Summary: Prothrombin Time (PT)

NCD 190.17

The terms of Medicare National Coverage Determinations (NCDs) are binding on all fee-for-service (Part A/B) Medicare Administrative Contractors (MACs) and Medicare Advantage (MA) plans. NCDs are not binding, however, on Medicaid and other governmental payers, nor are they binding on commercial payers in their non-MA lines of business.

Item/Service Description*

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

Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of factors may be related to decreased production or increased consumption of coagulation factors. The PT/INR is most commonly used to measure the effect of warfarin and regulate its dosing. Warfarin blocks the effect of vitamin K on hepatic production of extrinsic pathway factors.

A PT is expressed in seconds and/or as an international normalized ratio (INR). The INR is the PT ratio that would result if the WHO reference thromboplastin 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 prothrombin time is generally not useful in monitoring patients receiving heparin who are not taking warfarin.

2. A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example: swollen extremity with or without prior trauma; unexplained bruising; abnormal bleeding, hemorrhage or hematoma; petechiae or other signs of thrombocytopenia that could be due to disseminated intravascular coagulation.

3. A PT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example: dysfibrinogenemia; afibrinogenemia (complete); acute or chronic liver dysfunction or failure, including Wilson's disease and Hemochromatosis; disseminated intravascular coagulation (DIC); congenital and acquired deficiencies of factors II, V, VII, X; vitamin K deficiency; lupus erythematosus; hypercoagulable state; paraproteinemia; lymphoma; amyloidosis; acute and chronic leukemias; plasma cell dyscrasia; HIV infection; malignant neoplasms; hemorrhagic fever; salicylate poisoning; obstructive jaundice; intestinal fistula; malabsorption syndrome; colitis; chronic diarrhea; presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction; patients with bleeding or clotting tendencies; organ transplantation; presence of circulating coagulation inhibitors.

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

Limitations*

1. When an ESRD patient is tested for PT, testing more frequently than weekly 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.

*This language is a direct quote from the NCD.

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

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

Representative List of Covered ICD-10-CM Diagnosis Codes

The following diagnosis codes are among those identified as "ICD-10-CM Codes Covered by Medicare Program" in the CMS "National Coverage Determinations (NCD) Coding Policy Manual and Change Report (ICD-10-CM)" section that identifies covered diagnosis codes for the above-described NCD.

ICD-10 Code	Description
B19.20	Unspecified viral hepatitis C without hepatic coma
D50.9	Iron deficiency anemia, unspecified
D51.8	Other vitamin B12 deficiency anemias
D51.9	Vitamin B12 deficiency anemia, unspecified
D68.59	Other primary thrombophilia
D68.8	Other specified coagulation defects
D68.9	Coagulation defect, unspecified
E83.10	Disorder of iron metabolism, unspecified
E83.19	Other disorders of iron metabolism
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I48.0	Paroxysmal atrial fibrillation

ICD-10 Code	Description
I48.1	Persistent atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation
I50.9	Heart failure, unspecified
N92.5	Other specified irregular menstruation
N92.6	Irregular menstruation, unspecified
R06.02	Shortness of breath
R07.9	Chest pain, unspecified
R10.9	Unspecified abdominal pain
R79.1	Abnormal coagulation profile
R94.5	Abnormal results of liver function studies
Z79.01	Long term (current) use of anticoagulants

To view a full list of covered codes and the complete NCD, please visit the CMS website, www.cms.gov.

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