Medical Policy

BlueCross BlueShield of Kansas
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Title: Home Prothrombin Time Monitoring

Professional	**Institutional**
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DESCRIPTION

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 one high risk factor or more than one moderate risk factor). 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 below 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 dose levels are within the therapeutic range.

There are at least 3 sites/methods of monitoring anticoagulation:

- Physician's office (80%)—usually once a month
- Anticoagulation clinics (20%)—usually once every 2 to 3 weeks
- Home prothrombin time monitors (<5%)

Several different devices have been approved for marketing by the U.S. Food and Drug Administration (FDA) that may be purchased by the patient for in-home monitoring of chronic anticoagulant therapy. However, the FDA approval for all of these devices is based on the demonstration that appropriately trained patients could 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 telephone the results of the self-monitoring and receive further telephonic instructions on warfarin dosage.

POLICY

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

Home Protime Monitoring for patient convenience is **non-covered**.

RATIONALE

Since the original publication of this policy in 1997, several randomized studies have compared 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 like 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 have primarily focused on the intermediate outcome of time spent in the therapeutic range of warfarin, as measured by the International Normalized Ratio (INR).

Results of 8 randomized, controlled trials including over 2,000 patients have been published, and all have shown that self-monitoring and management was associated with a prothrombin time increase in the "time in therapeutic range" (TTR) from 6% to 34%. (1) Two of the larger trials also reported a decrease in adverse outcomes. For example, Beyth and colleagues reported on a study that randomized 325 patients who started warfarin therapy in the hospital during hospitalization to a self-monitoring and management group or a usual care group. (2) The self-monitoring group received patient education about warfarin, training to increase patient participation, self-monitoring of prothrombin time, and guideline-based management of warfarin dosing. At 6 months, the authors showed a lower rate of major hemorrhage in the self-monitoring group (5.7%) compared to the control group (12%) ($p=0.049$). After 6 months, there was no difference in the frequency of major bleeding between the groups. The time in therapeutic range also increased to 56% in the self-monitoring group, as compared to 32% in the usual care group.

The Early Self-Controlled Anticoagulation Trial (ESCAT) enrolled 1,200 patients who received mechanical heart valves and were randomized to either patient self-testing and management or usual care. Results of the first 200 patients who have been followed up

for 2 years have been published. (3) The authors evaluated complications on a 4-grade scale. For example, grade III was defined as a complication requiring hospitalization. In the treatment group, 9.5% required hospitalization compared to 15.3% in the usual care group, a 40% reduction.

In summary, the data consistently demonstrate that the use of self-monitoring and self-management results in an increased time in the therapeutic range, possibly leading to a reduction in hemorrhagic or embolic events. Since patients with mechanical heart valves represent the majority of patients studied so far, and since these patients are taking anticoagulants at higher levels, this subset of patients is most likely to benefit from self-monitoring and management.

2004 Update

A review of the peer-reviewed literature on MEDLINE for the period of 2002 through October 2004 found only 1 relevant study on home prothrombin time monitoring. In this study, Eldor and Schwartz evaluated home prothrombin time monitoring in 20 elderly patients who have atrial fibrillation with 20 matched controls for 12 months. (4) The study authors reported fewer prothrombin time values above or below the therapeutic range and high satisfaction in the study group. However, the median recorded prothrombin time value for both groups was within the therapeutic range. In addition, no hemorrhagic or thrombotic events occurred in either group. The authors concluded that home monitoring of anticoagulant therapy is feasible in a motivated population. Nevertheless, this study did not demonstrate greater improvements in health outcomes with home monitoring over traditional treatment in this population. Therefore, the policy statement was unchanged.

2006 Update

A review of the literature using MEDLINE for the period of October 2004 through July 2006 did not find any studies that would alter the conclusions or policy statements noted above. Information about the design has been reported in a VA Cooperative Study to compare patient self-testing to an anticoagulation service. (5)

2007–2008 Update

The policy was updated with a literature search on MEDLINE through January 2008. A number of studies have reported on home monitoring and patient self-monitoring in chronic oral anticoagulation with warfarin for conditions other than artificial heart valves. The results of 10 randomized studies were recently summarized. (6) This report indicated that the literature demonstrates that, in some populations (mechanical heart valves, chronic atrial fibrillation, venous thrombosis), the use of the home INR monitor is at least equivalent to laboratory testing or physician office testing with respect to time in treatment range (TTR). This report also commented on the low rate of adverse thromboembolic and hemorrhagic events in this population and indicated that while 2 of the studies reviewed showed decreased rates, the others did not. This report also commented on the concerns about selection bias and low enrollment rates in these

studies. They questioned whether results would generalize beyond patients who have demonstrated capability and motivation for undergoing self-management and for ongoing use of the device over time.

In 1 of the studies reviewed, Fitzmaurice and colleagues randomized 617 patients older than age 18 years and receiving warfarin (about 50% for atrial fibrillation) to intervention or routine care. (7) 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 is 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, Menendez-Jandula and colleagues reported on 737 patients with indications (about half had atrial fibrillation) for anticoagulant treatment. (8) 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%.

Given the overall consistent evidence for use of home anticoagulation monitoring in several chronic conditions such as mechanical heart valves, chronic atrial fibrillation, and deep venous thrombosis, 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, the policy statement is broadened to include a chronic condition that requires continuous oral anticoagulation with warfarin.

2009 Update

The policy was updated with a literature search on MEDLINE through February 2009. A Health Technology Assessment from the National Health Service (United Kingdom) examined the clinical effectiveness of patient self-monitoring in a systematic review. (9)

This report selected 16 randomized controlled studies (anticoagulation indication: 10 studies mixed, 3 mechanical heart valves (MHV), 2 atrial fibrillation (AF), and 1 combined MHV and AF). The report demonstrated a decrease in thromboembolic events (risk difference [RD] of -0.0224 [95% CI: -0.0334 to -0.0115]) and death (RD of -0.0170; 95% CI: -0.0287 to -0.0053) with no change in bleeding events with patient self-monitoring. Pooled estimates for time in therapeutic INR range were 71.8% in the patient self-monitoring group and 61.8% in the control group. The dropout rate in the patient self-monitoring group was 2% to 42%, as compared to 0 to 10% in the control group. Patients who withdrew after initial training tended to be female and older. The assessment concluded that patient self-monitoring was efficacious for successfully trained and compliant patients. The policy statement remains unchanged.

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

REVISIONS

09/18/2009	Policy added to bcbsks.com web site.

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