APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Prothrombin time home testing systems are portable, battery-operated instruments for the quantitative determination of prothrombin time from finger-stick whole blood. These products are designed to aid in the management of high-risk patients taking oral anticoagulants. Self-testing and/or self-management by the patient using home international normalization ratio (INR) monitors represent another model of care with the potential for improved outcomes as well as greater convenience. Self-testing can provide a convenient opportunity for increased frequency of testing when deemed necessary. The use of the same instrument may increase the degree of consistency in instrumentation, and self-testing provides the potential for greater knowledge and awareness of
therapy which may lead to improved compliance. In a randomized controlled trial, Gardiner and colleagues (2005) tested to see if patients could achieve accurate INR values through patient self-testing (PST) by means of the CoaguChek S (Roche Diagnostics, Lewes, UK). A total of 84 subjects (53 men, 31 women; median age of 59 years), receiving long-term oral anticoagulation (warfarin), were recruited. Subjects were randomized to weekly self-testing or continuing 4-weekly hospital laboratory monitoring of INR. Comparison of INRs (n = 234) showed no significant differences between the CoaguChek (median INR 3.02) and laboratory testing (median INR 3.07). There was excellent correlation between the two methods (r = 0.95), with 85% of CoaguChek results within 0.5 INR units of the laboratory method. On four occasions, differences of greater than 1 unit INR were obtained, but in each case the patient's anticoagulation was unstable (INR greater than 4.5 by both methods) and the differences in INR would not have altered patient management. Results showed that 87% of patients found self-testing straightforward, 87% were confident in the result they obtained and 77% preferred self-testing. These investigators concluded that PST is a reliable alternative to hospital clinic attendance and is acceptable to the majority of suitably trained patients.

In 2002, CMS issued a national coverage determination for the use of home prothrombin time INR monitoring for anticoagulation management for patients with mechanical heart valves on warfarin. More recently, a draft CMS Decision Memorandum (2007) concluded that there is sufficient evidence of the effectiveness of home prothrombin time (INR) monitoring for patients with a mechanical heart valve, chronic atrial fibrillation, or deep venous thrombosis. The monitor and the home testing must be prescribed by a treating physician and the following requirements must be met:

- The patient must have been anticoagulated for at least three months prior to use of the home INR devices; and
- The patient must undergo an educational program on anticoagulation management and demonstrated the correct use of the device prior to its use in the home; and
- The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following initiation of home monitoring; and
- Self-testing with the device should not occur more frequently than once a week.

**POSITION STATEMENT**

**Applicable To:**
- Medicaid
- Medicare

**Exclusions**

1. When an ESRD member 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 member 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 member's medical status.

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

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.

**Coverage**

Prothrombin Time Monitoring (PT) is **considered medically necessary** for home use PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or
venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. Medicare will cover the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin.”

In addition, PT monitoring is considered medically necessary in ANY of the following circumstances:

1. Used to assess members taking warfarin; OR,
   NOTE: The prothrombin time is generally not useful in monitoring members receiving heparin who are not taking warfarin.

2. Used to assess members 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); OR,

3. Used in evaluating members 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; OR,
   NOTE: 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. 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).

CODING

CPT® Codes – No applicable codes.

Covered HCPCS Level II Codes

G0248++ Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing prior to its use.

G0249++ Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week.

G0250++ Physician review, interpretation, and patient management of home INR testing for a patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes face-to-face verification by the physician that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week.

Non Covered HCPCS Level II ® Codes

E1399++ Durable medical equipment, miscellaneous, when billed for Home Prothrombin Monitor.

ICD-9-CM Procedure Code – No applicable codes.

Covered ICD-9-CM Diagnosis Codes

286.6 Defibrination syndrome
415.11  Iatrogenic pulmonary embolism and infarction
415.12  Pulmonary embolism and infarction: septic pulmonary embolism
415.19  Other Pulmonary embolism without acute cor pulmonale
427.31  Atrial fibrillation (established) (paroxysmal)
444.01-444.9  Arterial embolism and thrombosis
451.0-451.9  Phlebitis and thrombophlebitis
452    Portal vein thrombosis
453.0-453.9  Other venous embolism and thrombosis
459.0  Hemorrhage, unspecified
585.6  End stage renal disease
782.7  Spontaneous ecchymoses (Petechiae)
920-924.9  Contusion with Intact Skin Surface (hematoma)
V43.3  Heart valve replaced by other means [mechanical]
V58.61  Long-term (current) use of anticoagulants (Warfarin)

++CMS Transmittal 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08
NOTE: This test is not covered as E1399 durable medical equipment, miscellaneous. Therefore, claims submitted to DMERCs will not be paid. It is covered under the physician fee schedule. Also note that the cost of the device and supplies is included in the payment for G0249 and therefore not separately billed to Medicare. G0249 continues to include materials for 4 tests. Additionally, G0250 continues to mean per 4 tests and should be billed no more frequently than once every 4 weeks.

Covered ICD-10-CM Diagnosis Codes
D65  Disseminated intravascular coagulation (defibrination syndrome)
D68.59  Other primary thrombophilia
I26.90  - I26.99  Pulmonary embolism without acute cor pulmonale
I27.82  Chronic pulmonary embolism
I48.0  Atrial fibrillation
I74.01-I74.9  Arterial embolism and thrombosis
I80.00  - I80.9  Phlebitis and thrombophlebitis
I81  Portal vein thrombosis
I82.0-I82.91  Other venous embolism and thrombosis
N18.6  End stage renal disease
R23.3  Spontaneous ecchymoses
R58  Hemorrhage, not elsewhere classified
S00.03xA-S00.03xS  Contusion of scalp
S00.10xA-S00.12xS  Contusion of eyelid and periocular area
S00.33xA’-S00.33xS  Contusion of nose
S00.431A-S00.439S  Contusion of ear
S00.531A-S00.532S  Contusion of lip and oral cavity
S00.83xA-S00.83xS  Contusion of other part of head
S00.93xA-S00.93xS  Contusion of unspecified part of head
S05.10xA-S05.12xS  Contusion of eyeball and orbital tissues
S10.0xxxA-S10.0xxS  Contusion of throat
S10.83xA-S10.83xS  Contusion of other specified part of neck
S10.93xA-S10.93xS  Contusion of unspecified part of neck
S20.00xA-S20.02xS  Contusion of breast
S20.20xA-S20.229S  Contusion of thorax
S30.0xA-S30.0xS  Contusion of lower back and pelvis
S30.1xxA-S30.1xxS  Contusion of abdominal wall
S30.201A-S30.23xS  Contusion of external genital organs
S30.3xxA-S30.3xxS  Contusion of anus
S40.011A-S40.029S  Contusion of shoulder and upper arm
S50.00xA-S50.12xS  Contusion of elbow
S60.00xA-S60.059S  Contusion of finger without damage to nail
S60.10xA-S60.159S  Contusion of finger with damage to nail
S60.211A-S60.229S  Contusion of wrist and hand
S70.00xA-S70.02xS  Contusion of hip
S70.10xA-S70.12xS  Contusion of thigh
S80.00xA-S80.02xS  Contusion of knee
S80.10xA-S80.12xS  Contusion of lower leg
S90.00xA-S90.02xS  Contusion of ankle
S90.111A-S90.129S  Contusion of toe without damage to nail
S90.211A-S90.229S  Contusion of toe with damage to nail
S90.30xA-S90.32xS  Contusion of foot
O08.2  Embolism following ectopic and molar pregnancy
O22.20 - O22.23  Superficial thrombophlebitis in pregnancy
O22.30 - O22.33  Deep phlebothrombosis in pregnancy
O87.0  Superficial thrombophlebitis in the puerperium
O87.1  Deep phlebothrombosis in the puerperium
T80.1  Vascular complications following infusion, transfusion and therapeutic injection
T81.718  Complication of other artery following a procedure, not elsewhere classified
T81.72xD - T81.72xS  Complication of vein following a procedure, not elsewhere classified
Z95.2  Presence of prosthetic heart valve
Z79.01  Long term (current) use of anticoagulants (Warfarin)

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member’s benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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