Clinical Coverage Guideline

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; paraproteinemias; lymphoma; amyloidosis; acute and chronic leukemias; plasma cell dyscrasia; HIV infection; malignant neoplasms; hemolytic anemia; 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.

**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 eyelid and orbital tissues
S10.0xA-S10.0xS 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
S30.1xA-S30.1xS Contusion of abdominal wall
S30.201A-S30.23xS Contusion of external genital organs
S30.3xA-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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/2/2017, 1/12/2017</td>
<td>• Approved by MPC. No changes.</td>
</tr>
<tr>
<td>1/7/2016, 1/8/2015</td>
<td>• Approved by MPC. Coding changes.</td>
</tr>
<tr>
<td>1/9/2015, 12/6/2012</td>
<td>• Approved by MPC. No changes.</td>
</tr>
<tr>
<td>1/5/2012</td>
<td>• Approved by MPC. Reformatted references. No changes.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>• New template design approved by MPC.</td>
</tr>
</tbody>
</table>