Medicare National Coverage Determinations Manual

Chapter 1, Part 3 (Sections 170 – 190.34)

Coverage Determinations

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(Rev. 90, 07-25-06)

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(Rev. 1, 10-03-03)

170.1 - Institutional and Home Care Patient Education Programs

(Rev. 1, 10-03-03)
CIM 80-1

While the Act does not specifically identify patient education programs as covered services, reimbursement may be made under Medicare for such programs furnished by providers of services (i.e., hospitals, SNFs, HHAs, and OPT providers) to the extent that the programs are appropriate, integral parts in the rendition of covered services which are reasonable and necessary for the treatment of the individual's illness or injury. For example, educational activities carried out by nurses such as teaching patients to give themselves injections, follow prescribed diets, administer colostomy care, administer medical gases, and carry out other inpatient care activities may be reimbursable as a part of covered routine nursing care. Also, the teaching by an occupational therapist of compensatory techniques to improve a patient's level of independence in the activities of daily living may be reimbursed as a part of covered occupational therapy. Similarly, the instruction of a patient in the carrying out of a maintenance program designed for him/her by a physical therapist may be reimbursed as part of covered physical therapy.

However, when the educational activities are not closely related to the care and treatment of the patient, such as programs directed toward instructing patients or the public generally in preventive health care activities, reimbursement cannot be made since the Act limits Medicare payment to covered care which is reasonable and necessary for the treatment of an illness or injury. For example, programs designed to prevent illness by instructing the general public in the importance of good nutritional habits, exercise regimens, and good hygiene are not reimbursable under Medicare.

170.2 - Melodic Intonation Therapy

(Rev. 1, 10-03-03)
CIM 35-67

Melodic intonation therapy is a technique used in language rehabilitation. Its purpose is to teach aphasic patients to produce useful phrases by intoning them in a melodic pattern with strong rhythmic support. Limited studies by a few institutions show some benefit for a small number of nonfluent aphasic patients otherwise unresponsive to conventional therapy.

Melodic intonation therapy is a covered service only for nonfluent aphasic patients unresponsive to conventional therapy, and only when the conditions for coverage of speech pathology services are met. Please refer to the Medicare Benefit Policy, Chapter 15, "Covered Medical and Other Health Services," §220; the Medicare Claims Processing Manual, Chapter 5, "Part B Outpatient Rehabilitation and CORF Services," for these conditions of coverage.

170.3 - Speech -Language Pathology Services for the Treatment of Dysphagia

(Rev. 55, Issued: 05-05-06, Effective: 10-01-06, Implementation: 10-02-06)

Dysphagia is a swallowing disorder that may be due to various neurological, structural, and cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, or encephalopathies. While dysphagia can afflict any age group, it most often appears among the elderly. Speech-language pathology services are covered under Medicare for the treatment of dysphagia, regardless of the presence of a communication disability.

Patients who are motivated, moderately alert, and have some degree of deglutition and swallowing functions are appropriate candidates for dysphagia therapy. Elements of the therapy program can include thermal stimulation to heighten the sensitivity of the swallowing reflex, exercises to improve oral-motor control, training in laryngeal adduction and compensatory swallowing techniques, and positioning and dietary modifications. Design all programs to ensure swallowing safety of the patient during oral feedings and maintain adequate nutrition.

Cross-reference:

The Medicare Benefit Policy, Chapter 15, "Covered Medical and Other Health Services," §§220 and 230.3.

180 - Nutrition

(Rev. 1, 10-03-03)

180.1 - Medical Nutrition Therapy

(Rev. 1, 10-03-03)
CIM 80-3

Section 1861(s)(2)(V) of the Act authorizes Medicare part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. Regulations for medical nutrition therapy (MNT) were established at 42 CFR 410.130 - 410.134. This national coverage determination establishes the duration and frequency limits for the MNT benefit and coordinates MNT and diabetes outpatient self-management training (DSMT) as a national coverage determination.

Effective October 1, 2002, basic coverage of MNT, for the first year a beneficiary receives MNT, with either a diagnosis of renal disease or diabetes as defined at 42 CFR 410.130 is three hours, of administration. Also, effective October 1, 2002, basic coverage in subsequent years for renal disease or diabetes is two hours. The dietitian/nutritionist may choose how many units are administered per day as long as all of the other requirements in this NCD and 42 CFR 410.130-410.134 are met. Pursuant to the exception at 42 4CFR 410.132(b)(5), additional hours are considered to be medically

necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

Effective October 1, 2002, if the treating physician determines that receipt of both MNT and DSMT is medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in the NCD and 42 CFR 410.130-410.134 are met. Pursuant to the exception at 42 CFR 410.132(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

180.2 - Enteral and Parenteral Nutritional Therapy

(Rev. 1, 10-03-03)
CIM 65-10

Covered As Prosthetic Device

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are not covered under Part B in situations involving temporary impairments.

Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

Parenteral Nutrition Therapy Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than three months by the carrier's medical consultant or specially trained staff, relying on such medical and other documentation as the carrier may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.

Enteral Nutrition Therapy

Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or nonfunction of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the contractor's medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time. If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional Supplementation

Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

190 - Pathology and Laboratory
(Rev. 1, 10-03-03)

190.1 - Histocompatibility Testing
(Rev. 1, 10-03-03)
CIM 50-23

Histocompatibility testing involves the matching or typing of the human leucocyte antigen (HLA). This testing is safe and effective when it is performed on patients:

- In preparation for a kidney transplant;
- In preparation for bone marrow transplantation;
- In preparation for blood platelet transfusions (particularly where multiple infusions are involved); or

- Who are suspected of having ankylosing spondylitis.

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

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

190.2 - Diagnostic Pap Smears

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)
CIM 50-20, CIM 50-20.1

A diagnostic pap smear and related medically necessary services are covered under Medicare Part B when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated;

- Previous abnormal pap smear;

- Any abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa;

- Any significant complaint by the patient referable to the female reproductive system; or

- Any signs or symptoms that might in the physician's judgment reasonably be related to a gynecologic disorder.

Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer. (See section 210.2.)

190.3 - Cytogenetic Studies

(Rev. 1, 10-03-03)
CIM 50-29

The term cytogenetic studies is used to describe the microscopic examination of the physical appearance of human chromosomes. Medicare covers these tests when they are reasonable and necessary for the diagnosis or treatment of the following conditions:

- Genetic disorders (e.g., mongolism) in a fetus (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §20.1

- Failure of sexual development; or

- Chronic myelogenous leukemia.

- Acute leukemias lymphoid (FAB L1-L3), myeloid (FAB M0-M7), and unclassified; or

- Myelodysplasia.

190.4 - Electron Microscope
(Rev. 1, 10-03-03)
CIM 50-18

The electron microscope has been used in the examination of biopsies for years; its efficacy, and therefore its Medicare coverage, is not being questioned. However, there are less expensive methods for examining biopsies which are normally adequate. The additional expense for the electron microscope is normally warranted only when distinguishing different types of nephritis from renal needle biopsies or when there is an uncertain diagnosis from the pathologist. When an uncertain diagnosis from the pathologists results from a less expensive method of examination and an electron microscope examination is therefore necessary, both biopsy examinations are covered. Where the additional expense for an electron microscope examination is not warranted, payment is based upon the less costly methods of examining biopsies.

190.5 - Sweat Test
CIM 50-35

The sweat test is an important diagnostic tool in cystic fibrosis and may be covered when used for that purpose. Usage of the sweat test as a predictor of efficacy of sympathectomy in peripheral vascular disease is unproven and, therefore, is not covered.

190.6 - Hair Analysis
(Rev. 1, 10-03-03)
CIM 50-24

Not Covered

Hair analysis to detect mineral traces as an aid in diagnosing human disease is not a covered service under Medicare.

The correlation of hair analysis to the chemical state of the whole body is not possible at this time, and therefore this diagnostic procedure cannot be considered to be reasonable and necessary under §1862(a)(1) of the Act.

190.7 - Human Tumor Stem Cell Drug Sensitivity Assays
(Rev. 1, 10-03-03)
CIM 50-41

Human tumor stem cell drug sensitivity assays involve exposure of human tumor stem cell colonies grown in tissue culture to anticancer drugs and observing for cytotoxic effects. Their purpose is to screen potential anticancer drugs and predict the effects of these drugs on tumors of individual patients, to allow the selection of the most effective drug or drugs for that patient. Human tumor drug sensitivity assays are considered experimental, and therefore, not covered under Medicare at this time.

The Fluorescent Cytoprint Assay, a miniaturized organ culture system for cancer chemosensitivity testing, allows for qualitative visual estimation of cell kill using low power microscopy and a noncytotoxic fluoresence probe for cell viability. The clinical application of the assay, based on testing in tumor microorgans rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

190.8 - Lymphocyte Mitogen Response Assays

(Rev. 1, 10-03-03)
CIM 50-45

For Services Performed On or After May 16, 1983

The lymphocyte mitogen response assay measures the immune response of patient peripheral blood lymphocytes. It is a covered test under Medicare when it is medically necessary to assess lymphocytic function in diagnosed in munodeficiency diseases and to monitor immunotherapy.

It is not covered when it is used to monitor the treatment of cancer, because its use for that purpose is experimental.

190.9 - Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS)

(Rev. 1, 10-03-03)
CIM 50-52

Serologic testing is employed to detect antibodies to the AIDS virus which is currently identified by the term “human immunodeficiency virus (HIV).” The virus originally was named “human T-cell lymphotropic virus, type III (HTLV-III),” a term that remains in common usage.

Antibodies may be detected by a variety of immunoassay techniques, the most common being an enzyme-linked immunosorbent assay (ELISA). When an assay is reactive on initial testing, it should be repeated on the same specimen. A more specific test, (Western blot, immunofluorescent assay) is usually performed following repeatedly reactive ELISA results.

These tests may be covered when performed to help determine a diagnosis for symptomatic patients. They are not covered when furnished as part of a screening program for asymptomatic persons.

NOTE: Two enzyme-linked immunosorbent assay (ELISA) tests that were conducted on the same specimen must both be positive before Medicare will cover the Western blot test.

190.10 - Laboratory Tests - CRD Patients

(Rev. 1, 10-03-03)
CIM 50-17

Laboratory tests are essential to monitor the progress of CRD patients. The following list and frequencies of tests constitute the level and types of routine laboratory tests that are covered. Bills for other types of tests are considered nonroutine. Routine tests at greater frequencies must include medical justification. Nonroutine tests generally are justified by the diagnosis. The routinely covered regimen includes the following tests:

Per Dialysis

- All hematocrit or hemoglobin and clotting time tests furnished incident to dialysis treatments.

Per Week

- Prothrombin time for patients on anticoagulant therapy, and
- Serum Creatinine

Per Week or Thirteen Per Quarter

- BUN

Monthly

- CBC,
- Serum Calcium,
- Serum Chloride,
- Serum Potassium,
- Serum Bicarbonate,
- Serum Phosphorous,
- Total Protein,
- Serum Albumin,
- Alkaline Phospatase,
- AST,
- SGOT, and

- LDH.

Guidelines for tests other than those routinely performed include:

- Serum Aluminum - one every 3 months, and
- Serum Ferritin - one every 3 months

The following tests for hepatitis B are covered when patients first enter a dialysis facility: hepatitis B surface antigen (HBsAg) and Anti-HBs. Coverage of future testing in these patients depends on their serologic status and on whether they have been successfully immunized against hepatitis B virus. The following table summarizes the frequency of serologic surveillance for hepatitis B. Tests furnished according to this table do not require additional documentation and are paid separately because payment for maintenance dialysis treatments does not take them into account.

FREQUENCY OF SCREENING

	Vaccination and Serologic Status	**HbsAg Patients**	**Anti-HBs Patients**
Unvaccinated	Susceptible	Monthly	Semiannually
Unvaccinated	HBsAg Carrier	Annually	None
Unvaccinated	Anti-HBs-Positive (1)	None	Annually
Vaccinated	Anti-HBs-Positive (1)	None	Annually
Vaccinated	Low Level or No Anti-HBs	Monthly	Semiannually

(1) At least 10 sample ration units by radioimmunoassay or positive by enzyme immunoassay.

Patients who are in the process of receiving hepatitis B vaccines, but have not received the complete series, should continue to be routinely screened as susceptible. Between one and six months after the third dose, all vaccines should be tested for anti-HBs to confirm their response to the vaccine. Patients who have a level of anti-HBs of at least 10 sample ratio units (SRUs) by radioimmunoassay (RIA) or who are positive by enzyme immunoassay (EIA) are considered adequate responders to vaccine and need only be tested for anti-HBs annually to verify their immune status. If anti-HBs drops below 10 SRUs by RIA or is negative by EIA, a booster dose of hepatitis B vaccine should be given.

Laboratory tests are subject to the normal coverage requirements. If the laboratory services are performed by a free-standing facility, the facility must meet the conditions of coverage for independent laboratories.

190.11 - Home Prothrombin Time*/International Normalized Ratio* (*PT*/INR) Monitoring for Anticoagulation Management – *Effective March 19, 2008*

(Rev. 90, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

A. General

Use of the International Normalized Ratio (INR) *or prothrombin time (PT) - standard measurement for reporting the blood's clotting time)* - allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's *PT (extrinsic or tissue-factor dependent coagulation pathway)* compared to the mean *PT* for a group of normal individuals. Maintaining patients within *his/her prescribed* therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Warfarin (also prescribed under other trade names, e.g., Coumadin®) is a self-administered, oral anticoagulant (blood thinner) medication that affects the vitamin K-dependent clotting factors II, VII, IX and X. It is widely used for various medical conditions, and has a narrow therapeutic index, meaning it is a drug with less than a 2-fold difference between median lethal dose and median effective dose. For this reason, since October 4, 2006, it falls under the category of a Food and Drug Administration (FDA) "black-box" drug whose dosage must be closely monitored to avoid serious complications. A PT/INR monitoring system is a portable testing device that includes a finger-stick and an FDA-cleared meter that measures the time it takes for a person's blood plasma to clot

B. Nationally Covered Indications

For services furnished on or after *March 19, 2008,* Medicare will cover the use of home *PT/*INR monitoring for *chronic, oral* anticoagulation management for patients with mechanical heart valves*, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism)* on *w*arfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a), and *all of* the following requirements must be met:

1. The patient must have been anticoagulated for at least *3* months prior to use of the home INR device; *and,*

2. The patient must undergo a *face-to-face* educational program on anticoagulation management and *must have demonstrated the correct* use of the device prior to its use in the home; *and,*

3. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,

4. Self-testing with the device should not occur more frequently than once a week.

C. Nationally Non-Covered Indications

N/A

D. Other

1. All other indications for home PT/INR monitoring not indicated as nationally covered above remain at local Medicare contractor discretion.

2. This national coverage determination (NCD) is distinct from, and makes no changes to, the PT clinical laboratory NCD at section 190.17 of Publication 100-03 of the NCD Manual.

(This NCD last reviewed March 2008.)

190.12 - Urine Culture, Bacterial

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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.

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 know 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 of prostate).

6. Urine culture may be indicated to detect occult infection in renal transplantation 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 U.S. Preventive Services Task Force has concluded that screening for asymptomatic bacteriuria outside of the narrow indication for pregnant women is generally not indicated. There are insufficient data to recommend screening in ambulatory elderly 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.

190.13 - Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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.

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

Indications

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

2. Regular periodic measurement of plasma HIV RNA levels may be medically necessary to determine risk for disease progression in an HIV-infected individual and to determine when to initiate 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 situation 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 antiretroviral 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 of FDA-approved status.

190.14 - Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)
PM AB-02-100

Diagnosis of 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 use method is the Western Blot.

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

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

Indications

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

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.

2. The patient has another documented sexually transmitted disease, which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.

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

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

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

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

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

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

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

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

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

Limitations

1. HIV antibody testing in the United States is usually performed using HIV-1 or HIV-1/2 combination tests. HIV-2 testing is indicated if clinical circumstances suggest HIV-2 is likely (that is, compatible clinical finding 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-approved status for these tests.

190.15 - Blood Counts

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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.

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, lmphadenopathy, 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 indication 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 or 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 indication 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 transfusions, 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 related to differential count related to the WBC include, in addition to those already listed, storage diseases; mucopolysaccharidoses, and use of drugs that case leukocytosis such as G-CSF or CM-CSF.

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

Limitations

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

2. In some circumstances it may be appropriate to perform only a hemoglobin or hematocrit to assess the oxygen carrying capacity of the blood. When the ordering provider requests only 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.

190.16 - Partial Thromboplastin Time (PTT)

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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

Indications

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

2. A PTT may be used to assess patients with signs or symptoms of hemorrhage or thrombosis. For example: Abnormal bleeding, hemorrhage or hematoma petechiae or other signs of thrombocytopenia that could be dues 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; sepsis; vonWillebrand's disease; arterial and venous thrombosis, including the evaluation of hypercoagulable states; clinical conditions associated with nephrosis or renal failure; other acquired and congenital coagulopathies as well as thrombotic states.

4. A PTT may be used to assess the risk of thrombosis or hemorrhage in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. An example is as follows: evaluation prior to invasive procedures or operations of patients with personal or family history of bleeding or who are on heparin therapy.

Limitations

1. The PTT is not useful in monitoring the effects of warfarin on a patient's coagulation routinely. However, a PTT may be ordered on a patient being treated with warfarin as heparin therapy is being discontinued. A PTT may also be indicated when the PT is markedly prolonged due to warfarin toxicity.

2. The need to repeat this test is determined by changes in the underlying medical condition and/or 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/clinical-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

190.17 - Prothrombin Time (PT)

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: the partial thromboplastin time (PTT), PT, thrombin time, or a quantitative fibrinogen determination. The PT test is one in-vitro laboratory test used to assess coagulation. While the PTT assesses the intrinsic limb of the coagulation system, the PT assesses the extrinsic or tissue factor dependent pathway. Both tests also evaluate the common coagulation pathway involving all the reactions that occur after the activation of factor X.

Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of factors may be related to decreased production of increased consumption of coagulation factors. The PR/INR is most

commonly used to measure the effect of warfarin and regulate its dosing. Warfarin blocks the effect of vitamin K on hepatic production of extrinsic pathway factors. A PT is expressed in seconds and/or as an international normalized ration (INR). The INR is the PT ration 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.

Indications

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

2. A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example: swollen extremity with or without prior trauma; unexplained bruising; abnormal bleeding, hemorrhage, or hematoma; petechiae or other signs or 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 acquires. 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. APT 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 of a condition associated with coagulopathy; prior to the use of thrombolytic medication.

Limitations

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

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

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

4. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other that thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality of 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.

190.18 - Serum Iron Studies

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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 patients is fasting in the morning and has abstained form 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 transferring, a protein that binds and transports iron. TIBC quantifies transferring 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 transferring are within the reference range or low, and the percent saturation is elevated. Serum ferritin can be useful for both initiating and monitoring treatment for iron overload.

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

Indications

1. Ferritin, iron and either iron binding capacity or transferrin are useful in the differential diagnosis or iron deficiency, anemia and for iron overload conditions.

a. The following presentations are examples that may support the use of these studies for elevating 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 with width (RDW) and low or normal MCV); abnormal appetite (pica); acute or chronic gastrointestinal blood loss; hematuria; menorrhagia; malabsorption; status post-gastrectomy; status port-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 example that may support the se 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 anemia, 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 ion 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 or iron studies might alter the management of the primary diagnosis or might warrant direct treatment of an iron disorder or condition.

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

3. When an end stage renal disease (ESRD) patient is tested for ferritin, testing more frequently than every three months requires documentation of medical necessity (e.g., other than chronic renal failure or renal failure, unspecified).

4. It is ordinarily not necessary to measure both transferring 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 of on a subsequently obtained specimen. After a diagnosis of iron deficiency or iron overload is established, either iron/TIBC (or transferring) 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.

190.19 - Collagen Crosslinks, Any Method

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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

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

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

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

Indications

Generally speaking, collagen crosslink testing is useful mostly in “fast losers” of bone. The age when these bone markers can help direct therapy is often pre-Medicare. By the time a fast loser of bone reaches age 65, she will most likely have been stabilized by appropriate therapy or have lost so much bone mass that further testing is useless. Coverage for bone marker assays may be established, however, for younger Medicare beneficiaries and for those men and women who might become fast losers because of

some other therapy such as glucocorticoids. Safeguards should be incorporated to prevent excessive use of tests in patients for whom they have no clinical relevance.

Collagen crosslinks testing is used to:

1. Identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored.

2. Predict response (as assessed by bone mass measurements) to FDA approved antiresorptive therapy in postmenopausal women.

3. Assess response to treatment of patients with osteoporosis, Paget's disease or the bone, or risk for osteoporosis where treatment may include FDA approved antiresorptive agents, anti-estrogens or selective estrogens receptor moderators.

Limitations

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

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

190.20 - Blood Glucose Testing

(Rev. 28, Issued: 02-11-05, Effective: 01-01-05, Implementation: 03-11-05)

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 or an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

Indications

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in 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.

Effective January 1, 2005, the Medicare law expanded coverage to diabetic screening services. Some forms of blood glucose testing covered under this national coverage determination may be covered for screening purposes subject to specified frequencies. See 42 CFR 410.18 and section 90, chapter 18, of the Claims Processing Manual, for a full description of this screening benefit.

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).

190.21 - Glycated Hemoglobin/Glycated Protein

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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 assessment, 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 a s a result of glucocorticoid therapy). Glycated protein in serum/plasma assesses glycemic control over a period of 1-2 weeks. It may be reasonable and necessary to monitor glycated protein monthly in pregnant diabetic women. Glycated hemoglobin/protein test results may be low, indicating significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the patient's hypoglycemic state in those conditions.

Indications

Glycated hemoglobin/protein testing is 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 3 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 section provides the clinical basis for those situations in which testing more frequently than four

times per annum is indicated, and medically necessary 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.

190.22 - Thyroid Testing

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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

Laboratory evaluation of thyroid function has become more scientifically defined. Tests can be done with increased specificity, thereby reducing the number of tests needed to diagnose and follow treatment of most thyroid disease. Measurements of serum sensitive thyroid-stimulating hormone (TSH) levels, complemented by determination of thyroid hormone levels [free thyroxine (fT-4) or total thyroxine (T4) with Triiodothyronine (T3) uptake] are used for diagnosis and follow-up of patients with thyroid disorders.

Additional tests may be necessary to evaluate certain complex diagnostic problems or on hospitalized patients, where many circumstances can skew tests results. When a test for total thyroxine (total T4 or T4 radioimmunoassay) or T3 uptake is performed, calculation of the free thyroxine index (FTI) is useful to correct for abnormal results for either total T4 or T3 uptake due to protein binding effects.

Indications

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

- Distinguish between primary and secondary hypothyroidism
- Confirm or rule our primary hypothyroidism

- Monitor thyroid hormone levels (for example, patients with goiter, thyroid nodules, or thyroid cancer)

- Monitor dug therapy in patients with primary hypothyroidism

- Confirm or rule out primary hyperthyroidism

- Monitor therapy in patients with hyperthyroidism

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

It may be medically necessary to do follow-up thyroid testing in patients with a 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 of hypothyroidism are noted.

190.23 - Lipid Testing

(Rev. 28, Issued: 02-11-05, Effective: 01-01-05, Implementation: 03-11-05)

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise, genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease (including diabetes), and kidney disease.

In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol (LDL-C) and high

density lipoprotein cholesterol (HDL-C), are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Blood levels of the above cholesterol components including triglyceride have been separated into desirable, borderline and high-risk categories by the National Heart, Lung, and Blood Institute in their report in 1993. These categories form a useful basis for evaluation and treatment of patients with hyperlipidemia. Therapy to reduce these risk parameters includes diet, exercise and medications, and fat weight loss, which is particularly powerful when combined with diet and exercise.

Indications

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

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease, or any disease leading to the formation of atherosclerotic disease
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure
- Signs or symptoms of dyslipidemias, such as skin lesions
- As follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200-140 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 the lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.

When monitoring long-term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel at a yearly interval will

usually be adequate while measurement of the serum total cholesterol or a measured LDL should suffice for interim visits if the patient does not have hypertriglyceridemia.

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

Electrophoretic or other quantitation of lipoproteins may be indicated if the patient has a primary disorder of lipoid metabolism.

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

Limitations

Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid etretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis.

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

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

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

Any one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol, HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate

initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

If no dietary or pharmacologic 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.

190.24 - Digoxin Therapeutic Drug Assay

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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

Indications

Digoxin levels may be performed to monitor drugs 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 indication may include individuals:

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

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

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

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

Digoxin is indicated for the treatment of patients with heart failure due to systolic dysfunction and for reduction of the ventricular response in patients with atrial fibrillation of 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.

190.25 - Alpha-fetoprotein

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

Alpha-fetoprotein (AFP) is a polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

Indications

The 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, retroperitoneum, and mediastinum.

190.26 - Carcinoembryonic Antigen

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

Carcinoembryonic antigen (CEA) is a protein polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

Indications

The 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 situation, 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.

190.27 - Human Chorionic Gonadotropin

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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

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

190.28 - Tumor Antigen by Immunoassay - CA 125

(Rev. 47, Issued: 02-24-06, Effective: 01-01-06, Implementation: 01-03-06)

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses tumor antigen CA 125.

Indications

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

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

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

Limitations

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either

the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

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

(This NCD last reviewed November 2005)

190.29 - Tumor Antigen by Immunoassay CA 15-3/CA 27.29

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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

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 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 time necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

190.30 - Tumor Antigen by Immunoassay CA 19-9

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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: CA 19-9.

Indications

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

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

Limitations

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

190.31 - Prostate Specific Antigen

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

Prostate Specific Antigen (PSA), a tumor marker for adenocarcinoma of the prostate, can predict residual tumor in the post-operative phase of prostate cancer. Three to 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 form those in whom limited response is anticipated.

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

Indications

The 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.

190.32 - Gamma Glutamyl Transferase

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

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 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 is serum is almost always the result of liver disease or injury. It is specifically useful to differentiate elevated alkaline phosphatase level 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 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 Warning.)

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

Indications

1. To provide information about known or suspected hepatobiliary disease, for example:

    a. Following chronic alcohol or drug ingestion

b. Following exposure to hepatotoxins

c. When using medication known to have a potential for causing liver toxicity (e.g., following the drug manufacturer's recommendations)

d. Following infection (e.g., viral hepatitis and other specific infections such as amebiasis, tuberculosis, psittacosis, and similar infections)

2. To assess liver injury/function following diagnosis of primary or secondary malignant neoplasms

3. To assess liver injury/function in a wide variety of disorders and diseases known to cause liver involvement (e.g., diabetes mellitus, malnutrition, disorders of iron and mineral metabolism, sarcoidosis, amyloidosis, lupus and hypertension)

4. To assess liver function related to gastrointestinal disease

5. To assess liver function related to pancreatic disease

6. To assess liver function in patients subsequent to liver transplantation

7. To differentiate between the different sources of elevated alkaline phosphatase activity

Limitations

When used to assess liver dysfunction secondary to existing non-hepatobiliary disease with no change in signs, symptoms, or treatment, it is generally not necessary to repeat a GGT determination after a normal result has been obtained unless new indications are present.

If the GGT is the only "liver" enzyme abnormally high, it is generally not necessary to pursue further evaluation for liver disease for this specific indication.

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

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

190.33 - Hepatitis Panel/Acute Hepatitis Panel

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB-02-110

This panel consists of the following tests:

- Hepatitis A antibody (HAAb), IgM antibody;
- Hepatitis B core antibody (HBcAb), IgM antibody;
- Hepatitis B surface antigen (HBsAg) and;
- Hepatitis C antibody;

Hepatitis is an inflammation of the liver resulting from viruses, drugs, toxins, and other etiologies. Viral hepatitis can be due to one of at least five different viruses, designated hepatitis A, B, C, and E. Most cases are caused by hepatitis A virus (HAV), hepatitis B virus (HBV), or hepatitis C virus, (HCV).

The HAV is the most common cause of hepatitis in children and adolescents in the Untied 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 form infection. Although HAV is spread most commonly by fecal-oral exposure, standard immune globulin may be effective as a prophylaxis.

The HBV produces three separate antigen (surface, cores 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 6 months after its appearance. If HBsAg remains detectable for greater than 6 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 2-3 months following exposure. The IgM antibody gradually declines or disappears entirely 1-2 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 and HBV diagnosis. HBcAb, on the other hand, rises to a much higher titer and remain 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 4-6 months following exposure to infected blood or body fluids; in the U.S., sexual transmission accounts for 30-60 percent of new cases of HBV infection.

The diagnosis of acute HBV infection is best established by documentation of positive IgM antibody against the core antigen (HBcAb-IgM) and by identification of

a positive hepatitis B surface antigen (HBsAg). The diagnosis of chronic HBV infection is established primarily by identifying a positive hepatitis B surface antigen (HBsAg) and demonstrating positive IgG antibody directed against the core antigen (HBcAb-IgG). Additional tests such as hepatitis B e antigen (HBeAg) and hepatitis B e antibody (HBeAb), the envelope antigen and antibody, are not included in the hepatitis panel, but may be of importance in assessing the infectivity of patients with HBV. Following completion of a HBV vaccination series, HBsAB alone may be used monthly for up to 6 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 15-20 percent 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 2-4 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 2 weeks to 2 months later to exclude the possibility of hepatitis. Once a diagnosis is established, specific tests can be used to monitor the course of the disease.

Indications

1. To detect viral hepatitis infection when there are abnormal liver function test results, with or without signs or symptoms of hepatitis.

2. Prior to and subsequent to liver transplantation.

Limitations

After a hepatitis diagnosis has been established, only individual tests, rather than the entire panel, are needed.

190.34 - Fecal Occult Blood Test

(Rev. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)
PM AB 02-110

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

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

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

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

2. The heme-porphyrin assay measures heme-derived porphyrin and is least influenced by enterocolic metabolism or fecal storage. This assay does not discriminate dietary from endogenous heme. The capacity to detect proximal gut bleeding reduces its specificity for colorectal cancer screening but makes it more useful for evaluating overall GI bleeding in case finding for iron deficiency anemia.

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

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

Indications

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

2. To evaluate unexpected anemia.

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

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

Limitations

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

2. In patients who are taking non-steroidal anti-inflammatory drugs and have a history of gastrointestinal bleeding but no other sign, symptoms, or complaints associated with gastrointestinal blood loss, testing for occult blood may generally be appropriate no more than once every 3 months.

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

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R90NCD	07/25/2008	Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management	08/25/2008	6138
R55NCD	05/05/2006	Changes Conforming to CR 3648 Instructions for Therapy Services	10/02/2006	4014
R48NCD	03/17/2006	Technical Corrections to the NCD Manual	06/19/2006	4278
R47NCD	02/24/2006	Changes to the Covered Indications for Tumor Antigen by Immunoassay CA 125 to Add Primary Peritoneal Carcinoma	01/03/2006	4257
R28NCD	02/11/2005	Update of Laboratory NCDs to Reference New Screening Benefits	03/11/2005	3690
R17NCD	07/02/2004	Manualization of the Negotiated Clinical Diagnostic Laboratory National Coverage Determinations	N/A	2130
R10NCD	04/06/2004	Re-release of NCD Manual	N/A	N/A
R01NCD	10/01/2003	Initial Release of Manual	N/A	N/A