

## Medical Policy



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### Title: Home Prothrombin Time Monitoring

#### **Professional**

Original Effective Date: September 18, 2009  
Revision Date(s): June 29, 2012;  
August 20, 2013; November 24, 2015;  
August 4, 2016; December 1, 2016  
Current Effective Date: September 18, 2009

#### **Institutional**

Original Effective Date: October 19, 2009  
Revision Date(s): June 29, 2012;  
August 20, 2013; November 24, 2015;  
August 4, 2016; December 1, 2016  
Current Effective Date: October 19, 2009

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### **DESCRIPTION**

Patients who are prescribed chronic warfarin anticoagulation need ongoing monitoring that has generally taken place in a physician's office or anticoagulation clinic. Home prothrombin monitoring with a U.S. Food and Drug Administration (FDA)-approved device is proposed as an alternative to office or laboratory-based testing.

### **Background**

Warfarin is an effective anticoagulant for the treatment and prevention of venous and arterial thrombosis. Chronic warfarin therapy is recommended in all patients with mechanical heart valves and in some patients with chronic AF (atrial fibrillation) (ie, patients with risk factors that indicate a higher likelihood of stroke). Patients with

mechanical heart valves are frequently prescribed anticoagulants at higher levels than patients given anticoagulants for other indications, which puts them at higher risk of complications from warfarin therapy. Appropriate levels of warfarin anticoagulation are monitored with periodic prothrombin time measurements, as measured by the INR (International Normalized Ratio). The target INR range is 2.0 to 3.0 for most patients. An INR result greater than 3 indicates an increased risk of serious hemorrhage, while an INR less than 2 is associated with an increased risk of stroke. An INR of 6 indicates an increased risk of developing a serious bleed nearly 7 times that of someone with an INR less than 3. Therefore, monitoring of the prothrombin time is recommended to ensure that the prescribed dosing regimens result in INRs within the therapeutic range. Anticoagulation can be monitored: in the physician's office (usually once a month), at an anticoagulation clinic (usually once every 2 to 3 weeks), or at home.

For home prothrombin time monitoring to be effective, patients need to be appropriately trained and able to generate INR test results comparable to laboratory measures. Moreover, the clinical impact of home prothrombin time monitoring is related to improved warfarin management. Specifically, home prothrombin time monitoring permits more frequent monitoring and self-management of warfarin therapy with the ultimate goal of (1) increasing the time that the anticoagulation is within a therapeutic INR range (intermediate health outcome); and (2) decreasing the incidence of thromboembolic or hemorrhagic events (final health outcome). Home self-monitoring is typically associated with some form of self-management of warfarin therapy. In some cases, the patient may be supplied with treatment algorithms and instructed to alter the dose based on the results of self-monitoring. In other cases, the patient may be instructed to provide the results of the self-monitoring (eg, on the telephone or internet) and receive instructions on warfarin dosage.

### **Regulatory Status**

In January 2007, the CoaguChek® XS System (patient self-testing) (Roche Diagnostics) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices, including the CoaguChek SX System (professional, cleared in 2006). Other than a labeling change, the device is identical to the professional version of the CoaguChek XS System. The patient self-testing system is intended for self-monitoring of prothrombin time in patients who are on a stable regimen of anticoagulation medications.

Another device cleared by FDA for home prothrombin time monitoring includes the ProTime® Microcoagulation System (International Technidyne Corporation).

## **POLICY**

- A. The medical necessity of Home Prottime Monitoring will be considered on a case by case basis.
- B. Home Prottime Monitoring for patient convenience is **non-covered**.

**Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

## **RATIONALE**

The preferred study design to evaluate home prothrombin time (PT) monitoring is a randomized controlled trial (RCT) comparing home PT monitoring with either monitoring in a physician's office or monitoring in specialized coagulation clinics. As with any monitoring technology, one would ideally want to isolate the contribution of the monitored data itself from the possible impact of increased patient education or contact with health professionals that is typically associated with more intense monitoring. Final health outcomes would preferably focus on the incidence of hemorrhagic or embolic events. However, due to the low incidence of these events, published studies often report instead the intermediate outcome of time spent in the therapeutic range of warfarin, as measured by the international normalized ratio (INR). Prior research has established a strong link between time outside the therapeutic range and adverse events such as bleeding and thromboembolism. Therefore, time in the therapeutic range is a useful intermediate outcome for true health outcomes in this situation.

This policy was updated with searches of the MEDLINE database. The most recent literature search was performed for the period January 23, 2013, through February 3, 2014. Following is a summary of the literature to date.

### **Home Monitoring During Maintenance Therapy**

Most studies of home PT monitoring include patients who are already being treated with Coumadin, and therefore evaluate home monitoring in the setting of maintenance therapy. A 2010 Cochrane review evaluated the impact of self-monitoring and self-management of oral anticoagulation compared with standard monitoring.<sup>1</sup> Self-monitoring referred to use of point-of-care testing and self-management, which additionally involved having patients interpret the results and adjust the dose of medication themselves. The authors identified 18 RCTs (total N=4723 participants). The review identified 6 trials on self-monitoring, 11 trials on self-management, and 1 trial that reported both outcomes. (In reporting the findings, the term "home monitoring" will refer to self-monitoring or self-management). Three trials included only patients with mechanical heart valves (MHVs), 2 trials included patients with atrial fibrillation (AF), and 13 trials included patients with a mix of indications for oral anticoagulation. A pooled analysis of data from all 18 trials found that, compared with standard therapy, home monitoring reduced thromboembolic events by half (relative risk [RR], 0.50; 95% confidence interval [CI], 0.36 to 0.69). This difference was statistically significant ( $p < 0.01$ ). The intervention effect was larger in the self-management studies (pooled RR=0.47; 95% CI, 0.31 to 0.70;  $p < 0.001$ ) than in the self-monitoring studies (pooled RR=0.57; 95% CI, 0.32 to 1.00;  $p = 0.05$ ). A pooled analysis

of data from 9 trials found a statistically significant reduction in mortality with home monitoring compared with standard therapy (pooled RR=0.64; 95% CI, 0.46 to 0.89; p=0.007). In terms of potential harms, a pooled analysis of data from 14 trials did not find a significant difference in the risk of major hemorrhage with standard therapy compared with home monitoring. The relative risk was 0.87 (95% CI, 0.66 to 1.16; p=0.34). Compared with standard therapy, however, there was a significantly reduced risk of minor hemorrhage with home monitoring. Pooling data from 14 trials, the relative risk was 0.64 (95% CI, 0.54 to 0.77; p<0.001). Although this study reported that self-monitoring and self-management resulted in better outcomes without increasing the risk of major hemorrhage, home monitoring was not feasible for up to half of patients requiring anticoagulant therapy due to patient refusal, doctor recommendation, or inability to complete training.

A similar meta-analysis was published in 2011 by Bloomfield et al.<sup>2</sup> The newer meta-analysis included a large RCT by Matcher et al (2010) (described in more detail next), which was not available at the time the Cochrane systematic review was conducted. Study inclusion criteria included RCTs with adult subjects that compared home monitoring with monitoring in a physician's office or anticoagulation clinic; studies included adults receiving long-term (>3 months) therapy. The systematic reviews identified 22 trials; 5 on self-monitoring only and 14 that included self-management. Eight studies were limited to patients with MHVs, and the other 14 included patients with various indications. Three studies enrolled inception cohorts (patients who had started oral anticoagulation therapy in the previous 3 months), 8 studies did not enroll inception cohorts, and 8 studies were mixed or unclear about this inclusion criterion. (See later section on home self-monitoring from the beginning of treatment.) In a pooled analysis, there were significantly fewer major thromboembolic events in the self-monitoring and self-management group (99/4004 patients [2.5%]) compared with the standard treatment group (149/3755 [4.0%]; odds ratio [OR], 0.58; 95% CI, 0.45 to 0.75). Rates of major bleeding events did not differ significantly in the 2 groups. There were 283 of 4061 (7.0%) events in the home-monitoring group and 300 of 3806 (7.9%) in the standard treatment group (OR=0.89; 95% CI, 0.75 to 1.05). Similar to the Cochrane review, the authors noted the low rate of study participation in patients who met preliminary eligibility criteria. The authors did not conduct separate analysis of studies that did and did not enroll inception cohorts.

A 2012 meta-analysis by Heneghan et al used individual patient data; otherwise, the design was similar to the other published meta-analyses.<sup>3</sup> The investigators searched for RCTs comparing self-monitoring or self-management of oral anticoagulation by adults with management by a physician or anticoagulation clinic. This review did not discuss the issue of whether or not home monitoring occurred in the initial 3 months of anticoagulation therapy. The meta-analysis identified 21 eligible trials, but the authors were not able to obtain adequate data on 10 of the trials, therefore, they included data on 6417 participants from the other 11 trials. In a pooled analysis, there was a statistically significant reduction in thromboembolic events in the home PT monitoring group compared with the standard therapy group (hazard ratio [HR], 0.51; 95% CI, 0.31 to 0.85). There was not a significant difference between groups in the rate of major hemorrhagic events (HR=0.88; 95% CI, 0.74 to 1.06) or death (HR=0.82; 95% CI, 0.62 to 1.09).

Representative RCTs enrolling patients initially managed in a physician's office or anticoagulation clinic are described next.

In 2010, Matchar et al published findings from a large nonblinded multicenter Veterans Administration–sponsored randomized trial.<sup>4,5</sup> The trial, called the Home INR Study (THINRS), included patients who were taking warfarin because of MHVs and/or AF and were expected to be on warfarin indefinitely (operationally defined as 2 years). To be eligible, patients needed to participate in home monitoring training and pass a competency evaluation. A total of 3643 were trained and 2922 (80%) were randomly assigned to self-testing with an approved device once a week (n=1465) or monthly clinic-based testing (n=1457). There were 237 (8%) patients who required caregiver support to perform INR testing. Clinics in the study were required to be “high-quality” testing sites, defined as having a designated staff member for patient evaluation and follow-up, using a standard local protocol, and performing INR testing about once a month. Patients in the home monitoring group contacted the clinic with their test results. All participants had quarterly in-person evaluations. About 98% of the patients were men, 92% were white, and 92% had received anticoagulation treatment for at least 3 months. There were 1201 (82%) patients with AF and 351 (24%) with MHVs; 1113 (76%) had AF without MHV. Loss to follow-up was low and similar in the 2 groups, about 1%.

The primary efficacy outcome was time to the first major event (stroke, major bleeding episode, or death) and used Kaplan-Meier analysis; there were 8730 patient-years of follow-up. A total of 271 (19%) of patients in the self-testing group and 285 (20%) in the clinic-testing group experienced a major event. There was no statistically significant difference in time to first major event between groups (unadjusted HR=0.88; 95% CI, 0.75 to 1.04). Moreover, there were no significant between-group differences for the individual components of the primary outcome. For example, the rate of death was 152 (10%) in the self-testing group and 157 (11%) in the clinic-testing group (unadjusted HR=0.91; 95% CI, 0.73 to 1.12). However, the time during which the INR was in the therapeutic range, a secondary outcome, was somewhat higher in the self-testing group than the clinic-testing group (absolute difference, 3.8%; 95% CI, 2.7% to 5.0%); this difference was statistically significant (p<0.001). The investigators had hypothesized that home testing would be superior to clinic-based testing. They interpreted their finding of no difference between groups in the primary outcomes as an indication that there is no substantial negative effect of self-testing, and they recommended self-testing for patients who have limited access to high-quality anticoagulation clinics.

In a study published in 2005, Fitzmaurice et al randomized 617 patients older than age 18 years and receiving warfarin (30% for AF) to intervention or routine care.<sup>6</sup> Patients receiving intervention used a point-of-care device to measure INR twice a week and a simple dosing chart to interpret their dose of warfarin. No significant differences were found in percentage of time in the therapeutic range between self-management and routine care (70% vs 68%). Self-managed patients with poor control before the study showed an improvement in control that was not seen in the routine care group. Nine patients (2.8/100 patient-years) had serious adverse events in the self-managed group, compared with 7 patients (2.7/100 patient-years) in the routine care arm. The authors concluded that, with appropriate training, self-management was safe and reliable for a sizeable proportion of patients receiving oral anticoagulation and may improve the time spent in the therapeutic range for patients with initially poor control.

In a European study published in 2005, Menendez-Jandula et al reported on 737 patients with indications (30% had AF) for anticoagulant treatment.<sup>7</sup> The self-management group (n=368) received simple instructions for using a portable coagulometer weekly and self-adjusting treatment dose. The conventional management group (n=369) received usual care in an

anticoagulation clinic (monthly measurement and control of INR, managed by hematologists). The median follow-up period was 11.8 months. The unadjusted percentages of in-range INRs were 58.6% in the self-management group and 55.6% in the conventional management group (95% CI for difference, 0.4 to 5.4 percentage points). Twenty-seven patients (7.3%) in the conventional management group and 8 (2.2%) in the self-management group had major complications related to anticoagulant treatment; the unadjusted risk difference for major complications between groups was 5.1 percentage points (95% CI, 1.7 to 8.5 percentage points). This trial was performed at only 1 center and was not blinded. The dropout rate in the intervention group was 21%.

### Section Summary

Home INR monitoring is feasible for some patients on warfarin, but a large proportion are unable or unwilling to perform home monitoring. For patients who are able to self-monitor and who are suitably trained, evidence from multiple RCTs demonstrates that home monitoring is associated with better INR control.

### **Home Self-Monitoring From the Start of Outpatient Treatment**

Initiation of anticoagulation in the outpatient setting is more challenging than maintenance therapy. During the first few months of anticoagulation, INR levels require frequent monitoring and adjustment of Coumadin dose. The risk for adverse events is also higher during this period, particularly for hemorrhagic complications. As a result, the outcome of hemorrhagic complications is more important during this period compared with maintenance therapy.

Fewer RCTs have evaluated home PT monitoring beginning at or near the time they initiate oral anticoagulation therapy than in patients on a stable regimen of anticoagulant therapy. However, there are some published RCTs, which are described next:

Findings from the first 600 patients who completed the 2-year follow-up of the Early Self-Controlled Anticoagulation Trial (ESCAT) from Germany were published in 2001.<sup>8</sup> All patients had undergone mechanical heart valve replacement. A total of 295 patients were in the conventional group and 305 were in the INR self-management group. Self-management included training in use of the CoaguChek device 6 to 11 days after surgery and receiving a device after successful training. In the conventionally managed group, 62% of recorded INR values were within the stipulated range (2.5-4.5) during the entire observation period compared with 79% of INR values in the self-management group ( $p < 0.01$ ). Differences in the rate of complications did not differ significantly between groups. Rates of hemorrhagic events were 2.6% in the conventionally managed group and 1.7% in the self-management group, and rates of thromboembolic events were 2.1% and 1.2%, respectively ( $p > 0.05$ ).

In 2009, Hamad et al in The Netherlands published an RCT with 62 patients who had elective mechanical aortic valve replacement.<sup>9</sup> Patients were randomly assigned to conventional management or self-management using the CoaguChek device. Self-monitoring training was provided 3 weeks after surgery. After training, patients were supervised by clinic staff, and they had to pass an exam on self-monitoring before using the CoaguChek device at home. A total of 58 of 62 (94%) completed the 1-year follow-up; 29 in each group. The mean number of INR values per patient within the target range (2.5-4.5) was significantly higher in the self-management group ( $72.9\% \pm 11\%$ ) than in the conventionally managed group ( $53.9\% \pm 14\%$ ) ( $p = 0.01$ ). In addition, the mean number of days the INR value for each patient was outside the

target range was significantly higher in the conventionally managed group ( $28.6 \pm 14$ ) than the self-monitoring group ( $22.2 \pm 10$ ) ( $p < 0.001$ ). There were no significant differences between groups in postoperative complications or the mortality rate within 1 year of the operation.

In 2012, Thompson et al at Mayo clinic published an RCT evaluating in-hospital initiation of INR self-testing after mechanical heart valve replacement.<sup>10</sup> Patients were not selected for participation based on motivation for self-testing. A total of 200 patients were randomized to self-testing ( $n=100$ ) or usual care ( $n=100$ ). Both groups received education on warfarin anticoagulation including a class, video, and an informational booklet. The self-testing group additionally received a structured education program on early postoperative self-testing which included an overview of INR self-testing, proper methods for sampling using a finger stick, use of the coagulometer, and recording of the test results. A Food and Drug Administration–cleared device was used. Patients in the self-testing group performed tests once a week, used the telephone to record results, and phoned their physician for warfarin dosing instructions. The need for additional testing was at the discretion of the physician. For patients in the usual care group, frequency of testing and dose alteration was at the discretion of the primary physician.

During the 3-month study period, 14 patients (14%) withdrew from the self-testing group and 7 (7%) withdrew from the usual care group. Over the entire 3-month study period, the mean percentage of time patients spent in the INR therapeutic range was 53% (SD=27%) in the self-testing group and 48% (SD=25%) in the usual care group. The difference between groups was not statistically significant. However, when only data from the third month were examined, ie, the month in which patients were most experienced at self-testing, the self-testing group had a significantly greater percentage of time in the therapeutic range, 59% (SD=32%) versus 40% (SD=38%) ( $p=0.01$ ). During the study period, a total of 9 patients (9%) in the self-testing group and 7 patients (7%) in the usual care group experienced an adverse event. In the self-testing group, adverse events included transient ischemic attack (TIA) ( $n=2$ ), hemothorax ( $n=2$ ), evacuation of subdural hematoma ( $n=1$ ), bloody pericardial effusion ( $n=2$ ), pulmonary embolism ( $n=1$ ), and bleeding scalp ( $n=1$ ). Adverse events in the usual care group included TIA ( $n=1$ ), possible TIA ( $n=1$ ), temporary visual change ( $n=2$ ), bloody pericardial effusion ( $n=1$ ), bleeding after shaving ( $n=1$ ), and nose bleed ( $n=1$ ). The study was powered to detect clinically significant differences in time within the therapeutic range, not to detect differences in adverse events.

### Section Summary

There are fewer RCTs evaluating home monitoring in the initial treatment period compared with home monitoring that begins after several months of in-clinic management. Several European RCTs, which included substantial patient training and/or supervision, found that time in the therapeutic range improved with self-monitoring. A recent U.S. trial found from Mayo clinic found that time in the therapeutic range over the 3-month study period did not differ significantly in a self-monitoring versus usual care group. However, time in the therapeutic range was significantly higher in the self-monitoring group during the third study month, at which time patients had gained experience. The evidence supports that time in therapeutic INR can be improved with home monitoring, when patients are competent in the monitoring procedures, but the evidence on adverse events is not sufficient. In particular, the available studies have low numbers of hemorrhagic complications and may be underpowered to detect clinically important differences in that outcome.

**Summary of Evidence**

Data from multiple randomized controlled trials (RCTs) consistently demonstrate that the use of self-monitoring in patients who are initially managed in a clinical setting results in an increased time in the therapeutic range. Based on prior research, it is likely that time in therapeutic international normalized ratio (INR) is associated with improved health outcomes. Some studies also report a lower rate of hemorrhagic or embolic events, but this evidence is limited by high dropout and noncompliance rates that may have created imbalances between treatment groups. The evidence includes monitoring in several chronic conditions such as mechanical heart valves, chronic atrial fibrillation, and deep venous thrombosis, and therefore comparable results should be able to be obtained in other similar, but less prevalent, conditions that require continuous anticoagulation. Thus, based on the evidence and clinical context, home prothrombin time monitoring may be considered medically necessary for patients with chronic conditions that require continuous oral anticoagulation with warfarin who are able to self-monitor and who have undergone initial clinic-based anticoagulation management for at least 3 months.

The evidence is insufficient to conclude that the use of initial self-monitoring improves the net health outcome. RCTs with sufficient large samples that report health outcomes are needed to more thoroughly evaluate the safety and efficacy of home prothrombin time monitoring from the start of treatment. Therefore, the use of home monitoring during the initial treatment period is considered investigational.

**Practice Guidelines and Position Statements**

In 2012, the American College of Chest Physicians published evidence-based guidelines on management of anticoagulant therapy.<sup>11</sup> The guidelines include the following recommendations on home prothrombin time testing:

“For patients treated with VKAs [vitamin K antagonists] who are motivated and can demonstrate competency in self-management strategies, including the self-testing equipment, we suggest patient self-management rather than usual outpatient INR monitoring (Grade 2B). For all other patients, we suggest monitoring that includes the safeguards in our best practice statement 3.5.”

These safeguards include managing treatment in a systematic and coordinated fashion, educating patients and communicating effectively with patients about test results and dosing decisions.

**CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

**CPT/HCPCS**

- 99363 Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements)
- 99364 Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; each subsequent 90 days of therapy (must include a minimum of 3 INR measurements)
- G0248 Demonstration, prior to initiation 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's ability to perform testing and report results
- 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; testing not occurring more frequently than once a week; testing materials, billing units of service include 4 tests
- G0250 Physician review, interpretation, and patient management of home INR testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests

- In 2003, 3 HCPCS codes were introduced that specifically apply to home monitoring of prothrombin: G0248, G0249, and G0250. Typically, a 1-month to 6-week supply of test strips is requested, which can vary from 25 test strips to only 6 test strips if the patient only self-monitors once a week.
- Effective January 1, 2007, CPT codes became available for physician review and interpretation of International Normalized Ratio (INR) testing for outpatient management of warfarin therapy: 99363, 99364.

**ICD-9 Diagnoses**

- 427.31 Atrial fibrillation
- 453.40- Acute venous embolism and thrombosis of deep vessels of lower extremity (code range)
- 453.42
- V43.3 Organ or tissue replaced by other means; Heart valve

**ICD-10 Diagnoses** (Effective October 1, 2015)

I48.2	Chronic atrial fibrillation
I82.401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity
I82.402	Acute embolism and thrombosis of unspecified deep veins of left lower extremity
I82.403	Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I82.411	Acute embolism and thrombosis of right femoral vein
I82.412	Acute embolism and thrombosis of left femoral vein
I82.413	Acute embolism and thrombosis of femoral vein, bilateral
I82.421	Acute embolism and thrombosis of right iliac vein
I82.422	Acute embolism and thrombosis of left iliac vein
I82.423	Acute embolism and thrombosis of iliac vein, bilateral
I82.431	Acute embolism and thrombosis of right popliteal vein
I82.432	Acute embolism and thrombosis of left popliteal vein
I82.433	Acute embolism and thrombosis of popliteal vein, bilateral
I82.441	Acute embolism and thrombosis of right tibial vein
I82.442	Acute embolism and thrombosis of left tibial vein
I82.443	Acute embolism and thrombosis of tibial vein, bilateral
I82.491	Acute embolism and thrombosis of other specified deep vein of right lower extremity
I82.492	Acute embolism and thrombosis of other specified deep vein of left lower extremity
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.4Y1	Acute embolism and thrombosis of unspecified deep veins of right proximal lower extremity
I82.4Y2	Acute embolism and thrombosis of unspecified deep veins of left proximal lower extremity
I82.4Y3	Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral
I82.4Z1	Acute embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.4Z2	Acute embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.4Z3	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
Z95.2	Presence of prosthetic heart valve

**REVISIONS**

09-18-2009	Policy added to bcbsks.com web site.
06-29-2012	Description section updated.
	Rationale section added.
	In Coding section: <ul style="list-style-type: none"> <li>▪ Added diagnoses codes to the policy as they were not previously reflected: 427.31, 453.40-453.42</li> </ul>
	References updated.
08-20-2013	Description section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Added ICD-9 Code: V43.3</li> </ul>

	<ul style="list-style-type: none"> <li>▪ ICD-10 Diagnoses Codes added</li> </ul>
	Rationale section updated
	References updated
11-24-2015	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Updated coding notations.</li> </ul>
	References updated
08-04-2016	In Description Regulatory Status section: <ul style="list-style-type: none"> <li>▪ Removed "Alere™ (formerly Hemosense) INRatio®2 PT/INR Monitoring System" following Alere's announcement on July 12, 2016 to initiate voluntary withdrawal of the Alere INRatio and INRatio2 PT/INR Monitor System.</li> </ul>
12-01-2016	Policy reviewed with no updates needed.

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