Cigna Medical Coverage Policy

Subject **Prothrombin Time Home Testing Systems**

Effective Date **5/15/2014**
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Hyperlink to Related Coverage Policies

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Coverage Policy

Coverage for prothrombin time home testing systems is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for prothrombin time home testing systems is available, the following conditions of coverage apply.

Cigna covers a prothrombin time home testing system as medically necessary for an individual receiving long-term oral anticoagulation therapy (i.e., six months or longer) who is a suitable candidate for self-management.

Cigna does not cover additional software or hardware required for downloading data from home prothrombin time testing systems to computers for the management of anticoagulation because each is considered a convenience item and not medically necessary.

General Background

Prothrombin time (PT) home monitoring systems are portable, battery-operated instruments for the quantitative determination of PT from fingerstick whole blood. These products are generally designed to aid in the management of patients requiring long-term oral anticoagulation therapy for indications such as mechanical heart valves, atrial fibrillation, and venous thromboembolism (Centers for Medicare and Medicaid Services [CMS], 2008). There are several types of point of care (POC) PT monitors on the market, including office,

anticoagulation clinic, or home settings. For home testing, the instrument selected should be extremely easy to use with a limited number of steps.

Technological advances in PT measurement offer the potential for both simplifying and improving oral anticoagulation management. Portable PT monitors suitable for patient self-testing at home are currently available. The monitors measure the thromboplastin-mediated clotting time that is then converted to a plasma PT or an international normalized ratio (INR) (Macik et al., 2001). The INR is calculated as follows: INR = patient PT divided by mean normal PT. Studies indicate that the results of home PT self-monitoring appear to be as good as those of the standard laboratory equipment studied. POC PT instruments using capillary blood correlated well with the reference laboratory for both health care provider (i.e., venous sample, r=93) and the patient (i.e., capillary sample, r=93). PT results for fingersticks performed by both the patient and the health care provider were equivalent and correlated highly (r=91) (Hirsh, et al., 2003).

Patient self-testing (PST) and patient self-management (PSM) with home POC PT monitors allows the patient the ability to test when it is needed and to adjust the dose as needed. A systematic review of indicated that self-monitoring of anticoagulation led to significant reductions in thromboembolic events, all-cause mortality, and major hemorrhage (Heneghan, et al., 2006). It has also been found that patient self-monitoring was more effective than usual care provided by family doctors and as effective as good-quality specialized anticoagulation clinics in maintaining the quality of anticoagulation therapy.

Patient training is required before PT self-monitoring is undertaken to ensure that the patient knows the proper technique to obtain and apply a capillary blood sample and how to use and maintain the POC monitoring device. Patients should have a working knowledge of hemostasis and oral anticoagulation therapy, the potential adverse effects, and possible consequences of drug interactions to enable them to respond and make appropriate treatment adjustments. Patient educators include specially trained teachers, anticoagulant nurses, and physicians. Training on technique and use of PT self-monitoring usually occurred in small groups of one to six patients.

Some monitors have associated data management systems including software which may provide an easier way to track test results and communicate them with a physician or health care professional. Data management systems, including software, associated with home PT monitors is generally considered a convenience and not medically necessary. There is insufficient peer-reviewed literature to support the use of data management systems in improving health outcomes.

U.S. Food and Drug Administration (FDA)
The FDA has approved portable testing devices that are available by prescription for home use as Class II devices through the 510(k) process. They include, but are not limited to:

- ProTIME® microcoagulation analyzer (International Technidyne Corporation [ITC], Edison, NJ)
- CoaguChek® XS System (Roche Diagnostics Corporation, Indianapolis, IN)
- Alere INRatio®2 PT/INR Home Monitoring System (HemoSense, Miilpitas, CA)
- AvoSure™ PT (Avocet Medical Inc., San Jose, CA)

Literature Review
To clarify the value of self-monitoring of oral anticoagulation, Heneghan et al. (2012) conducted a systematic review and meta-analysis of individual patient data in 11 randomized trials (6417 participants) that proposed to address several gaps in the evidence, including an estimate of the effect on time to death, first major hemorrhage, and thromboembolism. The review compared the effects of self-monitoring (self-testing) or self-management (self-testing and self-dosage) of anticoagulation with control and dosage by personal physician, anticoagulation management clinics, or managed services, or reported the clinical outcomes of thromboembolic events and major bleeding episodes. The review found a significant reduction in thromboembolic events in the self-monitoring group (hazard ratio 0·51; 95% CI 0·31–0·85) but not for major hemorrhagic events (0·88, 0·74–1·06) or death (0·82, 0·62–1·09). Participants younger than 55 years demonstrated a significant reduction in thrombotic events (hazard ratio 0·33, 95% CI 0·17–0·66), as did participants with mechanical heart valve (0·52, 0·35–0·77). Analysis of the major outcomes in the very elderly (age≥85 years; n=99) showed no significant adverse effects of the intervention for all outcomes.

Bloomfield et al. (2011) reported on a meta-analysis of 22 randomized, controlled trials (8413 patients) to determine whether, for outpatient adults receiving long-term anticoagulant therapy, management of oral anticoagulant therapy using PST (alone or in combination with PSM) compared with oral anticoagulant therapy managed entirely by health care professionals in clinical settings is associated with fewer thromboembolic complications and decreased all-cause mortality, without an increased risk for a major bleeding event. The review was performed as part of the Veterans Administration (VA) Evidence-based Synthesis Program (ESP) Center. The review found that self-monitoring, with or without self-management of warfarin dosing, resulted in fewer deaths and thromboembolic events than usual care, without an increase in serious bleeding events.

Garcia-Alamino et al. (2010) reported on a Cochrane review that evaluated the effects of self-monitoring or self-management of oral anticoagulant therapy compared to standard monitoring. The review included 18 randomized trials with 4,723 participants. Pooled estimates demonstrated significant reductions in both thromboembolic events (pooled risk ratio [RR] 0.50, 95% confidence interval [CI] 0.36 to 0.69) and all-cause mortality (RR 0.64, 95% CI 0.46 to 0.89). The reduction in mortality was found to be significant after the removal of low-quality studies (RR 0.65, 95% CI 0.46 to 0.90). Twelve trials reported improvements in the percentage of mean INR measurements in the therapeutic range. The authors concluded that compared to standard monitoring, patients who self-monitor or self-manage can improve the quality of their oral anticoagulation therapy. It was found that the number of thromboembolic events and mortality were decreased without increases in harms. However, it was noted that self-monitoring or self-management were not feasible for up to half of the patients requiring anticoagulant therapy with reasons including patient refusal, exclusion by their general practitioner, and inability to complete training.

A systematic review and meta-analysis of ten trials was conducted to evaluate the efficacy and safety of self-management of oral anticoagulant therapy for patients on long-term oral anticoagulant therapy (Christensen, et al., 2007). The authors noted various methodological problems with the majority of the trials. Outcomes measured included death, minor and major complications (thromboembolic and bleeding events) and time within the therapeutic INR range. Overall, self-management was associated with a reduced risk of death (relative risk (RR) =0.48, 95% confidence interval (CI) 0.29-0.79, p = 0.004), major complications (RR =0.58, 95% CI 0.42-0.81, p = 0.001), and with increasing time in the therapeutic INR range (weighted mean difference = 6.53, 95% CI 2.24-10.82, p = 0.003). There was no difference in minor complications (p = 0.96). The analysis suggests that self-management of oral anticoagulant therapy may have better outcomes than conventional therapy in highly selected patients.

A systematic review and meta-analysis of 16 randomized and eight non-randomized trials was conducted by the Health Technology Assessment Programme (United Kingdom) (Connock, et al., 2007). Patients self-monitoring was found to be as effective as usual care provided by family doctors and as effective as specialized anticoagulation clinics in maintaining the quality of anticoagulation therapy. There was no significant risk difference of major bleeding events between patients self-monitoring and usual care controls. Pooled analyses noted that compared with primary care or anticoagulation control clinics, self-monitoring was statically significantly associated with fewer thromboembolic events. The study concluded that “for selected and successfully trained patients, self-monitoring is effective and safe for long-term oral anticoagulation therapy.”

A systematic review and meta-analysis of 14 randomized, controlled trials was performed to assess the effects of self-monitoring or self-management of anticoagulation compared with standard monitoring (Heneghan, et al., 2006). Outcomes analyzed were: major hemorrhage, thromboembolic events, death, tests in range, minor hemorrhage, frequency of testing, and feasibility of self-monitoring. The pooled estimates showed significant reductions in thromboembolic events (i.e., odds ratio (OR) 0.45, 95% CI 0.30–0.68), all-cause mortality (OR 0.61, 95%CI 0.38–0.98), and major hemorrhage (OR 0.65, 95% CI 0.42–0.99). Trials of combined self-monitoring and self-adjusted therapy showed significant reductions in thromboembolic events (OR 0.27, (%5 CI 0.12–0.59) and death (OR 0.37, (95%CI 0.16–0.85), but no major hemorrhage (OR 0.93, 95% CI 0.42–2.05). No difference was noted in minor hemorrhage. Eleven trials reported improvements in the mean proportion of INR ratios in range. The authors report that self-management improves the quality of oral anticoagulation and that self-monitoring is not feasible for all patients and requires identification and education of suitable candidates.

Several randomized, controlled studies have been published that evaluate self-testing and self-management of oral anticoagulation therapy (Thompson, et al., 2013; Matchar, et al., 2010; Gardiner, et al, 2006; Mendez-Jandula, et al., 2005; Gadisseur, et al., 2003; Fitzmaurice, et al., 2002; Pierce, et al., 2000; Beyth, et al., 2000; Sawicki, et al., 1999).

The studies indicate that this testing is as safe and effective as that delivered by physicians and anticoagulation clinics and may be suitable for selected patients.

Professional Societies/Organizations
American College of Chest Physicians (ACCP) published evidenced based clinical practice guidelines for antithrombotic therapy and prevention of thrombosis (Guyatt, et al., 2012; Holbrook, et al., 2012). The guidelines note, "For patients treated with VKAs [vitamin K antagonist] 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*)."

The ACCP, as part of the clinical practice guidelines for antithrombotic therapy and prevention of thrombosis, published guidelines for antithrombotic therapy in neonates and children (Monagle, et al., 2012). The guidelines include for children receiving vitamin K antagonists (VKAs), "that INR monitoring with point-of-care monitors be made available where resources make this possible (Grade 2C*)".

*Grade 2B: Weak recommendation, moderate-quality evidence
Grade 2C: Weak recommendation, low- or very-low-quality evidence

Use Outside of the US
British Committee for Standards in Haematology (BCSH): BCSH guidelines for oral anticoagulation with warfarin include the following recommendation regarding self-testing (Keeling, 2011):
Self-Testing and self-management of warfarin is associated with improved anticoagulant control but may not be suitable for most patients.

Scottish Intercollegiate Guidelines Network (SIGN): Sign guidelines for the prevention and management of venous thromboembolism include the recommendation in the section for INR control (SIGN, 2011):
Patient self-testing and self-management supported by a dedicated and well trained anticoagulant team may be considered for selected patients.

Summary
The studies evaluating the use of portable point of care (POC) prothrombin time (PT) monitors indicate that the monitors are accurate and can be used appropriately by selected patients with adequate training who are motivated to perform self-testing. PT monitor limitations include the necessity for proper fingerstick blood sample technique for accurate results. Definitive patient selection criteria have not been established for self-monitoring of anticoagulation therapy. PT self-monitoring by patients receiving long-term warfarin therapy had been shown to be accurate and effective in maintaining anticoagulant control within target therapeutic ranges. Published studies have demonstrated that there are advantages to patient self-testing and that this testing is effective as anti-coagulation clinics in maintaining the quality of anticoagulation therapy. Guidelines from professional organizations include the use of POC monitors for selected patients who have received training.

Data management systems including the software associated with home PT monitors is generally considered a convenience and not medically necessary. There is insufficient peer-reviewed literature to support the use of data management systems in improving health outcomes in this population.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary and used to report a prothrombin time home testing system:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous
G0248	Demonstration, prior to initial use, of home INR (international normalized ratio)

	monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of the 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 use.
G0249	Provision of test materials and equipment for home INR monitoring to patient with either mechanical heart valves(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 patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets other coverage criteria; includes face-to-face verification by the physician at least once a year (e.g. during an evaluation and management service) that the patient used 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.

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