Medical Policy

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Title: Home Prothrombin Time Monitoring

Professional
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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 atrial fibrillation (i.e., 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 International Normalized Ratio (INR). For example, an INR result greater than 3 indicates a higher risk of serious hemorrhage, while 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. In contrast, an INR less than 2 is associated with an increased risk of stroke. 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.

In order 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 (e.g., 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 Corporation) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The 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.

Other devices cleared by the FDA for home prothrombin time monitoring include the ProTime® Microcoagulation System (International Technidyne Corporation) and the Alere™ (formerly Hemosense) INRatio® 2 PT/INR Monitoring System.

POLICY
A.   The medical necessity of Home Protime Monitoring will be considered on a case by case basis.

B.   Home Protime 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 trial comparing home prothrombin time monitoring to 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.

The most recent literature search was performed for the period January 2012 through January 23, 2013. Following is a summary of the literature to date.

Home monitoring during maintenance therapy
The majority of 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 to standard monitoring. (1) 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 randomized controlled trials (RCTs) (total of n=4,723 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 to 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<0001. The intervention effect was larger in the self-management studies (pooled RR: 0.47, 95% CI: 0.31 to 0.70, p=00003) 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 to 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 to home monitoring. The RR was 0.87, 95% CI: 0.66 to 1.16, p=0.34. Compared to standard therapy, however, there was a significantly reduced risk of minor hemorrhage with home monitoring. Pooling data from 14 trials, the RR was 0.64, 95% CI: 0.54 to 0.77, p<0.00001. 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 and colleagues. (2) The newer meta-analysis included a large RCT by Matcher and colleagues (2010) (described in more detail below) 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 to 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 mechanical heart valves 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 of 4,004 patients, 2.5%) compared to the standard treatment group (149 of 3,755, 4.0%), 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 283/4,061 (7.0%) events in the home-monitoring group and 300/3,806 (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 and colleagues used individual patient data; otherwise, the design was similar to the other published meta-analyses. (3) The investigators searched for RCTs comparing self-monitoring or self-management of oral anticoagulation by adults compared to 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 6,417 participants from the other 11 trials. In a pooled analysis, there was a statistically significant reduction in thromboembolic events in the home prothrombin time (PT monitoring group compared to 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 below.

In 2010, Matchar and colleagues published findings from a large non-blinded multicenter Veterans Administration-sponsored randomized trial. (4, 5) 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 3,643 were trained and 2,922 (80%) were randomly assigned to self-testing with an approved device once a week (n=1,465) or monthly clinic-based testing (n=1,457). 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 1,201 (82%) patients with AF and 351 (24%) with MHVs; 1,113 (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 8,730 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; the unadjusted hazard ratio (HR) was 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: 2.7-5.0%); 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 and colleagues randomized 617 patients older than age 18 years and receiving warfarin (approximately 50% for AF) to intervention or routine care. (6) 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 and colleagues reported on 737 patients with indications (approximately 50% had AF) for anticoagulant treatment. (7) 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%.

Conclusions: 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 studies report health outcomes in patients being home PT monitored at or near the time they initiate oral anticoagulation therapy than in patients on a stable regimen of anticoagulant therapy. As noted above, 3 of 21 studies included in the 2011 Bloomfield et al. meta-analysis (2) focused on patients who had started oral anticoagulation therapy in the past 3 months. One of these studies, Beyth et al., was not able to adequately isolate the impact of home PT-monitoring on health outcomes, since it included a multicomponent intervention of which home monitoring was only one part. In addition, only 46 of 163 (28%) patients randomized to the intervention group were able to monitor their prothrombin time themselves. (8) For another 50 (31%) patients, a spouse, other relative, or visiting nurse monitored their prothrombin time at home, while 36 (22%) were monitored conventionally. The other 2 RCTs included in the meta-analysis that included "inception cohorts" are briefly described below, as well as a third RCT that was published subsequent to the meta-analysis:

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. (9) 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 received a device after successful training. In the conventionally managed group, 62% of recorded INR values were within the stipulated range (2.5 to 4.5) during the entire observation period compared to 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 and colleagues in The Netherlands published an RCT with 62 patients who had elective mechanical aortic valve replacement. (10) 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 CoaguCheck device at home. A total of 58/62 (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 +/- 11%) than in the conventionally managed group (53.9 +/- 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 +/- 14) than the self-monitoring group (22.2 +/- 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 and colleagues at the Mayo clinic published an RCT evaluating in-hospital initiation of INR self-testing after mechanical heart valve replacement. (11) Patients were not selected for participation based on motivation for self-testing; they were excluded only if they seemed likely to be unable to comply with instructions e.g. limited ability to speak English. 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 informational booklet. The self-testing group additionally received a structured education program on early post-operative 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. An FDA-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 i.e., 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% (S: 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.

In addition, Gardiner and colleagues published a prospective cohort study from the U.K. in 2009 evaluating the acceptability and efficacy of home prothrombin time monitoring from the start of treatment. (12) A total of 188 of 318 (59%) consecutive patients referred for oral anticoagulation were considered eligible for self-monitoring and were offered the choice of self-monitoring or routine hospital anticoagulation and 84 chose to self-monitor. Seventy-two patients completed training and started self-monitoring; 26 completed their course of oral anticoagulation during the study period, and 42 were still self-monitoring at the end of the study period; 4 patients had incomplete data. Data from 67 out of the 84 (80%) patients who chose to self-monitor were

included in the analysis. Among the 104 patients who elected for routine anticoagulation, only 88 (85%) had sufficient data available to be included in the analysis. The median percent time spent in therapeutic range was 71% (95% CI: 64–75%) for the 67 self-monitoring patients and 60% (95% CI: 55–63%) for the 88 routine care patients; this difference was statistically significant (p=0.003). In the self-monitoring group, the incidence of adverse events included 1.7 major bleeds per 100 patient-years of follow-up, 8.4 minor bleeds per 100 patient-years, and 3.4 thromboses per 100 patient-years. In the routine care group, there were 5.4 major bleeds per 100 patient-years of follow-up, 16.2 minor bleeds per 100 patient-years, and 1.4 thromboses per 100 patient-years.

Conclusions: There are fewer RCTs evaluating home monitoring in the initial treatment period compared to 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 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

Data from multiple RCTs consistently demonstrate that the use of self-monitoring in patients who were 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 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 (ACCP) published evidence-based guidelines on management of anticoagulant therapy. (13) 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 (PSM) 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, three 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 01-01-07, CPT codes became available for physician review and interpretation of International Normalized Ratio (INR) testing for outpatient management of warfarin therapy: 99363, 99364.

<u>ICD-9 Diagnoses</u>

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

<u>ICD-10 Diagnoses</u> (Effective October 1, 2014)

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: ▪ Added diagnoses codes to the policy as they were not previously reflected: 427.31, 453.40-453.42
	References updated.
08-20-2013	Description section updated
	In Coding section: ▪ Added ICD-9 Code: V43.3 ▪ ICD-10 Diagnoses Codes added
	Rationale section updated
	References updated

REFERENCES

1.   Garcia-Alamino JM, Ward AM, Alonso-Coello P et al. Self-monitoring and self-management of oral anticoagulation. Cochrane Database Syst Rev 2010; (4):CD003839.
2.   Bloomfield HE, Krause A, Greer N et al. Meta-analysis: Effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes. Ann Intern Med 2011; 154(7):472-82.
3.   Heneghan C, Ward A, Perera R et al. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. Lancet 2012; 379(813):322-34.
4.   Matchar DB, Jacobson A, Dolor R et al. Effect of home testing of international normalized ratio on clinical events. N Engl J Med 2010; 363(17):1608-20.
5.   Matchar DB, Jacobson AK, Edson RG et al. The impact of patient self-testing of prothrombin time for managing anticoagulation: rationale and design of VA cooperative study #481- the Home INR study (THINRS). J Thromb Thrombolysis 2005; 19(3):163-72.
6.   Fitzmaurice DA, Murray ET, McCahon D et al. Self management of oral anticoagulation: randomised trial. BMJ 2005; 331(7524):1057.
7.   Menendez-Jandula B, Souto JC, Oliver A et al. Comparing self-management of oral anticoagulant therapy with clinic management: a randomized trial. Ann Intern Med 2005; 142(1):1-10.
8.   Beyth RJ, Quinn L, Landefeld CS. A multicomponent intervention to prevent major bleeding complications in older patients receiving warfarin. Ann Intern Med; 2000; 133(9):687-95.
9.   Kortke H, Korfer R. International normalized ratio self-management after mechanical heart valve replacement: is an early start advantageous? Ann Thorac Surg 2001; 72(1):44-8.
10. Hamad MA, van EE, van AT et al. Self-management program improves anticoagulation control and quality of life: a prospective randomized study. Eur J Cardiothorac Surg 2009; 35(2):265-9.
11. Thompson JL, Burkhart HM, Daly RC et al. Anticoagulation early after mechanical valve replacement: Improved management with patient self-testing. J Thorac Cardiovasc Surg 2012 [Epub ahead of print].
12. Gardiner C, Longair I, Pescott MA et al. Self-monitoring of oral anticoagulation: does it work outside trial conditions? J Clin Pathol 2009; 62(2):168-71.

13.   Holbrook A, Schulman S, Witt DM et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012; 141(2 Suppl):e152S-84S.

14.   Centers for Medicare and Medicare Services (CMS). Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management 190.11. Available online at: www.cms.gov. Last accessed January, 2013.