**Kaiser Foundation Health Plan
of Washington**

Clinical Review Criteria
Home INR Monitoring

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Criteria
For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11).
Local Coverage Determinations (LCD)	None
Local Coverage Article	Home PT/INR Monitoring (G0249) Billing and Coding (A55756)

For Non-Medicare Members
Kaiser Permanente has elected to use the Prothrombin Time (INR) Home Monitoring Device (A-0650) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:
- Documentation of initial start date for warfarin
- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedics, cardiology)

Home testing is usually not recommended for a frequency of more than once a week.

Additional software or hardware required for downloading data from home prothrombin time testing systems to computers for the management of anticoagulation will not be covered because each is considered a convenience item and not medically necessary.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Oral anticoagulation (OAC) therapy is used for the prophylaxis and /or treatment of thromboembolic complications of deep vein thrombosis, embolic stroke, pulmonary embolism, cardiac valve replacement, and atrial fibrillation, as well as postmyocardial infarction. The aim of the therapy is to maintain a level of anticoagulation that will prevent thromboembolic events without increasing the risk of hemorrhagic complications. Warfarin is an oral anticoagulant that interferes with the cyclic interconversion of vitamin K which in turn leads to depletion its dependant coagulation factors including prothrombin. It is estimated that more than a million patients are treated annually with warfarin in the USA (Koerner 1998).

In the USA, almost 40,000 mechanical heart valves are implanted annually. Mechanical valves are associated with a risk of thrombus formation and emboli. This risk is reduced by lifetime treatment with oral anticoagulants. Biologic implants on the other hand, have a lower thrombogeneity and do not require long-term anticoagulation. Thromboembolism, together with anticoagulant-induced hemorrhage, account for three fourths of all complications after mechanical heart valve replacement. These events were found to be associated with the intensity of oral anticoagulation therapy and fluctuation of international normalized ratio (INR) values. (Edmunds 1987).

Atrial fibrillation (AF), a common arrhythmia, is a leading cause of thromboembolism. It is common among the elderly, and its prevalence increases with age (1% among 60-year-old population, 5% among those aged 70-75 and >10% for 80+ years patients. (Ezekowitz 1999). The incidence of ischemic stroke among these patients may be as much as six times higher than among others with no AF. Studies show that oral anticoagulants significantly reduce the rate of stroke among AF patients (Eldor 2002). However, older patients treated with OAC have a higher rate of bleeding mainly due to the slower metabolization of the drug, and its interaction with other underlying chronic health problems. These patients should thus have better monitoring, and more rigorous regulation of the OAC to optimize their therapy, and prevent intracerebral hemorrhages, and other bleeding complications.

The intensity of anticoagulation treatment also needs to be controlled closely due to the narrow therapeutic range of warfarin, the potentially life-threatening effects of both over, and under-dosing, and its interaction with other drugs or foods like leafy green vegetables. Several other factors may affect the patients' response to warfarin control including compliance to therapy, underlying liver or kidney diseases, infections, diet, and others.

Oral anticoagulation therapy has been monitored for almost 50 years with the prothrombin time (PT) test. The test is easy to perform but its results may widely vary between institutions, and even within the same institution. In 1983 the WHO proposed the international normalized ratio (INR) in attempt to standardize PT measurements. The proposal was supported by the International Committee for Standardization in Hematology in 1985, and INR is the current standard for monitoring anticoagulation therapy. It is calculated as: INR= patient PT/mean normal PT). The recommended therapeutic INR range for oral anticoagulant therapy is 2.0-3.0 for the majority of indications. A higher range of 2.5-3.5 is recommended for patients with mechanical heart valves, and when therapy is recommended to prevent recurrent MI (Koerner 1998). Monitoring patients on OAC requires frequent testing, which in turn requires frequent venous punctures, and regular visits to a physicians' office or lab, as well as lab standardization. Patients on a stable OAC are seen every 4-6 weeks. It was found that at this rate of testing, 40-60% of the PT measurements fall in the desired therapeutic range (Hortskotte, 1998).

Patients using long-term OAC usually worry about complications, regular visits to the physician or lab, frequent venous punctures that may be difficult at times, dietary limitations, freedom at traveling, and other concerns that may affect their quality of life. There has always been an interest in developing an accurate faster and easier way to measure PT. Currently several monitors for finger stick testing of PT are available. These include CoaguChek, CoaguChek plus, ProTime Microcoagulation System, and Harmony INR Monitoring System. These monitors require only a finger stick whole blood rather than the citrated venous blood, and the patients can perform it at home. Among the other advantages of these systems is the immediate INR results, and convenience. In theory patient self-testing at home increases the duration when the patient is within the therapeutic INR range, increases compliance, and patient interaction with his physician, and allows better control of OAC, which in turn reduces morbidity and mortality.

Self-management or personal-self testing however is not suitable for everyone. Patients need to operate the machine, and self-sample blood, they have to be free from any major visual problems, tactile dysfunction, or severe tremors to be able to mechanically handle self-testing, they also have to be reliable and complying with the dosage algorithm.

After Joint Replacement Patients undergoing major orthopedic surgery; hip or knee arthroplasty, or hip fracture repair are in the highest risk category for venous thromboembolism (VTE) solely on the basis of the orthopedic procedure itself. Without prophylaxis, the rate of deep vein thrombosis or pulmonary embolism in these patients range from 40% to 84% and is the most common cause of death. It is thus recommended to use some type of prophylaxis for total knee replacement (TKR), total hip replacement (THR), and hip fracture surgery. The currently available methods of thromboprophylaxis include intermittent pneumatic calf compression, elastic compression stockings, or the use of pharmacological agents.

Warfarin is the most commonly used pharmacological agent followed by low molecular weight heparin (LMWH). The American College of Chest Physicians (ACCP) recommends either adjusted-dose warfarin (INR range 2.0 to 3.0); started preoperatively or immediately after the hip or knee replacement, or SC LMWH therapy. The duration of thromboprophylaxis is controversial and varies widely between practices, ranging from 1-12 weeks postoperatively. Studies have shown a peak incidence of postoperative DVT two to three weeks after total hip arthroplasty. This, together with the shorter durations of hospitalization, extending the use of antithrombotic prophylaxis for up to 5 weeks is becoming more common (Schuringa 1999, Geerts 2001, Frederick 2003, He Xing 2008).

The intensity of anticoagulation treatment needs to be controlled closely due to the narrow therapeutic range of warfarin, its interaction with several other drugs and foods, and the potentially life-threatening effects of both over- and under-dosing of the drug. Monitoring patients on oral anticoagulation (OAC) therapy requires frequent testing, which in turn requires frequent venous punctures, laboratory standardization, and regular clinical visits.

There in an ongoing interest in developing a faster and easier way to accurately measure prothrombin time (PT). Currently several home testing systems have received FDA approval for use. These include CoaguChek, CoaguChek plus, ProTime Microcoagulation System, INRatio Prothrombin Time Monitoring System, Harmony INR Monitoring System, AcuSure, and Rubicon. These monitors may be used at home and only require a fingerstick whole blood rather than the citrated venous blood. They also give immediate INR results. In theory, patient self-testing at home increases the duration within the therapeutic INR range, increases compliance, patient interaction with his physician, and allows better control of OAC which reduces morbidity and mortality. Personal self-testing with or without self-management is however is not suitable for everyone. Patients have to be reliable and free from any major visual problems, tactile dysfunction, or severe tremors to be able to mechanically handle self-testing. They also have to comply with the dosage algorithm.

Medical Technology Assessment Committee (MTAC)

Home INR Monitoring
08/13/2003: MTAC REVIEW
Evidence Conclusion: Ideally the outcomes of randomized controlled studies for the effectiveness of a test should demonstrate its effect in altering treatment and improving the health outcomes. Two important health outcomes, bleeding and thromboembolism, were only studied in ESCAT (Kortke 2001), and time in the therapeutic range, an intermediate outcome, was used in all other studies. Kortke et al, in the ESCAT randomized controlled trial, followed 600 patients with mechanical heart valves for at least 2 years (25-51 months). They evaluated the event rates, as well as time in the therapeutic range. Less than 10% of the randomized sample took part in the 25-30-month follow-up. Patients in the self-management group had significantly less overall grade III complications (severe hemorrhage or thromboembolism) compared to those in the standard care group. The trial also showed that significantly more measurements were in the therapeutic range among patients in the self-management group. Sawicki's RCT in which 84% of the participants had heart valve replacement, also showed that a higher proportion of patients in the self-management group were within the INR target range compared to those in the routine care group. This difference was only statistically significant at three months of follow-up but not after six months. In Watzke's trial, 57% of the patients had mechanical heart replacement, and 24.5 % had atrial fibrillation. It also showed that a higher proportion of measurements among patients in the self-management group were in the therapeutic range vs. those in the standard care group, however the P value was not provided. Eldor's study on elderly patients with atrial fibrillation was too small, nonrandomized and had insufficient power to detect any difference between the groups. In conclusion there is some evidence that selected patients with mechanical heart valve replacement, who self-monitor their PT, and self manage their OAC therapy, have better control of their INR values, than those receiving a standard care. Only one trial with several limitations, showed some benefit in reducing the severe complications associated with OAC treatment. The other studies had insufficient sample sizes, and follow-up durations to study that outcome. It is worth noting that the studies were conducted among selected groups of patients and cannot be generalized to all patients with mechanical heart replacement. There is insufficient evidence to determine the effect of home INR monitoring on patients with atrial fibrillation.
Articles: The search yielded 28 articles. Many were reviews and tutorials. Abstracts, and studies conducted to evaluate the accuracy of the portable PT monitoring systems were not reviewed. The purpose of this review is assessing the home use of the monitors for patients with mechanical heart valves, or atrial fibrillation, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). There were three randomized controlled trials, and three non-randomized controlled studies on self-testing/home INR monitoring. Trials conducted among patients with mechanical heart valves, or atrial fibrillation were selected. *The following articles was critically appraised:* Kortke H, and Korfer R. International Normalized Ratio self-management after mechanical heart valve replacement: is an early start advantageous? *Ann Thorac Surg* 2001; 72:44-48. See

Evidence Table Sawicki PT. A structured teaching and self-management program for patients receiving oral anticoagulation. A randomized controlled trial. *JAMA* 1999; 281:145-150. See Evidence Table Watzke H.H, Forberg E, Svolba G, et al. A Prospective Controlled Trial Comparing Weekly Self-Testing and Self-dosing with the Standard Management of Patients on Stable Oral Anticoagulation. *Thromb Haemost* 2000; 83: 661-665. See Evidence Table Eldor A, and Schwartz J. Self-management of oral anticoagulants with a whole blood prothrombin-time monitor in elderly patients with atrial fibrillation. *Pathophysiol Haemost Thromb* 2002; 99-106. See Evidence Table

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/01/2005: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: Ideally the outcomes of randomized controlled studies for the effectiveness of a test should demonstrate its effect in altering treatment and improving the health outcomes. Clinical endpoints for studies on self-management of anticoagulation therapy would be bleeding and thromboembolic complications. However, time within therapeutic INR range was used by some studies as a surrogate outcome to assess the quality of treatment based on self-management. In ESCAT I study (Koertke 2001) previously reviewed, 1,200 patients 6-11 days after a mechanical heart replacement were randomly divided into two groups: one monitored by family physicians, and the other controlling INR values at home. Patients were followed for at least 2 years (25-51 months) and the primary outcome was the rate of thromboembolic events and hemorrhage, and stability of INR values. Six hundred patients (50% of the randomized sample) were included in the analysis, dropouts and deaths were not included, and analysis was not based on intention to treat. The results of the trial showed that patients in the self-management group had significantly less overall grade III complications (severe hemorrhage or thromboembolism) compared to those in the standard care group. It also showed that significantly more measurements were in the therapeutic range among patients in the self-management group. ESCAT II study (Koertke 2003) was a large (N=3,300), multicenter RCT that randomized patients to two INR targets for self-management. The primary outcomes were the rate of thromboembolic events and hemorrhage, and the stability of INR values. It is an ongoing trial and the published articles only present the interim analysis with data on 55% of the total sample size. The investigators compared the results of the two INR targets for self-management in this trial and included data on thromboembolism and bleeding for the group controlled by general practitioner from ESCAT I study, which is not a valid comparison. ESCAT I was conducted years earlier, in a single center, and on a different group of patients. In this latter study, patients in the self-managed group had a higher mean INR value (3.0) compared ESCAT II study (2.8 for the conventional-dose INR, and 2.4 in the low-dose INR patients with aortic valve replacement). Overall, the interim results of ESCAT II study show that 72% to 74% of the patients in the low and conventional INR range, respectively, were within target range. The bleeding and thromboembolic rates were <1% in each of the two groups. There was no difference between them the in thromboembolic rates, and the difference in the bleeding rates did not reach statistical difference. There is no new evidence to determine the effect of home INR monitoring on patients with atrial fibrillation.
Articles: The search yielded 20 newer articles many of which were reviews and editorials. Studies conducted to evaluate the accuracy of the portable PT monitoring systems were excluded. The purpose of this review is to assess the home use of the monitors for patients with mechanical heart valves or atrial fibrillation, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). There were two publications on one large randomized controlled trial (ESCAT II) that compared two INR targets for self-management of anticoagulants after mechanical valve replacement, a small RCT that included patients with different indications for anticoagulation, and small case series with intermediate outcomes. SMART, a large ongoing trial on self-management of anticoagulation was also identified but no results were published to date. The ESCAT II trial was critically appraised: Kortke H, Minami K, Boethig, et al. INR self-management permits lower anticoagulation levels after mechanical heart valve replacement. *Circulation* 2003;108 II:75-78. Kortke H, Zittermann A, Minami K, et al. Low-dose International normalized ratio self-management: A promising tool to achieve low complication rates after mechanical heart valve replacement. *Ann Thorac Surg* 2005; 79:1909-1914.

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/07/2006: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: The previous MTAC reviews of home INR monitoring showed some evidence that selected patients with mechanical heart valve replacement who self-monitor and manage their OAC therapy, may have better control of their INR values, than those receiving standard care. All studies were conducted among selected groups of patients and the results might not be generalized to all patients with mechanical heart

replacement. There was insufficient evidence to determine the safety and efficacy of home INR monitoring on clinically important outcomes as thromboembolic events, major hemorrhage, and death. There was also insufficient evidence to determine the benefit of home INR monitoring in patients with atrial fibrillation. Heneghan et al's recent meta-analysis (2006) assessed the effects of self-monitoring with/ or without or self-management of anticoagulation compared with standard monitoring. The meta-analysis had valid methodology, was well-conducted, and 10 out of the 14 studies it included were judged to be of good quality. The authors also performed a sensitivity analysis by excluding the studies with the lowest quality. However, the control groups in the trials received their routine care in different settings. The results of a recent meta-analysis (van Walraven, 2006) showed that the study setting has a major influence on anticoagulation control. Moreover, the majority of the trials included in Heneghan's meta-analysis, provided education and training sessions only to the patients randomized to self-testing, not to the entire study population. Education increases awareness, motivation, and may modify the patient's attitude and behavior. The education and training were given after randomization, and those who could not complete the training sessions or were incapable of self testing and/or self-management either left the study or were transferred to the routine care group. This resulted in a high dropout rate (20% to > 30%) in the intervention groups, and intention to treat analysis was not conducted in all the trials, which could overestimate the observed results. Ideally, training would be performed prior to randomization to eliminate those who are unable to complete it, and/or are incapable of self testing or self-management, from participating in the trial. The results of this meta-analysis indicate that the thromboembolic events, major bleeds, and death rates were significantly lower in the self-monitoring groups versus the controls who were managed by their personal physicians, anticoagulation management clinics, or managed service. Those who both self-tested and self-adjusted their therapy dose had significantly lower thromboembolic events and mortality rates but a non-significant reduction the rate of hemorrhage. The difference in thromboembolic event rates was not significant between the intervention and control groups in the pooled results of the 3 trials conducted among patients with mechanical heart valves. The authors did not report on the difference in major hemorrhage or death rate among these patients, and no subgroup analysis was provided for patients with atrial fibrillation. Kaiser Permanente INTC recalculated some of the results of Heneghan's meta-analysis using ITT analysis, and found no significant differences between the intervention and routine care group in the percent of subjects with a mean INR in the therapeutic range, and in the major hemorrhagic events in the self-management vs. those receiving care in AMS (anticoagulation management services). Fitzmaurice, et al's (2005) study was a relatively large, multicenter, randomized, and controlled trial. However, it had several limitations and potential biases. Less than 25% of the eligible patient agreed to participate in the trial and were actually randomized to the study groups. Training on self-testing was given after randomization and only to the intervention group not to the entire population, which resulted in a higher dropout rate (43%) in the self-management group compared to 11% of those in the routine care group. Those who were considered incapable of self managing withdrew from the trial or were returned to the routine care group. The study population who self-selected to enroll was younger and included more men than the eligible population. Moreover, participants in the intervention group tested their INR more frequently than those in the routine care group (mean every 12 days vs.38 days) group, and apparently received more care, which is another potential source of bias. Patients in the routine care group were managed in a variety of models including anticoagulation clinics, hospital outpatient clinics, and primary care clinics which may have an influence on their anticoagulation control, and outcomes. Overall the results of this RCT show no significant differences between the intervention and routine care groups in the percent of time spent within therapeutic INR range (primary outcome) or in the rates of serious bleeding, or serious thrombosis. Patients in a target INR of 3.5 had poorer control before and during the study compared to those with target INR of 2.5. However, patients in the intervention group with a 3.5 target INR showed a significant improvement between the pre-study and study periods. No such improvement was observed for those with a 2.5 INR target in either group, or those with a 3.5, target in the routine care group. These results of the Heneghan's meta-analysis and Fitzmaurice's RCT may not be generalizable to all patients treated with long-term oral anticoagulants. The study participants were highly motivated, mainly younger, willing to take and complete a structured training course on self-management, and capable of performing self-testing correctly and reliably.

Articles: The search revealed 7 newer randomized trials that were published after the last review, as well as a meta-analysis of RCTs that assessed the effects of self-monitoring or self-management of anticoagulation compared with standard monitoring. Only three of the recent RCTs were relevant (Fitzmaurice 2005, Voler 2005, and Menedez-Jandula 2005). The latter two were included in the meta-analysis. Studies conducted to compare two home INR monitors, or to evaluate the accuracy of the portable PT monitoring systems were excluded. The purpose of this review is to assess the home use of the monitors for patients receiving long-term anticoagulation treatment, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). Two ongoing trials were also identified: 1. Self-Management of Anticoagulation, a Randomized Trial (SMART) which is a large multicenter trial on self-management of anticoagulation and, 2. The Home INR Study (THINRS) with more than 400 patients from VA Medical Centers with atrial fibrillation and/or mechanical heart valve who are expected to be anticoagulated indefinitely. The trial compares anticoagulation (AC) management using home monitoring devices to high quality management implemented by an AC service. It will have a

minimum of 2 years of follow-up, and the primary outcome is event rates (stroke, bleeding or death). Heneghan's (2006) meta-analysis and the RCT that was not included in the meta-analysis were critically appraised. Heneghan C, Alanzo-Coello P, Garcia-Alamino JM et al. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet 2006; 367:404-11.See Evidence Table Fitzmaurice DA, Murray ET, McCahon D, et al. Self-management of oral anticoagulation: randomized trial. BMJ 2005;331:1057- See Evidence Table

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/01/2008: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: There is insufficient evidence to determine that: Home INR monitoring after joint replacement surgery increases the percentage of time spent within the therapeutic INR range, compared to routine care. Home INR monitoring, vs. routine care, after joint replacement surgery is effective in reducing the deep vein thrombosis and pulmonary embolic events rates, without increasing hemorrhagic events.
Articles: The search did not reveal any RCT that compared outcomes of monitoring of INR post joint replacement at home vs. in the hospital or anticoagulation management centers. There was only one published empirical study on the home prophylaxis with warfarin after hip and knee arthroplasty. Schuringa P, Yen D. Home prophylactic warfarin anticoagulation program after hip and knee arthroplasty. Can J Surg. 1999; 42:360-362. See Evidence Table.

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT or HCPC® Codes	Description
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 four 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 four tests

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/10/2002	01/05/2010 MDCRPC, 05/04/2010 MDCRPC, 03/01/2011 MDCRPC, 01/03/2012 MDCRPC, 11/06/2012 MDCRPC, 09/03/2013 MPC, 07/01/2014 MPC, 05/05/2015MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC, 09/04/2018MPC, 09/03/2019MPC, 09/01/2020MPC, 09/07/2021MPC , 09/06/2022MPC , 09/05/2023MPC, 02/13/2024MPC, 02/04/2025MPC	09/01/2020

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/01/2020	Added Medicare LCA A55756