CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Prothrombin Time Home Testing Systems**

Effective Date 12/15/2008
Next Review Date……..7/15/2010
Coverage Policy Number 0109

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Hyperlink to Related Coverage Policies

Pharmacogenetic Testing for Warfarin Metabolism

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2008 CIGNA*

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 prothrombin time home testing systems as medically necessary for individuals receiving long-term oral anticoagulation therapy (i.e., six months or longer) who are suitable candidates 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 it is considered a convenience item and not medically necessary.

General Background

Technological advances in point of care (POC) prothrombin time (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. 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 POC (i.e., office, anticoagulation clinic, or home) PT monitors on the market. For home testing, the instrument selected should be extremely easy to use with a limited number of steps (Hirsh, et al., 1998).

The validity of POC monitors was initially established by Lucas et al. (1987). Lucas reported a correlation coefficient of 0.96 between reference plasma PT and capillary whole blood PT in 858 samples from 732 subjects. Results were similar for capillary and venous whole blood; a variation in hematocrit between 23% and 58% did not alter the performance of the instrument. 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 training 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. Details vary regarding the training and education received by patients during clinical trial investigation of PT self-monitoring and self-management. 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. Patients had no problem learning the practical aspects of self-testing and management, regardless of age.

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 such as:

- ProTIME® microcoagulation analyzer (International Technidyne Corporation [ITC], Edison, NJ).
- CoaguChek® XS, CoaguChek® PST, and CoaguChek® S Systems (Roche Diagnostics Corporation, Indianapolis, IN).
- INRatio® System (HemoSense, Miilpitas, CA).

Literature Review
Sawicki et al. (1999) reported a randomized, single-blind, multicenter (five centers) trial [RCT] (n=197) to investigate the effects of patient self-management of oral anticoagulation therapy (OAT) on accuracy of control and measures of treatment-related quality of life. Patients were randomized to an oral anticoagulation self-management group based on structured treatment and teaching program and INR self-monitoring. The control group received conventional care as provided by family physicians, including referral to specialists if necessary. The main outcome measures were the deviation of INR values from the individual INR target range squared, and the five categories of treatment-related quality of life. The authors report that the deviation of INR value from the mean of the INR target range was significantly lower in the intervention group at three months compared to the control group (i.e., 0.65 versus 0.83 [p= 03]). The authors assert that the self-monitoring group had INR

values within the target range more frequently. Treatment related quality-of-life measures, especially treatment satisfaction scores, were significantly higher in the self-monitoring group compared to controls.

Beyth et al. (2000) reported an RCT (n=325) that assigned patients to intervention (n=163) or to usual care (n=162). The intervention consisted of patient education regarding warfarin training to increase patient participation, self-monitoring of PT, and guideline-based management of warfarin dosing. The outcome measures at six months were: major bleeding, death, recurrent venous, thromboembolism, and therapeutic control of anticoagulant therapy. Throughout the six months, the proportion of treatment time during which the INR was within the therapeutic range (i.e., 2.0–3.0) was higher in the intervention group than in the usual care group (i.e., 56% versus 32%; $p< 0.001$). The authors concluded that a multicomponent comprehensive program of warfarin self-management reduced the frequency of major bleeding in older patients.

Pierce et al. (2000) compared ProTIME POC monitor INR results to INR results obtained in a hospital's laboratory setting. A total of 35 patients participated in the study. Pearson correlation and T-test were used to compare the results of the ProTIME instruments to the laboratory data. The correlation coefficient for the POC versus the laboratory instruments ranged from 0.88 to 0.99. The average correlation for all paired data was 0.914. The authors reported that there was no statistical difference between the POC and the laboratory instruments. The POC whole-blood coagulation monitor INR results were comparable to those of the hospital system.

Fitzmaurice et al. (2002) reported an RCT to compare routine primary care management of OAT to patient self-management to test whether patient self-management is as safe, in terms of clinical effectiveness, as primary care management within the United Kingdom, as assessed by therapeutic INR control. Patients receiving warfarin from six general practices who satisfied study entry criteria were eligible to enter the study. Eligible patients were randomized to either patient self-management or control (i.e., routine primary care management) for six months. The intervention comprised two training sessions of one to two hours duration. Patients were allowed to undertake patient self-management on successful completion of training. INR testing was undertaken using a CoaguChek device, and regular internal/external quality control tests were performed. Patients were advised to perform INR tests every two weeks, or weekly if a dose adjustment was made. Dosage adjustment was undertaken using a simple dosing algorithm. Seventy-eight of 206 (38%) patients were eligible for inclusion and, of these, 35 (45%) declined involvement or withdrew from the study. Altogether, 23 intervention and 26 control patients entered the study. The authors reported that there were no significant differences in INR control (i.e., percent time in range: intervention, 74%; control, 77%). There were no serious adverse events in the intervention group, with one fatal retroperitoneal hemorrhage in the control group. The authors concluded that the data demonstrated that patient self-management is as safe as primary care management for a selected population. The authors noted that further studies are needed to elucidate whether this model of care is suitable for a larger population.

Gadisseur et al. (2003) conducted an RCT to determine whether patient self-management of OAT improves the quality of care delivered by anticoagulation clinics. In this study by two Dutch anticoagulation clinics, 341 patients between ages 18–75 and receiving long-term OAT were divided into four groups: an existing routine care group of patients untrained in self-management; a routine care group of trained patients; a group managed weekly at an anticoagulation clinic where INRs were measured by trained patients; and weekly patient self-management. A two-step randomization procedure was followed: first, a randomization was performed to distribute patients (i.e., without informing them) to the existing care group or to receive training in self-management; second, trained patients were randomized to the three other study groups. Only 25.6% of invited patients agreed to participate in the training program. Patients who remained in the existing care group were within the INR target range 63.5% of the time. The type of coumarin taken was a major predicting factor of OAT quality. In all study groups, phenprocoumon outperformed acenocoumarol by 11.6%. Weekly management with phenprocoumon led to a 6.5% improvement (95% CI) in time in the INR target range when patients were managed at an anticoagulation clinic and to an 8.7% improvement (95% CI) when patients were self-managed. Weekly management with acenocoumarol did not improve the quality of OAT. The authors concluded that with selected patients, the quality of OAT obtained through patient self-management is at least as high as that delivered by specialized physicians at anticoagulation clinics. The authors reported that weekly management of OAT with long-acting phenprocoumon has to be preferred at anticoagulation clinics or where possible, through patient self-management.

Yang et al. (2004) reported that home PT monitoring by patients can increase testing frequency and may thus decrease complications associated with oral anticoagulant therapy. A literature review of clinical studies suggests that home PT monitoring is more effective than uncoordinated management and is as effective as care through specialized anticoagulation clinics for keeping INRs within a therapeutic range. The authors reported that there are accurate and reliable instruments available, but paramount to the success of home PT monitoring is sound patient selection, appropriate patient training, and consistent quality control.

Mendez-Jandula et al. (2005) compared the quality of control and the clinical outcomes of OAT in self-managed patients versus patients following conventional management in an RCT. Patients (n=737) with indications for anticoagulant treatment were studied. 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 (i.e., 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 (i.e., difference of 3.0%). Twenty-seven patients (7.3%) in the conventional management group and eight (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%. Fewer patients had minor hemorrhages in the self-management group (14.9%) than in the conventional management group (36.4%). Fifteen patients (4.1%) in the conventional management group, and six patients (1.6%) in the self-management group died. The trial was performed at only one center and was not blinded. The dropout rate in the intervention group was 21%. The authors reported that compared to conventional management by an anticoagulation clinic, self-management of OAT achieved a similar level of control. The authors noted that major complications and minor hemorrhages were less common in the self-management group.

Gardiner et al. (2006) conducted a prospective, randomized controlled trial comparing the quality of warfarin control achieved by patient self-management (PSM) to that of patient self-testing (PST) against existing care in anticoagulation clinics. One hundred four patients who had been receiving warfarin therapy for over eight months agreed to take part in the study. Patients were randomized into the PSM group (n=55) or the PST group (n=49). INR was measured using the CoaguChek S every two weeks for six months. Of the original group, 77 completed the study with similar drop-out rates for both groups. The time spent within the therapeutic range for PSM and PST were 69.9% and 71.8% respectively. When the two groups were combined, significant improvement over the past six months was noted. The amount of time spent in therapeutic range in individual patients improved as well. The authors concluded that the quality of warfarin control in the PSM and PST groups may be superior to that achieved by anticoagulation clinics.

Heneghan et al. (2006) reported a systematic review and meta-analysis of all RCTs that assessed the effects of self-monitoring or self-management (self-testing and self-dosage) of anticoagulation compared with standard monitoring. Outcomes analyzed were: major hemorrhage, thromboembolic events, death, tests in range, minor hemorrhage, frequency of testing, and feasibility of self-monitoring. Fourteen RCTs self-monitoring: 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. Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and lower mortality than those who self-monitor alone. The authors report that self-monitoring is not feasible for all patients and requires identification and education of suitable candidates.

Christensen et al. (2007) conducted a systematic review and meta-analysis of ten trials to evaluate the efficacy and safety of self-management of oral anticoagulant therapy for patients on long-term oral anticoagulant therapy. The ten trials (n = 2,724 patients) compared self-management with conventional treatment. 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.

Professional Societies/Organizations
International Society on Thrombosis and Hemostasis [ISTH] (1999): ISTH reports that medical consensus among physicians is mixed, some expressing concern over the possibility that operator errors in PT self-monitoring may lead to fatal outcomes that may go undetected and unreported. It was submitted that management by a high-quality anticoagulation clinic may provide the best care for those unable to travel to a testing facility without significant difficulty. At the 17th congress of the ISTH held in Washington, DC (August 1999), a group of international experts reported on the developments in patient PT self-testing and self-management in their respective countries. It was concluded that PT self-management and self-monitoring of OAT has the potential to improve therapeutic control, decrease hemorrhagic and thromboembolism adverse events. As a result, there would be improved patient satisfaction with treatment and a decrease in the labor-intensive monitoring by physicians and facilities.

American Society of Hematology [ASH] (2000): ASH reports that a number of studies have demonstrated the ability of patients to perform self-testing and obtain an accurate result. Patients can then call their physician and obtain instructions for warfarin dose adjustment. Patient self-testing can also incorporate patient self-management of warfarin dosing, and a number of studies have shown this model of care to be safe and effective as well (Ansell et al., 2000).

British Society for Haemotology (2005): Evidence-based guidelines were established for the British Society for Haemotology by the British Committee for Standards in Haemotology Haemostasis and Thrombosis Task Force (Fitzmaurice et al., 2005) regarding self-management and self-testing of oral anticoagulation therapy. The recommendations included the following:

- Only patients with long-term indications for warfarin therapy should be considered for self-testing or -management.
- The ability of the patient to perform an INR must be assessed by a trained healthcare professional prior to allowing home testing.
- The ability of the patient to correctly interpret an INR result must be assessed by a healthcare professional prior to allowing self-management.
- Patients considered for self-testing or -management must have a documented INR target in line with accepted guidelines and clinical practice.
- Patients with a history of noncompliance are contraindicated for patient self-testing or self-management.
- Patients who perform self-management must be reviewed at least every six months by the responsible clinician.
- Electronic quality control, where available, should be used each time the monitor is used.
- Patients should participate in a formal educational program.
- The patient's monitor should be assessed in an anticoagulation center.
- A venous sample should be collected at the same time as a point of care test and should be carried out every six months for stabilized 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. Randomized controlled trials (RCTs) that have evaluated the efficacy of PT self/parent-monitoring in pediatric patients are lacking. Definitive patient selection criteria have not been established for self-monitoring of anticoagulation therapy. However, 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.

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: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	Description
E1399[†]	Durable medical equipment, miscellaneous
G0248	Demonstration, at initial use of home INR monitoring for patient with mechanical heart valve(s) under the direction of the physician: includes demonstrating 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 the persons ability to perform testing.
G0249	Provision of test materials and equipment for home INR monitoring to a patient with mechanical heart valves(s): includes provision of materials in the home for use in the home and reporting of test results to physician per four tests.

ICD-9-CM Diagnosis Codes	Description
427.31	Atrial fibrillation
451.19	Deep vein thrombosis
V43.3	Aortic/mitral valve replacement
	Multiple/varied

[†]**Note: Covered when medically necessary and used to report a prothrombin time home testing system.**

References

1. Ansell J, Hirsh J, Dalin J, Bussey H, Anderson D, Poller L, et al. Managing oral anticoagulant therapy. Chest. 2001;119:225-388.

2. Ansell J, Weitz J, Comerota A. Advances in Therapy and the management of antithrombotic drugs for venous thromboembolism. Hematology (Am Soc Hematol Educ Program). 2000;:266-84.

3. Ansell J, Jacobsom A, Levy J, Voller H, Hasenkam JM. Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. International consensus guidelines prepared by International Self-Monitoring Association for Oral Anticoagulation. Int J Cardiol. 2005 Mar 10;99(1):37-45.

4. Beyth R, Quinn L, Landerfield S. A multicomponent intervention to prevent major bleeding complications in older patients receiving warfarin. Ann Intern Med. 2000;133(9):687-95.

5. Bradbury MJE, Taylor G, Short P, Williams MD. A comparative study of anticoagulant control in patients on long-term warfarin using home and hospital monitoring of the international normalised ratio. Arch Dis Child. 2008 Apr;93(4):303-6.

6. Catlett JP, Alving BM. Update in hematology. Ann Intern Med. 2002 Jan 15;136(2):136-43.

7. Centers for Medicare and Medicaid Services. Decision Memo for Prothrombin Time (INR) Monitor for Home Anticoagulation Management (CAG-00087R). Mar 19, 2008. Accessed May 29, 2008. Available at URL address: https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=209

8. Christensen TD, Johnsen SP, Hjortdal VE, Hasenkam JM. Self-management of oral anticoagulant therapy: a systematic review and meta-analysis. Int J Cardiol. 2007 May 16;118(1):54-61.

9. Cromheecke M, Levi M, Colly L, de Mol B, Prins M, Hutten B, et al. Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomized cross-over comparison. Lancet. 2000;356(9224):97-102.

10. ECRI. ECRI recommended specifications Coagulation analyzers, whole blood. Healthcare Product Comparison System. Copyright® 2004 ECRI. Publication date: 10/04/2003.

11. Fitzmaurice D, Murray E, Gee k, Allan T, Hobbs F. A randomized controlled trial of patient self management of oral anticoagulation treatment compared with primary care management. J. Clin. Pathol. 2002;55;845-9.

12. Fitzmaurice DA, Gardiner C, Kitchen S, Mackie I, Murray ET, Machin SJ. An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation. Br J Haematol. 2005 Oct;131(2):156-65.

13. Gadisseur A, Breukink-Engbers W, van der Meer F, van den Besselaar A, Sturk A, Rosendaal F. Comparison of the Quality of Oral Anticoagulant Therapy Through Patient Self-management and Management by Specialized Anticoagulation Clinics in the Netherlands: A Randomized Clinical Trial. Arch Intern Med. 2003;163:2639-46.

14. Gardiner C, Williams K, Longair I, Mackie IJ, Machin SI, Cohen H. A randomised control trial of patient self-management of oral anticoagulation compared with patient self-testing. Br J Haematol. 2006 Mar;132(5):598-603.

15. Hanuschka P, Lian J. Ostreocalcin and matrix GlA-protein: vitamin K-dependent proteins in bone. Physiol Rev. 1989;69:990-1047.

16. HAYES Medical Technology Directory™. Self-monitoring and self-management of oral anticoagulant therapy. Lansdale PA: HAYES, Inc. ©2003 Winifred S. Hayes, INC. Oct 4, 2006. Update Search Nov 9, 2007.

17. Hemosense, Inc. The INRatio® Monitor. Accessed Mar 29, 2008. Available at URL address: http://www.hemosense.com/professional/inratio.shtml

18. Heneghan C, Alonso-Coello P, Garcia-Alamino JM, Perera R, Meats E, Glasziou P. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet. 2006 Feb 4;367(9508):404-11.

19. Hirsh J, Dalen J, Anderson D, Poller L, Bussey H, Ansell J, et al. Oral Anticoagulants Mechanism of Action, Clinical Effectiveness, and Optimal Therapeutic Range. CHEST. 1998;114:445S-69S.

20. Hirsh J, Fuster V, Ansell J, Halperin J. American Heart Association/American College of Cardiology Foundation Guide to Warfarin Therapy. Circulation. 2003;107:1692-711.

21. Institute for Clinical Systems Improvement. Anticoagulation therapy supplement. Updated Apr 2006. Accessed May 29, 2008. Available at URL address: http://www.icsi.org/guidelines_and_more/guidelines__order_sets___protocols/cardiovascular/anticoagulation_therapy_supplement/anticoagulation_therapy_supplement_5.html

22. International Society on Thrombosis and Haemostasis. Working Group/Liaison Reports. Accessed May 3, 2007. Available at URL address: http://www.med.unc.edu/isth/welcome

23. International Technidyne Corporation. ProTime® Microcoagulation System. Accessed May 29, 2008. Available at URL address: http://www.itcmed.com/products_4.html

24. Koertke H, Minami K, Boethig D, Breymann Th, Seifert D, Wagner N, et al. INR self-management permits lower anticoagulation levels after mechanical heart valve replacement. Circulation. 2003;108:11-75.

25. Le DT, Weibert RT, Sevilla BK, Donnelly KJ, Rapaport SI. The international normalized ratio (INR) for monitoring warfarin therapy: reliability and relation to other monitoring methods. Ann Intern Med. 1994 Apr 1;120(7):552-8.

26. Lucas FV, Duncan A, Jay R, Coleman R, Craft P, Chan B, Winfrey L, Mungall DR, Hirsh J. A novel whole blood capillary technic for measuring the prothrombin time. Am J Clin Pathol. 1987 Oct;88(4):442-6.

27. Macik B, Rand J, Konkle B. Thrombophilia: What's a practioner to do? Hematology 2001;(1):322-50.

28. Matchar DB, Jacobson AK, Edson RG, Lavori PW, Ansell JE, Ezekowitz MD, 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 Jun;19(3):163-72.

29. McCahon D, Fitzmaurice A, Murray E, Fuller C, Hobbs R, Allan T, et al.. SMART: self-management anticoagulation a randomized trial. BMC Fam Pract 2003;4:11-30.

30. Menéndez-Jándula B, Souto J, Oliver A, Montserrat I, Quintana M, Gich I, et al.. Comparing self-management of oral anticoagulant therapy with clinic management: A randomized trial. Ann Intern Med. 2005;142:1-10.

31. Pierce M, Crain l, Smith J, Mehta V. Point of care versus laboratory measurement of the international normalized ratio. Am J Health-Syst Pharm, 2000;57:2272-84.

32. Quest Diagnostics. Prothrombin Time. Updated Sep 25, 2006. Accessed May 30, 2008. Available at URL address: http://www.questdiagnostics.com/kbase/topic/medtest/hw203083/consider.htm

33. Roche Diagnostics Corporation. CoaguChek® Systems. Accessed May 29, 2008. Available at URL address: http://www.poc.roche.com/coaguchek/rewrite/content/en_IE/30:30/article/POC_general_article_52.htm

34. Sawicki P. A structured teaching and self management program for patients receiving oral anticoagulation: a randomized controlled trial. JAMA. 1999;281(2):145-50.

35. Scolaro KL, Stamm PL, Lloyd KB. Devices for ambulatory and home monitoring of blood pressure, lipids, coagulation, and weight management, part 2.Am J Health Syst Pharm. 2005 Sep 15;62(18):1894-903.

36. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Accessed May 3, 2007. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2091

37. Yang DT. Home Prothrombin Time Monitoring: A Literature Analysis. Am J Hematol. 2004 OCT; 77(2):177-86.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	7/15/2008	0109	Prothrombin Time Home Testing Systems
Great-West Healthcare	7/12/2006	04.230.02	Prothrombin Time (Protime) Monitor for Home Use