CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 17 **Date: JULY 2, 2004**

CHANGE REQUEST 2130

I. SUMMARY OF CHANGES: This transmittal manualizes the 23 laboratory negotiated rulemaking national coverage determinations (NCDs). These NCDs are currently contained in PM AB-02-110 and have been converted to the NCD manual without change to the narrative. Coding guidance contained in the PM is not being manualized but is available in the NCD Coding Manual on the Internet at cms.hhs.gov/ncd/labindexlist.asp.

MANUALIZATION – EFFECTIVE DATE: Not Applicable
IMPLEMENTATION DATE: Not Applicable

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	1/190.12/Urine Culture, Bacterial
N	1/190.13/Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)
N	1/190.14/Human Immunodeficiency Virus (HIV) Testing (Diagnosis)
N	1/190.15/Blood Counts
N	1/190.16/Partial Thromboplastin Time (PTT
N	1/190.17/Prothrombin Time (PT)
N	1/190.18/Serum Iron Studies
N	1/190.19/Collagen Crosslinks, Any Method
N	1/190.20/Blood Glucose Testing
N	1/190.21/Glycated Hemoglobin/Glycated Protein
N	1/190.22/Thyroid Testing
N	1/190.23/Lipid Testing
N	1/190.24/Digoxin Therapeutic Drug Assay
N	1/190.25/Alpha-fetoprotein
N	1/190.26/Carcinoembryonic Antigen
N	1/190.27/Human Chorionic Gonadotropin
N	1/190.28/Tumor Antigen by Immunoassay – CA 125

N	1/190.29/Tumor Antigen by Immunoassay CA 15-3/CA 27.29
N	1/190.30/Tumor Antigen by Immunoassay CA 19-9
N	1/190.31/Prostate Specific Antigen
N	1/190.32/Gamma Glutamyl Transferase
N	1/190.33/Hepatitis Panel/Acute Hepatitis Panel
N	1/190.34/Fecal Occult Blood Test

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 17	Date: July 2, 2004	Change Request 2130

SUBJECT: Manualization of the Negotiated Clinical Diagnostic Laboratory National Coverage Determinations

I. GENERAL INFORMATION

A. Background: On November 23, 2001, CMS published a final rule (66 FR 58788) on coverage and administrative policies for clinical diagnostic laboratory services. The rule included an addendum that contained 23 national coverage determinations (NCDs) that had been developed under negotiated rulemaking. We implemented these NCDs through Program Memorandum AB 02-110, which became effective November 25, 2002.

B. Policy: By way of this CR, we are manualizing the 23 negotiated laboratory NCDs into publication 100-03, the National Coverage Determination Manual. The narrative of the NCDs is being manualized unchanged. The coding guidelines that are associated with these NCDs is available in the NCD Coding Manual, which is published quarterly on the Internet at cms.hhs.gov/ncd/labindexlist.asp. Since this policy has been implemented for nearly 2 years, no action on the part of the contractors is required at this time.

C. Provider Education: None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
N/A		

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: Not Applicable **Implementation Date: Not Applicable** **Pre-Implementation Contact(s):** Jackie Sheridan-Moore 410-786-4635 **Post-Implementation Contact(s):** Jackie Sheridan-Moore 410-786-4635	**These instructions shall be implemented within your current operating budget.**

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

Sections 160 thru 200

Table of Contents

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

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.

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

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-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 dues 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. 17, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

PM AB-02-110

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.

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

PM AB-02-110

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.

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

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

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 - Antigen by Immunoassay – CA 125

(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 tumor antigen CA 125.

Indications

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.

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.

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 advance 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 sign of symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

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

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.

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

Indications

PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs 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 is 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.)

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).

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.

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.

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