Home Prothrombin Time Monitoring

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required for Medicare Advantage for the materials and equipment; preauthorization is not required for all other products but recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Patients who are prescribed chronic warfarin anticoagulation need ongoing monitoring that has generally taken place in a physician’s office or anticoagulation clinic. Home prothrombin monitoring with a U.S. Food and Drug Administration (FDA)-approved device is proposed as an alternative to office or laboratory-based testing.

Background

Warfarin is an effective anticoagulant for the treatment and prevention of venous and arterial thrombosis. Chronic warfarin therapy is recommended in all patients with mechanical heart valves and in some patients with chronic atrial fibrillation (i.e., patients with risk factors that indicate a higher likelihood of stroke). Patients with mechanical heart valves are frequently prescribed anticoagulants at higher levels than patients given anticoagulants for other indications, which puts them at higher risk of complications from warfarin therapy. Appropriate levels of warfarin anticoagulation are monitored with periodic prothrombin time measurements, as measured by the International Normalized Ratio (INR). For example, an INR result greater than three indicates a higher risk of serious hemorrhage, while an INR of six indicates an increased risk of developing a serious bleed nearly seven times that of someone with an INR less than three. In contrast, an INR less than two is associated with an increased risk of stroke. Therefore, monitoring of the prothrombin time is recommended to ensure that the prescribed dosing regimens result in INRs within the therapeutic range. Anticoagulation can be monitored: in the physician’s office (usually once a month), at an anticoagulation clinic (usually once every two to three weeks), or at home.

In order for home prothrombin time monitoring to be effective, patients need to be appropriately trained and able to generate INR test results comparable to laboratory measures. Moreover, the clinical impact of home prothrombin time monitoring is related to improved warfarin management. Specifically, home prothrombin time monitoring permits more frequent monitoring and self-management of warfarin therapy with the ultimate goal of: 1) increasing the time that the anticoagulation is within a therapeutic INR range (intermediate health outcome); and 2) decreasing the incidence of thromboembolic or hemorrhagic events (final health outcome). Home self-monitoring is typically associated with some form of self-management of warfarin therapy. In some cases, the patient may be supplied with treatment algorithms and instructed to alter the dose based on the results of self-monitoring. In other cases, the patient may be instructed to provide the results of the self-monitoring (e.g., on the telephone or internet) and receive instructions on warfarin dosage.
Regulatory Status

In January 2007, the CoaguChek® XS System (patient self-testing) (Roche Diagnostics Corporation) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices, including the CoaguChek SX System (professional, cleared in 2006). Other than a labeling change, the device is identical to the professional version of the CoaguChek XS System. The patient self-testing system is intended for self-monitoring of prothrombin time in patients who are on a stable regimen of anticoagulation medications.

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

Related Protocol

Genetic Testing for Warfarin Dose

Policy (Formerly Corporate Medical Guideline)

At-home monitoring of chronic warfarin therapy is not medically necessary in patients who require continuous anticoagulation for chronic medical conditions. These conditions include, but are not limited to, patients with mechanical heart valves and chronic atrial fibrillation.

Medicare Advantage

For Medicare Advantage at-home monitoring of chronic warfarin therapy may be considered medically necessary in patients who require continuous anticoagulation for chronic atrial fibrillation, mechanical heart valve(s) or, venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) and have been on anti-coagulations for at least three months.

The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home and the patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring. Self-testing with the device should not occur more frequently than once a week.

For Medicare Advantage, this is a diagnostic testing benefit provided by a physician, independent testing facility or other qualified provider; it is not a durable medical equipment benefit.

Benefit Application

For General Business, home monitoring (self-management) while safe and with the potential to be effective, has not been shown to be superior to standard monitoring (physician office or anticoagulation clinics) for patients with chronic atrial fibrillation or deep venous thrombosis and is more costly than standard monitoring. Therefore, benefit or contract language describing the “least costly alternative” as part of medical necessity definition is applicable.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.
It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


