(s) must be used as described.

Sources of Information

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Stamm WE, and TM Hooton. 1993. Management of urinary tract infections in adults. N. Engl. J. Med. 329:1328-1334.

United States Preventive Services Task Force (1996). Guidelines for screening for asymptomatic bacteriuria.

Lachs MS, Nachamkin I, Edelstein PH et al. 1992. Spectrum bias in the evaluation of diagnostic tests: lessons from the rapid dipstick test for urinary tract infection. Ann. Int. Med. 117:135-140.

EDIT 2

Human Immunodeficiency Virus Testing (Prognosis including monitoring)

Other Names/Abbreviations: HIV-1 or HIV-2 quantification or viral load

Description:

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

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

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

HCPCS Codes (alpha numeric, CPT © AMA):

Code:	Descriptor:
87536	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, quantification
87539	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, quantification

ICD-9-CM Codes Covered by Medicare Program

Code:	Descriptor:
042	Human immunodeficiency virus [HIV] disease
079.53	Human immunodeficiency virus, type 2 [HIV-2]
647.60-647.64	Other viral diseases complicating pregnancy (including HIV-I and II)
795.71	Nonspecific serologic evidence of human immunodeficiency virus [HIV]
V08	Asymptomatic human immunodeficiency virus [HIV] infection status

Indications

1. A plasma HIV RNA baseline level may be medically necessary in any patient with confirmed HIV infection.

2. Regular periodic measurement of plasma HIV RNA levels may be medically necessary to determine risk for disease progression in an HIV-infected individual and to determine when to initiate or modify antiretroviral treatment regimens.

3. In clinical situations where the risk of HIV infection is significant and initiation of therapy is anticipated, a baseline HIV quantification may be performed. These situations include:

a. Persistence of borderline or equivocal serologic reactivity in an at-risk individual.

b. Signs and symptoms of acute retroviral syndrome characterized by fever, malaise, lymphadenopathy and rash in an at-risk individual.

Limitations

1. Viral quantification may be appropriate for prognostic use including baseline determination, periodic monitoring, and monitoring of response to therapy. Use as a diagnostic test method is not indicated.

2. Measurement of plasma HIV RNA levels should be performed at the time of establishment of an HIV infection diagnosis. For an accurate baseline, 2 specimens in a 2-week period are appropriate.

3. For prognosis including anti-retroviral therapy monitoring, regular, periodic measurements are appropriate. The frequency of viral load testing should be consistent with the most current Centers for Disease Control and Prevention guidelines for use of anti-retroviral agents in adults and adolescents or pediatrics.

4. Because differences in absolute HIV copy number are known to occur using different assays, plasma HIV RNA levels should be measured by the same analytical method. A change in assay method may necessitate re-establishment of a baseline.

5. Nucleic acid quantification techniques are representative of rapidly emerging and evolving new technologies. As such, users are advised to remain current on FDA-approval status.

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

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Other Comments

Assessment of CD4+ T cell numbers is frequently performed in conjunction with viral load determination. When used in concert, the accuracy with which the risk for disease progression and death can be predicted is enhanced.

Sources of Information

CDC. 1998. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. MMWR 47 (RR-5).

CDC. 1998. Guidelines for the use of antiretroviral agents in pediatric HIV infection. MMWR 47 (RR-4).

CDC. 1998. Public Health Service Task Force recommendations for the use of antiretroviral drugs in pregnant women infected with HIV-1 for maternal health and for reducing

perinatal HIV-1 transmission in the United States. MMWR 47 (RR-2).

Carpenter, C.C., M.A. Fischi, S.M. Hammer, et . al. 1998. Antiretroviral therapy for HIV infection in 1998. Updated recommendations of the international AIDS society-USA panel. A.M.A. 280:78-86.

Saag, M.S., M. Holodniy, D.R. Kuritzkes, et al. 1996. HIV viral load markers in clinical practice. Nature Medicine 2(6): 625-629.

EDIT 3

Human Immunodeficiency Virus Testing (Diagnosis)

Other Names/Abbreviations: HIV, HIV-1, HIV-2, HIV1/2, HTLV III, Human T-cell lymphotropic virus, AIDS, Acquired immune deficiency syndrome

Description:

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

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

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

assays, is required to establish a definitive determination of HIV infection.

***HCPCS Codes* (alpha numeric, CPT © AMA):**

Code:	Descriptor:
86689	Qualitative or semiquantitative immunoassays performed by multiple step methods; HTLV or HIV antibody, confirmatory test (for example, Western Blot)
86701	Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV-1
86702	Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV-2
86703	Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV-1 and HIV-2, single assay
87390	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple step method; HIV-1
87391	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple step method; HIV-2
87534	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique,
87535	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, amplified probe technique
87537	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, direct probe technique
87538	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, amplified probe technique

ICD-9-CM Codes Covered by Medicare Program

Code:	Description:
003.1	Salmonella septicemia
007.2	Coccidiosis (Isoporiasis)
007.4	Cryptosporidiosis
007.8	Other specified protozoal intestinal diseases
010.00-010.96	Primary tuberculous infection
011.00-011.96	Pulmonary tuberculosis
012.00-012.86	Other respiratory tuberculosis
013.00-013.96	Tuberculosis of meninges and central nervous system
014.00-014.86	Tuberculosis of intestines, peritoneum and mesenteric glands
015.00-015.96	Tuberculosis of bones and joints
016.00-016.96	Tuberculosis of genitourinary system
017.00-017.96	Tuberculosis of other organs
018.00-018.96	Miliary tuberculosis
027.0	Listeriosis
031.0-031.9	Diseases due to other mycobacteria
038.2	Pneumococcal septicemia
038.43	Septicemia (Pseudomonas)
039.0-039.9	Actinomycotic infections (includes Nocardia)
041.7	Pseudomonas infection
042	HIV disease (Acute retroviral syndrome, AIDS-related complex)
046.3	Progressive multifocal leukoencephalopathy
049.0-049.9	Other non-arthropod-borne viral diseases of central nervous system
052.0-052.8	Chickenpox (with complication)
053.0-053.9	Herpes zoster
054.0-054.9	Herpes simplex
055.0-055.8	Measles (with complication)
070.20-070.23	Viral hepatitis B with hepatic coma
070.30-070.33	Viral hepatitis B without mention of hepatic coma
070.41	Acute or unspecified hepatitis C with hepatic coma
070.42	Hepatitis delta without mention of active hepatitis B disease with hepatic coma
070.44	Chronic hepatitis C with hepatic coma

070.49	Other specified viral hepatitis with hepatic coma
070.51	Acute or unspecified hepatitis C without hepatic coma
070.52	Hepatitis delta without mention of active hepatitis B disease without hepatic coma
070.54	Chronic hepatitis C without hepatic coma
070.59	Other specified viral hepatitis without hepatic coma
070.6	Unspecified viral hepatitis with hepatic coma
070.9	Unspecified viral hepatitis without hepatic coma
078.0	Molluscum contagiosum
078.10-078.19	Viral warts
078.3	Cat-scratch disease
078.5	Cytomegaloviral disease
078.88	Other specified diseases due to Chlamydiae
079.50	Retrovirus unspecified
079.51	HTLV-I
079.52	HTLV-II
079.53	Human immunodeficiency virus, type 2
079.59	Other specified Retrovirus
079.88	Other specified chlamydial infection
079.98	Unspecified chlamydial infection
085.0-085.9	Leishmaniasis
088.0	Bartonellosis
090.0-090.9	Congenital syphilis
091.0-091.9	Early syphilis symptomatic
092.0-092.9	Early syphilis, latent
093.0-093.9	Cardiovascular syphilis
094.0-094.9	Neurosyphilis
095.0-095.9	Other forms of late syphilis, with symptoms
096	Late syphilis, latent
097.0-097.9	Other and unspecified syphilis
098.0-098.89	Gonococcal infections
099.0	Chancroid
099.1	Lymphogranuloma venereum
099.2	Granuloma inguinale
099.3	Reiter’s disease
099.40-099.49	Other nongonococcal urethritis

099.50-099.59	Other venereal diseases due to Chlamydia trachomatis
099.8	Other specified venereal diseases
099.9	Veneral disease, unspecified
110.1	Dermatophytosis of nail
111.0	ityriasis versicolor
112.0-112.9	Candidiasis
114.0-114.9	Coccidioidomycosis
115.00-115.99	Histoplasmosis
116.0-116.2	Blastomycotic infection
117.3	Aspergillosis
117.5	Cryptococcosis
118	Opportunistic mycoses
127.2	Strongyloidiasis
130.0-130.9	Toxoplasmosis
131.01	Trichomonal vulvovaginitis
132.2	Phthirus pubis
133.0	Scabies
136.2	Specific infections by free living amebae
136.2	Pneumocystosis
136.8	Other specified infectious and parasitic disease (for example, microsporidiosis)
176.0-176.9	Kaposi's sarcoma
180.0-180.9	Malignant neoplasm of cervix uteri
200.20-200.28	Burkitt's tumor or lymphoma
200.80-200.88	Lymphosarcoma, other named variants
201.00-201.98	Hodgkin's disease
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.9	Unspecified protein-calorie malnutrition
280.0-280.9	Iron deficiency anemias
285.9	Anemia, unspecified
287.3	Primary thrombocytopenia
288.0	Agranulocytosis
288.8	Other specified disease of white blood cells
294.8	Other specified organic brain syndromes (chronic)
310.1	Organic personality syndrome
322.2	Chronic meningitis
336.9	Unspecified disease of spinal cord
348.3	Encephalopathy unspecified

354.0-354.9	Mononeuritis of upper limbs and mononeuritis multiplex
356.8	Other specified idiopathic peripheral neuropathy
363.20	Chorioretinitis, unspecified
425.4	Other primary cardiomyopathies
473.0-473.9	Chronic sinusitis
481-482.9	Pneumococcal pneumonia
484.1	Pneumonia in cytomegalic inclusion disease
486	Pneumonia, organism unspecified
512.8	Other spontaneous pneumothorax
516.8	Other specified alveolar and parietoalveolar pneumonopathies
528.2	Oral aphthae
528.6	Leukoplakia of oral mucosa
530.2	Ulcer of esophagus
583.9	Nephropathy with unspecified pathological lesion in kidney
588.8	Other specified disorders resulting from impaired renal function
647.60-647.64	Other viral diseases complicating pregnancy (use for HIV I and II)
682.0-682.9	Other cellulitis and abscess
690.10-690.18	Seborrheic dermatitis
696.1	Other psoriasis
698.3	Lichenification and lichen simplex chronicus
704.8	Other specified diseases of hair and hair follicles
706.0-706.9	Diseases of sebaceous glands
780.6	Fever
780.79	Other malaise and fatigue
783.21	Abnormal loss of weight
783.40	Lack of expected normal physiological development
785.6	Enlargement of lymph nodes
786.00	Respiratory abnormality, unspecified
786.05	Shortness of breath
786.2	Cough
786.3	Hemoptysis
786.4	Abnormal sputum
787.91	Diarrhea
795.71	Nonspecific serologic evidence of human immunodeficiency virus
799.4	Wasting disease

V01.7	Contact with or exposure to communicable diseases, other viral diseases
V71.5	Rape

Indications

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

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.
2. The patient has another documented sexually transmitted disease which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.

3. The patient has documented acute or chronic hepatitis B or C infection that identifies a significant risk of exposure to HIV and the potential for an early or subclinical infection.

4. The patient has a documented AIDS-defining or AIDS-associated neoplasm.

5. The patient has a documented AIDS-associated neurologic disorder or otherwise unexplained dementia.

6. The patient has another documented AIDS-defining clinical condition, or a history of other severe, recurrent, or persistent conditions which suggest an underlying immune deficiency (for example, cutaneous or mucosal disorders).

7. The patient has otherwise unexplained generalized signs and symptoms suggestive of a chronic process with an underlying immune deficiency (for example, fever, weight loss, malaise, fatigue, chronic diarrhea, failure to thrive, chronic cough, hemoptysis, shortness of breath, or lymphadenopathy).

8. The patient has otherwise unexplained laboratory evidence of a chronic disease process with an underlying immune deficiency (for example, anemia, leukopenia, pancytopenia, lymphopenia, or low CD4+ lymphocyte count).

9. The patient has signs and symptoms of acute retroviral syndrome with fever, malaise, lymphadenopathy, and skin rash.

10. The patient has documented exposure to blood or body fluids known to be capable of transmitting HIV (for example, needlesticks and other significant blood exposures) and antiviral therapy is initiated or anticipated to be initiated.

11. The patient is undergoing treatment for rape. (HIV testing is a part of the rape treatment protocol.)

For a comprehensive tabulation of AIDS-defining and AIDS associated conditions, refer to information source document #5.

Limitations

1. HIV antibody testing in the United States is usually performed using HIV-1 or HIV-½ combination tests. HIV-2 testing is indicated if clinical circumstances suggest HIV-2 is likely (that is, compatible clinical findings and HIV-1 test negative). HIV-2 testing may also be indicated in areas of the country where there is greater prevalence of HIV-2 infections.

2. The Western Blot test should be performed only after documentation that the initial EIA tests are repeatedly positive or equivocal on a single sample.

3. The HIV antigen tests currently have no defined diagnostic usage.

4. Direct viral RNA detection may be performed in those situations where serologic
testing does not establish a diagnosis but strong clinical suspicion persists (for example, acute retroviral syndrome, nonspecific serologic evidence of HIV, or perinatal HIV infection).

5. If initial serologic tests confirm an HIV infection, repeat testing is not indicated.

6. If initial serologic tests are HIV EIA negative and there is no indication for confirmation of infection by viral RNA detection, the interval prior to retesting is 3-6 months.

7. Testing for evidence of HIV infection using serologic methods may be medically appropriate in situations where there is a risk of exposure to HIV. However, in the absence of a documented AIDS defining or HIV associated disease, an HIV associated sign or symptom, or documented exposure to a known

HIV-infected source, the testing is considered by Medicare to be screening and thus is not covered by Medicare (for example, history of multiple blood component transfusions, exposure to blood or body fluids not resulting in consideration of therapy, history of transplant, history of illicit drug use, multiple sexual partners, same-sex encounters, prostitution, or contact with prostitutes).

8. The CPT Editorial Panel has issued a number of codes for infectious agent detection by direct antigen or nucleic acid probe techniques that have not yet been developed or are only being used on an investigational basis. Laboratory providers are advised to remain current on FDA-approval status for these tests.

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

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Documentation Requirements

Appropriate HCPCS/CPT code (s) must be used as described.

Sources of Information

CDC, 1993. Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 41 (No. RR17).

CDC, 1994. Revised classification system for human immunodeficiency virus infection in children less than 13 years of age.

CDC, 1998. Guidelines for treatment of sexually transmitted diseases. MMWR 47 (RR1):11-17.

Piatak, M., M.S. Saag, L.C. Yang, et al. 1993. High levels of HIV-1 in plasma during all stages of infection determined by competitive PCR. Science 259:1749-1754.

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Vasudevachari, M.D., R.T. Davey, Jr., J.A. Metcalf, and H.C. Lane. 1997. Principles and procedures of human immunodeficiency virus serodiagnosis. In Manual of Clinical Laboratory Immunology (Fifth ed.); N.R. Rose, E.C. de Macario, J.D. Folds, H.C. Lane, and R.M. Nakamura (ASM Press, Washington, DC).

EDIT 4

Blood Counts

Other Names/Abbreviations: CBC

Description:

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

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

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

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

HCPCS Codes **(alpha numeric, CPT © AMA):**

Code:	**Descriptor:**
85007	Blood count; blood smear, microscopic examination with manual differential WBC count
85008	Blood count; blood smear, microscopic examination without manual differential WBC count
85013	Blood count, Spun microhematocrit
85014	Blood count, hematocrit (Hct)
85018	Blood count, Hemoglobin
85025	Blood count, complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85027	Blood count, complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)
85048	Blood count, leukocyte(WBC), automated

ICD-9-CM Codes Covered by Medicare Program:

Any ICD-9-CM code not listed in either the non-covered section or the medical necessity section.

Indications:

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

1. Indications for a CBC generally include the evaluation of bone marrow dysfunction as a result of neoplasms, therapeutic agents, exposure to toxic substances, or pregnancy. The CBC is also useful in assessing peripheral destruction of blood cells, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic, or lymphoproliferative processes, and immune disorders.

2. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with anemia or other red blood cell disorder (e.g., pallor, weakness, fatigue, weight loss, bleeding, acute injury associated with blood loss or suspected blood loss, abnormal menstrual bleeding, hematuria, hematemesis, hematochezia, positive fecal occult blood test, malnutrition, vitamin deficiency, malabsorption, neuropathy, known malignancy, presence of acute or chronic disease that may have associated anemia, coagulation or hemostatic disorders, postural dizziness, syncope, abdominal pain, change in bowel habits, chronic marrow hypoplasia or decreased RBC production, tachycardia, systolic heart murmur, congestive heart failure, dyspnea, angina, nailbed deformities, growth retardation, jaundice, hepatomegaly, splenomegaly, lymphadenopathy, ulcers on the lower extremities).

3. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with polycythemia (for example, fever, chills, ruddy skin, conjunctival redness, cough, wheezing, cyanosis, clubbing of the fingers, orthopnea, heart murmur, headache, vague cognitive changes including memory changes, sleep apnea, weakness, pruritus, dizziness, excessive sweating, visual symptoms, weight loss, massive obesity, gastrointestinal bleeding, paresthesias, dyspnea, joint symptoms, epigastric distress, pain and erythema

of the fingers or toes, venous or arterial thrombosis, thromboembolism, myocardial infarction, stroke, transient ischemic attacks, congenital heart disease, chronic obstructive pulmonary disease, increased erythropoietin production associated with neoplastic, renal or hepatic disorders, androgen or diuretic use, splenomegaly, hepatomegaly, diastolic hypertension.)

4. Specific indications for CBC with differential count related to the WBC include signs, symptoms, test results, illness, or disease associated with leukemia, infections or inflammatory processes, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic or lymphoproliferative disorder, use of drugs that may cause leukopenia, and immune disorders (e.g., fever, chills, sweats, shock, fatigue, malaise, tachycardia, tachypnea, heart murmur, seizures, alterations of consciousness, meningismus, pain such as headache, abdominal pain, arthralgia, odynophagia, or dysuria, redness or swelling of skin, soft tissue bone, or joint, ulcers of the skin or mucous membranes, gangrene, mucous membrane discharge, bleeding, thrombosis, respiratory failure, pulmonary infiltrate, jaundice, diarrhea, vomiting, hepatomegaly, splenomegaly, lymphadenopathy, opportunistic infection such as oral candidiasis.)

5. Specific indications for CBC related to the platelet count include signs, symptoms, test results, illness, or disease associated with increased or decreased platelet production and destruction, or platelet dysfunction (e.g., gastrointestinal bleeding, genitourinary tract bleeding, bilateral epistaxis, thrombosis, ecchymosis, purpura, jaundice, petechiae, fever, heparin therapy, suspected DIC, shock, pre-eclampsia, neonate with maternal ITP, massive transfusion, recent platelet transfusion, cardiopulmonary bypass, hemolytic uremic syndrome, renal diseases, lymphadenopathy, hepatomegaly, splenomegaly, hypersplenism, neurologic abnormalities, viral or other infection, myeloproliferative, myelodysplastic, or lymphoproliferative disorder, thrombosis, exposure to toxic agents, excessive alcohol ingestion, autoimmune disorders (SLE, RA and other).

6. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include, in addition to those already listed, thalassemia, suspected hemoglobinopathy, lead poisoning, arsenic poisoning, and spherocytosis.

7. Specific indications for CBC with differential count related to the WBC include, in addition to those already listed, storage diseases/mucopolysaccharidoses, and use of drugs that cause leukocytosis such as G-CSF or GM-CSF.

8. Specific indications for CBC related to platelet count include, in addition to those already listed, May-Hegglin syndrome and Wiskott-Aldrich syndrome.

Limitations

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

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

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

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

ICD-9-CM Codes That Do Not Support Medical Necessity:

Code:	Description:
078.10-078.19	Viral warts
210.0-210.9	Benign neoplasm of lip, oral cavity, and pharynx
214.0	Lipoma, skin and subcutaneous tissue of face

216.0-216.9	Benign neoplasm of skin
217	Benign neoplasm of breast
222.0-222.9	Benign neoplasm of male genital organs
224.0	Benign neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid
230.0	Carcinoma in situ of lip, oral cavity and pharynx
232.0-232.9	Carcinoma in situ of skin
300.00-300.09	Neurotic disorders
301.0-301.9	Personality disorders
302.0-302.9	Sexual deviations and disorders
307.0	Stammering and stuttering
307.20-307.23	Tics
307.3	Stereotyped repetitive movements
307.80-307.89	Psychalgia
312.00-312.9	Disturbance of conduct, not elsewhere classified
313.0-313.9	Disturbance of emotions specific to childhood and adolescence
314.00-314.9	Hyperkinetic syndrome of childhood
363.30-363.35	Chorioretinal scars
363.40-363.43	Choroidal degeneration
363.50-363.57	Hereditary choroidal dystrophies
363.70-363.9	Choroidal detachment
366.00-366.9	Cataract
367.0-367.9	Disorders of refraction and accommodation
371.00-371.9	Corneal opacity and other disorders of cornea
373.00-373.9	Inflammation of eyelids
375.00-375.9	Disorders of lacrimal system
376.21-376.9	Disorders of the orbit, except 376.3 Other exophthalmic conditions
377.10-377.16	Optic atrophy
377.21-377.24	Other disorders of optic disc
384.20-384.25	Perforation of tympanic membrane
384.81-384.82	Other specified disorders of tympanic membrane
385.00-385.9	Other disorders of middle ear and mastoid
387.0-387.9	Otosclerosis
388.00-388.5	Other disorders of ear
389.00-389.9	Hearing loss
440.0-440.1	Atherosclerosis of aorta and renal artery
443.81-443.9	Other and unspecified peripheral vascular disease
448.1	Capillary nevus, non neoplastic
457.0	Postmastectomy lymphedema syndrome

470	Deviated nasal septum
471.0-471.9	Nasal polyps
478.0	Hypertrophy of nasal turbinates
478.4	Polyp of vocal cord or larynx
520.0-520.9	Disorders of tooth development and eruption
521.00-521.9	Diseases of hard tissues of teeth
524.00-524.9	Dentofacial anomalies, including malocclusion
525.0-525.9	Other diseases and conditions of teeth and supporting structures
526.0-526.3	Diseases of the jaws
527.6-527.9	Diseases of salivary glands
575.6	Cholesterolosis of gallbladder
600.0-600.9	Hyperplasia of prostate
603.0	Encysted hydrocele
603.8	Other specified types of hydrocele
603.9	Hydrocele, unspecified
605	Redundant prepuce and phimosis
606.0-606.1	Infertility, male azoospermia and oligospremia
608.1	Spermatocele
608.3	Atrophy of testis
610.0-610.9	Benign mammary dysplasia
611.1-611.6	Other disorders of breast
611.9	Unspecified breast disorder
616.2	Cyst of Bartholin's gland
618.0-618.9	Genital prolapse
620.0-620.3	Noninflammatory disorders of ovary, fallopian tube, and broad ligament
621.6-621.7	Malposition or chronic inversion of uterus
627.2-627.9	Menopausal and post menopausal disorders
628.0-628.9	Infertility, female
676.00-676.94	Other disorders of breast associated with childbirth and disorders of lactation
691.0-691.8	Atopic dermatitis and related disorders
692.0-692.9	Contact dermatitis and other eczema
700	Corns and callosities
701.0-701.9	Other hypertrophic and atrophic conditions of skin
702.0-702.8	Other dermatoses
703.9	Unspecified disease of nail
706.0-706.9	Diseases of sebaceous glands
709.00-709.4	Other disorders of skin and subcutaneous tissue
715.00-715.98	Osteoarthrosis
716.00-716.99	Other and unspecified arthropathies

718.00-718.99	Other derangement of joint
726.0-726.91	Peripheral enthesopathies and allied syndromes
727.00-727.9	Other disorders of synovium, tendon, and bursa
728.10-728.85	Disorders of muscle ligament and fascia
732.0-732.9	Osteochondropathies
733.00-733.09	Osteoporosis
734	Flat foot
735.0-735.9	Acquired deformities of toe
736.00-736.9	Other acquired deformities of limb
737.0-737.9	Curvature of spine
738.0-738.9	Other acquired deformity
739.0-739.9	Nonallopathic lesions, not elsewhere classified
830.0-839.9	Dislocations
840.0-848.9	Sprains and strains of joints and adjacent muscles
905.0-909.9	Late effects of musculoskeletal and connective tissue injuries
910.0-919.9	Superficial injuries
930.0-932	Foreign body on external eye, in ear, in nose
955.0-957.9	Injury to peripheral nerve
V03.0-V06.9	Need for prophylactic vaccination
V11.0-V11.9	Personal history of mental disorder
V14.0-V14.8	Personal history of allergy to medicinal agents
V16.0	Family history of malignant neoplasm, gastrointestinal tract
V16.3	Family history of malignant neoplasm, breast
V21.0-V21.9	Constitutional states in development
V25.01-V25.9	Encounter for contraceptive management
V26.0-V26.9	Procreative management
V40.0-V40.9	Mental and behavioral problems
V41.0-V41.9	Problems with special senses and other special functions
V43.0-V43.1	Organ or tissue replaced by other means, eye globe or lens
V44.0-V44.9	Artificial opening status
V45.00-V45.89	Other post surgical states
V48.0-V48.9	Problems with head, neck, and trunk
V49.0-V49.9	Other conditions influencing health status
V51	Aftercare involving the use of plastic surgery

V52.0-V52.9	Fitting and adjustment of prosthetic device and implant
V53.01-V53.09	Fitting and adjustment of devices related to nervous system and special senses
V53.1	Fitting and adjustment of spectacles and contact lenses
V53.31-V53.39	Fitting and adjustment of cardiac device
V53.4	Fitting and adjustment of orthodontic devices
V53.5	Fitting and adjustment of other intestinal appliance
V53.6	Fitting and adjustment of urinary devices
V53.7	Fitting and adjustment of orthopedic devices
V53.8	Fitting and adjustment of wheelchair
V53.9	Fitting and adjustment of other and unspecified device
V54.0-V54.9	Other orthopedic aftercare
V55.0-V55.9	Attention to artificial openings
V57.0-V57.9	Care involving use of rehabilitation procedures
V58.5	Orthodontics
V59.01-V59.9	Donors
V61.0-V61.9	Other family circumstances
V62.2-V62.9	Other psychosocial circumstances
V65.2	Person feigning illness
V65.3	Dietary surveillance and counseling
V65.40-V65.49	Other counseling, not elsewhere classified
V65.5	Person with feared complaint in whom no diagnosis was made
V65.8	Other reasons for seeking consultation
V65.9	Unspecified reason for consultation
V66.0-V66.9	Convalescence and palliative care
V67.3	Follow-up examination following psychotherapy
V67.4	Follow-up examination following treatment of healed fracture
V69.3	Problems related to lifestyle, gambling and betting
V71.01-V71.09	Observation and evaluation for suspected conditions not found, mental
V72.0-V72.2	Special investigations, examination of eyes and vision, ears and hearing, dental
V72.4-V72.7	Special investigations, preganancy exam, radiologic exam, laboratory exam, diagnostic skin and sensitization tests
V72.9	Special investigation, unspecified

V76.10-V76.19	Special screening for malignant neoplasms, breast
V76.2	Special screening for malignant neoplasms, cervix

Documentation Required:

Appropriate HCPCS/CPT code (s) must be used as described.

Sources of Information:

Wintrobe's Clinical Hematology, G. Richard Lee et al editors, Lea & Febiger, 9th edition, Philadelphia PA 1993.

Hematology, Clinical and Laboratory Practice, R. Bick et al editors, Mosby-Year Book, Inc., St. Louis, Missouri, 1993.

"The Polycythemias", V. C. Broudy, Medicine, Chapter 5.V. Scientific American, New York, NY 1996.

Laboratory Test Handbook, D.S. Jacobs et al, Lexi-Comp Inc, 4th edition, Cleveland OH 1996.

Cancer: Principals & Practice of Oncology, DeVita, et al., 5th edition, Philadelphia: Lippincott-Raven, 1997.

Cecil Textbook of Medicine, Bennett, et al., 20th edition, Philadelphia: W.B. Saunders, 1996.

Williams Hematology, Beutler, et al., 5th editiion, New York: McGraw-Hill, 1995.

EDIT 5

Partial Thromboplastin Time

Other Names/Abbreviations: PTT

Description:

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: The partial thromboplastin time (PTT), prothrombin time (PT), thrombin time (TT), or a quantitative fibrinogen determination. The partial thromboplastin time (PTT) test is an in vitro laboratory test used to assess the intrinsic coagulation pathway and monitor heparin therapy.

HCPCS Codes (alpha numeric, CPT © AMA):

Code:	Descriptor:
85730	Thromboplastin time, partial (PTT); plasma or whole blood

ICD-9-CM Codes Covered by Medicare Program:

Code:	Description:
002.0-002.9	Typhoid and paratyphoid
003.0-003.9	Other Salmonella infections
038.9	Unspecified Septicemia
042	Human immunodeficiency virus (HIV) disease
060.0-060.9	Yellow fever
065.0-065.9	Arthropod borne hemorrhagic fever
070.0-070.9	Viral Hepatitis
075	Infectious mononucleosis
078.6	Hemorrhagic nephrosonephritis
078.7	Arenaviral hemorrhagic fever
120.0	Schistosomiasis haematobium
121.1	Clonorchiasis

121.3	Fascioliasis
124	Trichinosis
135	Sarcoidosis
155.0-155.2	Malignant neoplasm of liver and intrahepatic bile ducts
197.7	Malignant neoplasm of liver, specified as secondary
238.4	Polycythemia vera
238.7	Other lymphatic and hemapoietic tissues
239.9	Neoplasm of unspecified nature, site unspecified
246.3	Hemorrhage and infarction of thyroid
250.40-250.43	Diabetic with renal manifestations
269.0	Deficiency of Vitamin K
273.0-273.9	Disorders of plasma protein metabolism
275.0-275.9	Disorders of iron metabolism
277.1	Disorders of porphyrin metabolism
277.3	Amyloidosis
285.1	Acute posthemorrhagic anemia
286.0	Congenital factor VIII disorder - Hemophilia A
286.1	Congenital factor IX disorder - Hemophilia B
286.2-286.3	Other congenital factor deficiencies
286.4	von Willebrand's disease
286.5	Hemorrhagic disorder due to circulating anticoagulants
286.6	Defibrination syndrome
286.7	Acquired coagulation factor deficiency
286.9	Other and unspecified coagulation defects
287.0-287.9	Purpura and other hemorrhagic conditions
289.0	Polycythemia, secondary
325	Phlebitis and thrombophlebitis of intracranial venous sinuses
360.43	Hemophthalmos, except current injury
362.30-362.37	Retinal vascular occlusion
362.43	Hemorrhagic detachment of retinal pigment epithelium
362.81	Retinal hemorrhage
363.61-363.63	Choroidal hemorrhage
363.72	Choroidal detachment
368.9	Unspecified Visual Disturbances
372.72	Conjunctive hemorrhage
374.81	Hemorrhage of eyelid

376.32	Orbital hemorrhage
377.42	Hemorrhage in optic nerve sheaths
379.23	Vitreous hemorrhage
380.31	Hematoma of auricle or pinna
403.01, 403.11, 403.91	Hypertensive Renal Disease with renal failure
404.02, 404.12, 404.92	Hypertensive Heart and Renal Disease with renal failure
410.00-410.92	Acute myocardial infarction
423.0	Hemopericardium
427.31	Atrial fibrillation
427.9	Cardiac dysrhythmias, unspecified
428.0	Congestive heart failure, unspecified
429.79	Mural thrombus
430-432.9	Cerebral hemorrhage
433.00-433.91	Occlusion and stenosis of precerebral arteries
434.00-434.91	Occlusion of cerebral arteries
435.9	Focal neurologic deficit
444.0-444.9	Arterial embolism and thrombosis
446.6	Thrombotic microangiopathy
447.2	Rupture of artery
448.0	Hereditary Hemorrhagic telangiectasia
451.0-451.9	Phlebitis and thrombophlebitis
453.0-453.9	Other Venous emboli and thrombosis
456.0	Esophageal varices with bleeding
456.1	Esophageal varices without bleeding
456.8	Varices of other sites
459.89	Ecchymosis
530.7	Gastroesophageal laceration – hemorrhage syndrome
530.82	Esophageal hemorrhage
531.00-535.61	Gastric-Duodenal ulcer disease
537.83	Angiodysplasia of stomach and duodenum with hemorrhage
537.84	Dieulafoy lesion (hemorrhagic) of stomach and duodenum
556.0-557.9	Hemorrhagic bowel disease
562.02-562.03	Diverticulosis of small intestine with hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon with hemorrhage
568.81	Hemoperitoneum (nontraumatic)
569.3	Hemorrhage of rectum and anus
570	Acute and subacute necrosis of liver

571.0-573.9	Liver disease (in place of specific codes listed)
576.0-576.9	Biliary tract disorders
577.0	Acute pancreatitis
578.0-578.9	Gastrointestinal Hemorrhage
579.0-579.9	Malabsorption
581.0-581.9	Nephrotic Syndrome
583.9	Nephritis, with unspecified pathological lesion in kidney
584.5-584.9	Acute Renal Failure
585	Chronic Renal Failure
586	Renal failure
593.81-593.89	Other disorders of kidney and ureter, with hemorrhage
596.7	Hemorrhage into bladder wall
596.8	Other disorders of bladder, with hemorrhage
599.7	Hematuria
607.82	Penile hemorrhage
608.83	Vascular disorders of male genital organs
611.8	Hematoma of breast
620.7	Hemorrhage of broad ligament
621.4	Hematometra
622.8	Other specified disorders of cervix, with hemorrhage
623.6	Vaginal hematoma
623.8	Other specified diseases of the vagina, with hemorrhage
624.5	Hematoma of vulva
626.6	Metrorrhagia
626.7	Postcoital bleeding
627.0	Premenopausal bleeding
627.1	Postmenopausal bleeding
629.0	Hematocele female not elsewhere classified
632	Missed abortion
634.00-634.92	Spontaneous abortion
635.10-635.12	Legally induced abortion, complicated by delayed or excessive hemorrhage
636.10-636.12	Illegally induced abortion, complicated by delayed or excessive hemorrhage
637.10-637.12	Abortion unspecified, complicated by delayed or excessive hemorrhage
638.1	Failed attempt abortion, complicated by delayed or excessive hemorrhage

639.1	Delayed or excessive hemorrhage following abortion and ectopic and molar pregnancies
639.6	Complications following abortion and ectopic and molar pregnancies, embolism
640.00-640.93	Hemorrhage in early pregnancy
641.00-641.93	Antepartum hemorrhage
642.00-642.94	Hypertension complicating pregnancy, childbirth, and the puerperium
646.70-646.73	Liver disorders in pregnancy
656.00-656.03	Fetal maternal hemorrhage
658.40-658.43	Infection of amniotic cavity
666.00-666.34	Postpartum hemorrhage
671.20-671.54	Phlebitis in pregnancy
673.00-673.84	Obstetrical pulmonary embolus
674.30-674.34	Other complications of surgical wounds, with hemorrhage
710.0	Systemic Lupus erythematosus
713.2	Arthropathy associated with hematologic disorders (note: may not be used without indicating associated condition first)
713.6	Arthropathy associated with Henoch Schonlein (note: may not be used without indicating associated condition first)
719.10-719.19	Hemarthrosis
729.5	Leg pain/calf pain
733.10-733.19	Pathologic fracture associated with fat embolism
762.1	Other forms of placental separation with hemorrhage (affecting newborn code – do not assign to mother’s record)
764.90-764.99	Fetal intrauterine growth retardation
767.0-767.1	Subdural and cerebral hemorrhage
767.8	Other specified birth trauma, with hemorrhage
770.3	Fetal and newborn pulmonary hemorrhage
772.0-772.9	Fetal and neonatal hemorrhage
774.0-774.7	Other perinatal jaundice
776.0-776.9	Hemorrhagic disease of the newborn
780.2	Syncope
782.4	Jaundice, unspecified, not of newborn
782.7	Spontaneous ecchymoses Petechiae
784.7	Epistaxis
784.8	Hemorrhage from throat

785.4	Gangrene
785.50	Shock
786.05	Shortness of breath
786.3	Hemoptysis
786.50	Chest pain, unspecified
786.59	Chest pain
789.00-789.09	Abdominal pain
790.92	Abnormal coagulation profile
800.00-800.99	Fracture of vault of skull
801.00-801.99	Fracture of base of skull
802.20-802.9	Fracture of face bones
803.00-803.99	Other fracture, skull
804.00-804.99	Multiple fractures, skull
805.00- 806.9	Fracture, vertebral column
807.00-807.09	Fractures of rib(s), closed
807.10-807.19	Fracture of rib(s), open
808.8-808.9	Fracture of pelvis
809.0-809.1	Fracture of trunk
810.00-810.13	Fracture of clavicle
811.00-811.19	Fracture of scapula
812.00-812.59	Fracture of humerus
813.10-813.18	Fracture of radius and ulna, upper end, open
813.30-813.33	Fracture of radius and ulna, shaft, open
813.50-813.54	Fracture of radius and ulna, lower end, open
813.90-813.93	Fracture of radius and ulna, unspecified part, open
819.0-819.1	Multiple fractures
820.00–821.39	Femur
823.00-823.92	Tibia and fibula
827.0–829.1	Other multiple lower limb
852.00–853.19	Subarachnoid subdural, and extradural hemorrhage, following injury, Other and specified intracranial hemorrhage following injury
860.0-860.5	Traumatic pneumothorax and hemothorax
861.00-861.32	Injury to heart and lung
862.0-862.9	Injury to other and unspecified intrathoracic organs
863.0-863.99	Injury to gastrointestinal tract
864.00-864.19	Injury to liver
865.00-865.19	Injury to spleen
866.00-866.13	Injury to kidney
867.0-867.9	Injury to pelvic organs

868.00-868.19	Injury to other intra-abdominal organs
869.0-869.1	Internal injury to unspecified or ill defined organs
900.00-900.9	Injury to blood vessels of head and neck
901.0-901.9	Injury to blood vessels of the thorax
902.0-902.9	Injury to blood vessels of the abdomen and pelvis
903.00-903.9	Injury to blood vessels of upper extremity
904.0-904.9	Injury to blood vessels of lower extremity and unspecified sites
920 - 924.9	Contusion with intact skin surface
925.1-929.9	Crushing injury
958.2	Secondary and recurrent hemorrhage
959.9	Injury, unspecified site
964.2	Poisoning by anticoagulants
964.5	Poisoning by anticoagulant antagonists
964.7	Poisoning by natural blood and blood products
980.0	Toxic effects of alcohol
989.5	Snake venom
995.2	Unspecified adverse effect of drug, medicinal and biological substance (due to correct medicinal substance properly administered)
996.70-996.79	Other complications of internal prosthetic device
997.02	Iatrogenic cerebrovascular infarction or hemorrhage
998.11	Hemorrhage or hematoma complicating a procedure
999.2	Other vascular complications of medical care
V12.3	Personal history of diseases of blood and blood forming organs
V58.2	Admission for Transfusion of blood products
V58.61	Long term (current use) of anticoagulants
V72.81	Pre-operative cardiovascular examination
V72.83	Other specified pre-operative examination
V72.84	Pre-operative examination, unspecified

Indications:

1. The PTT is most commonly used to quantitate the effect of therapeutic unfractionated heparin and to regulate its dosing. Except during transitions between heparin and warfarin therapy, in general both the PTT and PT are not necessary together to assess the effect of anticoagulation therapy. PT and PTT must be justified separately. (See "Limitations" section for further discussion.)

2. A PTT may be used to assess patients with signs or symptoms of hemorrhage or thrombosis. For example:

abnormal bleeding, hemorrhage or hematoma petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation

swollen extremity with or without prior trauma

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

dysfibrinogenemia
afibrinogenemia (complete)
acute or chronic liver dysfunction or failure, including Wilson's disease
hemophilia
liver disease and failure
infectious processes
bleeding disorders
disseminated intravascular coagulation
lupus erythematosus or other conditions associated with circulating inhibitors, e.g., Factor VIII Inhibitor, lupus-like anticoagulant, etc.
sepsis
von Willebrand's disease
arterial and venous thrombosis, including the evaluation of hypercoagulable states
clinical conditions associated with nephrosis or renal failure
other acquired and congenital coagulopathies as well as thrombotic states.

4. A PTT may be used to assess the risk of thrombosis or hemorrhage in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. An example is as follows:

evaluation prior to invasive procedures or operations of patients with personal or family history of bleeding or who are on heparin therapy

Limitations:

1. The PTT is not useful in monitoring the effects of warfarin on a patient's coagulation routinely. However, a PTT may be ordered on a patient being treated with warfarin as heparin therapy is being discontinued. (See coding guidelines for instructions on the use of code V58.61 in this situation.) A PTT may also be indicated when the PT is markedly prolonged due to warfarin toxicity.

2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of heparin.

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

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

Blue Book of Diagnostic Tests; PL Liu; Saunders

Wintrobe's Clinical Hematology; 9th Ed, 1993, Lea and Febiger

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

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

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

"College of American Pathologists Conference XXXI on Laboratory Monitoring of Anticoagulant Therapy," Arch Pathol Lab Med, Vol 122, Sep 1998, P 782-798.

Lupus Anticoagulants/Antiphospholipid-protein Antibodies: The Great Imposters, Triplett DA, Lupus 1996:5:431

EDIT 6

Prothrombin Time

Other Names/Abbreviations: PT

Description:

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

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

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

HCPCS Codes (Alpha numeric CPT © AMA):

Code:	**Descriptor:**
85610	Prothrombin Time

ICD-9-CM Codes Covered by Medicare Program:

Code:	Description:
002.0-002.9	Typhoid and paratyphoid
003.0-003.9	Other Salmonella infections
038.9	Unspecified Septicemia
042	Human Immunodeficiency virus (HIV) disease
060.0-060.9	Yellow fever
065.0-065.9	Arthropod-borne hemorrhagic fever
070.0-070.9	Viral hepatitis
075	Infectious mononucleosis
078.6	Hemorrhagic nephrosonephritis
078.7	Arenaviral hemorrhagic fever
084.8	Blackwater fever
120.0	Schistosomiasis
121.1	Clonorchiasis
121.3	Fascioliasis
124	Trichinosis
134.2	Hirudiniasis
135	Sarcoidosis
152.0-152.9	Malignant neoplasm of small intestine, including duodenum
155.0-155.2	Malignant neoplasm of liver and intrahepatic bile ducts
156.0-156.9	Malignant neoplasm of gallbladder and extrahepatic bile ducts
157.0-157.9	Malignant neoplasm of pancreas
188.0-189.9	Malignant neoplasm of bladder, kidney, and other and unspecified urinary organs
198.0	Secondary malignant neoplasm, kidney
198.1	Secondary malignant neoplasm, other urinary organs
200.00-200.88	Lymphosarcoma and reticulosarcoma
202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue
223.0-223.9	Benign neoplasm of kidney and other urinary organs
238.4	Polycythemia vera
238.5	Histocytic and mast cells – neoplasm of uncertain behavior
238.6	Plasma cells – neoplasm of uncertain behavior
238.7	Other lymphatic and hematopoietic tissues
239.4	Neoplasm of unspecified nature, bladder

239.5	Neoplasm of unspecified nature, other genitourinary organs
239.9	Neoplasm of unspecified nature, site unspecified
246.3	Hemorrhage and infarction of thyroid
250.40-250.43	Diabetic with renal manifestations
263.0-263.9	Other and unspecified protein/calorie malnutrition
269.0	Deficiency of Vitamin K
269.2	Unspecified vitamin deficiency
273.0-273.9	Disorders of plasma protein metabolism
275.0	Disorders of iron metabolism
277.1	Disorders of porphyrin metabolism
277.3	Amyloidosis
280.0	Iron deficiency anemia, secondary to blood loss - chronic
280.9	Iron deficiency anemia, unspecified
281.0	Pernicious anemia
281.1	Other Vitamin B12 Deficiency Anemia, NEC
281.9	Unspecified Deficiency Anemia, NOS
285.0	Sideroblastic anemia
285.1	Acute posthemorrhagic anemia
286.0-286.9	Coagulation defects
287.0-287.9	Purpura and other hemorrhagic conditions
290.40-290.43	Arteriosclerotic dementia
325	Phlebitis and thrombophlebitis of intracranial venous sinuses
342.90-342.92	Hemiplegia NOS
360.43	Hemophthalmos, except current injury
362.18	Retinal vasculitis
362.30-362.37	Retinal vascular occlusion
362.43	Hemorrhagic detachment of retinal pigment epithelium
362.81	Retinal hemorrhage
363.61-363.72	Choroidal hemorrhage and rupture, detachment
368.9	Unspecified Visual Disturbances
372.72	Conjunctival hemorrhage
374.81	Hemorrhage of eyelid
376.32	Orbital hemorrhage
377.42	Hemorrhage in optic nerve sheaths
377.53	Disorders of optic chiasm associated with vascular disorders
377.62	Disorders of visual pathways associated with vascular disorders
377.72	Disorders of visual cortex associated with vascular disorders

379.23	Vitreous hemorrhage
380.31	Hematoma of auricle or pinna
386.2	Vertigo of central origin
386.50	Labyrinthine dysfunction, unspecified
394.0-394.9	Diseases of the mitral valve
395.0	Rheumatic aortic stenosis
395.2	Rheumatic aortic stenosis with insufficiency
396.0-396.9	Diseases of mitral and aortic valves
397.0-397.9	Diseases of other endocardial structures
398.0-398.99	Other rheumatic heart disease
403.01, 403.11, 403.91	Hypertensive Renal Disease with renal failure
404.02, 404.12, 404.92	Hypertensive Heart and Renal Disease with renal failure
410.00-410.92	Acute myocardial infarction
411.1	Intermediate coronary syndrome
411.81	Coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease
413.0-413.9	Angina pectoris
414.00-414.06	Coronary atherosclerosis
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
415.0-415.19	Acute pulmonary heart disease
416.9	Chronic pulmonary heart disease, unspecified
423.0	Hemopericardium
424.0	Mitral valve disorders
424.1	Aortic valve disorder
424.90	Endocarditis, valve unspecified, unspecified cause
425.0-425.9	Cardiomyopathy
427.0-427.9	Cardiac dysrhythmias
428.0-428.9	Heart failure
429.0-429.4	Ill-defined descriptions and complications of heart disease
429.79	Other certain sequelae of myocardial infarction, not elsewhere classified
430	Subarachnoid hemorrhage
431	Intracerebral hemorrhage
432.0-432.9	Other and unspecified intracranial hemorrhage

433.00-433.91	Occlusion and stenosis of precerebral arteries
434.00-434.91	Occlusion of cerebral arteries
435.0-435.9	Transient cerebral ischemia
436	Acute, but ill-defined cerebrovascular disease
437.0	Cerebral atherosclerosis
437.1	Other generalized ischemic cerebrovascular disease
437.6	Nonpyogenic thrombosis of intracranial venous sinus
440.0-440.9	Atherosclerosis
441.0-441.9	Aortic aneurysm and dissection
443.0-443.9	Other peripheral vascular disease
444.0-444.9	Arterial embolism and thrombosis
447.1	Stricture of artery
447.2	Rupture of artery
447.6	Arteritis, unspecified
448.0	Hereditary hemorrhagic telangiectasia
448.9	Other and unspecified capillary diseases
451.0-451.9	Phlebitis and thrombophlebitis
452	Portal vein thrombosis
453.0-453.9	Other venous embolism and thrombosis
455.2	Internal hemorrhoids with other complication
455.5	External hemorrhoids with other complication
455.8	Unspecified hemorrhoids with other complication
456.0-456.1	Esophageal varices
456.8	Varices of other sites
459.0	Hemorrhage, unspecified
459.10-459.19	Postphlebetic syndrome
459.2	Compression of vein
459.81	Venous (peripheral) insufficiency, unspecified
459.89	Other, other specified disorders of circulatory system
511.8	Other specified forms of effusion, except tuberculosis
514	Pulmonary congestion and hypostasis
530.7	Gastroesophageal laceration - hemorrhage syndrome
530.82	Esophageal hemorrhage
531.00-535.61	Gastric ulcer, duodenal ulcer, peptic ulcer, gastrojejunal ulcer, gastritis and duodenitis
555.0-555.9	Regional enteritis

556.0-556.9	Ulcerative colitis
557.0-557.9	Vascular insufficiency of intestine
562.02 - 562.03	Diverticulosis of small intestine with hemorrhage
562.10	Diverticulosis of colon w/o hemorrhage
562.11	Diverticulitis of colon w/o hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon with hemorrhage
568.81	Hemoperitoneum (nontraumatic)
569.3	Hemorrhage of rectum and anus
571.0-571.9	Chronic liver disease and cirrhosis
572.2	Hepatic coma
572.4	Hepatorenal syndrome
572.8	Other sequelae of chronic liver disease
573.1-573.9	Hepatitis in viral diseases, other and unspecified disorder of liver
576.0-576.9	Other disorders of Biliary tract
577.0	Acute pancreatitis
578.0-578.9	Gastrointestinal hemorrhage
579.0-579.9	Intestinal Malabsorption
581.0-581.9	Nephrotic Syndrome
583.9	Nephritis, with unspecified pathological lesion in kidney
584.5-584.9	Acute Renal Failure
585	Chronic Renal Failure
586	Renal failure, unspecified
593.81-593.89	Other specified disorders of kidney and ureter
596.7	Hemorrhage into bladder wall
596.8	Other specified disorders of bladder
599.7	Hematuria
607.82	Vascular disorders of penis
608.83	Vascular disorders of male genital organs
611.8	Other specified disorders of breast - hematoma
620.7	Hematoma of broad ligament
621.4	Hematometra
622.8	Other specified noninflammatory disorders of cervix
623.6	Vaginal hematoma
623.8	Other specified noninflammatory disorders of the vagina
624.5	Hematoma of vulva
626.2-626.9	Abnormal bleeding from female genital tract
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding

629.0	Hematocele female, not classified elsewhere
632	Missed abortion
634.10-634.12	Spontaneous abortion, complicated by excessive hemorrhage
635.10-635.12	Legally induced abortion, complicated by delayed or excessive hemorrhage
636.10-636.12	Illegally induced abortion, complicated by delayed or excessive hemorrhage
637.10-637.12	Abortion unspecified, complicated by delayed or excessive hemorrhage
638.1	Failed attempted abortion, complicated by delayed or excessive hemorrhage
639.1	Delayed or excessive hemorrhage following abortion and ectopic and molar pregnancies
639.6	Complications following abortion and ectopic and molar pregnancies with embolism
640.00-640.93	Hemorrhage in early pregnancy
641.00-641.93	Antepartum hemorrhage, abruptio placentae, and placenta previa
642.00-642.94	Hypertension complicating pregnancy, childbirth, and the puerperium
646.70-646.73	Liver disorders in pregnancy
656.00-656.03	Fetal maternal hemorrhage
658.40-658.43	Infection of amniotic cavity
666.00-666.34	Postpartum hemorrhage
671.20-671.94	Venous complications in pregnancy and the puerperium except legs, vulva and perineum
673.00-673.84	Obstetrical pulmonary embolism
674.30-674.34	Other complications of obstetrical surgical wounds
713.2	Arthropathy associated with hematological disorders
713.6	Arthropathy associated with hypersensitivity reaction
719.15	Hemarthrosis pelvic region and thigh
719.16	Lower leg
719.19	Multiple sites
729.5	Pain in limb
733.10	Pathologic fracture, unspecified site
746.00-746.9	Other Congenital anomalies of heart
762.1	Other forms of placental separation and hemorrhage
767.0-767.1	Birth trauma, subdural and cerebral hemorrhage and injury to scalp
767.8	Other specified birth trauma
770.3	Pulmonary hemorrhage

772.0-772.9	Fetal and neonatal hemorrhage
774.6	Unspecified fetal and neonatal jaundice
776.0-776.9	Hemorrhagic disease of the newborn
780.2	Syncope and collapse
782.3	Edema
782.4	Jaundice, unspecified, not of newborn
782.7	Spontaneous ecchymosis
784.7	Epistaxis
784.8	Hemorrhage from throat
785.4	Gangrene
785.50	Shock without mention of trauma
786.05	Shortness of breath
786.3	Hemoptysis
786.59	Chest pain, other
789.00-789.09	Abdominal pain
789.1	Hepatomegaly
789.5	Ascites
790.92	Abnormal coagulation profile
790.94	Euthyroid sick syndrome
791.2	Hemoglobinuria
794.8	Abnormal Liver Function Study
800.00-800.99	Fracture of vault of skull
801.00-801.99	Fracture of base of skull
802.20-802.9	Fracture of face bones
803.00-803.99	Other and unqualified skull fractures
804.00-804.99	Multiple fractures involving skull or face with other bones
805.00-806.9	Fracture, vertebral column
807.00-807.09	Fractures of rib(s), closed
807.10-807.19	Fracture of rib(s), open
808.8-808.9	Unspecified fracture of pelvis
809.0-809.1	Ill-defined fractures of bones of trunk
810.00-810.13	Fracture of clavicle
811.00-811.19	Fracture of scapula
812.00-812.59	Fracture of humerus
813.10-813.18	Fracture of radius and ulna, upper end, open
813.30-813.33	Shaft, open
813.50-813.54	Lower end, open
813.90-813.93	Fracture unspecified part, open
819.0-819.1	Multiple fractures involving both upper limbs, closed and open
820.00-821.39	Fracture of neck of femur
823.00-823.92	Fracture of tibia and fibula
827.0-829.1	Other multiple lower limb
852.00-853.19	Subarachnoid subdural, and extradural hemorrhage, following injury, Other and

	specified intracranial hemorrhage following injury
860.0-860.5	Traumatic pneumothorax and hemothorax
861.00-861.32	Injury to heart and lung
862.0-862.9	Injury to other and unspecified intrathoracic organs
863.0-863.90	Injury to gastrointestinal tract
864.00-864.19	Injury to liver
865.00-865.19	Injury to spleen
866.00-866.13	Injury to kidney
867.0-867.9	Injury to pelvic organs
868.00-868.19	Injury to other intra-abdominal organs
869.0-869.1	Internal injury to unspecified or ill defined organs
900.00-900.9	Injury to blood vessels of head and neck
901.0-901.9	Injury to blood vessels of the thorax
902.0-902.9	Injury to blood vessels of the abdomen and pelvis
903.00-903.9	Injury to blood vessels of upper extremity
904.0-904.9	Injury to blood vessels of lower extremity and unspecified sites
920-924.9	Contusion with intact skin surface
925.1-929.9	Crushing injury
958.2	Secondary and recurrent hemorrhage
959.9	Injury, unspecified site
964.0-964.9	Poisoning by agents primarily affecting blood constituents
980.0-980.9	Toxic effect of alcohol
981	Toxic effect of petroleum products
982.0-982.8	Toxic effects of solvents other than petroleum-based
987.0-987.9	Toxic effect of other gases, fumes or vapors
989.0-989.9	Toxic effect of other substances chiefly non-medicinal as to source
995.2	Unspecified adverse effect of drug, medicinal and biological substance (due to correct medicinal substance properly administered)
996.82	Complication of transplanted liver
997.02	Iatrogenic cerebrovascular infarction or hemorrhage
997.4	Digestive system complications
998.11-998.12	Hemorrhage or hematoma complicating a procedure
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
V42.81-V42.89	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

Indications:

1. A PT may be used to assess patients taking warfarin. The prothrombin time is generally not useful in monitoring patients receiving heparin who are not taking warfarin.

2. A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example:

- swollen extremity with or without prior trauma
- unexplained bruising
- abnormal bleeding, hemorrhage or hematoma
- petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation

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

- dysfibrinogenemia
- afibrinogenemia (complete)

- acute or chronic liver dysfunction or failure, including
- Wilson's disease and Hemochromatosis
- disseminated intravascular coagulation (DIC)
- congenital and acquired deficiencies of factors II, V, VII, X;
- vitamin K deficiency
- lupus erythematosus
- hypercoagulable state
- paraproteinemia
- lymphoma
- amyloidosis
- acute and chronic leukemias
- plasma cell dyscrasia
- HIV infection
- malignant neoplasms
- hemorrhagic fever
- salicylate poisoning
- obstructive jaundice
- intestinal fistula
- malabsorption syndrome
- colitis
- chronic diarrhea
- presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction
- patients with bleeding or clotting tendencies
- organ transplantation
- presence of circulating coagulation inhibitors

4. A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example:

- evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy.
- prior to the use of thrombolytic medication

Limitations:

1. When an ESRD patient is tested for PT, testing more frequently than weekly (the frequency authorized by 3171.2, Fiscal Intermediary Manual, or 2231.3 Medicare Carrier 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)]

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

3. Since the INR is a calculation, it will not be paid in addition to the PT when expressed in seconds, and is considered part of the conventional prothrombin time, 85610.

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

ICD-9-CM Codes That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Sources of Information:

CMD Clinical Laboratory Workgroup

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EDIT 7

Serum Iron Studies

Description:

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

Iron deficiency is the most common cause of anemia. In young children on a milk diet, iron deficiency is often secondary to dietary deficiency. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary deficiency or malabsorption. Following major surgery the patient may have iron deficient erythropoiesis for months or years if adequate iron replacement has not been given. High doses of supplemental iron may cause the serum iron to be elevated. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions.

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

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

Transferrin and ferritin belong to a group of serum proteins known as acute phase reactants, and are increased in response to stressful or inflammatory conditions and also can occur with infection and tissue injury due to surgery, trauma or necrosis. Ferritin and iron/TIBC (or transferrin) are affected by acute and chronic inflammatory conditions, and in patients with these disorders, tests of iron status may be difficult to interpret.

HCPCS Codes **(alpha numeric, CPT © AMA):**

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

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
200.00-208.91	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 diencephalohypophysial origin
256.31-256.39	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
282.60-282.63	Sickle-cell anemia
282.69	Other sickle-cell anemia
285.0	Sideroblastic anemia (includes hemochromatosis with refractory anemia)
285.1	Acute post-hemorrhagic anemia
285.21	Anemia in end-stage renal disease
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	Anorexia 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
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
537.84	Dieulafoy lesion (hemorrhagic) of stomach and duodenum
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 with hemorrhage
562.03	Diverticulitis of small intestine with 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
569.86	Dieulafoy lesion (hemorrhagic) 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
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	Pruritus and related conditions
704.00-704.09	Alopecia
709.00-709.09	Dyschromia
713.0	Arthropathy associated with other endocrine and metabolic 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
790.01-790.09	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

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 disturbances

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

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

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

5. Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (e.g., nickel, cadmium, aluminum, 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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Sources of Information:

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EDIT 8

Collagen Crosslinks, Any Method

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

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
256.31-256.39	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	Symptomatic menopausal or female climacteric state
627.4	Symptomatic 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

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered 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.

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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.

EDIT 9

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.

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
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	Hemochromatosis
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	Peripheral retinal degeneration
362.81-362.89	Other retinal disorders
362.9	Unspecified retinal disorders
365.04	Borderline glaucoma, ocular hypertension
365.32	Corticosteroid-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	Unspecified disorder of optic nerve and visual pathways
378.50-378.55	Paralytic strabismus
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 salivary 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	Choledocholithiasis
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
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
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	Pruritus ani
698.1	Pruritus 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
783.21	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-V23.9	Supervision of high risk pregnancy
V58.69	Long term current use of other medication
V67.2	Follow-up examination, following chemotherapy
V67.51	Follow up examination with high-risk medication not elsewhere classified

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

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.

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EDIT 10

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

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

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 11

Thyroid Testing

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)

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
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	Pituitary dwarfism
253.4	Other anterior pituitary disorders
253.7	Iatrogenic pituitary disorders
255.2	Adrenogenital disorders
255.4	Corticoadrenal insufficiency
256.31-256.39	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	Hypercarotenemia
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 extrapyramidal 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 ophthalmoplegia
376.30-376.31	Exophthalmic conditions, unspecified and constant
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, unspecified
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
564.00-564.09	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
780.99	Other general symptoms
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
783.21	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

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
V67.00-V67.9	Follow-up examination

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

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.

EDIT 12

Lipids

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 or whole blood, total
83715	Lipoprotein, blood; electrophoretic separation and quantitation
83716	Lipoprotein, blood: high resolution fractionation and quantitation of lipoprotein cholesterol (for example, electrophoretic, nuclear magnetic resonance, ultracentrifugation)
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721	Lipoprotein, direct measurement, LDL cholesterol
84478	Triglycerides

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 marasmas
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	Senile corneal changes
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 atherosclerosis of artery bypass graft
414.05	Coronary athrscl-unspec graft
414.06	Coronary atherosclerosis of coronary artery of transplanted heart
414.10	Aneurysm of heart (wall)
414.11	Coronary vessel aneurysm
414.12	Dissection of coronary artery

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	Heart disease, unspecified
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	Cerebral atherosclerosis
437.1	Other generalized ischemic cerebrovascular disease
437.5	Moyamoya disease
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

Indications:

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

- assessment of patients with atherosclerotic cardiovascular disease;
- evaluation of primary dyslipidemia;
- any form of atherosclerotic disease;
- diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism;
- secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure; 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 etretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis.

Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc.

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

When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it is reasonable to perform the lipid panel annually. A lipid panel (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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 13

Digoxin Therapeutic Drug Assay

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)

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
398.91	Rheumatic Heart Failure
402.01	Hypertensive heart disease, malignant with heart failure
402.11	Hypertensive heart disease, benign with heart failure
402.91	Hypertensive heart disease, unspecified with heart failure
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 tendineae
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
780.71-780.79	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.

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 14

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

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
277.03	Cystic fibrosis with gastrointestinal manifestations
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
V10.43	Personal history of malignant neoplasm, ovary
V10.47	Personal history of malignant neoplasm, testis

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.

ICD-9-CM Codes That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 15

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)

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
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
V10.05	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
V10.3	Personal history of malignant neoplasm, breast
V10.43	Personal history of malignant neoplasm, ovary
V67.2	Follow-up examination following chemotherapy

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 16

Human Chorionic Gonadotropin

Other Names/Abbreviations: hCG

Description:

Human Chorionic Gonadotropin

HCPCS Codes (Alpha numeric, CPT © AMA):

Code:	Descriptor:
84702	Gonadotropin, chorionic (hCG); quantitative

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 specified
181	Malignant neoplasm of placenta
183.0	Malignant neoplasm of ovary
183.8	Other specified sites of uterine adnexa
186.0	Malignant neoplasm of undescended testis
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
633.90-633.91	Unspecified 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 puerperium
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	Normal pregnancy

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, hypertension 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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 17

Tumor Antigen by Immunoassay - CA125

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

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

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 CA125 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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Documentation Requirements:

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

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.

EDIT 18

Tumor Antigen by Immunoassay
CA 15-3/CA 27.29

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)

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 (breast)
198.81	Secondary malignant neoplasm (breast)
V10.3	Personal history of malignant neoplasm, breast

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 19

Tumor Antigen by Immunoassay
CA 19-9

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

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

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 20

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

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

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 That Do Not Support Medical Necessity

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 21

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)

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
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
304.00-304.93	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
642.50-642.54	Severe pre-eclampsia

646.70, 646.71, 646.73	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 dehydrogenase
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 nonmedicinal 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

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

EDIT 22

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

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

HCPCS Codes (alpha numeric, CPT © AMA):

Code:	Descriptor:
80074	Acute Hepatitis Panel

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
789.61	Localized abdominal tenderness (RUQ)
794.8	Nonspecific abnormal results of function
996.82	Complications of transplanted organ, liver
999.3	Other infection following infusion, injection, transfusion, or vaccination
V72.85	Liver transplant recipient evaluation

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 That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

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.

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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.

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

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EDIT 23

Fecal Occult Blood

Description:

The fecal occult blood test detects the presence of trace amounts of blood in stool. The procedure is performed by testing one or several small samples of one, two or three different stool specimens.

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

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

1) Immunoassays recognize antigenic sites on the globin portion and are least affected by diet or proximal gut bleeding, but the antigen may be destroyed by fecal flora.

2) The heme-porphyrin assay measures heme-derived porphyrin and is least influenced by enterocolic metabolism or fecal storage. This assay does not discriminate dietary from endogenous heme. The capacity to detect proximal gut

bleeding reduces its specificity for colorectal cancer screening but makes it more useful for evaluating overall GI bleeding in case finding for iron deficiency anemia.

3) The guaiac-based test is the most widely used. It requires the peroxidase activity of an intact heme moiety to be reactive. Positivity rates fall with storage. Fecal hydration such as adding a drop of water increases the test reactivity but also increases false positivity.

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

HCPCS Codes (alpha numeric, CPT © AMA):

Code:	Descriptor:
82270	Blood, occult, by peroxidase activity (eg guaiac); feces, 1-3 simultaneous determinations

ICD-9-CM Codes Covered by Medicare Program:

Code:	Description:
003.0	Salmonella gastroenteritis
003.1	Salmonella septicemia
004.0-004.9	Shigellosis
005.0-005.9	Other food poisoning (bacterial)
006.0-006.9	Amebiasis
007.0-007.9	Other protozoal intestinal diseases
008.41-008.49	Intestinal infections due to other specified bacteria
009.0-009.3	Ill-defined intestinal infections
014.00-014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands
040.2	Whipple's disease

095.2	Syphilitic peritonitis
095.3	Syphilis of liver
098.0	Gonococcal infection, acute, lower genitourinary tract
098.7	Gonococcal Infection anus and rectum
098.84	Gonococcal endocaritis
123.0-123.9	Other cestode infection
124	Trichinosis
127.0-127.9	Other intestinal helminthiases
139.8	Late effects of other and unspecified infectious and parasitic diseases
150.0-157.9	Malignant neoplasm of digestive organisms
159.0-159.9	Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum
176.3	Kaposi's sarcoma, gastrointestinal sites
197.4-197.5	Secondary malignant neoplasm of intestines
197.8	Secondary malignant neoplasm of other digestive organs and spleen
199.0	Disseminated malignant neoplasm
204.00-204.91	Lymphoid leukemia
205.00-208.91	Leukemia
211.0-211.9	Benign neoplasm of other parts of digestive system
228.04	Hemangioma of intra-abdominal structures
230.2-230.9	Carcinoma in situ of digestive organs
235.2	Neoplasm of uncertain behavior of stomach, intestines, and rectum
235.5	Neoplasm of uncertain behavior of other and unspecified digestive organs
239.0	Neoplasm of unspecified nature, digestive system
280.0-280.9	Iron deficiency anemias
285.0-285.9	Other and unspecified anemias
286.0-286.9	Coagulation defects
287.0-287.9	Purpura and other hemorrhagic conditions
448.0	Hereditary hemorrhagic telangiectasia
455.0-455.8	Hemorrhoids

456.0-456.21	Esophageal varices with or without mention of bleeding
530.10-535.61	Diseases of the esophagus, stomach, and duodenum
536.2	Persistent vomiting
536.8-536.9	Dyspepsia and other specified and unspecified functional disorders of the stomach
537.0-537.4	Other disorders of stomach and duodenum
537.82-537.83	Angiodysplasia of stomach and duodenum
537.84	Dieulafoy lesion (hemorrhagic) of stomach and duodenum
537.89	Other specified disorders of stomach and duodenum
555.0-558.9	Non-infectious enteritis and colitis
560.0-560.39	Intestinal obstruction/impaction without mention of hernia
562.10-562.13	Diverticulosis/diverticulitis of colon
564.00-564.9	Functional digestive disorders, not elsewhere classified
565.0-565.1	Anal fissure and fistula
569.0	Anal and rectal polyp
569.1	Rectal prolapse
569.3	Hemorrhage of rectum and anus
569.41-569.49	Other specified disorders of rectum and anus
569.82-569.83	Ulceration and perforation of intestine
569.84-569.85	Angiodysplasia of intestine with or without mention of hemorrhage
569.86	Dieulafoy lesion (hemorrhagic) of intestine
571.0-571.9	Chronic liver disease and cirrhosis
577.0-577.9	Diseases of the pancreas
578.0-578.9	Gastrointestinal hemorrhage
579.0	Celiac disease
579.8	Other specified intestinal malabsorption
596.1	Intestinovesical fistula
617.5	Endometriosis of intestine
780.71	Chronic fatigue syndrome
780.79	Other malaise and fatigue
783.0	Anorexia
783.21	Abnormal loss of weight
787.01-787.03	Nausea and vomiting
787.1	Heartburn
787.2	Dysphagia

787.7	Abnormal feces
787.91	Diarrhea
787.99	Other symptoms involving digestive system
789.00-789.09	Abdominal pain
789.30-789.39	Abdominal or pelvic swelling, mass, or lump
789.40-789.49	Abdominal rigidity
789.5	Ascites
789.60-789.69	Abdominal tenderness
790.92	Abnormal coagulation profile
792.1	Nonspecific abnormal findings in stool contents
793.6	Nonspecific abnormal findings on radiological and other
794.8	Nonspecific abnormal results of function studies, liver
863.0-863.90	Injury to gastrointestinal tract
864.00-864.09	Injury to liver without mention of open wound into cavity
864.11-864.19	Injury to liver with open wound into cavity
866.00-866.03	Injury to kidney without mention of open wound into cavity
866.10-866.13	Injury to kidney with open wound into cavity
902.0 -902.9	Injury to blood vessels of abdomen and pelvis
926.11-926.19	Crushing injury of trunk, other specified sites
926.8	Crushing injury of trunk, multiple sites
926.9	Crushing injury of trunk, unspecified site
964.2	Poisoning by agents primarily affecting blood constituents, anticoagulants
995.2	Unspecified adverse effect of drug, medicinal, and biological substance
V10.00-V10.09	Personal history of malignant neoplasm, gastrointestinal tract
V12.00	Personal history of unspecified infectious and parasitic disease
V12.72	Personal history of colonic polyps

V58.61	Long term (current) use of anticoagulants
V58.69	Long term (current) use of other medications
V67.51	Following treatment with high risk medication, not elsewhere specified

Indications:

1. To evaluate known or suspected alimentary tract conditions that might cause bleeding into the intestinal tract.

2. To evaluate unexpected anemia.

3. To evaluate abnormal signs, symptoms, or complaints that might be associated with loss of blood.

4. To evaluate patient complaints of black or red-tinged stools.

Limitations:

1. Code 82270 is reported once for the testing of up to three separate specimens (comprising either one or two tests per specimen).

2. In patients who are taking non-steroidal anti-inflammatory drugs and have a history of gastrointestinal bleeding but no other signs, symptoms, or complaints associated with gastrointestinal blood loss, testing for occult blood may generally be appropriate no more than once every three months.

3. When testing is done for the purpose of screening for colorectal cancer in the absence of signs, symptoms, conditions, or complaints associated with gastrointestinal blood loss, HCPCS code G0107 (Colorectal cancer screening; fecal-occult blood test, 1-3 simultaneous determinations) should be used. Coverage of colorectal cancer screening is described in CMS Program Memorandum Transmittal No. AB-97-24 (November, 1997).

ICD-9-CM Codes That Do Not Support Medical Necessity:

Any ICD-9-CM code not listed in either of the ICD-9-CM covered or non-covered sections.

Sources of Information:

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NCD MANUAL UPDATES

DATE	REASON	RELEASE	CHANGE	EDIT
11/25/02	CPT code removed from CR2130	2003100	Removed 87087 Per CMS	1 Culture Bacterial, Urine
11/25/02	CR2194 Annual Updates of ICD-9-CM New Codes	2002400	ICD-9 code 780.9(Other general symptoms) replaced. Adding new code 780.99	1 Culture Bacterial, Urine 11 Thyroid Testing
11/25/02	Description changed in CR2130 and the Federal Register. 780.9 Other general symptoms (hyperthermia)	2003100	Changed description to: Other general symptoms	11 Thyroid Testing
11/25/02	CR 2130 Narrative and ICD-9-CM mismatch 99.8 Other specified venereal disease 99.9 Venereal disease unspecified	2003100	Changed ICD-9-CM codes to 099.8 and 099.9	3 Human Immunodeficiency Virus Testing (Diagnosis)
11/25/02	CR2194 Revised description: Congestive heart failure 428.0	2002400	Changed description to: Congestive heart failure, unspecified	5 Partial Thromboplastin Time 11 Thyroid Testing
11/25/02	CR2194 Revised description: Menopausal or female climacteric states 627.2	2002400	Changed description to: Symptomatic menopausal or female climacteric states	8 Collagen Crosslinks, Any methods
11/25/02	CR2194 Revised description: States associated with artificial menopause 627.4	2002400	Changed description to: Symptomatic states associated with artificial menopause	8 Collagen Crosslinks, Any methods
11/25/02	CR2194 Annual Updates of ICD-9-CM Additional Truncated Codes 414.06	2002400	ICD-9 code 414.06 added to Coronary atherosclerosis 414.00-414.05	6 Prothrombin Time 9 Blood Glucose Testing 12 Lipids
11/25/02	CR2194 Annual Updates of ICD-9-CM Additional Truncated Codes 414.12	2002400	ICD-9 code 414.12 added to aneurysm and dissection of heart 414.10-414.19	9 Blood Glucose Testing 12 Lipids

11/25/02	CR2194 Annual Updates of ICD-9-CM New Sub-category V54.1 Aftercare for healing traumatic fracture	2002400	New ICD-9 codes V54.10-V54.17, V54.19, added to Other orthopedic aftercare V54.0-V54.9	4 Blood Counts
11/25/02	CR2194 Annual Updates of ICD-9-CM New Sub-category V54.2 Aftercare for healing pathologic fracture	2002400	New ICD-9 codes V54.20-V54.27, V54.29, added to Other orthopedic aftercare V54.0-V54.9	4 Blood Counts
11/25/02	CR2194 Annual Updates of ICD-9-CM Additional Truncated Codes V54.8 Other orthopedic aftercare	2002400	New ICD-9 codes V54.81, V54.89 added to Other orthopedic aftercare V54.0-V54.9	4 Blood Counts
11/25/02	CR2194 Annual Updates of ICD-9-CM New Code 823.4 Torus fracture Additional Truncated Codes	2002400	ICD-9 codes added to Fracture of tibia and fibula (823.00-823.92) 823.40, 823.41, and 823.42	5 Partial Thromboplastin Time 6 Prothrombin Time
11/25/02	CR2194 Annual Updates of ICD-9-CM New Sub-categories 428.2 Systolic heart failure 428.3 Diastolic heart failure 428.4 Combined systolic and diastolic heart failure	2002400	ICD-9 codes added to heart failure (428.0-428.9) 428.20-428.23, 428.30-428.33, 428.40-428.43	6 Prothrombin Time 7 Serum Iron Studies 12 Lipids 13 Digoxin Therapeutic Drug Assay
11/25/02	CR2194 Annual Updates of ICD-9-CM New sub-category 443.2 Other arterial dissection	2002400	ICD-9 codes added for Other peripheral vascular disease (443.0-443.9) 443.21, 443.22, 443.23, 443.24, 443.29	6 Prothrombin Time
11/25/02	CR2194 Annual Updates of ICD-9-CM Additional Truncated Codes 459.1 Postphlebitic syndrome	2002400	ICD-9 codes 459.1 replaced with 459.10, 459.11, 459.12, 459.13, and 459.19 for Postphlebitis syndrome	6 Prothrombin Time

11/25/02	CR2194 Annual Updates of ICD-9-CM Additional Truncated Codes V23.4 Pregnancy with other poor obstertric history	2002400	ICD-9 codes added for Supervision of high risk pregnancy (V23.0-V23.9) V23.41 and V23.49	9 Blood Glucose Testing
11/25/02	CR2194 Annual Updates of ICD-9-CM Additional and Truncated Codes 438 Late effects of cerebrovascular disease	2002400	ICD-9 codes added to Late effects of cerebrovascular disease (438.0-438.9) 438.6, 438.7, 438.83, 438.84, 438.85	12 Lipids
11/25/02	CR2194 Annual Updates of ICD-9-CM Additional Truncated Codes 633.9 Unspecified ectopic pregnancy	2002400	ICD-9 codes added to unspecified ectopic pregnancy (633.9) 633.90 and 633.91	16 Human Chorionic Gonadotropin
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 521.0 (Diseases of hard tissue of teeth) changed to 521.00	4 Blood Counts
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code V59.0 (Blood) Changed to V59.01-V59.02, V59.09	4 Blood Counts
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 733.1(Pathologic fracture, unspecified site) changed to 733.10	6 Prothrombin Time
11/25/02	CR2130 Corrections	2003100	ICD-9 code 813.38 (Shaft, open) changed to 813.33 Radius with ulna	6 Prothrombin Time
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 863.9(Injury to gastrointestinal tract) changed to 863.90	6 Prothrombin Time
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 790.0 (Abnormality of red blood cells) changed to 790.01 and 790.09	7 Serum Iron Studies
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 256.3 (Other ovarian failure) changed to 256.31 and 256.39	8 Collagen Crosslinks, Any Method 11 Thyroid Testing
11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 564.0 (Constipation) changed to 564.00-564.02, 564.09	11 Thyroid Testing 23 Fecal Occult Blood

11/25/02	CR2130 Corrections Code not truncated	2003100	ICD-9 code 200.0-208.91 (Malignant neoplasm of lymphatic and hematopoietic tissue) changed to 200.00	7 Serum Iron Studies
11/25/02	CR2130 Correction Removed second sentence from #1 in the limitations section. The reference in the Federal Register was to a different code and that code has been deleted.	2003100	1. CPT 87086 may be used one time per encounter. ~~CPT 87086 and 87088 are not used concurrently.~~	1 Culture, Bacterial, Urine
11/25/02	CR2194 Revised Diagnosis Code Title 414.10 Of heart (wall)	2002400	414.10 Aneurysm of heart (wall)	12 Lipids
11/25/02	CR2194 Annual Updates of ICD-9-CM New code added.	2003100	ICD-9 code 277.03 (Cystic Fibrosis with gastrointestinal manifestations)	14 Alpha-fetoprotein
11/25/02	CR2194 Annual Updates of ICD-9-CM New code added.	2003100	ICD-9 code 537.84 Dieulafoy lesion (hemorrhagic) of stomach and duodenum	5 Partial Thromboplastin Time 7 Serum Iron Studies 23 Fecal Occult Blood
11/25/02	CR2194 Annual Updates of ICD-9-CM New code added.	2003100	ICD-9 code 569.86 Dieulafoy lesion (hemorrhagic) of intestine	7 Serum Iron Studies 23Fecal Occult Blood
11/25/02	CR2194 Annual Updates of ICD-9-CM New codes added.	2003100	ICD-9 code 771.81-771.83 Other infection specific to the perinatal period.	1 Culture, Bacterial, Urine
11/25/02	Codes listed in the Federal Register. Missing in CR2130	2003100	Added ICD-9-CM codes 634.00-634.02(Spontaneous abortion, complicated by genital tract and pelvic infection), 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 puerperium	16 Human Chorionic Gonadotropin

11/25/02	CR2130 Revised description: Benign neoplasm of skin 214.0	2003100	Changed description to: Lipoma, skin and subcutaneous tissue of face	4 Blood Counts
11/25/02	Codes listed in the Federal Register. Missing in CR2130.	2003100	Added ICD-9-CM codes 216.0-216.9 (Benign neoplasm of skin)	4 Blood Counts
11/25/02	CR2194 Revised description: Hypertensive heart disease, malignant with CHF 402.01	2002400	Changed description to: Hypertensive heart disease, malignant with heart failure	13 Digoxin Therapeutic Drug Assay
11/25/02	CR2194 Revised description: Hypertensive heart disease, benign with CHF 402.11	2002400	Changed description to: Hypertensive heart disease, benign with heart failure	13 Digoxin Therapeutic Drug Assay
11/25/02	CR2194 Revised description: Hypertensive heart disease unspecified with CHF 402.91	2002400	Changed description to: Hypertensive heart disease, unspecified with heart failure	13 Digoxin Therapeutic Drug Assay
11/25/02	CR2130 list wrong ICD-9-CM code 401.1	2003100	Federal Register list ICD-9-CM code 401.0	12 Lipids
11/25/02	Federal Register and CR 2130 listed code 780.2 in error	2003100	Removed ICD-9-CM code 780.2 (syncope and collapse). Added ICD-9-CM code 780.02 (General symptoms, transient alteration of awareness)	1 Culture, Bacterial, Urine
11/25/02	Federal Register and CR2130 list ICD-9-CM code as 272.0-272-4	2003100	Changed ICD-9-CM codes to 272.0-272.4	9 Blood Glucose Testing
11/25/02	Federal Register and CR2130 list ICD-9-CM code as 793.6/793.7	2003100	Changed ICD-9-CM codes to793.6-793.7	20 Prostate Specific Antigen
04/01/03	CPT codes removed from CR2130	2003200	Procedure codes 87184 and 87186	1 Culture Bacterial, Urine
04/01/03	CPT codes deleted after grace period of 03/31/03 CR 2578	2003200	85021, 85022, 85023, 85024, 85031, 85590, 85595	4 Blood Counts
01/01/03	ICD-9 CM code terminated as of 12/31/02 per CR2194	2002400	780.9	1 Culture Bacterial, Urine 11Thyroid Testing

01/01/03	ICD-9 CM code terminated as of 12/31/02 per CR2194	2002400	V54.8	4 Blood Counts
01/01/03	ICD-9 CM code terminated as of 12/31/02 per CR2194	2002400	459.1	6 Prothrombin Time
01/01/03	ICD-9 CM code terminated as of 12/31/02 per CR2194	2002400	V23.4	9 Blood Glucose Testing
01/01/03	ICD-9 CM code terminated as of 12/31/02 per CR2194	2002400	633.9	16 Human Chorionic Gonadotropin
04/01/03	CPT codes revised description: Blood count; manual differential WBC count (includes RBC morphology and platelet estimation) 85007	2003100	Changed description to: Blood count; blood smear, microscopic examination with manual differential WBC count	4 Blood Counts
04/01/03	CPT codes revised description: Blood count; manual blood smear examination without differential parameters 85008	2003100	Changed description to: Blood count; blood smear, microscopic examination without manual differential WBC count	4 Blood Counts
04/01/03	CPT codes revised description: Blood count; other than spun hematocrit 85014	2003100	Changed description to: Blood count; hematocrit (Hct)	4 Blood Counts
04/01/03	CPT codes revised description: Blood count; hemogram and platelet count, automated, and automated complete differential WBC count (CBC) 85025	2003100	Changed description to: Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count	4 Blood Counts
04/01/03	CPT codes revised description: Blood count; hemogram and platelet count, automated 85027	2003100	Changed description to: Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)	4 Blood Counts

04/01/03	CPT codes revised description: Blood count; white blood cell (WBC) 85048	2003100	Changed description to: Blood count; leukocyte (WBC), automated	4 Blood Counts
11/25/02	ICD-9 CM code/ description mismatch: Diverticulosis of small intestine without hemorrhage 562.02	2003200	Changed description to: Diverticulosis of small intestine with hemorrhage	7 Serum Iron Studies
11/25/02	ICD-9 CM code/ description mismatch: Diverticulitis of small intestine without hemorrhage 562.03	2003200	Changed description to: Diverticulitis of small intestine with hemorrhage	7 Serum Iron Studies
04/01/03	ICD-9 CM added per CR 2578	2003200	282.60, 282.61, 282.62, 282.63, 282.69, 285.21	7 Serum Iron Studies